Enabling Delivery of Long-Acting Injectable Pre-Exposure Prophylaxis Options in Asia-Pacific

Insights from Eight Focus Countries

Cambodia, Indonesia, Fiji, Malaysia, Papua New Guinea, Philippines, Thailand and Viet Nam

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This report is a result of multi-stakeholder collaboration. We hope it serves as a valuable resource to accelerate the introduction and scale-up of effective PrEP options for all in need, bringing the Asia-Pacific region closer to achieving the 2030 goal of ending AIDS.

Table of Contents

Acronyms

ART	Antiretroviral treatment
BPOM	Badan Pengawas Obat dan Makanan / National Agency of Drug and Food Control, Malaysia)
CAB-LA	Cabotegravir
CAB-ULA	Ultra-long-acting formulation of cabotegravir
CBO	Community-based organization
DAS	Department of AIDS and STIs
DFAT	Department of Foreign Affairs and Trade (Australian Government)
DoH	Department of Health
DSD	Differentiated service delivery
DVR	Dapivirine vaginal ring
ED-PrEP	Event-driven PrEP
FGD	Focus group discussion
FNU	Fiji National University
GAM	UNAIDS Global AIDS Monitoring
GBV	Gender-based violence
HIVST	HIV self-testing
IHRI	Institute of HIV Research and Innovation
KPAC	Key Population Advocacy Consortium
KII	Key informant interview
KPLHS	Key Population-Led Health Services
LA PrEP	Long-acting PrEP (including CAB-LA, LEN and other long-acting products)
LAI	Long Acting injectable
LEN	Lenacapavir
LLMIC	Low- and Lower-Middle-Income Countries
MAC	Malaysian AIDS Council
MoHMS	Ministry of Health and Medical Services
MoPH	Ministry of Public Health
MSP	Medical Services in the Pacific
NCHADS	National Center for HIV/AIDS, Dermatology and STD
NDoH	National Department Of Health (PNG)
NGO	Non-government organization
NHPSP	National Health Policies, Strategies and Plans
PEPFAR	The President's Emergency Plan for AIDS Relief
PNG	Papua New Guinea
PQP	Prequalification of Medicines Program
RHAC	Reproductive Health Association of Cambodia
SOP	Standard of Operating Procedure
STI	Sexually transmitted infection
TA	Technical assistance
TDF/3TC	Tenofovir disoproxil fumarate and lamivudine
TDF/FTC	Tenofovir disoproxil fumarate and emtricitabine
TGA	Therapeutic Goods Administration
UHC	Universal Health Coverage
WHO	World Health Organization

Executive summary

The primary purpose of this scoping study is to investigate the potential for integrating long acting (LA) pre-exposure prophylaxis (PrEP) into the national HIV prevention strategies of eight focus countries in the Asia-Pacific region: Cambodia, Indonesia, Fiji, Malaysia, Papua New Guinea (PNG), Philippines, Thailand and Viet Nam. As a scoping exercise, it aims to provide a rapid assessment of current PrEP policies, strategies and implementation practices. It identifies factors that can enable successful introduction, implementation and sustainability of LA PrEP. Implementation enablers and barriers are also investigated. Stakeholders' perspectives were particularly insightful and consistent across countries, including key population organizations and networks as well as international development partners.

The case for the fast-track introduction of LA PrEP in Asia and the Pacific region is abundantly clear and compelling. There is an emerging HIV prevention crisis with rapidly growing epidemics in Afghanistan, Fiji, Papua New Guinea, Pakistan and the Philippines. The region already has the world's second largest HIV epidemic, home to an estimated 6.9 million [6.2 million–7.8 million] people living with HIV[1] and accounting for a quarter of annual new HIV infections globally (23%), estimated at 300,000 a year[7]. There is a real risk of failing to meet the ending AIDS goal by 2030.

PrEP implementation across the Asia-Pacific region is generally still at an early stage. HIV prevention programs for those most in need - key populations - are underfunded[2]. As of 2024, regional PrEP coverage remains very low, with less then 10% of the 2025 regional target of 8.2 million PrEP users achieved. This trails very far behind the estimated need. Implementation is currently focused on oral PrEP, with limited publicly available data for CAB-LA or DVR, indicating that implementation of these products is either not yet underway or is at a very early stage.

The Asia-Pacific region urgently needs to scale up impactful PrEP programming. In this regard, the prioritizing of new effective LA PrEP options is a strategic necessity. The introduction of the long action injectable (LAI) PrEP *Lenacapavir* (LEN) is critically important; administered twice yearly, it offers a more effective and user-friendly alternative to oral PrEP. Another LAI PrEP, CAB-LA, is also safe and effective but with administration every 8 weeks. The arrival of these and other new pipeline PrEP products will change the paradigm from single to multiple options and introduce the concept of informed choice. This is a paradigm shift that will require strategic attention to capacity building of PrEP providers and all key stakeholders.

Consultations were conducted with a wide range of stakeholders. Country snapshots were prepared for the 8 focus countries, covering country PrEP strategies, PrEP program enablers and barriers that need to be considered when planning to introduce new options. The following are selected to exemplify key barriers to be addressed going forward:

- Insufficient domestic resources for HIV prevention: Most countries remain heavily reliant on donor funding.
- Social and political obstacles: A resurgence of conservative politics risks further marginalizing key populations, creating new barriers to prevention. This is particularly relevant for transgender people and men who have sex with men.
- Gaps in capacity and infrastructure: More investment is urgently needed in capacity building for PrEP programs. A comprehensive approach is required, which includes education on PrEP and treatment literacy.

- Insufficient attention to demand generation: Historically, inadequate attention has been given to creating demand for PrEP that is relevant to the needs of all key populations.

Learning from oral PrEP implementation. Lessons must be learned in terms of enabling factors for and barriers to effective service delivery. These can inform policy development and planning for LEN introduction. This study investigates the PrEP landscape of 8 focus countries providing a spectrum of country implementation experiences for lesson learning, ranging from oral PrEP introduction to scaling up of multiple PrEP options, including LA PrEP.

A pathway has been developed with key stages for the introduction and scaling up of all PrEP products, including LEN, exemplified by the oral PrEP roll out process. It comprises a series of 3 stages together with enabling programmatic outputs. These are set out below:

Stage 1: Preparation for introduction:

Preparatory activities for introducing a new long-acting PrEP, such as LEN at a country level involve a multi-faceted approach, including regulatory approval, policy development, stakeholder engagement, infrastructure assessment and provider training.

Activity 1. **PrEP product availability, pricing and procurement**. Rapid progress has been made in terms of arrangements for generic licensing and manufacturing to enable access to LEN in 120 low and middle-income countries. Generic LEN is scheduled to come onstream in 2027, thus providing a window for preparation at country level for its introduction. Pricing has been agreed at US$ 40 per person per year, which is broadly comparable with current pricing for oral PrEP. Procurement should be planned for the arrival of approved generic LAI options. Resource mobilization is a key concern.

Activity 2. Regulatory approval. No country has yet obtained regulatory approval for LEN. Gilead has identified the Philippines, Thailand and Viet Nam as priority countries for this first, critically important step. A strategic approach is needed to accelerate this process. Important "how to" lessons can be learned from the process of regulatory approval of oral PrEP across the region.

Activity 3. National PrEP Guidance. No country (except Thailand) has developed National PrEP Guidelines for LEN. Thailand is a leader and has revised PrEP guidelines to include LEN. There is a significant task to be accomplished in updating existing National PrEP Guidelines to include detailed technical guidance for implementing delivery of LEN. This may be accelerated by taking advantage of regional cooperation mechanisms. Pacific Island Countries would benefit from a regional approach to support National PrEP Guideline development and expedite the process. Cambodia has developed a suite of standard of operating procedures (SOPs) covering the essential details for implementation of oral PrEP, CAB LA and DVR. They offer an example of good practice.

Activity 4. National PrEP Policy. National policies on PrEP are currently embedded in National PrEP Guidelines and/or National AIDS Strategic Plans in all 8 focus countries. Given the complexity of introducing multiple PrEP options among different populations, involving the principle of choice, there may be considerable advantages in developing a stand-alone policy document to facilitate planning, stakeholder engagement and accountability. Policy for LEN delivery needs to be developed and aligned with policies for other PrEP options.

Activity 5. National PrEP implementation planning. This is currently a component of the National HIV Strategic Plans of at least 13 countries in the Asia Pacific region. All 8 focus countries have integrated PrEP into their broader National HIV Strategic Plans, but the level of detail varies widely. Cambodia and Viet Nam provide the most detailed attention, with Cambodia emphasizing a strategy for PrEP in differentiated service delivery and Viet Nam having a focus on capacity building.

Given the increasing diversity of PrEP implementation across countries, different target groups and involving different products and service delivery modalities, it would seem to be critically important to develop a comprehensive costed national implementation plan for PrEP combined with an M&E framework. A number of countries in sub-Saharan Africa have successfully developed and used such implementation plans to achieve large scale uptake of PrEP. These offer useful lessons and guidance for the Asia-Pacific region, where there is only one example of a National PrEP Implementation Plan (in draft): Fiji's National Implementation Framework for PrEP. This document, provides a structured plan for implementing a complex series of activities, including planning and budgeting, supply chain management and delivery platforms.

Countries need a comprehensive national PrEP strategic implementation plan with clear specification of targets, objectives, activities, outputs and costings. While detailed strategic planning is needed for LEN implementation, it will be important for planning for other PrEP options to be included in the same framework. This should include M&E arrangements to track progress.

All PrEP implementation planning, including for LEN, needs to include the following enabling factors:

- Health system strengthening and integration: The capacity of health systems to integrate new PrEP options must be carefully planned and resourced;
- Differentiated Service Delivery (DSD): This enables PrEP service delivery to be tailored to the specific needs and preferences of key populations;
- Community-led delivery and engagement: Community-based organizations especially those using the KPLHS model are recognized as an effective and preferred delivery approach;
- Demand creation: A strong demand creation infrastructure is needed for all PrEP products including LEN. Messaging must be culturally relevant, community-led and emphasize empowerment and choice rather than a narrow biomedical focus.

Stage 2: Implementation:

Activity 6. Introduction of PrEP product(s). Delivery of LAI PrEP/LEN requires a strategic approach to implementation involving navigation of complex operational, financial and social issues. In the 8 focus countries, there is an emerging model of PrEP service delivery, utilizing a set of interventions emphasizing client-centered and DSD in combination with the KPLHS approach.

Key components include: HIV testing and HIV Self Testing (HIVST), demand generation/creation, integration with existing healthcare services and capacity building for service delivery. Supply chain requirements must also be addressed. Stigma reduction programming is needed as this is a significant barrier to uptake.

Stage 3: Scaling up:

Activity 7. Going to scale. Scaling up of LEN will require consolidation of the program components listed above. While this is a longer-term development, it is clear that this will need further investments in supply chain management, M&E and sustainable financing.

Part 1

Background

Chapter 1: Introduction

1.1 Purpose

The primary purpose of this scoping study is to investigate the potential for integrating long acting (LA) PrEP into the national HIV prevention strategies of eight focus countries in the Asia-Pacific region: Cambodia, Indonesia, Fiji, Malaysia, Papua New Guinea (PNG), Philippines, Thailand and Viet Nam. While the focus remains on these eight countries, the study also draws upon evidence from PrEP implementation across other countries in the region, incorporating insights that prove useful to the study's objectives.

As a scoping exercise, this study aims to provide a rapid assessment of current PrEP policies, strategies and implementation practices. It identifies factors that can enable successful introduction, implementation and sustainability of LA PrEP. Barriers and bottlenecks are also be investigated. This study aims to document lessons learned that can inform future PrEP program planning and implementation efforts, with a particular interest in the adoption and scaling up of LA-PrEP.

This study is offered as a resource for PrEP implementation throughout the Asia-Pacific region, especially for those initiating and scaling up LA PrEP services. The key audiences for this study are Ministries of Health, National AIDS Programs and PrEP providers, including community-based and key population-led organizations and other relevant stakeholders and partners at regional and global levels, including the Gates Foundation, the Department of Foreign Affairs and Trade (DFAT) of the Australian Government, the Global Fund, the Kirby Institute, UNAIDS and other UN agencies.

This work also aligns with global efforts supported by the Bill & Melinda Gates Foundation in collaboration with UNAIDS and the Global HIV Prevention Coalition to accelerate access to long-acting HIV prevention options, including Lenacapavir.

1.2 Objectives

This scoping study is operationalized in four objectives:

1. Regional landscape analysis: To provide an overview of the current PrEP implementation landscape in the Asia-Pacific region;
2. PrEP country status report: To review the current PrEP implementation status in 8 focus countries, including policies, planning and guidelines; services and delivery modalities; PrEP demand and uptake; capacity building and technical support needs; and prospects for sustainability;
3. Key factors in LA PrEP programming: To identify and document the factors enabling the introduction, integration, scaling up and sustaining of LAI-PrEP services in the 8 focus countries, including policy and regulatory reform; effective service delivery models and practices; generating PrEP demand and promoting uptake; and capacity development and technical support needs; and
4. Recommendations for LA PrEP scaling up: To assess the prospects and formulate recommendations for regional and national scaling up of LA PrEP, particularly LEN.

