UNIT NO. 2

THE ROLE OF THE FAMILY DOCTOR IN HIV MEDICINE

Dr Lee Cheng Chuan

ABSTRACT

The outlook of people living with HIV (PLHIV) has changed for the better. With the discovery of effective drugs HIV is more like a chronic disease. The family doctor has several roles in HIV medicine: find, test, treat, and retain. Find - at risk individuals, and reduce their HIV risks. Test – to diagnosis those with acute HIV infection, to identify the asymptomatic patients, and to identify those with AIDS defining illnesses. Treat - participate in shared care management with HIV specialists. Retain – retain wellbeing of PLHIV - monitor for complications, provide patient education to help them minimise complications. Routine testing for HIV infection is now the practice. For treatment, A combination ART regimen consisting of two NRTIs + one active drug from one of the classes: NNRT, PI, INSTI, or a CCRS antagonist. Retaining the wellbeing of PLHIV requires monitoring for complications, and providing patient education to help them minimise complications.

Keywords: People living with HIV, Acute sero-conversion, Asymptomatic infection, AIDS, Opportunistic infection, Rapid tests

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INTRODUCTION

The outlook of people living with HIV (PLHIV) has changed for the better. With the discovery of effective drugs HIV is more like a chronic disease. There is still the lingering stigma and discrimination of it as a dread disease preventing at risk patients from coming forward for testing, and also some of the at risk individuals may let their guard down with regards to HIV prevention measures. The family doctor has several roles in HIV medicine: find, test, treat, and retain. Find - at risk individuals, and reduce their HIV risks. Test – to diagnosis those with acute HIV infection, to identify the asymptomatic patients, and to identify those with AIDS defining illnesses. Treat - participate in shared care management with HIV specialists. Retain – retain wellbeing of PLHIV - monitor for complications, provide patient education to help them minimise complications.

HIV & AIDS DEFINED

The HIV Virus. Human immunodeficiency virus (HIV) is a blood-borne, sexually transmissible virus. Two distinct species of HIV (HIV-1 and HIV-2) have been identified. Both are retroviruses in the Retroviridae family, Lentivirus genus and each is composed of multiple subtypes, or clades. All clades of HIV-1 tend to cause similar disease, but the global distribution of the clades differs. Almost all HIV infections in Singapore are caused by HIV-1 (DSC Management Guidelines 2013) [1].

Transmission. The virus is transmitted one of several ways: via sexual intercourse, shared intravenous drug instruments, and mother-to-child transmission (MTCT), which can occur during pregnancy, labour, and breastfeeding (DSC Management Guidelines 2013) [1].

Phases

HIV produces cellular immune deficiency characterised by the depletion of helper T lymphocytes (CD4+ cells). The loss of CD4+ cells results in the development of opportunistic infections and neoplastic processes. Clinical HIV infection undergoes 3 distinct phases:

1. Acute seroconversion
2. Asymptomatic phase and
3. AIDS

Acute Seroconversion. During this phase, the infection is established and a proviral reservoir is created. Seroconversion may take a few weeks, up to several months. Symptoms during this time may include fever, flu-like illness, lymphadenopathy, and rash. These manifestations develop in approximately half of all people infected with HIV.

Asymptomatic phase. At this stage in the infection, persons infected with HIV exhibit few or no signs or symptoms for a few years to a decade or more. Viral replication is clearly ongoing during this time, and the immune response against the virus is effective and vigorous. The most current understanding of HIV pathogenesis is that the body undergoes a constant inflammatory process causing damage to all organ systems and premature ageing and because of this, experts are pushing for earlier treatment regardless of CD4 counts.

AIDS. When the immune system is damaged enough that significant opportunistic infections begin to develop, the person is considered to have AIDS. A CD4+ T-cell count less than 200/μL is also used as a measure to diagnose AIDS, although some opportunistic infections develop when CD4+ T-cell counts are higher than 200/μL, and some people with CD4 counts under 200/μL may remain relatively healthy. Opportunistic infections and conditions include the following (* added in the 1993 AIDS surveillance case definition) are shown in Table 1.

