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GUIDELINES ON ANTIRETROVIRAL THERAPY (ART) AMONG ADULTS AND ADOLESCENTS WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION

I. RATIONALE

The World Health Organization projects that 45 million people will get infected with Human Immunodeficiency Virus (HIV) between 2002 and 2010. Of this, 40% will come from Asia and Pacific if current prevention efforts are not continued. Prevention efforts however, should be complemented with making treatment available to as many HIV positive and AIDS cases as possible.

In the Philippines, although the HIV and AIDS national prevalence is less than 0.1% of the population, the number of people affected by HIV and AIDS continues to grow.

The National Epidemiology Center (NEC) AIDS registry reported that as of December 2008, 3,589 cases of HIV antibody seropositive individuals had been identified in the Philippines, and on the same month, there were 565 PLHIV on antiretroviral therapy (ART).

In line with the global initiative on Universal Access, the health sector has to facilitate access to antiretroviral drugs (ARVs) by People Living with HIV (PLHIV) in need of treatment. A major step of this endeavor is the provision of guidelines to health care providers on the proper use of ARVs in the management of PLHIV. According to WHO, evidence from many parts of the world indicates that introducing treatment in affected communities can reduce the fear, stigma, and discrimination that surround HIV/AIDS, increase uptake of HIV testing and counseling, and reinforce prevention efforts.

Significant decrease in morbidity and mortality due to AIDS has been observed in countries where ARVs are widely used. To ensure safe and effective use of ARVs, there must be standardized treatment guidelines, continuous access to medicines and laboratory facilities for monitoring treatment response and toxicity associated with use of the ARVs, and availability of counseling services for patients to reinforce adherence to ART.

This guideline adapted the current recommendations of WHO for HIV Infection in Adults and Adolescents (2006) in its approach to the delivery of a comprehensive HIV treatment and care, in harmony with current local practices and experiences in treating PLHIV for 3 years in Philippines.

II. OBJECTIVE

To provide standards for the use of ARVs among adults and adolescent living with HIV in the Philippines.

III. SCOPE AND LIMITATION

This guideline is intended for physicians from government and private health facilities managing PLHIVs with established referral networks to Department of Health (DOH) – designated treatment hubs. Management of HIV infections among pregnant women and children will be discussed in a separate guideline.

IV. DEFINITION OF TERMS

1. **Adherence counseling** – Includes provision of information on HIV, manifestations of the disease, and benefits and side-effects of ARVs; discussion on how the medications should be taken stressing on the importance of not missing any doses as well as risks associated to poor adherence, assessment of adherence to include identifying obstacles to adherence, and treatment planning to enhance adherence.

2. **Antiretrovirals (ARVs**) – Drugs that are given to people living with HIV infection to improve or maintain their immune function.

3. **HIV and AIDS Core Team (HACT)** – A multi-disciplinary team composed of doctors, nurses, pharmacists, social workers, and other health care providers that implements prevention, treatment and care services for HIV and AIDS in the hospital setting. Its specific functions are described in the Administrative Order Number 18 s. 1995 (Revised Guidelines in the Management of HIV/AIDS Patients in the Hospital).

4. **HIV Counseling and Testing** – A confidential process that enables individuals to examine their knowledge and behavior in relation to their personal risks of acquiring or transmitting HIV. Counseling helps an individual decide on whether or not to undergo HIV testing and provides support to an individual receiving his or her test results.

5. **Immune reconstitution inflammatory syndrome (IRIS)** – A spectrum of clinical signs and symptoms resulting from the restored ability of an individual's immune system to mount an inflammatory response and this is associated with immune recovery during ART. Also defined as paradoxical clinical worsening due to a sub-clinical and unrecognized opportunistic pathogen or previously known treated opportunistic pathogen in a setting of adequate response to ART.

6. **Opportunistic infections** – Illnesses caused by various organisms, some of which usually do not cause disease in persons with healthy immune systems. Persons living with advanced HIV infection may suffer opportunistic infections of the lungs, brain, eyes and other organs.

7. **People Living with HIV (PLHIV)** – Refers to people living with HIV infection. With proper management and provision of ART, these individuals can continue to live well and be productive for many years.

