



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

January 4, 2021

DEPARTMENT MEMORANDUM

No. ~~2020~~ 0017
2021

FOR: ALL UNDERSECRETARIES AND ASSISTANT SECRETARIES, DIRECTORS OF BUREAUS/SERVICES AND CENTERS FOR HEALTH DEVELOPMENT; MINISTER OF HEALTH – BANGSAMORO AUTONOMOUS REGION IN MUSLIM MINDANAO, CHIEFS OF MEDICAL CENTERS, HOSPITALS, SANITARIA, TREATMENT AND REHABILITATION CENTERS AND DOH-DESIGNATED HIV TREATMENT HUBS, EXECUTIVE DIRECTORS OF SPECIALTY HOSPITALS, PHILIPPINE NATIONAL AIDS COUNCIL AND OTHER ATTACHED AGENCIES; AND ALL OTHERS CONCERNED

SUBJECT: Interim Guidelines on Pre-Exposure Prophylaxis (PrEP) for the Prevention of HIV Infection in the Philippines

I. BACKGROUND

The Philippines has maintained the HIV prevalence among the general population at less than 1%, albeit, there has been a 203% increase in the estimated new HIV infections from 2010 to 2018. Progress in achieving prevention targets has been slow, as indicated by low condom use and low comprehensive knowledge of HIV prevention and transmission among key populations.

In 2015, the World Health Organization (WHO) recommended the use of daily oral pre-exposure prophylaxis (PrEP) using a two-drug combination tenofovir and emtricitabine as an additional option for people at substantial risk of HIV infection.

In 2017, the The Love Yourself, with support from the Department of Health through the Research Institute for Tropical Medicine and the Global Fund project, has implemented the 24-month demonstration study that examined community-based delivery of HIV PrEP for males having sex with males (MSM) and transgender women (TGW) at high risk for HIV infection. Among the 250 enrolled in the PrEP, no new cases of HIV infection detected and no side effects reported. There were no increase in diagnoses of sexually transmitted infections (STI) over time. The zero HIV infection outcome of the project provides additional evidence for scaling-up PrEP.

In 2019, the WHO updated its guidelines to include event-driven PrEP which offers flexibility, choice, and convenience to MSM and has the potential to reduce the cost of drugs, pill burden and toxicity, and improve continuation among those who find daily pill-taking challenging.

II. OBJECTIVE

The interim guidelines provide details on the delivery of pre-exposure prophylaxis (PrEP) services for people at substantial risk of HIV infection.

III. SCOPE

These guidelines are intended for use by STI and HIV service providers, coordinators, heads or managers of facilities with HIV services, community-based organizations, and other facilities offering PrEP services from public and private sectors.

IV. DEFINITION OF TERMS

- A. **ARS (Acute retroviral syndrome)** - is a condition that may develop as early as 2 to 4 weeks after someone contracts HIV. Possibility of ARS is considered if there are flu-like signs and symptoms such as sore throat, swollen lymph glands, and body aches, and the client reports condomless sex in the past 14 days.
- B. **Daily Oral PrEP** – requires taking a single pill of tenofovir (TDF)/emtricitabine (FTC) daily and dosing regimen is appropriate for all people, irrespective of gender, sexual orientation, or risk behavior.
- C. **Event-driven PrEP (ED PrEP)** – is a dosing regimen recommended ONLY for MSM and consists of a double dose (two pills) of TDF/FTC, which serves as the loading dose, taken between two and 24 hours in advance of sex; then a third pill is taken 24 hours after the first two pills, and a fourth pill 48 hours after the first two pills.
- D. **Pre-exposure prophylaxis (PrEP)** - is the use of antiretroviral (ARV) drugs by people to prevent contracting HIV.
- E. **Sero-conversion** – is the change from a seronegative to a seropositive HIV status.