1.3 Methods

This scoping study is designed to rapidly and comprehensively meet the above-mentioned specific objectives and produce a valuable resource for LA PrEP implementation and scale-up. To achieve this, data were collected from primary key informants and secondary sources through a comprehensive desk review. Both data collection and analysis were guided by research questions developed to ensure relevance to the study's purpose and objectives, maintain data quality, facilitate consistent and plausible analysis and maximize the utility of the outputs. On the basis of the results of the data collection, key recommendations for regional and national scaling up as well as technical support activities are provided.

1.3.1 Desk review

A desk review was conducted to collect secondary data, comprehensively addressing study objectives 1, 2 and 3. These secondary sources included:

- Published work regarding regional and national PrEP implementation landscapes, encompassing studies on policy and regulatory environments, resourcing, service delivery modalities, systems capacity and technical requirements and PrEP demand and uptake;
- Regional and national health systems documentation, including relevant policies, regulations, strategies and plans, as well as descriptions and reports on PrEP implementation modalities, demand, uptake and program, service delivery and PrEP utilization reports and data; and
- PrEP implementation data from the eight focus counties.

1.3.2 Key informant interviews

Consultations with stakeholders were conducted through key informant interviews (KIIs) to validate secondary data and gather additional insights, informing the findings for study objectives 1, 2, and 3.

Focus group discussions (FGDs) were held for Indonesia and PNG as per recommendations from the national key stakeholders

Interviews were conducted with representatives from multilateral institutions, such as WHO, UNAIDS, international NGOs and PrEP implementing partners, including AVAC and FHI 360; representatives from pharmaceutical companies such as Gilead Sciences and ViiV; and also, academics, experts and regional key population organizations/networks such as APCOM and the Seven Alliance. At the country level, interviews were conducted with representatives from health departments, national AIDS programs, key population-led/community-based organizations. KIIs and FGDs were conducted online, recorded with permission and transcribed for reference.

A list of stakeholders consulted is provided at Annex 1.

Chapter 2: PrEP and HIV Prevention in the Asia-Pacific region

2.1 Overview

The Asia and the Pacific region currently face a growing HIV prevention crisis. HIV epidemics are fast growing in Afghanistan, Fiji, Papua New Guinea, Pakistan and the Philippines. The region already has world's second largest HIV epidemic. It is estimated that in 2024 it was home to 6.9 million [6.2 million–7.8 million] people living with HIV[3] and accounts for a quarter of annual new HIV infections globally (23%) – estimated at 300,000 a year. The region accounts for 23% of global new HIV infections.

People from key populations - gay men and other men who have sex with men, transgender women, female, male and transgender sex workers, people who inject drugs and their sex partners – are disproportionately affected by HIV in the region. These populations and their sex partners in 2022 accounted for 79% of new HIV infections[4]. Moreover, between 2010 and 2022, numbers of new HIV infections increased by 32% among gay men and other men who have sex with men and by 85% among non-client sex partners of people from key populations[5].

It follows that effective HIV prevention interventions are particularly important among people from key populations and their non-client sex partners. Progress is being made in increasing access to combination HIV prevention services across much of the region. The recent introduction of oral PrEP service delivery in multiple countries is a significant step forward in Asia, but major gaps exist and most countries have yet to achieve scale in programming.

Recent data on coverage of prevention services reveal far from optimal levels. HIV prevention programs for key populations are underfunded[6]. A 64% resource gap has been identified for the Asia Pacific region to meet its 2025 HIV-related targets. The median coverage of prevention services in 2024 was 47% among sex workers (11 reporting countries), 38% among transgender people (five reporting countries), 32% among gay men and other men who have sex with men (seven reporting countries) and 21% among people who inject drugs (six reporting countries)[7].

The need to invest in new PrEP options, particularly long-acting injectables (LA-PrEP), is a matter of urgent public health. While oral PrEP is an effective tool, its slow and inadequate adoption across the region, coupled with significant changes in the global health funding landscape, threaten to reverse gains in HIV epidemic control.

Regional PrEP coverage is currently low, remaining below 10% of the target and trailing very far behind the estimated need. Only around 200,000 people used oral PrEP at least once in 2024, compared with the target of 8.2 million people by 2025. Increased investment is crucial to address the limitations of oral PrEP, programming and to diversify the prevention toolkit to meet diverse needs and strengthen the overall public health response.

2.2 Current PrEP implementation

2.2.1 Early stage of implementation

PrEP implementation across the Asia-Pacific region is generally still at an early stage, but a number of countries are making notable progress in implementing oral PrEP. Statistical data for PrEP uptake is currently focused on oral PrEP, with limited publicly available data for CAB-LA or DVR, indicating

that implementation of these new products is either not yet underway or is at a very early stage. Implementation of LEN, the newest LAI PrEP product, has not yet begun.

2.2.2 Diverse scale in oral PrEP implementation

There is considerable variation in the number of people on oral PrEP across the Asia-Pacific region. See Box 1 below:

Box 1. Available country data on number of people currently on PrEP (2024)

The highest rates of oral PrEP uptake in the Asia-Pacific region include **Viet Nam** (~74,315), followed by **Indonesia** (~46,052), **Thailand** (~32,991) and **Cambodia** (~31,006), all of which have achieved significant scale-up.

Other countries are in earlier stages of implementation but are making steady progress. **Pakistan** (~8,643), **Nepal** (~4,187) and **Myanmar** (~3,086) all have growing PrEP programs.

At the introductory stage are **Lao PDR** (~1,068), **India** (~2,000) and **Bangladesh** (~550).

In the Pacific, implementation is at a very early stage, with **PNG** being the only country to report data (~604). The Pacific region as a whole lags behind Asia in terms of PrEP implementation.

In summary, there is much to do to scale up PrEP uptake and end AIDS in the Asia-Pacific region. Countries need to take stock, learn lessons from oral PrEP programming, apply these and plan for introduction and scale up of new PrEP products.

2.3 Ending the HIV epidemic with new PrEP tools

The arrival of new LA-PrEP options, such as two-monthly CAB-LA and twice-yearly LEN, offers a more effective and user-friendly alternative to daily oral PrEP. The new options, which are highly effective and have a long duration, can provide a more potent tool to reverse the upward trend of the HIV epidemic. In trials (HPTN 083), CAB-LA was found to be 66% more effective at reducing the risk of HIV compared to oral PrEP. For LEN, trials demonstrated a reduction in HIV acquisition by 89% compared to oral PrEP.

Despite its proven efficacy, the widespread uptake of oral PrEP is limited by adherence challenges and stigma. The burden of a daily pill regimen makes consistent use difficult, leading to low uptake and retention. In socially conservative countries such as Malaysia and Indonesia, the discreet nature of an injectable option can remove the social stigma and privacy concerns associated with carrying a pill bottle, which has proved a major barrier to uptake. Studies show that adolescents and young adults in countries such as Thailand and Viet Nam prefer less frequent injections, indicating that LA-PrEP can reach a demographic not yet served by existing models.

Access to CAB-LA and LEN is still limited outside of clinical trials in the Asia-Pacific region[8]. There is a need for more data on its efficacy and safety in specific populations such as transgender men and non-binary individuals[9] [10]. There can be side effects such as injection-site reactions, which can be

an adherence barrier for some. The infrequent nature of injections may lead to less frequent sexually transmitted infection (STI) screening, which is a concern for public health.

No single prevention method works for everyone. The principle of offering a "prevention menu" has proven to be an effective public health strategy[11] [12]. By offering a range of options – daily pills, on-demand pills, the vaginal ring and long-acting injectables – countries can cater to the diverse needs and preferences of their key populations[13] [14]. This can attract and retain people who may have discontinued oral PrEP or those who simply prefer a long-acting method.

Investing in new PrEP options can be a catalyst for strengthening entire health systems. The introduction of LA-PrEP requires countries to update clinical guidelines, train healthcare workers on new procedures and build a more robust supply chain. This process can contribute to modernizing health systems and improve their capacity to deliver other complex health services efficiently. Ultimately, new PrEP options can provide the final push needed to end the HIV epidemic in countries with rising infection rates, helping them move closer to the UNAIDS 95-95-95 targets.

Part 2

Stakeholder Consultations

Chapter 3: Stakeholder perspectives

Consultations with over 70 stakeholders, including representatives from key population organizations, pharmaceutical companies, INGOs and international development partners, have provided valuable insights into current PrEP programming and the future of LA PrEP in the Asia-Pacific region.

There is considerable optimism across all stakeholder groups for the introduction of LA PrEP, especially LEN, due to its clear advantages and potential to significantly impact the HIV epidemic. However, this optimism is hedged with caution. While the valuable experience gained from implementing oral PrEP can inform a more effective rollout, many unknowns remain regarding the practicalities of injectable PrEP. Currently, there is no regulatory approval for LEN in any country in the region.

Regional PrEP Landscape

PrEP programming in the region is generally in its early stages of development, focusing on user choice and the flexibility to switch between HIV prevention options. Despite this, Cambodia, Indonesia, Philippines, Thailand and Viet Nam have made significant and innovative advances in rolling out PrEP services for key populations. Their distinctive contributions offer a valuable opportunity for cross-learning and garnering the necessary political will.

Overall oral PrEP uptake in the region is very low. While an understanding of the barriers is improving, these issues need to be systematically addressed in policy and planning for LA PrEP introduction and scale up.

Insufficient domestic resources for HIV prevention: Most countries remain heavily reliant on donor funding. This reliance is precarious; for instance, the loss of USAID funding has negatively impacted PrEP programs in several countries, leading to service delivery cutbacks and a loss of provider motivation. Uncertainty also surrounds the level of future Global Fund support for new LAI PrEP products such as LEN.

Social and political obstacles: A resurgence of conservative politics risks further marginalizing key populations, creating new barriers to prevention. This is particularly relevant for transgender people and men who have sex with men. In some countries, such as Indonesia, Malaysia and the Philippines, the introduction of new PrEP products requires a sensitive approach to navigate religious concerns.

Gaps in capacity and infrastructure: More investment is urgently needed in capacity building for PrEP programs. A comprehensive approach is required, which includes education on PrEP and treatment literacy. Additionally, there is a lack of resources for implementation science and for documenting client experiences. The development of HIV testing and self-testing services is crucial. Countries already have testing protocols; the key issue is adoption and scale-up of differentiated HIV testing including HIV self-testing (HIVST). HIVST is one of the facilitating factors for PrEP uptake and retention.

Insufficient attention to demand generation: Historically, insufficient attention has been given to creating demand for PrEP that is relevant to the needs of key populations. Moving forward, messaging must be culturally relevant, community-led and emphasize personal empowerment and

choice, rather than a narrow biomedical focus. Priority attention has largely been given to men who have sex with men and transgender women, and a more inclusive approach is needed to bring in other key populations such as sex workers.

Limited access to injectable PrEP: Uptake of CAB-LA has been very limited, delivered through the private sector -private clinics and general practitioners (GPs). For example, in Cambodia, approximately 153 people are on CAB-LA out of 35,000 PrEP users at the time of the interview with stakeholders in August 2025, highlighting the early stage of development and the need to address these implementation challenges. Similarly, low levels of uptake of and access to CAB-LA are reported in Malaysia, Philippines and Thailand. These services are currently only available in private clinics.

LA PrEP product pipeline

- A clear market leader: LEN is positioned as a clear market leader due to its six-month injection interval, which significantly reduces the burden on both clients and the healthcare system. While the large injection volume requires specialized health worker training, its superior dosing schedule and favorable cost profile are major advantages.
- Pipeline products offer additional opportunities: MK-8527, a once-monthly oral pill, is in EXPrESSIVE Phase 3 trials in Malaysia, Philippines, Thailand and Viet Nam. Globally, seventeen countries are hosting sites for the Phase 3 efficacy trials. MK-8527 was found to be safe and well-tolerated in Phase 2 clinical trials. These trials build crucial research infrastructure and provide a valuable alternative for clients who may prefer a pill to an injection.
- Uncertainty of CAB-LA implementation: In contrast, the future of CAB-LA is uncertain due to supply constraints, high costs and operational complexity, which has resulted in very limited uptake in the region to date.

Implementing LA PrEP: A path forward

Scaling up implementation of LA PrEP will benefit from learning from the successes and shortcomings of oral PrEP delivery and addressing the specific challenges of this injectable technology. There is a strong and growing demand among key populations for a variety of user-friendly PrEP options. Greater community involvement will be crucial from the outset.

Key Implementation Requirements

While WHO guidelines for LEN are being adopted, operational readiness lags behind. A successful rollout requires strategic planning and targeted support in several key areas:

- National PrEP strategic planning: Countries need a comprehensive national PrEP strategic implementation plan with clear targets, objectives, timelines and costings. This must include an M&E framework to track progress and ensure accountability.
- Health system strengthening and integration: The capacity of health systems to integrate new PrEP options must be carefully planned and resourced. This includes comprehensive training for health workers on large-volume injection administration and adverse event management. Robust client tracking and recall systems are also essential to ensure clients return for their multi-month injections.
- Community-led delivery: Community-based organizations (CBOs) especially those using the Key Population-Led Health Services (KPLHS) model are recognized as an effective and

preferred delivery approach. Their integration is critical and a phased approach, perhaps transitioning from physician-led to nurse-led administration, could be an effective strategy.

