
JAMAICA

# CLINICAL MANAGEMENT OF HIV DISEASE

## Guidelines for Medical Practitioners

**2017**

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## Guidelines for Medical Practitioners

# Ministry of Health Jamaica

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# GLOSSARY OF TERMS

| | |
|---|---|
| AIDS | Acquired immunodeficiency syndrome |
| ART | Anti-Retroviral Therapy |
| CMV | Cytomegalovirus |
| CSW | Commercial Sex Worker |
| CXR | Chest X-Ray |
| ELISA | Enzyme Linked Immuno-Sorbent Assay |
| FDC | Fixed Dose Combination |
| GBV | Gender Based Violence |
| HAART | Highly Active Antiretroviral Therapy |
| HAD | HIV Associated Dementia |
| HIV | Human Immunodeficiency Virus |
| HRT | Hormone Replacement Therapy |
| HST | HIV/STI/TB unit |
| HSV | Herpes Simplex Virus |
| HPV | Human Papilloma Virus |
| INSTI | Integrase Strand Transfer Inhibitor |
| IPT | Intermittent Preventative Therapy |
| IUD | Intra-Uterine Device |
| LGBTQ | Lesbian, Gay, Bisexual, Transgender, Queer (Questioning) |
| MAC | Mycobacterium Avium Complex |

| | |
|---|---|
| MCMD | Minor Cognitive Motor Disorder |
| MSM | Men who have Sex with Men |
| NHP | National HIV/STI Programme |
| NNRTI | Non-Nucleoside Reverse Transcriptase Inhibitor |
| NRTI | Nucleoside Reverse Transcriptase Inhibitor |
| NSAID | Non-Steroidal Anti-Inflammatory Drug |
| OI | Opportunistic Infection |
| OVC | Orphans and Vulnerable Children |
| PCP | Pneumocystis Pneumonia |
| PCR | Polymerase Chain Reaction |
| PHDP | Positive Health, Dignity and Prevention |
| PI | Protease Inhibitor |
| PID | Pelvic Inflammatory Disease |
| PITC | Provider Initiated Testing and Counselling |
| PLHIV | People Living with HIV |
| pMTCT | Prevention of Mother to Child Transmission |
| PrEP | Pre-Exposure Prophylaxis |
| STI | Sexually Transmitted Infection |
| TB | Tuberculosis |
| TMP/SMX | Trimethoprim/Sulfamethoxazole |
| VL | Viral Load |
| VMMC | Voluntary Medical Male Circumcision |

# FOREWORD BY HST SMO

Ever unfolding evidence in HIV disease, has led to continuous improvements in treatment and care offerings for PLHIV. The landscape is dynamic and treatment and care modalities are constantly changing. Even as these guidelines are being finalized, a whole new body of evidence is emerging which will require careful consideration inclusive of the programmatic and financial implications.

Two constants, however, are the need for psychosocial support and the need for an enabling environment for PLHIV and persons at risk of HIV to freely access services. Both underpin the success of the prevention and treatment and care responses and the overall trajectory of Jamaica's HIV epidemic.

It is anticipated that these guidelines will serve to improve the services offered to PLHIV thereby improving outcomes and reducing HIV transmission

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December 2016

# INTRODUCTION

# INTRODUCTION

Internationally, there has been a significant shift in the response to the HIV epidemic. Policy recommendations to move towards the "End of AIDS" are being implemented. These include the UNAIDS 90-90-90: An ambitious Treatment Target to Help End the AIDS Epidemic and the WHO Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach. The fundamental changes involve:

- The provision of antiretroviral therapy regardless of CD4 count
- Expansion of preventative technologies
- Target setting for viral load suppression rates

In the almost 40 years since the onset of the HIV epidemic, over 78 million people have been infected with the virus worldwide. HIV is now the fourth leading cause of death and the impact of the disease has been especially devastating in the developing world where 95% of the cases are still found. In Jamaica, AIDS is the leading cause of death in the 15 to 49 year old age group and is the second leading cause of death in children aged 1 to 4 years. The epidemic has been particularly concentrated among vulnerable populations, with late presentation and opportunistic infection continuing to be significant factors affecting the overall outcomes of patients.

The estimated adult (aged 15-49) HIV prevalence in 2016 is 1.6% with an estimated 30,000 people infected. The vulnerable populations that have been identified as major contributors to the epidemic include sex workers, men who have sex with men (MSM) and heterosexuals engaging in high risk sexual behaviours accounting for 4.1%, 32.2% and 2.8% respectively. Based on the latest estimates, approximately 28% of all cases are unaware of their status and 50% of those requiring treatment are actually receiving it. However, the National HIV/STI programme (NHP) has made a significant impact on the epidemic exemplified by the decline in new cases of HIV by approximately 25% since the beginning of the epidemic (Jamaica UNGASS Report 2012)

Between 1982 and the end of 2015, 34,125 cumulative HIV cases have been reported in Jamaica and 9,517 deaths have been attributed to AIDS. While the epidemic has affected all parishes, the highest rates have been reported in St. Andrew and St. James. The Jamaican HIV continuum of care shows significant gaps at all stages, indicating the need to build on previous gains by tweaking the current approaches. After diagnosis with HIV, the linkage to care rates are around 73%. Of those linked to care and provided with ART, only 14% are achieving viral suppression (NHP Epi Update 2015).

Since 2004, the widespread rollout of combination antiretroviral therapy has dramatically improved the rates of morbidity and mortality and improved quality of life. One of the priorities for the NHP is to strengthen the treatment, care and support of persons living with HIV to decrease the disparity between those requiring and those receiving ART.

This comprehensive treatment protocol has been revised to provide up to date information on HIV treatment and care to which all persons living with HIV (PLHIV) are entitled.

The specific aims of these guidelines are to:

1. **Improve the quality of care** in the diagnosis and management of persons living with HIV, with the aim to standardize treatment practices.
2. **Improve the quality of life** among persons living with HIV.
3. **Reduce the economic burden** of HIV infection by preventing opportunistic infections, reducing the impact of chronic diseases and reducing inappropriate diagnostic tests and treatment.
4. **Reduce the rate of new cases** of HIV by implementing the UNAIDS 90-90-90 framework, the expanded prevention technologies and 'Test and Treat' strategies.

# Promotion of Optimal Health

# Promotion of Optimal Health

## Positive Living for Persons Living with HIV

**Providers must discuss in detail the concepts surrounding "Positive Living for persons living with HIV".**

Positive prevention embodies the potential impact persons living with HIV have on decreasing new HIV infections and improving health outcomes in those infected. This requires on-going discussion and support at every visit. Providers should communicate in a non-judgmental manner and engage clients using motivational interviewing skills and other effective techniques. Providers should:

- Convey to clients that HIV is a chronic disease that can be adequately managed.
- Encourage patients to realize their role in their treatment and care partnerships between themselves and their providers.
- Emphasize risk reduction practices, maintenance of a healthy lifestyle, adherence to medication and appointments.

The guiding principles of Positive Health, Dignity and Prevention (PHDP) are:

- Promotion of human rights – the right to privacy, confidentiality, informed consent and voluntary disclosure
- People living with HIV have the right to enjoy full sexual and reproductive health.

The core elements of PHPD are:

- Sexual and reproductive health – this includes practicing safer sex, avoiding other STIs, reducing the chance of unwanted pregnancies or planning for safe conception and healthy pregnancy.
- Delay of HIV progression – increasing access to effective HIV management (ART is potentially the best prevention strategy currently available), as well as support to explore healthy nutrition, adequate exercise, and reducing harmful behaviours.
- Promoting shared responsibility to reduce the risk of HIV transmission – to increase the esteem and confidence of PLHIV to protect their own sexual health and avoid passing on the infection.

| Components of Positive Prevention | HIV transmission facts | Strategies | Outcomes |
|---|---|---|---|
| Prevent transmission of the HIV virus to the uninfected | Worrisome increase in new infections especially in adolescents, MSM, women, sex workers and other vulnerable populations.<br><br>Low safer sex practices among HIV discordant couples | Encourage and support safer sex practices, "Know Your Status" Campaign, PITC, Opt- out testing for STI clients, antenatal clients and other vulnerable populations. Support disclosure among partners, partner notification, and couple counselling | Increased adherence to safer sex practices<br>Increased disclosure among partners<br>Increased awareness of serostatus<br>Decrease in new HIV infections |
| Prevent the possibility of HIV re-infection | Documented evidence exists that HIV-1 infected clients can be re-infected by different strains of HIV-1.<br>Initial infection by HIV-1 provides no benefit in immunity against re-infection.<br>Dual infection by HIV-1 and HIV-2 has also been documented.<br>There can be considerable diversity between the original HIV strain and the second strain, or only marginal difference between the strains.<br>Progression of HIV disease is more rapid in patients infected with multiple HIV strains. | For a patient on ART, the new HIV strain may not be sensitive to the specific ARVs the patient is currently taking.<br>A change of ART regimen may be required.<br>ARVs that are effective against both strains are needed. These are difficult to select without resistance-testing | For ART clients (current or past users), it decreases the potential of transmitting ARV-resistant HIV strains. |

| Components of Positive Prevention | HIV transmission facts | Strategies | Outcomes |
|---|---|---|---|
| Prevent other sexually transmitted infections<br>Screen all PLHIV for syphilis at baseline and at least annually if sexually active<br>Screen all clients for other STI as well if available | Sexually transmitted infections increase risk of both acquisition and transmission of HIV.<br><br>For HIV-infected persons, contracting other STI may accelerate progression of HIV disease. | Consistent and correct use of condoms.<br><br>Comprehensive screening and treatment of all STIs in PLHIV | Decreased incidence of STI.<br><br>Improved wellness in PLHIV |
| Prevent other infectious diseases – | HIV-infected persons may be more prone to contracting other infectious diseases due to immuno - suppression | Ensure proper food handling techniques, avoid direct contact with animal excreta, unnecessary visits to hospitals, aggressive precaution in outbreaks (e.g. influenza), Provide appropriate OI prophylaxis and vaccinations | Reduced illness and hospitalization-related development of OI and other infectious diseases |
| Make informed decisions about health choices | HIV infection and ART can predispose persons to chronic diseases e.g. cancer, diabetes mellitus, cardiovascular diseases | Patient education; collaborative relationship between client and health care team | Improved wellness and reduced illness and hospitalizations related to HIV disease among PLHIV |
| Make informed decisions around contraception and pregnancy | | Encourage dual protection, Initiate conversations about family planning | Reduction of unplanned pregnancies, improve pMTCT of HIV & Syphilis |

## Recommended Reading


1. Antiretroviral Treatment for HIV Prevention. Consultation, 2-4 November 2009 WHO
2. Essential prevention and care Interventions for Adults and Adolescents living with HIV in Resource-Limited Settings 2008 WHO
3. Advancing the Sexual and Reproductive Health and Human Rights of PLHIV- A guidance package 2009 Global Network of PLHIV
4. Incorporating HIV Prevention into the Medical care of Persons Living with HIV MMWR 2003 CDC
5. Other activities, services and strategies: incorporating HIV Prevention into the medical care of PLHIV CDC 2009
6. pMTCT Jamaica guidelines

# HIV Testing, Counselling and Psychological support

## HIV Testing

Routine HIV screening is recommended in the following situations:

- Annual HIV screening of all sexually active persons between the ages of 16-49
- All patients accessing care at a hospital, public health centre or private practitioner annually
- All STI Clinic Attendees
- All Antenatal Clinic Attendees

Rapid testing using either finger stick or oral swab methodology is recommended. All initial positive test results must have confirmatory testing performed. The rapid testing algorithm that should be followed in the field for Jamaica can be found in Appendix 7.

**ALL POSITIVE RESULTS MUST BE REPORTED TO THE MINISTRY OF HEALTH VIA THE CLASS I NOTIFICATION FORM AND THE HIV CONFIDENTAIL REPORTING FORM**

**Pre-test Counselling**

This aspect of the HIV screening process is **no longer an absolute requirement for** provider initiated testing and counselling (**PITC);** the concept of PITC requires the opportunity for the patient to "opt-out" of testing (the patient must be informed that an HIV test is being performed and given the opportunity to refuse the test). The following pre-test information should be provided:

- Explain that it is now standard practice to provide HIV testing to everyone regardless of risk
- Emphasize that the test is confidential
- Explain the benefits of early detection
- Explain what a negative and a positive result means
- Re-assure that if positive, treatment and care is readily available
- Allow the patient an opportunity to opt-out
- Obtain oral consent

**Post-test counselling**

All patients should be notified in person of the test result.

Post-test counselling is a component of disclosing results and administered as followed:

If the result is negative:

- Provide the blood results with an explanation
- Reinforce safe sexual behaviours
- Discuss retesting in 3-6 months if recent high risk exposures
- Answer any questions
- Facilitate referral to support services.

If the result is positive

- Provide blood result and explain its meaning
- Clarify the difference between HIV and AIDS

If the setting is favourable these concepts should also be discussed

- Emphasize that patients can live with HIV/AIDS
- Encourage patient to share their diagnosis with a close family member or friend
- Discuss medical follow up options
- Discuss partner notification
- Reinforce safe behaviours
- Emphasize availability for future contact
- Begin treatment literacy/readiness discussion

## Counselling and Psychological Support

Counselling must be part of the HIV testing and treatment programme. The objectives of psychological support and counselling are:

1. to assist persons to cope with HIV
2. to prevent the transmission of HIV to others
3. to prevent re-infection
4. to enable PLHIV to improve the quality of their life and the outcome of the disease through empowerment to take responsibility for their own care.

Some common psychosocial concerns, which may need referral either to a psychologist or to a social worker, are:

- Reaction to life threatening illness
- Reaction to need for partner notification
- Effects of illness and treatment e.g. medication
- Social stigma if illness revealed; threat of rejection by family, termination of employment.
- Dealing with sexuality and changing sexual behaviours
- Economic implications e.g. cost of treatment, loss of employment
- Inordinate anxiety and/or depression in PLHIV (These conditions are more common in PLHIV than in the average population.)

# Linkage and Retention in care

The objectives of linkage and retention activities are primarily to promote entry into an established HIV treatment and care facility after the initial diagnosis and to maintain engagement throughout the treatment course. The effects of poor linkage and retention lead to:

- Increased risk of horizontal and vertical HIV transmission
- Poor adherence to ART
- Increased risk of HIV drug resistance development and transmission
- Ultimately leading to a reduced quality of life for PLHIV

Currently in Jamaica, of the 30,313 estimated to be infected with HIV, only 57% (17,251) persons have been linked to care, which represents 74.5% of all persons diagnosed with the virus. Additionally, of those persons linked to care, 56.5% (9747) persons have been retained in care.

The specific objectives of the Referral and Linkage activities in Jamaica include:

- To increase access to HIV care and treatment services.
- To decrease attrition in newly diagnosed HIV patients.
- To ensure that newly diagnosed HIV positive patients are linked early to appropriate HIV support services.
- To identify and address barriers to linkage to HIV care and treatment services.
- To identify appropriate referral and linkage processes in different settings;
    - HIV testing site being the same as HIV treatment site,
    - HIV testing site being different from HIV treatment site,
    - Outreach HIV testing

Comprehensive guidelines can be found in the Jamaica National HIV/STI Programme, **Patient Retention and Recovery: Standard Operating Procedures, 2014** and the **Case Management Protocol.**

**Retention** in care is notoriously difficult to achieve uniformly across all populations. A multitude of complex, dynamic factors have been associated with lack of retention in many settings. These can be summarized into the following:

1. Structural
    a. Health Service delivery issues
        i. Access to treatment and monitoring: treatment site access, including pharmacy waiting times, stock out of ART or CD4/viral load testing supplies etc
        ii. Acceptable service delivery: non-discriminatory environments providing appropriate treatment for all populations
    b. Individual issues

i. Competing priorities e.g. employment
ii. Poverty
iii. Health literacy
iv. Internalized stigma
v. Migration

Interventions that can improve retention should be tailored to the individual client and include:

| | **Step 1: HIV testing to enrolment in care** | **Step 2: Enrolment in care to ART eligibility** | **Step 3: Eligibility testing to enrolment in ART** | **Step 4: ART enrolment to lifelong retention** |
|---|---|---|---|---|
| **Patient level** | Adequate pre- and post- test counsel-ing, Point of care CD4 testing<br><br>Linkage to prevention services including condoms, needle/syringe program, OST, peer educators<br><br>Education: health, reduction of stigma Post-test messaging<br><br>Smart card/ unique identifier for better patient tracking | Patient education, empowerment, advocacy, treatment literacy<br>SMS messaging<br><br>Point of care testing<br>Mobile HIV testing and counseling services<br>Reduce frequency of visits and waiting times<br><br>TMP/SMX prophylaxis<br>Isoniazid prophylaxis in congregate settings<br><br>Drug prescriptions to match visits<br>Reimburse transport costs according to need<br>STI prevention & treatment services<br>Nutritional support<br>Smart card/ unique identifier for better patient tracking | SMS messaging<br><br>Community/ Peer support groups<br><br>Community Health Workers (CHW)<br><br>Smart card/ unique identifier for better patient tracking | SMS messaging<br><br>Community/Peer Adherence Support Groups<br><br>Reduce drug toxicities<br><br>Single daily pill containing ART<br><br>Drug prescriptions to match visits<br><br>Nutritional support<br><br>Reimburse transport Costs according to need<br><br>Smart card/ unique identifier for better patient tracking |

| | Step 1: HIV testing to enrolment in care | Step 2: Enrolment in care to ART eligibility | Step 3: Eligibility testing to enrolment in ART | Step 4: ART enrolment to lifelong retention |
|---|---|---|---|---|
| **Healthcare facility level** | Decentralization of HIV testing and counseling<br><br>Address staff attitudes and improve interactions with patients<br><br>Integration of services - e.g. HIV testing in TB centres; STI services, Drug dependence treatment services<br>family planning services<br>nutrition services<br>Engagement of community partners, peer educators | Integration of services<br><br>Reduce clinic waiting times by fast-track system based on negative screening tools (triage)<br><br>Address staff attitudes and improve interactions with patients | Integration of services<br><br>Address staff attitudes and improve interactions with patients | Integration of services<br><br>Address staff attitudes and improve interactions with patients<br><br>Integrate/link with drug dependence treatment<br><br>Link with community & home-based care<br><br>Case management |

## [1]Oral Health

- Poor oral health and dentition can complicate the medical management of PLHIV by affecting adherence to ART and exacerbating nutritional and psychosocial problems.

- All HIV infected patients should receive routine biannual comprehensive oral maintenance.
- Information sharing between physicians and dentists should also take place.

[1] Adopted from WHO: Retention in HIV Programmes – Defining Challenges and identifying solutions. Meeting Report 13-15 September 2011, Geneva.

