



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 24 2018

ADMINISTRATIVE ORDER

No: 2018-0024

SUBJECT: Revised Policies and Guidelines on the Use of Antiretroviral Therapy (ART) among People living with Human immunodeficiency virus (HIV) and HIV-exposed infants

I. RATIONALE

The HIV epidemic in the country continuously remains a threat to the health of Filipinos. Although the national HIV prevalence remains low at less than 1%, the dramatic rise in the number of People Living with HIV (PLHIV) in the past 10 years and increase of the number of newly diagnosed cases per day, (from 1 case per day in 2008 to 31 cases per day in 2018), are signals that steered concerted efforts to address this public health problem.

Since September 2015, countries have adopted the new Sustainable Developmental Goals (SDG) set to be achieved in 15 years. Aligned with this is the expansion of access to treatment which is the heart of the new treatment targets for 2020 with the aim of ending the AIDS epidemic as a public health threat by 2030. The 90-90-90 targets include 90% of the people living with HIV know their status, 90% of the people who know their HIV status are receiving antiretroviral therapy (ART) and 90% of the people receiving ART are virologically suppressed.

The WHO **Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection** released in June 2016 recommended that all PLHIV be provided with ART regardless of immunologic or clinical condition. Early use of ART keeps PLHIV alive and healthier. Likewise, ART helps reduce the risk of transmitting the virus to their sexual and drug-sharing partners. Strategic approaches such as “test early”, “treat early”, and “treat all” remove limitations on eligibility for ART among Filipinos living with HIV. As such, all populations and age groups are now eligible for treatment, including pregnant women and children. Understandably, this will bring us one step closer to achieving universal access to HIV treatment and care, and ending AIDS as a public health threat.

This guideline is developed to ensure safe and effective use of ART in a scale up program.

II. OBJECTIVE

General Objectives:

This Order aims to provide standards for the use of ART among adults and children infected with HIV and infants exposed to HIV in the Philippines.

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Specific objectives:

- 1) To provide an updated, evidence-based and age specific standards for physicians in the country on ART for adults and children infected with HIV and infants exposed to HIV positive mothers.
- 2) To define the roles and responsibilities of the different stakeholders in the implementation of these guidelines.

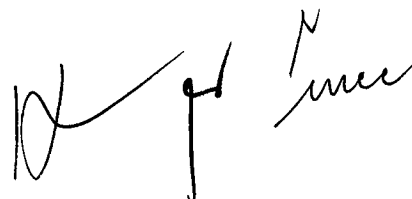
III. SCOPE AND COVERAGE

This Order covers physicians from government and private health facilities managing patients infected and have access to Department of Health (DOH) – designated treatment hubs or primary HIV care clinics. It provides guidance on initiating ART for all PLHIV, and ARV prophylaxis for infants born to HIV-infected mothers.

It sets the **minimum** requirements for initiation and monitoring of ART. Additional laboratory and/or diagnostic tests may be requested according to the discretion of the attending physician and when clinically indicated.

IV. DEFINITION OF TERMS

1. **Adherence counseling** - includes provision of information on HIV, manifestations of the disease, and benefits and side-effects of ARV drug; discussion on how the medications shall 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. **Antiretroviral (ARV) drug** - drug used in the treatment and prevention of HIV infection. Different classes of antiretroviral drugs act at different stages of HIV life cycle thereby stopping or interfering with the production of the virus in the body.
3. **Antiretroviral therapy (ART)** - refers to the use of a combination of three or more ARV drugs to achieve viral suppression. This generally refers to lifelong treatment.
4. **Confirmed HIV positive test result** - a series of reactive test results using rapid HIV diagnostic algorithm (rHIVda) by identified HIV Testing Service (HTS) sites, or Western Blot or Nucleic Amplification Test (NAT) as performed by National Reference Laboratory/San Lazaro Hospital STD AIDS Cooperative Central Laboratory (NRL/SLH SACCL) or any DOH accredited laboratories.
5. **HIV Drug Resistance (HIVDR)** – the ability of HIV to mutate and reproduce itself in the presence of antiretroviral drugs.
6. **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 health facilities. Its specific functions are described in the DOH Operating Guidelines for HIV and AIDS Core Team handbook.
7. **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 subclinical and unrecognized opportunistic pathogen or previously known treated opportunistic pathogen in a setting of adequate response to ART.
8. **Linkage to care** - a process of action and activities that would link people testing for HIV and diagnosed with HIV to appropriate treatment, care and support services.



