

แนวทางการจัดบริการ ยาป้องกันก่อนการสัมผัสเซื้อเอชไอวี ประเทศไทย ปี 2564

Thailand National Guidelines for Pre-Exposure Prophylaxis (PrEP) 2021

แนวทางการจัดบริการยาป้องกันก่อนการสัมผัสเชื้อเอชไอวี ประเทศไทย ปี 2564 ได้ผ่านการตรวจประเมิน และรับรองมาตรฐานผลิตภัณฑ์ เพื่อการเฝ้าระวัง ป้องกัน ควบคุมโรคและภัยสุขภาพ กรมควบคุมโรค ณ วันที่ 25 สิงหาคม 2564

Citation: Division of AIDS and Sexual Transmitted Diseases. Department of Disease Control. Thailand National Guidelines for Pre-Exposure Prophylaxis (PrEP) 2021. Edition 2. Nonthaburi: Department of Disease Control (TH); 2021.

Advisors:

Dr. Opas Karnkawinpong, Director-General of the

Department of Disease Control, MOPH

Dr. Preecha Prempree, Deputy Director-General, Department of Disease Control, MOPH

Dr. Taweesap Siraprapasiri, Medical Doctor, Advisory Level, Department of Disease Control, MOPH

Dr. Cheewanan Lertpiriyasuwat, Director of the Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH, MOPH

Dr. Hansa Raksakom, Director of Division of Occupational and Environmental Diseases, Department of Disease Control, MOPH

Panel of medical experts to consider the completeness of the content

Assoc. Prof. Dr. Thanyawee Phuthanakij, Faculty of Medicine, Chulalongkorn University

Assoc. Prof. Dr. Thana Khocharoenporn, Faculty of Medicine, Thammasat University

Dr. Ekchitra Sukkul, Medical Accreditation Institute (Public Organization)

Dr. Nittaya Phanuphak Pungpapong, Institute for Research and Innovation in HIV

Dr. Peerawong Weerarak, Faculty of Medicine, Siriraj Hospital, Mahidol University

Editors

Dr. Montinee Wasantiupapokakorn, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH

Dr. Supanut Thitiphatakorn, Institute for HIV Research and Innovation (IHRI)

Ms. Chomnad Manopaiboon, Thailand MOPH - U.S.CDC Collaboration (TUC)

Assistant Editors

Mr. Yuthaphum Srikhamchin, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Mr. Thanawong Buasorn, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Mrs. Usanee Kritsanavarin, Thailand MOPH – U.S.CDC Collaboration (TUC)

Content Managers

Mrs. Pornthip Khem-ngern, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Mrs. Nuchanart Kaewdamkoeng, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Ms. Ploenphit Prommali, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Ms. Naparat Phataprayoon, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Miss Areerat Yuttapreechanan, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Ms. Narumon Busamongkol, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH Mrs. Busaba Tantisak, Global Fund Project Management Office, Department of Disease Control

Ms. Chomnad Manopaiboon, Thailand MOPH – U.S.CDC Collaboration (TUC)

Mrs. Usanee Kritsanavarin, Thailand MOPH – U.S.CDC Collaboration (TUC)

- Ms. Farida Langkafah, Thailand MOPH U.S.CDC Collaboration (TUC)
- Mr. Prin Visavakum, Thailand MOPH U.S.CDC Collaboration (TUC)
- Mr. Somboon Nookhai, Thailand MOPH U.S.CDC Collaboration (TUC)
- Ms. Monsicha Poolsawat, UNICEF Thailand
- Dr. Supanut Thitiphatakorn, Institute for HIV Research and Innovation
- Dr. Kantinan Rungthanatada, National Health Security Office
- Dr. Weerawat Manosutthi, Bamrasnaradura Institute
- Dr. Rapeepan Rattanawongnara-Mord, Faculty of Medicine, Ramathibodi Mahidol University
- Dr. Supannee Jirajariyavej, Taksin Hospital
- Dr. Thitisan Palakawong Na Ayudhya, Public Health Service Center 28, Krungthonburi, BMA
- Dr. Chantaphat Phrueksawan, Public Health Service Center 26, Chao Khun Phra Prayoonwong, BMA
- Mr. Pipattananon Taree, Lerdsin Hospital
- Ms. Prapaporn Kitwattanachai, Udon Thani Hospital
- Ms. Lisa Kanthamala, Independent Scholar
- Ms. Areewan Charoenruen, Independent Scholar
- Mr. Veeraphan Ngammee, Ozone Foundation
- Mr. Chamrong Phaengnongyang, SWING Foundation
- Mr. Thitiyanan Nakpor, SISTER Foundation
- Mr. Thanachai Chaisalee, Rainbow Sky Association of Thailand
- Ms. Lawan Santichinkul, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH
- Mr. Yuthaphum Srikhamchin, Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH

