Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 30 2022

ADMINISTRATIVE ORDER
No. 2022- 0024

SUBJECT: **Guidelines on Differentiated Treatment for People Living with Human Immunodeficiency Virus (PLHIV) and Prophylaxis for HIV-Exposed Infants**

I. RATIONALE

The Human Immunodeficiency Virus (HIV) epidemic in the country remains a threat to the health of Filipinos. Although the national HIV prevalence remains low at less than 1%, the number of newly diagnosed cases per day continues to increase which has steered concerted efforts from both government and private sectors including community-based organizations (CBOs) to address this public health problem by intensifying targeted interventions to reach out key populations and People Living with HIV (PLHIV) and provide HIV services for prevention, treatment, care, and support.

Aligned with the Sustainable Development Goals (SDGs) is the expansion of access to prevention, testing, and treatment to reach the 95-95-95 targets which refer to 95% of the people living with HIV will know their status, 95% of people with HIV are receiving antiretroviral therapy (ART) and 95% of the people receiving ART are virologically suppressed.

Strategic approaches on "test early", "treat early", and "treat all" remove limitations on ART initiation. Likewise, viral suppression achieved through high adherence to optimized and life-saving ART significantly reduces the risk of HIV transmission to sexual and drug-sharing partners.

Updated World Health Organization (WHO) treatment guidelines recommend the use of Dolutegravir (DTG) as preferred first-line ART regimen due to rapid viral suppression, low toxicity, fewer drug interactions, and high genetic barrier to developing HIV drug resistance. Use of optimized ART regimens and employing a differentiated or person-centered approach in the delivery of HIV treatment services will bring us one step closer towards achieving universal access to HIV treatment and care, ending AIDS as a public health threat and attainment of goals of the Universal Health Care Act and FOURmula ONE (Fl) for Health.

II. OBJECTIVE

This Administrative Order is issued to provide differentiated or person-centered approach and updated and evidence-based standards and guidance on initiating and monitoring of ART among adults, children, and infants infected with HIV and antiretroviral (ARV) prophylaxis for infants exposed to HIV in the Philippines.

III. SCOPE OF APPLICATION

This Administrative Order shall apply to the Department of Health (DOH) – HIV treatment facilities and other government and private health facilities managing PLHIV. In the case of Bangsamoro Autonomous Region in Muslim Mindanao (BARMM), the adoption of these guidelines shall be in accordance with RA 11054 (Bangsamoro Organic Act) and the subsequent laws and issuances to be issued by the Bangsamoro government.

IV. DEFINITION OF TERMS

A. **Adherence counseling** – refers to provision of information on HIV, manifestations of disease, benefits and side-effects of ART, how ARV medications shall be taken, importance of not missing any doses to achieve viral suppression, risks associated with poor adherence, assessment of adherence including identifying obstacles to adherence, and treatment planning to enhance adherence through face-to-face or digital health platforms.

B. **Antiretroviral drug (ARV)** – refers to medicines used in the treatment and prevention of HIV infection. Different classes of ARV act at different stages of HIV life cycle thereby stopping or interfering with viral replication in the body.

C. **Antiretroviral therapy (ART)** – refers to a lifelong treatment using a combination of three or more ARV drugs to achieve viral suppression.

D. **Established on ART** – refers to PLHIV stable on ART for more than 6 months who: have no symptoms and concurrent infections, excluding other treated chronic health conditions with good control; understand the significance of adherence; are provided with adequate counseling; and with evidence of treatment success i.e., at least one suppressed viral load result within the past 5 months (or CD4 cell count >200 cells/mm^3 in adolescents and adults or >350 cells/mm^3 in children three to five (3-5) years old, if VL is not available), and weight gain.

E. **High risk infants** – refers to infants born to women with HIV who have received less than four weeks of ART at the time of delivery, or with viral load > 1000 copies/ml in the four weeks before delivery, if viral load measurement is available, or born to women with incident HIV infection during pregnancy or breastfeeding, or identified for the first time during postpartum period, with or without a negative HIV test prenatally.

F. **HIV infection** – refers to the presence of HIV in the body as evidenced by a reactive diagnostic HIV antigen/antibody test.

G. **Immune reconstitution inflammatory syndrome (IRIS)** – refers to a spectrum of clinical signs and symptoms resulting from the restored ability of an individual's immune system to mount an inflammatory response, associated with immune recovery during ART. Also defined as paradoxical clinical worsening due

to a subclinical and unrecognized opportunistic pathogen or previously known treated opportunistic pathogen in a setting of adequate response to ART.

H. **Lost to follow up** – refers to a PLHIV who failed to access HIV care services 30 days (one month) from the last expected date of consult or last (run-out) pill.

I. **Multi-Month Dispensing (MMD)** – refers to a differentiated or person-centered approach of providing six months' supply or more of ARV for PLHIV established on ART depending on the need and situation.

J. **Nucleoside reverse transcriptase inhibitors (NRTIs)** - refer to antiviral agents that bind to the reverse transcriptase enzyme and alter its structure and inhibit its function in the transcription of ribonucleic acid (RNA) into deoxyribonucleic acid DNA.

K. **Non-nucleoside reverse transcriptase inhibitors (NNRTI)** - refer to antiviral agents that bind non-competitively to the reverse transcriptase enzyme and prevent viral RNA conversion to DNA.

L. **Opportunistic Infections** - refer to infections caused by pathogens (bacteria, fungi, parasites or viruses) that occur more often or are more severe in people with weakened immune systems than in people with healthy immune systems.

M. **Protease Inhibitors (PI)** - refer to antiviral agents that act by interfering with enzyme protease that cleave proteins which HIV cells need to develop and mature.

N. **Viral suppression** – refers to an undetectable viral load of equal to or less than 50 RNA copies/ml.

V. GENERAL GUIDELINES

A. Antiretroviral therapy (ART) shall be initiated within the same day upon recognition of HIV infection, whenever possible, regardless of clinical and immunologic status.

B. Early initiation of ART in patients with opportunistic infection (OI) reduces risk of mortality. However, ART initiation should be delayed in patients being treated for Tuberculosis (TB) meningitis, cryptococcal meningitis, and cytomegalovirus (CMV) retinitis to prevent immune reconstitution inflammatory syndrome (IRIS).

C. Adherence shall be assessed and reinforced at every follow-up consultation to prevent drug resistance and treatment failure.

D. Patients who are already established on ART shall be maintained and monitored on their current ART regimen and providers shall employ multi-month dispensing.

E. All HIV-exposed infants shall be given ARV prophylaxis starting at birth or when HIV exposure is recognized postpartum.

VI. SPECIFIC GUIDELINES

A. All DOH-procured ARV shall be made available in DOH designated HIV treatment facilities.

B. Trained health service providers shall perform adherence counseling prior to treatment initiation and while on treatment and include discussion on benefits of treatment, management of possible side effects, and adherence issues. A 95% adherence rate is desired to prevent drug resistance.