In Singapore, sexual contact remains the primary mode of HIV transmission. The infection is most commonly transmitted among men who have sex with men, followed by persons who engage in high-risk heterosexual contact. Receptive anal

DR LEE CHENG CHUAN,
Senior Consultant, Department of Infectious Disease,
Tan Tock Seng Hospital. Adjunct Associate Professor,
Yong Loo Lin School of Medicine, National University
of Singapore

TABLE 1. OPPORTUNISTIC INFECTIONS IN AIDS

- Candidiasis of bronchi, trachea, or lungs
- Candidiasis, esophageal
- Cervical cancer, invasive*
- Coccidioidomycosis, disseminated or extrapulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic
- intestinal (duration >1 month)
- Cytomegalovirus disease (other than liver, spleen, or nodes)
- Cytomegalovirus retinitis (with vision loss)
- Encephalopathy, HIV-related
- Herpes simplex: chronic ulcer or ulcers (duration >1 month) or bronchitis, pneumonitis, or oesophagitis
- Histoplasmosis, disseminated or extrapulmonary
- Isosporiasis, chronic intestinal (duration >1 month)
- Kaposi sarcoma
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of the brain
- *Mycobacterium avium* complex or *Mycobacterium kansasii* infection, disseminated or extrapulmonary
- *M tuberculosis* infection, any site (pulmonary* or extrapulmonary)
- *Mycobacterium* infection with other species or unidentified species, disseminated or extrapulmonary
- *Pneumocystis* pneumonia
- Pneumonia, recurrent*
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of the brain
- Wasting syndrome due to HIV infection

Source: DSC Guidelines, 2013

intercourse is associated with the highest incidence of HIV infection, followed by insertive anal intercourse and receptive vaginal intercourse.

Risk of sexual transmission of HIV infection is increased in the presence of another sexually transmitted infection, which may compromise natural barriers to infection. Hence, the importance of treating all STIs in people at risk of HIV (Romanelli & Methany, 2009) [2].

FIND - SCREEN AT RISK PATIENTS AND PREVENT HIV

Screening is important in identifying HIV infection and is now a routine component of primary care. Early and regular screening increases life expectancy because treatment is initiated earlier. Screening of pregnant women and treatment of those who are HIV-positive significantly reduce vertical transmission. Reducing the rate of perinatal HIV infection to less than 2 percent of HIV-associated pregnancies per year can be achieved (Kaplan, 2009) [3].

The HIV infection risk groups are – Men who have sex with men (MSM), history of STIs, sex workers, and clients of sex workers. Casual sex workers are now an increasing group of infected people.

AIDS disease individuals – Those presenting with prolonged viral fever, attack of zoster, psoriasis, unexplained oral thrush, and loss of weight, etc.

Routine testing for HIV infection

In 2006, the Centers for Disease Control and Prevention issued new HIV screening recommendations (Table 2) [4]. Standard screening for HIV consists of an enzyme immunoassay (EIA), followed by the confirmatory Western blot test. Low-risk patients with indeterminate test results should be reassured, and the Western blot should be performed again after three months. In patients with risk factors, repeat tests after one, two, and six months are advised. Tests to screen blood, plasma, and oral secretions have virtually equal reliability (greater than 99 percent sensitivity and specificity). Several screening tests, such as Oraquick, Uni-Gold, and Recombigen, are available. If an acute retroviral syndrome is suspected, testing of viral load should be performed in conjunction with an EIA, because the EIA may take weeks or months to convert. Similar recommendations have been also issued by the American Academy of Family Physicians (Aug 2007); American College of Physicians (2009); Preventive Services Task Force (Apr 2007), and WHO (Romanelli & Methany, 2009) [2].

TABLE 2. CENTERS FOR DISEASE CONTROL AND PREVENTION RECOMMENDATIONS FOR HIV SCREENING

Adults and adolescents

- In all health care settings, screening for HIV infection should be performed routinely in patients 13 to 64 years of age.
- Physicians should initiate screening, unless prevalence of undiagnosed HIV infection in their patients has been documented to be less than 0.1 percent. In the absence of existing data for HIV prevalence, physicians should initiate voluntary HIV screening until they establish that the diagnostic yield is less than one per 1,000 patients screened, at which point such screening is no longer warranted.
- All patients initiating treatment for tuberculosis should be screened routinely for HIV infection.
- Patients at high risk of HIV infection should be screened at least annually. All patients seeking treatment for STIs, including all patients attending STI clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavioral risks for HIV infection.
- HIV screening is recommended after the patient is notified that testing will be performed unless the patient declines (opt-out screening).
- Separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.