9. **Opportunistic infections** - illnesses caused by organisms, that do not usually 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.
10. **People Living with HIV (PLHIV)** - refers to persons infected with Human Immunodeficiency Virus. With proper management and provision of ART, these individuals can continue to live well and be productive for many years.
11. **Prevention of Mother to Child Transmission (PMTCT) of HIV** – a comprehensive intervention which comprises four-pronged strategies to prevent HIV among infants and young children.
12. **Primary HIV Care Clinic** – a private or public health facility that provides out-patient primary care services to PLHIV including but not limited to HTS, clinical management, patient monitoring, and other care and support services. ARV treatment can also be accessed through these facilities.
13. **Treatment Hub** - a secondary or tertiary hospital with an established HIV/AIDS Core Team (HACT) and accredited by DOH to provide ART and whose services include but not limited to HIV Counseling and Testing, in-patient and out-patient clinical management, patient monitoring and other care and support services.
14. **Viral Load assay** - measure of HIV genetic material called RNA from virus particles called virions in the blood plasma.

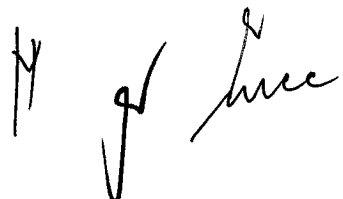
V. GENERAL GUIDELINES

1. ART shall be initiated in all persons with confirmed positive HIV test result regardless of clinical and immunologic status.
2. The timing of ART initiation in the presence of certain opportunistic infections shall be delayed to prevent adverse effects of immune reconstitution inflammatory syndrome (IRIS). These include TB or tuberculosis (2 weeks after starting TB medications), cryptococcal meningitis (5-6 weeks after starting anti-fungal medications), and cytomegalovirus (CMV) retinitis (after at least 14-21 days of ganciclovir/valganciclovir).
3. Early identification of TB among PLHIV shall be done through careful assessment of signs and symptoms (fever, cough, night sweats, weight loss) and diagnosis using cartridge-based nucleic acid amplification test for Mycobacterium tuberculosis (MTB)/ resistance to rifampicin (RIF). Prompt initiation of TB treatment is essential to improve survival of patients. TB diagnosis and management shall be based on the latest National TB Control Program Policies and Guidelines.
4. Adherence shall be assessed and reinforced every follow-up visit to prevent drug resistance and treatment failure.
5. Patients already stable on their current ART regimen shall be maintained on said regimen and monitored accordingly.
6. All HIV-exposed infants shall be given ARV prophylaxis at birth or when HIV exposure is recognized postpartum.

VI. IMPLEMENTING GUIDELINES

A. Performance of adherence counseling

The success of ARV therapy largely depends on the patient's adherence to treatment. The benefits of treatment, management of possible side effects and adherence issues are discussed during adherence counseling. A 95% adherence rate is required to prevent the development of drug resistance from ARV. Adherence counseling shall always be done prior to and while on treatment.



B. Initiation of ARV Treatment (See Annex 1: Antiretroviral Drugs and Doses, Instructions on Administration, and Major Types of Toxicities)

Table 1. List of Antiretroviral Drugs

Class of ARV	Generic Name of ARV
Nucleotide/Nucleoside Reverse Transcriptase Inhibitors (NRTI)	Tenofovir (TDF) Lamivudine (3TC) Abacavir (ABC) Zidovudine (AZT)
Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)	Efavirenz (EFV) Rilpivirine (RPV) Nevirapine (NVP)
Protease Inhibitors (PI)	Lopinavir/ritonavir (LPV/r) Darunavir (DRV) Ritonavir (RTV)

1. Recommended Regimen for Adults and Adolescents (≥10 years of age)

a. First line Regimen: 2 NRTI + 1 NNRTI

i. Preferred first line NRTI: TDF + 3TC

ii. Alternative first line NRTI: ABC + 3TC

ABC is preferred over TDF for patients with estimated Creatinine clearance of < 60 ml/min.

iii. First line NNRTI: EFV

RPV is an alternative NNRTI to EFV that may only be initiated for asymptomatic patients 12 years old and above, with known cluster of differentiation 4 (CD4) cell count of greater than 350 cells/mm³, non-pregnant and not on Rifampicin-containing regimen. It is also contraindicated among patients taking antacids, Histamine 2 blockers or proton pump inhibitors.

