



CONSOLIDATED GUIDELINES FOR HIV CARE IN GHANA



October 2022



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Test, Treat & Track



October 2022

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ABBREVIATIONS / ACRONYMS



AIDS	- Acquired Immune Deficiency Syndrome
AIS	- Adenocarcinoma in situ
ANC	- Antenatal Clinic
ART	- Antiretroviral Therapy
CKC	- Cold Knife Conization
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
HPV	- Human Papilloma Virus
HTS	- HIV Testing Service
HSS	- HIV Sentinel Survey
IBSSS	- Integrated Biological Behavioural Surveillance Survey
IPD	- In-patient Department
TPT	- TB Preventive Therapy
INSTIs	- Integrase Strand Transfer Inhibitors
LLETZ	- Large-Loop Excision of the Transformation Zone
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
TAF	- Tenofovir Alafenamide
TB	- Tuberculosis

TLD	- Tenofovir/Lamivudine/Dolutegravir drug combination
TLE	- Tenofovir/Lamivudine/Efavirenz drug combination
UNAIDS	- The Joint United Nations Programme on HIV/AIDS
VIA	- Visual inspection with Acetic Acid
VL	- Viral Load
VLSUP	- Viral Load Scale-up Plan
WHO	- World Health Organization
WHO/AFRO	- World Health Organization/ Regional Office for Africa



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FOREWORD



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

This updated national HIV Care guidelines include newly recommended HIV testing and linkage strategies, ARV drug regimens, formulations and diagnostics that are appropriate to the local setting. This version provides an update to the previous consolidated guidelines. The national guideline review process

included extensive consultations with various stakeholders through workshops and technical working group meetings. The purpose of reviewing the existing guideline is to ensure that the country is up to date with current trends and recommendations in HIV care.

This document remains the basis for planning and organisation of HIV service delivery at all levels of implementation in both government, non-governmental and private health institutions in 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 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 has a low HIV prevalence, with the epidemic being generalized in the population. In 2020, the HIV prevalence was 1.68% with an estimated 346,120 persons living with HIV (PLHIV) (GAC National and subnational HIV and AIDS estimates and projections, 2020 report).

A total of 1,837,149 HIV tests were conducted in 2020 with a yield of 3.2%. Of these 861,030 (47%) were pregnant women with a yield of 1.5%. Thirty-one thousand and thirty-five (31,035) persons were newly enrolled on ART in 2020 contributing to the total 208,811 active clients on ART by end of December 2020. As the number of persons living with HIV on ART increases, the HIV population is projected to increase as AIDS-related deaths decrease. Of all people living with HIV in Ghana as at the end of December 2020, 63% knew their status; 95% were on ART and 73% were virally suppressed (2020 NACP Annual Report, 2021).

The median HIV prevalence in women attending antenatal care in 2020 was 2.0% (HSS Report 2020, 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.

Differentiated strategies across the cascade of HIV care therefore are being implemented to meet the needs of different populations to accelerate progress towards achieving the ambitious 95-95-95 targets of which Ghana is currently at 63-95-73 (GAC National and subnational HIV and AIDS estimates and projections, 2020 report).

Differentiated Service Delivery is a client-centred approach to address challenges by adapting services to the needs of clients while reducing the burden on the health system. The principles of differentiated service delivery may be applied from testing through to ART initiation, long-term ART delivery and achieving virological suppression. Differentiated service delivery is also not just for clients successfully established on ART. Service delivery should be adapted for clients with advanced HIV disease both at ART initiation, where there is evidence of treatment failure on ART and for specific populations. Refer to the Differentiated Service Delivery Operational Manual.

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 DOTS corners, Emergency Room, ANC, PNC, CWC, OPD and Nutritional Rehabilitation Units. PLHIV should also be offered family and partner testing, so their contacts are diagnosed as well (family-based index client testing). 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.

Treat All is the strategy being used to offer ART to all HIV positive clients linked to care, irrespective of WHO staging of the disease or the CD4 cell count/ml.

If they are established on ART, PLHIV can be given clinic appointments twice a year (quarterly for children below 5 years). 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.

Currently, viral load testing is used to monitor clients on treatment. Any client who is not virally suppressed has to be managed according to national guidelines (see Appendix 7).

These updated guidelines take into consideration recommendations made by the WHO in the July 2021 guidelines including Dolutegravir for treatment of children below 20kg.

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 ambitious UNAIDS 95-95-95 goals by 2025 and epidemic control (UNAIDS, 2020).

PURPOSE

The purpose of this updated document is to provide current HIV care guidelines for all age groups and populations in Ghana.

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.



SUMMARY OF UPDATES



NEW

Following updates to the WHO guidelines in July 2021, it became necessary to update these national guidelines to incorporate key recommendations relevant to Ghana's context with the aim of providing current standardized and comprehensive HIV care guidelines for the country. Below are details of the main updates.

New definition of 'established on ART'

The 2021 WHO consolidated guidelines recommends an updated terminology for a 'stable client on ART' to 'established on ART'. This recommendation has been adopted, therefore the new definition for 'established on ART' is:

- receiving ART for at least six months;
- no current illness, which does not include well-controlled chronic health conditions;
- good understanding of lifelong adherence: adequate adherence counselling provided; and
- evidence of treatment success: at least one suppressed viral load result within the past six months (if viral load is not available: CD4 count >200 cells/mm³ or CD4 count >350 cells/mm³ for children 3-5 years or weight gain, absence of symptoms and concurrent infections).

Chapter One: HIV TESTING AND COUNSELLING SERVICES (HTS)

Legal and Ethical Issues

Regulations pertaining to the disclosure of an individual's HIV status to a partner and informed consent in accordance with the legal framework for providing HIV services in Ghana, L.I 2403 of the Ghana AIDS Commission Regulation, 2020 have been included in this updated guideline.

HIV Testing Services

- Integrated testing for HIV, syphilis and hepatitis B is also recommended to all pregnant women at least once.
- Re-testing of pregnant women during the 3rd trimester.
- Point-of-care nucleic acid testing to diagnose HIV among infants and children younger than 18 months of age.

Recommendations for testing and retesting during ART initiation have also been included as follows:

- For women who are already known to be living with HIV, their syphilis status should be determined.
- Retesting among people with HIV who already know their status, including those on treatment, is not recommended as it can provide inconsistent results if the person with HIV is on ART.

HIV Testing and Counselling Approaches

- A social network-based approach to testing has been introduced in this update.

Chapter Four

Antiretroviral Therapy

This chapter has been updated to include the preferred and alternative second-line ART regimens for adults, adolescents,

children and infants including recommendations for using DTG 10 based regimen for children above 3 kg and more than four weeks old. Consistent with broader efforts to improve toxicity profiles, Tenofovir alafenamide (TAF) has also been included as an option in special circumstances.

Chapter Five

Elimination of Mother-To-Child Transmission (EMTCT)

The first two prongs of the EMTCT strategy- Primary prevention of HIV infection in women of childbearing age and prevention of unintended pregnancies among women infected with HIV have been included in this updated guideline.

The algorithm for early infant diagnosis has also been described. The management of Syphilis in pregnant women has also been updated.

Chapter Seven

Changing or Interrupting Therapy

The diagnosis of treatment failure based on WHO definitions has been updated to include clinical, immunological and virological failure.

Chapter Nine

Managing Advanced Disease

This guideline has been updated with a section on Managing Advanced Disease documenting WHO guidelines' recommended package of interventions for clients presenting with advanced HIV disease.

Chapter Ten

Pre and Post Exposure Prophylaxis

PrEP has been documented as being safe even among pregnant

women. Dapivirine vaginal ring has been recommended as an acceptable option for PrEP in women who are unable or do not want to take oral PrEP. Long acting cabotegravir (CAB-LA) has also been added to the PrEP options for HIV-1.

Chapter Thirteen

HIV Care During Covid-19 And Future Outbreaks

To provide mitigation measures against interruptions in HIV services during emergencies, as was observed with the COVID-19 pandemic, considerations have been outlined in this update for integration of management of outbreaks/emergencies with HIV care.

Included in this update are treatment considerations specific for COVID-19 infections and vaccination in a PLHIV.

Chapter Fourteen

HIV and Noncommunicable Diseases

Considerations for the management of NCDs including mental health conditions in PLHIV have been included.

Chapter Fifteen

The recommendations for management of cervical cancer among PLHIV based on the Screen, Triage and Treat Approach have been included.

Tables and Figures

Figures depicting algorithms for HIV testing for different populations, early infant diagnosis, TB screening and various scenarios for the cervical cancer Screen Triage and Treat Approach.



Appendices

Monitoring of Treatment

An update in the definition of clients on ART who are virologically suppressed has also been adopted. Whereas it used to be defined as having a VL \leq 1000 copies/ml, the new definition is VL \leq 50 copies/ml. An updated algorithm to provide guidance on monitoring and the respective actions to be taken based on the new definition is included in this guideline.



CHAPTER ONE

**HIV TESTING AND
COUNSELLING SERVICES
(HTS)**

HIV testing is a process that determines whether a person is infected with HIV or not by detecting antibodies or antigens associated with HIV in blood and other body fluids. HIV testing is the gateway to prevention, care, treatment and support services for PLHIV. Through HTS people can learn about and accept their sero-status in a confidential environment where they are counseled on strategies to prevent infection to self and others, receive emotional care and be referred for medical and psychosocial services when appropriate. HTS also helps to decrease stigma as it encourages community acceptance of PLHIV and willingness to participate in national response to HIV/AIDS. Those who are not HIV-infected will be linked to appropriate services to prevent HIV infection and those who use drugs, to harm reduction services. This process comprises the provision of pre-test information, HIV testing, disclosure and post-test counselling and education.

1.1 HIV TESTING AND COUNSELLING: GUIDING PRINCIPLES

The guiding principles for HIV Testing and Counselling (HTC) are Confidentiality, Informed consent, Post-test Counselling and support services, Correct test results and Connection to 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 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.

4. Correct test results:

Providers of HTS must strive to provide high quality testing services. Quality Assurance mechanisms should ensure that people receive a correct diagnosis

5. Connection to services:

In the context of “test and treat” HTS providers should ensure they provide immediate linkage to treatment, care and support

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. Counsellors 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. HTS 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 HTS services are provided within a health facility, it is necessary to distinguish between Client-Initiated Testing and Counselling (CITC) and Provider-Initiated Testing and Counselling (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.



NEW

Written results

HTS sites must provide written results which must be dated and signed. Clients requesting testing for official reasons, such as employment or to obtain a visa, where written results are required, should be referred to an approved laboratory, hospital or clinic for the type of testing.

Legal and Ethical issues

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

For the disclosure of an individual's HIV status to a partner, the following regulations should apply:

1. A health care provider may inform the partner of a person under care of the health care provider of the HIV status of that person only if the following conditions are met:
 - a) the health care provider reasonably believes in good faith

- that the partner is at significant risk of transmission of HIV from the person;
- b) the person living with HIV has been counselled to inform the partner;
 - c) the health care provider is satisfied that the person living with HIV does not intend to inform the partner;
 - d) the health care provider has informed the person living with HIV of the intention to disclose the HIV positive status of that person to the partner; and
 - e) the disclosure to the partner is made in person and with appropriate counselling or referral for counselling.
2. Sub regulation (1) shall not apply where the health care provider reasonably believes that the disclosure of the information may result in
- a) violence;
 - b) abandonment; or
 - c) an action that may have a severe negative effect on the physical or mental health and safety of the
 - (i) person living with HIV;
 - (ii) children of a person living with HIV; or
 - (iii) someone who is close to the person living with HIV

Further guidance on the legal framework for providing other HIV services in Ghana can be found in the L.I 2403, section 32, Ghana AIDS Commission Regulation, 2020.

Right to privacy

Privacy is particularly emphasized in the context of HIVAIDS,

given the stigma and discrimination associated with HIV/AIDS. Adequate safeguards must be in place at the HTS- 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 HTS must not constitute a source of discrimination against the individual (HTS 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 HTS must be fully explained to the client to ensure informed consent. Informed consent may be verbal or written. In case of written consent, forms must be signed or thumb printed by the client

before testing. The age of consent as provided by the L.I 2403, section 23 and 24, Ghana AIDS Commission Regulation, 2020 are as follows:

1. *A person of the age of sixteen years or above may give consent to be tested for HIV*
2. *A trained service provider shall assist a person of the age of sixteen years or above who consents to be tested, to know the HIV status of that person*
3. *A parent, a legal guardian or the next of kin of a person who*
 - a) *Is below the age of sixteen years; or*
 - b) *Has a mental incapacity may give consent for that person to be tested for HIV*
4. *Despite subregulation (3), where the person is below the age of sixteen years and it is in the best interest of the person, a trained service provider shall assist that person to*
 - a) *Know the HIV status of that person;*
 - b) *Have access to follow-up services available*
5. *Where the person who is below the age of sixteen years is a student at a residential educational institution, the head of the institution, or a representative of the head of the institution may, if the parents of that person or the next of kin of that person are unavailable, give consent to the test.*

Where a person, or a parent or guardian of a person accepts or declines a test for HIV, a healthcare provider shall record that fact in the medical file of that person.

Protecting human rights within an HTS site

In addition to information giving, counselling, confidentiality and informed consent, protecting the human rights of HTS clients should be promoted through the adoption of an ethical code of conduct for all those involved in HTS 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.

1.2 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 the client to visit the 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 the 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 the client would 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 the client decides to undergo testing, obtain informed consent before the test is done.
- Provide opportunity for the client to ask questions.

1.3 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 were not detected in your blood”.
- Pause for the client to assimilate results communicated.
- Assess understanding by asking the client to tell you what the test result means.
- Ask the client how he or she feels about the result and allow expression of emotional reactions.
- Continue with counselling on behavioural change either to maintain negative status or live positively with positive test results only when the 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 behaviour 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, the need for and benefits of lifelong adherence to ARVs including Undetectable=Untransmissible (U=U) messages, as well as plans for partner notification, and testing.
- For clients with negative test results, discuss the need for comprehensive HIV prevention services even throughout pregnancy and breastfeeding to help them remain HIV-negative. This includes counselling, condom use, harm reduction, and pre- and post-exposure prophylaxis as needed.
- Perform a psychosocial support assessment.



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- Encourage clients to accept and live positively even if they face stigma and discrimination (S&D) as well as psychological problems.
- Counsel the 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).

1.4 HIV TESTING AND COUNSELLING APPROACHES

Client Initiated Testing and Counselling (CITC)

This is traditionally known as Voluntary Counselling and Testing (VCT). In this type of HTS, the individual of his own accord goes to an HTS site 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 the following categories of persons:

- 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 (STIs),
- 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 the following units:

- Inpatient Department (IPD)
- TB unit,
- STI clinic,
- RCH settings,
- PMTCT sites,

Clients presenting at OPDs, including referrals to other support services are to be offered PITC services after appropriate triaging has been done .