**Specific Disease Conditions**

- Oral Hairy Leucoplakia
  - Epstein-Barr Virus (EBV) infection
  - Shaggy, hyperkeratotic lesions on the lateral aspects of the tongue.
  - A sign of advanced HIV disease requiring the commencement of ART.

- Oro-pharygeal Candidiasis (See treatment of Common Infections)

- Gingivitis
  - Linear gingival erythema
  - Necrotizing ulcerative gingivitis/periodontitis
  * Recommend consultation with a dental professional.

- Oral Ulcers
  - Aphthous ulcers: Minor (<10mm) or Major(>10mm)
    Appearance: Solitary lesion, sloughy base and erythematous halo
  - HSV ulcers: Groups of vesicles that transform into small ulcers and may coalesce.
  -Other: CMV, MAC, Histoplasma, Cryptococcus, neoplasm

  * Usually self-limiting. For ulcers that disturb eating, compromising nutrition, topical mixtures with analgesia, antibiotics and steroids can be prepared.

- Xerostomia (dry mouth)
  - HIV-related salivary gland disease

- Malignancy
  - Kaposi sarcoma
  - Non-Hodgkin's Lymphoma

# Initial Evaluation of the HIV Infected Patient

# Initial Evaluation of the HIV Infected Patient

When the diagnosis of HIV infection has been serologically confirmed, the patient should be counselled and undergo a complete assessment as described below.

In counselling the patient it is important to recognize the patient as an individual and listen to his/her concerns. The physician or health care worker must be understanding and non-judgmental, willing to explain issues and address fears. Management of the HIV positive patient must emphasize

1. The need for a positive approach to life, reinforcing that HIV is not a death sentence
2. The need to disclose their status to all sexual partners and to identify a confidant, whether friend or family member, to provide support
3. Safe sexual practices and positive prevention
4. The critical importance of adherence to medication, clinical visits and investigations.

## History Taking

In taking the history, attention must be paid to **maintaining confidentiality:**

- Confidential record keeping procedures
- Discussing only with those who need to know
- Treating patients in a non-discriminatory manner
  - Which may include enquiring about gender identification of clients

**HIV History**

- Date and place of HIV testing (document any previously negative tests)
- Management of HIV disease prior to presentation
  - Previous opportunistic or AIDS defining illnesses
  - Previous CD4 counts or viral load assessments
  - Previous exposure to ART (including adherence levels)
  - Use of prophylaxis

**General Health**

- General well-being
  - Dental Health
  - Routine health screening (e.g. Pap smear date and result)
  - Last eye examination
- Constitutional symptoms
- Past Medical History
  - Previous sexually transmitted infections (date and treatment received)
  - Chronic illnesses (Diabetes, hypertension, cardiovascular disease, dyslipidemia, kidney or liver disease, mental health disease, hepatitis, sickle cell)
- Immunization status- specifically hepatitis B, HPV, pneumococcus, influenza, BCG

**Drug History**

- Medication and dosage of prescription and non-prescription therapies
- Substance use (Cigarettes, crack, cocaine, alcohol, marijuana etc.)
- Any known allergies

**Sexual History**

Successful sexual history taking requires the establishment of a good rapport with the patient. The appropriate history includes:

1. **Sexual practices**
   - Number and gender of **past and present** partners,
   - Type of sexual contact (oral, genital, anal)
   - Any sexual contact with commercial sex workers

2. **Previous or present STI (see STI Manual)**

3. **Partner Notification**
   Sexual contacts need to be identified and arrangements made for them to be counselled and tested or contact traced (while preserving confidentiality of information source). Explain that the source of the information will be kept confidential. Encourage partners to come in, or go to their regular doctor.

4. **Contraceptive use** – ask about condom usage, and other forms of family planning methods being used.

5. **Past Obstetric/Gynaecological History**

**Family History**

- Family history of illnesses (including TB, hypertension, diabetes mellitus)
- Other HIV positive family members (e.g. children)

**Occupational History**

Increased risk for opportunistic infections

- travel
- occupation (e.g. farming, pet shop workers), hobbies
- pets
- crowds
- hospitals
- incarceration

**Social History**

- Availability of amenities (housing, water, electricity, access to refrigeration)
- Employment status, sources of financial support
- Availability of friend and/or family support
- Children (age and sero-status)

**Review of systems**

| **GENERAL** | **GI** | **RS** | **CVS** | **CNS** | **GU** | **SKIN** |
|---|---|---|---|---|---|---|
| Night Sweats | Oral Lesions | SOB | Chest Pain | Depression | Discharge | Rash |
| Lethargy | Diarrhoea | Chest Pain | Palpitations | Anxiety | Sores Ulcers | Sores |
| Weight Loss | Dysphagia | Cough | Ankle Swelling | Headaches | Warts | Itching |
| Fever | Vomiting | Wheezing | | Neck Pain | Urinary Symptoms | Abnormal Growths |
| Anorexia | Odynophagia | Prolonged nasal stuffiness | | Visual Disturbances | | |
| Lymphaden opathy | | | | Seizures | | |

## Comprehensive Physical Examination

The steps outlined below should be conducted at ***each*** clinical visit:

- Vital signs
  – temperature, pulse, respiratory rate, blood pressure
- Anthropometrics
  - weight, height, waist measurement
- General
  – pallor, body habitus (wasting, fat distribution)
- Oral cavity
  - ulcers, thrush, poor dentition, gingival disease, pharyngeal STI
- Dermatologic examination
  - The entire skin, taking particular note of conditions such as herpes zoster, folliculitis, seborrheic eczema, severe tinea corporis, abscesses, straightening and thinning of hair, BCG scar
- Examine all lymph node areas noting any enlargements and tenderness
- Breast examination should be offered initially and then annually
- Abdominal examination
  – distension, obesity and hepatosplenomegaly
- CVS:
  - Displaced apex beat, heart sounds, elevated JVP, ankle swelling
- RS:
  - Signs of pulmonary infiltrates, pneumothorax, pleural effusion
- MS:
  - Wasting with globally decreased power, arthropathy, peripheral neuropathy
- Rectal/genital examination noting the presence of peri-anal/genital herpes or genital warts, evidence of proctitis, anal smear for those having anal receptive intercourse.
- Pelvic examination noting vaginal discharge and cervical erosions (Pap smear see pg 43).
- Eyes: fundoscopy
- ENT: Recurrent acute sinusitis, chronic sinusitis hearing loss, vertigo
- CNS: paralysis, monoparesis, hemiparesis, cranial nerve abnormalities

## Laboratory Evaluation

- CD4 count **(all HIV positive patients must have an initial CD4 count followed by 3 and 6 monthly tests until patient is virally suppressed as well as for staging disease and diagnosing opportunistic infections where necessary)**
- Viral load assessment should begin 6 months post-ART commencement)
- CBC (Hb, WBC, diff, plat.)
- VDRL or RPR
- Urinalysis
- HBsAg
- Anti-HCV Ab
- Urea and electrolytes
- Liver Enzymes, serum proteins.
- Fasting lipid profile
- Fasting Blood Glucose
- Pap smear
- Mantoux test
- Anal smears where indicated
- HTLV 1

*For recommendations on the scheduling of future laboratory evaluations please see:*
***Section 5: Antiretroviral Therapy Maintenance***

## Packages of Care

Packages of care have been established and should be supplied to all PLHIV regardless of CD4 count

1. **Standard Package of Care to be offered to all PLHIV**

Psychological assessment

- To include assessment of treatment readiness
- Assessment for depression

Social Assessment

- GBV screening
- Food security
- Financial security

Prevention assessment

1. Assessment of sexual activity, provision of condoms (and lubricant) and risk reduction counselling (if indicated)
2. Assessment of partner status and provision of partner testing or referral
3. Assessment for STIs and (if indicated) provision of or referral for STI/partner treatment
4. Assessment of family planning needs and (if indicated) provision of contraception or safer pregnancy counselling or referral
5. Assessment of treatment readiness and (if indicated) support or referral
6. Assessment of need and (if indicated) refer or enrol PLHIV in community-based programs
7. Assessment of nutritional status for all new patients, followed by annual assessments
8. Annual review by Contact Investigators

Medical management

- Medical, psychological and social history and physical examination (including cervical/anal examination)
- Baseline investigations and (as indicated) additional investigations
- HIVDR testing as indicated
- OI screening/prophylaxis/management
- ART in the context of treatment readiness
  Assessment for adverse events
  Referral for specialist management as indicated

2. **Enhanced Package of Care**

Adolescent PLHIV/OVC/PLHIV pregnant women/MSM/CSW

- Routine enrolment in psychological care including motivational interviewing
- Routine cancer screening (cervical, ano-rectal and prostatic cancers)
- Routine screening for HPV

Sero-discordant couples

- Support pre-exposure prophylaxis in the private sector, in conjunction with proper screening and counselling

HIV/TB

- Screening of HIV positive inmates in congregate settings for TB
- Access to Tb prevention, screening and treatment services
- offer IPT in congregate settings to HIV positive inmates

# Clinical Management of HIV Disease

# Clinical Management of HIV Disease

## *1. Management of Acute HIV Infection*

Acute HIV infection is the first constellation of symptoms that occurs from 2-4 weeks after exposure, affecting between 40%-90% of individuals. Its presentation can range from mild non-specific symptoms to severe illness requiring hospitalization in rare cases. Symptoms range from fever, sore throat, lymphadenopathy, rash, diarrhoea and myalgias. Aseptic meningitis can also occur with symptoms of headache, photophobia and neck stiffness.

The symptoms of acute HIV infection are self-limiting and last for up to 4 weeks. ELISA and Western Blot analyses will likely be negative; however, p24 antigen, PCR and viral load testing will reveal a positive result. Most patients do not present at this stage and the symptoms often go unrecognized, but may be revealed with a detailed history.

Management consists of early recognition and symptomatic treatment. During this phase of the disease, the HIV viral load is very high and patients are at increased risk of transmitting the virus. Therefore, recognition and early diagnosis of HIV infection is important in order to institute appropriate positive prevention messages to avoid further spread of the virus. **ART is now to be offered to all PLHIV once diagnosed and assessed to be treatment ready.**

Primary infection is followed by an asymptomatic period, which lasts an average of 10 years in most individuals.

## *2. Management prior to Antiretroviral Therapy Commencement*

**While being optimized for treatment, the emphasis in this phase of management is on:**

- **Prevention of HIV transmission**
  - Positive prevention messages
  - Education in consistent condom use and negotiation
  - Management of any STIs

- **Preparation for ART commencement**
  - Patient optimization* (*See below*)
  - Monitoring CD4 counts 6-12 monthly
  - Performing all baseline evaluations

- **Prevention and management of chronic diseases and other illnesses**
  - Healthy diet and exercise practices
  - Screening and control of hypertension, diabetes and dyslipidemia
  - Smoking prevention
  - Substance abuse counselling

- **Promotion of general health practices**
  - Health screening: Pap smear, breast examination, prostate evaluation, anal smear
  - Immunizations: According to national guidelines, avoiding live vaccines,
  . Hepatitis B vaccine should be considered.
  - Dental Care
  - Family Planning

* **<u>Patient optimization</u>**

This is an active process of identifying barriers to ART adherence prior to commencement. Issues that should be addressed include:

- HIV knowledge including fears and perceptions of ART
- Motivation and self-efficacy
- Stigma and discrimination
- Social support systems
- Transportation and nutritional issues
- Depression or other mental health disease
- Substance abuse counselling

## *3. Adherence*

Adherence to antiretroviral therapy is critical if patients are to achieve and maintain undetectable viral loads and avoid preventable opportunistic infections. Adherence is critical to HIV infections because

1. The virus has a very high replication and mutation rate – if drug doses are missed the virus quickly begins to replicate, and in the presence of low levels of drug, will develop viral mutations conferring drug resistance.
2. Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI) have broad class resistance: when resistance to one drug develops; often resistance is developed to all the drugs in that class, e.g. K103N mutation in NNRTI drugs.
3. Protease Inhibitors (PI) can retain activity to other drugs within the class following failure depending on how long the patient remains on the failing PI containing regime.

Before initiating therapy, adherence must be made part of the patient's routine care. Learn as much as possible about the patient's health history, level of literacy, beliefs and attitudes about HIV, social support, housing, medical insurance, alcohol and drug use, mental illness and any other pressing issues which may be potential barriers to compliance. **Studies have shown that patients who miss no more than 1 drug dose per month (95% adherence) do significantly better than those who miss more than 1 dose per month (< 95% adherence). It is important to emphasize this at each visit.**

Other factors have been found to be predictive of adherence or non-adherence among HIV infected individuals

- Large pill burden and dosing frequency - be alert to actual strength of dose, because patients often get tablets from other sources
- Medication with food restriction
- Length of time of therapy – adherence decreases with time
- Adverse drug reactions

Adherence improves with:

- Self – efficacy - the belief in one's ability to take medication as instructed
- Belief that medication can fit into their day.
- Understanding the relationship of viral resistance and adherence
- Previous adherence
- Trust in doctor
- Patient friendly system of care that facilitates access to medicine
- Reminders to fill prescriptions for medication
- General patient education

Strategies to improve adherence include:

- Establishing trust between patient and the healthcare team
- Educate, inform patients and serve as a source of information
- Anticipate and treat side effects
- Avoid adverse drug reactions
- Reduce dose frequency and number of pills if possible
- Monitor on-going adherence, intensify management in periods of low adherence (more frequent visits, recruitment of family and friends to support treatment plan.)
- Develop concrete plan for specific regimen, relation to meals, daily schedule and side effects.
- Consider impact of new diagnoses on adherence (e.g. depression, liver disease, wasting syndrome)
- Directly observed therapy in hospital settings
- Psychosocial issues must be taken into consideration (e.g. incarcerated patients, homeless patients)

Measures of adherence include:

- Self reports: standardized 3 question assessment
- Pill counts
- Pharmacy related measure: Medication possession ratio

## *4. Antiretroviral Therapy Commencement*

### ***When to start***

**All adults and adolescents should be offered ART regardless of CD4 count, with prior patient optimization (see above pg 23).**

Criteria for more rapid commencement on ART:

- Late stage pregnancy (Third trimester)
- Active Tuberculosis
- HIV Associated Nephropathy
- Any AIDS defining illness

**Prophylaxis with Trimethoprim/Sulfamethoxazole (TMP/SMX) should also be offered when CD4 < 350cells/mm$^3$ and discontinued when CD4>350 cells/mm$^3$ for 3-6 months** (see section on prophylaxis).

**Pregnant women**:

- Should begin or continue triple therapy (HAART) regime, which is compatible with the pMTCT regimes as indicated below.
- Commence HAART for women in pregnancy as SOON AS DIAGNOSED
- Regardless of CD4 count: Standard first line regimens should be prescribed based on tolerability and CONTINUED after pregnancy (WHO Option B+)

**Rapid Initiation of ART**

In patients with very low CD4 counts ( <200 cells/mm$^3$), the following actions should be taken:

- Commence TMP/SMX prophylaxis immediately
- At the first session for treatment optimization, complete the initial assessment and education, AND commence first line ART.
- Continue with optimization sessions, while continuing ART.

## ***What to Start***

**Recommended first line antiretroviral regimens for adolescents and adults**

| | **Column A** | **Column B** |
|---|---|---|
| **FIRST CHOICE** | Tenofovir/Lamivudine (TDF/3TC) | Efavirenz (EFV) |
| **SECOND CHOICE** | Abacavir or Zidovudine/Lamivudine (ABC or AZT/3TC) | Nevirapine (NVP) |

***Choose 1 from column A and 1 from column B.***
***The FIRST OPTION for treatment should be the fixed-dose combination of tenofovir/lamivudine/efavirenz unless contra-indicated (See Table: Characteristics of antiretroviral agents)***

***For Patients with reactions to lamivudine (3TC), see above, the emtricitabine (FTC) alternative incombination with tenfovir is available by completing both the ARV Sensitivity Confirmation Form (Appendix 14) and the ARV Request Form (Appendix 15).***

These are the standard regimes recommended. Please refer to specialist centre for further guidance if necessary.

The initial regimen is thought to be the most important regimen because it is associated with the greatest probability of achieving prolonged viral suppression.

The reasons for altering an initial antiretroviral regimen include intolerance, poor adherence, drug toxicity, the occurrence of active tuberculosis or treatment failure.

Subsequent regime options will depend on the choice of the initial regimen. **ART changes due to treatment failure may require changing the entire regimen**.

Failure to continuously emphasize the critical importance of medication adherence and the avoidance of frequent medication interruptions, along with a lack of instruction on

safer sex practices and other harm reduction interventions, will contribute to the evolution and spread of HIV drug resistance.

If the supply of one component of a multi-drug regimen is interrupted, a suitable replacement should be instituted to avoid treatment failure. If no alternative is available the entire regimen should be switched. Temporary discontinuation, in the case of stock outs, may also be considered, under the guidance of an experienced provider, until all drugs can be administered simultaneously.

However, the potential for drug resistance is not a reason to delay the commencement of HAART. Patient education and strict attention to drug adherence, utilizing a multi-disciplinary team approach, are the components of an appropriate response. The benefits of ART to the individual and to society overwhelm the potential risk of the development of drug resistant virus strains at a population level.

## ***When to Switch***

The prerequisite for assessment of treatment failure is **adequate adherence (>95%)** for at least the last 3-6 months.
Criteria for treatment failure:

- Virologic failure: Confirmed (two or more) VL > 1,000 copies/ml 3 months apart
  Failure to suppress VL after 6 months of initial ART

Suspect treatment failure:

- Immunologic failure: CD4 counts fall below pre-treatment level
- Clinical failure: New or Recurrent AIDS defining illness after 6 months of ART

**Recommended Second Line antiretroviral regimens for adolescents and adults**

| | Column A | Column B |
|---|---|---|
| **FIRST CHOICE** | 1. Tenofovir/Lamivudine (TDF/3TC) | 1. Atazanavir/ritonavir ATV/r |
| **SECOND CHOICE** | 2. Abacavir or Zidovudine /Lamivudine (ABC or AZT/3TC) | 2. Lopinavir/ritonavir (LPV/r) |

***Choose 1 from column A and 1 from column B***

***Consultation with the HIV/STI/TB unit or an experienced HIV healthcare provider is recommended after failure of first line therapy.**

***For Patients with reactions to lamivudine (3TC), see above, the emtricitabine (FTC) alternative in combination with tenofovir is available by completing both the ARV Sensitivity Confirmation Form (Appendix 14) and the ARV Request Form (Appendix 15).***

## *5. Antiretroviral Therapy Maintenance*

The purpose of this section is to outline the reduction in the requirements of monitoring for stable versus unstable patients. All patients should be treated as STABLE unless initial evaluations indicate otherwise as shown below.