Printing

Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH

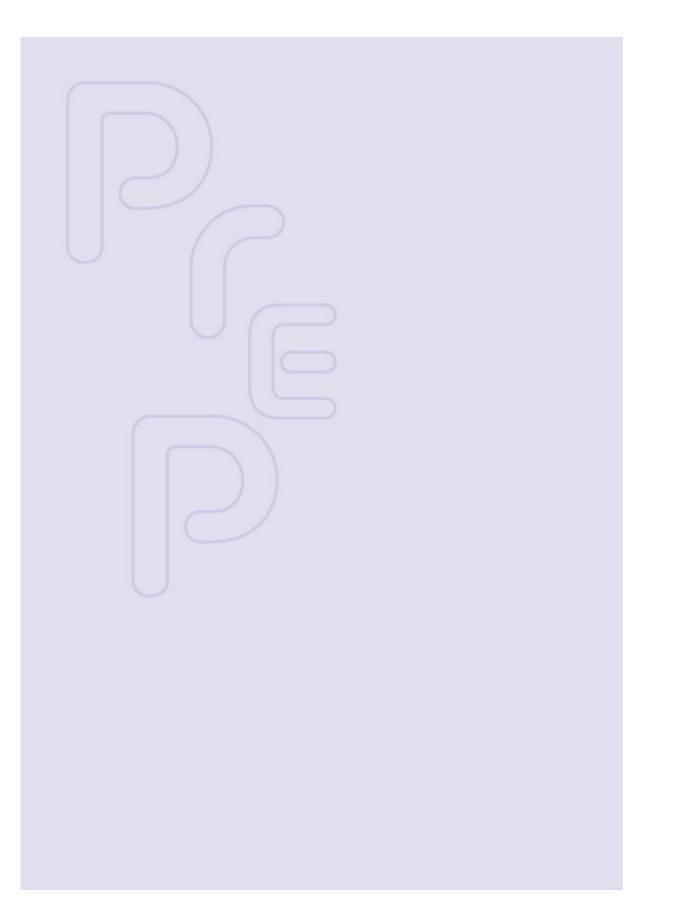
Financial Support

MOPH-TUC Coordinating Unit (Co-Unit), US CDC

Print Run

2nd printing (Revised Edition) 4,000 copies Place of publication: Graphic and Design Publishing House ISBN: 978-616-11-4746-4

© Division of AIDS and Sexually Transmitted Infections, Department of Disease Control, MOPH



Preface

At the present time, HIV prevalence in Thailand is still unacceptably high in Key Populations. Thus, the government is promoting intensive interventions to reduce HIV incidence, in line with the National Strategy on Ending AIDS 2017-30. Strategy 1 focuses on accelerating the provision of highly effective prevention services to cover the populations with high-risk and in high-risk areas of the country. As part of this effort, the Thai National AIDS Committee has approved, in principle, the policy to promote HIV pre-exposure prophylaxis (PrEP) for populations who cannot avoid short-term risk of HIV transmission.

To be effective, quality PrEP services must be conveniently and equally available to those in need before anticipated exposure to risk. This principle is consistent with the national health security policy that people with risk for HIV be able to access HIV prevention services to reduce new infections and help the country progress toward the Ending AIDS goal. This national policy has support from relevant technical and capacity building agencies.

The Department of Disease Control of the Ministry of Public Health (MOPH) through the Division of AIDS and Sexually Transmitted Infections, together with the MOPH–TUC Coordinating Unit and other related network partners, has continually advocated for a Thai PrEP service policy. Although the effectiveness of PrEP in preventing HIV infection has been recognized internationally, there are still challenges to implementation that require cooperation from all sectors in order to provide effective access to people at risk of HIV to client-friendly PrEP services which conform with the Thai context. The roll-out of PrEP nationwide also requires on-going monitoring and evaluation of service delivery to reduce the gap in service coverage and ensure that PrEP is being used safely and cost-effectively.

In order to consistent provide quality PrEP services, there need to be standard operational procedures to align the actions of service providers. Such a set of guidelines will guarantee that any client can expect the same standard PrEP service wherever they seek it. In 2018, the Division of AIDS and STIs, together with MOPH–TUC Coordinating Unit and network partners, produced the first version of Guidelines for Pre-exposure Prophylaxis for Thai providers. Since then, there have been advancements and new technology in the provision of PrEP. Thus, it is appropriate to update the 2018 guidelines to incorporate these advances. The development of this version of the PrEP guidelines has been through collaborative work and discussions with stakeholders and practitioners to propose improvements so that the Thai PrEP service has optimum reach and cost-effectiveness, and continues to help pave the way to ending the AIDS threat in Thailand, which is the ultimate goal of the policy and program.

Division of AIDS and STIs Department of Disease Control, Ministry of Public Health July 30, 2021

Contents

Chapter 1 Introduction

- 1.1 Summary of PrEP services in the guidelines
- 1.2 Objectives of developing the guidelines
- 1.3 Key elements of the guidelines
- 1.4 Users of the guidelines

Chapter 2 Background and Importance of PrEP Services in Thailand

- 2.1 From research to development of PrEP services
- 2.2 PrEP service delivery model in Thailand