The first user of the test result is the health care provider who uses the HIV test to make a diagnosis and provide appropriate treatment and/or referral. There are three types of PITC. These are: routine offer, diagnostic and mandatory testing.

Routine PITC

Routinely offered PITC is when HTS 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.

Diagnostic PITC

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

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.

1.5 PROVISION OF HTS SERVICES IN GHANA

To increase access to HIV diagnosis and detection of persons living with HIV, HTS shall be provided in both public and private health care facilities: In addition to improving access to HIV testing, differentiated testing models should be prioritized to identify those people living with HIV who do not yet know their status in order to appropriately link them to HIV services.

Hence, identifying high-yield testing strategies for the general population and supporting testing in specific populations with high HIV prevalence (female sex workers, men who have sex with men etc) should be prioritized.

For the general population, high-yield strategies that should be prioritized include:

- Facility-based provider-initiated testing and counselling (PITC).
All clients presenting with sexually transmitted infection (STIs), TB and clients presenting with symptoms and signs of HIV should be tested with priority.
- Index client testing both at facility and community.
- HIV self-testing in the community.
- Social Network-Based testing 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 HTS provider visits a community and offers HTS 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 HTS providers to visit their communities or homes to conduct HTS for them or their family members. The trained health care professionals or HTS providers visit the home with their consent and offer HTS services to their partner(s), spouse(s), or family member(s). Thus, community HTS includes aspects of both PITC and CITC.

1.6 COUPLE AND PARTNER HIV COUNSELLING AND TESTING

Couple and partner HIV testing and counselling including disclosure should be encouraged, supported and offered in all settings where HIV testing and counselling is provided, including antenatal, TB clinics, STI clinics, hospitals, Primary Health Care; health posts, community led HTS. Couple/partner testing and counselling can identify sero-concordant and sero-discordant 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



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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, or 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 and offered by the service providers. Partner consent is not mandatory for HIV testing and counselling.



1.7 SOCIAL NETWORK-BASED APPROACH

Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention. Details of the implementation can be found in the 2022 Differentiated Service Delivery (DSD) Operational Manual.

1.8 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. Under some circumstances and depending on national legal requirements, a child considered to be sufficiently mature may give consent for an HIV test (See Chapter 2 of 2022 DSD Operational Manual).

Point-of-care nucleic acid testing should be used to diagnose HIV among infants and children younger than 18 months of age where available.

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 six 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. To diagnose all HIV-exposed infants who initially tested negative in the first six weeks of life with virologic testing at nine months;
4. At 18 months, confirm the HIV status of children born to HIV positive mothers 3 months after complete cessation of breastfeeding.
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.
 - Through sexual abuse or
 - Through contaminated needle sticks or receipt of potentially infectious blood or blood products (or through other routes, e.g. wet nursing).

(Refer to algorithm for Early infant Diagnosis, Chapter 5, Figure 5.5.3)

1.9 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 HTS 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 is discussed with the parents or guardians from the time of diagnosis.
- The process of disclosure is 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. This needs to be done 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 counselling to prepare and enable them to support disclosure in their children. Health care workers should be equipped with knowledge and skill on disclosure counselling.

1.10 HIV TESTING AND COUNSELLING 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 can give consent to receive HTS. Counselling 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 client'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.

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.

1.11 HIV TESTING AND COUNSELLING 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.

1.12 HIV TESTING AND COUNSELLING AMONG KEY AND AT RISK 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 guards peers in an effort to reach high risk men.

1.13 HIV SELF-TESTING (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 eliminates travel distances or long waiting periods 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 683. 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-based, shall be periodically evaluated and recommended for use in-country by the Ministry of Health (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.

1.14 HIV TESTING ALGORITHM FOR NON-PREGNANT POPULATIONS IN 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 below. Currently the kits recommended for testing in Ghana are First Response HIV 1&2 (first test), First Response HIV/Syphilis Duo (first test for pregnant women), Oraquick HIV 1&2 (Second test) and SD Bioline HIV 1&2 (Third test).



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For women who are already known to be living with HIV, their syphilis status should be determined.



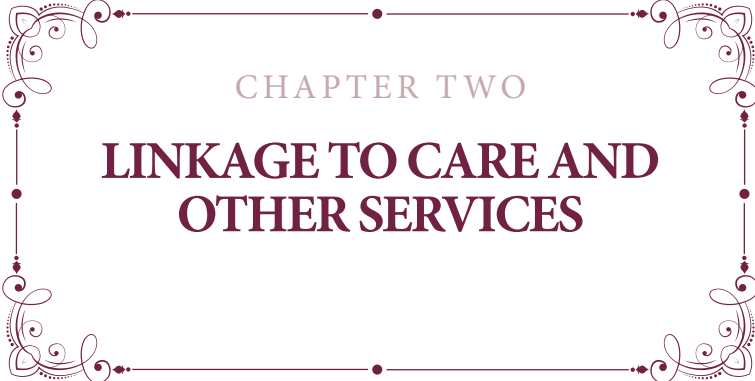
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Retesting among people with HIV who already know their status, including those on treatment, is not recommended as it can provide inconsistent results if the person with HIV is on ART.



Diagnosing HIV infection in children under 18 months

Diagnosis of HIV infection in babies born to women living with HIV 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.



CHAPTER TWO

LINKAGE TO CARE AND OTHER SERVICES

Linkage is defined as a set 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. With reference to people with HIV, 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 comorbidities. This is especially important to prevent clients from being lost to follow-up. Making 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 expert clients patients; and using new technologies such a social, medical, and mobile phone reminder text messaging.

LINKAGE STEPS (see Chapter 3)

- 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.
- 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 (Chapter 2, Page 13).

2.1 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 and Care for Orphans Vulnerable Children
- Psychosocial Support and STI services
- NCD services including mental health

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, lay workers, 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.



CHAPTER THREE

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.

ART initiation can be differentiated according to the following categories of clients:

- Persons presenting to care when clinically well (Stage 1 and 2 and CD4 >200 cells/mm³)
- Persons presenting to care with advanced HIV disease (Stage 3 or 4 and/or CD4 <200 cells/mm³).

An individual clinically stable on ART, now described as ‘established on ART’ is a PLHIV:

- *receiving ART for at least six months;*
- *no current illness, which does not include well-controlled chronic health conditions;*

- *good understanding of lifelong adherence: adequate adherence counselling provided; and*
- *evidence of treatment success: at least one suppressed viral load result within the past six months (if viral load is not available: CD4 count >200 cells/mm³ or CD4 count >350 for children 3-5 years or weight gain, absence of symptoms and concurrent infections).*

Refer to Differentiated Service Delivery For HIV in Ghana Operational Manual Chapter 4.

Clinical Evaluation

A comprehensive clinical evaluation is 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 as these may influence the choice of therapy.
- Assessing nutritional status.
- Assessing capacity to adhere to treatment.
- Assessing clinical stage and CD4 count for decisions on provision of the advanced HIV disease package.

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 3 for TB screening algorithm) and Hepatitis B and C.

- Past Medical History including diagnosis of tuberculosis.
- Drug history including treatment for TB and Hepatitis.
- 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 substance abuse.

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).
- To detect advanced HIV disease at presentation
- Whether female clients are pregnant.
- The presence of opportunistic infections.
- The presence of co-morbid diseases.



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Further information on the client's baseline laboratory tests can be seen in Table 3.1 below. Within the context of Good Clinical Practice, these baseline tests should not be a barrier to ART initiation. ART can be initiated while the laboratory tests are done after ART. Where a laboratory 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.

A package of interventions including screening, treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation and intensified adherence support interventions is strongly recommended for everyone presenting with advanced HIV disease.

PLHIV presenting for the first time or those returning to care should undergo history and clinical examination to evaluate for opportunistic infections (such as signs and symptoms of TB meningitis and signs and symptoms suggesting cryptococcal meningitis) before rapid ART initiation is offered. Immediate ART initiation is contraindicated among people living with HIV who have cryptococcal meningitis because of the increased

mortality presumed to be caused by immune reconstitution inflammatory syndrome in the central nervous system.

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) Pregnancy Test (Females)
Respiratory examinations	TB screening GeneXpert Chest X-ray
Serological Test	Hepatitis B Surface antigen
Immunological test	CD4
<i>These tests are performed depending on signs, symptoms or age</i>	Histology on skin and lymph node biopsy Kidney biopsy Screening for STIs Pap smear, HPV DNA Abdominal Ultrasound



CHAPTER FOUR

ANTIRETROVIRAL THERAPY

The current National HIV Strategic Plan and Health Sector Strategic framework 2021-2025 has a goal of enrolling at least 95% of persons living with HIV on ART and achieve viral load suppression in 95% by 2025 in accordance with new UNAIDS 95-95-95 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

4.1 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.

4.2 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)
Abacavir (ABC)	Tenofovir Alafenamide (TAF)	Efavirenz (EFV)	Ritonavir boosted Lopinavir (LPV/r)	Dolutegravir (DTG)
Zidovudine (AZT/ZDV)	Tenofovir Disoproxil Fumarate (TDF)	Nevirapine (NVP)	Ritonavir boosted Atazanavir (ATV/r)	Raltegravir (RAL)
Lamivudine (3TC)		Dapivirine (DPV)	Ritonavir boosted Darunavir (DRV/r)	Cabotegravir (CAB-LA)
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, where available. 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 – 4.10 below, show the recommended drug combinations for use 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.



Table 4.2

Preferred and alternative first-line ART regimens for adults, adolescents, children and neonates

Populations	Preferred first-line regimen	Alternative first-line regimen	Special circumstances
Adults and Adolescents (including pregnant women)	TDF + 3TC (or FTC) + DTG	TDF + 3TC + EFV 400mg	TDF + 3TC (or FTC) + EFV600mg AZT + 3TC + EFV 600 mg TDF + 3TC (or FTC) + PI/r TDF + 3TC (or FTC) + RAL
Children	ABC + 3TC + DTG	ABC + 3TC + LPV/r TDF+ 3TC (or FTC) + DTG	ABC + 3TC + DTG TDF + 3TC (or FTC) + PI/r ABC + 3TC + EFV ABC + 3TC + RAL AZT + 3TC + EFV AZT + 3TC + LPV/r (or RAL)
Neonates	AZT (or ABC) + 3TC + RAL	AZT + 3TC + NVP	AZT + 3TC + LPV/r



Table 4. 3 Preferred and alternative second-line ART regimens for adults, adolescents, children and infants

Populations	Failing first-line regimen	Preferred second-line regimen	Alternative second-line regimens
Adults and Adolescents (including pregnant women)	TDF + 3TC (or FTC) + DTG	AZT+ 3TC + ATV/r (or LPV/r)	AZT + 3TC + DRV/r
	TDF + 3TC (or FTC) + EFV (or NVP)	AZT +3TC + DTG	AZT + 3TC + ATV/r (or LPV/r or DRV/r)
	AZT + 3TC +EFV (or NVP)	TDF+ 3TC (or FTC) + DTG	TDF + 3TC (or FTC) + ATV/r (or LPV/r or DRV/r)
Children and Infants	ABC + 3TC + DTG	AZT+ 3TC + LPV/r (or ATV/r)	AZT +3TC + DRV/r
	ABC (or AZT) +3TC + LPV/r	AZT (or ABC) + 3TC + DTG	AZT (or ABC) +3TC + RAL
	ABC (or AZT) + 3TC + EFV	AZT (or ABC) + 3TC + DTG	AZT (or ABC) +3TC + LPV/r
	AZT + 3TC + NVP	ABC + 3TC + DTG	(or ATV/r) ABC + 3TC + LPV/r (or ATV/r)

4.3 CONSIDERATIONS FOR 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); Dual HIV-1 and HIV-2 infection; HIV-1 infection; HIV-2 infection.

Table 4.4**Considerations for 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 phenobarbitone) 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.

Drugs	Caution	Comments
Alternative Regimen		
Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)	<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>
Abacavir (ABC) + Lamivudine(3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)	ABC is contraindicated in ABC hypersensitivity	<p>TDF can be used in place of ABC.</p> <p>Use ABC if client not eligible for TDF or ZDV.</p>

Table 4.5

Considerations for 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) Tenofovir (TDF) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r) (or Atazanavir/r (A)	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. 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 4.6**Considerations for 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	If possible, consider optimization using genotyping before selecting 3rd line regimen. DRV/r must be taken with food. 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. DTG can be used as 3rd line in place of RAL but should be taken twice daily
Second Alternative	DRV/r +2NRTIs ±NNRTI	DRV/r must be taken with food in PI-experienced patients. DRV/r should be given 600mg/100mg twice daily DTG can be used as 3rd line in place of RAL but should be taken twice daily

4.4 CONSIDERATIONS FOR ART REGIMEN FOR CHILDREN

Table 4.7 Considerations for 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 in severe anaemia (Hb < 8g/dL) Raltegravir to be replaced with LPV/r after two weeks of life. DTG can be used after 4 weeks of life and weight 3kg
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 in severe anaemia (Hb < 8g/dL) Replace NVP with LPV/r after two weeks of life.

Table 4.8

Considerations for First-Line ART Regimen for Children

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.	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	Replace ABC with ZDV
3- 19.9Kg	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG)	Abacavir is contraindicated in Abacavir hypersensitivity <i>As long as the child is above 3 kg and more than four weeks old</i>	Replace ABC with ZDV

Weight band	Drugs	Contra- indications/ Caution	Comments
Alternate Regimen			
≥30Kg	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
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) + DTG	Zidovudine is contraindicated in severe anaemia (<8g/dL)	ABC can replace ZDV

Weight band	Drugs	Contra- indications/ Caution	Comments
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 4.9 Considerations for Second-Line ART Regimen for Children

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

Weight band	Initial First-line regimen	Preferred second line regimen	Contraindications/ caution	Comments
≥30Kg	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
20 to 29.9Kg	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Dolutegravir (DTG) Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	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

Weight band	Initial First-line regimen	Preferred second line regimen	Contraindications/ caution	Comments
20 to 29.9Kg	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	
3 to 19.9Kg	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + DTG	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	
	Abacavir (ABC) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Lopinavir/r (LPV/r)	Zidovudine (ZDV) + Lamivudine (3TC) (or Emtricitabine (FTC)) + DTG	ABC is contraindicated in ABC hypersensitivity ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	

Weight band	Initial First-line regimen	Preferred second line regimen	Contraindications/ caution	Comments
3 to 19.9Kg	Zidovudine (ZDV) (or Abacavir (ABC)) + Lamivudine (3TC) + Lopinavir (LPV/r)	Abacavir (ABC) (or Zidovudine (ZDV)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + DTG	ABC is contraindicated in ABC hypersensitivity	
	Abacavir (ABC) (or Zidovudine (ZDV)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + Efavirenz (EFV)	Zidovudine (ZDV) (or Abacavir (ABC)) + Lamivudine (3TC) (or Emtricitabine (FTC)) + DTG/ Lopinavir/r (LPV/r)	ZDV is contraindicated in severe anaemia (Hb < 8g/dL)	EFV is contraindicated if less than 3 years old or weighs less than 10Kg.