### *I. Management of Stable Patients on Antiretroviral Therapy*

Stable patients are defined as:

- Continuous ART supply for more than 1 year.
- Consistent undetectable viral load
- No significant adverse reactions to ART

The visit schedule for stable patients should follow the below:
- Initial visit
- 3 Month
- 6 Month
- 12 Month
- Thereafter: Stable patients can reduce the frequency of visits and monitoring to 6-12 monthly.

| | **History** | **Physical Examination** | **Laboratory Examination** | **Special Considerations** |
|---|---|---|---|---|
| **Initial visit** | Full History (pg 16. | Full Examination (pg 19 | Full Laboratory Screening (pg20…. | |
| **3 Month** | Assessment of:<br>- Adherence<br>- Side effects<br>- Sexual activity<br>- Prevention methodology | Full Examination (pg 19…. | Follow up of initial laboratory results. POC CD4 monitoring should be continued until >350cells/$mm^3$ | |
| **6 Month** | Assessment of:<br>- Adherence<br>- Side effects | Full Examination (pg 19…. | Second VL test to evaluate adequate | |

| | | | | |
|---|---|---|---|---|
| | - Sexual activity<br>- Prevention methodology | | response to treatment (VL should be suppressed by 6months.<br><br>CD4 count as above | |
| **12 Month** | | Full Examination (pg 19…. | CBC<br>Liver enzymes urea and electrolytes<br>Serum lipids<br>Repeat VL to ensure continued suppression.<br>syphilis screening<br>CD4 count if <350cells/$mm^3$ | |
| **Thereafter** | Follow-up of outstanding issues.<br>A space to discuss arising issues. | Full Examination (pg 19…. | CBC<br>Liver enzymes, serum lipids, urea and electrolytes<br>Annual VL if suppressed<br>syphilis screening<br>CD4 count if <350cells/$mm^3$ | Repeat syphilis screening for MSM.<br>The aging population (>60 years) should have annual mammograms and colonoscopy<br>Those with risk factors for diabetes, hypertension or dyslipidemia should have annual screening as appropriate |

## *II. Management of Unstable Patients on Antiretroviral Therapy*

Unstable patients are defined as:

- Continuous ART supply for more than 1 year.
- Consistently detectable viral load
- Significant adverse reactions to ART

The visit schedule for unstable patients should follow the below:
- Initial visit
- 3 Month
- Monthly visits to address all barriers to achieving a suppressed viral load.
- Thereafter: Once outstanding problems have been resolved, Unstable patients can be switched to the schedule for Stable patients.

| | **History** | **Physical Examination** | **Laboratory Examination** | **Special Considerations** |
|---|---|---|---|---|
| **Initial visit** | Full History (pg 16…. | Full Examination (pg 29…. | Full Laboratory Screening (pg 20…. | |
| **3 Month** | Assessment of:<br>- Adherence<br>- Side effects<br>- Sexual activity<br>- Prevention methodology | Full Examination (pg 19…. | Follow up of initial laboratory results. | |
| **Intensive follow up:**<br>**- Adverse events: weekly until resolved**<br>**- Adherence: monthly until resolved** | Assessment of:<br>- Adverse events<br><br>-Factors affecting adherence (pg 26…) | Specific examination of systems affected by ART or affecting ability to take ART | Follow up of abnormal results associated with Adverse events | |
| **Thereafter**<br><br>**Once** | Follow-up of outstanding issues. | Full Examination (pg 19. | CBC<br>Liver enzymes urea and | Repeat syphilis screening for MSM. |

| | | | | |
|---|---|---|---|---|
| **resolved, patient can be switched to schedule for Stable Patients** | A space to discuss arising issues. | | electrolytes<br>Serum lipids<br>Repeat VL<br>CD4 count<br>Syphilis screening | The aging population should have annual mammograms and colonoscopy |

**Recommencing therapy after prolonged discontinuation**

- Address reasons for discontinuation and possible future impact on ART of these factors.
- Resolve all new or pre-existing barriers to ART adherence to the greatest extent possible prior to recommencing ART
- TMP/SMX prophylaxis and vitamin supplementation should be offered during this process. Perform CD4 and VL analyses.
- **Recommence ART with previous active regime**
- Repeat CD4 and VL at 3 months.
- Repeat CD4 (if 3month result was <350cells/$mm^3$) and VL at 6 months (to ensure suppression). If VL not suppressed with evidence of good adherence, consider treatment failure and switching ART regimes.
- If the interruption of ART is greater than 2 weeks, NVP dosing should recommence once daily for the first 2 weeks.

| Generic name Trade name | Adult dosage | Paediatric Dosage | Potential side effects and monitoring | Food effect | Drug Interactions | Intervention |
|---|---|---|---|---|---|---|
| **NRTIs** | | | | | | |
| Zidovudine (AZT, ZDV) | 300mg b.d. | 180mg/kg b.d. | Anaemia, neutropenia, nausea, headache, Fatigue<br>CBC every 6-12 months | Take without regard to meals | Increased risk of neutropenia with TMP-SMX and ganciclovir. | Severe anaemia or neutrophils <1000/mm3- alternative NRTI<br>GI intolerance- take with food or alt. NRTI |
| Lamivudine (3TC) | 150mg b.d. | 4mg/kg b.d. | Lethargy, anaemia, Mild rash, diarrhoea, nausea, hair loss.<br>Pancreatitis may occur in children | Take without regard to meals | TMP-SMX increases 3TC levels | Pancreatitis (children only)- alternative NRTI, |
| Tenofovir (TDF) | 300mg o.d. | Age ≥2 years 8mg/kg o.d. maximum 200mg | Nausea, renal toxicity, bone mineral loss | Take without regard to meals | | |
| **Generic name Trade name** | **Adult dosage** | **Paediatric Dosage** | **Potential side effects and monitoring** | **Food effect** | **Drug Interactions** | **Intervention** |
| Abacavir (ABC) | 300mg b.d. | 8mg/kg q12h maximum: 300mg b.d. | Hypersensitivity reaction (esp. in 1st 8 weeks): fever, rash, nausea, vomiting, malaise, fatigue, anorexia, | Take without regard to meals | Alcohol increases ABC levels. | Hypersensitivity- confirm diagnosis discontinue ABC and do not re-challenge |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | sore throat, cough, SOB. **<u>Discontinue and never re-challenge</u>** | | | |
| **NNRTIs** | | | | | | |
| Nevirapine (NVP) | 200mg o.d. x 2wks then 200mg b.d. | 120mg/m2 /dose q12h x 2wks, then 200mg/m2/dose b.d. | Rash, fever, thrombocytopenia, elevated LFTs, hepatitis, rash<br>Monitor liver function tests (ALT) at 2-4 week intervals during 1st 3 months, then every 1-3 months | Take without regard to meals | Ketoconazole, rifampicin not recommended.<br>Decreases rifabutin, clarithromycin, ethinyl oestradiol levels (additional or alternate contraception advised | Hepatitis: otherwise unexplained increase in ALT to >5xULN- avoid NVP and EFV, use PI<br>Rash: if accompanied by fever, mucous membrane involvement, blistering, desquamation and/or Stevens Johnson syndrome, use PI avoid NVP and EFV |
| Efavirenz (EFV) | 600mg o.d. | 10-15kg 200mg<br>15-20kg 250mg<br>20-25kg 300mg<br>25-32kg 450mg<br>33-40kg 510mg<br>>40kg 600mg o.d. | Rash, headache, dizziness, light headedness, elevated LFTs, nightmares, caution with driving machinery for 1st 3 weeks<br>Hepatitis<br>Warn of possible inactivation of oral contraceptives | Take on an empty stomach before bedtime | Rifampicin decreases Efavirenz levels. Rifabutin levels decreased<br>Clarithromycin levels decreased, alternate recommended. | CNS toxicity usually resolves in 2-3 weeks<br>Rash: as with NVP above |
| **Generic name Trade name** | **Adult dosage** | **Paediatric Dosage** | **Potential side effects and monitoring** | **Food effect** | **Drug Interactions** | **Intervention** |
| Etravirine (ETR) | 200mg b.d. | >6yrs 5.2mg/kg b.d. | Rash, myopathy, peripheral neuropathy | Take after meals | Rifampin | Rash: as with NVP,<br>Myopathy, neuropathy discontinue if severe. |
| **PIs** | | | Warn of fat redistribution | | Rifampin, sildenafil, | Fat redistribution- consider NVP or EFV |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | Obtain fasting glucose an blood lipids at baseline and three months after commencement, followed by annual screening | | salmeterol, Statins (simvastatin + lovastatin contraindicated), OCP, anticonvulsants, warfarin, benzodiazepines. | Diabetes-adjust diet + oral hypoglycemics<br>Increased LDL cholesterol or triglyceride>1000 use statins atorvastatin, rosuvastatin or consider ATV |
| Lopinavir (LPV) | 400mg b.d boosted with ritonavir. | 230 – 350 mg/m2 b.d. | GI intolerance: nausea, vomiting diarrhoea<br>Dyslipidaemia<br>Hyperglycemia<br>Serum transaminase elevation<br>Warn of fat redistribution | Take without regard to meals | Calcium channel blockers<br>Warfarin | Taking tablets with food in the initial stages can improve GI tolerance. |
| Atazanavir (ATV) | 300mg o.d. – boosted with ritonavir<br><br>400mg o.d. - unboosted | 25-32kg: 200 mg ATV/100 mg RTV<br><br>32-39kg: 250 mg ATV/100 mg RTV | Indirect hyperbilirubinemia<br>Hyperglycemia<br>Nephrolithiasis | Take without regard to meals | $H_2$Receptor blocker and PPI contraindicated | Hyperbilirubinemia is non-pathogenic, switch to LPV if cosmetic concerns |
| **Generic name Trade name** | **Adult dosage** | **Paediatric Dosage** | **Potential side effects and monitoring** | **Food effect** | **Drug Interactions** | **Intervention** |
| Darunavir (DRV) | 600mg bd Boosted with ritonavir | 10 – 20 mg/kg q b.d. | Skin rash (sulphonamide moiety)<br>Diarrhoea and vomiting<br>Headache<br>Serum transaminase elevation | Take without regard to meals | Paroxetine | Stevens-Johnson syndrome, erythema multiforme requires discontinuation. |

| Generic name<br>Trade name | Adult dosage | Paediatric Dosage | Potential side effects and monitoring | Food effect | Drug Interactions | Intervention |
|---|---|---|---|---|---|---|
| **Integrase Inhibitor (INSTI)**<br>Raltegravir (RAL) | 400mg b.d. | | Nausea, Headache<br>Diarrhoea, Pyrexia<br>CPK elevation, muscle weakness, rhabdomyolysis | Take without regard to meals | Rifampin | Discontinuation may be required with rhabdomyolysis. |
| Dolutegravir (DTG) | INSTI naïve<br>50mg o.d.<br><br>INSTI-experienced<br>50mg b.d. | (weight>30kg)<br>35mg o.d.<br><br>(weight>40kg)<br>50mg od | Insomnia, fatigue, headache | Take without regard to meals | Dofetilide | |

**CHARACTERISTICS OF ANTIRETROVIRAL AGENTS**

- **For Patients with reactions to lamivudine (3TC), see above, the emtricitabine (FTC) alternative in combination with tenofovir is available by completing both the ARV Sensitivity Confirmation Form (Appendix 14) and the ARV Request Form (Appendix 15).**

## *6* Primary Prophylaxis protocols for common opportunistic infections

**Pneumocystis Jirovecci Pneumonia**

**Indicators for PCP prophylaxis**

- Routine primary prophylaxis – CD4 count < 350 cells/ml
- The presence of oral candidiasis
- Other minor signs or any AIDS defining illness e.g. papular urticaria

TMP/SMX 1 D/S tablet /day or 2 SS tablets/day or 1 D/S tablet 3 times weekly, until CD4 counts > 350 cells/ml for > 3months.

Patients who experience mild-moderate allergic symptoms to TMP/SMX consider desensitization (**Appendix 4**)
*Or* Dapsone 100mg/day *(check G6PD levels; if deficient do not give dapsone)*

*Withhold all prophylaxis in the first trimester of pregnancy*

**Tuberculosis**
**Indicators for TB prophylaxis**
Not routinely recommended in Jamaica.
However, in congregate settings the provision of IPT should be considered.

**Toxoplasma Gondii**
**Indicators for toxoplasma prophylaxis**

- Previous positive serology
- CD4 count< 100/$mm^3$

TMP/SMX 1 D/S tablet/day

*Or* Dapsone 50mg/day + Pyrimethamine 50mg/week *(check G6PD levels before starting dapsone)*

*Withhold prophylaxis in the first trimester of pregnancy*

**Mycobacterium Avium Complex**

***Indicators for MAC prophylaxis***

- CD4 count< 50/$mm^3$

Azithromycin 1200mg weekly
OR Clarithromycin 500mg b.d

*Withhold azithromycin and clarithromycin in the first trimester of pregnancy*

**Cytomegalovirus**

**Early recognition of CMV Retinitis for early treatment**

- CD4 counts < 50cells/$mm^3$ perform ophthalmic examination looking for cotton wool exudates or haemorrhages. Ophthalmology specialist intervention should be accessed where available.
- Advise patients with respect to early recognition of floaters and acute visual loss.

**Cryptococcal Infection**

Routine prophylaxis is **not recommended**.

# 7 Treatment Guidelines for Opportunistic and Common Infections

**Commencing ART in the setting of an Acute Opportunistic Infection**

- Cases of opportunistic infections for which there is no specific therapy (e.g. cryptosporidiosis, microsporidiosis or progressive multifocal leukoencephalopathy) ART should be commenced immediately.
- For PCP, the optimal time of ART commencement is within 10-14 days of therapy, once PCP therapy is shown to be tolerated.
- For TB delay ART until 2 weeks to 2 months of anti-TB therapy (see section TB Co-infection).
- For opportunistic infections with a higher risk for immune reconstitution syndrome (Cryptococcus, non-tuberculous mycobacterial infections), initial phases of therapy for the opportunistic infection should be completed prior to ART commencement.

**Immune Reconstitution Inflammatory Syndrome**

- This is defined as the worsening of signs and symptoms due to known infections or the development of disease due to occult infections, resulting from an excessive inflammatory response by a re-invigorated immune system following the initiation of anti-retroviral therapy.
- Clinical manifestations vary depending on the underlying opportunistic infection, generally more severe symptoms than those expected from the responsible opportunistic infection.
- Presentation can occur anywhere between 6 weeks to 6 months after commencement of ART.
- Treatment generally involves the use of NSAIDs or steroids. Treatment for the underlying opportunistic infection may also be warranted.

# Specific Treatment - Opportunistic and Common Infections

## Pneumocystis Pneumonia (PCP)

**Symptoms**

- The most common presenting symptoms are progressive shortness of breath, non-productive cough and fever.
- Auscultatory physical findings often limited and not in keeping with the level of hypoxia at presentation.
- CXR may show bilateral, diffuse, interstitial infiltration involving all portions of the lung.

**Treatment**

- TMP/SMX 15-20mg/kg/day q6h p.o./IV x 21 days

  **Alternatives**
  Clindamycin 600-900mg IV q6h. x 21 days,
  300-450mg p.o. q6h. x 21 days
  Or

  Dapsone 100mg once daily
  Trimethoprim 15mg/kg once daily (For mild to moderate disease)

  Adjunctive corticosteroids: Prednisone 40mg daily, with tapering dose.
  (Severe PCP – A-a gradient >35, $PaO_2$ <70mmHg)

**Secondary prophylaxis**

- TMP/SMX 1 DS (2 SS) once daily
  or
  Dapsone 100mg once daily

  Until CD4> 350mg for at least 3 months

**Mycobacterium Tuberculosis**:

All patients at EVERY visit must be evaluated for TB infection. Symptom directed screening should be initiated with the following: Cough > 2 weeks, fever and weight loss.

**Symptoms**

| **Presentation of pulmonary TB in early and late HIV infection** | | |
|---|---|---|
| Features of PTB | Stage of HIV infection | |
| | early | late |
| Clinical picture | Often resembles post primary PTB | Often atypical presentation |
| Sputum smear result | Often positive | Often negative |
| CXR appearance | Often cavities | Often infiltrates with no cavities or normal |

**Treatment**

For uncomplicated pulmonary infection

- **Initial Quadruple therapy for 2 months (Inpatient)**

INH 10-20mg/kg/day, Rifampicin 10-20mg/kg/day,

Pyrazinamide 15-30mg/kg/day, Ethambutol 15-25mg/kg/d

- **Maintenance therapy for 4 months**

INH 10-20mg/kg/day, Rifampicin 10-20mg/kg/day

***Notify to local health department within 24 hours of suspicion of diagnosis***
**(For more detail see section TB Co-infection)**

## Candidal Infections

**Symptoms**

- May present as whitish plaques on the oral mucosal, less commonly as erythematous macule, glossitis or an adherent pseudomembrane. Oral candidiasis may be a sign of advanced disease but is not considered AIDS-defining
- Extention into the oesophagus can occur and is considered AIDS-defining. Oesophageal involvement is usually associated with **odynophagia** (pain on swallowing).

**Treatment**

**Oropharyngeal**

- Fluconazole 100mg once daily. x 1 week

**Candidal Oesophagitis**

- Fluconazole 200mg once daily x 2-3 weeks

## Cryptococcal Meningitis

**Symptoms**

- Fever, dull headache, malaise, blurred vision, altered personality, altered mental status
- Nausea, vomiting
- CSF – lymphocytosis, CSF cryptococcal Ag positive in over 90%, India ink positive in 50-60%

**Treatment (Inpatient)**

- **Initial therapy**
  Amphotericin B 0.7-1.0 mg/kg/day + flucytosine 100mg/kg/d IV for 10-14 days, *may be nephrotoxic, reduce dose in renal patients*
  Alternatives: Amphotericin B 0.7-1.0 mg/kg/day + Fluconazole 800mg daily for 10-14 days
  +/- Therapeutic lumbar puncture
  Or Fluconazole 12mg/kg/day up to 800mg

- **Consolidation**
  Fluconazole 800mg daily for 8 weeks

- **Maintenance**
  Fluconazole 200mg daily until CD4 counts > 200cells/$mm^3$ for at least 1 year.

In HIV infected individuals with recent diagnosis of cryptococcal meningitis ART initiation should be deferred until there is evidence of a sustained clinical response to antifungal therapy, and after 4 weeks of induction and consolidation treatment with amphotericin and fluconazole or 4-6 weeks of treatment with high dose oral fluconazole induction and consolidation.