Chapter 3 Clinical and laboratory information on PrEP

- 3.1 Effectiveness of PrEP
 - 3.1.1 Effectiveness of Daily PrEP
 - 3.1.2 Effectiveness of On-demand-PrEP
- 3.2 PrEP indications
- 3.3 PrEP recipients (eligibility criteria)
- 3.4 Information on current regimen for oral PrEP
- 3.4.1 PrEP regimen
 - 3.4.2 Food and absorption
 - 3.4.3 Adverse reactions
 - 3.4.4 Side effects of PrEP
 - 3.4.5 Drug storage
 - 3.4.6 PrEP drug interactions
 - 3.4.7 Drug use in patients with kidney disease
 - 3.4.8 Drug use in patients with liver disease
- 3.5 Issues to consider when initiating PrEP and following up
- 3.6 Acute HIV infection
 - 3.6.1 Acute HIV infection
 - 3.6.2 Diagnosis of acute HIV infection while taking PrEP
- 3.7 Laboratory examination
 - 3.7.1 Laboratory examinations at and after PrEP initiation
 - 3.7.2 Knowledge of diseases at the beginning and after the start of PrEP
 - 3.7.2.1 Monitoring of renal function
 - 3.7.2.2 Examination and follow-up for the treatment of STIs
 - 3.7.2.3 Hepatitis B virus testing and monitoring
 - 3.7.2.4 Hepatitis C screening and monitoring
 - 3.7.2.5 Bone Marrow Density Assessment
- 3.8 PrEP intake
 - 3.8.1 Daily PrEP intake
 - 3.8.2 On-demand PrEP
- 3.9 Stopping PrEP
- 3.10 In the event that the service recipient has chronic HIV risk
- 3.11 PrEP dosing after nPEP
- 3.12 Considerations for pregnant women

- 3.13 In case of HIV sero-conversion while taking PrEP
- 3.14 Considerations for providers when initiating PrEP services

Chapter 4 PrEP Service Arrangement

- 4.1 PrEP service management flowchart
- 4.2 Components of PrEP service provision
- 4.3 Service process
- 4.4 Same-day PrEP service model
- 4.5 Different types of services that meet the needs of the target group
- 4.5.1 Civil Society health center services by Key Populations (KPLHS)
- 4.5.2 PrEP service delivery model during the Covid-19 epidemic in Thailand

Chapter 5 Counseling Services for PrEP

- 5.1 Counseling process
- 5.2 Information about PrEP
- 5.3 PrEP service options and PrEP counseling procedures
 - 5.3.1 Counseling services before starting PrEP
 - 5.3.2 Counseling and follow-up services during PrEP intake
 - 5.3.3 Counseling services before stopping PrEP

Chapter 6 PrEP Service Arrangements for Specific Target Groups

- 6.1 Discordant couples
- 6.2 Men who have sex with men
- 6.3 Transgender women
- 6.4 Adolescents
- 6.5 Pregnant women
 - 6.5.1 Provision of PrEP for pregnancy planning (preconception)
 - 6.5.2 PrEP service provision during pregnancy (antenatal)
 - 6.5.3 PrEP service provision after childbirth and during lactation (postpartum and breastfeeding)
- 6.6 Persons who inject drugs

Chapter 7 Creating Demand and Promoting Access to PrEP Services

- 7.1 The process for creating demand and promoting access to PrEP services
- 7.2 Communication guidelines on PrEP
- 7.3 Communication strategy level and promoting access to PrEP services
- 7.4 PrEP communication strategies
- 7.5 Strategies for creating demand and supporting access to PrEP
 - 7.5.1 Motivating and supporting access to PrEP Access in the service unit setting
 - 7.5.2 Motivating and supporting access to PrEP outside the service unit setting

Chapter 8 Monitoring and Evaluation of PrEP Services

- 8.1 Framework for monitoring and evaluation of PrEP services in Thailand
- 8.2 Indicators according to the PrEP Cascade in Thailand
- 8.3 Roles and responsibilities in monitoring and evaluation at each level
- 8.4 Resources for monitoring operations and data recording
- 8.5 Guidelines for recording data in the NAP Plus system

References

Appendix

Appendix A Other PrEP formulations

Appendix B Interactions between PrEP and other drugs

Appendix C Estimating Creatinine Clearance with the Cockcroft-Gault Equation

Appendix D Experience of providing PrEP services during Covid-19 in 16 Community Health Centers, Department of Health, Bangkok Metropolitan Administration

Appendix E Experience of providing PrEP services during Covid-19 by Key Population groups

Appendix F Information from the Adolescent PrEP Service Monitoring System

Appendix G Recording procedure and information to be recorded in the NAP Plus system

Appendix H Order of the Department of Disease Control No. 1868/2563; Subject: Appointment of a working group to develop guidelines to provide HIV Pre-Exposure Prophylaxis (PrEP) in populations with high-risk behavior

List of Tables

Table 1.1 Summary of PrEP Services Table 1.2 New issues presented in this guidelines Table 3.1 PrEP efficacy from research projects Table 3.2 Indications for PrEP Table 3.3 Considerations for PrEP initiation and follow-up Table 3.4 Signs and symptoms of acute HIV infection Table 3.5 Key issues concerning acute HIV infection and PrEP intake Table 3.6 Summary of laboratory tests at initiation and after PrEP initiation Table 3.7 Screening and monitoring of kidney function Table 3.8 Summary of laboratory examinations at the beginning and after the start of PrEP Table 3.9 Hepatitis B screening and PrEP management in hepatitis B-infected persons Table 3.10 Selection of daily PrEP regimens Table 3.11 Choosing between Daily PrEP and On-demand PrEP Table 3.12 Key points in On-demand PrEP counseling Table 3.13 Stopping PrEP Table 5.1 Check-list of topics and main discussion points before starting PrEP Table 6.1 Guidelines after HIV test results for fertility planning for discordant couples Table 6.2 Guidelines for the care of an HIV-negative pregnant woman with an HIV+ partner who is a member of a highrisk group for HIV infection, and assessment of duration since last HIV exposure Table 6.3 Guidelines for the care of postpartum and lactating HIV-negative women whose partners are HIV+ and still engages in risk behavior