C. Treatment initiation for PLHIV shall be based on the following preferred and alternative first line regimen: *(Please see Annex A: Antiretroviral Drugs and Doses, Instructions on Administration, and major types of toxicities.):*

1. Newly diagnosed or treatment-naïve adults, adolescents, children and infants aged 4 weeks and/or ≥3 kg shall be initiated on Dolutegravir-containing regimens with optimal formulation as the preferred first line regimen.
    a. Tenofovir (TDF) + Lamivudine (3TC) + Dolutegravir (DTG) is the preferred first line regimen for adults, adolescents, and children weighing more than 30 kg.
        i. DTG can be prescribed for adult women and adolescent girls of childbearing age or potential who wish to become pregnant or who are not otherwise using or accessing consistent and effective contraception if they have been fully informed of the potential increase in the risk of neural tube defects (at conception and until the end of the first trimester). If a woman was identified as pregnant only after the first trimester, DTG shall be initiated or continued for the duration of the pregnancy.
        ii. Patients on Rifampicin require a dose adjustment of DTG twice daily. *(Please see Annex A for appropriate dosage.)*
    b. An alternative first line regimen of TDF + 3TC + Efavirenz (EFV) shall be offered as an option for patients who are taking Rifampicin or women and adolescent girls who are pregnant or of child bearing potential who prefer EFV over DTG after appropriate counseling
    c. An alternative first line regimen of TDF + 3TC + Rilpivirine (RPV) shall be offered for patients 12 years old and above who do not want DTG and do not tolerate EFV, with known CD4 T-cell count greater than 200 cells/mm^3, and NOT taking Rifampicin.
        i. RPV is contraindicated among patients taking antacids, Histamine 2 blockers or proton pump inhibitors.
        ii. Abacavir (ABC) is preferred over TDF for patients with creatinine clearance <60 ml/minute or with history of chronic kidney disease or with risk for kidney disease (i.e. diabetes, hypertension, urolithiasis).
    d. ABC + 3TC + DTG (using optimal DTG formulations) is the preferred first line regimen for infants aged 4 weeks and/or weighing ≥3 kg and children up to 30 kg

i. Alternative first line regimen is ABC + 3TC + Lopinavir/ritonavir (LPV/r)
ii. Use Zidovudine (AZT) if ABC is not available

e. For neonates, the preferred first line regimen is AZT + 3TC + Nevirapine (NVP)
i. Alternative first line regimen is AZT + 3TC + LPV/r
ii. Use ABC if AZT is not available

2. Lost to follow up PLHIV, those on ART for more than 6 months but with history of poor adherence or clinical deterioration, or stopped taking ART for varied medical, personal, economic, or social reasons and are returning to care, shall be re-started to treatment and managed as follows:
a. Continue the DTG-containing regimen and test for viral load and drug resistance after three (3) months.
b. Patients previously initiated on Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI) or Protease Inhibitors (PI)-containing first line regimen shall be re-started on the following DTG-containing **first line** regimen as follows:
i. AZT + 3TC + DTG if previously on first line regimen TDF or ABC + 3TC + NNRTI or LPV/r
ii. TLD or ABC + 3TC + DTG if previously on first line regimen AZT + 3TC + (NNRTI or LPV/r)

D. All PLHIV on ART require regular clinical and laboratory monitoring for ARV toxicity and clinical improvement. Close and more frequent monitoring is important during the first six months of initiation to identify immediate toxicities that could adversely affect adherence.

1. Clinical monitoring for **ARV toxicity** is done on the minimum at 2, 4, 8, and 12 weeks after ART initiation and every six months once the patient is established on ART.
a. Clinical signs and symptoms shall be evaluated during each follow up visit since ARV toxicity may not appear immediately and may develop only after prolonged intake of the drugs. (Please refer to Annex A for ARV toxicities.)
b. Most ARV side effects are manageable and do not require change in regimen.

2. Laboratory tests required for monitoring ARV toxicity depend on specific regimen. The physician can request additional laboratory tests if clinically indicated as follows:
a. For TDF-containing regimens, serum creatinine within 6 months of ART initiation, then every 12 months or as needed
b. For EFV-containing regimens, lipid profile (triglyceride, total cholesterol and LDL) within 6 months, then every 12 months or as needed
c. For AZT-containing regimens, CBC at 2, 4, 8, 12 and 24 weeks after starting AZT then every 6 months or as needed

d. For PI-containing regimens, lipid profile (triglyceride, total cholesterol and LDL) and FBS within 6 months then every 12 months or as needed.

3. Clinical and virologic monitoring of treatment response and identifying early treatment failure for timely change of regimen shall be performed regularly.
   a. Clinical monitoring for treatment response is done at two (2), four (4), eight (8), and 12 weeks after ART initiation, and every six months once the patient is established on ART.
   b. To detect early treatment failure, viral load monitoring must be done within three (3) to six (6) months after ART initiation.
   c. The first viral load test result shall be made available and reviewed within six months of ART initiation.
   d. If virologically suppressed, repeat VL after six (6) months and every 12 months thereafter.
   e. If poor adherence is suspected, enhance adherence counseling to ensure the patient is on continuous ART for four to eight (4-8) weeks before the blood draw for VL testing.

4. Monitor for drug interactions of ARV with other drugs that the patient is taking (including alternative medicines, herbal remedies and dietary supplements) when initiating ART and during treatment maintenance. *(See Annex B: Key drug interactions and suggested management.)*

5. All PLHIV on ART shall be appropriately diagnosed and managed for treatment failure.
   a. Suspect treatment failure when there is no clinical improvement during the first 3 months of ART among symptomatic patients or when there is recurrence or a new clinical event indicating severe immune deficiency (WHO clinical stage 3 or 4) after three (3) months of effective therapy. (See Annex C: WHO Clinical Staging of HIV Disease in adults, adolescents and children.)
   b. If treatment failure is suspected, a viral load test must be done to confirm the diagnosis. The patient must be on continuous ART for 4-8 weeks before blood draw for VL testing.
   c. Treatment failure should be differentiated from immune reconstitution inflammatory syndrome (IRIS) wherein exacerbation of previously coexisting subclinical infections (e.g. TB) may occur, resulting in an apparent worsening of disease after initiating ART. In IRIS, ART should not be interrupted.
   d. Viral load test shall be interpreted as follows: *(Please see diagram in Annex D: Interpretation of VL Test result.)*
      i. PLHIV with VL $\geq$ 1,000 copies/mL shall be tested for HIV drug resistance (HIVDR) and shifted to second line regimen
      ii. PLHIV with VL $\leq$ 50 copies/mL shall be retested routinely as scheduled

iii. PLHIV with VL >50 to <1000 copies/mL shall be provided with enhance adherence counseling and VL testing shall be repeated after 3 months

6. Switching of ART regimen when there are signs of adverse drug effects shall not be delayed as this may cause harm and may affect adherence leading to drug resistance and treatment failure.
   a. Switch Tenofovir to Abacavir when estimated creatinine clearance is less than 60 ml/minute. (See Annex E: Cockcroft-Gault (CG) Formula or https://qxmd.com/calculate/calculator_51/crcl-cockroft-gault for the online calculator.)
   b. Switch Efavirenz to Dolutegravir if patients develop adverse reactions. Patients who refused dolutegravir may be offered Rilpivirine if with known CD4 T-cell count greater than 200 cells/mm3 and not taking Rifampicin.
   c. Switch Zidovudine to Tenofovir or Abacavir for patients who developed anemia.
   d. Switch Lopinavir/ritonavir to Dolutegravir if patients develop adverse reactions.