## Toxoplasma encephalitis

### Symptoms

- +/- fever, headache
- altered mental status e.g. confusion, lethargy, delusional behaviour, cognitive impairment in 60% of patients
- seizures, focal signs
- IgG positive serology.
- CT scan shows multiple ring enhanced lesions of toxoplasmosis, however nothing may be seen
- If no treatment response after initial 2 weeks of therapy, may consider brain biopsy.

### Treatment

- **Initial treatment – Complete 6 weeks**
  Pyrimethamine 200mg loading dose then 50mg (<60kg weight), 75mg (>60kg weight) daily + folinic acid 10 -25mg daily.
  Sulfadiazine 1g (<60kg weight) 1.5g (>60kg weight) daily
- **Alternatives to Sulfadiazine component** (use pyrimethamine as described above)
  Clindamycin 600mg q6h p.o. or I.V.
  Azithromycin 1,200mg weekly.
  **Alternative Regime**
  TMP/SMX 10-15mg/kg/d divided q6-8h x 6weeks
- **Chronic Maintenance therapy –** With significant clinical and radiologic improvement.
  Continued until CD4 count >200cells/$mm^3$ for at least 6 months of ART
  Pyrimethamine 25-50mg + folinic acid 10-25mg daily
  Sulfadazine 200-400mg divided 2-4 times daily

## Herpes Simplex

**Symptoms**

- Grouped vesicular lesions, usually in the oral and anogenital region
- Large chronic erosions refractory to treatment can be considered as AIDS-defining

**Treatment**

- Acyclovir 400mg q8h for 7-10 days.
- Valaciclovir 1gm twice daily for 7-10 days.
- Chronic suppressive therapy valaciclovir 500mg b.d. or acyclovir 400mg b.d.

## Herpes Zoster

**Symptoms**

- A painful, unilateral, vesicular, **multidermatomal** involvement is considered AIDS-defining

**Treatment**

- Acyclovir 800mg orally five times daily for 7-10 days *or*

- Valaciclovir 1g p.o. t.i.d. x 7-10 days *or*
- Acyclovir 30mg/kg IV daily x 7-10 days for severe cases.
- Analgesics

## Cytomegalovirus retinitis

**Symptoms**

- Decreased visual acuity, presence of floaters or unilateral visual field loss are common presenting complaints.

- Ophthalmic examination can reveal large creamy granular areas with perivascular exudates and haemorrhages on the fundus.

- CMV also cause CNS, gastro intestinal and pulmonary disease.

**Treatment**

Refer to Ophthalmologist

- Ganciclovir intraocular therapy plus valganciclovir 900mg twice daily

- Maintenance therapy valganciclovir 900mg once daily
  Discontinue with inactive disease and CD4 >100 cells/$mm^3$ for 6 months.

**Mycobacterium Avium Complex**

Presents at a late stage of HIV disease and requires referral to a specialist centre

**Symptoms**

- May present as fever, malaise, weight loss, anaemia, neutropoenia
- Chronic diarrhoea and abdominal pain
- Chronic malabsorption
- Extra-biliary obstructive jaundice
- Blood culture, lymph node biopsy.

**Treatment**

- Clarithromycin 500mg twice daily. + ethambutol 15mg/kg/day +/- Rifabutin 300mg once daily.
  Alternative: Azithromycin 500mg once daily replacing clarithromycin.

# 8 Treatment Guidelines for other AIDS-defining Illnesses

## HIV Wasting Syndrome

- Characterized by a loss in **total** body mass, in contrast to the more localized lipoatrophy.

**Diagnosis**

Remains a diagnosis of exclusion (rule out opportunistic infections, gastrointestinal infections and malignancies) and is characterized by:

- Unintentional weight loss >10%
- Chronic diarrhoea ± fever

**Treatment**

- Commence ART: may not reverse wasting
- Nutritional supplementation (targeted vitamin and calorie replacement)
- Exercise if appropriate
- Treatment of exacerbating nausea and diarrhoea
- Testosterone replacement therapy may be considered in cases of deficiency

## HIV Associated Nephropathy (HIVAN)

HIV can infiltrate renal parenchymal cells and cause direct damage to the kidney. Patients may present with mild renal impairment or overt renal failure.

Diagnosis

- Presentation usually of chronic renal failure
- Kidneys tend to be normal/large sized
- lower limb oedema uncommon
- Hypertension not usually associated

Treatment

No specific treatment is available. However, early commencement of ART, with doses adjusted for renal function (**Appendix 5**) can lead to a significant improvement or complete reversal in renal dysfunction.

## HIV Associated Neurocognitive Disease (HAND)

HIV can cause direct effects on the CNS and replicates in macrophages and microglia. HAND describes a constellation of neurocognitive disorders ranging from mild impairment of function (minor cognitive motor disorder – MCMD) to more severe, debilitating dementia (HIV-associated dementia – HAD) comprising a combination of mood, motor and cognitive deficits.

### Symptoms

MCMD

- Impaired Concentration and memory
- Slowed movements and impaired coordination
- Personality change, irritability, emotional lability

HAD

- Acquired abnormality in motor function
- Decline in motivation, emotional control, social behaviour
- Impaired memory/learning
- Impaired attention concentration
- Impaired speech/language
- Difficulty with reasoning/abstraction

### Treatment

There is no specific treatment for HAND. Commencement of ART may reverse the disease process. ART agents that have good CNS penetration may be of additional benefit in these cases (NRTI: abacavir, zidovudine and emtricitabine; NNRTI: nevirapine; PI: lopinavir)

# HIV and Women

The general management for HIV, in terms of ART choices, effectiveness and monitoring, do not differ significantly between men and women. However, there are several nuances to the care of the HIV infected woman.

**Women infected with HIV Recommendations**

- Counselling and psychological support.
- Advice on condom use (male and female) and condom negotiation.
- Advice on family planning and pregnancy outcomes.
- Screening for cervical dysplasia (Pap smear), which has a higher incidence in HIV positive women, is more likely to progress to cancer and more likely to present at a more advanced stage of disease. Pap smears should be performed every 6 months until at least 3 consecutive negative pap smear results. Then annual screening is recommended.
- More aggressive therapy for gynaecological infections as compared to the HIV negative population is recommended.
- Comprehensive sexual and reproductive health counselling including access to appropriate contraceptive devises.

In addition, several interactions of HIV are peculiar to woman including:

- Changes in menstruation and fertility
- Osteoporosis
- Contraception
- Adverse drug reactions

**Changes in menstruation and fertility**

Women may experience the following changes in their menstrual cycle and fertility, especially with low CD4 counts and advanced HIV infection:

- Extended time between periods.
- Missed periods without pregnancy.
- Dysfunction of oestrogen and progesterone production leading to reduced fertility and early menopause.

**Osteoporosis**

Women, particularly post-menopausal women, in the general population are at an increased risk of osteoporosis. This risk can be exacerbated by both HIV infection and ART agents. Agents that have been found to be associated with osteoporosis include tenofovir and a class effect with boosted PIs. However, presently there is no evidence to suggest an indication for changes in screening or treatment of osteoporosis in the HIV population.

**Contraception**

There are several methods of contraception available to women, however in the HIV population many of these techniques are not recommended.

- Condoms: both male and female condoms should be used consistently to prevent pregnancy, transmission on HIV and most other sexually transmitted infections.
- Intra-uterine devices have been shown to be safe and effective in HIV infected women. However, there is an increased risk of PID and its complications, in women who continue to engage in high risk sexual behaviour, associated with these devices.
- Hormonal contraception can be used, but should be limited to parenteral preparations, e.g. Depo Provera, implant devices and IUDs as there are significant drug-drug interactions between ART and oral contraceptive pills.
- **Dual contraception is recommended**.

**Adverse Drug Reactions**

Women *may* face an increase in drug reactions to certain ART agents, including:

- Lactic acidosis with NRTI (especially stavudine and didanosine)
- Hepatotoxicity and rash with nevirapine (use when CD4 counts < 200 cells/ml)
- Higher risk of lipodystrophy

Certain gynaecological conditions may be more common in HIV positive women and must be diagnosed and treated early. Some conditions may require ART commencement including:

- Recurrent or resistant vaginal candidiasis.
- Severe, frequent or refractory HSV genital lesions (**commence ART**).
- Severe, frequent or resistant pelvic inflammatory disease.
- Aggressive HPV-related infections (Cervical/vaginal/penile carcinoma-**commence ART**)

# HIV and Key Populations

The WHO has defined key populations as comprising the following groups:

- Men who have sex with men (MSM)
- People who inject drugs
- Sex workers
- Transgender people

There has been an increased effect of HIV on key populations. Since the beginning of the epidemic, the MSM population in particular, has had greater rates of infection than the general population. Recent estimates in 2013 in Jamaica have shown a prevalence rate of 33.2% in the MSM population versus 1.8% for the general population. Sexual orientation and gender identity remain taboo subjects in the Caribbean region which results in under reporting and increased barriers to health care for this population. Layered stigma and social discrimination have been identified as important factors associated with the poor outcomes experienced by this population. There is also an increased burden of mental health disease, including anxiety and depression, as well as substance abuse. In Jamaica, injection drug use is highly uncommon and is not a recognised risk group.
This chapter will highlight some of the specific considerations for this population. However, much of the clinical management for HIV in this population remains the same as for the general population

**Prevention**

- Health literacy, as with the general population, is one of the cornerstones of prevention efforts. Tailored messaging, as determined by the specific risk behaviour, must be provided; particularly education to reduce transmission risk and dispel myths.

- Consistent condom use remains a mainstay for the prevention of HIV and STIs. For the populations who engage in anal sex, education around the use and the provision of water-based lubricants is essential. For female SW, education and provision of female condoms can assist with overcoming power imbalances affecting successful condom negotiations.

- This population, especially the lesbian population, must be educated about the risk of transmission via shared sex toys and the need for disinfection of these toys after use.

- Sero-sorting, defined as a person choosing a sexual partner known to be of the same HIV sero-status in order to reduce the risk of acquiring or transmitting HIV.

- HIV testing and counselling with specific prevention messages can result in significant reductions in transmission and risk behaviour.

- Access to appropriate interventions for substance abuse should be provided as with the general population.

- New biomedical prevention techniques have been recently explored in this population, however they are not routinely recommended in Jamaica and cases should be referred to an experienced HIV healthcare provider.

**Treatment**

- Access to ART, choice of ART and monitoring of ART response, should follow the same guidelines as for the general population, providing acceptable, safe and affordable treatment and care.
- A tailored approach to the specific needs identified above is recommended.
- The transgender population may require additional considerations:
    - Hormone replacement therapy
        - Estrogens
        - Anti-androgens
        - Testosterone
    - Interaction of hormones with ART
        - Drug interactions, particularly with estrogrens occur with the ART classes NNRTIs and PIs (see Appendix 11).
    - Primary Care
        - Trans women
            - Mammogram
              Annual manual examination and mammogram. Intensive investigation of breast symptoms.
            - Prostate
              Annual rectal examination and PSA.
            - Prolactin
              1-2 years after commencing hormone replacement therapy.

- Trans men
    - Testosterone
      Levels should be checked at the mid cycle of administration for anxiety, 6 months after commencing, or resistance.
    - Haemoglobin and lipids
      Haemoglobin levels should be compared to age-appropriate male levels
      Annual lipid screening especially if over 30 years of age.
    - Mammogram
      Annual mammogram commencing after age 40. Determine mode of breast removal (either mastectomy or liposuction/reduction).
    - Pelvic Examination and pap smear
      Annual pelvic examination and pap smears
    - Thyroid screening
      Annual Thyroid hormone screening
    - Bone density
      5-10 years after commencing testosterone therapy.

**Specific Sexual and Reproductive Health Interventions**

- For STIs, the treatment remains as with the general population. However, screening for asymptomatic urethral, pharyngeal and rectal infections, e.g. chlamydia, gonorrhoea and syphilis should be conducted more frequently than in the general population.
- Syphilis screening should be conducted annually for MSM and trans women.
- SW should be screened for STIs, even in the absence of symptoms, at least annually

**Psychological Support**

This is highly recommended for key populations. The high rates of HIV and other STIs reflects a complex interaction of psycho-social and economic barriers to HIV prevention and treatment. As such, the response to these populations must comprehensively address these issues in order to achieve successful interventions.

**Recommended Reading**

WHO. Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people: Recommendations for a public health approach. 2011.

WHO. Consolidated guidelines on HIV prevention, diagnosis, treatment, and care for key populations. 2014.

WHO/PAHO. Blueprint for the provision of comprehensive care for Trans persons and their communities in the Caribbean and other Anglophone Countries. Available at: **http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=28440&lang=en**

# HIV and Ageing

The age of the population of PLHIV in Jamaica is steadily increasing. This is, in part, a result of the increased life expectancy due to the availability of HAART, but also the increasing contribution of the older age group to the number of new infections occurring. The general treatment of this population for HIV remains similar to the younger adult. However there are additional aspects of their management that require consideration.

A few key points in this population:

- **Poor CD4 count recovery** with HAART in the elderly population. The mechanism of this poor immune response is part due to the natural immune senescence seen in aging coupled with the immune depletion of HIV. It is also noted the elderly population generally have fibrotic lymph nodes with poor regenerative capacity. This effect may not be persistent and CD4 count responses may improve over time with ART.

- **Later presentation** to treatment and care with corresponding low CD4 counts seen. Elderly patients often don't consider themselves at risk for HIV and safe sexual practices must be emphasized.

- **High frequency of comorbid illness** with high potential for treatment related toxicities. With aging, there is a gradual decline in the function of the liver and the kidneys, decreasing the metabolism of pharmacologic agents resulting in high drug levels and increased toxicity.

- **Increased risk of drug-drug interactions** with polypharmacy required for co-morbid illnesses.

- **Misinterpretation** of some non-specific symptomatology of HIV as due to aging, e.g. fatigue.

- **Cancer risk**: No studies have proven the need for more stringent cancer screening protocols for non-AIDS defining cancers in the PLHIV population. However, elderly PLHIV are at increased risk for some non-AIDS defining cancers, e.g. primary lung or liver cancers.

- **Bone disease:** is another important factor for consideration especially osteopenia and osteoporosis. Vitamin D and Calcium supplementation should be considered

early in the management of the elderly PLHIV.

- **Neurological and psychosocial health**: age and HIV infection are independent risk factors for the development of dementia. High viral load and low CD4 counts have also been associated with an increased risk.

- **Improved adherence** in older patients has however been noted compared to their younger counterparts to ART regimes.

**Recommended reading**

Simone MJ, Appelbaum J. HIV in older adults. *Geriatrics*. Dec2008;63(12):6-12.

Grabar S, Kousignian I, Sobel A, et al. Immunologic and clinical responses to highly active antiretroviral therapy over 50 years of age. Results from the French Hospital Database on HIV. *AIDS*. Oct 21 2004; 18(15):2029-2038.

Kirk JB, Goetz MB. Human immunodeficiency virus in an aging population, a complication of success. *J Am Geriatr Soc*. Nov 2009; 57(11):2129-2138.

Justice AC. HIV and aging: time for a new paradigm. *Curr HIV/AIDS Rep*.May 2010; 7(2):69-76.

# HIV and Chronic Diseases

**HIV and Cardiovascular Disease**

Many studies have supported the increased risk of cardiovascular disease in PLHIV. The underlying mechanisms appear to be complex, with factors associated with HIV itself, ART and traditional risk factors all playing a role. Despite this complexity, control of traditional, modifiable risk factors continues to have the greatest impact on cardiovascular disease including:

- Diet
- Exercise
- Tobacco Smoking
- Diabetes Mellitus

Specific ARVs which are associated with cardiovascular disease are summarized below:

- A few reports on the association between zidovudine and dilated cardiomyopathy have been published, although the risk remains low. Many studies have been conducted to investigate the association between abacavir and myocardial infarction and the latest meta-analysis failed to show a conclusive result. Studies on NRTI-sparing regimes have showed favourable lipid effects and may be of use in difficult cases.

- NNRTI: Long term use of these agents may be associated with increases in lipid parameters. The impact appears to be variable between patients.

- PI: All PI drugs are associated with dyslipidemia, but the degree of effect varies within the class. Lopinavir is associated with the greatest increases while atazanavir and darunavir have the lowest impact on lipid parameters.

## The Management of Dyslipidemia

### Diagnosis

Samples for lipid profiles should be taken after a minimal of 8 hours, preferably 12 hours, of fasting.

An estimate of the cardiovascular risk of each patient can be attained using the Framingham Risk Score. Framingham Risk Calculator can be accessed online free of charge at: http://www.cphiv.dk/TOOLS/Framingham/tabid/302/Default.aspx

Framingham Risk Assessment

| Risk Category | Percentage Risk for CVD in 10 years | Recommendations |
|---|---|---|
| Low risk | <10% | Lifestyle modification |
| Intermediate Risk | 10-20% | B/P< 120/80<br>Lipid Lowering therapy<br>Acetylic Acid |
| High Risk | >20% | B/P< 120/80<br>Lipid Lowering therapy<br>Acetylic Acid<br>Cardiology Referral |

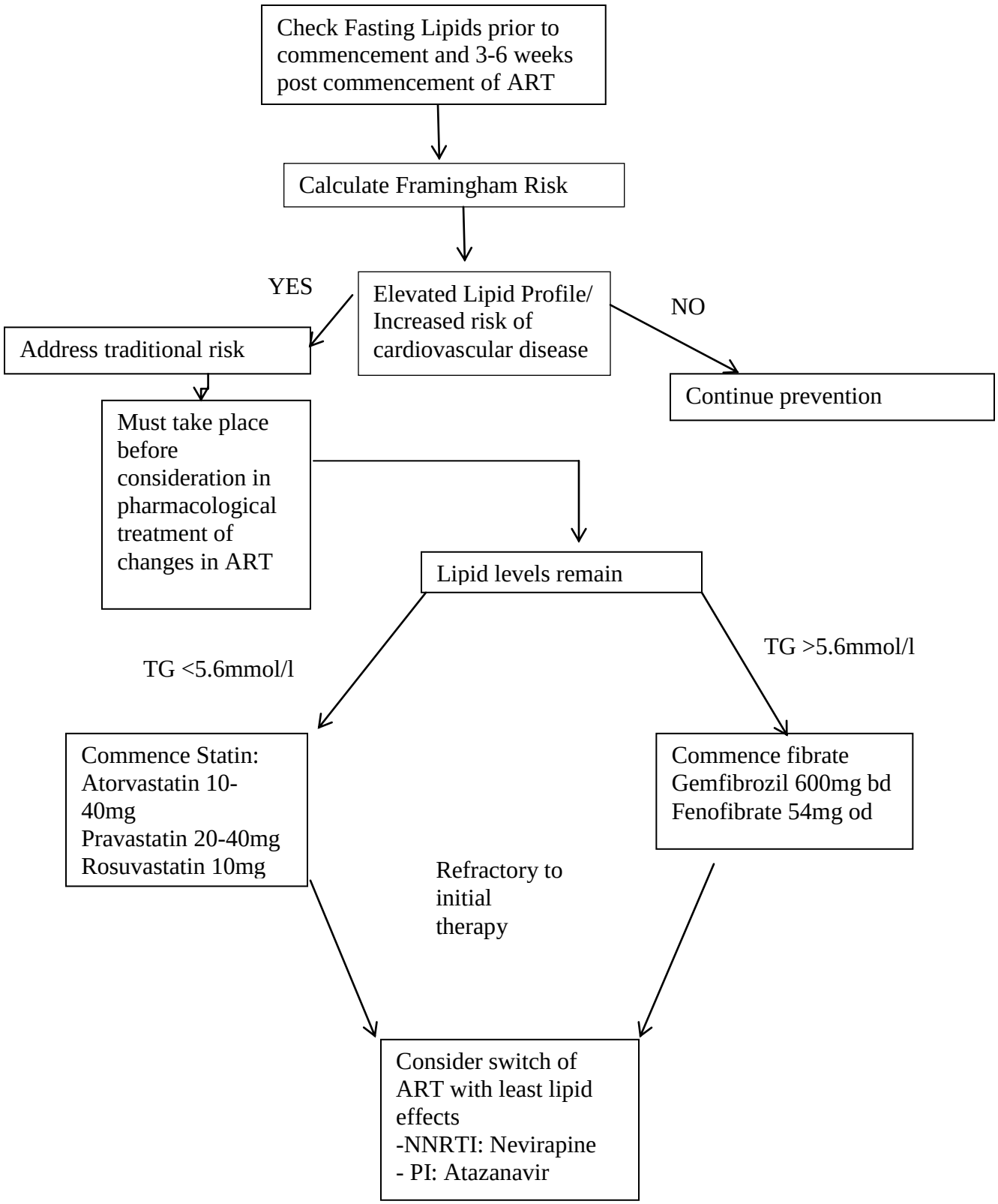
Monitoring of lipid levels should also be done at the time of switching ART and annually for all PLHIV receiving therapy, especially in those receiving PI –based therapy.