Table 4.10

Considerations for Third-Line ART Regimen for Children

Recommended Third-line regimen	Contraindications/ caution	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.

Tenofovir alafenamide (TAF) is a prodrug of Tenofovir . Studies have suggested improved renal and bone safety markers compared with TDF. Therefore, TAF may be considered an option for special circumstances when bone and renal toxicity are a particular concern (such as the presence of osteoporosis or mild chronic renal disease and concomitant use of nephrotoxic drugs).



Transitioning to optimal DTG-based drug regimens for children

DTG-based regimens provide a more efficacious and tolerated option that overcomes potential resistance to NNRTIs and provides the opportunity to fully harmonize regimens across children and adults.

Based on the anticipated individual (palatability, potency, ease of administration, once-daily administration, and drug–drug interaction profile) and programmatic (cost, simplification and consolidation of demand and procurement) benefits, the WHO recommends a rapid programmatic transition to DTG-based regimens for infants and children who are currently established on ART regardless of their current regimen.



NEW

4.5 RECOMMENDATIONS FOR SPECIAL CONDITIONS

4.5.1 *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 Abacavir (ABC) or paediatric formulations of Tenofovir, if available + (Emtricitabine (FTC) or Lamivudine (3TC) + DTG. 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 4.3. When they fail first line, the recommended second line is AZT + TDF + 3TC + PI.



NEW

4.5.2 *TB/HIV Co-Infection*

Persons living with HIV should be systematically screened for TB disease at each visit to a health facility using the algorithm for diagnosis of TB (Appendix 3).

In using differentiated delivery the aim of TB/HIV integration is to ensure that:

- All clients diagnosed with TB are tested for HIV as an entry point to HIV care.
- Intensified case finding (ICF) is implemented so that all HIV positive clients are screened for TB at every clinical visit. TB screening does not need to be performed at every refill visit unless the client has a respiratory complaint. Refer to Differentiated Service Delivery in HIV in Ghana, Operational Manual, Chapter 7

Newly diagnosed PLHIV who are screened negative for TB should be provided TB Preventive Therapy (TPT) in accordance with the National Guidelines for Latent TB Infection Management in Ghana

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. The metabolism of Integrase Strand Transfer Inhibitors (INSTIs) such as DTG have been found to be affected by the enzyme inducing effect of Rifampicin. The dose of DTG



NEW

needs to be adjusted because of drug–drug interactions with rifampicin to ensure effective during co-treatment for TB in terms of suppressing viral loads, time to suppress viral loads and improvement in CD4 cell counts.

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 should be treated in accordance with the National Tuberculosis Programme Guidelines. Preferred first line in this case is TDF + 3TC (or FTC) + DTG but where DTG is not tolerated or contraindicated, replace with EFV. Revert to standard first line upon completion of TB treatment. 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, with rapid initiation of ART once TB meningitis and other nervous system infections have been ruled out. 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.

For children on DTG-based regimen, DTG should be taken twice daily in TB management on Rifampicin-containing TB therapy. The DTG dose will need to remain twice daily for two weeks after the last dose of rifampicin has been given.

Table 4.11 *Guidance for adjusting ART when rifampicin-based TB treatment starts*

	ART regimen	What to do when TB treatment is started
Neonates	RAL-based ^a	Dose adjustment needed: see the annexes for ARV dosing
	NVP-based	Change of regimen needed: NVP to be replaced as soon as possible with DTG or LPV/r (with appropriate dose adjustment)
Children	DTG-based	Dose adjustment needed
	LPV/r-based	Transition to DTG-based regimen (with appropriate dose adjustment) is preferable, and if not possible, LPV/r dose adjustment is needed: see the annexes for ARV dosing
	RAL-based regimen	Transition to DTG-based regimen (with appropriate dose adjustment) is preferable, and if not possible, RAL dose adjustment is needed: see the annexes for ARV dosing



	ART regimen	What to do when TB treatment is started
	ATV/r-based regimen	Change of regimen needed: replace ATV/r with DTG if DTG naive, with LPV/r if DTG experienced
	DRV/r-based regimen	Change of regimen needed: replace DRVr with DTG if DTG naive, with LPV/r if DTG experienced

^a Preferred for ART initiation while receiving TB treatment.

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

Transition to the preferred DTG-based regimen with appropriate dose adjustment and start TB treatment as soon as possible.

Drug resistant TB

Start ART for all persons with HIV and drug-resistant TB, requiring second-line anti-TB drugs irrespective of CD4 cell count, as early as possible (within the first eight weeks) following initiation of anti-TB treatment



4.6 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 4.12 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	More common with PIs and INSTIs. Include hyperlipidaemia, fat accumulation, insulin resistance, diabetes and osteopenia. Lipodystrophy is also associated with Zidovudine. The risk of cardiovascular events with Abacavir (ABC) is still debatable.
ALLERGIC REACTIONS	Skin rashes and hypersensitivity reactions, more common with the NNRTI drugs but also seen with certain NRTI drugs, such as ABC and some PIs.
HEPATIC TOXICITY	Liver enzyme elevation with DTG especially in patients with HBV or HCV co-infection. DRV/r also causes liver enzyme elevation
MUSCULAR TOXICITY	Muscle weakness and sometimes rhabdomyolysis seen with RAL

4.7 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.

4.8 GRADING OF ADVERSE EVENTS

Table 4.13 *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

4.9 GUIDING PRINCIPLES IN THE MANAGEMENT OF ARVS ADVERSE EVENTS

1. Evaluate concurrent medications and establish whether the toxicity is attributable to an ARV or to a non-ARV medication taken at the same time.
2. Consider other disease processes (e.g. viral hepatitis in an individual on ARVs who develops jaundice) because not all problems that arise during treatment are caused by ARVs.

3. Manage the adverse event according to severity:
 - Grade 4 (severe life-threatening reactions): Immediately discontinue all ARVs, manage the medical event (i.e. symptomatic and supportive therapy) and reintroduce ARVs 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 ARVs should be stopped until the client is stabilized.

CHAPTER FIVE

ELIMINATION OF MOTHER-TO-CHILD TRANSMISSION (EMTCT)

NEW

Mother-to-child transmission of HIV (MTCT), also known as ‘vertical transmission’, refers to the transmission of HIV from a mother (living with HIV) to her child during pregnancy, labour, delivery or breastfeeding. Interventions to eliminate this transmission should aim at preventing HIV infection in women; preventing unintended pregnancies among women living with HIV; preventing mother-to-child transmission of HIV; and providing care and support to women living with HIV and their infants.

5.1 EMTCT GUIDING PRINCIPLES

The EMTCT guidelines are developed in line with 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 as well as keeping their mothers alive. The programme includes:

1. Integrated delivery of interventions for EMTCT within reproductive, maternal, newborn child and adolescent health services including links between the services 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 and girls living with HIV, their children and families. For this to happen, interventions to prevent MTCT need to be integrated into reproductive, maternal, neonatal child and adolescent health services, services for sexually transmitted infections and programmes for HIV treatment and care.
2. Women's health is the overarching priority in decisions about ARV treatment before and during pregnancy to improve maternal and child survival. For pregnant women living with HIV, treatment reduces maternal mortality and morbidity. It is the most effective method of preventing MTCT of HIV by securing maternal health and improving the chances of survival of her child.
3. Necessity for highly effective ARV regimens and simple formulations for eliminating transmission to infants and young children.
4. Task sharing to remove all barriers to identifying the infected and initiation of therapy within EMTCT and ANC, Labour & Delivery (L&D) units, PNC and other childcare settings.

5. Urgent need to scale up services to achieve equitable national coverage and universal access aiming for impact and equity.
6. Emphasizing partnerships with 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 childbearing 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.

NEW

Primary prevention of HIV infection in women of childbearing age

This includes prevention of HIV among women of reproductive age within services related to reproductive health such as antenatal care, postpartum and postnatal care and other health and HIV service delivery points, including working with community structures. Education about HIV and contraception is also

crucial. Comprehensive education with focus on gender rights and gender power dynamics have been found to be effective in reducing HIV and other sexually transmitted infections (STIs).

Prevention of unintended pregnancies among women infected with HIV

This involves providing appropriate counselling and support, and contraceptives, to women living with HIV to meet their unmet needs for family planning and spacing of births, and to optimize health outcomes for these women and their children.

When women living with HIV are supported through family planning services to plan when they do and do not have children, the number of children being born with HIV reduces. The integration of family planning services into HIV services is an important approach to making both more accessible to women and couples living with HIV.

The first 2 components are addressed in detail 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 component 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, and sexual and reproductive health (SRH) in general.
- Both client and provider-initiated testing and counselling strategies.
- Antiretroviral therapy and management of opportunistic infections.
- Continued supportive counselling for all mothers living with HIV.
- Counselling on and support for infant feeding and Early Childhood Development (ECD).
- PrEP for pregnant and breastfeeding women at substantial risk of acquiring HIV

Outreach/community-based services

- Psychosocial care and community support for both HIV prevention and care.
- 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 FOR 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 counselling 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. HIV negative pregnant women at substantial risk of acquiring HIV, in addition to benefiting from PrEP may be eligible for interventions (except for ART) for pregnant women living with HIV below. 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 (and Syphilis) 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 labor shall be offered HIV testing and counselling. 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 counselling. 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 HIV 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 counselling and Testing

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

5.5 HIV TESTING ALGORITHMS FOR EMTCT

All pregnant women should be tested for HIV, syphilis and Hepatitis B virus (HBV) at least once and as early as possible in the pregnancy. For Pregnant women the First Response combo (first test) should be an integrated testing for HIV, Syphilis and Hepatitis B and if reactive for HIV, followed by Oraquick HIV 1&2 (Second test) and SD Bioline HIV 1&2 (Third test). Testing for HBV should be done at the same time as the duo HIV/syphilis test.



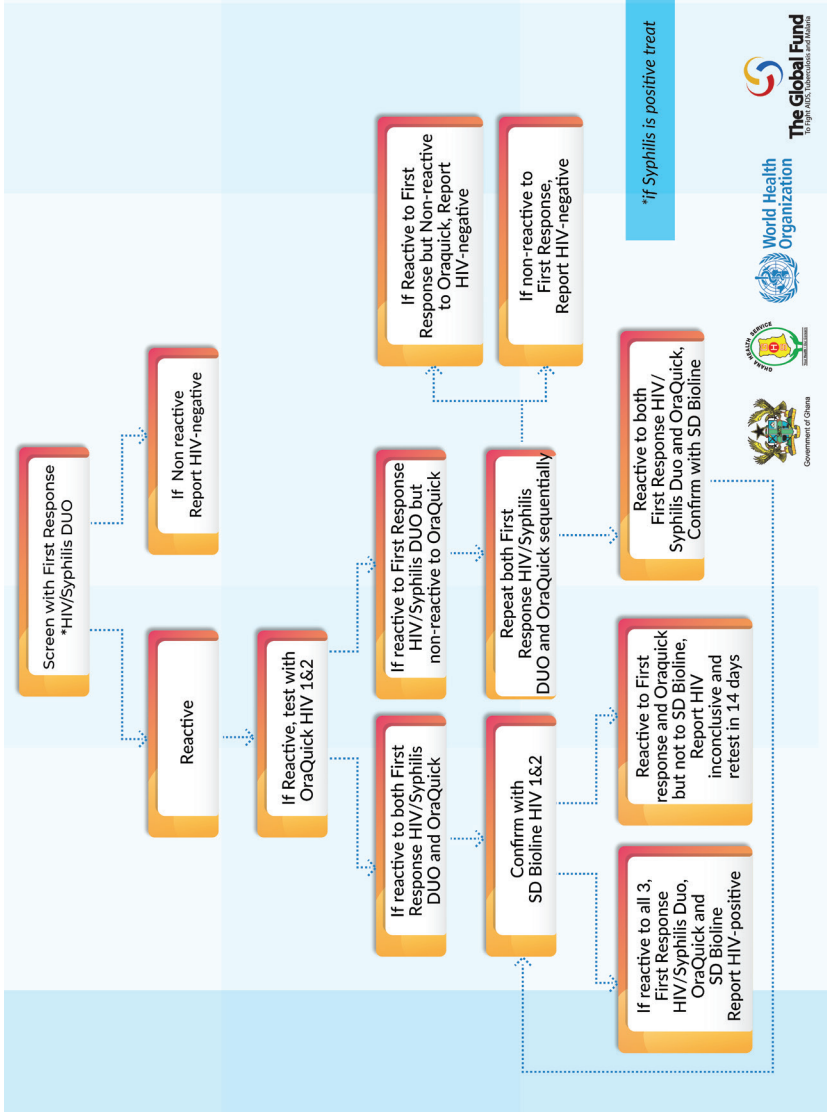
A pack of First response kit which includes the HIV/syphilis duo and Hepatitis B test kit should be used if available. Re-testing for HIV in pregnant women (who initially tested negative) should be done at 34weeks.

Provider-assisted referral for ART services should be offered to people with HIV as part of a comprehensive package of testing and care.