b. Second line regimen: 2 NRTI + Boosted PI

i. Preferred second line: 2 NRTI + LPV/r

- Zidovudine (AZT) + 3TC + LPV/r if previously on TDF or ABC

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

ii. Alternative second line: 2 NRTI + DRV + RTV

- Zidovudine (AZT) + 3TC + DRV + RTV if previously on TDF or ABC

- Tenofovir (TDF) or ABC + 3TC + DRV + RTV if previously on AZT

2. Recommended Regimen for Children (3 – less than 10 years old)

First line regimen: 2 NRTI + 1 NNRTI

a. Preferred first line NRTI: ABC + 3TC

b. Alternative first line NRTI: AZT or TDF + 3TC

TDF is preferred over AZT for children with anemia (hemoglobin levels ≤ 10g/dL)

c. Preferred first line NNRTI: EFV

d. Alternative first line NNRTI: NVP

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3. Recommended Regimen for Infants and children less than 3 years old

Table 2: Sequencing of ARV regimen for newborn starting treatment

	0-2 weeks →	2 weeks – 3 months →	3- 36 months
Preferred	AZT+3TC+NVP	ABC or AZT + 3TC + LPV/r	ABC or AZT + 3TC + LPV/r
Alternative	AZT+3TC+NVP		ABC or AZT + 3TC + LPV/r

Where viral load monitoring is available, consideration can be given to substitute LPV/r with EFV at 3 years of age after viral suppression is sustained. In addition, Abacavir is preferred over Zidovudine for anemia in neonates (hematocrit level <40%).

C. Monitoring while on ART

ART is a lifelong therapy and requires continuous monitoring. Close and more frequent monitoring is important during the first six months of initiation to identify immediate toxicities that could adversely affect adherence and early treatment failure for timely change of regimen.

1. Monitoring for ARV Toxicity

The following are the minimum laboratory tests in monitoring for ART toxicity. The physician can request additional tests if clinically indicated.

- a. For TDF containing regimen:
 - Serum creatinine within 6 months of initiation then every 12 months or as needed.
- b. For EFV-containing regimen:
 - Lipid profile (triglyceride, total cholesterol and low density lipoproteins or LDL) within 6 months then every 12 months or as needed.
- c. For AZT-containing regimen:
 - Complete blood count (CBC) at 2, 4, 8, 12 and 24 weeks after starting AZT then every 6 months or as needed.
- d. PI-containing regimen:
 - Lipid profile (triglyceride, total cholesterol and LDL) and fasting blood sugar (FBS) within 6 months then every 12 months or as needed.

2. Monitoring response to treatment

A positive response to treatment is seen in a clinically stable patient, with no recurrence of opportunistic infections, and with improvement of weight and well-being, stable immune status based on clinical assessment and evaluation, maximal viral suppression and improved quality of life.

- a. Clinical Response (See Annex 2: WHO Clinical Staging of HIV Disease in adults, adolescents and children)

Frequency of clinical monitoring shall depend on patient's response to ART. Patients shall be followed-up on the minimum, at 2, 4, 8, and 12 weeks after starting ART and every six months once patient has been assessed to be stable. Reassessment of clinical condition and assessment of symptoms of drug toxicities

should be made every visit. Clinical response is recommended to be used together with viral load determination to detect treatment failure.

Clinical failure is defined among adults and adolescents as a new or recurrent clinical event indicating severe immunodeficiency (WHO clinical stage 4) after 6 months of effective treatment. In children it is defined as a new or recurrent clinical event indicating advanced or severe immunodeficiency (WHO clinical stage 3 and 4 with the exception of TB) after 6 months of effective treatment. This 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, the switching of ART is inappropriate.

While all PLHIV are recommended to be started on ART regardless of CD4 cell count, CD4 determination is still needed for prophylaxis and management of opportunistic infections based on the 2016 PSMID Clinical Practice Guidelines for the Prevention, Diagnosis, and Treatment of Opportunistic Infections in HIV-infected Adults and Adolescents in the Philippines.

b. Virologic Response

Viral load assay shall be done 6 months after initiating ART to detect early virologic failure. Patient must be on ART continuously for 4-8 weeks before doing the test to ensure detection of drug resistant strains. If treatment failure is considered viral load assay must be done before any change or shift on ART regimen.

Virologic failure is defined as plasma viral load above 1000 copies/mL at any time beyond 6 months.

For stable patients, another viral load test is done after 6 months and every 12 months thereafter.

D. Change of ART Regimen

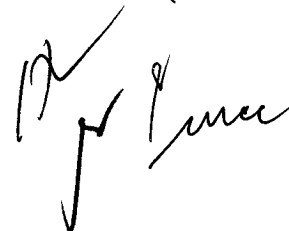
1. Drug toxicity and side effects (See Annex 1: Antiretroviral Drugs and Doses, Instructions on Administration, and Major Types of Toxicities)

Delaying substitutions or switches in drugs when there are signs of adverse drug effects may cause harm and may affect adherence leading to drug resistance and treatment failure.

Symptom-directed laboratory monitoring for safety and toxicity can be used for those receiving ART.