7. Patients who are failing on first line regimen shall be shifted to second line regimen.
   a. Adults, adolescents, children, and infants aged 4 weeks and/or ≥3 kg who are failing on first line regimen shall be shifted to the following preferred second line regimen:
      i. From NRTI: TDF or ABC + 3TC to NRTI: AZT + 3TC
      ii. From NRTI: AZT + 3TC to NRTI: TDF or ABC + 3TC
      iii. From 2 NRTI + DTG to 2 NRTI + LPV/r
      iv. From 2 NRTI + NNRTI or PI to 2 NRTI + DTG (using optimal formulations)

8. Infants born to HIV-infected mothers shall be given ARV prophylaxis at birth or when HIV exposure is recognized postpartum. *(Please see Annex F. Simplified Infant Prophylaxis Dosing Recommendations)*
   a. Infants of mothers who received ART in pregnancy for at least 4 weeks and are breastfeeding or on replacement feeding shall be given daily NVP for 6 weeks.
   b. Infants born to mothers with HIV who are at high risk of acquiring HIV whether on breastfeeding or replacement feeding shall be given dual prophylaxis with AZT twice daily and NVP once daily for the first 6 weeks of life.
   c. Breastfed infants who are at high risk of acquiring HIV, including those first identified as exposed to HIV during the postpartum period, shall continue infant prophylaxis for an additional 6 weeks (total of 12 weeks of infant prophylaxis) using either AZT twice daily and NVP once daily or NVP alone.
   d. If the mother is known to be not virally suppressed, extend infant prophylaxis beyond 12 weeks.

e. Early infant prophylaxis shall be started within 6-12 hours postpartum or the soonest time if potential exposure was detected late. In the absence of timely early infant diagnosis, if the infant is considered as high-risk exposure for HIV, with high clinical index of suspicion of HIV infection, and pending definitive diagnosis, AZT or (ABC) + 3TC + NVP shall be initiated.

9. The presence of HIV infection in infants and children less than 18 months old shall be established following the existing early infant diagnosis algorithm.

10. Managing co-infections shall be as follows:
    a. HIV and TB co-infection
        i. Prompt initiation of TB treatment is essential to improve survival of patients. TB management shall be based on the latest National TB Control Program Policies and Guidelines. (Please refer to NTP MOP, 6th edition through https://doh.gov.ph/sites/default/files/publications/NTP_MOP_6th_Edition.pdf.
        ii. Early identification of tuberculosis among PLHIV shall be done through careful assessment of signs and symptoms (fever, cough, night sweats, weight loss) at every visit and by doing chest X-ray upon diagnosis of HIV and at least annually. GeneXpert shall be done anytime a patient has TB signs and symptoms or chest X-ray findings suggestive of TB.
        iii. ART shall be started as soon as possible from initiating TB treatment, regardless of CD4 count, except when signs and symptoms of meningitis are present. For patients with TB meningitis, initiate ART after completion of the intensive phase of TB treatment.
        iv. Patients shall be monitored closely for side effects of both TB and HIV treatment.
        v. Switching of regimen shall be considered for patients already on ART who are diagnosed with TB because of possible drug interaction with TB medication (i.e. Rifampicin).
        vi. Infants and children receiving DTG-based regimens should continue their ART regimen using a twice daily dose of DTG for the duration of TB treatment. In children receiving an LPV/r-containing regimen, LPV/r should be super-boosted to achieve a 1:1 ratio between LPV and ritonavir (RTV). A heat-stable tablet of 25 mg of RTV may be used for super-boosting where available. Alternatively, children may use an efavirenz (EFV)-based regimen or nevirapine-containing regimen for the duration of TB treatment and should return to using LPV/r once TB treatment has been completed.
        vii. PLHIV who do not have active TB shall be given TB preventive treatment following the national guidelines.

viii. The HACT physician shall closely coordinate with the TB-treating physician to ensure safety and effectiveness of the HIV / TB management.

b. HIV and Hepatitis B and C co-infection
   i. The risk of HBV and HCV infection is higher among PLHIV, therefore all people infected with HIV shall be screened for Hepatitis B surface antigen (HBsAg) (and offered HBV vaccination if non-immune) and HCV.
   ii. Viral hepatitis is an increasing cause of morbidity and mortality among PLHIV. A comprehensive approach includes prevention, diagnosis, and treatment and care of patients with HIV co-infected with Hepatitis B and/or Hepatitis C.
   iii. Treatment of Hepatitis B and C shall be based on current treatment guidelines. *(Please refer to DC 2017-0273 : National HIV, AIDS and STI Prevention and Control Program Recommendation for Testing, Diagnosis, and Treatment of Chronic Hepatitis C Among People Living with Human Immunodeficiency Virus (PLHIV) through https://bit.ly/3KBpZbqand DM 2020-0532: Revised Interim Guideline on the Management of Hepatitis B infection through https://bit.ly/3kCipTd.)*
   iv. All PLHIV with hepatitis co-infection shall be followed up more closely because of the risk of drug-related interactions of some ARV with anti-HCV drugs *(Please see Annex B.)*
   v. Co-infection with Hepatitis B should be treated with a Tenofovir-based regimen provided that there is no contraindication to TDF. TDF should continue even for those who shifted to second-line ART.

c. HIV and Other Opportunistic Infections
   i. The risk of occurrence of opportunistic infections (OIs) among PLHIV is higher for those with severe immunosuppression. Multiple OIs can present in persons with severely depressed CD4 counts.
   ii. Initiate ART 4-6 weeks after starting anti-fungal medications for PLHIV with cryptococcal meningitis.
   iii. Initiate ART after at least 14-21 days of ganciclovir/valganciclovir for PLHIV with CMV retinitis.
   iv. Further details on prevention and management of OIs are indicated in DM 2020-0338: Adoption of PSMID Clinical Practice Guidelines on the Prevention, Diagnosis and Treatment of Opportunistic Infections in Human Immunodeficiency Virus Infected Adults and Adolescents in the Philippines which can be accessed through https://tinyurl.*com/HIV-OIs*.

11. Monitoring and Evaluation *(Please See Annex G: National Program Indicators on HIV and ART treatment).*
    a. All HIV treatment facilities shall maintain and update patient records and report and adhere to existing recording and reporting processes and timelines.

b. Confidentiality of records and reports shall be ensured.

VII. ROLES AND RESPONSIBILITIES

A. Disease Prevention and Control Bureau (DPCB) shall:

1. Coordinate with the Philippine National AIDS Council (PNAC) for strengthened collaboration with government and civil society organizations in the implementation of HIV service delivery and monitoring and evaluation, as well as resource mobilization.

2. Convene the HIV technical working group (TWG) to review annually this guideline through consultation with clinicians, and representatives from HIV treatment facilities and PLHIV community;

3. Forecast centrally ARV needs of PLHIV and ensure timely procurement and distribution of ARV to treatment hubs in coordination with DOH-Procurement Service;

4. Receive and manage donated ARV drugs for PLHIV.

5. Ensure provision of references and capability-building activities such as clinical management trainings related to the implementation of these guidelines;

6. Ensure that ARV to be procured by the DOH are included in the Philippine National Formulary.

B. Centers for Health Development (CHD) shall:

1. Disseminate these guidelines and related materials to DOH HIV treatment facilities, other public and private health facilities, and regional and local chapters of professional medical societies;

2. Organize trainings on the clinical management of HIV infection for HIV/AIDS Core Team (HACT) in coordination with DPCB;

3. Strengthen the health care provider network among HIV treatment facilities including partners from local government units, private clinics, other government agencies, non-government or community-based organizations, and support groups within the region to ensure differentiated service delivery of HIV services.

4. Conduct regular coordination and monitoring activities among DOH designated HIV treatment facilities.

5. Ensure that HIV treatment facilities utilize One HIV, AIDS, and STI Information System (OHASIS) for recording and reporting of HIV services.