Figure 5.1

HIV Testing Algorithm for Antenatal clients





5.5.1 Algorithm for Early Infant Diagnosis (EID)

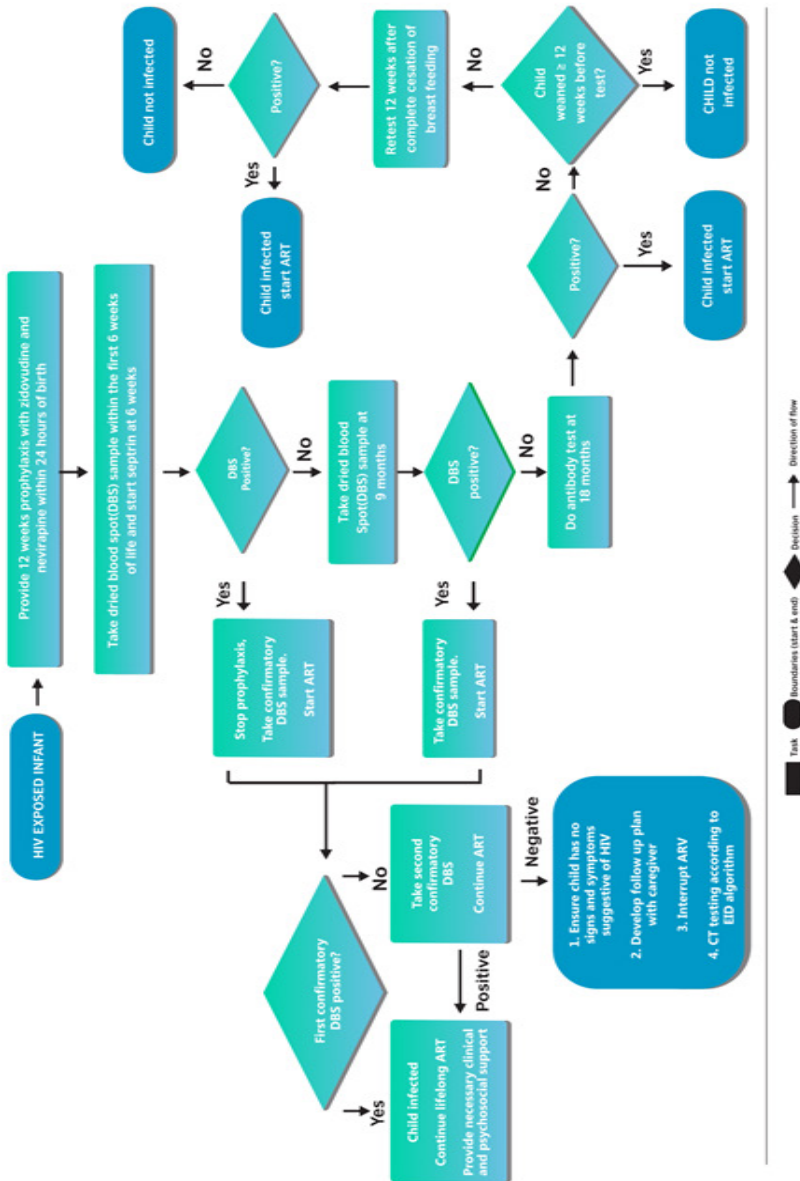
- a. **Zero to six weeks test in HIV-Exposed Infants:** Samples from HIV-Exposed Infants (HEIs) should be collected for HIV PCR testing within the first 6 weeks of life.
- b. **Test for infants who test negative within the first six weeks of life:** Samples from HIV-Exposed Infants (HEIs) who tested negative within the first six weeks of life should be collected at 9 months for HIV PCR testing.
- c. **Test for infants who test negative at 9 months of life:** Samples from HIV-Exposed Infants (HEIs) who tested negative at 9 months should be tested at 18 months using the national antibody testing algorithm.
- d. Infants with positive HIV PCR test results should have a repeat test at ART initiation. The ART initiation should not be delayed whilst waiting for the repeat test results.
- e. A negative HIV test for an HEI who is still breastfeeding, is inconclusive.

For HIV PCR, the negative test result is conclusive six weeks after complete cessation of breast feeding.

For antibody testing in children 18 months and above, a negative test result is conclusive 12 weeks after complete cessation of breast feeding. Figure 5.5.3 below shows the algorithm for early infant prophylaxis and diagnosis.

NEW

Figure 5.2 Algorithm for Early infant prophylaxis and diagnosis



5.5.2 Recommended Antiretroviral Protocols for EMTCT

Antiretroviral therapy shall be given to all pregnant and breastfeeding women living with HIV 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 mothers living with HIV for EMTCT.**

NEW

The regimens for pregnant women are the same as for the general population.

5.5.2.1 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) + DTG

The alternate regimen for EMTCT are:

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

5.5.2.2 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 is recommended for up to 12 months; with first 6 months being exclusive breastfeeding.

5.6 CARE FOR PREGNANT WOMEN

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 counselling 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.

NEW

5.6.1 Management of Syphilis in Pregnant Women

Clients with or without HIV who are found to have syphilis should be managed and the treatment should be given as early as possible when detected during pregnancy. The recommended management for syphilis is the same as for those who do not have HIV and is based on the current National Standard Treatment guidelines as follows:

a. Recommended regimen

Benzathine Penicillin G, IM, 1.2 MU in each buttock (total dose 2.4 MU) stat.

Alternative regimen

- Procaine benzylpenicillin, 1.2 million IU daily, by intramuscular injection, for 10 consecutive days

Alternative regimen for penicillin-allergic pregnant women

For those with penicillin-allergy, the recommendation is to use, with caution, erythromycin 500 mg orally four times daily for 14 days or ceftriaxone 1 g intramuscularly once daily for 10–14 days or azithromycin 2 g once orally

Although erythromycin and azithromycin treat the pregnant women, they do not cross the placental barrier completely and as a result the foetus is not treated. It is therefore necessary to treat the newborn infant soon after delivery.

Alternative regimen for penicillin-allergic non-pregnant patients

- Doxycycline 100mg orally twice daily for 14 days
OR
- Tetracycline, 500mg orally 4 times daily for 14 days

5.6.2 Before Pregnancy

Adopting practices that ensure that women are able to plan when they do and do not have children, whilst maintaining safer sexual practices is key to having better outcomes when the women decide to get pregnant.

- Health Information and Education
- Maternal nutrition.
- Safer sex practices.
- Counselling and support for Family planning.
- HIV Testing and Counselling
 - Routine Offer (Provider-Initiated TC),
 - Partner(s) HIV Testing and Counselling

5.6.3 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
 - Offer PrEP to HIV negative women at substantial risk of acquiring HIV infection.
- Follow up counselling 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 and HBV).
- Provision of information on early recognition and treatment of STIs
- Follow up care and treatment of HIV positive women
- Viral Load Assessment
- Clinical assessment (WHO staging; see Appendix)
- 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).

Viral load testing for pregnant women

NEW

Whenever possible, use same-day point-of-care testing for viral load testing of pregnant and breastfeeding women to expedite the return of results and clinical decision-making. If this is not available, viral load specimens and results for pregnant and breastfeeding women should be given priority across the laboratory referral process (including specimen collection, testing and return of results).

Adherence counselling should be provided at all antenatal care and postnatal visits to ensure that viral suppression is maintained throughout pregnancy and breastfeeding.

For all pregnant women, regardless of ART initiation timing: conduct viral load testing at 34–36 weeks of gestation (or at the latest at delivery) to identify women who may be at risk of treatment failure and/or may deliver infants at higher risk of perinatal transmission.

Action: if viral load >50 copies/ml, follow the treatment monitoring algorithm

Where available, consider infant nucleic acid testing at birth.

In addition:

a) For pregnant women receiving ART before conception: conduct a viral load test at the first antenatal care visit (or when first presenting) to identify women at increased risk of in utero transmission.

Action: If viral load >50 copies/ml, follow treatment monitoring algorithm and consider infant nucleic acid testing at birth where available.

b) For pregnant women starting ART during pregnancy: conduct a viral load by three months after ART initiation to ensure that there has been rapid viral suppression.

Action: If viral load >50 copies/ml, follow the treatment monitoring algorithm.

Regardless of the maternal viral load, the infants of mothers starting ART at any time during pregnancy could be considered for birth testing where available.

c) For all breastfeeding women, regardless of when ART was initiated: conduct a viral load test three months after delivery and every six months thereafter to detect viraemic episodes during the postnatal period.

Action: if viral load >50 copies/ml, follow the treatment monitoring algorithm, conduct infant HIV testing immediately and consider reinitiating enhanced postnatal prophylaxis for the infant.

5.6.4 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 testing and counselling 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 partogram 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 HTS and retesting offered to women found to be negative but at a substantial risk of HIV infection.
- Information Education and Counselling (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 Counselling 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).

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).
 - ✓ Counselling on safe sex and FP?

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 HEI 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, developmental assessments. Assess to also determine whether the child is receiving nurturing care. 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) or blood sample for early infant diagnosis (EID).

6week postnatal clinic visit

Mother

- Ensure that all routine assessments have been carried out for the mother 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. Assess to also determine whether the child is receiving nurturing care. 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 or integration 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 or not gaining weight appropriately.
- 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:

- ✓ HIV PCR test if not yet done.
- ✓ Initiate ART in all HIV infected infants 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.

5.7.5 Infant Feeding

For breastfed infants, refer Algorithm for EID (Figure 5.5.3) 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 counselling sessions shall take place sometime during ANC after post-test counselling.

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.



NEW

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 be avoided in the first 6 months.

In settings in which health services provide and support lifelong ART, including adherence counselling, and promote and support breastfeeding among women living with HIV, the duration of breastfeeding may not be restricted. Mothers living with HIV (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first six months of life, introducing appropriate complementary foods thereafter and continue breastfeeding until 12 months. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.

However, mothers living with HIV and health-care workers can be reassured that ART reduces the risk of postnatal HIV transmission in the context of breastfeeding. Although exclusive breastfeeding is recommended, practising mixed feeding is not a reason to stop breastfeeding in the presence of ARV drugs.

Evaluation of Child at 18 Months and above

At 18 months the definitive HIV infection status of all HIV-

exposed children should be determined using antibody test. If the child is still breastfeeding, the test should be repeated at least 12 weeks after cessation of breastfeeding.

- ✓ 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 Psychosocial and Community Support

Women shall be supported and encouraged to undergo pre-marital and couple counselling and testing for HIV. Women who test positive shall be provided with follow-up counselling 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 counselling 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.

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 services 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.

CHAPTER SIX

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.

NEW

With the accelerated introduction of new ARV drugs, often occurring in the context of limited clinical experience outside trial settings, pharmacovigilance systems should be developed

or strengthened as efforts to optimize ARV drugs for children are ongoing. The transition to optimal formulations can happen concurrently with pharmacovigilance strengthening activities. Existing pharmacovigilance systems can be modified to include newly available and optimal ARV drugs for children rather than developing parallel systems, which can be both time and cost intensive. Updating pharmacovigilance reporting forms and systems is important to capture adverse drug reactions during DTG introduction and possible drug intolerance to DTG.

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 Effect

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 above. 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 ≤ 50 copies/ml (which is usually reported as viral suppression).

INTERPRETATION OF HIV VIRAL LOAD TESTING RESULTS

Viral loads 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. Inpatients 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 in antiretroviral regimen. (REFER Appendix 7 Treatment monitoring algorithm)

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

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

- a. Routine viral load monitoring for early detection of treatment failure, obtain and review result by 6 months after ART initiation, 12 months after ART initiation and yearly 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.

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.

6.2.2 ANCILLIARY TESTS



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 or INSTI's).
- BUE and Creatinine.
- Liver function tests (ALT, AST).



CHAPTER SEVEN

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
- Persistent 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 trained healthcare worker 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.

DIAGNOSIS OF TREATMENT FAILURE

Table 7.1

WHO definitions of clinical, immunological and virological failure for the decision to switch ART regimens

Failure	Definition	Comments
Clinical failure	<p>Adults and adolescents New or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4 condition) after six months of effective treatment.</p> <p>Children New or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 clinical conditions except for TB) after six months of effective treatment.</p>	<p>The condition must be differentiated from immune reconstitution inflammatory syndrome occurring after initiating ART.</p> <p>For adults, certain WHO clinical stage 3 conditions (pulmonary TB and severe bacterial infections) may also indicate treatment failure.</p>
Immunological failure	<p>Adults and adolescents CD4 count at 250 cells/mm³ following clinical failure or Persistent CD4 cell count below 100 cells/mm³</p> <p>Children <i>Younger than five years</i> Persistent CD4 cell count below 200 cells/mm³.</p> <p><i>Older than five years</i> Persistent CD4 cell count below 100 cells/mm³.</p>	<p>Without concomitant or recent infection to cause a transient decline in the CD4 cell count. Current WHO clinical and immunological criteria have low sensitivity and positive predictive value for identifying individuals with virological failure. There is currently no proposed alternative definition of treatment failure and no validated alternative definition of immunological failure.</p>

Failure	Definition	Comments
Virological failure	Viral load above 1000 copies/mL based on two consecutive viral load measurements three months apart, with adherence support following the first viral load test. Switch ART after first viral load >1,000 copies/mL for those receiving NNRTI-based regimens.	An individual must be taking ART for six months before it can be determined that a regimen has failed. Individuals with viral load > 50 to ≤ 1000 copies, maintain ARV regimen, enhance adherence counselling and repeat viral load testing after three months. Consider switch after second viral load > 50 to ≤ 1000 copies/mL if people are on NNRTI-based ART.

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.

Viral suppression: Viral suppression is a viral load that is undetectable (equal to or less than 50 copies/ml).

Low-level viraemia: Low-level viraemia is one or more viral load results that are detectable (more than 50 copies/ml) but equal to or less than 1000 copies/ml.

Table 7.2 *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.

CHAPTER EIGHT

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

8.1 MANAGEMENT OF OPPORTUNISTIC INFECTIONS

This should follow established protocols for the management of opportunistic infections. Opportunistic infections need to be treated as much as possible before the initiation of ART.

8.1.1 *Cryptococcal disease*

Cryptococcal meningitis accounts for an estimated 15% of all people dying from AIDS-related causes globally, three quarters of which are in sub-Saharan Africa. Less common presentations of cryptococcal disease include pulmonary disease, skin, lymph node and bone disease

Management

Immediate ART initiation is not recommended for adults, adolescents and children living with HIV who have cryptococcal meningitis because of the risk of increased mortality and ART initiation should be deferred 4–6 weeks from the initiation of antifungal treatment

Induction

The following is recommended as the preferred induction regimen.

- For adults, adolescents and children, a short-course (one-week) induction regimen with amphotericin B deoxycholate (1.0 mg/kg per day) and flucytosine (100 mg/kg per day, divided into four doses per day) or
- Two weeks of fluconazole (1200 mg daily, 12 mg/kg per day for children and adolescents) + flucytosine (100 mg/kg per day, divided into four doses per day) (39) or
- Two weeks of amphotericin B deoxycholate (1.0 mg/kg per day) + fluconazole (1200 mg daily, 12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily)

Consolidation

Fluconazole (400–800 mg daily for adults or 6–12 mg/kg per day for children and adolescents up to a maximum of 800 mg daily) (for eight weeks following the induction phase)

Maintenance (or secondary prophylaxis)

Fluconazole (200 mg daily for adults or 6 mg/kg per day for adolescents and children) is recommended for the maintenance phase

Routine use of adjunctive corticosteroid therapy during the induction phase is not recommended in treating adults, adolescents and children who have HIV-associated cryptococcal meningitis

Pneumocystis jirovecii pneumonia

Pneumocystis jirovecii pneumonia is a leading cause of mortality among hospitalized adults (13%) and children (29%) living with HIV.

Management

Septtrin 4 tablets (1920mg) bd

Toxoplasmosis

Cerebral toxoplasmosis is the most frequent cause of expansive brain lesions among adults living with HIV not receiving co-trimoxazole.

Management

Sulphadiazine 1gm 6hrly x 6 weeks + Pyrimethamine 100mg st, 50mg dly x 6 weeks+ Folinic acid 10-25mg dly

Or

Septtrin 4 tablets (1920mg) bd

Or

Clindamycin 450-600mg +Pyrimethamine 200mg stat then 50-75mg daily + leucovorin/folinic acid 10-20mg daily X 6 weeks

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 Cotrimoxazole 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 below 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 established 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.	

