Guideline on PrEP service delivery at community-led facility.

At present, prevalence of HIV infection in the Key Populations (KP) in Thailand is still is high. Therefore, it is important to undertake prevention and intervention measures to address this issue. The key mission is to reduce new HIV infections in high-risk population groups. Additionally, there is a need to enhance the accessibility of services for KP to promote their access to preventive and health-promoting services. This includes reducing new HIV infections, increasing access to services, and promoting KP health. This will strengthen community-based service delivery systems. The success of these tasks depends on collaboration and integration of efforts from all relevant sectors. Civil Society Organizations (CSO) have played a significant role in collaborating to provide services, including Pre-Exposure Prophylaxis (PrEP). Services also involve counseling and guidance to prevent HIV infection, blood testing, and care for people living with HIV (PLHIV). Care involves monitoring service recipients and assisting the target population in accessing these services. Furthermore, it includes accessing services for the prevention and treatment of diseases related to HIV, such as sexually transmitted infections (STI), tuberculosis (TB), hepatitis B (HBV), and hepatitis C (HCV).

Therefore, for the smooth and effective implementation of Pre-Exposure Prophylaxis (PrEP) services to prevent HIV, in accordance with the authority granted in Section 7, Paragraph 2, of the Ministry of Public Health regulations concerning individuals under the jurisdiction of ministries, departments, the Bangkok Metropolitan Administration, Pattaya City, provincial administrative organizations, municipalities, and local administrative organizations, as proclaimed by the Thai Cabinet in the Royal Gazette or the Thai Government Gazette, the task of practicing medicine is delegated to medical professionals. This includes healthcare professionals as defined in the Medical Profession Act (Version 4) of 2019, Section 7, Paragraph 2, of the Ministry of Public Health regulations concerning individuals under the jurisdiction of ministries, departments, the Bangkok Metropolitan Administration, Pattaya City, provincial administrative organizations, municipalities, and local administrative organizations, as proclaimed by the Thai Cabinet in the Royal Gazette or the Thai Government Gazette. The practice of pharmaceuticals is also delegated to pharmaceutical professionals, as defined in the Pharmacy Profession Act of 2019, Section 7, Paragraph 2, of the Ministry of Public Health regulations concerning individuals under the jurisdiction of ministries, departments, municipalities, and provincial administrative organizations.

The Tambon Administrative Organizations (TAO), Bangkok Metropolitan Administration, Pattaya City, and other special local administrative organizations as specified

by law or the Thai Government Gazette, are authorized to engage in the medical technical profession under the control of officers who are medical technicians or healthcare professionals (Version 3)2019. Therefore, the Ministry of Public Health has established guidelines for providing PrEP services for clinical sites and CSO as follows:

1. Objectives

1.1 To establish service linkages between healthcare facilities and CSO for the provision of PrEP services under the AIDS response policy.

1.2 To efficiently and comprehensively provide HIV services, as well as services for syphilis, gonorrhea, chlamydia, or other STI, ensuring accessibility and coverage for the target population.

1.3 To reduce the incidence of new HIV infections, leading towards the goal of ending the threat of AIDS by 2030.

2. Details and steps in implementation

2.1 Registration

Encourage CSO personnel to engage with KP groups to access the Reach, Recruit, Test, Treat, and Retain (RRTTPR) service package. Additionally, facilitate the registration of these populations for services with the CSO.

2.2 Pre-test counseling (HIV) and client assessment before dispensing PrEP

For CSO personnel who have undergone training in courses specified by the Ministry of Public Health (or equivalent) and have received a certificate of knowledge and competency from the Ministry of Public Health, or a guarantee provided by the service provider regarding competency in screening for HIV and other STI, thoroughly assess the readiness and understanding of service recipients. Additionally, provide detailed and accurate counseling on PrEP, and must be under the supervision of healthcare professionals and pharmaceutical professionals, according to the following steps:

2.2.1 Assess the risk, readiness, and understanding of the service recipient thoroughly, providing detailed and accurate counseling on medication, such as potential side effects and the dosing regimen.

2.2.2 Assess whether the client might have latent (undetectable) HIV infection ('Window period'). If found to be within the Window period, emphasize the importance of testing in the first month.

2.2.3 Assess symptoms of acute HIV infection, including commonly observed signs such as fever, diarrhea, rash, enlarged lymph nodes, and other relevant

symptoms like muscle pain and weight loss. If the service recipient exhibits these symptoms, suspect acute HIV infection. These cases may not be ready to start medication yet.