6. Augment the ARV supply as necessary.

C. HIV Treatment Facility through its HIV AIDS Core Team (HACT) shall:

1. Provide treatment and clinical monitoring of PLHIV, based on the most recent DOH guidelines;

2. Provide technical assistance to other health facilities and community-based organizations in need of trainings on the clinical management of HIV infection;

3. Monitor stock status of ARV to ensure uninterrupted supply.

4. Provide person-centered approach or differentiated service delivery of HIV services, including ARV drugs.

5. Submit monthly reports to DPCB, EB and DOH-CHD.

D. Epidemiology Bureau (EB) shall:

1. Conduct systematic data collection and analysis with Infectious Disease Office for Prevention and Control Division (IDPCD), DOH-CHD and partners;

2. Provide technical assistance to programs to enhance and standardize recording and reporting forms and management of data;

3. Analyze and disseminate reliable and timely information on NASPCP performance indicators.

E. Philippine National AIDS Council (PNAC) shall:

1. Monitor programs and activities related to the implementation of Republic Act 11166 and this guideline.

F. STD/AIDS Central Cooperative Laboratory (SACCL) shall:

1. Continue updating and issue evidence-based HIV testing algorithm for general and key population;

2. Establish the quality assurance system for CD4 and viral load testing.

G. Research Institute for Tropical Medicine (RITM) shall:

1. Work in coordination with HIV treatment facilities to conduct viral load assays and drug resistance testing of PLHIV as recommended in these guidelines.

H. Philippine Health Insurance Corporation (PHIC) shall:

1. Implement updated Outpatient HIV/AIDS treatment (OHAT) package based on this guideline;

2. Review inpatient and OHAT packages to ensure sustainable treatment for PLHIV.

3. Civil Society Organizations / Community Based Organizations are encouraged to:

4. Work in coordination with the members of the HACT in the HIV treatment facilities in providing care and support for PLHIV;

5. Conduct operations research/demonstration projects on the community-access of ARV in coordination with HIV treatment facilities;

6. Implement community-based ARV adherence programs through face-to-face or virtual platforms.

I. Local Government Units are encouraged to:

1. Work in coordination with the members of the HACT in the HIV treatment facilities in providing treatment, care and support for PLHIV;

2. Support CHDs in establishing HIV and AIDS Core team (HACT) in every district municipality /city hospital / provincial hospital to ensure provision of HIV and AIDS service delivery in their locality;

3. Support their local health personnel to undertake continuous skills and competency updating to further enhance and advance quality HIV and AIDS service delivery;

4. Ensure functional and efficient referral system among contiguous LGU and national hospitals for PLHIV.

5. Allocate funds for provision of HIV services for PLHIV.

J. World Health Organization and other Bi-lateral Partners are encouraged to:

1. Provide technical support in ensuring the implementation of this guideline.

VIII. SEPARABILITY CLAUSE

If any clause, sentence, or provision of this Order shall be declared invalid or unconstitutional, the other provisions unaffected thereby shall remain valid and effective.

VIII. IX. REPEALING CLAUSE

The Administrative Order (AO) 2018-0024 or Revised Policies and Guidelines on the Use of Antiretroviral Therapy (ART) Among People Living with Human Immunodeficiency Virus (HIV) and HIV-exposed Infants and all other issuances, rules and regulations inconsistent with or contrary to the provisions of this AO are hereby repealed, amended or modified accordingly.

IX. X. EFFECTIVITY CLAUSE

This Order shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines Law Center.

for **FRANCISCO T. DUQUE III, MD, MSc**
Secretary of Health

JUN 3 0 2022

Annex A. Antiretroviral Drugs and Doses, Instructions on Administration, and Major Types of Toxicities

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTI)					
Abacavir (ABC) Tablet: 300 mg	**Target dose:** **Child** 3 months to 16 years, 8 mg/kg twice daily (maximum 300 mg twice daily) in combination with other antiretroviral agents **Adult,** 300 mg twice daily or 600 mg once daily in combination with other antiretroviral agents	May be administered with or without food	Serious and sometimes fatal hypersensitivity reactions. Lactic acidosis and severe hepatomegaly with steatosis Fat redistribution	Hepatic impairment.	Stop permanently if hypersensitivity reaction occurs Mild hepatic dysfunction, reduce dose to 200 mg twice daily Moderate to severe hepatic dysfunction – DO NOT use
Lamivudine (3TC) 100 mg and 150 mg tablet/film-coated tablet 10 mg/ml suspension 240 ml bottle	ADULT, oral dose of 150 mg twice daily or 300 mg once daily. CHILD, 1-3 months, 4 mg/kg/dose twice daily. 3 months to 16 years, 4 mg/kg/dose twice daily	Administer orally with no regard to meals	Precautions: Lactic acidosis and severe hepatomegaly with steatosis Use with caution in patients with renal impairment		Dose reduction recommended

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Tenofovir (TDF) Tablet: 300 mg	Target dose: 8 mg/kg or 200 mg/m2 (maximum of 300 mg) <u>Child:</u> 14-19.9 kg: 150 mg once daily 20-29.9 kg: 200 mg once daily 30-34.9 kg: 300 mg once daily <u>Adolescent/Adult:</u> 300 mg once daily	Take without regard to meals	Chronic kidney disease Acute kidney injury Fanconi syndrome	Underlying renal disease Older than 50 years of age; BMI < 18.5 or low body weight (<50kg) notably in females Untreated diabetes Untreated hypertension Concomitant use of nephrotoxic drugs or a boosted PI	Substitute with AZT or ABC Do not initiate TDF at estimated glomerular filtration rate (eGFR) < 50 mL/min, uncontrolled hypertension, untreated diabetes, or presence of renal failure
			Decrease in bone mineral density	History of osteomalacia (in adults) and rickets (in children) and pathological fracture Risk factors for osteoporosis or bone density loss Vitamin D deficiency	
			Lactic acidosis or severe hepatomegaly with steatosis	Prolonged exposure to nucleoside analogues Obesity Liver disease	

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Zidovudine (AZT) Capsule: 100 mg Tablet: 300 mg (60 per bottle) Suspension: 50 mg/5 ml (10 mg/ml) (240 ml bottle)	**Target dose:** 180-240 mg/m^2 every 12 hours or 160 mg/m^2/dose every 8 hours (up to a maximum dose of 200 mg every 8 hours) **ARV prophylaxis dose for HIV-exposed infants**: Oral target dose 4 mg/kg every 12 hours starting within 12 hours after birth and continuing up to 6 weeks of age, following national recommendations **Adult,** 200 mg three times daily or 300 mg twice daily	Take orally without regard to meals	Use with caution in patients with renal impairment and in patients with anaemia Haematologic toxicity Lactic acidosis Severe hepatomegaly		CrCl <15mL/minute: 100mg every 6-8 hours, alternate dosing: 100mg 3 times a day or 300 mg once a day; End-Stage Renal Disease on Intermittent Hemodialysis (admin dose after dialysis on dialysis days): 100mg every 6-8 hours, alternate dosing: 100mg 3 times a day or 300mg/day. Peritoneal Dialysis: 100mg every 6-8 hours