Table 8.1 Monitoring and evaluation tools

Table 8.2 Step-by-step definitions of the Thailand PrEP Cascade used in monitoring operations

List of Figures

- Figure 1.1 HIV prevalence among key populations
- Figure 2.1 Background of PrEP service provision in Thailand
- Figure 3.1 Diagram showing how to take On-demand PrEP
- Figure 4.1 PrEP service provision process
- Figure 4.2 Flowchart of laboratory diagnostics for screening before PrEP
- Figure 4.3 Same-day PrEP service
- Figure 4.4 Different types of services that meet the needs of the target group
- Figure 4.5 PrEP service process by Key Population groups (KPLHS)
- Figure 5.1 Counseling for follow-up during PrEP
- Figure 6.1 Guidelines for ANC or delivery of an HIV-negative pregnant woman whose partner is HIV+
- Figure 6.2 Guidelines for HIV pre-test counseling at a Couples Clinic
- Figure 6.3 PrEP services for persons who inject drugs

อภิธานศัพท์

	อักษรย่อ	อักษรย่อ คำเต็ม		ความหมาย		
	3TC Lamivudine			ยาต้านไวรัสลามิวูดิน		
	АНІ	Acute HIV Infection		การติดเชื้อเอชไอวีระยะเฉียบพลัน		
	AIDS	DS Acquired immunodeficiency		drome โรคเอดส์ (กลุ่มอาการภูมิคุ้มกันเสื่อม)		
	ALT			ค่าเอนไซม์ของการตรวจการทำงานของตับ		
	Anti-HBs	Hepatitis B Surface antibody	การตรวจหาภูมิต้านทานต่อเชื้อไวรัสตับอักเสบบี			
	ART	Antiretroviral treatment		การรักษาด้วยยาต้านไวรัส		
	AST	Aspartate aminotransferase	ค่าเอนไซม์ของการตรวจการทำงานของตับ			
อักษรย่อ	CAD.	คำเต็ม		ความหมาย		
KPLHS	Key populatio	on-led health services	การจัดบริการที่นำ	าโดยกลุ่มประชากรหลัก		
LPV/r	Lopinavir/rito				การมีเพศสัมพันธ์	
	Mobile PrEP			EP ร่วมกับการออกหน่วย Mobile VCT		
MSM	Men who hav	ve sex with men	ชายมีเพศสัมพันธ์	กับชาย		
NAT	Nucleic acid a	amplification test	วิธีการตรวจหากา	รติดเชื้อจากสารพันธุกรรม		
NAP	National AIDS Program		ระบบสารสนเทศการให้บริการผู้ติดเชื้อเอชไอวี/ผู้ป่วยเอดส์แห่งชาติ			
NG	Neisseria gon	orrhoeae	เชื้อแบคทีเรียที่เป็	นสาเหตุของโรคหนองใน		
nPEP	HIV non-occupational post-exposure prophylaxis		การป้องกันการติดเชื้อเอชไอวีหลังการสัมผัสที่ไม่ใช่จากการทำงาน			
NSAID	Non-steroidal anti-inflammatory drug		ยาต้านการอักเสบชนิดที่ไม่ใช่สเตียรอยด์			
	On-demand PrEP		การกิน PrEP เฉพาะช่วง			
	Online bookii	Online booking		การจองคิวผ่านระบบออนไลน์		
РМТСТ	Prevention of mother-to-child transmission		การป้องกันการถ่ายทอดเชื้อเอชไอวีจากแม่สู่ลูก		หาแอนติบอดีและ	
PEP	HIV post-exposure prophylaxis		การป้องกันการติดเชื้อเอชไอวีหลังการสัมผัส			
PrEP	HIV pre-exposure prophylaxis		การป้องกันการติเ			
	Pre-test counseling		การให้การปรึกษา			
	Post-test counseling		การให้การปรึกษาหลังตรวจเลือด			
PWID	People who inject drugs		ผู้ใช้สารเสพติดด้วยวิธีฉีด			
RRTTR	Reach-Recruit-Test-Treat-Retain		การเข้าถึง-การเข้าสู่บริการ-ตรวจเอชไอวี-การรักษา-การคงอยู่ในระบบ			
	Same-day PrEP		รูปแบบการบริการ PrEP ภายในวันเดียว			
	Serodiscordant couple		คู่ผลเลือดต่าง			
STIs	Sexually transmitted infections		โรคติดต่อทางเพศ			
	Social harm		ผลกระทบทางสัง			
TAF	Tenofovir alafenamide		ยาต้านไวรัสทีโนโฟเวียร์แอละฟีนาไมด์ (ทีเอเอฟ)			
TDF	Tenofovir disoproxil fumarate		ยาต้านไวรัสทีโนโฟเวียร์ไดโซพรอกซิลฟูมาเรต (ทีดีเอฟ)			
	Telehealth		รูปแบบการให้บริการทางการแพทย์ทางไกล (โทรเวช)		งเพศสัมพันธ์ และ	
TGW	Transgender women		หญิงข้ามเพศ			
TUC	Thailand MOPH - US CDC Collaboration		ศูนย์ความร่วมมือไทย - สหรัฐ ด้านสาธารณสุข		อเอซไอวี	
U=U			ตรวจไม่เจอเชื้อ = ไม่สามารถแพร่เชื้อต่อได้			
VCT	Voluntary cou	unseling and testing	การให้การปรึกษาก่อนการตรวจเลือดเพื่อตรวจหาการติดเชื้อเอชไอวี ด้วยความสมัครใจ			
VL				เริ่มาณไวรัสในกระแสเลือด		
	Window period		ช่วงเวลาหลังจากที่ได้รับเชื้อแต่ยังตรวจหาเชื้อไม่พบ			