- Pricing and procurement: Pricing and voluntary licensing are key issues. Availability of CAB-LA is extremely limited in Malaysia and Thailand, while Cambodia and PNG have negotiated lower pricing. A regional approach to procurement and scaling up quickly is seen as more advantageous than investing in small pilot projects.

Addressing barriers to LAI-PrEP uptake

Even with new products and improved delivery models, significant barriers remain.

- Stigma reduction and demand creation: Stigma continues to be a major obstacle to demand for PrEP. While the multi-month dispensing of LAI PrEP can help with issues such as geographical mobility, a strong demand creation infrastructure is needed. Messaging must be culturally relevant, community-led and emphasize empowerment and choice rather than a narrow biomedical focus.
- Strategic prioritization: There is a significant gap between the epidemiological need and realistic implementation targets. Stakeholders recommended that LEN implementation should start with 2-3 countries to ensure that limited resources are not spread too thinly.
- Advocacy for sustainability: The Asia-Pacific region is currently missing from global funding initiatives for LAI PrEP. A coordinated regional advocacy strategy is urgently needed to secure access to affordable LEN and ensure long-term sustainability.
- Community concerns: Concerns about LEN accessibility, side effects and convenience must be addressed through the root causes and structural barriers in LEN access.

Part 3

The Foundations for PrEP Introduction and Scaling Up

Chapter 4: PrEP product availability, pricing and procurement

4.1 Towards A Menu of PrEP Options

The increasing availability of different PrEP options will likely have a fundamentally important role in ending the HIV epidemic in the Asia-Pacific region. Providing choice of PrEP products is key to success as no single option will address all needs[15]. There are already several PrEP products being rolled out with ongoing preparations for the introduction of LEN underway. Oral PrEP products (Truvada and generics) are most advanced in terms of implementation scale to date. WHO Guidelines are now available for Oral PrEP, DVR and Injectable PrEP products (CAB-LA and LEN). These need to be adopted and adapted for national regulatory approval and normative guidance development.

The promise of PrEP combined with the recent arrival of new WHO approved PrEP products provide a golden opportunity to revolutionize HIV prevention and realize the goal of ending AIDS by 2030. Research findings suggest that expanding the menu of PrEP options to better meet the diverse needs and preferences of end users could improve uptake and use[16]. The approval of affordable generic LAI PrEP methods with different administration routes, discreet formulations and less frequent dosing will potentially enable easier access, more effective use, reduce stigma and, in some cases, allow for the implementation of more flexible delivery channels.

At the country level, lessons will need to be learned from the programmatic rollout of oral PrEP, the pioneering product. This has been challenging due to a complex set of implementation issues including system-level constraints (e.g. cost, policy, planning and operational barriers), social-level factors (e.g. stigma and lack of normalization of HIV prevention) and individual behaviors (e.g. adherence)[17]. These have all contributed to limiting overall coverage and impact[18]. Going forward these constraints will need to be addressed to effectively scale up all modalities of PrEP programming and open up access to options for those in need.

Countries will need to develop national PrEP policies and implementation strategies involving multiple product options for optimal population coverage. This will also involve integration within national health systems. It will be necessary to conduct an injectable PrEP market assessment. Future generic versions will likely be essential for impactful scaling-up.

Key issues and activities

This involves the first set of critically important preparatory activities for the introduction of LEN at country level. It is important to ensure that national introduction of the new PrEP product is considered by existing technical working groups and governance structures[19].

1) **Procurement planning:** LEN needs to be a registered product or receive an import waiver. It needs to be included in the National Essential Medicines list. Procurement planning requires the following:
   - **Demand forecasting:** It is necessary to forecast demand as accurately as possible to determine the required volume of LEN for procurement.
   - **Procurement strategy:** A procurement strategy needs to be developed. This should involve the selection of the most efficient procurement modality. A competitive and transparent process should be ensured that follows national and international financial regulations.

- **Pricing:** Generic LEN pricing is currently agreed at an annual cost of US$ 40 with the product scheduled to be available in 2027. Modelling has shown that generic LEN can be produced at US$ 35-47 per person annually, potentially lowering to US$ 25 with scale.
- **Contract negotiation**: Negotiations with GILEAD or generic producers must ensure clear terms and conditions, including pricing, payment schedules and warranties, while integrating the product as part of a comprehensive PrEP program.

2) **Funding mechanisms:** Countries need to identify and secure funding for both LEN and associated service delivery costs. This may involve leveraging Global Fund or PEPFAR support, exploring domestic funding options and negotiating access pricing with the manufacturer.

3) **Supply chain planning:** Countries are encouraged to leverage existing national ARV procurement and distribution mechanism to streamline the process. Selected sites must be assessed to ensure that they can meet the requirements for storage and administration. LEN should be included in supply chain systems – procurement, logistics verification, traceability, stock monitoring, distribution, etc.

4) **Identify policy changes:** An early assessment needs to be made of any policy changes that will be needed to enable the introduction of LEN delivery by a range of providers including nurses and lay providers and in diverse settings such as community centers, pharmacies and CBOs.

5) **Service delivery planning:**

- **Community engagement:** Attention needs to be given to developing community engagement to ensure equitable access. This includes addressing stigma and discrimination.
- **Provider training:** Planning for healthcare personnel training should be considered, including specific training for LEN delivery, including injection technique, side effect management and adherence support.

4.2 Current PrEP options

The latest available PrEP products are presented below:

Injectable Lenacapavir (LEN)

LEN is a new long-acting HIV prevention product that can be taken as two subcutaneous 1.5ml injections every 26 weeks, with oral loading doses of 600mg over two consecutive days beginning on the day of the first injection. It is a capsid inhibitor that prevents viral replication and maturation.

LEN offers up to 100% protection against HIV in key populations. There are no restrictions on use during adolescence, pregnancy or breastfeeding, The WHO published its guidelines on LEN in July 2025[20]. These endorse LEN with safety and implementation strategies. WHO recommends using rapid diagnostic tests for individuals initiating or continuing PrEP, including LEN and cabotegravir (See below), This makes possible same-day initiation of PrEP in community settings[21]. LEN is now included in the WHO pre-qualification list.

With the potential to produce up to 10 million doses by 2026, its success will depend on coordinated efforts by governments, donors and civil society to address issues of price, policy and programmatic

readiness. While LEN is already approved for HIV treatment in multiple regions, it was approved by the US FDA for PrEP in June 2025 as a significant advance in HIV prevention.

The most immediate implication is the high cost of new, patented LA PrEP products. While oral PrEP is widely available in cheaper generic forms, LA PrEP has a list price that is prohibitively expensive for most low- and middle-income countries. For example, the U.S. list price for a one-year supply of LEN is over US$ 28,000. This creates a major barrier to access and puts significant strain on national health budgets and donor funds. The way forward is through the manufacture of generic PrEP products. Generic LEN pricing is currently agreed at an annual cost of US$ 40 with the product scheduled to be available in 2027. Modelling has shown that generic LEN can be produced at US$ 35-47 per person annually, potentially lowering to US$ 25 with scale.

Voluntary licenses are in place with generic manufacturers in Egypt, India and Pakistan to enable access to LEN in 120 low- and middle-income countries. Key donors and partners have committed to supporting LEN rollout as a transformative HIV prevention tool. The goals are to expand access to affordable long-acting PrEP for underserved groups while matching oral PrEP cost. The Global Fund has offered to support LEN in the Global Fund reallocation letter for 9 sub-Saharan Africa countries: Eswatini, Kenya, Lesotho, Mozambique, Nigeria, South Africa, Uganda, Zambia and Zimbabwe. PEPFAR will offer LEN roll-out support in 10 countries including the Philippines, the sole Asia-Pacific regional representative.

Injectable cabotegravir (CAB-LA)

CAB-LA, the first long-acting PrEP option, is administered every eight weeks and has been proven to be safe and highly effective. It is an integrase strand transfer inhibitor that prevents establishment of infection. In two major trials, CAB-LA resulted in a 66% and 89% relative reduction in HIV risk compared to daily oral PrEP (HPTN 083 and HPTN 084, respectively), largely due to its less demanding regimen. WHO guidance (2022) recommends offering CAB-LA as an additional prevention choice, particularly for those who find it difficult to take daily tablets[22]. A voluntary license agreement with the Medicine Patent Pool allows for generic manufacturing and the product is eligible for Global Fund procurement.

A qualitative research study explored the experiences of CAB-LA implementation among adolescent girls and young women in Zambia[23]. Overall, participants described high levels of satisfaction, in contrast with the burden of daily pill-taking and limited side effects. Injectable PrEP was more discreet and allowed users to avoid PrEP stigma

Generic CAB-LA could cost between US$ 1.5-34 per person per year (pppy) at full-scale manufacturing, according to studies and forecasts, though the exact price will vary by region and manufacturer, with some recent projections for branded CAB-LA being much higher. There are significant opportunities to reduce formulation costs with increased volumes, reaching similar levels to other injectable products. CHAI estimated the cost of goods sold (COGS) for generic CAB-LA to be between US$ 30-40 per person per year at launch, potentially falling to US$ 14-18 pppy at higher volumes.[24]

The Dapivirine Vaginal Ring (DVR)

The Dapivirine Vaginal Ring (DVR) is the first long-acting, user-controlled, non-systemic HIV prevention product approved for women. It is a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI). Recommended by the WHO Guideline Development Group in 2021 as an additional

prevention option for women at substantial risk of HIV, the DVR is a woman-initiated, easy-to-use ring that slowly releases the drug into the vagina over one month. The risk of HIV is reduced within 24 hours of insertion. While current evidence suggests oral PrEP has greater efficacy, DVR is a safe and viable option for women, including during breastfeeding. It is currently approved for cisgender women only. There is no research currently available to support DVR for other populations. DVR is eligible for Global Fund procurement.

Oral PrEP: Truvada: TDF/FTC/3TC

Oral PrEP, typically a daily pill, Truvada (TDF/FTC or TDF/3TC), is a highly effective HIV prevention method approved in 2012, and method recommended by the WHO in 2015 for all people at substantial risk of HIV as part of a comprehensive prevention package[25]. Policy and program decisions are guided by data from the original randomized clinical trials as well as newer studies.

Widely available in generic form, its safety and efficacy are well-established through clinical trials and national programs. The WHO (2024) states that some people may use PrEP for a single event (for example, sex on only one day), or for infrequent "single" events that are weeks or months apart. This is sometimes called event-driven PrEP (ED-PrEP) or 2+1+1. This is primarily taken up by men who have sex with men, with two doses are taken before sex and one dose per day is continued for two days after potential sexual exposure[26]. The price for the current standard of care for generic TDF/FTC is currently listed at US$ 48 per person per year according to the USAID Global Health Supply Chain Program e-Catalog.

With funding support from DFAT, UNAIDS implemented a scoping study on the Prices of Antiretroviral Medicines to Treat and Prevent HIV in Asia and the Pacific. This scoping study reviews ARV prices and their associated factors across the Asia-Pacific region. Global AIDS Monitoring data on ARV volumes and prices in 2024 was compiled and analyzed, complemented by key informant interviews. The study indicated that that TDF/FTC and TDF-3TC have been procured at US$ 46 and US$ 34 per person per year respectively. Afghanistan, Bhutan and Indonesia paid US$ 34 using international procurement[27]. The Philippines reported paying US$ 57 using domestic funding. It is notable that these were the only Asia-Pacific countries that submitted PrEP cost data for the GAM 2024.

4.3 More PrEP options are on the way

Beyond existing and newly approved options, the HIV prevention pipeline includes innovative products that could further transform the landscape.

MK-8527

One such product is MK-8527, a long-acting PrEP agent being developed by Merck. This drug is a novel oral reverse transcriptase translocation inhibitor with pharmacokinetic properties supporting once-monthly dosing[28]. Data from Phase 1 clinical trials presented in 2024 showed promise that this extended-duration oral regimen could provide a powerful new tool to address the challenges of daily adherence and persistence that are common with current oral PrEP options. A Phase II study tested three different doses; all were well tolerated. Most side effects were mild to moderate, including headache, nausea and fatigue. There were no HIV acquisitions during the study. The positive safety results support progression to large scale efficiency studies (EXPrESSIVE 10 and 11).

If successful, MK-8527 could offer a new level of convenience, bridging the gap between daily pills and long-acting injectables and further diversifying the prevention toolkit to meet the needs of more individuals. Studies suggest that many potential PrEP users would prefer less frequent dosing options for HIV prevention.

CAB-ULA

A new, ultra-long-acting formulation of cabotegravir (CAB-ULA), with the potential for dosing intervals of four months or more, is currently in a registration study. This investigational product is being developed by ViiV Healthcare to offer an even more convenient alternative to the current two-monthly CAB-LA regimen. This research represents a new frontier in long-acting HIV prevention, moving beyond the current two-month regimen to offer a truly ultra-long-acting option that could further transform the HIV prevention landscape.

Chapter 5: Regulatory approval and national guidance

5.1 Regulatory approval

Regulatory approval is crucial for the national introduction of both oral and injectable PrEP because it ensures the medication's safety and efficacy. Without it, PrEP cannot be legally prescribed or made available to the public, which severely hinders its ability to reduce new HIV infections. This process safeguards public health and maintains public trust. Local pilot projects or demonstration trials are often a key precursor to obtaining national regulatory approval, as they provide essential, in-country evidence of PrEP effectiveness.