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTI)					
Efavirenz (EFV) Syrup: 30 mg/ml (Note: syrup requires a higher dosage than capsules) Tablet: 600 mg	**Child:** Capsule (liquid) dose: 10-15 kg: 200 mg (270 mg = 9 ml) once daily 15-<20kg: 250 mg (300 mg = 10ml) once daily 20-<25 kg: 300 mg (360 mg = 12 ml) once daily 25-<33 kg: 350 mg (450 = 15 ml) once daily 33-<40 kg: 400 mg (510 mg = 17 ml) once daily Max dose: >40 kg: 600 mg once daily **Adolescent/Adult:** 600 mg daily	Take on an empty stomach and before bedtime as severe dizziness is possible upon initiation of therapy that resolves or becomes tolerable after a few days	Severe skin and hypersensitivity reactions	Risk factor(s) unknown	For central nervous system (CNS) symptoms, dose at night time. Consider using EFV at a lower dose (400 mg/day) substitute with NVP or integrase inhibitor (DTG) if EFV 400 mg is not effective in reducing symptoms. For severe hepatotoxicity or hypersensitivity reactions, substitute with another therapeutic class (integrase inhibitors or boosted PIs)
			Hepatotoxicity	Underlying hepatic disease – hepatitis B virus (HBV) and hepatitis C virus (HCV) coinfection; Concomitant use of hepatotoxic drugs	
			Convulsions	History of seizures	
			Persistent central nervous system toxicity (such as abnormal dreams, depression or mental confusion, anxiety)	Depression or other mental disorder (previous or at baseline) Daytime dosing	
			Gynecomastia	Risk factor(s) unknown	Substitute with NVP or another therapeutic class (integrase inhibitors or boosted PI)

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Nevirapine (NVP) Oral Soln: 10 mg/ml Tablet: 200 mg	**<u>Infant/Child:</u>** 15-30 days: 5 mg/kg/dose once daily for 2 weeks, then 120 mg/m2/dose twice daily for 2 weeks, then 200mg/m2/dose twice daily >30 days to 13 years: 120 mg/m2/dose once daily for 2 weeks, then 120-200 mg/dose twice daily **Adolescent/Adult:** As severe hypersensitivity may develop during initiation, trial period should be done by giving **200 mg once daily for 14 days** together with full dose of NRTI. If there is no sign of hypersensitivity, then give full dose at 200 mg every 12 hours	- Take without regard to meals - Not recommended to be co-administered with rifampicin - Tablets are scored and can be divided into two equal halves to give a 100 mg dose; can be crushed and combined with a small amount of water or food and immediately administered - If mild/moderate rash develops, hold drugs; when rash clears, restart dosing from beginning of dose escalation; if severe rash, discontinue drug	**STOP** if any one is observed: 1. Fever or feverish sensation 2. Flu-like symptoms such as muscle or body pains Hepatoxicity Severe skin rash and hypersensitivity reaction (Stevens-Johnsons Syndrome)	Underlying hepatic disease hepatitis B virus (HBV) and hepatitis C virus (HCV) coinfection Concomitant use of hepatotoxic drugs High baseline CD4 cell count (CD4 > 250 cells/mm3 in women; CD4>400 cells/mm3 for men)	If hepatotoxicity is mild consider substitution with EFV, including in children 3 years and older. For severe hepatoxicity, and hypersensitivity and in children under the age of 3 years, substitute with another therapeutic class (boosted PIs)

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Rilpivirine (RPV) 25mg/tablet	**Adults/Adolescents (non-pregnant):** 25 mg tablet once daily	Take one tablet orally with meal. Not recommended to be co-administered with rifampicin Not to be taken with antacids, histamine 2 blockers or proton pump inhibitors.	Skin and Hypersensitivity Reactions: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), with Rilpivirine. Depressive Disorders Most common adverse drug reactions (incidence > 2%) of at least moderate to severe intensity (> Grade 2) Hepatotoxicity	Reported in patients with underlying liver disease, including hepatitis B or C co-infection, or in patients with elevated baseline transaminases.	Discontinue treatment if hypersensitivity or rash with systemic symptoms or elevations in hepatic serum biochemistries develop and closely monitor patient. Contact your doctor right away if you experience any mental or mood changes (eg, depressed mood, unusual negative thoughts, anxiety, restlessness). Also consider monitoring liver functions tests

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
PROTEASE INHIBITORS (PI)					
Lopinavir/ ritonavir (LPV/r) Tablet: Lopinavir 200mg/ Ritonavir 50 mg Oral Soln: 80 mg/ml Lopinavir plus 20 mg/ml Ritonavir (Note: oral solution contains 42% alcohol)	**Infant/Child:** >6 months to 13 years: 225 mg/m^2 LPV/ 57.5 mg/m^2 Ritonavir twice daily or weight-based dosages 7-15 kg: 12mg/kg LPV / 3 mg/kg Ritonavir/dose twice daily 15-40 kg: 10 mg/kg LPV / 5 mg/kg Ritonavir twice daily Max dose: >40kg: 400 LPV/100 mg Ritonavir (3 capsules or 5ml) **Adult:** 2 tablets every 12 hours	Take without regard to meal Not recommended to be co-administered with rifampicin	Diarrhea		Substitute with DRV/r
			Hepatotoxicity	Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs	If LPV/r is used in first-line ART for children, substitute with NVP for children younger than 3 years and EFV for children 3 years and older. If LPV/r is used in second line ART for adults, and the person has treatment failure with NNRTI in first-line ART, consider integrase inhibitors
			Pancreatitis	Advanced HIV disease, alcohol misuse	
			QT interval prolongation	Congenital long QT syndrome Hypokalemia Concomitant use of drugs that may prolong the QT interval	
			Electrocardiographic abnormalities (PR and QT interval prolongation, *torsades de pointes*)	People with pre-existing conduction system disease Concomitant use of other drugs that may prolong the PR or QRS intervals Congenital long QT syndrome Hypokalaemia	Use with caution in people with pre-existing conduction disease or those on concomitant drugs that may prolong the PR or QRS intervals
			Dyslipidemia	Cardiovascular risk factors such as obesity and diabetes	Substitute with another therapeutic class (integrase inhibitor)

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
INTEGRASE INHIBITORS					
Dolutegravir 10 mg 25 mg 50 mg tablets	**Adults:** 50 mg orally once daily **Adults with TB/HIV coinfection:** 50 mg orally twice daily **Children 4 WEEKS or older:*** DTG 5 mg dispersible tablets or DTG 10 mg scored dispersible tablets: 3kg to <6kg = 10mg once daily 6kg to <10kg = 15mg once daily 10 kg to <15kg = 20 mg once daily 15kg to <20kg = 25 mg once daily DTG 50 mg film-coated tablets: ≥20 kg = 50 mg once daily **Children with TB/HIV coinfection:** Twice daily dosage	Oral administration with or without food Take at least 2 hours before or 6 hours after taking products containing aluminum or magnesium (such as antacids, laxatives, buffered medications), calcium or iron supplements (including vitamins/ minerals that contain calcium or iron). Do not co-administer with Phenytoin and Phenobarbital. 50 mg/tab twice daily for patients taking Rifampicin or Carbamazepine	Allergic reactions Pre-conception, first trimester of pregnancy		Women should be provided with information about benefits and risks to make an informed choice regarding the use of DTG or other ART**

* Considerations for introducing new antiretroviral drug formulations for children: policy brief July 2020 https://www.who.int/publications/i/item/9789240007888

** Update of recommendations on first- and second-line antiretroviral regimens. Geneva, Switzerland: World Health Organization; 2019 https://www.who.int/hiv/pub/arv/arv-update-2019-policy/en /