Pregnant women

- HIV screening should be included in the routine panel of prenatal screening tests for all pregnant women.
- Repeat screening in the third trimester is recommended in certain jurisdictions with elevated rates of HIV infection among pregnant women.

SOURCE: CDC, 2006 [4] (MMWR Recomm Rep 2006 Sep 22:55(RR-14):1-17

Notes: HIV = human immunodeficiency virus; STI = sexually transmitted infection.

TEST - EARLY DIAGNOSIS OF ACUTE INFECTION

Diagnosis can occur at any stage of human immunodeficiency virus infection. The acute retroviral syndrome that occurs shortly after infection is characterised by constitutional symptoms and is often difficult to differentiate from common community-acquired viruses such as mononucleosis or influenza.

At least 50 (and up to 90) percent of patients with acute HIV infection develop symptoms consistent with acute infection although timing and duration are variable. For most symptomatic patients, acute illness develops within one to four weeks. The most prevalent symptoms are fever, fatigue, myalgias/arthralgias, rash (typically erythematous maculopapular exanthema), and headache. Patients may also experience anorexia, pharyngitis, lymphadenopathy, mucocutaneous ulcerations, diarrhoea, or a combination of these symptoms. Severe manifestations of acute HIV infection (e.g., meningoincephalitis, myelitis), although rare, have been described. Physical examination is nondiagnostic but may be notable for hepatosplenomegaly. CD4 lymphocyte counts exhibit a marked transient decrease during acute infections (Chu & Selwyn, 2010) [5].

Suspicion will be with the patient with high risk (e.g., MSM or persons who share needles) but one should retain a low threshold to consider acute infection in anyone presenting with any constellation of suggestive symptoms. Evaluation should include a thorough and accurate assessment of all activities that potentially involve HIV exposure, including heterosexual intercourse with a long term partner (Chu & Selwyn, 2010) [5].

HIV testing

The diagnosis of HIV infection is made by the detection of circulating antibodies to HIV. Antibodies are identified by the use of a screening test, usually an enzyme-linked immunosorbent assay (ELISA), followed by definitive diagnosis using a Western Blot assay. HIV antibody is detectable in at least 95% of patients within 3 months after infection.

In some situations such as pre-seroconversion or neonatal infection, measurement of HIV antibodies may be unreliable. In these instances, diagnosis of infection may use direct detection of HIV itself such as quantification of plasma HIV RNA, HIV viral

DNA, or HIV antigen or by detection and amplification of virus in a tissue culture.

Screening Antibody tests

The ELISA or EIA test is the standard screening test for HIV infection. Recombinant or native HIV antigens, fixed in a solid phase, are exposed to and bound by HIV antibodies in test serum. The presence of these antibodies is then detected by a second anti-human antibody, with a sensitivity of >99.5%. Most commercially available ELISA kits contain antigens from both HIV-1 and HIV-2 and are able to detect infection with either of these viruses. A positive ELISA test is usually observed within 3-6 weeks following infection. The weeks between infection and seropositivity are termed the "window period" and are associated with high levels of circulating HIV, and potentially more efficient transmission. Commercial fourth- generation screening assays, which combine antigen and antibody screening, may reduce this window period to 6 days. False-positive test results are rare and the specificity of the ELISA is >99.8%.

Confirmatory Antibody Tests

The Western Blot is the definitive diagnostic test for HIV infection. The Western Blot (WB) assay detects antibodies in patient sera that react with a number of different viral proteins. A positive WB is defined by the detection of antibodies to all of the 3 main groups of HIV proteins – envelope (gp160, gp120 or gp41), gag (p24) and polymerase (p66 or p51).

An indeterminate WB assay is most commonly caused by the presence of unrelated antibodies that are cross-reactive with HIV proteins. It is possible that an indeterminate result is due to early HIV infection and incomplete evolution of the anti-HIV immune response. An indeterminate test result should be repeated at 1, 2 and 3 months to exclude an evolving pattern.