National regulatory approval for PrEP allows for the availability of new and effective HIV prevention options to be integrated into national prevention strategies and to reach a broader population at risk. This process facilitates the development of national PrEP guidelines, which then enable the scaling up of PrEP services, ultimately reducing new HIV infections by ensuring that safe and high-quality preventatives are accessible to those who need them. For novel PrEP formulations, such as CAB-LA and LEN, national regulatory approval is a prerequisite to their introduction and availability to the public.

Obtaining regulatory approval for LEN will involve demonstrating its safety and efficacy through comprehensive clinical trials, followed by a rigorous review process by national and international regulatory bodies.

Clinical Research is the most critical part, involving large-scale human clinical trials in multiple phases to gather data on safety and efficacy. For LEN PrEP, the landmark Phase 3 PURPOSE 1 and PURPOSE 2 trials demonstrate high efficacy (100% in some populations) and a good safety profile, primarily with injection site reactions as the most common side effect.

5.2 Regulatory review and submission

This process may involve:

- **Filing for approval:** Submitting applications with all relevant data to the respective regulatory bodies.
- **Priority/Accelerated Review:** Given the significant public health interest in LEN, priority review and accelerated assessment timetables may be used to expedite the evaluation.
- **Regulatory assessment:** Expert committees at the participating agencies rigorously assess the data to ensure the medicine meets quality, safety and efficacy standards for its intended use.
- **National Adaption:** Local regulatory authorities in other countries can leverage approvals from stringent regulatory authorities (SRAs) to streamline their own review processes.

The PrEP regulatory approval landscape

Table 1 provides an overview of the status of regulatory approval for 4 PrEP products in the 8 focus countries.

LEN: No country in the Asia-Pacific region has yet obtained regulatory approval for LEN. Gilead has identified the Philippines, Thailand and Viet Nam as priority countries for this first, critically important step. LEN was accepted for WHO pre-qualification on October 6, 2025. This will allow for

an accelerated registration in countries that participate in the WHO's Collaborative Registration Procedure.

Table 1: PrEP regulatory approval status in the 8 focus countries

Country	Oral PrEP	CAB-LA	LEN	DVR
Cambodia	Approved: TDF+3TC approved by DDF/MoH (2019)	Approved (2025) by MoH	-	Approved August (2025) by MoH
Indonesia	Approved: TDF/FTC (2022) & TDF/3TC (2023)	-	-	-
Fiji	The Ministry of Health and Medical Services (MHMS) has guidelines for PrEP use. Regulatory approval is managed by the Fiji Medicine Regulatory Authority (MRA).	-	-	-
Malaysia	Approved: Truvada (2016) and generic (2022) were approved. The National Pharmaceutical Regulatory Agency (NPRA) regulates these products.	Approved (2024) The Drug Control Authority (DCA) has endorsed the registration of Apretude for PrEP.	-	-
Papua New Guinea	Approved: Tenofovir Disoproxil Fumarate and Lamivudine	-	-	-
Philippines	Approved: Truvada (2016) and generic (2023)	Approved (2024)	Prioritized by Gilead for national regulatory filing	-
Thailand	Approved (2016) and generic (2023)	Approved (2024)	Prioritized by Gilead for national regulatory filing	-
Viet Nam	Approved: Truvada (2015) and generic (2019)	(pending) Dossier submitted (under review)	Prioritized by Gilead for national regulatory filing	-
Number approved	8	4	0	1

CAB-LA: Regulatory approval for CAB-LA has been obtained in several Asia-Pacific countries, including China, Malaysia, Myanmar, the Philippines, Thailand and Cambodia. ViiV Healthcare has

been working strategically to expand this approval. Lessons can be learned from the successful process in these countries to accelerate approval in others where it is still pending, such as Viet Nam. The majority of countries in Asia and all in the Pacific have yet to obtain regulatory approval for CAB-LA.

DVR: Only Cambodia has obtained regulatory approval for DVR. With funding support from DFAT, a UNAIDS-supported feasibility study in Cambodia, Indonesia, PNG and the Philippines has laid the groundwork for its introduction[1]. The findings from this study can be used to further expedite the regulatory approval process for DVR in the region.

Oral PrEP: After a slow start, the Asia-Pacific region has seen significant progress in national regulatory approvals for oral PrEP. The majority of countries, including Cambodia, China, Indonesia, Malaysia, the Philippines, Thailand and Viet Nam, have approved Truvada and its generics in the past five years. This opens the way for governments and civil society to rapidly scale up oral PrEP services.

A few countries in Asia have yet to obtain regulatory approval for Oral PrEP. These include Afghanistan, Bangladesh, Brunei, Maldives, Mongolia and Pakistan. The Pacific Island Countries lag behind. Regulatory approval for Oral PrEP has yet to be obtained in any of these, including Fiji and Papua New Guinea. There is a clear need for a concerted regional approach to accelerate regulatory approval in countries which have yet to do so in Asia and especially in the Pacific.

Advancing regulatory approval of LAI PrEP

Lessons can be learned from regulatory approval of Oral PrEP that can be applied to other PrEP products, especially LAI PrEP regimens which have yet to gain national regulatory approval. Experience emphasizes the need for robust clinical trials, careful attention to potential side effects, addressing adherence challenges, ensuring equitable access and integrating PrEP into comprehensive HIV prevention strategies and national health systems.

The rollout of oral PrEP has provided key lessons for introducing new options. Global or regional approvals of new PrEP products can help simplify work for national regulators. For example, Zimbabwe reviewed South Africa's guidance on oral PrEP and adapted it. Similarly, Kenya did not participate in DVR studies but reviewed global outcomes and approved DVR on that basis. Cooperative and strategic approaches to obtaining regulatory approval could significantly benefit the Asia-Pacific region if adapted and adopted.

Collaboration is crucial, as evidenced by successful partnerships between drug license holders and national regulators that have expedited approvals for CAB-LA. A multi-country approach shows promise, allowing countries to adapt guidance and learn from the experiences of others, as seen with Zimbabwe and Kenya. This collective learning can accelerate implementation and streamline the licensing process. Additionally, political will is a major enabler, as strong government leadership and supportive policymakers can break down bottlenecks and accelerate the entire process from approval to implementation. Despite progress, significant challenges remain.

[1] UNAIDS. (2024). Acceptability and Feasibility Assessment for the DVR in Indonesia, Cambodia, the Philippines and Papua New Guinea.

The immediate challenge is to accelerate regulatory approval of LAI PrEP both CAB-LA and LEN in Asia and the Pacific. Despite the challenges, lessons from oral PrEP rollout have strengthened health systems and provided learning that will be useful for scaling up LAI PrEP[29]. A strategic approach involving cooperative partnerships will be necessary to take full advantage of the opportunities for HIV prevention that are present. Lessons can be learned from ViiV's strategic approach to inform regulatory approval of CAB LA. Planning is being undertaken to obtain regulatory approval for LEN, commencing with Gilead support in the Philippines, Thailand and Viet Nam. There is a clear need for a concerted regional approach to accelerate regulatory approval for LAI PrEP in countries across the Pacific.

LAI PrEP regulatory approval would be improved by better coordination, facilitation, information sharing and lesson learning. Inefficiencies slow down regulatory approval. However, approvals can be expedited through proactive efforts involving drug license holders as evidenced by recent CAB-LA approvals. A multi-country approach shows promise. Accelerating approvals requires multi-stakeholder collaboration and process refinement.

5.3 National PrEP Guidelines

Critically important technical guidance

National guidelines for PrEP serve to provide standardized, evidence-based recommendations for healthcare providers, promote equitable access for at-risk populations and ensure the effective implementation of PrEP as a key public health strategy to reduce HIV transmission.

National Guidelines are crucial for ensuring effective and ethical implementation, guiding healthcare providers and promoting informed decision-making by individuals at risk of HIV. Such guidelines provide a framework for identifying individuals who would benefit from PrEP, standardizing its use and addressing potential challenges such as safety and efficacy in integration into healthcare systems. They can support the integration of PrEP into routine healthcare settings and systems, such as primary care, making it more accessible to those who need it and more sustainable.

By providing clear guidance and recommendations, national guidelines can help to raise awareness about PrEP and promote its uptake among eligible individuals. Guidelines also help to provide a framework for monitoring and evaluating PrEP implementation, allowing for ongoing improvements and adjustments to ensure its effectiveness and impact.

In summary, the purpose of national PrEP guidelines includes the following:

- **Standardizing Care:** Guidelines ensure that all clients can expect the same standard of PrEP services, regardless of where they seek care (public or private sectors).
- **Guiding healthcare providers:** They provide clear, evidence-based instructions for clinicians on who is eligible for PrEP, optimal medication choices, baseline assessments, monitoring and counseling.
- **Increasing access and uptake:** By clarifying the process and eligibility, the guidelines help reduce barriers and promote access to PrEP for people at substantial risk of HIV infection, including key populations.

- **Optimizing public health efforts:** National guidelines support the integration of PrEP into existing health services, which helps optimize implementation and cost-effectiveness at a population level.
- **Ensuring safety and efficacy:** They emphasize essential safety measures, such as confirming HIV-negative status before initiation to prevent drug resistance and conducting regular follow-up and testing for HIV and other STIs.
- **Addressing misconceptions and stigma:** The guidelines help inform both providers and the public about the efficacy and safety of PrEP, which can help overcome stigma and encourage people to discuss their risk factors openly with healthcare professionals.
- **Promoting combination prevention:** PrEP is framed as part of a comprehensive prevention plan, which also includes condom use, STI screening and treatment and risk-reduction counseling, to provide holistic sexual health management.
- **Facilitating policy and funding:** Clear national guidance helps advocate for policies that ensure PrEP services and medications are covered by insurance and public health programs, removing financial barriers for patients.

WHO provides technical guidance on PrEP implementation through a range of technical papers which are used to inform the preparation of national PrEP guidelines. The most recent documents (2022-2025) provide implementation guidance to support program managers, policy makers, researchers, health workers, communities. These are set out below:

- Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis (PrEP). (Geneva: World Health Organization: 2025). (https://www.who.int/publications/i/item/9789240111608)
- Implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: provider module for oral and long-acting PrEP. (Geneva: World Health Organization: 2024). (https://www.who.int/publications/i/item/9789240097230)
- Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical Brief. (Geneva: World Health Organization: 2022). (https://www.who.int/publications/i/item/9789240053694)
- Guidelines on long-acting injectable cabotegravir for HIV prevention. (Geneva: World Health Organization: 2022.) (https://www.who.int/publications/i/item/9789240054097)

National PrEP guidelines are country-specific sets of recommended practices for PrEP, a strategy that uses antiretroviral medications for HIV prevention to reduce the risk of HIV infection. These guidelines are informed by the content of WHO Guidelines, which are adopted and adapted to local context. They detail eligibility criteria (e.g., being HIV-negative and at substantial risk), require baseline HIV testing and provide recommendations for different PrEP products, covering oral medications, DVR and LAI PrEP. The guidelines also outline requirements for monitoring, managing potential side effects and ensuring effective delivery to high-risk populations to reduce HIV acquisition.

Guidance is also required for community engagement and demand generation, roles and responsibilities of PrEP implementation (service providers, NGOs and CBOs). The Fiji PrEP guideline[2] has included all these elements in addition to the medical/clinical aspects.

The regional landscape

National PrEP guidelines and standard operating procedures provide a crucial technical framework for implementing PrEP effectively. A review of guidelines from 15 Asian countries and 1 Pacific nation reveals a number of insights and challenges, particularly concerning their timeliness and content. This set of guidelines provides an opportunity for cross-learning and can inform the development of PrEP guidelines in other countries across the Asia-Pacific region.

The current status of national PrEP guidelines is as follows:

- Asia: National PrEP guidelines have been obtained for Bangladesh (2019), Bhutan (2024), Cambodia (2022), China (2021), India (2022), Indonesia (2023), Republic of Korea (2017), Lao PDR (2022), Malaysia (2025), Myanmar (2023), Pakistan (2017), the Philippines (2021), Singapore (2024), Sri Lanka (2023) and Thailand (2023). In Viet Nam, national PrEP guidelines are not available as a single document but are integrated into various national strategies related to HIV prevention and treatment.
- The Pacific: In the Pacific region, formal national PrEP guidelines were found only for Fiji (2025), highlighting a significant gap across other Pacific Island nations.

National PrEP guidelines are typically technical documents with a strong focus on the clinical management of PrEP. They provide detailed policy and implementation guidance in key areas such as:

- Eligibility criteria and approved regimens: They define who is eligible for PrEP and what approved drug options can be used.
- Service delivery modalities: They outline how PrEP can be implemented to better meet client needs and stop HIV transmission, including roles and responsibilities for healthcare providers.
- Clinical management and care: They provide detailed procedures for a range of clinical issues, from initial assessment and prescribing to ongoing monitoring and care.

There is some variation across the available National PrEP Guidelines in terms of presentation, content and focus. In general, National PrEP Guidelines are technical documents and have a strong focus on the clinical management of PrEP by health professionals in different settings. Accordingly, there is a strong focus on PrEP service delivery modalities and procedures, with guidance on:

- Eligibility criteria, approved PrEP regimens and options; and
- Service delivery modalities and procedures and clinical management and care.