2.2.4 Obtain a medical history regarding chronic conditions, such as diabetes, high blood pressure, and chronic kidney disease.

2.2.5 Evaluate readiness for medication adherence and follow-up appointments. In this regard, service providers should establish agreements regarding medication adherence and follow-up appointments, ensuring that service recipients understand the importance of taking medication correctly, and consistently attending follow-up appointments. Assessing the potential to conduct adequate follow-up adherence can be challenging, but it is crucial before initiating medication. Provide counseling on the benefits of adhering to follow-up appointments and the potential drawbacks of not attending follow-up appointments. This helps increase awareness of the importance of returning for blood tests. Emphasize the advantages of attending follow-up appointments in the first month, as it is crucial for service recipients to return for HIV testing, especially when some individuals may be in the Window period.

2.3 Laboratory procedures

2.3.1 Case of CSO registered as a medical technology clinic

After providing pre-service counseling for the client, CSO personnel should next verify and confirm the identity of the client by asking for their name, surname, and Thai national ID number. Additionally, screen for HIV infection and other STI such as syphilis. Also, assess kidney function (Creatinine and CrCl) based on the considerations outlined in Table 1, and test for hepatitis B virus (HBsAg). The HBsAg test may be omitted if a previous anti-HBs result has been reactive/positive. In all cases, send the test results to the partnering healthcare facility for documentation in the national laboratory information system. Notify the relevant personnel for counseling and ongoing care for the service recipient.

Table 1: Kidney Function Criteria for Clients Seeking PrEP*

Chronic condition affecting the kidney	Age (yrs)	First test	Follow-up test every 6 - 12 months
no	< 30	None needed	None needed
no	30 - 49	Test	Those with CrCl < 90
no	≥ 50	Test	Test
yes	All age groups	Test	Test

***Give special considerations to clients who are seeking on-demand PrEP

2.3.2 Cases of CSO not registered as a medical technology clinic

After service recipients have received counseling, CSO personnel should proceed to verify and confirm the client's identity by asking for their name, surname, and Thai national ID number. Additionally, schedule appointments for referrals to conduct screening for HIV and other STI at another clinic or partnering healthcare facilities.

2.4 Other blood testing

In cases where additional blood tests are needed, CSO personnel should send the laboratory test results and service recipient information to the partnering healthcare facility for further blood testing.

2.5 Recording data

The healthcare facility records the service recipient's information in the health registry database system, and submits a medication order request for the supervising physician's consideration.

2.6 Consideration of the lab test results, diagnosis and dispensing PrEP

2.6 Medication Prescription and Counseling:

2.6.1 If the physician Prescribes for PrEP, the service provider responsible for dispensing medication should provide guidance on medication usage considering effectiveness, safety, and suitability for the service recipient or specific medication user. Emphasis should be placed on the medication administration method, limitations, and

restrictions. The service recipient should be informed of this information and also be informed to attend scheduled follow-up appointments.

2.6.2 In case the physician does not prescribe PrEP, the service provider should advise the service recipient to adopt alternative methods for preventing HIV infection, such as using condoms, and recommend regular blood testing (at least every 6 months) or more frequently in the case of potential exposure to HIV.

2.6.3 If the HIV test results are received, and the physician concurs, the service provider or CSO personnel should communicate the lab results and provide counseling to the service recipient. In the case of HIV-positive results, the service provider should advise the service recipient to start antiviral medication immediately. In the case of negative results, the service provider should consider prescribing PrEP medication, and provide information on medication usage. The service provider should also inform the service recipient about kidney function test results (Creatinine and eGFR) and testing for HBV (HBsAg). It is essential to note that the kidney function test HBsAg results may take more than 1 day to be available. Therefore, when the results are ready, the service provider should promptly inform the service recipient, for example, through a phone call. In the case of abnormal test results, the following actions should be taken:

(1) In case of abnormal kidney filtration rate (eGFR < 60 mL/min), the following actions should be taken:

(1.1) If it is not possible to start PrEP, discontinue the medication immediately, and recommend using condoms for every episode of sex

(1.2) Refer the service recipient to a specialist physician for kidney-related issues

(1.3) Evaluate the intake of vitamins, supplements, whey protein, and other related factors.

(2) In case of Hepatitis B virus infection (HBsAg: Positive), PrEP can be taken. The presence of HBV infection should not be a contraindication for PrEP, as PrEP medications can also effectively treat HBV infection. However, it is essential to emphasize continuous daily medication intake and discourage self-discontinuation, as it may lead to drug-resistant HBV. The final decision depends on the physician's discretion.