The primary goal of management is the reduction in low density lipoprotein (LDL). Treatment guides for lipid levels can be found with the US National Cholesterol Education Program Adult Treatment Panel (NCEP ATP III).

ATP III LDL-cholesterol goals and cut points for therapeutic lifestyle changes and drug therapy in different risk categories

| Risk category | LDL-cholesterol goal | LDL-cholesterol level at which to initiate therapeutic lifestyle changes | LDL-cholesterol level at which to consider drug therapy |
|---|---|---|---|
| Coronary heart disease (CHD) or CHD risk equivalent (10-year risk >20 percent)* | < 2.58 mmol/L | ≥ 2.58 mmol/L | ≥ 3.36 mmol/L; drug optional at 2.58 to 3.33 mmol/L |
| 2 or more risk factors (10-year risk ≤20 percent)Δ | < 3.36 mmol/L | ≥ 3.36 mmol/L | 10-year risk 10 to 20 percent: > 3.36 mmol/L<br>10-year risk <10 percent: ≥ 4.13 mmol/L |
| 0 to 1 risk factor◊ | < 4.13 mmol/L | ≥ 4.13 mmol/L | ≥ 4.91 mmol/L; LDL-cholesterol lowering drug optional at 4.13 to 4.88 mmol/L |

**Treatment Algorithm for Dyslipidemia**



**Drug-Drug Interaction Considerations**

Interaction between ART and lipid lowering therapies occurs at the level of the CYP 450 enzyme system in the liver. Significant drug-drug interactions can occur as outlined below:

| Lipid Lowering Drug | Effects of Drug Combinations | | | |
|---|---|---|---|---|
| | Ritonavir | Other PI | Efavirenz | Nevirapine |
| Simvastatin | AVOID USE | | | |
| Lovastation | | | | |
| Atorvastatin | Caution, start with low doses | Caution, start with low doses | Probably None | Probably None |
| Pravastatin | Possible reduced effect | Probably None | Probably None | Probably None |
| Rosuvastatin | Caution, start with low doses | Caution, start with low doses | Probably None | Probably None |
| Gemfibrozil | Induction Possible reduced effect | Probably None | Probably None | Probably None |
| Fenofibrate | Induction Possible reduced effect | Probably None | Probably None | Probably None |

**Recommended Reading**

Dube MP, Stein JH, Aberg JA, et al. Guidelines for the evaluation and management of dyslipidemia in human immunodeficiency virus (HIV)-infected adults receiving antiretroviral therapy: recommendations of the HIV Medical Association of the Infectious Disease Society of America and the Adult AIDS Clinical Trials Group. Clin Infect Dis. 2003 Sep 1; 37(5):613-27.

Expert Panel on Detection Evaluation and Treatment of High Blood Cholesterol in Adults. Executive summary of the third report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). JAMA. 2001 May 16; 285(19):2486-97.

Stein JH**.** Managing cardiovascular risk in patients with HIV infection. JAIDS. 2005; 38:115-123.

## INSULIN RESISTANCE AND DIABETES MELLITUS

Patients may present to care already being diabetic or it may develop de novo after commencing ART. Several ART agents have been associated with hyperglycemia and diabetes. Offending agents include:

- PI: most commonly associated with lopinavir

**Diagnosis**

Fasting blood glucose assessments should be conducted as part of the initial investigation of all PLHIV presenting to care.

- Fasting blood glucose > 5.6 mmol/l and 2 hour post-prandial > 7.8 mmol/l indicate impaired glucose tolerance.
- Fasting blood glucose >7.0 mmol/l indicating overt diabetes

Evaluations should also be repeated 3-6 months after commencing or switching ART. HbA1c levels can also be utilized, but may underestimate hyperglycemia in PLHIV.

**Treatment**

Due to the underlying pathology of insulin resistance in this population, insulin sensitizers such as metformin (treatment of choice in overweight individuals), or thiazolidinediones can be utilized.

# HIV and Co-Infections

## Hepatitis B

HIV co-infection impacts hepatitis B (HBV) disease in the following ways:

- Decreased chance of spontaneous clearance
- Acceleration of progression of chronic HBV disease
- Increased risk of hepatocellular carcinoma

The management of HIV and hepatitis B co-infection involves the following

- Determination of hepatitis B activity: treatment is required for chronic (>6 months), active infection (elevated ALT or evidence of fibrosis).
- Use of ART agents that have activity against both hepatitis B and HIV: tenofovir and lamivudine/emtricitabine (e.g. Truvada).

**Diagnosis**

Serological testing for hepatitis B should include: HBsAg ± HBeAg
Monitoring of ALT levels can assist in determining activity (> 1-2x Upper Limit of Normal)

**Treatment**

Co-infected patients should be offered 2 active agents against hepatitis B (**tenofovir AND emtricitabine/lamivudine)**
If while on therapy, HIV virologic failure occurs, the next line of treatment for HIV must still include these agents treating hepatitis B. The risk of sudden discontinuation of hepatitis therapy is a flare of HBV which may be life threatening.

**Immunization**

PLHIV should be offered HBV vaccination and for the best responses should be administered when CD4 counts are at least >200 cells/ml. Only patients who are HBsAb and HBsAg negative should be offered immunization.

**Recommended Reading**

Nunez M, Soriano V. Management of patients co-infected with hepatitis B virus and HIV. Lancet Infect Dis. 2005; 5:374-384

## Tuberculosis

All patients at EVERY visit must be evaluated for TB infection. Symptom directed screening should be initiated with the following: Cough > 2 weeks, fever and weight loss.

### Clinical Presentation

- CD4 count> 350cells/ml: Typical presentation with:
  - Constitutional symptoms: fever, night sweats, weight loss, cough >2-3 weeks and haemoptysis.
  - Pulmonary infiltrates in upper lobe with possible cavitation
- CD4 count <350cells/ml: Extra-pulmonary and atypical pulmonary presentations become more common

Extra-pulmonary infection commonly involves:

- Lymph nodes – lymphadenitis
- Brain – Meningitis, tuberculoma
- Bone – typically spinal involvement (Pott's Disease)
- Adrenal gland – adrenal insufficiency

### Diagnosis

Diagnosis typically begins with the history and examination. Investigations include:

- Mantoux test (>5mm in the HIV co-infected patient)
- Chest X-ray
- Sputum analysis for acid-fast bacilli, culture and sensitivity.

Asymptomatic cases with a positive Mantoux test >5mm and a negative chest x-ray should be diagnosed as **Latent TB**

### Treatment

**In Jamaica, treatment for TB requires admission to Hospital** (National Chest, University Hospital of the West Indies or Cornwall Regional Hospital)
Active pulmonary disease should be treated for a total of 6 months with a rifampin containing regimen:

- Induction: 2 months with 4 active agents (rifampin, isoniazid, ethambutol and pyrazinamide)
- Maintenance: 4 months with 2 active agents (rifampin and isoniazid)

For extra-pulmonary disease, treatment should be extended to between 9-12 months depending on the site of infection.

Latent TB should be treated with isoniazid 300mg with vitamin B6 50mg daily for 6 months.

ART commencement in the face of active TB

- The ideal regime in this situation is **Truvada and Efavirenz and is recommended regardless of CD4 count**.
- IRIS is of particular concern with early initiation of ART
- Tolerability of anti-TB therapy must first be demonstrated prior to ART commencement
- **CD4< 50cells/ml consider ART after 2 weeks of anti-TB therapy**
- **CD4> 50cells/ml ART can be delayed up to 8 weeks of anti-TB therapy.**

**All patients should be offered TMP/SMX prophylaxis.**

Prophylaxis against TB with Isoniazid therapy is not currently recommended in Jamaica.

**Recommended reading**

PAHO. Caribbean Guidelines for the Prevention, Treatment, Care, and Control of Tuberculosis and TB/HIV. PAHO 2010

WHO. TB/HIV: A clinical manual, second edition. WHO 2004

MOH. Tuberculosis Prevention and Control. Procedure Manual. MOH 2007.

## Management of Genital Disease

In Jamaica, STI co-infection is one of the major drivers of HIV transmission. **All HIV positive patients must be screened for STIs.**

History:

- Full sexual history
- Duration and location of lesions
- Abnormal discharge, pruritus, odour, burning, pelvic pain in women
- Previous history of genital ulcers (e.g. syphilis or herpes) or genital discharge
- Any associated symptoms (e.g. inguinal lymphadenopathy)
- Any past or present treatment

Examination:

- Number, dimensions and location of lesion
- Examination of genital discharge and speculum examination in women
- Presence of pigmentation, oedema, erythema, induration, exudates, tenderness
- Associated oral lesions, lymphadenopathy or rash.
- Examination of the pharynx and anus

Laboratory Evaluation:

- Syphilis serology
- ± Herpes Ab

## Genital Ulcer Disease

### *Syphilis*

- **Diagnosis**
  HIV positive patients may have unusually high titers or false negatives, but generally serology can be interpreted in the usual manner.
- **Presentation**
  Solitary, firm, painless ulcer, spontaneously resolves in 6 weeks. However, presentation may be atypical.
- **Treatment**
  Primary, secondary and early latent: benzathine penicillin 2.4 MU IM weekly x 2wks
  For penicillin allergy: Doxycycline 100mg b.d. x 15 days

Late latent, unknown duration:
CSF positive – crystalline penicillin 18-24MU/day (3 to 4 MU IV q4hx 10-14 days.)
CSF negative – 2.4 MU benzathine penicillin weekly x 3 wks
Follow up serological exams for all stages of syphilis should be done at 3, 6, 12, 24 months.

Screen the CSF with serum titers >1:32 prior to commencing specific treatment.
*CSF examination may not always be available prior to treatment and should be considered if no response to standard therapy within 3-12 months.

***Herpes simplex***

- HIV positive patients may have more frequent, prolonged, and severe episodes with progressive immunosuppression; lesions may be atypical in appearance or location. Viral shedding increases with declining CD4 counts.
- Treatment: first episode: valaciclovir 1gm b.d. x 7-10dys.
  acyclovir 400mg t.i.d. x 7-10dys.

  Recurrences: valaciclovir 500mg b.d. x 5dys.
  acyclovir 400mg t.i.d. x 7-10dys

  Chronic suppressive therapy: valaciclovir 500mg daily
  acyclovir 400mg b.d.

  Severe disease: Double standard dosing for 5 – 7 days
  or until clinical resolution
  ART is also recommended

**Urethral/vaginal discharge**

Treatment of urethral/vaginal discharge follows a syndromic management system.
Further information can be found at:
**Brathwaite AR. 2001. Practical case management of common STI syndromes. NHP, MOH, Jamaica.**

# HIV Drug Resistance

# HIV Drug Resistance

HIV drug resistance can be classified as either:

1. Primary (transmitted resistance): Infection with a drug resistant virus
2. Secondary: Developed resistance due to inappropriate ART exposure

In Jamaica, the current rates of HIV drug resistance are, 12.6 % for primary (transmitted resistance) and 82.3 % for secondary resistance. The specific ART classes affected are primarily the NRTIs and NNRTIs. There have been PI mutations identified, however these have been limited to persons on second line, PI-based, regimes with protracted periods of intermittent non-adherence to ART.

**In order to assure capture of drug resistance mutations, HIV drug resistance can only be assessed in the setting of adequate adherence (see pg 23).** Sample collection for HIVDR should be collected either:

1. After 6 weeks of continuous therapy on their current regime
2. Within 2 weeks of switching to a new regime (with adequate adherence to prior regime)

The Candidates to be initially assessed for HIV resistance testing will be those with:

1. **Confirmed virologic failure on a second line, boosted protease inhibitor regime**

2. **Confirmed failure to virologically suppress after 6 months of first line therapy.**

## HIV Resistance testing in Jamaica: Considerations and Procedure

- **Sex**
- **Age**
- **Previous ART exposure**:
  pMTCT
  First Line
  Second line
  Additional Exposures

- **Length of time on ART**:
  First line
  Second Line

- **Adherence to present regime**:
  On- time pharmacy refill percentage in past 6/12:……..

- **Confirmed Virologic failure to present regime with adequate adherence:**

  1st Viral load……copies/ml

  2nd Viral Load……..copies/ml

- **Likely Location of HIV infection:**
  Local:
  International:

- **Any risk factors for exposure to resistant virus**
  IV Drug use
  International/local incarceration
  Known HIV positive partner with history of failing previous ART lines

  Other considerations:
- Prevention of HIV spread - Condom use and no other current STI, one partner
- Willingness to adhere to continued medical care and safer sex practices
- Higher weighting if discordant couple (prevent TDR)
- General health status in last 6 months

**Procedure for Resistance Testing**

1. Application form (**Appendix 12**) fully completed and submitted to resistance board.
2. Monthly review by HIVDR Board
3. Communication from the board to HIV care provider re: disposition of the application
4. Appropriate sample collection and sample transportation to the resistance lab
5. Bi-monthly case review (in order to avoid 4+ week turnaround time for resistance testing) by resistance board, to build consensus around recommendation for new ART regime
6. Communication of ART recommendation to the HIV care provider by the resistance board
7. Communication by the board to the TCS Director for release of ART to pharmacy location provided in the application form referred to in Step 1.

Essential Criteria

1. **Adherence**
   - On-time pharmacy refill % in last 6/12
   - Ability to adhere to new medication
   - Years on ART:
   First line……..
   Second Line……..

2. **Transmitted Drug Resistance Prevention**
   - High risk behaviors
   - Disclosure of sero-status
   - Discordant couple

3. **Pre-existing Risk Factors for Resistance**
   - International incarceration
   - IV Drug use
   - Source of HIV infection from area with high prevalence of resistance

# Third Line Antiretroviral Therapy

# Third Line Antiretroviral Therapy

**Third line therapy in Jamaica will have the following guiding principles:**

- **Preservation of new classes of drugs for future regimens**
- **Construction of new regimes guided by HIV resistance testing**
- **Coordinated centrally to ensure monitoring and appropriate allocation**

The specific ART agents available for regimes after standardized secondline therapy are:

1. Darunavir/ritonavir (PI)
2. Etravirine (NNRTI)
3. Raltegravir (INSTI)
4. Dolutegravir (INSTI)

With the availability of newer antiretroviral agents, a suppressive regime should be able to be constructed for **ALL PLHIV**.

*Each provider should however note, third line therapy will not solve ongoing social, psychological or structural issues that affect a patient's ability to respond to first or second line therapy.*

**Access to Third Line Therapy**

1. The request for HIV drug resistance testing (Appendix 11) will be the first step in accessing Third line therapy for each patient.

2. Upon receipt of the HIVDR results a regime will be developed in collaboration with the HIV provider and the agreed ART regime will be released for use by that patient.

# Post-Exposure Prophylaxis

## Management of Occupational Exposure to HIV

**Prevention of occupational exposure to HIV includes risk assessment and risk reduction activities such as**:

- Using Universal Precautions;
- Wearing heavy-duty gloves when disposing of "sharps";
- Assessing protective and other equipment for risk and safety;
- Adopting safe techniques and procedures, such as
    - Disposing of needles without recapping, or recapping using the single-handed method
    - Using sterile nasal catheters and other resuscitation equipment,
    - Using a separate delivery pack for each delivery, and
    - Not using episiotomy scissors to cut the umbilical cord.
- Making appropriate disinfectants and cleaning materials available
- Sterilizing equipment properly

**<u>Accidental exposure to Blood and Body Fluids</u>**

The following steps should be followed in case of accidental exposure to blood or blood products inclusive of needle stick injuries.

**Immediately following an exposure to blood or body fluids:**

**1. Exposed area should be thoroughly washed with running water**

- Needle sticks and cuts should be washed with water.
- Splashes to the nose, mouth or skin should be flushed with water.
- Eyes should be irrigated with clean water or saline
- **The use of bleach, alcohol, Savlon or other disinfectants is not recommended.**

**2. The incident should be promptly reported (See Appendix 10).**

- In hospital - to the infection control nurse or designate on each shift.
- At Health Centre to the Nurse in Charge (Public Health Nurse - to the parish Medical Officer of Health)
- At the lab to the Chief Medical Technologist or designated individual

**3. Exposure Report Form should be completed.(Appendix 10)**

- This should be done while interviewing the affected person.
- The completed form must be submitted to the Parish Medical Officer of Health.