Using both EIA and WB tests, the sensitivity and specificity exceed 99.9%. Antibody testing can be performed on individuals approximately 1 month after a high-risk sexual exposure. If negative, the test should be repeated again 3 months (window period) after the exposure.

Rapid Tests

Rapid tests are screening tests where results are available in 10-20 minutes. If performed correctly, they detect HIV antibodies with sensitivities similar to currently available EIAs. A negative rapid HIV test result requires no further confirmatory testing. A positive test requires confirmation by both EIA and WB testing.

Four rapid HIV tests have been approved by the US Food and Drug Administration (FDA):

- OraQuick® (and its newer version OraQuick® Advance) Rapid HIV-1/2 Antibody Test (OraSure Technologies, Inc., Bethlehem, PA);
- Reveal™ (and its newer version Reveal™ G2) Rapid HIV-1 Antibody Test (MedMira, Halifax, Nova Scotia);
- Uni-Gold Recombigen® HIV Test (Trinity BioTech, Bray, Ireland);
- Multispot HIV-1/HIV-2 Rapid Test (Bio-Rad Laboratories, Redmond, WA).

The Determine HIV-1/HIV-2 (Abbott) rapid test kit is used at the DSC clinic (approved by USAID).

HIV p24 antigen detection

The first marker to appear following infection is free viral p24 antigen. This can be detected using an EIA test. Fourth generation HIV serology tests incorporate testing for both antibodies as well as for the p24 antigen, therefore reducing the window period further.

Polymerase chain reaction (PCR) test

PCR for HIV DNA is available in special circumstances e.g. for infants of mothers with HIV infection to distinguish active infection of the infant from passive transfer of maternal antibodies, and in cases where the WB test is indeterminate in a patient with high-risk behaviour. PCR technology is also employed for quantitative measurement of plasma HIV RNA, this is used to guide and monitor ARV treatment.

Who to test

HIV testing is specifically recommended in the following situations:

- for all individuals who seek evaluation and treatment for STIs
- individuals with signs and symptoms suggestive of HIV-related illnesses
- individuals whose behaviour puts them at risk for HIV infection
- individuals who consider themselves at risk or request the test
- pregnant women
- individuals with active TB
- donors of blood, semen, and organs.

Post-test Counselling – Negative test

- Reinforce information on safer sex practices to reduce the risk of acquiring HIV
- The significance of "the window period" and the necessity and timing of a repeat test should be discussed with the patient

Post-test Counselling – Positive test

- Providers should expect individuals to be distressed when first informed of a positive HIV test result
- Individuals who test positive for HIV antibody should be counselled concerning the behavioral, psychosocial, and medical implications of HIV infection
- Prevention counseling must be given before leaving the testing site
- A referral letter should be written and an appointment made at the CDC, TTSH
- AIDS helpline numbers should be given for any future needs (Tel: 6295 2944)

Anonymous HIV Counselling and Testing

This is operated by Action for AIDS on Tuesday and Wednesday evenings from 6.30 pm to 8 pm and Saturdays from 1 to 4 pm, at the DSC Clinic, 31 Kelantan Lane, Singapore 200031.

TREAT - PARTICIPATE IN SHARED CARE MANAGEMENT WITH HIV SPECIALISTS

Appropriate management with combination antiretroviral therapy extends the patient's life, most often for many years. Therapy is lifelong and complicated by pill burden, cost, adverse effects, and drug interactions.

Each HIV-infected patient entering into care should have a complete medical history, physical examination, and laboratory evaluation and should be counselled regarding the implications of HIV infection. The goals of the initial evaluation are to confirm the presence of HIV infection, obtain appropriate baseline historical and laboratory data, ensure patient understanding about HIV infection and its transmission, and initiate care as recommended by established guidelines. Baseline information can then be used to define management goals and plans.