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)					
	3.0-5.9	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	2.5ml	5.0ml	5.0ml	10.0ml	10.0ml	-
Dispersible tablets 100/20 mg	1	2	2	4	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 ‘ademe’) 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.

CHAPTER NINE

MANAGING ADVANCED DISEASE

NEW

A package of interventions including screening, treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation and intensified adherence support interventions should be offered to everyone presenting with advanced HIV disease.

Advanced HIV disease for adults and adolescents including children five years and older is defined as having a CD4 cell count of less than 200 cells/mm³ or WHO clinical stage 3 or 4 disease.

Children older than two years who have been receiving ART for more than one year and are clinically established should not be considered to have advanced disease and should be eligible for multi-month ART dispensing.

Advanced HIV disease includes people presenting to care for the first time following an HIV diagnosis and people who have treatment failure and consequent decline in CD4 cell count. Individuals who had previously initiated ART and are re-

engaging with care after a period of ART interruption should be assessed for advanced HIV disease and should be offered the advanced HIV disease package as appropriate.

People presenting with advanced HIV disease are at high risk of death, even after starting ART, with the risk increasing with decreasing CD4 cell count, especially with CD4 cell count <100 cells/mm³. Advanced HIV disease is also associated with increased health-care costs increased risk of opportunistic infections, immune reconstitution inflammatory syndrome, incomplete immune reconstitution, higher viral reservoirs, higher inflammation, increased risk of AIDS-related and non-AIDS-related comorbidities, use of more health-care services and more frequent monitoring needs.

Leading causes of mortality among adults with advanced HIV disease globally include TB, severe bacterial infections, cryptococcal disease, histoplasmosis, toxoplasmosis and *Pneumocystis jirovecii* pneumonia. Other invasive fungal infections have been recently estimated as contributing significantly to the number of people dying from AIDS-related causes

Children and adolescents who had previously initiated ART and are re-engaging with care after a period of ART interruption should be assessed for advanced HIV disease and should be offered the advanced HIV disease package as appropriate.

The major causes of morbidity and mortality among children living with HIV in low- and middle-income countries are pneumonia (including *P. jirovecii* pneumonia), TB, bloodstream infections, diarrhoeal disease and severe acute malnutrition.

Assessing Advanced HIV disease

CD4 count should be used to identify people with advanced HIV disease. If not available, WHO staging should be used. All children younger than five years who are not already receiving ART are considered to have advanced HIV disease.

Lack of same-day availability of CD4 count results should not be a barrier to initiating ART on the same day.

Table 13.1 summarizes the specific components of the package of interventions that should be offered to people presenting with advanced HIV disease. The algorithm for providing a package of care for people with advanced HIV disease is shown in Figure 13.1.



Table 9.1

Components of the package of care for people with advanced HIV disease

	Intervention	CD4 cell count	Adults	Adolescents	Children <10 years
Screening and diagnosis	Screening tools for TB disease for adults and adolescents: WHO-recommended four symptom screen, chest X-ray, C-reactive protein, WHO recommended molecular rapid diagnostic test for TB, alone or in combination. Screening tools for TB disease among children: symptom screening for children living with HIV.	Any	Yes	Yes	Yes (symptom screen only)
	WHO-recommended molecular rapid diagnostics as the first test for pulmonary TB diagnosis among those who screen positive for TB and investigations for extrapulmonary TB as applicable; chest X-ray may also be used to support investigations.	Any	Yes	Yes	Yes
	LF-LAM to assist TB diagnosis among people with symptoms and signs of TB	≤200 cells/mm ³ (inpatient) ≤100 cells/mm ³ (outpatient) Or any CD4 count with symptoms or if seriously ill	Yes	Yes	Yes
	Cryptococcal antigen screening	Recommended for <100 cells/mm ³ and considered for 200 cells/mm ³	Yes	Yes	No

	Intervention	CD4 cell count	Adults	Adolescents	Children <10 years
Prophylaxis and pre-emptive treatment	Co-trimoxazole prophylaxis	<350 cells/mm ³ or clinical stage 3 or 4. Any CD4 count in settings with high prevalence of malaria or severe bacterial infections	Yes	Yes	Yes
	TB preventive treatment ^a	Any	Yes	Yes	Yes
	Fluconazole pre-emptive therapy for cryptococcal antigen-positive people without evidence of meningitis	<100 cells/mm ³	Yes	Yes	Not applicable (screening not advised)
ART initiation	Rapid ART initiation ^b	Any	Yes	Yes	Yes
	Defer initiation if clinical symptoms suggest meningitis (TB or cryptococcal)	Any	Yes	Yes	Yes
Adapted adherence support	Tailored counselling to ensure optimal adherence to the advanced HIV disease package, including home visits if feasible	<200 cells/mm ³	Yes	Yes	Yes

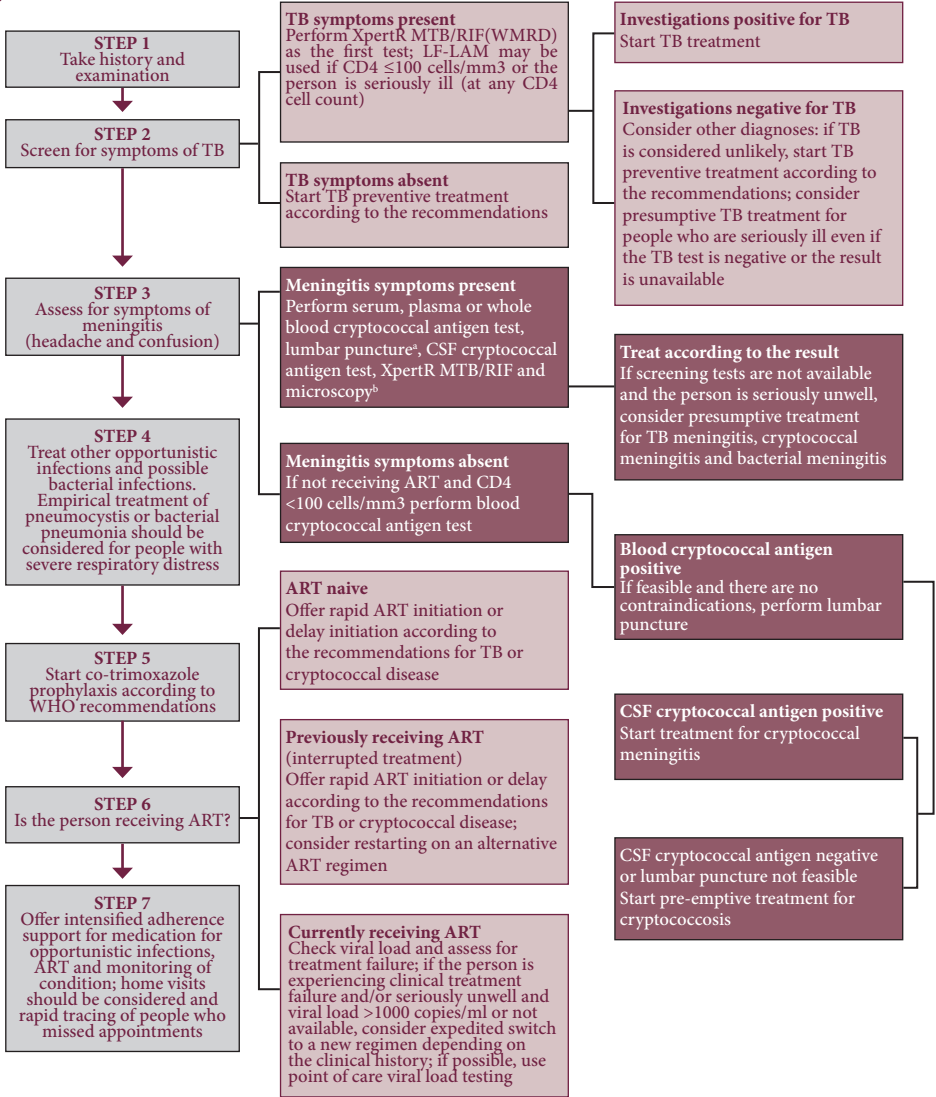
^a TB preventive treatment should be provided in accordance with current WHO guidance.

^b People receiving a positive WHO four-symptom screen should initiate ART while being evaluated for TB if clinical signs and symptoms of meningitis are absent.

A seriously ill adult is defined as having any of the following danger signs: respiratory rate ≥ 30 breaths per minute; heart rate ≥ 120 beats per minute; or unable to walk unaided. Other clinical conditions, such as body temperature $\geq 39^{\circ}\text{C}$, can also be considered based on local epidemiology and clinical judgement



Figure. 9.1 *Algorithm for providing a package of care for people with advanced HIV disease*



ART: antiretroviral therapy; CSF: cerebrospinal fluid; TB, tuberculosis; LF-LAM: lateral flow urine lipaarabinomannan assay.

^a Everyone who is cryptococcal antigen positive and has headache or confusion should have a lumbar puncture.

^b In settings where test results are available quickly, testing for cryptococcal infection before TB infection would be more cost-effective.

CHAPTER TEN

PRE AND POST EXPOSURE PROPHYLAXIS

10.1 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. 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 and STI prevention and management.



NEW

PrEP is safe to use during pregnancy to block or prevent the acquisition of HIV by the pregnant woman in a sero-discordant relationship. The benefits of preventing HIV acquisition in the mother, and the accompanying reduced risk of mother-to-child HIV transmission outweigh any potential risks of PrEP, including any risks of fetal and infant exposure to TDF and FTC in PrEP regimens.



NEW

PrEP can be delivered through the use of a vaginal ring containing dapivirine, a novel non-nucleoside reverse transcriptase inhibitor (NNRTI). This could provide an acceptable option for women who are unable or do not want to take oral PrEP. The dapivirine vaginal ring, which is worn in the vagina, is made of silicone and contains dapivirine, which is released into the vagina slowly over one month. The ring should be worn continuously in the vagina for one month and then should be replaced by a new ring. The risk of HIV-1 infection is reduced 24 hours after ring insertion.

In addition, long-acting cabotegravir (CAB-LA), an integrase strand transfer inhibitor (INSTI), has been recommended by WHO as pre-exposure prophylaxis (PrEP) for HIV-1. It is also safe and highly effective in preventing acquisition of HIV infection among those who are at substantial risk.

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 <50 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 condom use.

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 7 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.

Refer to the National PrEP Implementation Guide for additional details on CAB-LA and Dapivirine ring.

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 when:

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.

10.2 POST EXPOSURE PROPHYLAXIS (PEP)

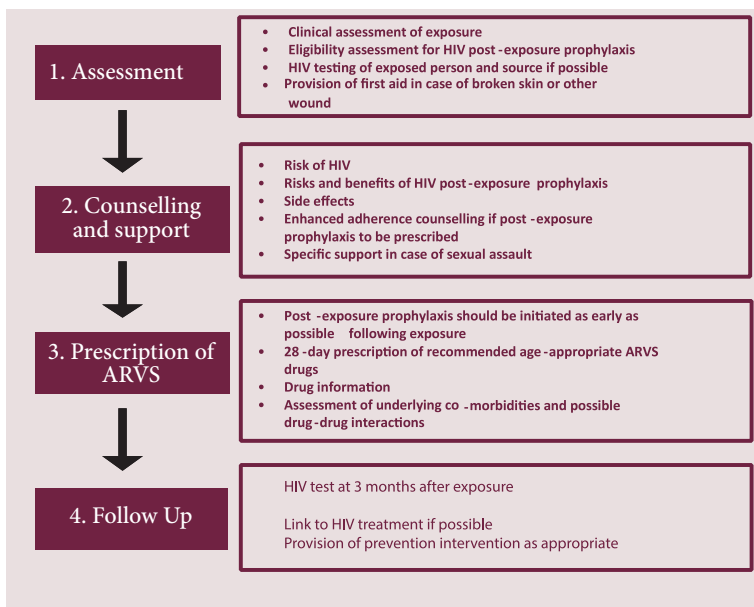
The use of Antiretroviral drugs for post-exposure prevention of HIV infection following occupational exposure to HIV for health workers has been ongoing since the early 1990s. The provision of HIV post-exposure prophylaxis has in recent years been extended to other non-occupational exposures, including 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.

Table 10.1

Care pathway for people exposed to HIV



10.2.1 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.

10.2.2 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.

10.2.3 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.

10.2.4 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 10.2 Recommended ARVS for PEP

Age Group	RECOMMENDED PROPHYLAXIS
Children (<10 years old)	AZT + 3TC (or FTC) + DTG or LPV/r OR ABC + 3TC(or FTC) + LPV/r or TDF + 3TC (or FTC) + LPV/r can be considered as alternative regimen if the child weighs above 30kg.
Adults and Adolescents (including pregnant and lactating mothers)	TDF + 3TC+ DTG or LPV/r

10.2.5 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 baseline and follow-up investigations may need to be done to determine HIV sero-status, and to monitor the level of drug toxicity.

Table 10.3 *Recommended monitoring of drug toxicity and HIV serology of exposed individuals*

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

10.2.6 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.

10.3.1 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 with 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”

10.3.2 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 worker's privacy should be respected and confidentiality maintained. Reporting and recordkeeping should be in accordance with the national occupational health policies.

10.3.3 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 pregnancy and 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.

- ✓ 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 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.

10.3.3.1 *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.

10.3.3.2 *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.

10.3.3.3 *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.

10.3.3.4 *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 CT 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.

10.3.3.5 *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 CT for future HIV testing.
 - b. Six-week and three-month follow-up visits:
 - i. Offer CT 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.

10.3.4 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.



CHAPTER ELEVEN

SUPPLY CHAIN MANAGEMENT AND RATIONAL USE OF HIV COMMODITIES

11.1 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.

11.1.1 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.

11.1.2 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.

11.1.3 *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.

11.1.4 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.

11.1.5 ***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 and AIDS 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.

11.1.6 *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.

11.1.7 *Ghana Integrated Logistics Management Information System (GhiLMIS)*

The current LMIS system uses manual process 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.

11.1.8 *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.

11.1.9 *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).

11.1.10 ***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.

11.1.11 ***Post-Market Surveillance***

Post-market surveillance is a set of activities conducted by regulatory authorities and manufacturers, to collect and evaluate experience gained from health products that have been placed on the market and to identify the need to take any action. Post-market surveillance is a crucial tool for the country to ensure that health products continue to be safe and well performing, and to ensure actions are undertaken if the risk of continued use of the health product outweighs the benefit. The evaluation of post-market surveillance experiences can also highlight opportunities to improve the health product.



CHAPTER TWELVE

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.

12.1 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.

12.2 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.

12.2.1 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).

12.2.2 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.

CHAPTER THIRTEEN

HIV CARE DURING COVID-19 AND FUTURE OUTBREAKS

NEW

The COVID-19 pandemic slowed HIV community mobilization efforts while exposing weak health systems and deteriorating socio-economic conditions. The pandemic resulted in interruptions to health services and supplies, affecting ART and other essential services for many PLHIV.