Computation of Body Surface Area:

$$\text{BSA } (m^2) = \sqrt{\frac{\text{Ht (Cm)} \times \text{Wt (kg)}}{3600}}$$

Annex B. Key ARV drug interactions and suggested management

ARV drug	Key interactions	Suggested Management
Abacavir (ABC)	No major interactions reported	
Dolutegravir (DTG)	Rifampicin	DTG dose adjustment needed to twice daily dosage, 50 mg bid
	Carbamazepine, Phenobarbital, Phenytoin	Dose adjustment likely to be needed, 50 mg bd. (not studied)
	Mg-containing antacids, multivitamins, iron or calcium supplements	Dolutegravir should be administered 2 hours before or 6 hours after taking medications containing polyvalent cations, such as antacids, multivitamins, iron or calcium supplements
	Metformin	Dose adjustment of metformin may be needed (levels may increase with DTG)
	St John's Wort	Dose adjustment expected to be needed to 50 mg bd
Efavirenz (EFV)	Amodiaquine	Use an alternative antimalarial agent
	Methadone	Adjust the methadone dose as appropriate
	Hormonal contraceptives	Use alternative or additional contraceptive methods to prevent HIV transmission and unintended pregnancies, as EFV may lower efficacy of some long-acting hormonal contraceptives
	Astemizole and Terfenadine	Contraindicated: Use an alternative anti-histamine agent
	Ergotamine, dihydroergotamine	Do not coadminister
	Midazolam, triazolam	Do not coadminister
	St John's Wort	Do not coadminister
Lamivudine	Trimethoprim (decreases excretion of lamivudine)	Monitor closely
	Ganciclovir, Valganciclovir, Ribavirin	Enhanced risk of adverse or toxic effects of Lamivudine. Do not prescribe together

ARV drug	Key interactions	Suggested Management
Boosted PI Lopinavir/ ritonavir (LPV/r)	Rifampicin	Substitute Rifampicin with Rifabutin; Adjust the dose of LPV/r or substitute with 3 NRTIs (for children)
	Lovastatin and Simvastatin	Use an alternative cholesterol-lowering agent
	Hormonal contraceptives	Use alternative or additional contraceptive methods
	Methadone and Buprenorphine	Adjust methadone and bruprenorphine doses as appropriate
	Astemizole and Terfenadine	Contraindicated: Use alternative antihistamine agent
	Omeprazole	Use an alternative proton pump inhibitor
	Amiodarone, lidocaine	Use an alternative anti-arrhythmic
	Ergotamine, dihydroergotamine	Do not coadminister
	Midazolam, triazolam	Do not coadminister
	St John's Wort	Do not coadminister
	TDF	Monitor renal function
	Likely or potential interactions with Boosted PI requiring dose adjustments/monitoring: 1. Some anti-malarials 2. Some anti-fungals (Ketoconazole, Itraconazole) 3. Anti-psychotics (**contraindicated: Fluphenazine, also for EFV**) 4. Anticonvulsants 5. Recreational drugs with potential interactions with PI: a. Cocaine s b. GHB c. Methamphetamine d. Ecstasy e. Mephedrone f. Ketamine g. Sildenafil (contraindicated) h. Diazepam i. Fentanyl 6. Antidepressants (Fluoxetine, amitriptyline) 7. Gliclazide 8. Dexamethasone *Reference: Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach– 2nd ed. 2016 Annex 13: https://www.who.int/hiv/pub/arv/arv-2016/en/*	

ARV drug	Key interactions	Suggested Management
Nevirapine (NVP)	Rifampicin	Substitute NVP with EFV
	Itraconazole and Ketoconazole	Use an alternative antifungal agent
	Astemizole and Terfenadine	Contraindicated: Use alternative antihistamine agent
	Dihydroergotamine	Do not coadminister
	Phenobarbitone	Do not coadminister
	St John's Wort	Do not coadminister
Rilpivirine (RPV)	Rifampicin	Do not coadminister
	Omeprazole	Do not coadminister
	Dexamethasone	Do not coadminister
	Antacids (e.g., aluminum or magnesium hydroxide, calcium carbonate)	The combination of Rilpivirine and antacids should be used with caution as co-administration may cause significant decreases in Rilpivirine plasma concentrations (increase in gastric pH). Antacids should only be administered either at least 2 hours before or at least 4 hours after Rilpivirine.
	H2-Receptor Antagonists: Cimetidine Famotidine Nizatidine Ranitidine	The combination of Rilpivirine and H2-receptor antagonists should be used with caution as co-administration may cause significant decreases in Rilpivirine plasma concentrations (increase in gastric pH). H2-receptor antagonists should only be administered at least 12 hours before or at least 4 hours after Rilpivirine.
	Macrolide or ketolide antibiotics: Clarithromycin Erythromycin Telithromycin	Concomitant use of Rilpivirine with Clarithromycin, Erythromycin or Telithromycin may cause an increase in the plasma concentrations of Rilpivirine (inhibition of CYP3A enzymes). Where possible, alternatives such as Azithromycin should be considered.
	Antifungal Agents: Fluconazole Itraconazole Ketoconazole Posaconazole Voriconazole	Concomitant use of Rilpivirine with azole antifungal agents may cause an increase in the plasma concentrations of Rilpivirine (inhibition of CYP3A enzymes). No Rilpivirine dose adjustment is required when Rilpivirine is co-administered with azole antifungal agents. Clinically monitor for breakthrough fungal infections.
	Carbamazepine, Phenobarbital, Phenytoin	Do not coadminister
	St John's Wort	Do not coadminister
	Note: Rifampicin, Omeprazole and other proton-pump inhibitors, systemic dexamethasone (except single dose) may decrease RPV plasma concentration	

ARV drug	Key interactions	Suggested Management
Tenofovir	Daclatasvir, Sofosbuvir/Velpatasvir (Increases the level or effect of Tenofovir)	Monitor closely Note that these ARVs are not commonly used in the Philippines
Zidovudine (AZT)	Ribavirin and pegylated interferon alpha-2a	substitute AZT with TDF

Sources:

1. Philippines National Formulary, 8th edition, 2019
2. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed. 2016 Annex 13: https://www.who.int/hiv/pub/arv/arv-2016/en/
3. University of Liverpool, HIV drug interactions checker https://www.hiv-druginteractions.org/checker
4. Liverpool HIV iChart Apps:
   App store: https://apps.apple.com/gb/app/liverpool-hiv-ichart/id979962744
   Google play:
   https://play.google.com/store/apps/details?id=com.liverpooluni.icharthiv&hl=en_GB