Guidance can highlight ways that PrEP can be implemented to better meet client needs and stop HIV transmission, as well as outlining roles and responsibilities and the monitoring needed to make implementation a success.

[2] Fiji Ministry of Health and Medical Services. (2025). HIV Pre-Exposure Prophylaxis in Fiji: Implementation guidelines

The need to update the National PrEP Guidelines

The publication dates of most of the national PrEP guidelines obtained indicate they are not fully up to date in terms of the latest WHO guidance. The most recent WHO guidelines, released in 2024 and 2025, include recommendations for LAI PrEP, such as CAB LA and LEN. However, almost all national guidelines obtained predate these WHO updates. Consequently, they tend to focus solely on providing guidance for oral PrEP delivery and do not include any guidance on LAI PrEP. This creates an urgent need for substantive revision to reflect the latest technical guidance for the new PrEP options. Countries are currently working on this. In stakeholder consultations, interest was expressed in the availability of technical assistance to expedite the process and ensure quality.

Table 2: PrEP Options in National PrEP Guidelines in the 8 focus countries

Country	Oral PrEP	CAB-LA	LEN	DVR
Cambodia	X	X	-	X
Fiji	Draft Implementation Guidelines for PrEP (2025). This includes guidance on Oral PrEP, DVR and CAB-LA	Draft Implementation Guidelines for PrEP (2025). This includes guidance on Oral PrEP, DVR and CAB-LA	-	Draft Implementation Guidelines for PrEP (2025). This includes guidance on Oral PrEP, DVR and CAB-LA
Indonesia	X	-	-	Interim guideline (2025 addendum) for pilot implementation in 2 sites
Malaysia	X	X	-	-
Papua New Guinea	X	-	-	-
Philippines	X	-	-	-
Thailand	X	X	X	-
Viet Nam	X	-	-	-
Total	**8**	**4**	**1**	**3**

- Four countries have integrated CAB-LA in the National PrEP Guidelines. Cambodia issued a SOP for CAB-LA in 2025 (See Table 2). This includes detailed guidance on CAB LA implementation procedures, community engagement and demand creation, CAB LA management and monitoring and capacity building. Three phases of implementation are set out for the period 2024-2026. The SOP therefore includes key elements of policy and strategic planning.
- Fiji has included CAB-LA in Draft Implementation Guidelines for PrEP (2025), awaiting approval.
- Malaysia issued its updated PrEP guidelines in 2025. These include a brief section on CAB LA, lacking the full details necessary for national implementation. It is noted that this has been approved by NPRA as HIV PrEP, but it is not yet listed in the MoH drug formulary.
- Three countries have developed national guidelines for DVR: Cambodia, Fiji and Indonesia (interim guidelines)
- Thailand has recently included CAB-LA and LEN in the National PrEP Guidelines.

5.4 The way forward

There is a significant task to be accomplished in updating all National PrEP Guidelines to include detailed clinical guidance for implementing delivery of LEN in Asia and the Pacific. Many countries have yet to develop national guidelines for CAB-LA. Pacific Island Countries might benefit from a regional approach to support National PrEP Guideline development and expedite the process.

Chapter 6: Policies and planning for introduction and scaling up

National Health Policies, Strategies and Plans (NHPSPs) play an essential role in defining a country's vision, policy directions and strategies for ensuring the health of its population. NHPSPs provide a framework in almost every country for dealing with the complex range of issues needed to improve health outcomes. This includes HIV prevention and the delivery of PrEP to those in need.
An important step in advancing PrEP implementation and fostering sustainability is the process of integration into NHPSPs and the national health system as a whole.

Effective PrEP policy focuses on increasing accessibility, ensuring equitable distribution and integrating PrEP into a comprehensive HIV prevention strategy that is tailored to individual needs and contexts. It is a public health approach that considers PrEP as a program rather than just a pill.

Key components of effective PrEP policy include:

- **Accessibility and Affordability:** Policies should ensure PrEP medication and associated clinical services (visits, laboratory tests) are available and affordable, ideally with no cost-sharing through insurance or government programs. Financial assistance programs are crucial for the uninsured or underinsured.
- **Targeted Outreach and Awareness:** PrEP needs to be promoted to populations at substantial risk of HIV acquisition, including gay and bisexual men, transgender individuals, sex workers and people who inject drugs. General awareness campaigns are also important to reduce stigma and encourage individuals to seek information.
- **Integrated Care and Combination Prevention:** PrEP policy should not replace other prevention methods but complement them as part of a comprehensive sexual health package. This includes:
    - Regular HIV and STI testing and treatment.
    - Risk-reduction counseling, including proper condom use.
    - Access to sterile injection equipment and harm reduction services for people who use and inject drugs.
    - Contraception and safer conception counseling.
- **Person-Centered Service Delivery and Choice:** Recognizing that individuals have diverse needs and preferences, policies should support different PrEP options (daily oral, on-demand oral, long-acting injectable, vaginal ring) and varied service delivery models (clinic-based, pharmacy-based, peer-led, telehealth). The "best" PrEP is the one a person is willing and able to use consistently.
- **Ongoing Medical Supervision and Adherence Support:** PrEP must be used under the guidance of a healthcare provider with regular follow-up visits to monitor HIV status, screen for side effects and support adherence. Adherence is critical to effectiveness.
- **Addressing Inequities and Structural Barriers:** Policies must explicitly address disparities in access among different racial/ethnic groups, genders and socioeconomic statuses. This involves tackling legal barriers, stigma and discrimination that may prevent people from accessing services.
- **Data and Monitoring Systems:** Robust monitoring and evaluation systems are necessary to track PrEP uptake, persistence and effectiveness at a population level to inform policy adjustments and identify underserved groups.

6.1 National PrEP policies in the Asia-Pacific Region

Policy is critically important for PrEP programming because it provides the foundational framework that enables a health system to legally and effectively deliver HIV prevention services at scale. Without supportive policies, PrEP cannot be made widely available or accessible to the populations who need it most. Policy needs to be considered from the outset when decisions are made concerning PrEP procurement, target populations and service delivery modalities.

In the Asia-Pacific region, national policies on PrEP are currently in the process of development as introduction and scale up take place. Specific stand-alone policy documents covering essential components of national PrEP provision were not found for any of the countries in the Asia-Pacific region. Instead, policy statements are currently set out in National PrEP Guidelines and National AIDS Strategies (See Table 3).

Table 3: National PrEP Policies and Plans in the 8 focus countries

Country	Stand-alone PrEP Policy	Integrated PrEP Policy in National PrEP Guidelines	Policy set in National PrEP Implementation Plan	PrEP policy integrated in National AIDS Plan
Cambodia	-	**X** (Includes CAB-LA)	-	**X** (2024-2028) and in the National Plan for HIV and STI in the Health Sector (2021-2025) for CAB-LA and DVR
Fiji	-	**X** (Includes CAB-LA)	**X** (National Implementation Framework for PrEP)	**X** (2024-2027) Oral PrEP
Indonesia	-	**X** (oral PrEP only – 2023 guideline; interim guideline 2025 addendum for DVR pilot)	X (National PrEP Expansion Plan 2024–2026 – operational roadmap for scaling up to 160 districts)	**X** (2021-2030) NSP – includes oral PrEP; the upcoming 2025–2029 RAN revision will also include long-acting PrEP
Malaysia	-	**X** (Includes CAB-LA)	-	**X** (2016-2030) Oral PrEP
Papua New Guinea	-	**X**	-	**X** (2024-2028) Oral PrEP
Philippines	-	**X** (Oral PrEP only)	-	**X** (2023-2028) Oral PrEP
Thailand	-	**X** (Includes CAB-LA)	-	**X** Operational plan (2023-2026)
Viet Nam	-	**X** (Oral PrEP only)	**X** (PrEP Scale up Plan: 2021-2025)	**X** (2021-2025) Oral PrEP
Total	**0**	**8**	**3**	**8**

The case for developing stand-alone PrEP policy

There is a significant gap in PrEP policy making in the Asia-Pacific region: the absence of specific, stand-alone national policy documents for PrEP. Instead, policy statements are embedded within broader national AIDS strategies and technical PrEP guidelines. The following issues make the case for developing a specific PrEP policy paper in addition to current arrangements using National PrEP Guidelines and National AIDS strategies.

High-level visibility and prioritization: A stand-alone PrEP policy would signal a clear, high-level government commitment and strategic direction. Without it, PrEP may be seen as a subordinate component of a larger HIV program, potentially affecting its visibility, political prioritization and

dedicated funding. It appears that PrEP has not yet achieved the status of a distinct national priority that warrants its own specific policy.

Audience and communications: Policies are primarily found in "normative PrEP guidelines," which are technical documents primarily aimed at health professionals. This creates a communication barrier. High-level policymakers, donors and the general public, including target populations—who are key to securing funding and buy-in—may not be the intended audience and could struggle to understand the government's strategic intent for PrEP. A standalone policy document could be crafted to appeal to a wider range of stakeholders, simplifying the message and securing broader support.

Flexibility and coherence: Embedding policy in technical guidelines offers a certain degree of flexibility, allowing for quicker updates as new technologies such as LAI-PrEP emerge. However, it also risks a lack of coherence. Without a single, guiding document, policy direction could become fragmented across various government documents, potentially leading to confusion about roles, responsibilities and long-term goals.

Dependence on external support: The reliance on incorporating policy into National AIDS Strategies suggests that PrEP programs may be influenced by external funding cycles and donor priorities. A stand-alone policy would give a country a stronger foundation for country ownership and could be used as a tool to advocate for domestic funding, a crucial step for the long-term sustainability of the program.

In summary, while national guidelines and strategies lay the groundwork for PrEP implementation, the absence of a standalone policy document may signal a lack of high-level political will and could present a structural barrier to the rapid and sustainable scale-up of PrEP, particularly for newer options such as LAI PrEP in the context of consumer choice of product.

6.2 National PrEP implementation planning

Effective national PrEP planning focuses on achieving equitable and widespread access for populations most at risk of HIV acquisition. Key elements include community engagement, provider education, financial accessibility and robust monitoring and evaluation.

Key Components of National PrEP Planning include the following:

- **Policy and Coordination:** Strong national leadership and coordination across all levels of government, partners and stakeholders are vital. Establishing clear policies, guidelines, roles and responsibilities ensures a harmonized and efficient implementation approach.
- **Equity and Accessibility:** A primary goal is to ensure fair and equitable access, especially for key populations who face significant disparities in PrEP access and utilization.
- **Community Engagement and Leadership:** Programs designed by and for the communities they serve are more effective. Active involvement of communities, people living with HIV and potential PrEP users in the design and implementation process creates ownership, advocacy and helps manage myths and misconceptions.
- **Healthcare Provider Training:** Healthcare providers play a crucial role in prescribing PrEP. Planning must include comprehensive provider education on PrEP guidelines and cultural humility training to mitigate clinician bias, which can be a barrier to access.

- **Diverse Service Delivery Models:** Offering a variety of service delivery options (e.g., traditional clinics, telemedicine, mobile services, community-based organizations) can help reach individuals in "PrEP deserts" and provide options tailored to individual needs.
- **Demand generation:** Demand generation and retention strategies to improve PrEP uptake and adherence are essential components. These can play a pivotal role in increasing PrEP awareness among key populations, minimizing access gaps and ensuring retention of PrEP services.
- **Financial Planning and Sustainability:** A national plan must address the affordability of medication, clinical visits and laboratory monitoring, particularly for the uninsured or under-insured. This requires transparent budgeting and resource mobilization strategies, leveraging both public and private sector strengths.
- **Supply Chain Management:** A successful program relies on a stable supply chain for medications and related commodities (e.g., test kits). Planning must ensure the right formulations are available in adequate quantities and at the right price.
- **M&E:** Integrated M&E systems are essential for tracking program performance, identifying gaps, measuring adherence and retention and informing policy adjustments. This includes surveillance mechanisms for HIV drug resistance and integrating PrEP indicators into national information systems.

6.3 National PrEP Implementation Plans

National PrEP Implementation Plans are likely to become crucial for translating increasingly complex PrEP policy and guidelines into action. While several countries in sub-Saharan Africa, such as Kenya, Nigeria, Zambia and Zimbabwe, have developed these plans, they are very rare in the Asia-Pacific region. Lessons from Africa's experience, particularly in planning, supply chain management and delivery, can be valuable for the Asia-Pacific.

Only one example of a National PrEP Implementation Plan was found for the Asia-Pacific: Fiji's National Implementation Framework for PrEP. This document, which is a work in progress, provides a promising start by laying out a structured plan for implementing a complex series of activities, including planning and budgeting, supply chain management and delivery platforms.

A notable example for a new product is Zambia's national plan for the implementation of CAB LA, which serves as a model for how countries can specifically plan for the introduction of new long-acting PrEP options. The relative scarcity of such documents in the Asia-Pacific highlights a significant gap that needs to be addressed to ensure the effective and rapid scale-up of PrEP in the region.

6.4 PrEP integrated in National AIDS Strategies in the Asia-Pacific region

The current status of PrEP implementation planning in the Asia-Pacific is a mixed picture. While a majority of countries have integrated PrEP into their broader National HIV Strategic Plans, the level of detail and approach to implementation varies widely.