**4. Assess the risk of acquiring Hepatitis B, Hepatitis C and HIV.**
Most exposures do not result in HIV infection. The risk of infection varies with the type of exposure (See table below) and factors such as:

- The amount of blood involved in the exposure
- The HIV status and the amount of virus in the patient's blood at the time of exposure
- The severity of the injury e.g. scalpel or large bore needle injury increases risk

**5. Patients at moderate and high risk of HIV and Hepatitis B infection should be considered for post exposure prophylaxis (PEP)**.
Initiation of PEP should be decided on a case-by-case basis and after full discussion with each exposed person. It should begin ideally within hours of exposure but no later than 72 hours.
Individuals who have not previously been immunized against Hepatitis B should commence the vaccine immediately and be given Hepatitis B Immunoglobulin if available.
6. **Ensure that the health worker is fully counselled regarding the potential implications of the injury** e.g. abstinence, symptoms of acute illness, side effects of drugs, psychological reactions. Refer for further counselling as required.

7. **Take blood for baseline HIV and Hepatitis B & C (if applicable) status.**
Repeat blood test for HIV antibodies and Hepatitis surface antigen (if applicable) at 3 and 6 months.

**Regime should be continued for four weeks unless the source patient is known and subsequently tests HIV negative.**

**MINISTRY OF HEALTH JAMAICA GUIDELINES ON HIV**
**POST EXPOSURE PROPHYLAXIS (PEP) TO**
**BLOOD OR OTHER BODY FLUIDS**

The risk of HIV-1 transmission varies based on the type of exposure and factors related to the source patient.

Type of exposure with infectious fluid

| **High Risk** | **Low Risk** |
|---|---|
| Percutaneous | Mucous membrane |
| Hollow bore needle | Solid needle |
| Deep penetration | Superficial injury |
| Visible blood | |

Source patient factors

- Known HIV positive
- Terminal AIDS patient, known high viral load

Infectious fluids

- Blood, CSF
- Semen, vaginal secretions
- pleural, peritoneal, pericardial, amniotic fluid

Non-infectious fluids (without visible blood)

- Urine, faeces, saliva, tears, gastric fluid

**HIV-1 and HIV-2 are not the only infectious agents that can be transmitted by accidental exposure to blood or other body fluids. After single percutaneous injury, the risk of transmission is estimated between 2- 40% for Hepatitis B virus, 3-10% for Hepatitis C virus and 0.2-0.5% for HIV.**

**During counselling patients should be reassured that WITHOUT TREATMENT, transmission occurs approximately once in every 300 instances of needlestick injury from a known HIV-positive source. Where PEP is recommended, the use of condoms is recommended for any sexual exposures for the duration of therapy.**

**RECOMMENDED PROPHYLAXIS FOLLOWING OCCUPATIONAL EXPOSURE TO KNOWN HIV +**

| Type of Exposure | Risk | Source | Antiretroviral | Suggested Regimen |
|---|---|---|---|---|
| **Percutaneous** | **High risk** | **Known HIV positive** | **Recommended** | **TDF/3TC+ ATV/r** |
| | **Low risk** | **Unknown Serostatus** | **Should be offered** (Consider for unknown serostatus) | **TDF/3TC+ ATV/r** **( Duration 4 weeks)** |
| **Mucous Membranes, Non-intact skin** | **Large volume** | **Known HIV positive** | **Should be offered** (Consider for unknown serostatus) | **TDF/3TC+ ATV/r** |
| | **Small volume (few drops)** | **Unknown Serostatus** | **Should be offered** (not recommended for unknown serostatus) | **TDF/3TC + ATV/r** **(Duration 4 weeks)** |

*****Alternatives for ART choices

- TDF/3TC alternative AZT/3TC
- ATV/r alternative LPV/r

**NOTE**

- **Prophylaxis should be offered ideally within hours of exposure, however clinical benefit remains up to 72hours.**

- **Begin prophylaxis if source patient is HIV positive or of unknown HIV Status as recommended - perform HIV serology on Source patient and if result is negative stop prophylaxis. If HIV screening refused by source patient consider as unknown HIV status and treat as recommended.**
- **Recommended dose for *TDF/3TC (Tenofovir+Lamivudine)* is one tablet PO once per day for four weeks**
- ***ATV/r (Atazanavir/ritonavir)* 300/100mg PO once per day for four weeks**
- **Conduct baseline HIV serology on exposed worker and repeat after three months**
- **Consider HIV drug resistance patterns in the multi-drug experienced source patient when selecting ART.**

## Non-Occupational Exposure

HIV may be transmitted through mucous membrane exposure to infected semen or blood. The risk and treatment is parallel to occupational exposure through mucous membrane contact. Trauma and STDs will enhance HIV transmission. Post exposure prophylaxis (PEP) when offered **within 72 hours** from exposure has been shown to reduce the risk of sero-conversion. PEP should be offered to all clients with self-perceived high risk of HIV acquisition.

*Eligibility criteria for PEP*

- Direct contact of vagina, mouth or anus with semen or blood from an infected source.
- Tissue damage or presence of blood at site of assault with or without physical injury.
- PEP should be offered as soon as possible following exposure, preferably within 24 hours and not beyond 72 hours from exposure.

Assessment should include

- History – duration of time since exposure
- Nature of exposure
- Physical Examination
- Emotional status – trauma following assault/exposure
- Readiness to consider possible HIV infection immediately following sexual exposure
- Decision making ability
- Support systems – psychosocial
- Clinical
- Education

Consider the HIV status of the Source

- Recommendations for initiating HIV PEP should *not* be based on likelihood of HIV infection of the source
- If HIV status confirmed, this should guide PEP recommendations
- The perceived sero-prevalence of HIV in a particular geographic location where the assault occurred should not influence the decision to recommend HIV PEP.

*Initiation of therapy*

Discussion should include

- Potential benefits of prophylaxis
- Possibility of side effects
- Nature/duration of treatment and monitoring
- Importance of adherence and drug resistance
- Assessment of patient's willingness and readiness to begin PEP.

***If pregnant***

- *Full discussion of benefits and risks of PEP for both maternal and foetal health should occur*
- *Therapy with certain antiretroviral agents during the first trimester may be associated with foetal toxicity*
- *Advise not to breast feed until definitive diagnosis has been made*

**Recommended Regimen**

**TDF/3TC *(Tenofovir+Lamivudine)* PLUS ATV/r (*Atazanavir/ritonavir*) one tablet each PO once per day**
**(Alternatives for TDF/3TC is Zidovudine/Lamivudine, For ATV/r is ritonavir boosted Lopinavir)**
***Both regimens should be continued for 4 weeks***

The provider should

- Educate the patient about clinical signs and symptoms of primary HIV infection
- Instruct him or her to seek immediate care from a specialist should they occur
- Review information the next day whether or not PEP is initiated
- **Focus should be placed on risk reduction techniques.**

Ensure patients have

- Appropriate arrangements for follow up care
- Referral to or consultation with a specialist
- Monitoring ARV therapy
- Repeat diagnostic testing

In the case of an indeterminate test or symptoms suggestive of primary HIV infection refer the patient to the NHP or an experienced HIV healthcare provider. Unless the

patient is confirmed to be HIV negative, the clinician should continue PEP (with **triple therapy**) until a definitive diagnosis is established.

- Baseline HIV serologic testing to be obtained prior to PEP initiation
- PEP should be started immediately after serologic testing
- Confidential HIV testing should be provided by the treating physician
- Repeat testing should be performed at 2-4 weeks with a combined Ab/Ag Rapid HIV test.
- Rape crisis counsellors should be active participants in the discussion where indicated.
- Recommend additional testing for
    - Hepatitis B and C
    - STDs: Trichomonas Vaginalis, Chlamydia, Gonorrhoea, Syphilis

- Follow up visit within 24 hours to review
    - PEP regimen
    - Adherence
    - Follow up care
    - If PEP was not initiated – possible initiation of PEP

# OTHER CONSIDERATIONS

# OTHER CONSIDERATIONS

The purpose of this section is to discuss new technologies for HIV prevention. These approaches are **NOT CURRENTLY RECOMMENDED** for use in Jamaica. However, exposure to this information is to sensitize HIV providers in Jamaica for techniques which may be implemented in the future.

## Pre-Exposure Prophylaxis

**Definition**
Pre-Exposure Prophylaxis (PrEP) is the provision of ART to **HIV-negative** persons **before** exposure to HIV infection. The science behind PrEP is consistent in the preventative benefits of this approach in many populations, including MSM, women, transgender, serodiscordant, female sex workers and people who inject drugs.

**The Science**
To date, there have been 11 randomized-controlled trials of PrEP use in various populations. One meta-analysis performed on 10 of these trials has revealed a 51% reduction in transmission risk for PrEP versus placebo. It is important to understand that all participants in these trials where exposed to combination prevention (see below). Therefore, in order to achieve these same benefits in a real world setting, **provision of only the PrEP drugs will not be sufficient.**

One of the key features identified in these studies was the need for high levels of **adherence** in order to achieve the benefits of reduced acquisition risk. The threshold level identified was 80% adherence. At levels below 40%, no benefit of PrEP in reducing HIV transmission has been identified.

The specific ART that have been studied thus far include *tenofovir* alone or in combination with *emtricitabine*. There has been no significant difference identified between these two combinations in the risk of transmission.

Protection against HIV transmission requires, **PRIOR TO EXPOSURE**, at least *7 doses* of ART for vaginal or *4 doses* for anal exposures.

**Implementation Considerations**

There are several considerations to make when implementing PrEP.

1. Health provider expansion
   An increase in the provider network who are trained and knowledgeable of the issues surrounding HIV transmission risk behaviours, provision of ART and monitoring of potential side effects

2. Laboratory Strengthening
   Regular HIV screening for persons accessing PrEP, before, during and after use, is required for appropriate monitoring. Monitoring of renal function is also recommended before and during PrEP use. Finally, screening for concurrent STIs is also a component of PrEP programmes.

3. Combination prevention programmes
   During the PrEP trials, provision of ART was only one component of a combination prevention programme, which included condom and lubricant provision, needle exchange and methadone maintenance therapy, education and empowerment techniques.

**The Jamaican Context**

In addition to the considerations mentioned above, there are additional concerns:

- Financial: expanded use of testing and ART supplies should be accounted for.
- Monitoring and evaluation of PrEP use to ensure appropriate reductions in HIV transmission are being achieved.

**Recommended Reading**

Wilton J, Senn H, Sharma M, Tan DH. Pre-exposure prophylaxis for sexually-acquired HIV risk management: a review. HIV/AIDS (Auckland, NZ). 2015;7:125–36.

Koechlin F. Values and preferences on the use of pre-exposure prophylaxis (PrEP) – a systematic review of the literature 2015. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/189977/1/WHO_HIV_2015.36_eng.pdf?ua=1 )

Haberer JE, Bangsberg DR, Baeten JM, Curran K, Koechlin F, Amico KR et al. Defining success with HIV pre-exposure prophylaxis: a prevention-effective adherence paradigm. AIDS. 2015;29:1277–85.

## Voluntary Medical Male Circumcision

**Definition**
Voluntary Medical Male Circumcision (VMMC) is the voluntary removal of the prepuce (foreskin) of the penis of adolescent or adult males. This portion of the penis is known to be at increased risk of HIV acquisition. This technique is proposed component HIV prevention programmes to reduce the risk of heterosexual female-to-male transmission of HIV.

**The Science**
Randomized-controlled trials have confirmed that VMMC has approximately a *60% reduction* in transmission risk of heterosexual female-to-male transmission of HIV.

**Implementation Considerations**
The benefits of VMMC have been hinged on increased uptake by the community and delivery of the procedures by trained providers to reduce complications.

1. Increased uptake of the procedure.
   Changes in cultural norms to increase acceptability of VMMC is a critical component. One approach that has been explored is to build a demand within the adolescent male population through education and sensitization programmes.

2. Healthcare provider training.
   Expanding the cadre of providers who are trained to conduct the procedure will be required for successful implementation of VMMC.

3. Service delivery
   Improvements in male-friendly delivery services to encourage the enrolment in VMMC programmes.

**The Jamaican Context**
Previous research on the acceptability of VMMC in Jamaica has shown low levels, 35% uptake for circumcision of themselves. However, between 50-75% of study participants indicated they would have their sons circumcised (*Figueroa et al*).

**Recommended Reading**
WHO/UNAIDS. WHO/UNAIDS technical consultation on male circumcision and HIV prevention: research implications for policy and programming – conclusions and recommendations; Montreux, 6–8 March 2007. Geneva: World Health Organization (WHO), Joint United Nations Programme on HIV/AIDS (UNAIDS); 2007.

Haacker M, Fraser-Hurt N, Gorgens M. Effectiveness of and financial returns to voluntary medical male circumcision for HIV prevention in South Africa: an incremental cost-effectiveness analysis. PLoS Med. 2016;13(5):e1002012

Figueroa JP, Cooper CJ. Attitudes towards male circumcision among attendees at a sexually transmitted infection clinic in Kingston, Jamaica. West Indian Med J. 2010 Jul;59(4):351-5.

# APPENDICES

## Appendix 1: CDC classification system for HIV-infected adolescents and adults

**Clinical categories**
The three clinical categories are:

**Category A**

Category A consists of one or more of the conditions listed below in an adolescent or adult (13 years or older) with documented HIV infection. Conditions listed in Categories B and C must not have occurred.
**asymptomatic HIV infection
**persistent generalised lymphadenopathy (PGL)
**acute (primary) HIV infection with accompanying illness (sometimes known as seroconversion illness) or history of acute HIV infection

**Category B**

Category B consist of symptomatic conditions in an HIV-infected adolescent or adult that are not included among conditions listed in Category C and that meet one of the following criteria:
**the conditions are attributed to HIV infection or are indicative of a defect in cell-mediated immunity, or
**the conditions are considered by physicians to have a clinical course or to require management that is complicated by HIV infection

This category includes all such symptomatic conditions, with the exception of those placed in Category C. Examples of conditions in this category include, but are not limited to:
**bacillary angiomatosis
**candidiasis (thrush) in the mouth and/or upper throat
**candidiasis of the vagina and/or vulva which is persistent, frequent, or responds poorly to treatment
**cervical abnormalities of moderate or severe extent or cervical cancer
**constitutional symptoms such as fever (38.5 C) or diarrhoea lasting longer than one month
**herpes zoster (shingles) involving at least two distinct episodes or more than one dermatome (skin area)
**idiopathic thrombocytopenia purpura
**listeriosis

**oral hairy leukoplakia
**pelvic inflammatory disease, particularly if complicated by tubo-ovarian abscess
**peripheral neuropathy

For classification purposes, Category B conditions take precedence over those in Category A. For example, someone previously treated for oral or persistent vaginal candidiasis (and who has not developed a Category C disease) but who is now asymptomatic should be classified in clinical Category B.

**Category C**

Category C includes the following conditions listed in the AIDS surveillance case definition. For classification purposes, once a Category C condition has occurred, the person will remain in Category C.
**Candida in the oesophagus, trachea, bronchi or lungs
**invasive cervical cancer
**coccidiodomycosis
**Cryptococcus outside the lungs
**cryptosporidiosis with diarrhoea lasting for more than one month
**CMV disease outside the liver, spleen or lymph nodes
**CMV retinitis
**herpes simplex virus causing prolonged skin problems or involving the lungs or oesophagus
**HIV-related encephalopathy
**chronic intestinal isosporiasis lasting longer than one month
**Kaposi's sarcoma
**Burkitt's, immunoblastic or primary (i.e. not involving other parts of the body) brain lymphoma
**Widespread Mycobacterium avium intracellulare (MAI), M kansasii or other species
**Pneumocystis carinii pneumonia (PCP)
**recurrent bacterial pneumonia
**progressive multifocal leukoencephalopathy (PML)
**recurrent Salmonella septicaemia
**toxoplasmosis of the brain
**HIV wasting syndrome

**CD4 count categories**

The three CD4 count categories are:

**Category 1:** MORE than500 cells/mm3

**Category 2:** 200 - 499 cells/mm3

**Category 3:** LESS than 200 cells/mm3

Categorisation should be based on the **lowest** accurate CD4 count, not necessarily the most recent one.

## Appendix 2: Revised WHO Clinical Staging Of HIV/AIDS For Adults And Adolescents

**Primary HIV infection**
Asymptomatic
Acute retroviral syndrome

**Clinical stage 1**
Asymptomatic
Persistent generalized lymphadenopathy (PGL)

**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**
**Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations**
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)
Oral candidiasis
Oral hairy leukoplakia
Pulmonary tuberculosis (TB) diagnosed in last two years
Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)
Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis
**Conditions where confirmatory diagnostic testing is necessary**
Unexplained anaemia (< 8 g/dl), and or neutropenia (<500/mm3) and or thrombocytopenia (<50 000/ mm3) for more than one month

**Clinical stage 4**

**Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations**

HIV wasting syndrome
Pneumocystis pneumonia
Recurrent severe or radiological bacterial pneumonia
Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration)
Oesophageal candidiasis
Extrapulmonary TB
Kaposi's sarcoma
Central nervous system (CNS) toxoplasmosis
HIV encephalopathy

**Conditions where confirmatory diagnostic testing is necessary:**

Extrapulmonary cryptococcosis including meningitis
Disseminated non-tuberculous mycobacteria infection
Progressive multifocal leukoencephalopathy (PML)
Candida of trachea, bronchi or lungs
Cryptosporidiosis
Isosporiasis
Visceral herpes simplex infection
Cytomegalovirus (CMV) infection (retinitis or of an organ other than liver, spleen or lymph nodes)
Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis, penicilliosis)
Recurrent non-typhoidal salmonella septicaemia
Lymphoma (cerebral or B cell non-Hodgkin)
Invasive cervical carcinoma
Visceral leishmaniasis

## Appendix 3: Renal and Hepatic Adjusted Dosing of ART

| ART | Renal Dysfunction (CrCl) | Haemodialysis | Hepatic Dysfunction |
|---|---|---|---|
| **Zidovudine** | **CrCl >15: 300mg od** | **300mg od** | **Consider decreased dose** |
| **Lamivudine** | **CrCl 30-49: 150mg od15-29: 100mg od 15-29: 199mg od, 5-14: 50mg od** | **25-50mg od** | **Usual dose** |
| **Tenofovir** | **CrCl 30-49: 300mg q48hrs 10-29: 300mg twice weekly** | **Avoid** | **Usual Dose** |
| **Abacavir** | **Usual dose** | **Usual dose** | **Usual dose for *CP class A, contraindicated for classes B & C** |
| **Nevirapine** | Usual dose | **Usual dose** | **Avoid with hepatotoxicity** |
| **EfavirenzNevirapine** | Usual doseUsual dose | **Usual doseUsual dose** | **Use with cautionAvoid with hepatotoxicity** |
| **Efavirenz** | **Usual dose** | **Usual dose** | **Use with caution** |
| **Lopinavir** | **Usual dose** | **Usual dose** | **Use with caution** |
| **AtazanavirLopinavir** | **Usual doseUsual dose** | **Usual doseUsual dose** | **Use with cautionUse with caution** |
| **Atazanavir** | **Usual dose** | **Usual dose** | **Use with caution** |