2.7 Review and approval of PrEP dispensing

CSO personnel should coordinate with the pharmacist to receive dispensed medications along with labels and instructions for service recipients.

2.8 Making an appointment to deliver PrEP and storage of PrEP drugs

After completing steps 2.6 and 2.7, CSO personnel should schedule a date, time, and delivery method to provide medications to the service recipient. They should inquire about the preferred method for receiving medication, and deliver it to the service recipient according to the agreed-upon date, time, and method. If it is not possible to deliver the medication on the day received from the pharmacist, CSO personnel should store the medication at the CSO according to the details specified in the accompanying document of these guidelines.

2.9 Follow-up and medication adherence information

2.9.1: When the service recipient decides to take medication, CSO personnel or service provider should assess appointment dates each time, namely, in Months 1, 3 and every 3 months thereafter.

2.9.2: CSO personnel or service provider should consistently and regularly follow up with service recipients to ensure effective medication intake, and prevent blood-related side effects while taking PrEP. This should be carried out as follows:

2.9.2.1 Evaluate side effects from taking medication, such as headaches and nausea. Normally, these symptoms should disappear within 1 week, and stopping medication should return things to normal, possibly with a slight increase in kidney function values.

2.9.2.2 Assess the regularity of medication intake, examining how the service recipient has been taking medication over the past month and whether it has been effective.

2.9.2.3 Evaluate the effectiveness of medication intake (PrEP Effective Use) with the following detailed assessment criteria:

(1) In the case of choosing daily continuous medication, for male service recipients, a minimum of 4 pills per week is recommended. For male service recipients using hormone therapy for gender transition or female service recipients, a minimum of 6 pills per week is recommended.

(2) In the case of choosing medication specifically for periods of anticipated risky sexual activity, follow this regimen: For the first instance, take 2 pills within a time window of 2 - 24 hours before engaging in sexual activity. For the second instance, take 1 pill after 24 hours have passed since the last sexual activity. For the third instance, take 1 final pill after an additional 24 hours have passed since the second pill. (Administer in the pattern 2 + 1 + 1).

(3) In the event of an assessment revealing that the service recipient is not adhering to the instructions in (1) or (2), CSO personnel or service provider should provide information or guidance on proper medication intake to the service recipient.

2.9.2.4 Evaluate the risk and risk behavior for HIV infection, and conduct assessment and counseling similar to the steps taken before initiating PrEP.

2.10 Services for clients experiencing a seroconversion

If the PrEP acceptor tests HIV+ after already starting on PrEP, the CSO personnel or service provider should assist in various aspects, such as referring the client to a clinic, and/or provide guidance on seeking convenient healthcare services. The service recipient should be encouraged to start antiretroviral therapy (ART), and must enter the healthcare system promptly and appropriately. Close and continuous monitoring is essential, especially regarding the mental well-being of the service recipient. Additionally, they should undergo assessments for depression and suicide risk.

2.11 Discontinuing PrEP

In cases where the service recipient assesses themselves as having no risk for HIV, they are allowed to discontinue PrEP. Alternatively, if there are indications of drug allergies or side effects, the physician may consider instructing the recipient to stop taking the medication, with the following details:

(1) Indications for discontinuing medication:

(1.1) Experience side effects from medication, such as abnormal kidney function, drug rash, hepatitis, etc.

(1.2) Contracting HIV infection

(1.3) Having symptoms or suspicion of acute HIV infection or receiving inconclusive HIV test results. In such cases, consult a physician for confirmation.

(1.4) The service recipient self-assesses as having no current or future risk behavior for HIV infection.

(2) Steps to Discontinue Medication:

(2.1) When a service recipient expresses a desire to stop taking the PrEP medication, the CSO personnel or service provider should inquire about recent HIV risk behavior or sexual activity and the effectiveness of recent medication.

(2.2) If the service recipient is adherent to the medication, males can stop taking the medication for a period of 2 days after engaging in sexual activity. For males using hormones for gender transition or females, the medication can be stopped for a period of 7 days after sexual activity.

(2.3) In cases of non-adherence to the medication, advise the service recipient to discontinue the medication after a negative test result or 4 weeks after the latest sexual activity. Schedule a follow-up HIV test for the service recipient.

(2.4) Conduct an HIV test each time the service recipient wishes to stop taking PrEP.

(2.5) Record information in the system, specifying the reason for discontinuing PrEP.

(2.6) In cases where a service recipient with HBV wishes to stop taking the medication, refer them to consult with the hospital's medical professional, emphasizing not to discontinue the medication independently as it may lead to HBV reactivation.