PrEP planning is now a component of the National HIV Strategic Plans of at least 12 countries, including Bangladesh, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Nepal, Pakistan, PNG, Philippines, Sri Lanka and Viet Nam. This represents a significant step forward in national policy commitment.

- Varying levels of detail: The level of detail on PrEP programming varies. Cambodia and Viet Nam provide the most detailed attention, with Cambodia emphasizing a strategy for PrEP in differentiated service delivery and Viet Nam having a pronounced focus on capacity building.
- Phased approaches: A phased introduction approach is evident in the earlier plans of Cambodia and Indonesia. These countries have graduated from phased to nationwide implementation.
- Fiji, Malaysia, Laos, Nepal and PNG are at an early introductory stage, with Fiji planning to conduct feasibility studies.

Country-specific examples:

- Bangladesh's Fifth National Strategic Plan for HIV and AIDS Response (2024-2028) sets out the integration of PrEP for key populations.
- Lao PDR National AIDS Strategy for 2021-2030 prioritizes the development of national PrEP guidelines.
- Myanmar's National Strategic Plan on HIV and AIDS, 2021-2025, prioritizes rapid initiation of PrEP in high-prevalence settings.
- Sri Lanka's National HIV/STI Strategy 2023-2027 includes scaling up access to PrEP and other prevention technologies.

The way forward

To include new LA and LAI PrEP options in national planning, countries should consider adopting a more comprehensive approach that integrates both strategic (3-5 years) and operational (1-year) planning. This involves a shift from a product-focused approach to a systemic one that considers policy, financing and community engagement.

A national plan for PrEP would typically include strategic components that address all stages of implementation, from foundational governance to service delivery and long-term sustainability. Key areas focus on creating an enabling environment, ensuring equitable access and monitoring program effectiveness.

Part 4

PrEP Program Implementation

Chapter 7: PrEP service delivery

7.1 The approach

Delivery of PrEP to those in need requires a strategic approach to implementation involving navigation of complex operational, financial and social issues. In the 8 focus countries, there is an emerging pattern of PrEP service delivery, utilizing a multi-faceted set of interventions emphasizing client-centered and differentiated service delivery (DSD) in combination with the key population-led health service delivery model (KPLHS), community-based and community-led models, nurse-led and lay provider models, pharmacy-delivered model and use of telehealth and digital platforms. Details on country PrEP program strategies, enabling factors and barriers are provided in Annex 2: Country snapshots.

Key components in PrEP service delivery include HIV testing including HIVST, demand generation, decentralization, integration with existing healthcare services and capacity building. Supply chain requirements must also be addressed.

7.1.1 Differentiated service delivery

Countries in the Asia-Pacific region are diversifying where and by whom PrEP is delivered. DSD is key to the success of this process. The key features of implementing DSD in PrEP rollout are the personalization, simplification, and decentralization of services to increase uptake, continuation, and overall public health impact. This approach moves beyond a "one-size-fits-all" model to cater to diverse individual needs and preferences. It is a person- and community-centered approach that adapts PrEP services to the diverse needs of different populations, moving beyond traditional clinic-based models to increase access and uptake.

This strategy is being successfully implemented across the Asia-Pacific region. Regardless of the type of PrEP, the service package remains comprehensive, including risk assessment, HIV and STI testing, consultations, medication and ongoing support to ensure clients receive holistic care. DSD also adapts the frequency and content of care to fit client needs. The standard for oral PrEP is a three-month follow-up for testing and prescription refills. However, the introduction of new options such as LA PrEP necessitates a change in service frequency, with follow-up appointments scheduled every two or six months.

Providers are trained on DSD models to adapt services to client needs and preferences. This can include options such as mobile clinics, telehealth and pharmacy-based services to improve convenience and access.

7.1.2 Demand generation

Demand generation strategies and retention strategies to improve PrEP uptake and adherence are essential to control the HIV epidemic[30]. These can play a pivotal role in increasing PrEP awareness among key populations, minimizing access gaps and ensuring retention of PrEP services. For a PrEP program to be effective, targeted populations need to be aware of its existence. It is critically important to examine and understand the awareness and willingness in these populations to take PrEP in order to best meet their needs[31].

Effective demand generation for PrEP in the Asia-Pacific region is a complex process that relies on several key, integrated strategies to overcome barriers such as stigma and lack of awareness. To effectively generate demand for PrEP, the key is to move beyond generic campaigns and adopt a targeted, community-centered approach that addresses both demand-side and supply-side barriers.

Key features for the successful implementation of PrEP demand generation in its rollout include a user-centered approach with tailored messaging, strong community engagement through peer support and integrated, non-stigmatizing service delivery models[32].

7.1.3 Supply chain management

Supply Chain Management is the process of overseeing and coordinating the flow of goods, information, and finances from the initial supplier to the end customer. It involves managing all the activities and relationships involved in the production, procurement and distribution of a product or service. Supply chain development is a critical, yet highly challenging, element of PrEP programming in the Asia-Pacific region, particularly with the introduction of new LAI options. The strategies vary based on a country's existing infrastructure, geographical complexity and level of donor support.

Supply chain development should be focused on managing the logistics for different modalities of PrEP service delivery. Effective supply chain management for PrEP rollout integrates core supply chain management principles with public health goals to ensure reliable and equitable access. Key features include accurate demand forecasting, reliable procurement and distribution, strong stakeholder collaboration, and technology integration for real-time visibility.

7.1.4 HIV testing and HIVST

HIV testing including HIV self-testing (HIVST) are critically important for PrEP programming because they serve as the mandatory gateway to PrEP initiation and are essential for client safety and effective prevention. HIVST specifically plays a crucial role in improving PrEP access by addressing the most significant barriers to traditional clinic-based testing. HIVST kits are highly accurate and have no association with increased drug resistance[33]. HIVST for PrEP is cost-effective to implement and can even be cost-saving. The majority of users interpret HIVST results correctly and report them accurately.

Effective implementation of HIV self-testing (HIVST) and rapid HIV testing in PrEP rollout is characterized by differentiated service delivery, client empowerment and convenience, high linkage to care and supportive policies. WHO guidelines on HIV testing are a key resource including detailed guidance on strategic planning for effective and efficient testing services. [34] They highlight the expanding role of self-testing and network-based testing services, as well as integration with sexually transmitted infections (STIs), including the use of syphilis self-test, dual HIV/syphilis self-tests and STI partner services.

7.1.5 Integration into the national healthcare system

PrEP integration into the national healthcare system is a crucial strategic step to achieve long-term epidemic control. The rationale is centered on ensuring sustainability, equitable access and comprehensive care. Examples across the Asia-Pacific demonstrate varying levels of success with different approaches.

Effective integration of PrEP into national healthcare systems requires a comprehensive, multi-faceted approach addressing health policy, service delivery, and community engagement. Key features include:

Policy and Governance

- **National Guidelines and Policies:** Establishing clear, evidence-based national guidelines on PrEP use, eligibility, and service delivery, and updating them to reflect the latest recommendations (e.g., long-acting PrEP options).
- **Supportive Legal Frameworks:** Enacting policies that permit a range of providers (nurses, pharmacists, community health workers) to prescribe and manage PrEP and ensuring age of consent laws allow at-risk adolescents to access services confidentially.
- **Dedicated Financing:** Forecasting and mobilizing sufficient domestic resources to guarantee equitable and efficient PrEP services, potentially by leveraging both public and private sector strengths and exploring reimbursement capacity through national insurance program.

Service Delivery

- **Integration into Existing Services:** Co-locating PrEP services within existing health clinics frequented by target populations, such as sexual health clinics, family planning, maternal and child health (MCH), and STI clinics, to normalize PrEP and reduce stigma.
- **Task Sharing/Shifting:** Optimizing the healthcare workforce by shifting PrEP-related tasks like education, risk assessment, and adherence counseling to a variety of trained staff, including lay and peer providers, to alleviate burden on physicians.
- **Streamlined Procedures:** Simplifying clinical procedures, such as allowing same-day PrEP initiation and minimizing follow-up visits for low-risk individuals (e.g., lab testing only), to reduce patient and provider burden.
- **Differentiated Care Models:** Offering diverse delivery options, including pharmacy-based PrEP, telemedicine, mobile services, and home-based care, to increase accessibility and meet varied client needs.

Health Workforce and Information Systems

- **Comprehensive Training:** Providing ongoing, competency-based training for all cadres of healthcare workers that not only builds clinical knowledge but also addresses stigma and provider bias to ensure sensitive, non-judgmental service provision.
- **Robust M&E:** Integrating PrEP data collection into existing national health information systems for standardization, accountability, and evidence-based decision-making to inform ongoing scale-up and evaluate impact.
- **Commodity Security:** Ensuring a consistent and centralized supply chain management for PrEP commodities, using existing infrastructure where possible, to prevent stockouts and ensure uninterrupted access.

7.1.6 Capacity building

Capacity building for PrEP involves a strategic approach to strengthening the skills, knowledge and resources of individuals and organizations to effectively deliver and sustain PrEP services. It is a

critical element of successful implementation and must be tailored to the different cadres involved, from healthcare professionals to community members.

Capacity building involves establishing a network of PrEP providers in various settings, including government hospitals and community-based drop-in centers, to ensure broad access. Effective capacity building for PrEP delivery involves a multi-faceted approach that strengthens individuals, organizations, and systems. Key features include provider training and support, differentiated and client-centered service models, community engagement and ongoing monitoring and evaluation.

Key Features of Capacity Building for PrEP Delivery include:

- **Targeted and Tailored Training for Providers:** Training programs must go beyond basic knowledge to build confidence and competency in specific tasks such as risk assessment, counseling, clinical management, and commodity management. Training methods should be interactive, using case studies and role-playing, and adapt to the local context and audience needs.
- **Support for Diverse Provider Cadres:** Building capacity involves empowering various health workers, including nurses, pharmacists, and trained lay providers and peer educators, to deliver PrEP services, thereby expanding the potential workforce.
- **Differentiated Service Delivery Models:** Services should be adapted to the specific needs and preferences of the target populations (e.g., key populations, adolescents, pregnant women). This includes offering PrEP through various accessible settings such as community centers, pharmacies, mobile clinics, and home-based delivery, not just centralized clinical sites.
- **Integration of Services:** PrEP delivery should be integrated into existing relevant health services like HIV testing and counseling, sexually transmitted infection (STI) testing and treatment, contraception services, and general primary care, for a more comprehensive approach.
- **Technology Integration:** Utilizing technology can enhance delivery and adherence. Features include mHealth (mobile health) strategies for reminders, telePrEP options for remote access, and clinical decision support systems for providers.
- **Client-Centered Care and Stigma Elimination:** Capacity building should emphasize delivering services without stigma and discrimination, fostering an environment where clients feel safe and respected. This requires training in cultural humility and client-centered decision support.
- **Community Engagement and Demand Creation:** Involving the community in program design and using peer navigators and PrEP champions helps create demand and ensures services are relevant and acceptable to the target population.
- **Ongoing Mentorship, Supervision, and Evaluation:** Capacity building is not a one-off event. It requires continuous coaching, mentorship, supervision systems, and a robust M&E framework to track progress, ensure quality control, and adapt to evolving needs and new PrEP products (e.g., long-acting injectables).
- **Resource Mobilization and Policy Support:** Ensuring adequate financial, technical, and material resources is critical for sustainability and scale-up. This includes advocating for supportive policies and a clear regulatory framework that enables PrEP delivery across various settings.

7.1.7 Monitoring and Evaluation (M&E)

Effective M&E of PrEP programming requires a systematic approach focusing on specific indicators related to program implementation and public health outcomes.

M&E for PrEP programming involves building integrated, longitudinal systems (e.g. electronic health records) to track PrEP uptake, adherence and outcomes, while adapting to evolving service models. Key challenges include harmonizing data across diverse funders and national systems and accurately assessing uptake among key populations e.g. men who have sex with men and transgender individuals. Practical M&E requires using data to inform implementation, engaging community partners and simplifying data collection to reduce the burden on implementers.

While M&E for PrEP programs are crucial for ensuring their effectiveness, it faces several pertinent issues, particularly with the introduction of new, long-acting options. These challenges stem from the complexities of measuring a preventative intervention, which is fundamentally different from monitoring lifelong treatment.

Countries in the Asia-Pacific region are tracking progress in PrEP delivery primarily through established metrics focused on uptake, active usage and integration into national reporting systems. However, tracking is often challenged by fragmented data systems and a lack of capacity to monitor retention and real-world impact.

PrEP-Specific Indicators

M&E for PrEP programs typically track metrics across the entire prevention cascade, from awareness to impact. It includes:

- **PrEP Uptake/Initiation:**
  - **New PrEP users:** The number of people starting PrEP for the first time.
  - **PrEP service availability:** Tracking access to PrEP services across different locations and populations.
- **Adherence and Persistence/Retention:**
  - **PrEP continuation:** The proportion of individuals who remain on PrEP over a specified period (e.g., at 6 or 12 months).
  - **Adherence measures:** Using objective methods like biomarker-based testing (e.g., urine or dried blood spot assays) to assess actual drug levels, which can help identify non-adherent clients and link them to support services.
  - **Visits and refills:** Tracking the number of PrEP visits and medication refills.
- **Program Quality and Safety:**
  - **Stock-outs:** Monitoring for stock-outs of PrEP drugs or HIV test kits, which can disrupt treatment and increase risk.
  - **HIV Seroconversion:** Tracking the number of new HIV diagnoses among PrEP users to assess program effectiveness, including an evaluation of drug resistance in those cases.
- **Impact:**
  - **Population-level impact:** Assessing the overall effect of the program on the target population's HIV incidence (new infection rates) using established HIV surveillance systems.