Chapter 1

Introduction

HIV infection is a major problem in Thailand and around the world, affecting overall public health, socio-economic development, and national security. HIV infection is not just a challenge for disease control and treatment. HIV has also exposed fundamental shortcomings in affected societies. For example, the HIV epidemic has tended to bring out negative stigma and discrimination against marginalized populations, and human rights violations against people living with HIV (PLHIV) and other affected people.

In 2020, it is estimated that Thailand had 460,000 PLHIV, with 4,800 new cases in that year, thirty-eight percent of which were among men who have sex with men (MSM).

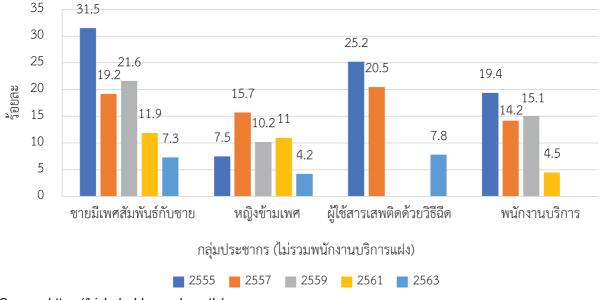


Figure 1.1 Prevalence of HIV among Key Populations ความชุกการติดเชื้อเอชไอวีในกลุ่มประชากรหลัก

In the past, Thailand has been successful in implementing policies and strategies for AIDS prevention and control. Many important Thai programs have included campaigns to educate the public, promotions for condom use, prevention strategies of mother-to-child transmission (MTCT) of HIV, and provision of affordable antiretroviral therapy (ART) for HIV infection. This effort has resulted in preventing more than two million Thais from being infected and dying from AIDS. In addition to these accomplishments, Thailand has helped pioneer the introduction of HIV pre-exposure prophylaxis (PrEP) in Asia, with a focus on groups with elevated HIV risk (e.g., MSM, transgender women, discordant couples who neglect to use condoms, persons who have difficulty preventing exposure to HIV, sex workers, STI patients and persons who inject drugs, etc.).

There is considerable evidence that taking certain formulations of ARV drugs (e.g., TDF/FTC) can be effective in preventing HIV infection prior to exposure (i.e., PrEP). Studies have found that PrEP can be highly effective in heterosexual couples (78% in the TDF2 Project), discordant couples (90% in the Partners PrEP Project), and MSM (100% in the iPrEx-OLE, IPERGAY and IPERGAY-OLE projects).

In 2021, there were 24,000-25,000 PrEP acceptors in Thailand. This set of guidelines is intended to help programs increase the coverage of PrEP for those in need. The content is based on the latest scientific data and information

Source: https://hivhub.ddc.moph.go.th/

from field implementation. It is the expectation that the study and application of these guidelines will help modernize PrEP service as a model for safe administration for vulnerable populations throughout Thailand.

1.1 Summary of this version of the national PrEP guidelines

New research findings on PrEP are being published every year. Plus, the HIV risk situation for groups of individuals tends to evolve over time. Therefore, these guidelines cover PrEP initiation, follow-up, and counseling services. Table 1.1 summarizes the fundamental steps in PrEP, while Table 1.2 presents new and emerging issues for consideration. For example, PrEP is recommended in the window period (before HIV infection can be verified) for individuals who are unable to avoid risk. The recommendation for On-demand PrEP for MSM is two PrEP tablets, 2-24 hours before sex. There are also guidelines for daily PrEP to shorten the time it takes for the drug to become effective.

Table 1.1: Summary of Key Components of the PrEP Guidelines

Торіс	Content
Key drug formulations	TDF/FTC, TDF/3TC or TAF/FTC (TAF/FTC are not to be used with women whose birth gender is female)
Follow-up appointment	Month 0, 1, quarterly
Laboratory examination	HIV at Month 0, 1, quarterly; kidney function (only in groups with risk of abnormal kidney function) Syphilis, gonorrhea, chlamydia, at Month 0, every 3-6 months; hepatitis B at Month 0, vaccination recommended for Hepatitis C at Month 0, and every 6-12 months Pregnancy at Month 0, and every time suspected
Minimum laboratory examination In the event of limitations preventing testing of all samples	HIV Kidney function (only in groups with risk of abnormal kidney function) Monitoring of hepatitis B (HBsAg, only those who have not yet acquired immunity)
Daily PrEP	Every group : The drug level will be sufficient to prevent infection after taking 1 tablet daily for 7 days MSM: The drug level will be sufficient to prevent infection after taking 2 TDF/FTC tablets at the same time (double dose) at least 2-24 hours before sexual intercourse
Discontinuing Daily PrEP	Every group : Take 1 pill a day for 7 days after last sexual intercourse MSM: Take 1 pill a day for 2 days after the last sex
On-demand PrEP: for MSM without hepatitis B infection	Take 2 TDF/FTC tablets at the same time (double dose) 2-24 hours before sexual intercourse. After that, take 1 tablet a day at the same time as the first dose for 2 days after intercourse (referred to as '2-1-1')
Effective use	Every group: Take at least 6 pills per week MSM: Take at least 4 pills per week
PrEP as part of the HIV prevention package	PrEP is part of the continuum of HIV prevention service, including counseling, ART, STI diagnosis and treatment, condom use, and periodic HIV VCT