Annex C. WHO Clinical Staging of HIV Disease in adults, adolescents and children

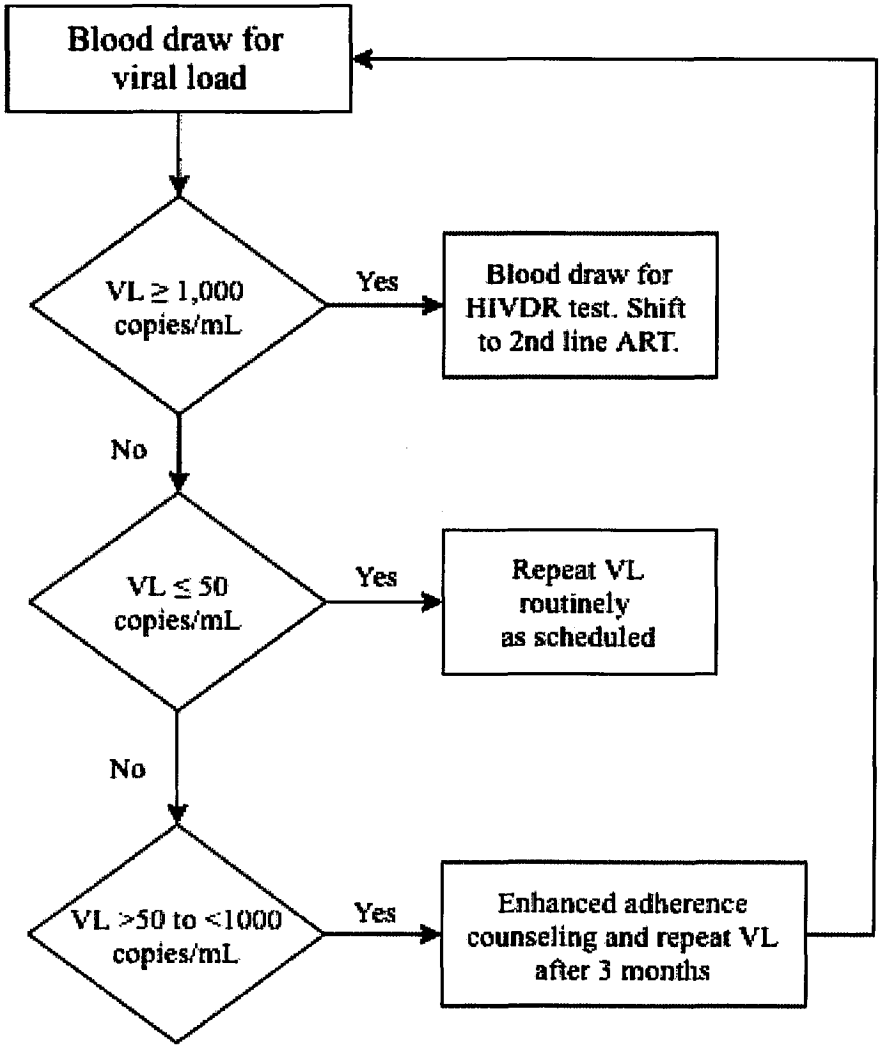
Adults and adolescents [a]	**Children**
Clinical Stage 1	
Asymptomatic Persistent generalized lymphadenopathy	Asymptomatic Persistent generalized lymphadenopathy
Clinical Stage 2	
Moderate unexplained weight loss (<10% of presumed or measured body weight) Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media, pharyngitis) Herpes zoster Angular cheilitis Recurrent oral ulceration Papular pruritic eruption Fungal nail infections Seborrhoeic dermatitis	Unexplained persistent hepatosplenomegaly Recurrent or chronic upper respiratory tract infections (otitis media, otorrhoea, sinusitis, tonsillitis) Herpes zoster Lineal gingival erythema Recurrent oral ulceration Papular pruritic eruption Fungal nail infections Extensive wart virus infection Extensive molluscum contagiosum Unexplained persistent parotid enlargement
Clinical Stage 3	
Unexplained severe weight loss (>10% of presumed or measured body weight) Unexplained chronic diarrhea for longer than 1 month Unexplained persistent fever (intermittent or constant for longer than 1 month) Persistent oral candidiasis Oral hairy leukoplakia Pulmonary tuberculosis Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteremia) Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis Unexplained anemia (<8 g/dl), neutropenia (<0.5 x 10^9/l) and/or chronic thrombocytopenia (<50 x 10^9/l)	Unexplained moderate malnutrition not adequately responding to standard therapy Unexplained persistent diarrhea (14 days or more) Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than one month) Persistent oral candidiasis (after first 6 weeks of life) Oral hairy leukoplakia Lymph node tuberculosis Pulmonary tuberculosis Severe recurrent bacterial pneumonia Acute necrotizing ulcerative gingivitis or periodontitis Unexplained anemia (<8 g/dl), neutropenia (<50 x 10^9/l) or chronic thrombocytopenia (<0.5 x 10^9/l) Symptomatic lymphoid interstitial pneumonitis Chronic HIV-associated lung disease, including bronchiectasis

Adults and adolescents	Children
Clinical Stage 4	
HIV wasting syndrome Pneumocystis (jirovecii) pneumonia Recurrent severe bacterial pneumonia Chronic herpes simplex infection (orolabial, genital or anorectal of more than 1 month duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs) Central nervous system toxoplasmosis HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis Chronic isosporiasis Disseminated mycosis (extrapulmonary histoplasmosis, coccidioidomycosis) Lymphoma (cerebral or B-cell non-Hodgkin) Symptomatic HIV-associated nephropathy or cardiomyopathy Recurrent septicaemia (including Nontyphoidal Salmonella) Invasive cervical carcinoma Atypical disseminated leishmaniasis	Unexplained severe wasting, stunting or severe malnutrition not responding to standard therapy Pneumocystis (jirovecii) pneumonia Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia) Chronic herpes simplex infection (orolabial or cutaneous of more than 1 month duration or visceral at any site) Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs) Extrapulmonary tuberculosis Kaposi sarcoma Cytomegalovirus infection (retinitis or infection of other organs with onset at age more than 1 month) Central nervous system toxoplasmosis (after the neonatal period) HIV encephalopathy Extrapulmonary cryptococcosis, including meningitis Disseminated nontuberculous mycobacterial infection Progressive multifocal leukoencephalopathy Chronic cryptosporidiosis (with diarrhea) Chronic isosporiasis Disseminated endemic mycosis (extrapulmonary histoplasmosis, coccidioidomycosis, penicilliosis) Cerebral or B-cell non-Hodgkin lymphoma HIV-associated nephropathy or cardiomyopathy

[a] In the development of this table, adolescents were defined as 15 years or older. For those aged less than 15 years, the clinical staging for children shall be used.

Source:
Adapted from WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children. Geneva, World Health Organization, 2007 *(www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf)*

Annex D: Interpretation of Viral Load Test



Annex E. Cockcroft-Gault (C-G) Formula

Formula to predict creatinine clearance from serum creatinine:*

Male: Creatinine clearance = $\frac{(140\text{-age}) \times \text{body weight (kg)}}{\text{Serum creatinine (mg/100ml)} \times 72}$

Female: Creatinine clearance = $\frac{(140\text{-age}) \times \text{body weight (kg)}}{\text{Serum creatinine (mg/100ml)} \times 72}$

Reference to online calculator: *https://qxmd.com/calculate/calculator_51/crcl-cockroft-gault)*

*Cockcroft DW, Gault MH. Prediction of creatinine clearance from serum creatinine. *Nephron.* 1976;**16**(1):31–41. doi: 10.1159/000180580. [PubMed] [CrossRef] [Google Scholar]

Annex F. Simplified Infant Prophylaxis Dosing Recommendations

Infant Age	Dosing of NVP	Dosing of AZT
Birth to 6 weeks		
Birth weight 2000–2499 g*	10 mg once daily (1 ml of syrup once daily)	10 mg twice daily (1 ml of syrup twice daily)
Birth weight ≥ 2500 g	15 mg once daily (1.5 ml of syrup once daily)	15 mg twice daily (1.5 ml of syrup twice daily)
>6 weeks to 12 weeks	20 mg once daily (2 ml of syrup once daily or half a 50 mg tablet once daily)	No dose established for prophylaxis; use treatment dose 60 mg twice daily 6 ml of syrup twice daily or a 60 mg tablet twice daily)

* For infants weighing < 2000 g and older than 35 weeks of gestational age, the suggested doses are NVP 2 mg/kg/dose once daily and AZT 4 mg/kg per dose twice daily. Premature infants younger than 35 weeks of gestational age should be dosed using expert guidance

Source:

Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach – 2nd ed. 2016 *https://www.who.int/hiv/pub/arv/arv-2016/en/*