Antiretroviral drugs are substituted with drugs belonging to the same ARV class (e.g. Abacavir for Tenofovir when renal failure occurs).

- a. Tenofovir shall be shifted to Abacavir when estimated Creatinine clearance is less than 60 mL/min. This is calculated using the Cockcroft-Gault C-G formula (See Annex 3).



- b. Patients who develop early (less than 3 months after initiating ART) severe adverse event to Efavirenz such as psychosis shall be referred to infectious disease specialist for further management.

Patients who develop adverse event (i.e. dizziness and severe psychosis) later than 3 months may be shifted to Rilpivirine if with undetectable viral load within the past 4 weeks, not on Rifampicin-containing regimen and non-pregnant. Rilpivirine is contraindicated among patients taking antacids, histamine 2 blockers or proton pump inhibitors.

2. Drug Interactions

The physician shall be aware of all the drugs that the patient is taking when initiating ART and during treatment maintenance. This includes alternative medicines, herbal remedies and dietary supplements. There are several key drug interactions and suggested management shown in Annex 4.

Patients on both ART treatment and TB treatment who developed adverse reactions to Efavirenz, shall also be referred to the Infectious disease specialist for further management.

3. Treatment Failure

It is very important to regularly assess patients for treatment failure, determine the reasons for these, and institute appropriate management immediately. Poor compliance to ART is the most common cause of treatment failure. If this is the identified cause, adherence counseling must be intensified and the current regimen continued. Viral load test must be done 4-8 weeks after to reassess response to treatment.

Patients with virologic failure shall be managed in close coordination with an infectious disease specialist. Blood specimen must be sent for HIV drug resistance (HIVDR) testing to the Research Institute for Tropical Medicine (RITM) before shifting to 2nd line regimen.

E. ARV Prophylaxis for infants born to infected mothers (See Annex 5. Simplified Infant Prophylaxis Dosing Recommendations)

Infants born to HIV-infected mothers shall be given ARV prophylaxis at birth or when HIV exposure is recognized postpartum. The table below summarizes the ranges of clinical scenarios and the duration of infant ARV prophylaxis.

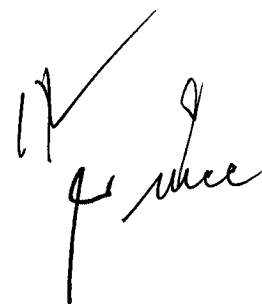


Table 3. Infant ARV Prophylaxis for different Clinical Scenarios

Scenario	Infant ARV prophylaxis	Duration
Infants of mothers who are receiving ART for at least 4 weeks and are breastfeeding	daily NVP	6 weeks
Infants of mothers who are receiving ART for at least 4 weeks and are on replacement feeding		
Infants born to mothers with HIV who are at HIGH RISK* of acquiring HIV (breastfed or formula fed)	Start treatment at birth (see Table 2)	6 weeks
Infants who are at HIGH RISK* of acquiring HIV including those first identified as exposed to HIV during the postpartum period (breastfeeding/replacement feeding)	Start treatment at birth (see Table 2)	12 weeks

*High Risk Infants are defined as those:

- Born to women with established HIV infection who have received less than four weeks of ART at the time of delivery, OR
- Born to women with established HIV infection 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, but mother is either with or without a negative HIV test prenatally.

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

The **Revised Guidelines on the Integrated Prevention of Mother to Child Transmission (PMTCT) of Human Immunodeficiency Virus (HIV)** shall serve as additional reference to all health care service delivery facilities.

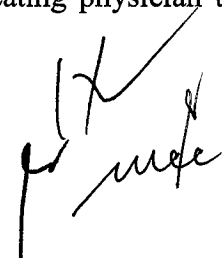
F. Managing HIV and TB co-infection

Anti-tuberculosis treatment shall be initiated first, followed by ART as soon as possible after the first two weeks of TB treatment. Patients shall be monitored closely for side effects.

Shifting 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).

For infants and children infected with HIV younger than 3 years, ABC + 3TC + AZT is recommended as an option for children who develop TB while on an ART regimen containing NVP or LPV/r. Once TB therapy has been completed, this regimen shall be stopped and the initial regimen should be restarted.

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



G. Managing HIV and Hepatitis B and C co-infection

Viral hepatitis is an increasing cause of morbidity and mortality among PLHIV. A comprehensive approach includes prevention, diagnosis, and treatment and care of patients infected with HIV co-infected with Hepatitis B and/or Hepatitis C.

The risk of hepatitis B virus (HBV) infection is higher among PLHIV, therefore all people infected with HIV shall be tested for Hepatitis B surface antigen (HBsAg) and vaccinated if non-immune.