The current indicator set for measuring PrEP programming are presented in the WHO *Consolidated guidelines on person-centered HIV strategic information: strengthening routine data for impact (*2022)[35]. The Consolidated Guidelines cover all essential data use cases (See Table 4). They ground measurement in client monitoring as the source of data required for management of facility, subnational and national programs. They are intended primarily for national and subnational HIV program managers, surveillance officers, partners and other stakeholders involved in the design and use of M&E systems, surveillance and tools for the collection, analysis and use of HIV health sector data.

Table 4: WHO indicators for PrEP programming

Number	Indicator	Definition
PRV2: (new)	Total PrEP recipients (Global AIDS Monitoring Indicator)	• Number of people who received PrEP at least once during the reporting period • Disaggregate by PrEP product, age, sex, key population, provider type, setting and location
PRV3	PrEP coverage target population and volume of PrEP	• % of people prescribed PrEP among those identified as being at elevated risk for HIV acquisition • Disaggregate by PrEP product, age, sex, key population, provider type, setting and location
PRV4:	Volume of PrEP prescribed	• Total volume of PrEP product prescribed • Total volume of each PrEP product prescribed or dispensed to PrEP clients within a period • Disaggregate by PrEP product, age, sex, key population, provider type, setting and location

The three specific indicators that concern PrEP programming involve the measurement in a reporting period (i.e. a specific year) of: i) the total number of PrEP recipients; ii) coverage of target population; and iii) volume of PrEP prescribed. Indicators PRV 2 and PRV3 can be considered as person-centered. This set of indicators is relatively new, having been introduced in 2022. This has implications for country-level capacity building of systems to operationalize these indicators.

Core M&E challenges for PrEP programming

The effectiveness of PrEP programs is hindered by severe systemic and technological limitations:

- Fragmented data systems: Many clinics use paper-based records, creating a barrier to real-time data aggregation and analysis. The lack of a unified electronic health record system prevents the longitudinal tracking of clients across different facilities.
- Resource overload: Insufficient staff resources, technical expertise and heavy workloads create a significant reporting burden on frontline providers, compromising data quality.
- Inconsistent reporting: Varying reporting requirements and indicators across different funders (PEPFAR, Global Fund) create inconsistency and add unnecessary complexity to data collection.

Strategic information for advocacy: M&E and research can provide strategic information for advocacy, particularly for LEN. Data can support evidence-based advocacy linked with the policy formulation that is needed for domestic financing/sustainability. Evidence-based advocacy involves developing the investment case, policy briefing on LEN and cost-effectiveness studies,

New M&E Demands of LAI PrEP

The introduction of LAI PrEP introduces unique M&E challenges:

- Retention monitoring: M&E systems require enhanced capacity to strictly track clients' follow-up visits for scheduled injections, as adherence to this precise schedule is crucial for preventing drug resistance.
- New indicators: Tracking must evolve to include new, specific metrics for dispensed units of each method and LAI PrEP continuation rates at 6- and 12-month intervals to accurately measure program impact.

7.1.8 Key population data and PrEP target-setting

Key population estimates are essential for PrEP program planning because they provide the foundational data needed to gauge the scope of the HIV epidemic and strategically allocate resources. Without accurate estimates, a country cannot effectively plan or monitor its HIV prevention response.

Estimating the total number of individuals at risk of HIV is a critical first step for effective PrEP target-setting. A global analysis found that the annual need for PrEP among four key populations – female sex workers, men who have sex with men, transgender women and people who inject drugs – is a significant 11.16 million person-years. However, in the Asia-Pacific region, gauging this need is hampered by significant gaps in population size estimates for these key groups. Data are particularly scarce for transgender people and people in prisons, with only Indonesia and Thailand able to provide comprehensive estimates for three or more key populations. This lack of data makes it challenging to set accurate targets, prioritize resources and gauge the true need for PrEP.

7.1.9 Financing arrangements

Long-term financing

Sustainable funding for PrEP is paramount for ending the HIV epidemic, yet it is challenged by growing funding gaps and donor fatigue. The impact of losing donor support, such as from PEPFAR, is becoming clearer in the Asia-Pacific region. While all countries rely on international donors to some extent, their progress in transitioning to domestic financing varies significantly, with implications for equity and service sustainability.

The regional impact of loss of PEPFAR/USAID support

The loss of PEPFAR/USAID support is significantly impacting PrEP programming in the Asia-Pacific region, particularly in countries that have historically relied on U.S. funding and technical assistance. The main consequences include:

- Loss of technical assistance (TA): The most significant impact is the loss of TA, which was crucial for developing and building the capacity of local programs, including community-based organizations. Countries such as Cambodia, Viet Nam, Indonesia, Laos and the Philippines have been particularly affected.

- Critical loss of funding: For example, in Nepal, PEPFAR has been the sole funder for the PrEP program, leaving its future sustainability and expansion in question.
- Delays in programming: The loss of support has caused delays in the expansion of oral PrEP and the introduction of new options such as LAI PrEP. In Cambodia and Indonesia, for example, the reduction in funding and human resources has affected program continuity and the ability to scale up.

Despite these challenges, the supply of PrEP drugs is generally not affected in countries such as Cambodia, where the Global Fund provides funding for oral PrEP, CAB-LA and the Dapivirine ring.

Dependence on Global Fund support

The Global Fund plays a critical role in funding PrEP programs in the Asia-Pacific, with countries showing different levels of reliance on its support. A number of countries in the region are highly dependent on the Global Fund as their primary or sole external donor for PrEP. PNG is almost entirely dependent on Global Fund country grants, with their programs operating in a parallel system to government health services.

Some countries have benefited from a combination of Global Fund and PEPFAR/USAID support but are now in a phase of transitioning towards greater domestic responsibility. Malaysia's PrEP pilot program was funded by the Global Fund, which is also a key partner in Viet Nam's transition from donor funding.

Challenges and implications

While the Global Fund's support is critical, a key challenge is the long-term sustainability of PrEP programs. The reliance on external funding makes programs vulnerable to the end of a grant cycle (e.g., GC7 in 2026 for many countries). This highlights the need for countries to secure dedicated domestic funding, either through national budgets or health insurance, to ensure the gains achieved are not lost. The Global Fund is actively supporting this transition through its Sustainability, Transition and Co-Financing Strategies, encouraging countries to gradually assume greater financial responsibility.

To guide this transition, UNAIDS has launched its HIV Response Sustainability Roadmap, which frames sustainability across five core domains, including sustainable and equitable financing. The Roadmap offers a structured methodology—from stakeholder-engaged sustainability assessments to phased financing strategies—helping countries develop country-specific sustainability roadmaps that strengthen political commitment, build institutional capacity, and lay critical groundwork for long-term national funding of HIV services. Through this roadmap, national and international partners are encouraged to collaborate in embedding HIV and PrEP into domestic health financing systems, ensuring sustained impact beyond donor dependency

Part 5

Learning from Oral PrEP Implementation in 8 Focus Countries

Chapter 8: Learning from oral PrEP implementation in 8 focus countries

8.1 Introduction

In preparing to implement LAI PrEP it will be important to learn lessons about what has worked well with regard to Oral PrEP programming and let these inform policy development and strategic planning. As yet there is no significant level of LAI PrEP implementation in the region. While each country has its own particular lessons to impart, there are enough commonalities in oral PrEP experience to inform a common approach to PrEP programming in the Asia-Pacific region.

This section identifies common enabling factors and barriers to PrEP service delivery. These examples are taken from the 8 PrEP country snapshots (See Annex 2). They are all relevant to the planning of LAI PrEP introduction and subsequent scale up. The development of this chapter has been informed by desk research and numerous stakeholder consultations (See Chapter 3).

8.2 Enabling factors

8.2.1 Political and financial enablers

This section covers the high-level commitment and financial mechanisms necessary for a sustainable PrEP program.

Political will and government leadership: All 8 countries (Cambodia, Indonesia, Fiji, Malaysia, PNG, Philippines, Thailand and Viet Nam) included in the scoping study have shown enthusiasm for more PrEP options, particularly LEN and the significant reduction of its generic price. This is a major enabler. Government leadership on PrEP is evident in all countries, but particularly strong in Cambodia. Country-level stakeholders are holding a series of discussions to prepare for the introduction of LA PrEP.

- In Cambodia, the leadership from National Centre for HIV/AIDS, STD and Dermatology (NCHADS) and the Ministry of Health, along with their commitment to adopting WHO recommendations, have facilitated rapid implementation. The Ministry of Health endorsement of PrEP was an important step and enabled an official launch in July 2019. Technical working groups have served to support guideline development and multi-partner collaboration. Multi-sectoral support involving different ministries has helped to create an enabling environment for PrEP programming.
- In PNG, the National AIDS Council is committed to broader support across all provinces for HIV prevention initiatives, aligning with government emergency response plans. Identified critical success factors include strong community engagement, government backing and a focused need for population-specific interventions to enhance prevention efforts.
- The government of Fiji has declared an HIV outbreak and launched a targeted 90-day containment plan. This has prompted a multi-sectoral response, with key institutions such as the Fiji National University (FNU) stepping up as partners in public health. This high-level political commitment is a crucial enabler for accelerating PrEP implementation.

Domestic Financing: Successful integration of oral PrEP into national health systems has taken place in some countries:

- Cambodia: PrEP is fully endorsed and integrated into the national health system. The government has shown a strong commitment to long-term sustainability;
- Malaysia: Government subsidies for PrEP services help make it more affordable for those in need. Since January 2023, the Malaysian Ministry of Health (MOH) and the Malaysian AIDS Council (MAC) have collaborated to dispense free PrEP at selected public health clinics in states with high HIV prevalence, including Selangor, Kuala Lumpur, Johor, Penang and Sabah. This program is aimed at scaling up PrEP use for an estimated 9,000 to 10,000 key population members. Malaysia is gradually integrating PrEP into public healthcare, although a significant portion of its program still relies on external funding. Cost subsidies have enabled the delivery of free PrEP in selected public health facilities where there is high HIV prevalence
- Domestic financing for PrEP in the Philippines is primarily from the national government's budget and the Philippine Health Insurance Corporation (PhilHealth) through its Outpatient HIV/AIDS Treatment (OHAT) package, which helps cover the biomedical aspect of HIV care. Despite this, the Philippines has faced significant challenges with PrEP scale-up due to a large funding gap and a heavy reliance on external donors, leading to a call for more sustainable domestic funding mechanisms, especially for community-led initiatives.
- The Pacific Island nations such as Fiji and PNG are in the early stages of integrating PrEP and remain heavily dependent on international donors such as PEPFAR and/or the Global Fund. Program sustainability is at risk without a clear, long-term plan for securing domestic government funding. For these countries, the key to the future is securing ongoing donor commitments while simultaneously working to integrate PrEP into national health budgets. In Papua New Guinea, strong political leadership and evidence-based advocacy led to the declaration of a national HIV crisis and mobilized over PGK 10 million in domestic funding—an important step toward sustainability.
- Thailand: PrEP is fully integrated into the country's universal health care (UHC) scheme. Thailand and Cambodia are models for sustainable financing. PrEP is fully integrated into Thailand's UHC scheme, making it free and independent from donor funding. This experience provides a blueprint for policy and funding models, ensuring long-term sustainability and independence from donor funding.
- Viet Nam, Indonesia and Malaysia are in a progressive transition towards domestic financing. Viet Nam has successfully used a public-private partnership model and plans to integrate PrEP into its national social health insurance. Indonesia is securing financing to expand its urban-focused pilot program to a nationwide, government-funded program.

8.2.2 Service delivery

This category focuses on the practical, on-the-ground components of PrEP delivery, from logistics to community engagement.

Phased implementation: In the focus countries with greater PrEP uptake, implementation has taken place in a phased approach.

- Cambodia: Oral PrEP implementation started in 2 urban centers and was gradually expanded to other provinces and sites. This has led to the decentralization of PrEP service delivery.

Strong community-led models: These include community- and KP-led health services (KPLHS). These organizations are trusted by key populations and have the expertise to deliver health services in a culturally competent and stigma-free manner. They can serve as key partners in raising awareness, creating demand and potentially even assisting with LA PrEP delivery.