There is the need to develop mitigation measures such that COVID-19 and other future pandemics do not cause massive interruptions to HIV services as was witnessed. The following operational considerations are proposed to maintain essential HIV services in the context of COVID-19 but can be adapted for future pandemics.

13.1 GENERAL CONSIDERATIONS

- HIV facility visits should be limited to those that are considered medically essential to reduce the risk and burden to recipients of care and healthcare providers.
- Facilities should consider shifting HIV services to within

the community, fully engaging community cadres or setting up temporary clinics within the community where applicable.

- For clients that require a facility visit, ensure all COVID-19 protocols are observed. Streamline clinic patient flow, stagger clinic appointments and conduct HIV care and treatments services in dedicated spaces that are physically separate from COVID-19 treatment areas. PLHIV with COVID-19 should however be treated at the COVID-19 dedicated areas.
- Where applicable, health care providers and patients should use telehealth options such as phone calls or other virtual options for routine or non-urgent consultations (including HIV adherence counselling), with careful consideration for patient privacy and confidentiality. This can also be applied to peer support groups and home visits.

Prevention

- Condom distribution, PrEP, and PEP may be particularly important during periods of ongoing confinement, in addition to preventive and psychosocial services for gender-based violence and child protection. Innovative ways such as using digital platforms where applicable, can be employed.
- HIV testing may be affected by reductions in facility utilization and community testing activities, however, it should be prioritized for patients with clinical suspicion of or known exposure to HIV, and in healthcare settings providing antenatal care, TB, sexually transmitted infection or malnutrition services. HIVST can be utilized where applicable to screen persons for further testing. Patient tracking, tracing and linkage to care should be conducted over the telephone or a virtual platform. Only when impossible should in-person tracking be conducted in which case PPEs should be provided.

ART

- Six month multi-month scripting should be offered to eligible clients.

Viral Load:

- Where prioritization is required, VL and early infant diagnosis services should first be provided to children, pregnant and breastfeeding women, and adults with recent documented non-suppression.
- Dried Blood Spot specimen collected during home visits can be used for EID in this context.
- Consideration should also be given to those with signs of treatment failure, and patients requiring initial VL assessment after ART initiation.



NEW

Treatment considerations

Dexamethasone is used at doses ranging from 6 mg up to 20 mg daily for short duration for people with COVID-19. At such doses, dexamethasone has a weak to moderate inducing effect that does not warrant any dose adjustment of EFV, NVP, PIs, DTG or RAL. Conversely, EFV and NVP may decrease dexamethasone concentrations, and doubling of the dexamethasone dose is therefore recommended. Currently no known drug–drug interactions between ARV drugs and the COVID-19 vaccines have been documented.



CHAPTER FOURTEEN

HIV AND NONCOMMUNICABLE DISEASES

Assessment and management of cardiovascular risk should be provided for all individuals living with HIV according to standard protocols recommended for general population.

Strategies for the prevention and risk reduction of cardiovascular diseases by addressing modifiable factors such as blood pressure, smoking, obesity status, unhealthy diet and lack of physical activity should be applied to all people living with HIV.

Compared with the general population, people living with HIV have increased risk of developing a range of chronic noncommunicable diseases, including cardiovascular disease, hypertension, diabetes, chronic obstructive pulmonary disease, kidney disease and cancer.

A package of essential noncommunicable disease interventions for assessing and managing the major noncommunicable diseases from the primary care level to the district hospital level

are mainly focused on cardiovascular disease risk, including high blood pressure, type 2 diabetes, chronic respiratory diseases (asthma and chronic obstructive pulmonary disease) and early identification of breast and cervical cancer.

14.1 CONSIDERATIONS FOR MANAGING NCDS IN PLHIV

Screening for cardiac, hypertension, renal, diabetes, neurocognitive disease should be done for all PLHIV including CALHIV. Children from age 3 should be screened for hypertension at every visit and checking blood sugar at least once a year. Monitoring growth, musculoskeletal and neurocognitive development in CALHIV is important. Human papillomavirus vaccination for adolescents is recommended. Screening for cervical cancer after sexual debut should be encouraged. School-based programmes to provide educational support to empower children to take control of their own health should be explored. Leveraging existing early child development platforms for supporting CWHIV.

Health education messages to prevent non-communicable diseases (NCDs) should be integrated into the routine health education messages at the OPD and in ART counselling. These should include advice on stopping smoking, a healthy diet that includes the reduction of salt, and having regular and adequate exercise.

Where NCDs are identified but can't be managed in the same ART clinic, arrangements should be made for co-management with other providers preferably on the same day.



14.2 Mental health among people living with HIV

People living with HIV are at high risk of mental, nervous system and substance use disorders with depression being one of the most prevalent mental health comorbidities in PLHIV. PLHIV who have depression are less likely to achieve optimal treatment adherence. Although chronic HIV care settings provide an opportunity to detect and manage depression among people living with HIV, it is often overlooked and unrecognized by healthcare providers. Treatment or lack of treatment for mental health disorders can affect general health, adherence to ARV drugs and retention in care and may lead to potential side-effects and drug–drug interactions being overlooked.

Assessment and management of depression should be included in the package of HIV care services for all individuals living with HIV. Linkage to community-based psychosocial support services should be encouraged.

Health care workers should suspect depression in a PLHIV presenting with symptoms such as:

- sadness,
- tearfulness
- emptiness or hopelessness
- frequent outbursts, irritability or frustration, even over small matters
- Loss of interest or pleasure in most or all normal activities, such as sex, hobbies, or sports
- Inability to sleep or excessive tiredness and lack of energy, so even small tasks take extra effort
- Changes in appetite — reduced or even increased appetite
- Slowed thinking, speaking or body movements

- Feelings of worthlessness or guilt, fixating on past failures or blaming yourself for things that aren't your responsibility
- Trouble thinking, concentrating, making decisions, and remembering things
- Frequent or recurrent mention of death, suicidal thoughts, suicide attempts or suicide
- Unexplained physical problems, such as back pain or headaches

When depression is suspected, the health care worker should

- provide counselling to help the PLHIV understand the need for seeking help from a mental health expert.
- Liaise with and link the PLHIV with the mental health expert/institution
- Follow up with the PLHIV to ensure that the necessary care has been provided
- Ensure that the PLHIV continues to receive care for HIV and other comorbidities.



CHAPTER FIFTEEN

HIV AND CERVICAL CANCER

Cervical cancer is one of the leading causes of mortality among women. Nearly all cases are caused by two strains of the human papillomavirus (HPV): HPV-16 and HPV-18 transmitted sexually. To prevent cervical cancer, the WHO recommends vaccinating girls aged 9 to 14 years, when most have not started sexual activity.

Compared to HIV-negative women, women living with HIV positive have been found to have a higher incidence of Human Papilloma virus infection. Early detection and treatment remain crucial in the prevention of advanced disease and associated morbidity and mortality.

15.1 SCREENING AND TREATMENT RECOMMENDATIONS TO PREVENT CERVICAL CANCER IN PERSONS LIVING WITH HIV

The WHO recommends the Screen, Triage and Treat approach for PLHIV. Cervical cancer screening and treatment should be provided to women, transgender men, and non-binary and intersex individuals who have a cervix.

Screening

This involves the use of Human Papilloma virus (HPV) DNA detection as the primary screening test for women living with HIV. However, if the existing programme has cytology or Visual inspection with acetic acid (VIA) as the primary screening test, rescreening with the same test should be continued until HPV DNA testing is operational among both the general population of women and women living with HIV.

Regular cervical cancer screening is recommended from the age of 25 years among women living with HIV at a regular screening interval of every 3 to 5 years when using HPV DNA detection as the primary screening test among women living with HIV.

Priority should be given to screening women living with HIV aged 25–49 years. When tools are available to manage women living with HIV aged 50–65 years, those in that age bracket who have never been screened should also be prioritized.

After the age of 50 years, WHO suggests screening is stopped after two consecutive negative screening results consistent with

the recommended regular screening intervals among both the general population of women and women living with HIV

Where HPV DNA testing is not yet operational, WHO suggests a regular screening interval of every 3 years when using VIA or cytology as the primary screening test, among both the general population of women and women living with HIV.

Triaging

- Triaging, using partial genotyping, colposcopy, VIA or cytology is recommended after a positive HPV DNA test.
- Women living with HIV who have screened positive on an HPV DNA primary screening test and then negative on a triage test, are retested with HPV DNA testing at 12 months and, if negative, move to the recommended regular screening interval (every 3 to 5 years).
- For women who had cytology as their primary screening test and tested positive, then had normal results on colposcopy, it is recommended that they are retested with HPV DNA testing at 12 months and, if negative, move to the recommended regular screening interval (every 3 to 5 years).
- Women living with HIV who have been treated for histologically confirmed CIN2/3 or adenocarcinoma in situ (AIS), or treated as a result of a positive screening test are to be
 - ▶ To be retested at 12 months with HPV DNA testing when available, rather than with cytology or VIA or co-testing
 - ▶ and, if negative, are to be retested again at 12 months
 - ▶ and, if negative again, move to the recommended regular screening interval

Treatment

Treatment should be initiated as soon as possible, among non-pregnant women, within six months to reduce the risk of loss to follow-up.

For pregnant women, treatment should be deferred until after pregnancy. In situations where treatment is not provided within the six-month period, the woman should be re-evaluated before treatment.

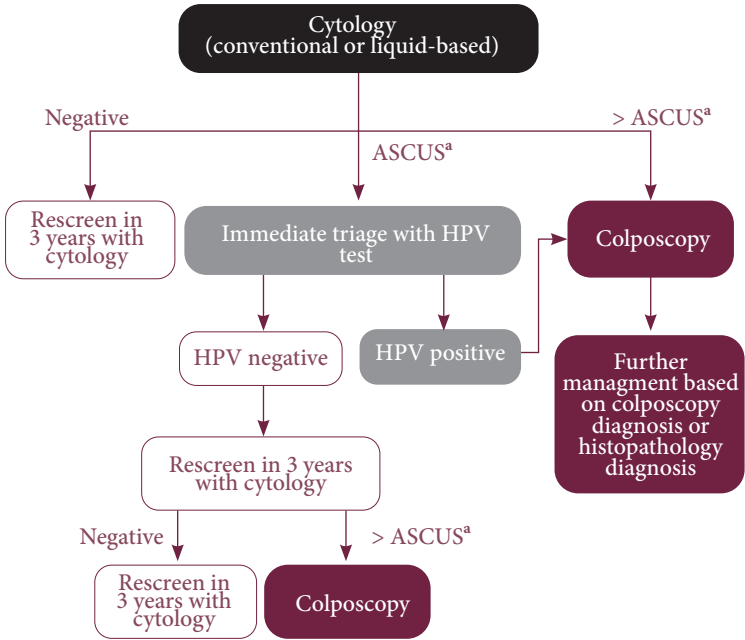
The recommended treatment is a large-loop excision of the transformation zone (LLETZ) or cold knife conization (CKC) for women who have histologically confirmed adenocarcinoma in situ (AIS).

Algorithms for the different scenarios of the Screen, Triage and Treat approach are provided below.



Figure 15.1. Primary Cytology Screening and Colposcopy Triage (Screen, Triage and Treat Approach)

For both the general population of women and women living with HIV

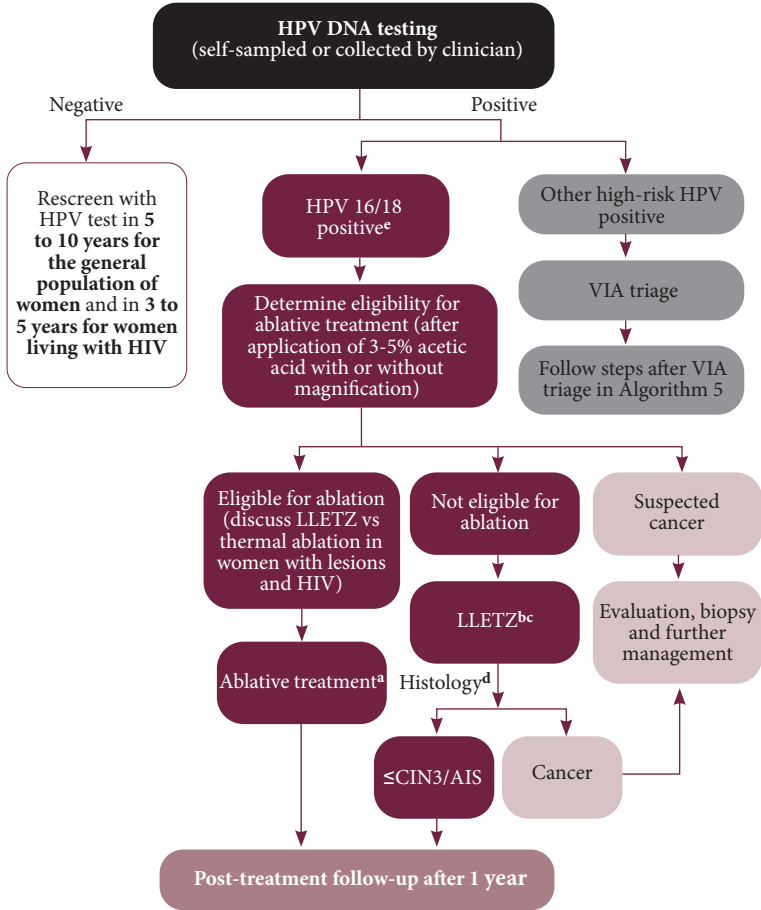


^aSome programmes prefer to use LSIL threshold. ASCUS; atypical squamous cells of undetermined significance; HPV; human papillomavirus; LSIL; low-grade squamous intraepithelial lesion.