V. GENERAL GUIDELINES

- A. Information on combination prevention from risk reduction behaviors, correct and consistent condom use with water-based lubricants, availability and access of pre-exposure prophylaxis (PrEP) shall be included in the package of HIV prevention services for key populations (KP) at substantial risk of HIV infection.
- B. All HIV health service providers including partners from other government and private health facilities and community-based organizations shall be engaged to improve knowledge, awareness of, and demand for PrEP.
- C. Government and donor procured PrEP shall be managed by the DOH and made available through the Centers for Health Development (CHD) in Social Hygiene Clinics, Primary HIV care clinics, HIV treatment hubs, including select community centers.
- D. Referral of client for PrEP and other HIV combination prevention services shall be enhanced, including those who test HIV negative after partner testing or self-screening.

VI. SPECIFIC GUIDELINES

- A. Programmatic requirements for PrEP service provision
 - 1. Human resource to provide counseling, screening, and follow-up monitoring;
 - 2. Access to clinicians for scripting and initiation;
 - 3. Access to laboratory services for baseline testing and monitoring;
 - 4. Commodity management procedures to order, handling and requesting;
 - 5. Monitoring and evaluation systems including documentation, quality assurance, and improvement, and reporting.
- B. Screening for substantial risk of HIV infection
 - 1. Individuals at **substantial risk** for HIV infection who will benefit most from PrEP:
 - a. Those who engage in sex with a PLHIV who is not virally suppressed or whose results of viral load testing are unknown (e.g., HIV serodiscordant couples);
 - b. Those having condomless or unprotected anal/vaginal/ or neovaginal sex in the past 6 months with more than one partner;
 - c. Those with history of STI in the past 6 months (diagnosed, symptoms, or self-report);

- d. Those using sex-enhancing drugs or non-sterile injecting equipment in the past 6 months;
- e. Those who have used HIV post-exposure prophylaxis (PEP) for sexual exposure in the past six months;
- f. Those who have a sexual partner with one or more HIV risk factors in the past 6 months;
- g. Those who requested PrEP

2. Clinical Indications:

- a. Must be HIV negative;
- b. Must be free of signs/symptoms of an acute retroviral syndrome (ARS) with no probable recent exposure to HIV;
- c. Must have a good renal function, if known (creatinine clearance > 60 mL/min);
- d. Must be free of any allergy or contraindications to PrEP medicines (TDF or FTC)
- e. Must weigh at least 35 kg.
- f. PrEP has no or minimal drug interactions with commonly prescribed medicines nor significant side-effects. PrEP can be used safely by most people, including pregnant or breastfeeding women, women using hormonal drugs for contraception, or transgender persons on gender-affirmative hormone therapy

C. Initiation of PrEP

1. Pre-initiation counseling on PrEP shall focus on ensuring understanding of PrEP as an additional prevention method and helping the client to decide whether PrEP is the right prevention tool. (*Please see Annex 1 at <https://bit.ly/prepannex>*).
2. All clients eligible and indicating interest in PrEP need to undergo the following essential diagnostic/laboratory tests and clinical assessment and evaluation:
 - a. HIV screening/testing within 7 days before PrEP initiation
 - i. Clients reactive to HIV screening should be immediately linked to care.
 - ii. If there is a history of recent HIV exposure (in the past 72 hours), consider PEP and re-test after 28 days. Complete a symptom checklist for possible acute HIV infection.
 - iii. After 28 days of PEP, PrEP can be started without a gap if the HIV test remains negative, and there is a substantial ongoing risk of HIV acquisition.
 - iv. For persons with constant potential exposure to HIV, there should be no gap between finishing PEP and starting PrEP.
 - b. Serum Creatinine test. Availability of Serum Creatinine test result should NOT delay PrEP initiation, unless there is clinical suspicion of poor renal function or pre-existing renal disease.
 - c. HBsAg test done within 30 days prior to PrEP initiation.
 - i. If the result is negative, recommend hepatitis B vaccination.
 - ii. If the result is positive, manage Hepatitis B per DM 2019-0465 (<http://bit.ly/hepbforms>).
 - d. STI screening (syndromic management or etiological diagnosis)
 - e. Hepatitis C antibody screening for MSM and PWID
 - f. Pregnancy assessment and testing for women and transgender men. PrEP can safely continue throughout pregnancy unless the client chooses to stop.
3. Dosing Regimen
 - a. Provide PrEP on the same day to HIV negative individuals without contraindications, while laboratory tests (creatinine, HBsAg) are sent for testing. Contact the PrEP user if test results require additional confirmation or treatment.
 - b. Prescribe PrEP for one-month supply at first visit, then two month's supply at second visit, and three month's supply thereafter. Based on compliance and other circumstances, more than 3 month's supply can be prescribed.
 - c. Daily Oral PrEP shall be used during periods of frequent sex or when sex is unpredictable. Anyone who meets the indications shall take Daily Oral PrEP.