Treatment of Hepatitis B and C shall be based on the latest available local treatment guidelines. All PLHIV with hepatitis co-infection shall be followed up more closely because of the major risk of drug-related interactions of some ARV with anti-hepatitis C virus (HCV) drugs (See **Annex 4: Key ARV drug interactions and suggested management**).

H. Monitoring and Evaluation (See Annex 6: National Program Indicators on HIV and ART treatment).

All primary HIV care clinics and treatment hubs shall maintain and update patient records and reports from which the following HIV indicators can be generated: a) Linkage to care, b) ART coverage indicators c) indicators for co-morbidities and d) indicators for prevention of mother to child transmission (PMTCT).

Existing flow and timelines of reports for Epidemiology Bureau (EB) and National HIV, AIDS and STI Prevention and Control Program (NASPCP) shall be followed. Confidentiality of records and reports shall be ensured by all health care workers. These data shall be made available for validation.

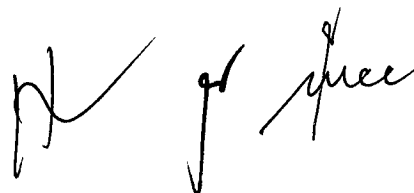
I. Roles and Responsibilities

1. Disease Prevention and Control Bureau (DPCB)

- a. Convene the HIV technical working group to regularly review this guideline through consultation with clinicians, representatives from the treatment hubs and PLHIV;
- b. Forecast centrally ARV needs of PLHIV and ensure timely procurement and distribution of ARV to treatment hubs in coordination with DOH-Procurement Service, Logistics Management Division and Regional Offices;
- c. Ensure provision of references and capability-building activities such as clinical management and primary care training related to the implementation of these guidelines;
- d. Ensure that antiretroviral drugs are included in the Philippine National Drug Formulary.

2. Department of Health - Regional Offices (RO)

- a. Disseminate these guidelines and other related reference materials to DOH-retained hospitals and private DOH - accredited tertiary medical centers; local government units, and regional chapters of the professional medical societies;
- b. Organize training on the clinical management and primary care for HIV and AIDS Core Team (HACT) of hospitals and other health facilities in coordination with DPCB;



- c. Strengthen service delivery network from local government units, private clinics, and various health facilities treatment hubs and primary HIV care clinics;
 - d. Conduct regular monitoring activities to primary HIV care clinics and treatment hubs;
 - e. Collate, analyze and submit reports to DPCB and EB.
- 3. Treatment Hubs through its HIV AIDS Core Team (HACT)**
- a. Provide treatment and clinical monitoring of PLHIV, based on the DOH-guidelines;
 - b. Provide technical assistance to other health facilities and community-based organizations in need of professional training on the clinical management of HIV infection;
 - c. Submit monthly reports to DPCB, EB and DOH-RO.
- 4. Primary HIV Care Clinic**
- a. Provide treatment and clinical monitoring of PLHIV, based on the DOH-guidelines;
 - b. Respond accordingly to referrals from various health facilities;
 - c. Submit monthly reports to DPCB, EB and DOH-RO.
- 5. Epidemiology Bureau (EB)**
- a. Conduct systematic data collection and analysis with DPCB, DOH-RO and partners;
 - b. Provide technical assistance to programs to enhance and standardize recording and reporting forms and management of data;
 - c. Analyze and disseminate reliable and timely information on NASPCP performance indicators.
- 6. San Lazaro Hospital - STD/AIDS Central Cooperative Laboratory (SLH-SACCL)**
- a. Continue updating and issue evidence-based HIV testing algorithm for general and key population;
 - b. Establish quality assurance system for CD4 testing and viral load testing.
- 7. Research Institute of Tropical Medicine (RITM)**
- a. Work in coordination with primary HIV care clinics and treatment hubs to conduct viral load assays, drug resistance testing and/or genotyping of PLHIV as recommended in these guidelines.
- 8. Philippine Health Insurance Corporation (PHIC)**
- a. Implement the Outpatient HIV/AIDS treatment (OHAT) package based on this guideline;
 - b. Review the inpatient and OHAT package to ensure sustainable treatment for PLHIV.
- 9. Civil Society Organizations for Care and Support** are encouraged to:
- a. Work in coordination with the HACT in providing care and support for PLHIV;
 - b. Conduct operations research/demonstration projects on community-access of ARV in coordination with treatment hubs;
 - c. Implement community-based ARV adherence program.
- 10. Local Government Units** are encouraged to:
- a. Work in coordination with the members of the HACT in the primary HIV care clinics and treatment hubs in providing care and support for PLHIV;

- b. Support DOH-RO in establishing HIV and AIDS Core team (HACT) in every district/municipality/city hospital to ensure provision of HIV and AIDS service delivery in their locality;
- c. Support their local health personnel to undertake continuous updating on skills and competency building enhancement activities for quality HIV service delivery (e.g. counseling, ARV clinical care management, and the like);
- d. Ensure functional and efficient referral system for PLHIV.