Table 1.2 New issues addressed in this version of the guidelines

Use of PrEP for recent exposure while still in the window	PrEP can be taken, but emphasize the importance of repeat testing 1 month after starting PrEP		
period			
HIV self-testing	Use a standard, quality self-test kit for HIV infection to monitor effective use; in case of lack of access to a 4 th generation		
	HIV test with high sensitivity		
Cost of PrEP under the NHSO system	NHSO reimburses the cost for PrEP service and related laboratory tests for those who have risk behavior		
	for HIV infection		
Use of t h e TAF/FTC PrEP regimen as an alternative to	TDF/FTC is not recommended for people with impaired renal function with a glomerular filtration rate (CrCl) < 60 ml/min		
TDF/FTC	Therefore, TAF/FTC can be considered as an alternative for those with CrCl > 30 ml/min, applicable to all population groups -		
	- Except for (at-birth female gender) women who engaged in receptive vaginal intercourse, and not used in an on-demand		
	format		
PrEP on demand	On-demand PrEP can be administered for MSM without hepatitis B		
Initiating and discontinuing Daily PrEP	Reduce the time for discontinuation of daily PrEP from 28 to 7 days after last intercourse		
	MSM: Start and stop daily PrEP as if on-demand		
Screening and monitoring liver function	Person age < 30 years does not need screening; person age \geq 30 years or has underlying kidney disease (e.g.,		
	diabetes mellitus, high blood pressure) at first screening; person age \geq 50 years, person with an underlying condition		
	related to kidney disease; or person with CrCl < 90 mL/min, who should be monitored every 6-12 months		
Telehealth models	Added this tracking option from the 1st month onwards to facilitate monitoring, and reduce the spread of the Covid-		
	19		
Administering PrEP by KPLHS	PrEP can be administered by trained key populations through qualified community health centers		

1.2 Objectives of this version of the national PrEP guidelines

1. Establish guidelines for administering pre-exposure prophylaxis so that implementation is up-to-date and consistent around the country

2. Serve as a guide for providing services, counseling, and caring for service recipients properly and appropriately

3. Promote access to HIV-infection prophylaxis for people with risk behavior for HIV transmission

1.3 Important components of the guidelines

- The introduction includes the situation of HIV infection among the Key Populations, a summary of PrEP services, and new issues that are addressed in this edition of the national guidelines
- Background and importance of PrEP service provision in Thailand, PrEP service model development, and policy advocacy
- Clinical and laboratory data about PrEP effectiveness in preventing HIV infection by taking PrEP, pre-initiation assessment, and PrEP acceptor follow-up, including guidelines for service provision in case of discontinuation of PrEP
- PrEP service delivery model and related services such as same-day PrEP service delivery, key population-led health services (KPLHS), and PrEP service during the era of Covid-19
- Counseling about PrEP initiation and discontinuation, and key discussion points for receiving PrEP acceptors
- PrEP service provision in specific target groups, e.g., discordant couples, MSM, transgender women, teenagers, pregnant women, and injection drug users

- Creating demand and promoting access to PrEP services for target groups, including communication guidelines, communication strategies, strategies for creating demand and supporting access to PrEP
- Monitoring and evaluation of PrEP service provision, including the Thailand PrEP Service Delivery Monitoring and Evaluation Framework, Thailand PrEP Cascade indicators, roles and tasks in monitoring and evaluation at each level, and resources for tracking the implementation and recording of PrEP services

Multi-disciplinary personnel: These are health care providers involved with the provision of HIV prevention and care who also support PrEP service for those in need. These personnel include physicians, nurses, counselors, laboratory staff, pharmacists, and other related personnel in public, private and civil society organizations.
 Personnel who work to support the operations of relevant agencies: These include staff of the local Provincial Public Health Office, the Disease Prevention and Control Office, and the Institute of Disease Prevention and Control in urban areas, among others.

All of this is in order to acknowledge each sector's contribution, and to encourage collaboration among support services consistent in terms of policies and standard operating procedures, so that service acceptors have convenient access to quality services for the maximum benefit intended.



For over 30 years, Thailand has confronted its HIV epidemic, and the country has been very successful in reducing the spread of HIV through a one hundred percent condom policy, preventing MTCT of HIV, and expanding coverage of affordable ART. This success has been the result of strong collaboration between the government, the private sector, Civil Society, and the network of PLHIV. The trend in new HIV infections has continued to decline. In 2019 and 2020, it was estimated that there were 5,446 and 4,855 new HIV cases, respectively. It is projected that, by 2030, there will be approximately only 2,850 new HIV cases in that year, half of which are among Key Populations and their partners. That projection is consistent with current HIV prevalence estimates by population group, where the higher-risk populations include MSM, transgender women (TGW), sex workers, and people who inject drugs (PWID).