- i. Dosing for Daily Oral PrEP using oral formulation of TDF/FTC shall be once a day, with or without food
 - ii. Maximum dose is two tablets per day
 - d. Everyone who is starting or restarting PrEP, will need to take five to seven days (for anal intercourse) or twenty days (for vaginal intercourse) of daily intake of PrEP before achieving protection against HIV infection. Additional HIV prevention measures should thus be taken during this period.
 - e. For MSM (whose only risk is through anal sex) who is starting or restarting on PrEP, should start with a double dose of TDF/FTC (two pills), 2-24 hours before having sex.
 - f. Except for MSM, PrEP users can stop 28 days after the last possible HIV exposure.
 - g. For MSM, (whose only risk is through anal sex), PrEP discontinuation may be done by taking a pill once a day for two days after the last possible HIV exposure.
 - h. Event-Driven PrEP can be considered for infrequent, anticipated or planned sex.
 - i. Dosing for ED-PrEP (for MSM only) using oral formulation of TDF/FTC shall be two pills as loading dose between two and 24 hours before sex; then a third pill taken 24 hours after the first two pills; and a fourth pill 48 hours after the first two pills (*Please see ANNEX 2 at <https://bit.ly/prepannex>.*)
 - ii. If more sex acts take place over the following days, a single PrEP pill can be continued daily for as long as sex continues, with a single daily pill taken for each of two days after the last sex act.
 - i. In consultation with the clinician, MSM can switch between daily and ED-PrEP based on changes in their sexual practices. (*Please see Annex 3A and 3B at <https://bit.ly/prepannex>.*)
 - 4. Clients with recent risk/exposure need to take two doses of PrEP at the regular time for another 48 hours, one on each of the two days after client's last risk.
- D. Stopping PrEP
 - 1. People can consider stopping PrEP if they are no longer at a substantial risk of acquiring HIV infection.
 - 2. Clients should consult a clinician whenever there's a decision to stop PrEP.
- E. Clinical Follow-up and Monitoring
 - 1. Clinicians may want to see their clients after one month for HIV re-testing, assessing early side effects, drug dispensing and adherence evaluation, and addressing any questions or difficulties.
 - 2. Follow up HIV screening to monitor status shall be scheduled after 1 month of PrEP and at least every 3 months thereafter.
 - a. Assess for signs and symptoms of acute HIV infection.
 - b. Individuals with an HIV-inconclusive status should stop PrEP and be retested after 14 days. The client may resume PrEP if the repeat test is negative.
 - c. In HIV seroconversion, stop PrEP, and rapidly link client to care. Receiving HIV treatment facility shall initiate treatment and secure a blood specimen for HIV drug resistance testing.
 - 3. Serum creatinine tests shall be done every 6 months or as indicated, especially if there is a history of conditions affecting the kidney, such as diabetes or hypertension. Discontinue PrEP if creatinine clearance falls below 60ml/min.
 - 4. STI screening (syndromic management or etiological diagnosis) shall be done at each follow-up or every 3 months and managed accordingly.
 - 5. For Hepatitis C antibody screening, consider testing MSM and PWID every 12 months. If positive, refer to a specialist for management.
- i. Follow-up Counseling for PrEP
 - 1. The following shall be emphasized during follow-up counseling:
 - a. PrEP dosing and side effects assessment
 - b. Risks of sharing PrEP drugs with peers