The following laboratory tests performed during initial patient visits can be used to stage HIV disease and to assist in the selection of antiretroviral (ARV) drug regimens:

- HIV antibody testing
- CD4 T-cell count
- Plasma HIV RNA (viral load)
- FBC, LFTS, renal function tests, thyroid function tests
- Urinalysis
- Serologies for hepatitis A, B, and C viruses
- Syphilis serology
- Toxoplasma and CMV antibody tests
- Fasting blood glucose and serum lipids
- CXR
- Genotypic resistance testing at entry into care, regardless of whether ART will be initiated immediately

Newly diagnosed HIV-infected persons should receive psychosocial evaluation including ascertainment of behavioral factors indicating risk for transmitting HIV. They may require referral for specific behavioural intervention (e.g; a substance abuse program), mental health disorders (e.g; depression), or emotional distress. They might require assistance with securing and maintaining employment and housing as well as medical insurance status and adequacy of coverage. Women should be counselled or appropriately referred regarding reproductive choices and contraceptive options.

The HIV Replication Cycle. Knowledge of the HIV replication cycle helps in the understanding of the mechanism of action of antiretrovirals. HIV is an enveloped virus that contains two copies of viral genomic RNA in its core. In addition to the copies of RNA, the viral core also contains enzymes required for HIV replication – reverse transcriptase, integrase, and protease. The first step in the HIV replication cycle is the interaction between the envelope proteins of the virus and specific host cell surface receptors (e.g. CD4 receptor). In the second step, the virus binds to a chemokine coreceptor CXCR4 or CCR5, resulting in conformational changes in the envelope proteins. This ultimately results in the "fusion" of the viral envelope and the host cytoplasmic membrane. Fusion creates a pore through which the viral capsid enters the cell. Following entry into the cell, the viral reverse transcriptase enzyme catalyses the conversion of viral RNA into DNA. This viral DNA enters the nucleus and becomes inserted into the chromosomal DNA of the host cell (integration). Expression of the viral genes leads to the production of precursor viral proteins. These proteins and viral RNA are assembled at the cell surface into new viral particles and leave the host cell by a process called budding, during which they acquire the outer layer and envelope. At this stage, the protease enzyme cleaves the precursor viral proteins into their mature

TABLE 3. COMBINATION ART REGIMEN

Regimen	A	B	C
Preferred	Efavirenz*	Tenofovir*^ Abacavir**	Lamivudine+** Emtricitabine*^
Alternative	Atazanavir/r Lopinavir/r Darunavir/r Raltegravir	Zidovudine+	
Specific groups	Nevirapine^^ Atazanavir++		

Choose one drug from columns A, B and C.
* Coformulated as Atripla (licensed for virologically suppressed patients only).
^ Coformulated as Truvada.
\+ Coformulated as Combivir
** Coformulated as Kivexa
^^ Only when CD4<250 cells/μL in female patients and <400 cells/μL in male patients
++ Where there are established cardiovascular disease risk factors and a PI is required.

products. If this final phase of the replication cycle does not occur, the released viral particles are noninfectious and not competent to initiate the replication cycle in other susceptible cells (Haseltine, 1991) [6].

Starting ART

More than 20 approved ARV drugs in 6 mechanistic classes are available to design combination regimens. These 6 classes include the nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (PIs), fusion inhibitors (FIs), CCR5 antagonists, and integrase strand transfer inhibitors (INSTIs).

A combination ART regimen generally consists of two NRTIs + one active drug from one of the following classes: NNRTI, PI (generally boosted with RTV), INSTI, or a CCR5 antagonist. See Table 3. Selection of a regimen should be individualised based on virologic efficacy, toxicity, pill burden, dosing frequency, drug-drug interaction potential, resistance testing results, and the patient's comorbid conditions.

Initiating Antiretroviral Therapy in Treatment-Naive Patients

There have been recent changes to recommendations on initiation of ART in treatment- naive patients. This is due to increasing evidence showing the harmful impact of ongoing HIV replication on AIDS and non-AIDS disease progression. In addition, the updated recommendations reflect emerging data showing the benefit of effective ART in preventing secondary transmission of HIV. The following recommendations have been accessed from:
http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf. as of September 2012. [7]

ART is recommended for all HIV-infected individuals. The strength of this recommendation varies on the basis of pretreatment CD4 cell count:
- CD4 count <350 cells/mm3 **[A]**
- CD4 count 350 to 500 cells/mm3 **[AII]**
- CD4 count >500 cells/mm3 **[BIII]**

Regardless of CD4 count, initiation of ART is strongly recommended for individuals with the following conditions:
- Pregnancy **[AI]**
- History of an AIDS-defining illness **[AI]**
- HIV-associated nephropathy (HIVAN) **[AI]**
- HIV/hepatitis B virus (HBV) coinfection **[AI]**

Proper management of HIV infection requires medical therapy, which for many patients should be coupled with behavioural and psychosocial services. Comprehensive HIV treatment services are available at the CDC, TTSH and patients should be referred there upon diagnosis of HIV infection.