8. **Treatment Hub** – A hospital facility with an established HIV/AIDS Core Team (HACT) providing prevention, treatment, care and support services to People Living with HIV (PLHIV) including but not limited to HIV Counseling and Testing, clinical management, patient monitoring and other care and support services. ARVs can

only be accessed through these facilities. Refer to annex[*] for the complete list treatment hubs in the country.

V. IMPLEMENTING GUIDELINES

A. Determine if Anti-Retroviral (ARV) is indicated

The decision to start a patient on ARV will be based on the clinical findings and/or CD4 level determination as shown in table 1. The benefits, toxicity, adherence issues and costs of the treatment must be a component of counseling.

Table 1. Criteria for Initiating Anti-retroviral Therapy (Adopted from WHO ART for HIV Infection in Adults and Adolescents 2006).

Criteria for Initiation of ARVs		
WHO Clinical Staging	**CD4 Testing Not Available**	**CD4 Testing Available**
I - Asymptomatic	Do not treat	Treat if CD4 cells is below 200 cells/mm3
II - Mild	Do not treat	
III - Advanced	Treat	Consider treatment if CD4 is below 350 cells/mm3 and initiate treatment before CD4 falls below 200 cells/mm3
IV - Severe	Treat	Treat irrespective of CD4 count

B. Perform Adherence Counseling

HIV can develop resistance to ARVs. The success of ARV therapy largely depends on patient's adherence to treatment. A 95% adherence rate is required to prevent the development of drug resistance. Adherence counseling should always be done prior to and while on treatment.

References and training on adherence counseling for anti-retroviral treatment (ART) will be provided by the DOH to participating physicians

C. Get Laboratory Tests prior to indicating ARV treatment

1. Complete Blood Count (CBC)
2. Chest x-ray, sputum Acid Fast Bacilli (AFB) and sputum culture to rule out active tuberculosis
3. Pregnancy test for females of reproductive age
4. Baseline urinalysis, fasting blood sugar, liver function test, creatinine, and lipid profile when indicated

D. Choose initial ARV Regimen

Recommended regimen (see annex[*] for dosages)

a. ***First line regimen***: NN RTI-based (2 N RTI + 1NN RTI)

i. First line N RTIs: Zidovudine (AZT) + Lamivudine (3TC)

Alternative first line N RTI:

a. Tenofovir (TDF) + Lamivudine (3TC)
b. Stavudine (d4T) + Lamivudine (3TC) – When TDF and AZT are contraindicated

ii. First line NNRTI:
Nevirapine (NVP)

Alternative first line NNRTI:

Efavirenz (EFV) – for patients with hypersensitivity to nevirapine and/or taking rifampicin. EFV is constraindicated in pregnant patients

b. ***Second line regimen:*** 2 NRTIs + Lopinavir/ritonavir (LPV/r)

- AZT + 3TC + LPV/r if previously on TDF
- TDF + 3TC + LPV/r if previously on AZT or d4T

E. Monitor for ARV toxicity

1. For AZT +3TC + EFV/NVP

a. CBC – every month for the first three months and every 4-6 months thereafter
b. SGPT, SGOT, alkaline phosphatase, amylase – after 1 month, after 6 months and every 12 months thereafter

2. For TDF + 3TC + EFV/NVP

a. annual creatinine and urinaysis
b. SGPT, SGOT, alkaline phosphatase, amylase – after 1 month, after 6 months and every 12 months thereafter

3. For d4T + 3TC + EFV/NVP

a. annual CBC
b. SGPT, SGOT, alkaline phosphatase, amylase – after 1 month, after 6 months and every 12 months thereafter
c. Total cholesterol, triglyceride, LDL – after 6 months and every 12 months thereafter

4. For PI—containing regimen (AZT/TDF + 3TC + (PI/r)

4.1 For TDF + 3TC + (LPV/r)

a. annual creatinine and urinalysis
b. Total cholesterol, triglyceride, LDL-after 6 months and every 12 months thereafter
c. FBS – after 6 months and every 12 months thereafter