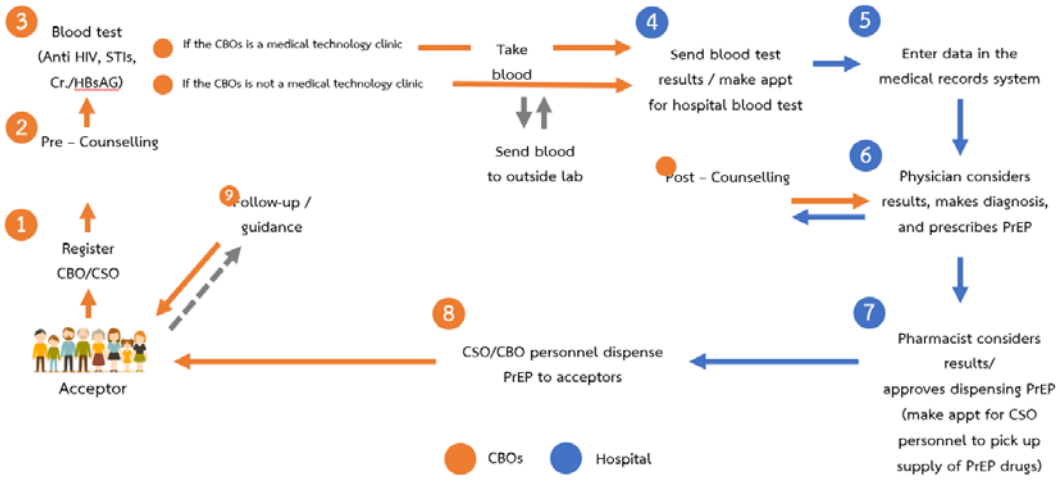
(2.7) For service recipients who stop taking medication due to side effects, such as abnormal kidney function, continuously monitor their symptoms even after discontinuation. The decision depends on the discretion of the hospital's medical professional.

(2.8) Encourage the service recipient to return for re-initiation of PrEP if self-assessment indicates a renewed risk of HIV infection. Additionally, recommend other preventive methods such as using condoms for every episode of sex.

2.12 Return to use of PrEP after a discontinuation

Service recipients who wish to resume medication after discontinuing PrEP for more than 1 month must undergo a risk assessment and evaluations based on various screening criteria, similar to the initial service visit. This will be considered as a new visit, labeled as Month 0, without counting subsequent visits. Schedule follow-up appointments for the service recipient in Month 1, Month 3, and every 3 months thereafter.

Flow Details and Operational Steps for PrEP Service for Clinical Facilities and CSO



Attachment

Guidelines for Managing Medication Inventory and Dispensing Practices for Pre-Exposure Prophylaxis (PrEP) for Service Recipients.

Item 1: Procedures

1.1 Documentation

Organize document storage in both physical and electronic formats, categorizing them as follows:

1.1.1 Folder or directory specifically for storing evidence of prescription orders and medication returns, with daily storage and further categorization into monthly documents.

1.1.2 Folder or directory exclusively for storing evidence of received medications, including forms sent by healthcare facilities. Ensure organized storage of medication delivery forms.

1.1.3 Folder or directory specifically for documents related to monthly reports.

Maintain these document categories according to the specifications in 1.1.1 - 1.1.3 above for a minimum of 5 years.

1.2 Medication Delivery and Record

1.2.1 For each medication delivery, a clear prescription from a physician is required. Patient's name, surname, and date of birth must be verified in accordance with the specified patient identification standards, and it must match the name and surname of the service recipient as indicated on the medication label Additionally, basic information must be provided to individuals picking up the medication, including the following details:

(1) Medication name and its indications

(2) Appropriate medication administration, dosage, and usage instructions

(3) Commonly encountered side effects and undesired effects resulting from drug interactions or interactions with food

(4) Precautions and guidelines to follow while using the medication

(5) Actions to take in case of problems arising from medication use

(6) Proper medication storage practices

1.2.2 If there are multiple Lot Numbers for the medication, the medication must be delivered according to the expiration date, following the First Expired, First Out (FEFO) principle. It is recommended that the prescription includes the following information:

(1) Full name or identifiable abbreviation of the service recipient

(2) UID, HN, PID, or any assigned identification number for each service recipient

(3) Physician's name along with the physician's signature

(4) Signature of the medication dispenser dispenser and delivery personnal

(5) List of dispensed medications

(6) Quantity of medications dispensed

(7) Lot Number and Expiration Date of the delivered medications

1.3 Stock inventory

1.3.1 Medication Receipt: When medications are sent from the healthcare facility to the CSO, follow the steps below:

(1) Inspect the medications by verifying the medication name, Lot Number, Expiration Date, and quantity against the accompanying documents.