Figure 15.2 HPV DNA Screening and HPV16/18 Triage (Screen, Triage and Treat Approach)

For both the general population of women and women living with HIV

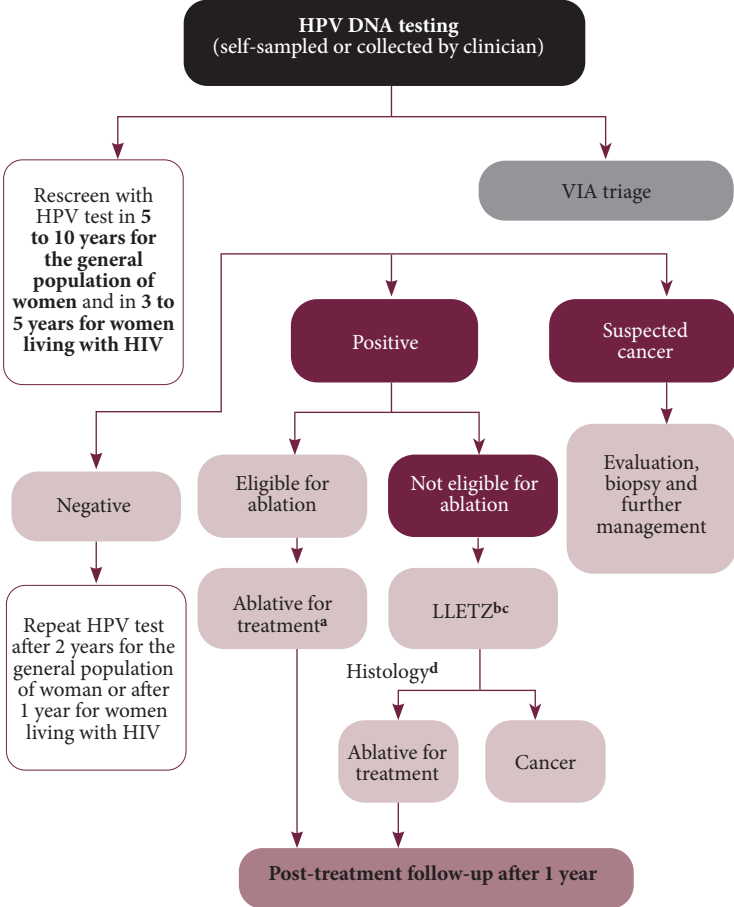


^a Ablative treatment includes cryotherapy and thermal ablation.
^b Cold knife conization (CKC) if LLETZ not available.
^c LLETZ and LEEP (loop electrosurgical excision procedure) indicate the same procedure.
^d Histology may not be available in certain settings; women should be advised to attend follow-up after 1 year or to report earlier, if they have any of the symptoms of cervical cancer.
^e May or may not be positive for HPV 45. AIS: adenocarcinoma in situ; CIN: cervical intraepithelial neoplasia; LLETZ: large-loop excision of the transformation zone; VIA: visual inspection with acetic acid.



Figure 15.3 Primary HPV DNA Screening and VIA Triage (Screen, Triage and Treat Approach)

For both the general population of women and women living with HIV



^a Ablative treatment includes cryotherapy and thermal ablation.
^b Cold knife conization (CKC) if LLETZ not available.
^c LLETZ and LEEP (loop electrosurgical excision procedure) indicate the same procedure.
^d Histology may not be available in certain settings; women should be advised to attend follow-up after 1 year or to report earlier, if they have any of the symptoms of cervical cancer.
 AIS: adenocarcinoma in situ; ON: cervical intraepithelial neoplasia; HPV: human papillomavirus; LLETZ: large-loop excision of the transformation zone; VIA: visual inspection with acetic acid.



Figure 15.4.

Primary HPV DNA Screening and Colposcopy Triage (Screen, Triage and Treat Approach)

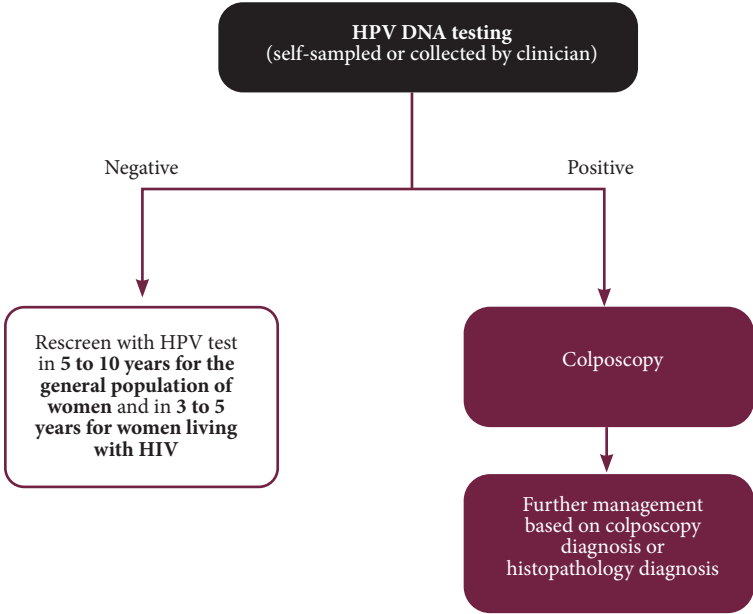




Figure 15.5. Primary HPV Screening and Cytology Triage Followed by Colposcopy (Screen, Triage and Treat Approach)

For both the general population of women and women living with HIV

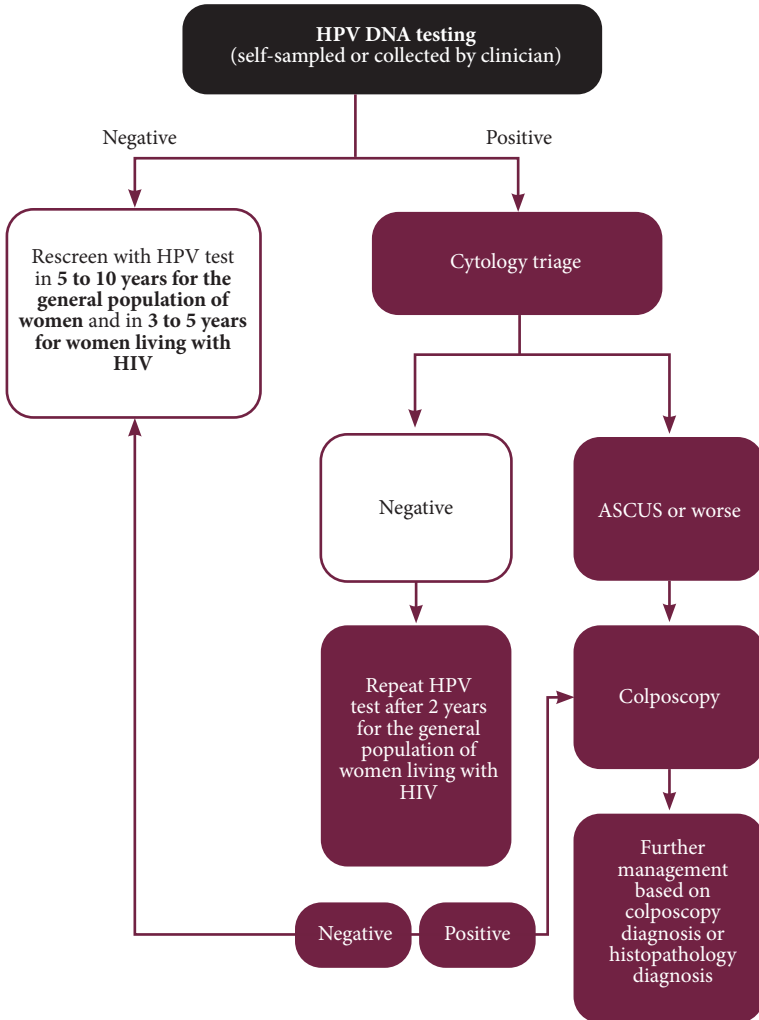
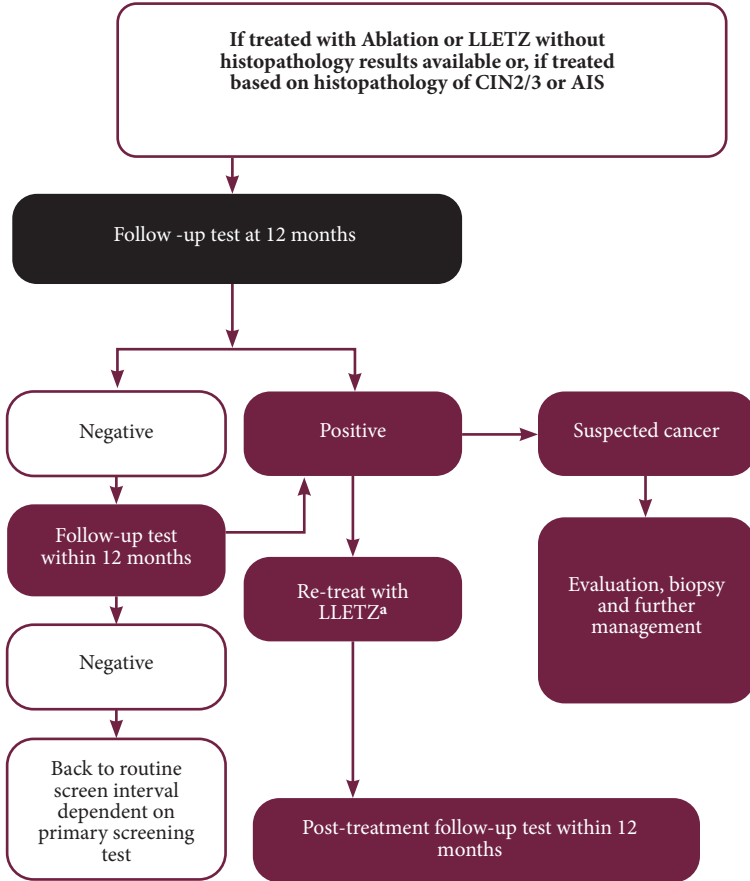




Figure 15.6. Follow-Up Tests At 12 Months Post-Treatment for Women Living with HIV



^a In circumstances where LLETZ not available, use cryotherapy or thermal ablation for retreatment if eligible.
AIS: adenocarcinoma in situ; CIN: cervical intraepithelial neoplasia; LLETZ: large-loop excision of the transformation zone.

APPENDICES



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

Stages	
Clinical Stage I	Asymptomatic Persistent generalized lymphadenopathy
Clinical Stage 2	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	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 10 ⁹ /l) and/or chronic thrombocytopenia (<50 x 10 ⁹ /l).

Stages	
Clinical Stage 4	<p>HIV wasting syndrome</p> <p>Pneumocystis (jiroveci) pneumonia</p> <p>Recurrent severe bacterial pneumonia</p> <p>Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month's duration or visceral at any site)</p> <p>Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)</p> <p>Extrapulmonary tuberculosis</p> <p>Kaposi sarcoma</p> <p>Cytomegalovirus infection (retinitis or infection of other organs)</p> <p>Central nervous system toxoplasmosis</p> <p>HIV encephalopathy</p> <p>Extrapulmonary Cryptococcosis, including meningitis</p> <p>Disseminated non-tuberculous mycobacterial infection</p> <p>Progressive multifocal leukoencephalopathy</p> <p>Chronic cryptosporidiosis</p> <p>Chronic Isosporiasis</p> <p>Disseminated mycosis (Extrapulmonary histoplasmosis, coccidioidomycosis)</p> <p>Lymphoma (cerebral or B-cell non-Hodgkin)</p> <p>Symptomatic HIV-associated nephropathy or cardiomyopathy</p> <p>Recurrent septicaemia (including non-typhoidal Salmonella)</p> <p>Invasive cervical carcinoma</p> <p>Atypical disseminated leishmaniasis</p>

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

A2.1 PERSONS AGED UNDER 15 YEARS WITH CONFIRMED LABORATORY EVIDENCE OF HIV INFECTION

Stages	
Clinical Stage 1	Asymptomatic Persistent Generalized Lymphadenopathy
Clinical Stage 2	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.

Stages	
Clinical Stage 3	<p>Unexplained moderate malnutrition a not adequately responding to standard therapy</p> <p>Unexplained persistent diarrhoea (14 days or more)</p> <p>Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one 1 month)</p> <p>Persistent oral candidiasis (after first 6 weeks of life)</p> <p>Oral hairy leukoplakia</p> <p>Lymph node tuberculosis</p> <p>Pulmonary tuberculosis</p> <p>Severe recurrent bacterial pneumonia</p> <p>Acute necrotizing ulcerative gingivitis or periodontitis</p> <p>Unexplained anaemia (<8g/dl), neutropenia (<0.5x 10⁹/l) and/or chronic thrombocytopenia (<50 x 10⁹/l).</p> <p>Symptomatic lymphoid interstitial pneumonitis</p> <p>Chronic HIV-associated lung disease, including bronchiectasis</p>

Stages	
Clinical Stage 4	<p>Unexplained severe wasting, stunting or severe malnutrition b not responding to standard therapy</p> <p>Pneumocystis (jiroveci) pneumonia</p> <p>Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)</p> <p>Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month's duration or visceral at any site)</p> <p>Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)</p> <p>Extrapulmonary tuberculosis</p> <p>Kaposi sarcoma</p> <p>Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month)</p> <p>Central nervous system toxoplasmosis (after the neonatal period)</p> <p>HIV encephalopathy</p> <p>Extrapulmonary Cryptococcosis, including meningitis</p> <p>Disseminated non-tuberculous mycobacterial infection</p> <p>Progressive multifocal leukoencephalopathy</p> <p>Chronic cryptosporidiosis (with diarrhoea)</p> <p>Chronic Isosporiasis</p> <p>Disseminated endemic mycosis (Extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis)</p> <p>Cerebral or B-cell non-Hodgkin lymphoma</p> <p>HIV-associated nephropathy or cardiomyopathy</p>

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.

A2.2

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 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.