RETAIN – RETAIN THE WELLBEING OF PLHIV

Retain the wellbeing of PLHIV - monitor for complications, provide patient education to help them minimise complications.

Routine office visit

Monitor symptoms, check for signs of HIV infection, check CD4 cell count and viral load. Worsening of HIV infection will include:
- New symptoms of nausea, vomiting, fatigue, fever, headache, chills, night sweats, cough, shortness of breath or diarrhea.
- Signs of weight loss, thrush or enlarging lymph nodes in the neck, axilla or groin.
- A drop in the CD4 cell count
- A rise in the viral load in your blood.

Frequency of visits
- See every 6 months as long as the CD4 cell count is higher than 500.
- See every 3 months if CD4 cell counts are below 500.
- Closer monitoring may be needed to check response to the medicine given or to check if HIV infection is getting worse.

Vaccinations
- Influenza vaccination yearly
- Pneumococcal vaccination every 5-7 years
- Hepatitis B vaccination for those who are non-immune.

Tests
- Pap smear six monthly for 2 smears and if normal to repeat yearly

Chemoprophylaxis
- TMZ prophylaxis for those with a CD4 cell count less than 200 – to prevent Pneumocystis jiroveci infection, and toxoplasmosis.
- Azithromycin, clarithromycin and rifabutin for those with a CD4 count of less than 50 to 75 – to protect against Mycobacterium avium.

Avoid jobs and activities that carry risks of infection
- Working in homeless shelters, hospitals, clinics, nursing homes or prisons can increase the risk of exposure to tuberculosis (TB) and other infectious diseases.
- Parents of children in day care and people who provide child care are at increased risk of catching cytomegalovirus (CMV) infection, cryptosporidiosis, hepatitis A and giardiasis from the children. The risk can be reduced through good hygiene practices, such as always washing your hands after changing diapers, after touching urine or saliva, after going to the bathroom and before a meal.
- Working with animals (for example, veterinary work or at a pet store, farm or slaughterhouse), may be at higher risk for infections such as cryptosporidiosis, toxoplasmosis, salmonellosis, campylobacteriosis or Bartonella infection. Avoid contact with young animals especially those that have diarrhea.
- Wash hands after gardening or other contact with soil.

"Safer sex"
- Condom use every time the individual has sex. A latex condom

also helps to reduce the risk of STI such as herpes, human papillomavirus (HPV) or a new strain of HIV that might be resistant to antiretroviral drugs.

• Avoid sex that results in oral exposure to feces (oral-anal contact).

• Safer sex also means using condoms if one has any doubts about whether the partner is infected or whether he or she is having sex with someone else. Use male latex condoms every time and lubricate with water based lubricants like KY Jelly. Vaseline as a lubricant is unsuitable because it can weaken the condom leading to leakage.

• If a man doesn't want to use a male condom, the partner should use a female condom. Female condoms may not be as effective as male condoms, but they offer some protection.

Partner notification

HIV-infected patients should be encouraged to notify their partners and to refer them for counselling and testing.

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LEARNING POINTS

- **The outlook of people with HIV (PLHIV) has changed for the better.**
- **With the discovery of effective drugs HIV is more like a chronic disease.**
- **The family doctor has several roles in HIV medicine: find, test, treat, and retain.**
- **Find - at risk individuals, and reduce their HIV risks.**
- **Test – routine testing for HIV infection is now the practice. For treatment,.**
- **Treat - use a combination ART regimen consisting of two NRTIs + one active drug from one of the classes: NNRT, PI, INSTI, or a CCRS antagonist..**
- **Retain – retain the wellbeing of PLHIV by monitoring for complications, and providing patient education to help them minimise complications.**