- c. Adherence assessment
 - i. Number of days client is on continuous intake of PrEP at the time of visit
 - ii. Number of days on PrEP before and after the last possible HIV exposure
 - d. Proper way to store PrEP medications
 - e. Sexual health protection (condom use, pregnancy, STI, alcohol, substance abuse)
 - f. Issues related to mental health (especially depression)
 - g. Intimate partner violence
2. Include provision of commodities for prevention (condoms and lubricant)
 3. Include reminder to consult the clinician whenever a decision is made to stop PrEP
- F. Monitoring and Evaluation
1. Monitoring and evaluation of PrEP implementation shall be measured by specific indicators. *Annexes 4 and 5 provide PrEP indicators.*
 2. Supportive supervision and mentorship for PrEP uptake and use shall be done semi-annually and on-demand to ensure continuous quality control and improvement (CQI) at the facility and regional level.
 3. All facilities offering PrEP shall maintain PrEP forms and submit monthly report to the Epidemiology Bureau and Regional Epidemiology and Surveillance Unit. *(Please see Annexes 7-11 at <https://bit.ly/prepannex>.)*
 4. Aligned with FDA regulations, all PrEP providers shall report any adverse side effects encountered to the FDA using existing pharmaco-vigilance mechanisms.

VII. PROGRAMMATIC CONSIDERATIONS

The roll-out of PrEP shall follow a phased approach as summarized below:

	Year 1	Year 2	Year 3
Geographic Area	NCR, Central Visayas, Central Luzon, and select Global Fund and PEPFAR Category A sites. Facilities in other regions which have the capacity and interest to deliver PrEP services	All other HIV category A cities	Nationwide

VIII. ROLES AND RESPONSIBILITIES

- A. Disease Prevention and Control Bureau (DPCB)
1. Set general direction, develop policies, and allocate resources for PrEP implementation
 2. Convene the HIV sub-technical working group to regularly review the PrEP Guidelines
 3. Coordinate the supply and distribution of donated PrEP drugs
- B. Epidemiology Bureau (EB)
1. Develop and implement the PrEP monitoring and evaluation plan
 2. Manage, process, and provide PrEP data to the DPCB and relevant partners
- C. Centers for Health Development (CHDs)
1. Disseminate the guidelines
 2. Provide technical and logistical support to relevant facilities
 3. Advocate to local government units for the availability of PrEP drugs and related services
 4. Strengthen service delivery network to ensure access to HIV services, including PrEP
 5. Conduct regular monitoring on the implementation of these guidelines
- D. Local Government Units (LGUs)
1. Institutionalize the implementation of these guidelines
 2. Ensure provision of quality PrEP services
 3. Conduct quality management of PrEP services and monitoring of PrEP implementation
 4. Ensure timely submission of reports and adherence to reporting standards
- E. Partners from public and private sector health facilities and community-based organizations
1. Provide PrEP services
 2. Ensure linkage of clients to HIV prevention services, including access to PrEP
 3. Conduct awareness and demand generation activities for PrEP

4. Ensure timely submission of reports and adherence to reporting standards

F. Development Partners

1. Support PrEP implementation through provision of technical assistance, augmentation of financial and logistical resources

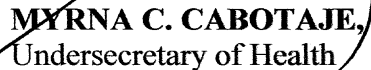
IX. FUNDING

The National HIV, AIDS, and STI Prevention and Control Program of the DPCB and CHDs shall allocate budget to support the implementation of these policies and guidelines, especially on capacity – building, monitoring and evaluation, and augmentation of PrEP drugs. In 2021 and 2022, PrEP Drugs shall be sourced out from HIV projects and grants. The LGUs may procure FDA-registered PrEP drugs based on their respective annual operational plans.

X. EFFECTIVITY

This Department Memorandum shall take effect immediately.

By Authority of the Secretary of Health:


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Undersecretary of Health
Public Health Services Team