A2.3

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

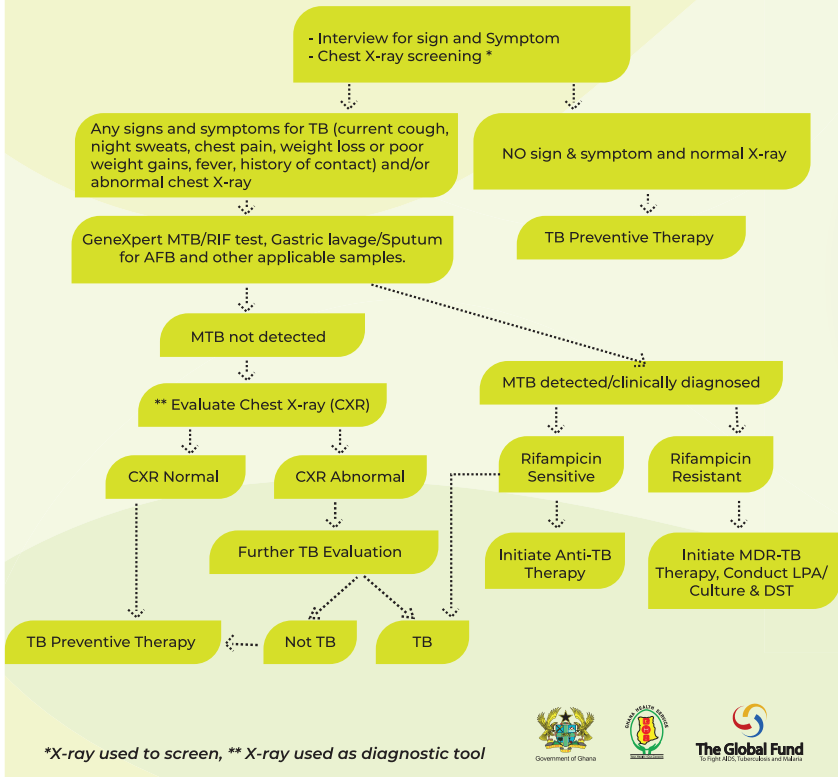
Classification of HIV associated immune deficiency	Age-related CD4 values			
	<11 months (%)	12-35 months (%)	36-59 months (%)	≥5yrs (cells/mm ³)
Not Significant	>35	>30	>25	>500
Mild	30-35	25-30	22-25	350-499
Advanced	25-30	20-25	15-20	200 - 349
Severe	<25	<20	<15	<200 or <15%

CD4% Formula:

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

APPENDIX 3 ALGORITHM FOR DIAGNOSIS OF TUBERCULOSIS

A3.1 CHILDREN LIVING WITH HIV

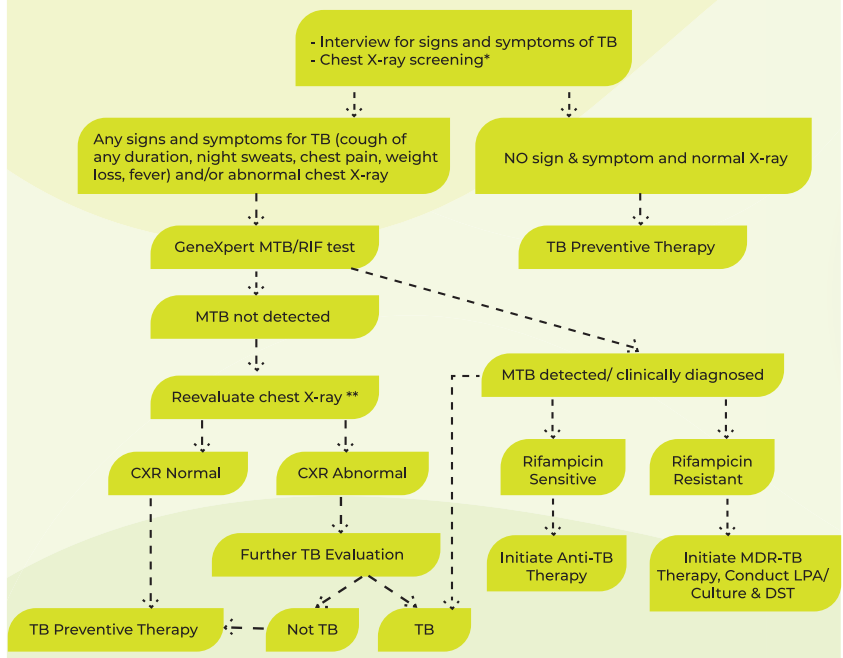


*X-ray used to screen, ** X-ray used as diagnostic tool





A3.2 ADULT & ADOLESCENT LIVING WITH HIV



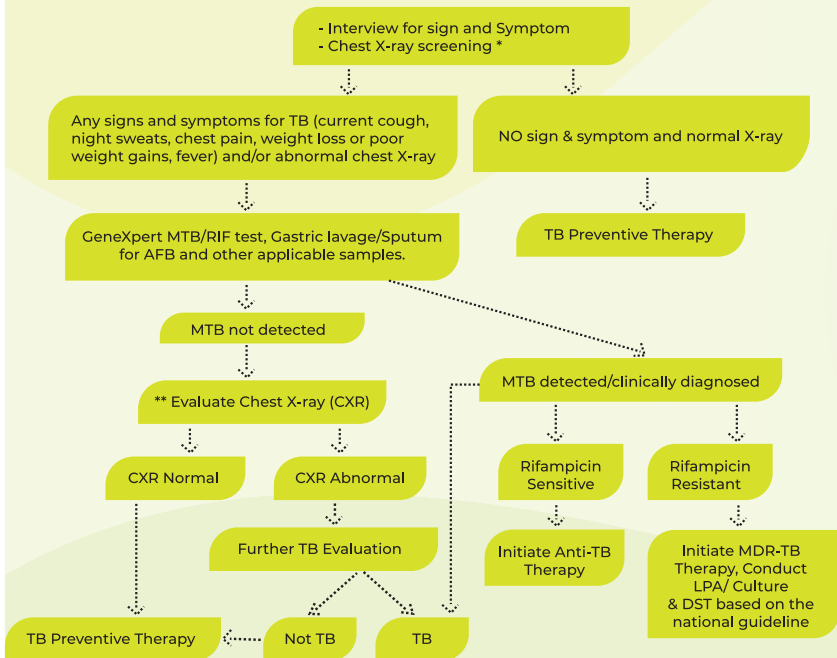
*X-ray used to screen, ** X-ray used as diagnostic tool



A3.3

CHILDREN IN CLOSE CONTACT WITH TB PATIENT

NEW

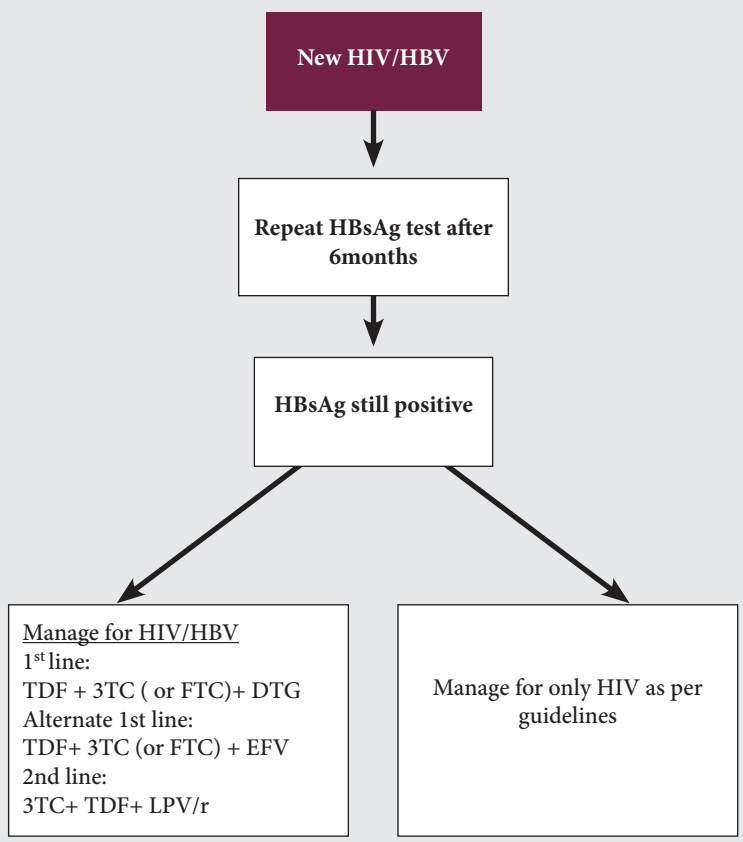


*X-ray used to screen, ** X-ray used as diagnostic tool



APPENDIX 4

ALGORITHMS 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	As part of the ARV regimen: Efavirenz Nevirapine (may increase risk of NVP toxicity) Tipranavir Other Drugs 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
Dolutegravir	Antacids, laxatives, multivitamin supplements and anticonvulsant such as carbamazepine
Efavirenz	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)
Emtricitabine	Lamivudine

DRUG	DRUG-DRUG INTERACTIONS
Lamivudine	Emtricitabine,
Lopinavir/Ritonavir	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,
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	Formulations	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
Abacavir	300 mg bid	Tablet	Nausea, Poor Appetite, Vomiting Fatigue Sleep disturbance	Hyper-sensitivity 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

Drug	Adult dosage	Formulations	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
Lamivudine (3TC)	150 mg bid	Tablet	Few side effects, rash, peripheral neuropathy reported	Lactic acidosis (Rare)	
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
TAF	25 mg once daily	Tablet	Weight gain, Dyslipidaemia		For children, adolescents, adults weighing 25 kg or more when used with unboosted regimens such as DTG
TDF	300 mg daily	Tablet		Nephrotoxicity (Rare)	To be taken with a meal
Zidovudine (AZT)	300 mg bid	Tablet	Nausea Headache Fatigue Muscle pain	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	Formulations	Dosage for children	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
Abacavir	Oral solution: 20mg/ml Tablet: 300mg	3 months to 16 years: 8 mg/ kg / dose bid (maximum, 600mg daily)	Nausea Poor Appetite Vomiting Fatigue Sleep disturbance	Hypersensitivity reaction Lactic acidosis	Caution in liver or renal disease Discontinue use if symptoms of hypersensitivity
 Dolutegravir	Dispersible Tablet: 10mg	3-<6 kg, 5mg once daily 6-<10 kg, 15mg once daily 10-<14 kg, 20mg once daily 14-<20 kg, 25mg once daily	Insomnia, weight gain/ clinical obesity	Neural tube defects, depression and suicide ideation	
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	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	Adult dosage	Formulations	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
	Oral solution: 30mg/ml (note syrup requires higher dosing than capsules)	As oral solution 40 kg and over, 720 mg oncedaily; 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			
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 12hourly 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

Drug	Adult dosage	Formulations	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
Lopinavir/ ritonavir(LPV/r)	Lopinavir/ Ritonavir tablet: 200mg/ 50mg Oral solution: Lopinavir/ Ritonavir:80/ 20mg per ml Lopinavir/ ritonavir tablets 100mg/ 50mg	<u>Surface area</u> 6months–13 years: Lopinavir, 225 mg/m ² + ritonavir, 56.25 mg/m ² twice daily <u>Weight based</u> 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, dys- lipidemia, li- podystrophy, headache	Hypersensi- tivity Pancreatitis Diabetes Mellitus	Preferably oral solution and capsules should be refrigerated; must be recon- stituted imme- diately prior to administration in water, milk, formula, pud- ding, etc- do not use acidic food or juices (increases bitter taste); solution stable for 6 hours Because of diffi- culties with use of powder, tab- lets preferred. Powder and tablets can be stored at room temperatures Take with food Drug interac- tions (less than ritonavir con- taining protease inhibitors

Drug	Adult dosage	Formulations	Adverse effects Minor, frequent	Adverse effects serious, dose limiting	Special instructions
					If Rifampicin co-administration, avoid use Store suspension at room temperature; must shake well Can give with food can be crushed and combined with small amount of water or food and immediately administered warn parents about Rash.
Zidovudine (AZT)	Syrup: 10mg/ml Capsules: 100mg Tablets: 300mg	Neonatal dose: Oral: 4mg/kg body weight 12hrly. Paediatric dose: 240mg/m ² every 12 hrs Max-300mg every 12hrs	Nausea Headache Fatigue Muscle pains	Anaemia, Neutropenia, gastrointestinal intolerance, Lactic acidosis	Caution in: pre-existing anaemia Liver and renal insufficiency. Can be administered with food Store at room temperature

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

Fixed dose combinations available in Ghana

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

APPENDIX 6

PEP FOR RAPE SURVIVORS

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 +
FTC 200mg daily for 28 days +
DTG 50mg daily x 28days

OR

TDF 300mg daily for 28 days +
FTC 200mg daily for 28 days +
LPV/r 400mg/100mg 12hourly x 28days

OR

AZT 300mg 12hourly x 28 days +
3TC 150mg 12 hourly x 28 days +
LPV/r 400mg/100mg 12hourly x 28days

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
Children 10 years and younger	AZT (or ABC) + 3TC + LPV/r OR DTG
	AZT and 3TC is the preferred backbone regimen for HIV PEP

A6.3 PEP AND MANAGEMENT RECORD FORM FOR RAPE SURVIVORS

Facility: _____

Date: _____

Name of Survivor: _____

Age: _____ Sex: _____

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

Location of Incident: _____

Brief Background and circumstances of the rape incident: _____

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

Details of Sexual Violence:

Raped by more than one person Yes No

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: _____

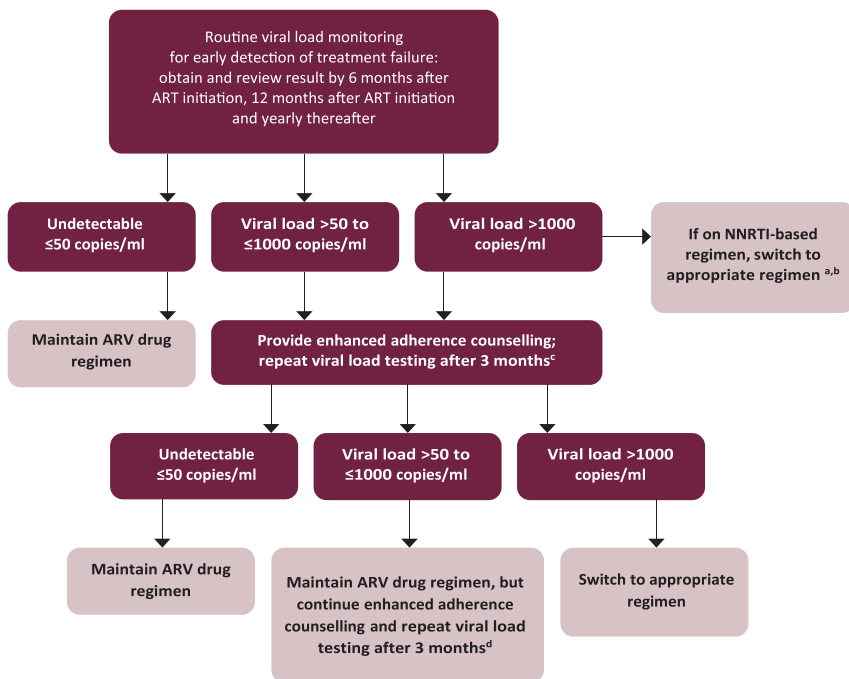
Signature: _____

Date: _____

A6.4 POST EXPOSURE PROPHYLAXIS OF HIV MONTHLY RETURNS FORM

Name of Facility:				
Month:				
Name of Person Filing Report:				
INDICATOR	Very low Risk	Low Risk	High Risk	
Total Number of Healthcare Workers (HCW) Reporting after Occupational Exposure				
Number Counsellor for HIV				
Number tested for HIV before PEP				
Number HIV positive				
Number starting PEP				
Number completing PEP				
Number of Rape Survivors Reporting				
Number Counsellor 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 TREATMENT MONITORING ALGORITHM



Adherence counselling should be provided at all visits to ensure that viral suppression is maintained or given priority throughout care

^a Switch after a single elevated viral load should be considered. ^b A second viral load may be considered before regimen switch if DTG-based regimens are unavailable, and the results of a viral load test can be returned and acted on rapidly. ^c Conduct same-day testing using point-of-care viral load testing for a repeat viral load test, where available, to expedite the return of results. If not available, viral load specimens and results for a repeat viral load test should be given priority across the laboratory referral process (including specimen collection, testing and return of results). ^d Consider switching ART for those receiving NNRTI-based regimens based on clinical considerations and address any adherence concerns.

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