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

- a. Provide technical support in ensuring the implementation of this guideline.

J. Financing

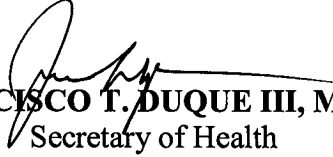
1. The DPCB shall allot funds for procurement of ARVs annually based on the forecasting by the National HIV, AIDS and STI Prevention and Control Program (NASPCP) — Infectious Disease Prevention and Control Division (IDPCD).
2. The DPCB along with the Philippine National AIDS Council (PNAC) Secretariat and the PLHIV shall continuously mobilize resources for funding to ensure sustainability of ARV treatment.

VII. REPEALING CLAUSE

This Order repeals related **Administrative Order 2014-0031** entitled “Policies and Guidelines on the Use of Antiretroviral Therapy (ART) Among People Living with Human Immunodeficiency Virus (HIV) and HIV-exposed Infants”.

VIII. EFFECTIVITY

This order shall take effect immediately upon approval.


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

Annex 1. 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)					
<p>Tenofovir (TDF)</p> <p>Tablet: 300 mg</p>	<p>Target dose: 8 mg/kg or 200 mg/m² (maximum of 300 mg)</p> <p><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</p> <p><u>Adolescent/Adult:</u> 300 mg once daily</p>	<p>Take without regard to meals</p>	<p>Chronic kidney disease Acute kidney injury Fanconi syndrome</p> <p>Decrease in bone mineral density</p> <p>Lactic acidosis or severe hepatomegaly with steatosis</p>	<p>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</p> <p>History of osteomalacia (in adults) and rickets (in children) and pathological fracture Risk factors for osteoporosis or bone density loss Vitamin D deficiency</p> <p>Prolonged exposure to nucleoside analogues Obesity Liver disease</p>	<p>Substitute with AZT or ABC</p> <p>Do not initiate TDF at estimated glomerular filtration rate (eGFR) < 50 mL/min, uncontrolled hypertension, untreated diabetes, or presence of renal failure</p>

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Non-nucleoside Reverse Transcriptase Inhibitors (NNRTI)					
<p>Efavirenz (EFV)</p> <p>Syrup: 30 mg/ml (Note: syrup requires a higher dosage than capsules)</p> <p>Tablet: 600 mg</p>	<p><u>Child:</u> 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</p> <p><u>Adolescent/Adult:</u> 600 mg daily</p>	<p>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</p>	<p>Severe skin and hypersensitivity reactions</p> <p>Hepatotoxicity</p> <p>Convulsions</p> <p>Persistent central nervous system toxicity (such as abnormal dreams, depression or mental confusion, anxiety)</p> <p>Gynecomastia</p>	<p>Risk factor(s) unknown</p> <p>Underlying hepatic disease – hepatitis B virus (HBV) and hepatitis C virus (HCV) coinfection; Concomitant use of hepatotoxic drugs</p> <p>History of seizures</p> <p>Depression or other mental disorder (previous or at baseline) Daytime dosing</p> <p>Risk factor(s) unknown</p>	<p>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.</p> <p>For severe hepatotoxicity or hypersensitivity reactions, substitute with another therapeutic class (integrase inhibitors or boosted PIs)</p> <p>Substitute with NVP or another therapeutic class (integrase inhibitors or boosted PI)</p>

Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
<p>Nevirapine (NVP)</p> <p>Oral Soln: 10 mg/ml</p> <p>Tablet: 200 mg</p>	<p><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</p> <p>>30 days to 13 years: 120 mg/m²/dose once daily for 2 weeks, then 120-200 mg/dose twice daily</p> <p><u>Adolescent/Adult:</u> 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</p>	<p>- Take without regard to meals</p> <p>- Not recommended to be co-administered with rifampicin</p> <p>- 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</p> <p>- If mild/moderate rash develops, hold drugs; when rash clears, restart dosing from beginning of dose escalation; if severe rash, discontinue drug</p>	<p>STOP if any one is observed:</p> <ol style="list-style-type: none"> 1. Fever or feverish sensation 2. Flu-like symptoms such as muscle or body pains <p>Hepatotoxicity</p> <p>Severe skin rash and hypersensitivity reaction (Stevens-Johnsons Syndrome)</p>	<p>Underlying hepatic disease hepatitis B virus (HBV) and hepatitis C virus (HCV) coinfection</p> <p>Concomitant use of hepatotoxic drugs High baseline CD4 cell count (CD4 > 250 cells/mm³ in women; CD4>400 cells/mm³ for men)</p>	<p>If hepatotoxicity is mild consider substitution with EFV, including in children 3 years and older.</p> <p>For severe hepatotoxicity, and hypersensitivity and in children under the age of 3 years, substitute with another therapeutic class (boosted PIs)</p>