***CP class – Child Pugh Class**

## Appendix 4: Desensitization with Trimethoprim/Sulfamethoxazole (TMP/SMX)

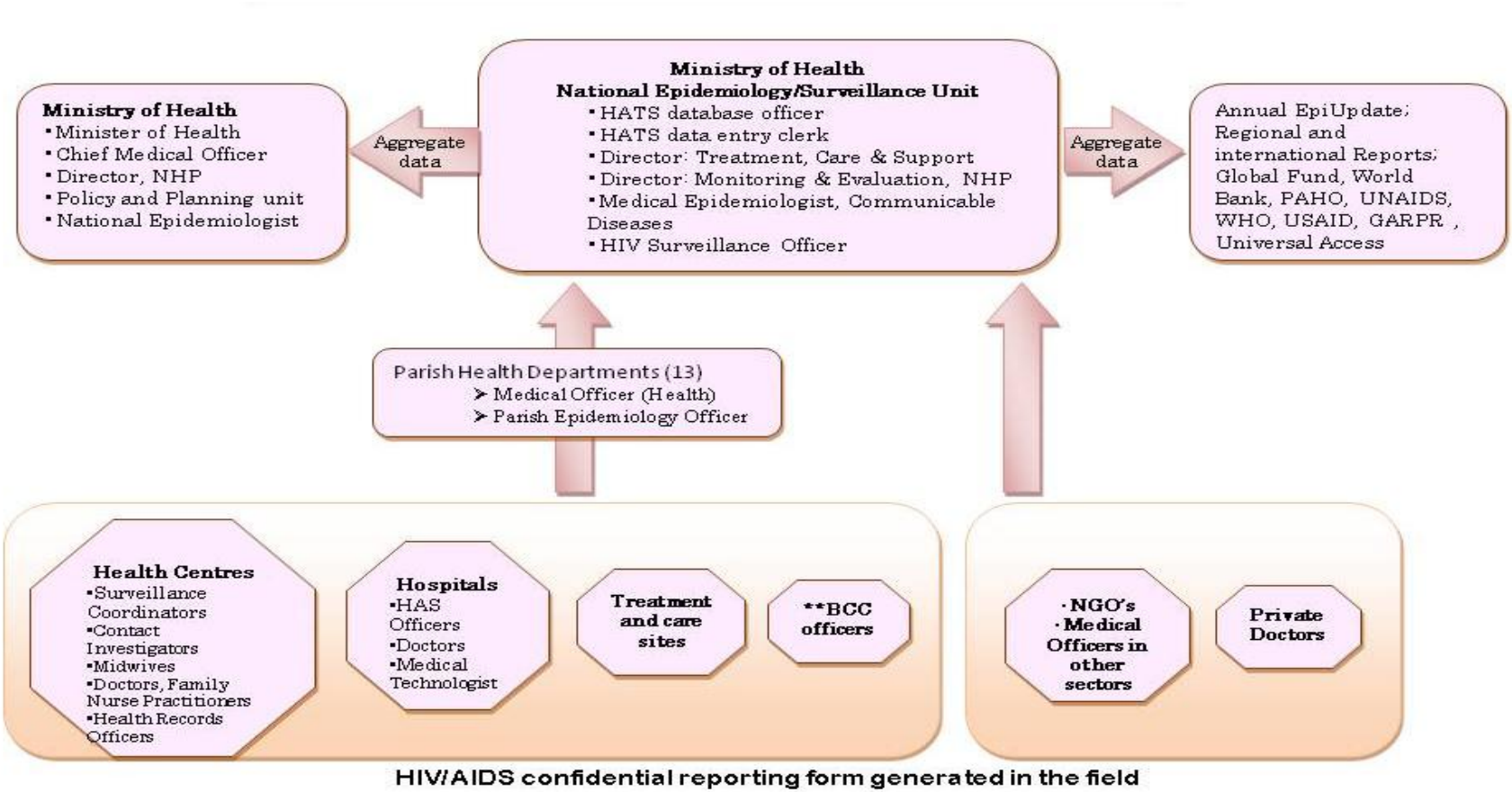
| DAY | DILUTION |
|---|---|
| 1 | 1:1,000,000 |
| 2 | 1:100,000 |
| 3 | 1:10,000 |
| 4 | 1:1,000 |
| 5 | 1:100 |
| 6 | 1:10 |
| 7 | 1:1 |
| 8 | Standard Suspension – 1mL 40mg SMX – 8mg TMP |
| ≥9 | 1DS tab/day |

**** Patients who experience mild reactions during the desensitization process should be maintained at that drug concentration and be treated symptomatically with anti-histamines until tolerance has been achieved.**

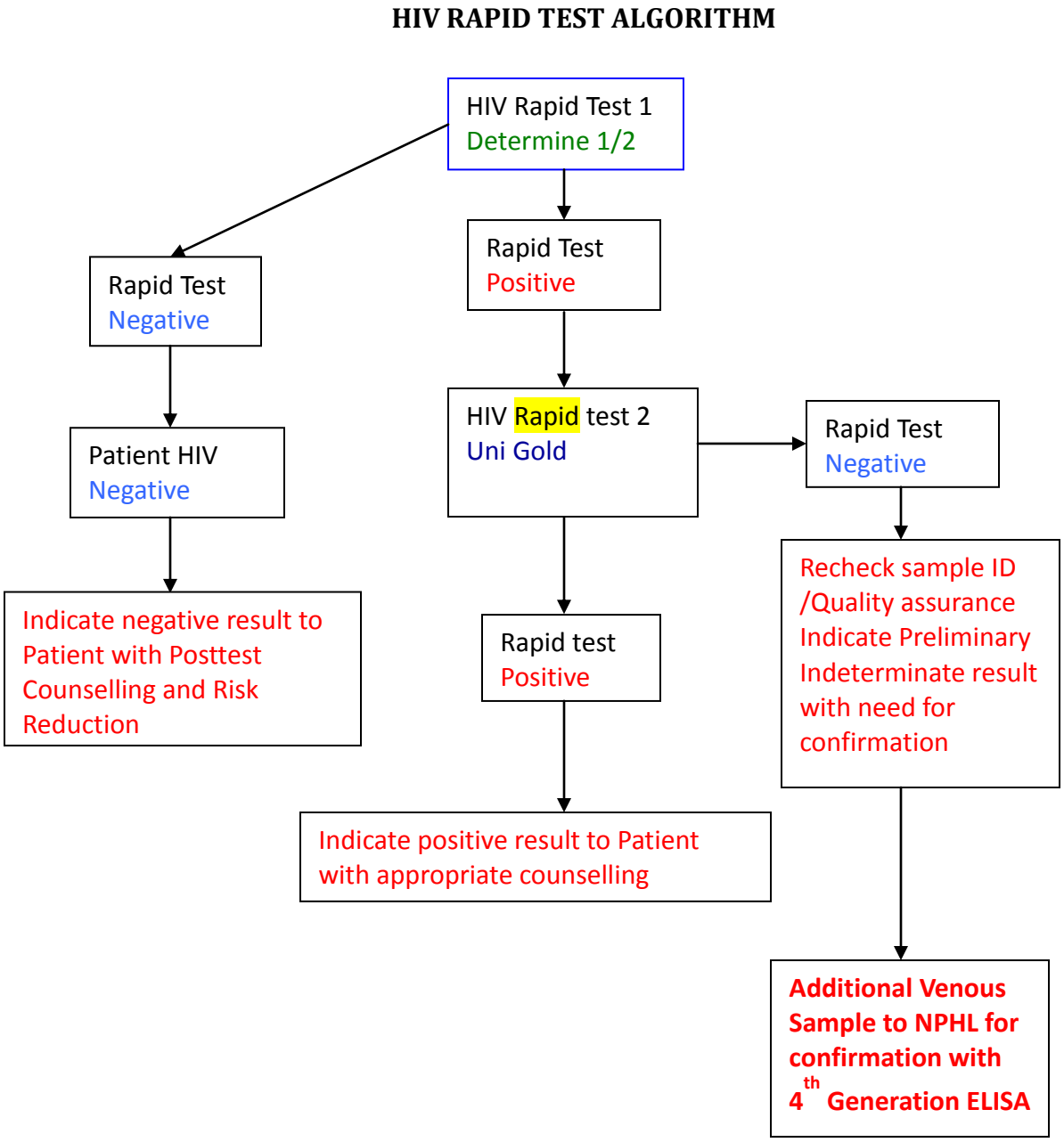
**Appendix 5: General Principles of Positive Health, Dignity and Prevention**

| Category | Specifics | Plan |
|---|---|---|
| General Risk Assessment | Knowledge on HIV transmission and prevention methods | - Opportunity to educate and correct misinformation<br>- Prioritize patients risk behaviours |
| Sexual Practices | -Build rapport<br>-Detailed sexual history identifying approach to sex, condom use and negotiation, factors surrounding risky sexual practices<br>- Screen for pregnancy | - Assess level of transmission risk<br>- Assess ability for consistent condom use, correct misinformation<br>- Supply with condoms and lubricants |
| Partner Notification | -Assess patient's thoughts and past experiences<br>- Assess fear of violence or discrimination. | - Initiate contact tracing<br>- Provide support and counselling for disclosure |
| STI Screening | -Screen at presentation and after sexual exposure to new partner (GUD is of particular concern for increased risk of transmission) | - Provide syndromic therapy |
| Substance Abuse (including alcohol) | -Assess use, experiences, desires of discontinuation<br>-Assess impressions of impact of use on sexual behaviour | - Assess readiness for quitting<br>- Provide access to intervention teams<br>- Provide specific risk reduction methods e.g. not sharing needles or straws (for cocaine) |
| Mental Health Assessment | -Assess past history of mental health illness including any pharmacotherapy<br>- Perform depression screen | -Provide access to mental health services |
| Antiretroviral Therapy (ART) | -Assess knowledge on relationship between viral load and transmission risk | - Provide access to ART and emphasize adherence<br>*Beware of increases in risky behaviour with new found "protection" |

## Appendix 6: Reporting algorithm



## Appendix 7: HIV algorithm for field rapid testing in Jamaica[2]



## Appendix8 – HIV/ AIDS Confidential Reporting Form – Page 1

**HIV/AIDS CONFIDENTIAL REPORTING FORM**
Send all reports to S.M.O, Surveillance Unit
2 King Street, Kingston
Ministry of Health,
Telephone: 967-1100/1/3/5, Fax # 967-1280
AIDS/STD Helpline Tel: 967-3830

**FOR THE EPI – UNIT ONLY: ACCESS #** _____

**TRN:** __ __ __-- __ __ __ _ __ __ _ Clinic Site _____ MEDICAL RECORD _____

TRANSFER: Yes ( ) No ( )
Trace ( ), Do not contact trace ( ), Contact partners only ( ), Update ( ), Copy sent to CI ( )

1. NAME: _____ (Last) _____ (First) _____ (Middle) _____ (Pet name) Sex: M( ), F( )
2. ADDRESS: _____ PARISH: _____ Tel: _____
2b. CHECK HERE IF HOMELESS ( )
3. D.O.B.: __ __/__ __/__ __ __ __ (dd mm yy) AGE: _____ yrs. (weeks if infant) OCCUPATION: _____ MARITAL STATUS: ____ employed ☐ unemployed ☐
4. HIGHEST LEVEL OF EDUCATION: _____
5. Number of children under 15 years of age: _____ 6. Deported? Y ( ) N ( ) _____ (Country)
7. NEXT OF KIN: _____ (Name) _____ (Relation) _____ (Address)
7b. MOTHER'S NAME _____
8. **Sexual contacts**

| (Surname) | First Name | Sex (m/f) | Relation | Address | Parish |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

9. SEXUAL PRACTICE of Patient: Heterosexual ( ) Homosexual ( ) Bisexual ( ) Not known ( )

10. **Risk History** Date: ____/____/____

| | In the past year | Ever |
|---|---|---|
| Blood transfusion | Y( ) N( ) | Y( ) N( ) |
| Crack/Cocaine use | Y( ) N( ) | Y( ) N( ) |
| Intravenous drug use | Y( ) N( ) | Y( ) N( ) |
| Current STI | Y( ) N( ) | Y( ) N( ) |
| History of STI | Y( ) N( ) | Y( ) N( ) |
| Genital Ulcers/sores | Y( ) N( ) | Y( ) N( ) |
| Sex with CSW | Y( ) N( ) | Y( ) N( ) |
| CSW | Y( ) N( ) | Y( ) N( ) |
| Multiple Partners | Y( ) N( ) | Y( ) N( ) |
| Ever in Prison | Y( ) N( ) | Y( ) N( ) |
| Victim of sexual assault | Y( ) N( ) | Y( ) N( ) |
| Sex with known HIV +ve person | Y( ) N( ) | Y( ) N( ) |
| Transactional sex | Y( ) N( ) | Y( ) N( ) |

11. **Clinical Status** Date: ____/____/____

| | | | |
|---|---|---|---|
| Weight loss (>10%) | Y( ) N( ) | Gen. Dermatitis | Y( ) N( ) |
| Cough (>4 weeks) | Y( ) N( ) | Gen. Lymphadenopathy | Y( ) N( ) |
| Fever (> 1 month) | Y( ) N( ) | Diarrhoea (> 1 month) | Y( ) N( ) |
| PCP | Y( ) N( ) | Kaposi's Sarcoma | Y( ) N( ) |
| Recurrent Pneumonia | Y( ) N( ) | Shingles | Y( ) N( ) |
| Tuberculosis: If Yes: Pulmonary / Extra Pulmonary / Disseminated | Y( ) N( ) | Candidiasis - If Yes: Oral / Oesophageal / Vaginal | Y( ) N( ) |
| CNS involvement | Y( ) N( ) | Invasive cervical cancer | Y( ) N( ) |
| Severe Bacterial Infection (Specify) _____ | Y( ) N( ) | Chronic Herpes simplex (>1 month) | Y( ) N( ) |
| **If pregnant, please complete box on reverse of this form** | | Other: | |

12. TRANSMISSION CATEGORY: Sexual ( ) Vertical ( ) IV Drug Use ( ) Haemophiliac ( ) Blood Transfusion ( )
13. CD4 COUNT_____CD4/CD8 ratio_____Date of CD4 count____/____/____Viral Load_____Date of Viral load____/____/____
14. IS PT ON ANTIRETROVIRAL TREATMENT (ARV)? Y( ) N( ) START DATE OF ARV: ____/____/____
14b. ARV Line: 1st line ( ) 2nd line ( ) Salvage therapy ( ) Unknown ( )

**Page 1 of 2** **P.T.O** .....

## Appendix 8 – HIV/ AIDS Confidential Reporting Form – Page 2

**Page 2 HIV/AIDS CONFIDENTIAL REPORTING FORM**

15. CURRENT STATUS OF PT: HIV (no symptoms) ( ) HIV (minimal symptoms) ( ) Advanced HIV (CD4 count 201 – 350) ( ) AIDS ( ) AIDS-related Death ( )

16. DATE OF ONSET OF SYMPTOMS: _____/_____/_____

17. **Date diagnosed as Advanced HIV/AIDS** ____/___/___ **Date of Death** ____/____/____ **Cause of Death** _____

18. **Rapid Test**: Date: ___/___/___ Result: Pos ☐ Neg ☐ Test Type: _____

**Where tested?** Antenatal Clinic ☐ Private Antenatal ☐ STI Clinic ☐ Blood Bank ☐ Hospital ☐ Private doctor ☐ Other ☐ Specify _____

Confirmatory HIV Test DATE: ___/___/___ Result: Pos ☐ Neg ☐ Test Type: _____ Lab: _____

19. Blood transfusion: _____/_____/_____ Hospital transfused: _____

20. **FOR PREGNANT WOMEN ONLY, PLEASE ENTER THE FOLLOWING INFORMATION:**

a. Estimated gestational Age: _____ weeks Estimated date of delivery: ____/____/____

b. Clinic site: _____ Parish_____ Clinic MRN #:_____

c. Patient referred to: VJH clinic ( ) UHWI ( ) Spanish Town ( ) CRH ( ) Mandeville ( ) St Ann's Bay ( )

Other: _____ Date of referral appointment: ____/____/____ Pt. Not referred ( ) Pt. Refused referral: ( )

d. Post test counselling done by: _____ (Enter name) Date of Post test counselling: ___/___/___

**Definitions:**

- **Transfer** -- Indicate if the patient transferred in from another treatment site or private physician.
- **Date (questions 10 & 11)** ---Date on which risk history of clinical status is being updated
- **Multiple partners** --- Persons who report having sex with more than one person within a year.
- **CSW** --- Commercial sex worker; exchange of sex for cash as a main source of income
- **Sexual Assault** --- Anal or vaginal intercourse without explicit consent; incident involved intimidation or threat or fear of violence
- **Transactional Sex** --- exchange of sex for food, goods or cash (but not as main source of income)
- **PCP** --- Pneumocystis Jiroveci Pneumonia
- **CNS involvement** --- Unexplained recent onset of seizures, dementia, toxoplasmosis, CMV, Cryptococcus, encephalopathy
- **Recurrent pneumonia** --- Two or more episodes within a 1-year period
- **Gen. lymphadenopathy** --- Two or more sites with enlarged lymph nodes
- **ARV Line**--Indicate HAART line patient is currently on/or last took - 1st, 2nd, or Salvage Therapy
- **Education**--No formal schooling, Basic, Primary/All Age, Secondary/High School, Tertiary, Skills training, Other (specify)
- **Marital Status** –legally married, common law, visiting union, single

**PLEASE NOTE:**

- Enter all dates in the format dd/mm/yyyy.
- Reporting physicians are advised to initiate interview of index case to identify sexual contacts and encourage partner notification.
- If all sexual partners have been investigated, please tick "Do not contact trace" on front of form.
- **DO NOT SEND PATIENTS to the Ministry of Health, 2-4 King Street with confidential reporting forms.**
- If you have an "update" on the clinical condition or death of a patient please complete and send new HIV Confidential Reporting Form.
- Send report under confidential cover to the MO(H) at the Parish Health Department or S.M.O. at top of page 1 of this form.