In 2016, Thailand developed an accelerated plan to end AIDS. A key strategy for reducing new infections and AIDS deaths is using ART to prevent HIV transmission (*'treatment as prevention'*). The key challenge to implementing the strategy is to reach the population in need, and recruit the infected into the ART program as soon as possible to suppress their viral load (Reach-Recruit-Test-Treat-Retain, RRTTR).

Thailand's approach to Ending AIDS during 2017-2030 consists of six main strategies. By 2030, the goal is to reduce the number of new HIV infections to less than 1,000 per year, reduce AIDS deaths to 4,000 per year, and reduce stigma and discrimination related to HIV by ninety percent from 2017. The Key Populations are the priority groups for implementation of the strategy.

However, based on analysis of recent trends and prospects, it appears that Thailand will not be able to achieve the target of reduced HIV incidence in the stated time frame. Studies have also identified gaps in the coverage of access to proactive prevention services

(Reach) and blood testing (Test) in the target population. Thus, unless there is an intensification of implementation, Thailand is at risk of failing in its aim to End AIDS by 2030. Accordingly, Thailand has introduced pre-

exposure prophylaxis (PrEP) to enhance HIV prevention among high-risk populations. In addition to promoting condom use for every episode of risky sex, PrEP is an effective component of preventive services in the RRTTPR package preduce new HIV infections and achieve the goal of Ending AIDS in Thailand by 2030.

Figure 2.1 History of PrEP Services in Thailand

Research on iPrEX internationally	2011	2012	2014
	Study: HPTN 052	Study as part of the program: Test & Treat for MSM and TGW	Included in the Thai national HIV prevention guidelines
2017	2016		2015
Review of HIV prevention and treatment guidelines	 Expand the study area and ask for cooperation from all government hospitals provide services. The service recipient is responsible for covering their own expenses. PrEP injectable research project in Thailand (HPTN 083) 		Dept. of Disease Control collaborates with TUC to implement pilot research in MSM and TGW
2018	2019	2020	2021
Expansion of the pilot project model to 25 provinces	UNAIDS conducts target setting	Pilot addition of PrEP to the benefits package: 2,000 PrEP acceptors	Expansion of benefits package service: 5,000 PrEP acceptors

2.1 From research to the development of PrEP services

Thailand has been working with other countries to study the efficacy of PrEP since its inception. In many countries around the world, PrEP has been found to be effective and, ever since 2010, has been integrated into many countries' mainstream HIV prevention programs. Key baseline studies showing the efficacy of PrEP that Thailand has participated are as follows:

• iPrEX is an international research program with many countries participating. In Thailand, the iPrEX study was conducted by the Institute of Health Sciences, Chiang Mai University which found that the ARV drug regimen of TDF/FTC reduced the risk of HIV infection among MSM by ninety-two percent.

• The Bangkok Tenofovir Study was conducted in several clinics in Bangkok. It was found that taking the PrEP TDF formula prevented HIV infection among PWID by forty-nine percent.

In addition, Thailand has also participated in research on innovative uses of PrEP, such as the HPTN 083 Project, which is an international research study. In Thailand, the HPTN study was conducted by the Institute of Health Sciences, Chiang Mai University, the Silom Community Clinic, the AIDS Research Center of the Thai Red Cross Society, and the Institute for HIV Research and Innovation. An injectable antiviral drug (cabotegravir) was administered to prevent HIV infection in the initial stages after exposure. Preliminary results indicate that injecting cabotegravir is sixty-six percent more effective in reducing HIV infection than oral TDF/FTC (see Appendix A: Cabotegravir Injection).

2.2 Models of PrEP in Thailand

Community-led Service Model: Princess PrEP

In 2016, the Thai Red Cross AIDS Research Center started the "*Princess PrEP*" project to honor Her Royal Highness Princess Soamsawali Krom Muen Suttanarinath, using the balance of funds from the Mother-to-Child AIDS Reduction Fund (which Her Highness endowed) for the purchase of PrEP. That supply of PrEP was provided for free for up to 1,000 MSM and TGW per year, from January 2016 - December 2018, through community-based organizations. Members of the local MSM/TWG population were trained by the Thai Red Cross Society AIDS Research Center so that they could provide knowledge and counseling to other MSM/TWG at risk of HIV infection. These lay health providers were trained to perform a rapid HIV test right in the home community, and then take those with a positive result to the local clinical facility for confirmation of the diagnosis and enrollment in ART. Those clients who tested HIV-negative could receive a supply of PrEP from the community clinic if they still anticipated unavoidable risk for HIV. As of this writing, there were nine community-led health Service centers providing PrEP in six provinces, namely the Rainbow Sky Association Health Center (Bangkok, Hat Yai/Songkhla, Ubon Ratchathani), Swing Foundation Health Center (Chiang Mai), and MPlus Foundation (Chiang Mai, Chiang Rai).