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

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Drug	Dose	Administration	Major types of Toxicity	Risk factors	Suggested Management
Protease Inhibitors (PIs)					
<p>Lopinavir/ritonavir (LPV/r)</p> <p>Tablet: Lopinavir 200mg/ Ritonavir 50 mg</p> <p>Oral Soln: 80 mg/ml Lopinavir plus 20 mg/ml</p> <p>Ritonavir (Note: oral solution contains 42% alcohol)</p>	<p><u>Infant/Child:</u></p> <p>>6 months to 13 years: 225 mg/m² LPV/ 57.5 mg/m² Ritonavir twice daily or weight-based dosages</p> <p>7-15 kg: 12mg/kg LPV / 3 mg/kg Ritonavir/dose twice daily</p> <p>15-40 kg: 10 mg/kg LPV / 5 mg/kg Ritonavir twice daily</p> <p>Max dose: >40kg: 400 LPV/100 mg Ritonavir (3 capsules or 5ml)</p> <p><u>Adult:</u> 2 tablets every 12 hours</p>	<p>Take without regard to meal</p> <p>Not recommended to be co-administered with rifampicin</p>	<p>Diarrhea</p> <p>Hepatotoxicity</p> <p>Pancreatitis</p> <p>QT interval prolongation</p> <p>Electrocardiographic abnormalities (PR and QT interval prolongation, <i>torsades de pointes</i>)</p>	<p>Underlying hepatic disease HBV and HCV co-infection Concomitant use of hepatotoxic drugs</p> <p>Advanced HIV disease, alcohol misuse</p> <p>Congenital long QT syndrome Hypokalemia Concomitant use of drugs that may prolong the QT interval</p> <p>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</p>	<p>Substitute with DRV/r</p> <p>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.</p> <p>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</p> <p>Use with caution in people with pre-existing conduction disease or those on concomitant drugs that may prolong the PR or QRS intervals</p>
			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
Darunavir (400 and 600 mg tablet)	<u>Adult and adolescents:</u> 800 mg Darunavir + 100 mg Ritonavir once daily	Darunavir co-administered with Ritonavir and food	Hepatotoxicity	Underlying hepatic disease HBV and HCV coinfection Concomitant use of hepatotoxic drugs	Substitute with LPV/r. When it is used in third-line ART, limited options are available
Ritonavir (100 mg tablet)	For PI-experienced patients, the recommended DRV/r dose is 600 mg DRV /100 mg RTV twice daily	Swallow tablets whole with a drink (e.g. water or milk)	Severe skin and hypersensitivity reactions	Sulfonamide allergy	For hypersensitivity reactions, substitute with another therapeutic class

Computation of Body Surface Area:

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

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Annex 2. WHO Clinical Staging of HIV Disease in adults, adolescents and children

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)

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

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Adults and adolescents	Children
Clinical Stage 4	
<p>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</p>	<p>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</p>

^aIn 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.

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Annex 3: Cockcroft-Gault C-G Formula

The Cockcroft-Gault formula is used for estimating the creatinine clearance from a patient's serum creatinine. Though this method does not directly measure the Glomerular Filtration Rate (GFR), it can be useful in providing guidance to drug dosing (Inker, Fan, & Levey, 2015). In addition to the serum creatinine, the Cockcroft-Gault formula approximates the creatinine clearance from other factors like age, gender and body weight. Also, this formula overestimates creatinine clearance in obese patients because of their increased weight. The Cockcroft-Gault formula is expressed as:

$$\text{Creatinine Clearance in Males} \left(\frac{\text{ml}}{\text{min}} \right) = \frac{(140 - \text{age}) \times \text{weight (kg)}}{\text{serum Creatinine} \left(\frac{\text{mg}}{\text{dl}} \right) \times 72}$$

or

$$\text{Creatinine Clearance in Females} \left(\frac{\text{ml}}{\text{min}} \right) = \frac{(140 - \text{age}) \times \text{weight (kg)}}{\text{serum Creatinine} \left(\frac{\text{mg}}{\text{dl}} \right) \times 72} \times 0.85$$

Reference:

Inker, L. A., Fan, L., & Levey, A. S. (2015). *Comprehensive Clinical Nephrology*. (R. J. Johnson, J. Feehally, & J. Floege, Eds.) (5th ed.). Philadelphia, PA: Elsevier. Retrieved from <https://www-clinicalkey-com.proxy1.athensams.net/#!/content/book/3-s2.0-B9781455758388000034?scrollTo=%23hl0001661>

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Annex 4. Key ARV drug interactions and suggested management

ARV drug	Key interactions	Suggested Management
Zidovudine (AZT)	Ribavirin and pegylated interferon alpha-2a	substitute AZT with TDF
Boosted PI Darunavir/ritonavir (DRV/r) 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 buprenorphine doses as appropriate
	Astemizole and Terfenadine	Use alternative antihistamine agent
	TDF	Monitor renal function
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	Use an alternative anti-histamine agent
Nevirapine (NVP)	Rifampicin	Substitute NVP with EFV
	Itraconazole and Ketoconazole	Use an alternative antifungal agent
	Astemizole and Terfenadine	Use alternative antihistamine agent
Ralpivirine (RPV)	Antacids (e.g., aluminum or magnesium hydroxide, calcium carbonate)	The combination of Ralpivirine and antacids should be used with caution as co-administration may cause significant decreases in Ralpivirine plasma concentrations (increase in gastric pH). Antacids should only be administered either at least 2 hours before or at least 4 hours after Ralpivirine.
	H2-Receptor Antagonists: Cimetidine Famotidine Nizatidine Ranitidine	The combination of Ralpivirine and H2-receptor antagonists should be used with caution as co-administration may cause significant decreases in Ralpivirine plasma concentrations (increase in gastric pH). H2-receptor antagonists should only be administered at least 12 hours before or at least 4 hours after Ralpivirine.

	<p>Macrolide or ketolide antibiotics:</p> <p>Clarithromycin Erythromycin Telithromycin</p>	<p>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.</p>
	<p>Antifungal Agents:</p> <p>Fluconazole Itraconazole Ketoconazole Posaconazole Voriconazole</p>	<p>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.</p>

Annex 5. Simplified infant prophylaxis dosing recommendations

Source: Antiretroviral drugs for treating pregnant women and preventing HIV infections in infants: recommendations for a public health approach. Geneva WHO, 2016)

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 \geq 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

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Annex 6. 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 estimated people living with HIV	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 have not returned 3 months after the last expected date of ARV pickup/refill or scheduled appointment D: Total number of PLHIV on ART accessing primary HIV care clinics and Treatment Hubs during the reporting period; excludes people who have died		Sex, age, key population, first or second regimen, location (hub), pregnancy or breastfeeding		Monthly

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Indicator	Numerator (N) / Denominator (D)	Relevance to cascade	Disaggregation	Sources and issues	Frequency of reporting
<p>Viral suppression Percentage of people living with HIV who have suppressed viral load 12 months after ART initiation</p> <p>Population-level denominator: Number of people on ART in the past 12 months</p> <p>Program-based denominator: Number of people on ART who had a viral load measurement in the past 12 months</p>	<p>N: Number of people living with HIV and on ART who have suppressed viral load (<1000 copies/ml) 12 months after ART initiation</p> <p>D: Total number of PLHIV tested for viral load 12 months after ART initiation</p>	<p>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.</p> <p>Viral load suppression among a cohort 12 months after ART initiation should also be monitored</p>	Sex, age, key population location	<p>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.</p> <p>Suppressed viral load is defined as <1000 copies/ml.</p>	Quarterly (Monthly pending)
<p>TB incidence in HIV care Percentage of PLHIV with incident TB</p>	<p>N: number of PLHIV diagnosed with TB</p> <p>D: Total number of PLHIV accessing Treatment hubs or primary HIV care clinics for TB during the reporting period</p>	<p>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</p> <p>TB treatment and early ART. This indicator also measures indirectly the extent of efforts to detect HIV-associated TB.</p>		HIV/AIDS and ART Registry (HARP) Form B and C	Monthly
<p>ART Coverage during TB treatment Percentage of PLHIV with incident TB who received treatment for both TB and HIV</p>	<p>N1: Number of PLHIV with active TB started on TB treatment</p> <p>D1: Total number of PLHIV enrolled in HIV care at Treatment Hubs or primary HIV care clinics with active TB during the reporting period</p> <p>N2: Number of TB patients in TB facilities who are tested for HIV</p> <p>D2: Total number of TB patients in TB facilities</p>	<p>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.</p>	Disaggregate outcome/specify how many have died	HARP Form B and C	Monthly

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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 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