(2) Upon receiving the medications from the healthcare facility:

- If the medication delivery is correct, arrange the medications in the storage room following the FEFO principle.
- Separate opened medication boxes from unopened ones.
- If discrepancies are found compared to the documents sent by the healthcare facility, inform them via email, keep the medications separate, refrain from placing them on the medication shelves, and immediately contact the hospital coordinator.

1.3.2 Drug stock management and reporting

(1) Daily Reporting: Input prescription information into the designated form and ensure complete and accurate data entry.

(2) Monthly Medication Counting: CSO personnel must conduct a monthly count of remaining medications, comparing it with the healthcare facility's summarized report (from daily form entries). If any discrepancies in Lot Numbers or expiration dates are identified, promptly notify the hospital coordinator.

(3) Medication Storage:

(3.1) The quantity of stored medications at CSO should cover more than 1.25 months (1 month and 1 week), not exceeding 3 months of the average medication consumption rate (bottles/month).

(3.2) In cases where CSO's storage space is insufficient based on the maximum stock level, store the maximum quantity of medications that the healthcare facility can accommodate.

(4) Verification:

(4.1) Representatives from the healthcare facility and CSO network should verify monthly medication delivery/returns data, comparing it with CSO's inventory.

(4.2) Representatives from the healthcare facility and CSO should inspect prescription documents and medication inventory at least every 3 months or as necessary.

Item 2: Stock management

The storage facility and system for maintaining medications must be adequately suitable and safe, ensuring storage conditions that align with health standards. This includes considerations for temperature, lighting, humidity, ventilation, proportional storage, and overall safety. The storage environment should adhere to technical principles related to public health, providing guidelines for efficient management and convenient facilities that support workplace practices according to occupational health standards. The medication storage area and refrigerators must have a continuous temperature monitoring system in place to ensure consistent storage conditions.

2.1 Drug storage area management

2.1.1 The medication storage area must implement measures to prevent unauthorized individuals from entering, both from outside and within the pharmacy section. The pharmacy has established preventive measures at two points: the first point is at the entrance to the pharmacy section, and the second point is at the entrance to the medication storage room within the pharmacy section. The entrance to the medication storage room has a locked door from the inside.

2.1.2 The medication storage area should be clean, hygienic, and regularly cleaned, including the storage space and surrounding areas.

2.1.3 The medication storage area should have sufficient electrical lighting to ensure accurate, precise, and safe work practices.

2.1.4 The space used for medication storage must have a sturdy structure, with adequate size to organize various types of medications systematically. The area should be compartmentalized, preventing cross-contamination, and clear signage displaying the names of medications should be placed on the shelves for easy identification.

2.2 Storage conditions and temperature monitoring

2.2.1 Each type of medication should be stored according to the conditions specified on the medication label or package insert. These specifications are derived from the results of stability testing conducted by the pharmaceutical manufacturer. Generally, medications that specify room temperature storage should not exceed 25°C or 30°C, depending on the specific medication.

2.2.2 The air conditioning system within the medication storage area should be kept operational 24 hours a day, even during non-operational hours, to maintain the temperature within the designated range (between 15°C - 30°C).

2.2.3 Pharmacists or pharmacy assistants should record the temperature in the medication storage area twice a day—both within the storage room and in the refrigerator used for medication storage. These records are kept for tracking and verification purposes.

2.2.4 If any temperature-related issues are identified, such as temperatures falling below 15°C or exceeding 30°C within the medication storage area, prompt investigation and corrective action should be taken.

2.2.5 Medical refrigerators and temperature monitoring devices should undergo a condition check or calibration at least once a year by a reliable and certified entity. A *Certificate of Calibration* should be obtained and kept as evidence.

2.3 Sub – Storage area management

The sub – storage area must be in suitable conditions adhering to technical standards in health, including temperature, lighting, humidity, ventilation, and safety. Additionally, it should have management guidelines and facilities conducive to occupational health practices, as follows:

2.3.1 The location for sub – storage and drug delivery must be clean, sanitary, and regularly cleaned.

2.3.2 There should be an electrical system providing sufficient lighting for accurate, precise, and safe work operations.

2.3.3 There should be a recording of temperature and humidity levels at least twice a day, maintaining room temperature not exceeding 25°C and humidity not exceeding 60% RH.

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