PATIENT'S DOCTOR: _____ Address/hospital: _____ Tel: ____-_____

SOURCE OF INFORMATION: _____ REPORTED BY: _____ Date reported: ____/____/____

**Confidential** patient counselling, information for providers, and automated information are available from AIDS/STD Helpline
Tel: 967-3830, 967-3764, 1-888-991-4444 Hours: 10:00 a.m. – 10:00 p.m. Monday through Friday
**Web Page: www.nhpjamaica.org**

**Revised: June 2012**

**Appendix 9 – Post Exposure Prophylaxis Reporting form**

HIV/STI/TB Programme - Ministry Of Health

Parish:_____

# Needle Stick, Sharp Object Injury and Fluid Exposure Report

1. **Name:** _____ **DOB:** _____ **Sex:** **M** **F**
   **Occupation:** _____
2. **Date/Time of Exposure/Injury:** _____
5. **Reported by:** _____ **Date:** _____
7. **Institution where exposure/injury occurred:** _____
8. **Where did the exposure/injury occur?**

| | | | | | |
|---|---|---|---|---|---|
| A | Ward *(specify)* _____ | ☐ | G | Operating Theatre | ☐ |
| B | Dressing Room | ☐ | H | Dialysis Unit | ☐ |
| C | Phlebotomy room | ☐ | I | Labour & Delivery Room | ☐ |
| D | Outpatient clinic | ☐ | J | Service/ Utility Area (*laundry, garage, disposal, etc*.) | ☐ |
| E | ICU | ☐ | K | Other *(specify):* _____ | |
| F | A&E / Casualty | ☐ | | | |

9. **Name of the source patient:** _____ ☐ Source Unknown
10. **Docket No.** _____ ☐ Not Applicable
11. **Source patient HIV Status:** ☐ Positive ☐ Negative ☐ Unknown

☐ Source Patient tests positive for other blood borne pathogen *(specify)* _____

12. **Type of exposure:** ☐ Sharp item ☐ Body Fluid exposure *(specify type and volume)*: _____
13. **In the case of body fluid exposure, was the skin of the exposed person intact? *(if not body fluid exposure skip this question)***

☐ YES ☐ NO (*explain )* _____ _____

14. **Specify Sharp Item** *(if not sharp item, skip to Question 17)*:

☐ Needle, specify gauge _____

☐ Blade

☐ Branula, specify gauge _____

☐ Glass, specify *(broken test tube, etc.)* _____

☐ Other Needle *(suture needle, etc.)* specify type & size

☐ Other *(specify)* _____

15. **Was the injury:** ☐ Superficial (little or no bleeding) ☐ Moderate (skin punctured, some bleeding)

☐ Severe *(deep stick/cut, or profuse bleeding)*

**16. If the injury was to the hands, did the sharp item penetrate:** *(check one)*

☐ Single pair gloves ☐ No gloves ☐ Other *(specify)*_____

**17. Did the injury/exposure occur:**

☐ Restraining Patient

☐ Disassembling device or equipment

☐ In preparation for reuse of reusable instrument *(sorting, disinfecting, sterilizing, etc.)*

☐ While recapping used needle

☐ Withdrawing a needle from rubber or other resistant material *(rubber stopper, I.V. port, etc.)*

☐ Device left on floor, table, bed or other inappropriate place

☐ Other after use, before disposal *(in transit to trash, cleaning, sorting, etc.)*

☐ From item left near or on disposal container

☐ While putting the item in a disposal container

☐ After disposal, stuck by item protruding from opening of disposal container

☐ Item placed on side of disposal container

☐ After disposal, item protruded from trash bag or inappropriate waste container

☐ Other, describe _____

**18. Describe the circumstances leading to this injury:** *(please note if a device malfunction was involved)*

_____

_____

_____

**19. State the location of the exposure/injury:** _____

**20. Hepatitis B immunisation?** ☐ None ☐ YES Dates: _____

**21. Immunisation Card seen?** ☐ YES ☐ NO

**22. Has the injured person had any previous needle stick injuries?** ☐ YES ☐ NO

**23. If yes, were the previous incidents reported?** ☐ NO ☐ YES Date(s): _____

**24. Risk Category:** ☐ Low ☐ Moderate ☐ High

**25. Was area bled/flushed/washed?** ☐ YES ☐ NO

**26. Was disinfectant used?**** ☐ YES ☐ NO

**NOTE: The use of bleach, alcohol, Savlon or other disinfectants is not recommended.

**27. Action taken by head of department:**

a. Counselling? ☐ YES ☐ NO

b. Blood taken for HIV testing? ☐ YES ☐ NO *(if "NO", explain)* _____

c. Blood taken for Hepatitis B Antigen? ☐ YES ☐ NO *(if "NO", explain)* _____

d. PEP Medication Given? *(see last page of this form for PEP Guidelines)*

☐ YES TYPE _____ Date/Time Started _____

☐ NO *(if "NO", explain)* _____

☐ Low Risk ☐ Not Available ☐ Exposed Person Refusal* ☐ Other *(specify)*_____

*In the case of refusal the exposed person must sign the attached waiver form

**To be sent to Medical Officer of Health for surveillance**

**Form completed by:**

Name: _____

Designation: _____

Signature: _____

## Post Exposure Prophylaxis (PEP) Dosages:

All of the following are to be given within 1-2 hours or at most 72 hours after exposure* and continued for four weeks:

Low Risk:

a. Zidovudine (AZT) 300 mg bid AND Lamivudine (3TC) 150 mg po bid

**OR**

b. Tenofovir/Lamivudine (TDF/3TC)1 tab od

High Risk: Either of the above PLUS

a. Lopinavir/Ritonavir (LPV/r) 2 tabs bid

**OR**

b. Atazanavir 300mg od with Ritonavir 100mg od (ATV/r).

*Studies in animals (no human studies done) suggest that treatment is not as effective when started more than 24-36 hours after exposure. PEP has no value after 72 hours in humans.

---

**PEP Refusal form:**

**I, _____, hereby waive my right to take the PE Prophylaxis to prevent possible infection of the HIV virus. I understand that by refusing to take the medication I am putting myself at greater risk for infection.**

Signed:

_____

Date:

_____

Witness signature:

_____

Witness (print name neatly):

_____

**Appendix 10 – Specific Interactions with Hormone Replacement Therapy, ART and other commonly Used Drugs**

| Drug | Interaction |
|---|---|
| **Non-Nucleoside Reverse Transcriptase Inhibitors** | |
| Efavirenz | Ethinyl estradiol levels increase 37% |
| Nevirapine | Ethinyl estradiol levels decrease 20% |
| **Protease Inhibitors** | |
| Atazanavir | Ethinyl estradiol AUC increase 48%<br>Norethindrone AUC increases 110% |
| Ritonavir | Ethinyl estradiol levels decrease 40% |
| Lopinavir/ritonavir | Ethinyl estradiol levels decrease 42% |

| **Estradiol and Ethinyl Estradiol** | |
|---|---|
| **Increased by** | **Decreased by** |
| Cimetidine | Dexamethasone |
| Clarithromycin | Phenobarbitol |
| Diltiazem | Phenylbutazone |
| Erythromycin | Phenytoin |
| Fluconazole | Progesterone |
| Fluoxetine | Rifampin |
| Fluvoxamine | |
| Grapefruit | |
| Isoniazid | |
| Itraconazole | |
| Ketoconazole | |
| Nefazodone | |
| Paroxetine | |
| Sertraline | |
| Verapamil | |

**Appendix 11 – HIV Drug Resistance Request Form**

## CRITERIA AND PROCEDURE FOR HIV GENOTYPE TESTING IN JAMAICA

### *Criteria for Testing*

The determination of treatment failure is to follow the national guidelines concerning **CONFIRMED VIROLOGIC FAILURE** – 2 or more Viral load > 1,000 copies/ml after at least 6 months of ART with **ADEQUATE ADHERENCE**.

1. Patients failing Second line therapy
2. Patients failing to suppress on first line therapy after 6 months

Additional risk factors for Transmitted Drug Resistance

- International travel/incarceration
- IV Drug use

****Patients must be on continuous therapy with adequate adherence for at least 6 weeks preceding the genotype test or within 2 weeks of switching.**

### *Procedure for Testing*

A. Email the Director, Treatment, Care & Support (TCS) (tomlinsonj@moh.gov.jm) to request genotype testing including the completed application form.
B. Request from will be sent with sample to the NPHL by health care provider
C. The Director, TCS will liaise with NHP HIV Drug Resistance (HIVDR) Board
   - If accepted, the Director, TCS will communicate with NPHL to perform the test and release result for the individual patient to the HIVDR Board
D. Results will be discussed at the NHP HIVDR Board meeting and an appropriate regime constructed. The HIVDR test results and the recommendations of the HIVDR Board will be provided to the healthcare provider.
E. Additional drugs (Raltegravir, Etravirine, Darunavir, +/- Maraviroc) will be made available for that particular patient at the pharmacy of their choice.

## SAMPLE COLLECTION FOR HIV GENOTYPE TESTING IN JAMAICA

***HIVDR samples are to be sent to the NHPL within 24 hours of collection***

- ✓ One (2) purple top tubes, 5 milliliters are to be collected
- ✓ Spin samples and take off plasma within 6 hours of collection (At non-NPHL lab sites)
- ✓ Store at 2 – 8 $^{0}$C and transport to the NPHL within 24 hours

## A. HIV Treatment Site Information

HIV Treatment
Site:……..……..……..……..
Referring Medical
Practitioner:……..……..……..…….
Contact Number…… Contact
Email……..……..……

## B. Patient Information

Medical Record
Number:……
Date of Birth: ……..…../……...../…….…… (dd/mm/yy)
Sex (circle one): Male / Female
Weight: ……. kg

| HIV Transmission Risk Factor | Check (x) all that apply |
|---|---|
| Sex Worker | |
| Men who have Sex with Men | |
| Homeless | |
| Crack/Cocaine User/Drug User | |
| Use of ARVs in multiple pregnancies | |
| Multiple partners | |
| Other (specify) | |

HIVDR sample sent to NPHL: □ Yes □ No
Date Sample Collected: ……(dd/mm/yy)

| Reason for Resistance Test Request | Check (x) all that apply |
|---|---|
| Established Virologic Failure | |

| | |
|---|---|
| Failure to suppress 6 months after first ART initiation | |
| ART Switch | |
| Blip | |
| Restart | |
| Other | |

**virologic failure – A confirmed viral load (≥2 consecutive samples) of greater than 400 copies/ml*
**Blip – temporary increases in viral load levels to less than 1,000 copies/ml*
**Restart – because of non-adherence*

*Complete below (1 – 4), for established virologic failure and failure to suppress greater than or equal to 6 months of therapy.*

1. Current ART Regime…….
   .

   Start Date……../……../……. (dd/mm/yy)

2. Viral Load & date of diagnosis of failure: …..…copies/ml;……./……../……. (dd/mm/yy)

3. Viral load & date of confirmed failure……copies/ml; ……./……../……..…. (dd/mm/yy)

4. Most recent CD4 Count & date:…….cells/$mm^3$ ; ……./……../……..…. (dd/mm/yy)

Medication possession ratio (MPR) of current regime:

| MONTH | Date Collected (dd/mm/yy) | Pharmacy | MPR | MPR Formula |
|---|---|---|---|---|
| Month 1 | | | | |
| Month 2 | | | | Month 2 – Month 1 /30 |
| Month 3 | | | | Month 3 – Month 1 /60 |
| Month 4 | | | | Month 4 – Month 1 /90 |
| Month 5 | | | | Month 5 – Month 1 /120 |
| Month 6 | | | | Month 6 – Month 1 /150 |

*Medication Possession Ratio (MPR) is an object pharmacy measure of adherence to treatment and is a simple ratio between the number of days the patient was in possession of ART, based on their pharmacy refill dates, compared to the number of days they should have been in possession.*

*Interpretation is the same as self-reported adherence, ie adequate adherence is greater than 95%.*

ART History (include periods of complete non-adherence by indicating a new Start Date)

| Test Results | ART Regime | Start Date (dd/mm/yy) | Stop Date (dd/mm/yy) | Reason for switch (provide test results) |
|---|---|---|---|---|
| | | | | |
| | | | | |
| | | | | |
| | | | | |

Previously described issues with ART Adherence:

| Reason for non-adherence | Yes/No | Specific problem encountered |
|---|---|---|
| Pill Burden | | |
| Dosing frequency | | |
| Side Effects | | |
| Other: | | |

Other Concurrent Medications:

……
……
……
……
……
……
……
……

Previous Intolerance/Allergy/Side effect/Adverse reaction to ART:

| ART | Adverse Reaction |
|---|---|
| | |
| | |
| | |
| | |
| | |
| | |

Relevant Past Medical History

| Medical History | Yes/No | Remarks |
|---|---|---|
| Chronic Hepatitis B | | |
| Hepatitis C | | |
| Ischaemic Heart Disease | | |
| Hyperlipidemia | | |
| Diabetes Mellitus | | |
| Peripheral Neuropathy | | |
| Chronic Kidney Disease | | |
| Myopathy | | |
| Pancreatitis | | |
| Lactic acidosis | | |
| Other: | | |

*Female patients only*

| Reproductive Health History | Yes/No | Current Contraceptive Use | Yes/No |
|---|---|---|---|
| Pregnant | | Nil | |
| Planning to conceive | | Oral Contraceptive Pill | |
| Not wishing to conceive | | Intra-Uterine Device | |
| Unable to conceive | | Depo-Provera | |
| | | Hormonal Implants | |

Results of previous genotype test:
……
…….
…..……
……
……
…….

## C. For HIVDR Board Use Only

| Resistance Testing Approved | Yes // No |
|---|---|
| Date of Sample…….(dd/mm/yy) | Date of HIVDR Board Review……(dd/mm/yy) |
| Date of Expected result……..…….(dd/mm/yy) | |

JAMHIVDR Number (to be assigned by the HIVDR Board):
……

**Appendix 12 – Ministry of Health Drug Monitoring Form**

# "PHARMWATCH"
# MINISTRY OF HEALTH DRUG MONITORING FORM


## Report drug failure and adverse reactions with medications and suspected counterfeit product

**An adverse reaction occurs when the patient outcome is:**

Death, life-threatening (real risk of dying), hospitalization (initial or prolonged), disability (significant, persistent or permanent), congenital defect, permanent impairment, allergic reactions, gastrointestinal distress.

**Report even if:**

- You're not certain whether the product caused the adverse reaction
- You don't have all the details

**Who can report?**

Any health care professional (Physician, Pharmacist, Dentist, Nurse) Any patient who has experienced an adverse drug reaction

**Where to report:**

**After completing, please return this form to**
**Standards & Regulation Division Ministry of Health**
**10-16 Grenada Way, Kgn 5**
**Tel:**

For additional information or for reporting online please visit the Ministry of Health's website at www.moh.gov.jm

**What happens when the Form is submitted?**

Any information provided in this form will be handled confidentially. The identities of the health care professional, patient or any other person reporting will be held in strict confidence and protected to the fullest extent. All reports will be assessed and causality analysis decided by Ministry of Health in due course. It is the ultimate responsibility of MOH to decide how to act on the information. It is also the responsibility of the Ministry to decide whether the incidences of reports will require further evaluation of drug performance. The Ministry will further provide the relevant pharmaceutical company with a summary of its findings and subsequent decision regarding intervention.

Prepared by: Maxine Gossell-Williams
Department of Basic Medical
Sciences Pharmacology Section

Princess Thomas Osbourne
Standards & Regulation Division
Ministry of Health

2009 May

"PharmWatch" is a collaborative effort between the Ministry of Health and the Pharmacology Section of the University of the West Indies.

# "PHARMWATCH" DRUG MONITORING FORM

**A. PATIENT DETAILS**

| 1.Patient Initials: (First, Last) | 3.Gender: M ☐ F | 3. Date of Birth: (mm/dd/yyyy) | 4. Ethnicity | 5. Weight:((Kg) | 6. Height: (cm) |
|---|---|---|---|---|---|
| | | | | | |

**B. SUSPECTED DRUG EVENT**

| 7. Outcomes attributed to use of drug (check all that apply):<br><br>Failure of therapy ☐ Allergy<br>Disability ☐ Life threatening<br>Hospitalisation<br>Death_____ mm/dd/yyyy<br><br>Other (describe)_____ | 8. Describe event or problem | 9.Date event started (mm/dd/yyyy)<br><br>10. Date event ended (mm/dd/yyyy) |
|---|---|---|
| 11. Describe action taken in response (e.g. drug changed, prolonged-therapy, increased dose) | 12. Describe other relevant history including abnormal laboratory test results, days of hospitalization. | |

**C. DRUG INFORMATION**

| 13.Name of suspected drug (give specific name on package) | 14. Dose & Route | 15. Indication | 16. Batch number if known |
|---|---|---|---|
| | | | |
| 17. Name of other drugs taken (give specific name on package) | 18. Dose & Route | 19. Indication | 20. Batch number if known |
| | | | |
| | | | |

| **D. REPORTING HEALTH PROFESSIONAL INFORMATION** | | | |
|---|---|---|---|
| 21. Profession:_____ | 24.Telephone: _____ | | |
| 27. Also reported to:**D. REPORTING HEALTH PROFESSIONAL** | | | |
| SignatureDate (mm/dd/yyyy)<br>23. Profession:_____ | 26.Telephone: _____ | | |

| 27. Also reported to: | |
|---|---|
| 25. Signature<br>Date (mm/dd/yyyy) | 28. |

**FOR OFFICIAL USE ONLY** Code No

| Received by:<br><br>Date received: | Action taken: |
|---|---|

**Appendix 13 – ARV Sensitivity Confirmation Form**

**MINISTRY OF HELTH**
**NATIONAL HIV/STI PROGRAMME**
**TREATMENT, CARE & PROTECTION UNIT**

**ARV SENSITIVITY CONFIRMATION FORM**

I hereby confirm that _____, _____
(Patient Name) (Docket Number)

attached to the _____ Treatment Site is having adverse reactions to Tenofovir/Lamivudine and recommend that he/she be reverted to Tenofovir/Emtricitabine.

He/she is attached to the _____ Pharmacy.

Attending Physician: _____ Date: _____
(Name & Signature)

***Please submit under confidential cover to: The Director, Treatment, Care & Support, HST, 10-16 Grenada Way, Kgn 5***

**OFFICIAL USE ONLY**

Received by: _____
_____
(Name & Title) (Date)

**Appendix 14 – Alternative ARV Request Form**

**MINISTRY OF HELTH**
**HIV/STI/TB PROGRAMME**
**TREATMENT, CARE & SUPPORT UNIT**

## ARV REQUEST FORM

**DATE:** _____

**TREATMENT SITE/PHARMACY:**

_____

**ARV REQUESTED:** **Tenofovir/Emtricitabine FDC 300/200mg TDF/FTC Tablets**

(for PLHIV having adverse reactions to Tenofovir/Lamivudine)

**DETAILS OF REQUEST:**

| **Patient: (Docket Number)** | **Attending Physician** | **Total Packs Requested** | **Total Packs Supplied** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| | Totals: | | |

**Requested by:** _____ **Date:** _____

**(Name and Title)**

**OFFICIAL USE ONLY**

Order filled by: _____

(Name & Title) (Date)

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