Models of PrEP services in the public hospital setting under the MOPH

2014: The steps for PrEP services were included in the 2014 Guidelines for HIV Testing and Prevention, and all hospitals were strongly encouraged to prescribe PrEP for eligible clients. At that time, the client had to cover the cost of service out-of-pocket.

2015: The Department of Disease Control, in partnership with the Thailand MOPH–U.S. CDC Collaboration, TUC, conducted a pilot research project on delivering PrEP services for MSM and TGW in two government hospitals. At around the same time, PrEP services were introduced through three community-based organizations. The PrEP2START Project was launched in 2017 using the RRTTPR principle in five hospitals of four provinces. The project was implemented at the field level as well as the policy level. The implementing partners included the relevant government agencies, civil society organizations, and the private sector.

In preparation for PrEP service roll-out during 2018-2019, the Department of Disease Control of the MOPH:

• produced a 2018 version of the guidelines for PrEP in populations at risk of HIV infection;

• increased the capacity of service units nationwide; prepared the service system to receive PrEP acceptors; and helped hospitals develop PrEP service teams through joint training of physicians, pharmacists, and nurses; and

• conducted communication and public relations to build understanding among target service recipient groups and service units that can provide PrEP services in the public, private and civil society sectors; developed educational media about PrEP, including a medication guide tailored to at-risk populations and the general public; called upon local civil society organizations to help educate their constituents who might need PrEP; and a variety of media and channels to maximize convenient access to information about PrEP, and how to get it locally. See the following URLs: https://buddystation.ddc.moph.go.th and https://www.facebook.com/buddystation

Policy advocacy for PrEP in Thailand

The provision of PrEP services in Thailand stems from the policy of the National AIDS Committee (chaired by the Prime Minister). In June 2016, the MOPH issued a request for cooperation to public hospitals around the country to consider providing PrEP services to eligible clients, with the understanding that the cost had to be covered by the client, since PrEP was not yet a part of the public health insurance scheme.

In 2018-19, an academic working group (supported by UNAIDS) conducted an exercise to project the need for PrEP in Thailand as a basis for setting targets and advocating for PrEP. This was an addition to the array of interventions to reduce HIV incidence and help the country reach the goal of Ending AIDS by 2030. The estimates suggested that, by 2020, there would be 143,948 people who needed PrEP in Thailand, comprised of 117,984 MSM, 9,209 TGW, 14,021 PWID, and 2,734 sero-

discordant couples. The Thai government then used the projections data as a basis to set goals and conduct advocacy to implement PrEP nationwide.

At around the same time, a study was conducted on the economic cost-effectiveness of PrEP services by the Health Intervention and Technology Assessment Program (HITAP) which concluded that they were economically cost-effective. When assessing cost-effectiveness in conjunction with the goal of ending AIDS by 2030, PrEP services in all risk groups are considered cost-effective because PrEP can help reduce the HIV incidence to less than 1,000 cases per year.

Based on the information about PrEP requirements and the results of such studies, advocates were able to persuade the National Health Security Board to include PrEP in the benefits package of the Thai universal coverage scheme (i.e., national health insurance). The National Health Security Board Meeting No. 6/2019 resolved to approve the inclusion of PrEP in the national insurance system, but stipulated that a pilot project first be conducted among the high-risk groups. In addition, the Board resolved that there be an intensive monitoring and evaluation system to track experience in the use of PrEP, and estimate HIV incidence reduction. The results of the pilot phase would then be the basis for deciding whether to expand PrEP availability throughout the country. The pilot study was carried out in 2020 by the AIDS Division of the Department of Disease Control and its network, with the support of UNAIDS and the Global Fund (GF).

The pilot project looked at the experience of 2,000 acceptors of PrEP (free of charge). A total of fortynine service providers from twenty-one provinces (in both the public and private sector) participated in the pilot project. In 2021, the target quota of PrEP acceptors was increased to 3,000 people, with a total of 154 service units joining the pilot study in fifty-six provinces across the country. During the entire pilot study, the total number of PrEP acceptors was 11,925 persons. However, that total accounted for only 8.3 percent of the estimated target of potential acceptors. Thus, it was assumed that there must be a gap between demand for PrEP and those who obtained it. Accordingly, the national program implemented measures to increase awareness, motivation and access to PrEP.

In addition to Thailand, many other countries have supported the use of PrEP for people at risk of contracting HIV, and have studied the effectiveness of PrEP at the population level. The following are some highlights of that experience outside of Thailand:

- A recent U.S. study by Smith et al, using data for 2012-16 from the U.S. National HIV Surveillance System, found that, of the ten states where coverage of PrEP was broadest, the annual HIV incidence decreased by four percent (95% CI [95% CI]: -5 to -3). When controlling for viral suppression variables in thirty-three areas, there was a 1.3 percent reduction in number of new cases of HIV per year for each additional 100 PrEP acceptors. It was concluded that expanding PrEP coverage could reduce the rate of new HIV infections.

- Likewise, a Scottish study by Estcourt et al, using data on MSM from 2015-19, found that, after introducing PrEP widely, the incidence of HIV infection dropped 0.6-fold (95% CI: 0.4 to 0.9) as compared to before PrEP was available. When considering PrEP only, the incidence of HIV infection was 0.2 times lower (95% CI: 0.1 to 0.7) as compared to before PrEP was administered. It was concluded that PrEP reduced the incidence of HIV infection at the population level.