Annex G. Program Indicators for HIV and ART treatment

Indicator	Numerator (N) / Denominator (D)	Relevance to cascade	Disaggregation	Sources and issues	Frequency of reporting
ART initiation	N: Number of PLHIV who are started on ART D: Total number of PLHIV diagnosed during the reporting period		Sex, age, key population, first or second regimen, location, pregnancy or breastfeeding, newly diagnosed & old	EB Form B	Monthly
Currently on ART Number and % of people living with HIV who are receiving ART	N: Number of people living with HIV who are currently receiving ART D: Number of PLHIV diagnosed during the reporting period	Measures the extent to which needs for ART are met	Sex, age, key population, first or second regimen, location (hub) , pregnancy or breastfeeding	The numerator is based on program statistics; the denominator is usually estimated using an internationally consistent model	Monthly
ART retention Percentage of people living with HIV who are on ART 12 and 24 months after Initiation	N: Number of ART patients alive and on ART at 12 and 24 months after initiating ART D: Number of patients initiating ART up to 12 and 24 months before the beginning of the reporting year. This includes those who died since starting therapy, those who have stopped therapy and those lost to follow-up as of month 12 and 24 mos. This excludes people who have permanently migrated out of the country.	Once on ART, treatment is lifelong. Retention on ART is important to achieve the desired outcomes of the HIV care cascade.	Sex, age, pregnancy or breastfeeding at initiation;	Follows cohorts of people living with HIV initiating ART. Systematic analysis of those lost to follow-up is required to determine true outcomes, including mortality patterns.	Annual
Lost to Follow-up Percentage of PLHIV on ART who are lost to follow-up	N: Number of PLHIV who failed to access HIV care services 30 days (1 month) from the last expected date of consult or expected day of last (run-out) pill D: Total number of PLHIV on ART accessing HIV treatment facilities during the reporting period; excludes people who have died		Sex, age, key population, first or second regimen, location (hub), pregnancy or breastfeeding		Monthly

Indicator	Numerator (N) / Denominator (D)	Relevance to cascade	Disaggregation	Sources and issues	Frequency of reporting
Viral suppression Percentage of people living with HIV who have suppressed viral load 12 months after ART initiation Population-level denominator: Number of people on ART in the past 12 months Program-based denominator: Number of people on ART who had a viral load measurement in the past 12 months	N: Number of people living with HIV on ART who have suppressed viral load (VL ≤ 50 copies/mL) 12 months after ART initiation D: Total number of PLHIV tested for viral load 12 months after ART initiation	Gauges the proportion of people on ART who have suppressed viral load. A large proportion with suppressed viral load implies a low rate of onward transmission. Viral load suppression among a cohort 12 months after ART initiation should also be monitored	Sex, age, key population location	Provides a cross-sectional view of viral load suppression among people on ART. Can also be assessed by time since initiation of ART, as a cohort. Suppressed viral load is defined as <1000 copies/ml.	Quarterly (Monthly pending)
TB incidence in HIV care Percentage of PLHIV with incident TB	N: number of PLHIV diagnosed with TB D: Total number of PLHIV accessing Treatment hubs or primary HIV care clinics for TB during the reporting period	Measures the burden of active TB disease among people living with HIV who are newly enrolled in HIV care. Early detection of TB among people living with HIV enables prompt TB treatment and early ART. This indicator also measures indirectly the extent of efforts to detect HIV-associated TB.		HIV/AIDS and ART Registry (HARP) Form B and C	Monthly
ART Coverage during TB treatment Percentage of PLHIV with incident TB who received treatment for both TB and HIV	N1: Number of PLHIV with active TB started on TB treatment D1: Total number of PLHIV enrolled in HIV care at Treatment Hubs or primary HIV care clinics with active TB during the reporting period N2: Number of TB patients in TB facilities who are tested for HIV D2: Total number of TB patients in TB facilities	Measures the extent to which HIV-positive TB patients receive ART during TB treatment. Both treatments are necessary to minimize mortality. High coverage indicates strong collaboration between the national HIV and TB programmes.	Disaggregate outcome/specify how many have died	**HARP Form B and C**	Monthly

Indicator	Numerator (N) / Denominator (D)	Relevance to cascade	Disaggregation	Sources and issues	Frequency of reporting
ARV Stock-out Percentage of facilities with stock-outs of antiretroviral drugs	N: Number of treatment hubs or primary HIV care clinics that had a stock-out of any ARV drugs during a reporting period D: Total number of reporting treatment hubs or primary HIV care clinics	Assesses performance of the supply chain system. At the facility level, measures ability of facilities to maintain supply of ARV drugs and avoid interruption of ART			Monthly
Early Infant diagnosis coverage Percentage of infants born to HIV+ women tested for HIV within 2 months of birth	N1: Number of HIV-exposed infants born within the past 12 months who received a virological HIV test within two months of birth. D1: Number of HIV positive women who delivered within the past 12 months (proxy measure for the number of infants born to HIV-infected women). N2: Number of infants who had a polymerase chain reaction (PCR) tests for HIV within 2 months of birth D2: Estimated number of live births to pregnant HIV-infected women during the reporting period D3: Number of HIV positive women who delivered within past 12 months	Measures early HIV diagnosis in infants, a critical first step toward early treatment. High coverage of early virological testing of infants helps initiate ART early in children with confirmed HIV infection and supports counselling on efforts to prevent seroconversion of those with a negative early test result.			Annual
Coverage of infant ARV prophylaxis Percentage of newborns of HIV+ women given ART prophylaxis	N1: Number of HIV-exposed infants born within the past 12 months who were started on ARV prophylaxis at birth. Population-based denominator: Number of HIV-positive women who delivered within the past 12 months. Facility-based denominator: Number of HIV-positive women who delivered in a facility within the past 12 months. N2: Number of infants born to HIV-infected women who received ART prophylaxis during the first 6 weeks of life D2: Number of HIV positive women who delivered within the past 12 months	Measures the effectiveness of programme efforts to reduce the risk of mother-to-child transmission (MTCT) in the immediate postpartum period		HARP	Monthly (Facility based denominator); with Population-based denominator at end of year

Indicator	Numerator (N) / Denominator (D)	Relevance to cascade	Disaggregation	Sources and issues	Frequency of reporting
Final mother-to-child transmission (MTCT) rate Percentage of HIV-exposed infants born in the past 12 months who are infected with HIV	N: Number of HIV-exposed infants born within the past 12 months who were infected with HIV D: Number of reported HIV positive women who delivered within the past 12 months .	Measures overall rate of transmission over the entire MTCT risk period. Validation criterion for the elimination of MTCT of HIV. Numerator could be used as a source to evaluate the other Elimination of mother-to-child transmission (EMTCT) validation criterion of <50 new child HIV infections per 100 000 births.		HARP Form A-MC	Monthly
Health Systems Number of Treatment Hubs	Disaggregation: % of regions with Treatment Hubs in their region % of DOH retained hospitals which are Treatment Hubs % of provincial hospitals which Treatment Hubs			Program Data	Annual
Health Systems Percentage of Treatment Hubs & primary HIV care clinics with access to CD4 testing	N: Number of Treatment Hubs and primary HIV care clinics with access to CD4 testing D: Number of Treatment Hubs and primary HIV care clinics			Program Data	Annual
Health Systems Percentage of Treatment Hubs that receive Out-patient HIV and AIDS Treatment (OHAT) package reimbursement	N: Number of Treatment Hubs that receive OHAT package reimbursement during the reporting period D: Total number of Treatment Hubs			Program Data	Annual
Health Systems Percentage of PLHIV on ART who avail OHAT package	N: Number of PLHIV on ART who avail of OHAT package D: Total number of PLHIV on ART during the reporting period			Program Data	Annual
Health Systems Percentage of PLHIV on ART in treatment hubs enrolled in PhilHealth	N: Number of PLHIV on ART enrolled in PhilHealth D: Total number of PLHIV on ART during the reporting period			Program Data	Annual