- Cambodia: Close collaboration with CBOs has been essential for developing demand generation. Trained peer educators are instrumental in providing education and support. Outreach workers from organizations such as Men's Health Cambodia (MHC) and Reproductive Health Association of Cambodia (RHAC) are vital sources of PrEP knowledge and motivation, actively targeting higher-risk populations and facilitating HIV testing. Night time outreach specifically targets hotspots, freelance key populations and individuals who are typically busy during the day, providing education, testing (HIV/Syphilis) and referral linkages.
- PNG: In response to low PrEP uptake, PNG is planning a transition from a facility-based to a community-based delivery model to improve the accessibility and uptake of PrEP services. A strategic shift toward community-based PrEP delivery is underway to tackle slow facility-based uptake, utilizing second-generation saliva-based testing for easier HIV screening. Community members are being trained beyond demand generation to support actual PrEP dispensing across multiple provinces. Community-based service delivery involves community-based platforms such as drop-in centers, outreach services and mobile services.
- Philippines: PrEP service delivery is built on CBOs which initiated oral PrEP services before government involvement, establishing a community-led precedent. There is a strong community presence but a funding vulnerability due to the shifting donor landscape. A social contracting mechanism is being advocated to enable CBO access to government funding. Key population-led organizations play key roles in PrEP advocacy and implementation, including social media campaigns, digital health tools and integration with HIV self-testing. Project PrEPpy involved community members as PrEP navigators and life coaches. A National PrEP Network in the Philippines serves as a hub for PrEP service providers.
- Thailand: In the KPLHS Model, CBOs run by key populations deliver a range of health and HIV services including PrEP programming. The model is KP-friendly and accessible with flexible working hours. A substantial portion of the country's PrEP users access their services through Key Population-Led Health Services (KPLHS). The success has led to its integration into the national health security system, with the government piloting its inclusion in its overall universal health care budget.

Differentiated service delivery (DSD): DSD has been a key feature of PrEP service delivery in several of the focus countries e.g. Cambodia, Indonesia, Malaysia, Philippines, Thailand and Viet Nam. This enables services to be tailored to the specific needs and preferences of key populations. The provision of choice is an important factor.

- Thailand and Philippines have pioneered KPLHS, where organizations such as the Institute of HIV Research and Innovation (IHRI) and its KP-led organization partners, including Caremat, Mplus, RSAT (Rainbow Sky Association of Thailand) and Service Worker in Group Foundation (SWING) in Thailand and LoveYourself in the Philippines operate dedicated clinics staffed by trained peer providers. This approach builds trust and provides a stigma-free environment.

- Viet Nam and Malaysia are leveraging private pharmacies, allowing pharmacists to provide PrEP services and increasing convenience and discretion for clients. Digital platforms are also expanding service locations and providers; in the Philippines the e-PrEPPY program offers an entirely virtual, community-led service that includes telemedicine consultations and home delivery of PrEP.
- In Cambodia, where injectable CAB-LA has been introduced, the DSD model is adapting to this new product. DSD for PrEP is implemented through multi-faceted, client-centered approaches to reach key populations at high risk of HIV infection[36]. By shifting services from traditional clinics to community-based settings and expanding PrEP options, the country is increasing accessibility and addressing the unique needs of different client groups.

Demand creation/generation: Demand generation has been a strong feature of PrEP scaling up in several focus countries e.g. Cambodia, Indonesia, Malaysia, Philippines, Thailand and Viet Nam. These can serve as a foundation for LA PrEP and a Multi-Option Choice Framework and User Preference Strategy. There is a growing demand for LA PrEP from key population communities who are already aware of its benefits. Providers report that clients are actively asking for this new prevention option, which can help drive uptake and create a compelling case for policy change. Countries have developed demand generation strategies and activities for oral PrEP.

Examples of demand creation programming in the 8 focus countries are presented below

- Community-led initiatives: This is a crucial feature, as demand is most effective when led by CBOs and peers who can build trust and provide a safe, stigma-free environment. In the Philippines, CBOs have spearheaded PrEP scale-up through campaigns such as "Free to Be U," while in Malaysia, community-led outreach employs PrEP navigators and peer educators to build trust. In Fiji and PNG, where the health system is fragmented, community-led initiatives are vital for reaching hard-to-reach populations.
- Targeted and digital communication: Campaigns must be co-developed with key populations to ensure messages are culturally appropriate and address specific barriers including stigma and low risk perception. In Thailand, the "TestBKK" campaign effectively uses social media and dating apps to reach key populations. In Malaysia, digital channels such as the "My PrEP Locator" provide a discreet way for clients to find services. This approach is also a key strategy in PNG and Fiji for reaching their target populations.
- Empowering messaging: Messaging should reframe PrEP as a tool for empowerment and health. In the Philippines, the "Free to Be U" campaign aims to empower individuals to live without fear or shame. In Cambodia, participants positively perceived PrEP because it offered free health check-ups and reduced discrimination.
- Integration with service delivery: Demand generation must be closely linked to a ready and accessible supply of PrEP. The Cambodian example highlights that despite high PrEP acceptability, barriers including long waiting times and a lack of confidentiality in clinics can hinder access. In Malaysia, provider education programs are a key strategy to ensure the healthcare system is prepared to meet the new demand created by outreach efforts. In PNG, partnerships with the National Department of Health are essential to ensure demand is linked to available services. Fiji has not started PrEP provision; the program is still in a preparation phase.

    - Indonesia: Demand generation campaigns have been a crucial component of the PrEP scale-up. The primary goal of these campaigns is to increase awareness of PrEP and drive uptake among eligible populations.

- Malaysia: JomPrEP App, a chatbot to support PrEP demand among men who have sex with men and transgender populations, My PrEP Locator to enable clients to find services and community-led PrEP navigators and peer educators to build trust and raise demand.
- Philippines: Free To Be U campaign has supported demand generation
- Thailand: PrEP in the City and Test BKK campaigns have been instrumental in raising awareness and creating demand for PrEP among key populations.
- Viet Nam: Hub and Spoke model integrate community-based organizations into the broader health system to generate demand and ensure access to services.

8.2.3 Capacity building

Some countries e.g. Malaysia have invested in capacity building for PrEP service delivery in urban and rural settings. Capacity building has included training for health care providers, pharmacies and community-based/KP-led service providers.

Comprehensive training for providers: Training and capacity building must evolve beyond basic oral PrEP prescription to include the technical aspects of administering LAI PrEP, comprehensive counseling and adherence support. A policy of task-shifting is vital to allow for widespread training of diverse cadres, including nurses, pharmacists and lay providers, ensuring services are decentralized and accessible [37]. For example, in Cambodia, comprehensive training for PrEP providers utilizes the Ministry of Health's Standard Operating Procedures (SOPs) and national guidelines. This training incorporates identifying at-risk populations, providing counseling, administering testing, managing different PrEP methods (oral, injectable) and ensuring proper follow-up care. It also covers new approaches including community-based delivery and differentiated service delivery models to increase access.

Community system strengthening (CSS). Capacity building must extend to the community level. CSS includes training community workers and peer educators on PrEP messaging, community engagement and referral pathways. Empowering individuals from key populations to make informed decisions and to advocate for their own health needs is a key component. Guidance on CSS has been developed by the Global Fund[38] [39].

In the Philippines, CSS for PrEP programming focuses on empowering CBOs to improve the design, delivery and monitoring of HIV prevention services. This involves:

- Increasing PrEP accessibility, particularly outside of urban centers.
- Building community capacity through training and advocacy.
- Integrating community-led responses into national strategies and coordinating with local governments and stakeholders.

8.2.4 Supply chain management

This plays a critical and multifaceted role in the successful and equitable delivery of PrEP services in the Asia-Pacific region. Its importance has grown significantly with the introduction of LA PrEP, which has different logistical requirements than daily oral PrEP.
Strategic approaches include the following:

- Public-private collaboration: Countries are strengthening collaboration between government and non-governmental partners. In Cambodia, the implementation strategy involves a public-private model to support program expansion.

- Donor-supported logistics: In countries with limited resources, the supply chain is heavily supported by international donors. In PNG, funding from USAID and the Global Fund covers commodity procurement, enabling the free service delivery of oral PrEP.
- Centralized procurement, decentralized distribution, community-clinic partnership and use of technology. Thailand uses this approach.
- "Hub and Spoke" Model and integration with existing health systems. Viet Nam uses this approach.

8.2.5 HIV testing and HIV Self -Testing (HIVST)

Recent WHO guidelines have simplified testing recommendations for long-acting injectable PrEP. In the Asia-Pacific region, several countries (Cambodia, Philippines, Thailand and Viet Nam) are advancing simplified HIV testing and monitoring for LA PrEP, moving beyond traditional hospital-based models (tele-PrEP, integrated-HIVST, KPLHS, differentiated PrEP).

- HIV testing is a foundational step for accessing PrEP in all eight focus countries. Strategies are increasingly differentiated, blending traditional clinic-based testing with innovative community-led and digital methods to overcome high levels of stigma and logistical barriers.
- CBOs and KPLHS are crucial, as they are trusted and provide stigma-free testing environments. CBOs and KPLHS are at the forefront of testing in the Philippines facilitating over 60% of PrEP initiations by the end of 2022. Cambodia leverages CBOs for outreach and rapid testing, and Thailand implements through the KPLHS model.

HIVST is a key entry point to PrEP services. It reduces stigma and increases privacy, increases testing coverage and facilitates innovative service delivery models. HIVST is recommended as part of the DSD model in Cambodia and is a highly integrated strategy in Thailand where it is included in the Universal Health Coverage (UHC) benefit package. The Philippines includes HIVST in its national guidelines. Viet Nam uses a web platform to distribute HIVST kits via courier or peer educators. In the Philippines, the introduction of HIV self-testing has enabled more people to know their HIV status which is a prerequisite for accessing PrEP. The Philippine Department of Health (DOH) has recognized this and included HIVST in its 2022 Guidelines for Implementing Differentiated HIV Testing Services to increase coverage. For an individual to start PrEP, they must first have a confirmed HIV-negative status. By making HIV testing more accessible and acceptable, HIVST serves as a crucial entry point to the PrEP continuum of care. The DOH's guidelines explicitly include HIVST as a strategy to "maximize options" for prevention and increase points of access to services.

8.2.6 Integration in the national health system and UHC

Integration of PrEP is important for sustainability. Most of the focus countries e.g. Cambodia, Indonesia, Malaysia, Philippines, Thailand and Viet Nam are making progress in integrating PrEP service delivery in the national health system to ensure a comprehensive approach for those in need. Viet Nam has integrated PrEP into its national health system through a strategy of using a mixed-model service delivery approach, including public and private clinics and community-led organizations. Examples from the 8 focus countries are provided below:

- Full Integration into UHC: Thailand is a regional leader. PrEP is provided free of charge to all high-risk Thai citizens through the National Health Security Office (NHSO)

- Integration into primary health care and subsidies: In Malaysia, PrEP services are introduced into public primary health care clinics, utilizing a community-clinic partnership model with PrEP navigators;
- Strategic public-private implementation: Malaysia, Thailand and Viet Nam have strong private sector involvement in PrEP service delivery. While public funds are used for treatment, the program relies heavily on external funding for prevention;
- Integrated service delivery: In Indonesia, PrEP has become a routine component of HIV service delivery and is integrated into existing HIV care. In Malaysia, PrEP services have been introduced into primary care clinics to improve access in public health care settings. In the Philippines, PrEP is being integrated into HIV services in the public health systems through a multi-pronged approach that combines supportive policies with innovative community-led service delivery model. In Thailand, PrEP is integrated into existing HIV and STI services, resulting in a more comprehensive approach to HIV care. In Viet Nam, PrEP is integrated into HIV and STI prevention services in a comprehensive approach to HIV care.

8.2.7 Monitoring and evaluation

Data-informed M&E in Viet Nam's PrEP programming is used to guide and improve service delivery by focusing on program quality, uptake and sustainability. Key strategies include using national and provincial dashboards for rapid review, implementing a system to track program quality indicators and conducting process evaluations that analyze programmatic data from both public and private clinics. This approach helps to identify urgent issues, tailor strategies for testing and PrEP campaigns and inform broader HIV prevention responses.

8.3 Barriers to PrEP implementation

8.3.1 Financial and structural barriers

This category focuses on the economic and system-level challenges to PrEP implementation, including funding, cost and health infrastructure.

- Limited government investment in HIV prevention: HIV prevention programming for key populations is underfunded. There remains a reliance on external funding for PrEP programming.
- Loss of international funding and technical assistance (TA): The loss of PEPFAR/USAID support is significantly impacting PrEP programming in the Asia-Pacific region. The most significant impact is the loss of TA, which was crucial for developing and building the capacity of local programs, including community-based organizations. Countries such as Cambodia, Viet Nam, Indonesia, Laos and the Philippines have been particularly affected. The loss of support has caused delays in the expansion of oral PrEP and the introduction of new options such as LA PrEP. In Cambodia and Indonesia, for example, the reduction in funding and human resources has affected program continuity and the ability to scale up. The reduction of funds from the Global Fund has hindered PrEP implementation widely.
- Readiness of healthcare system and infrastructure: The delivery of LA PrEP requires a different infrastructure and set of procedures compared to a daily oral pill. LA PrEP requires a steady supply chain and a system for regular injections. While oral PrEP can be dispensed through community-based organizations or pharmacies to increase access and reduce stigma, LA PrEP requires a clinic visit with a healthcare provider for an injection. This "re-medicalizes" PrEP, which can be a barrier for individuals who prefer more confidential or community-based services.

Low uptake of HIV testing services: This is reported in Fiji where uptake of HIV testing is low due to inadequate HIV testing capacity. Uptake of HIV testing is low due to a lack of awareness and limited testing options. Undiagnosed cases in the population are driving HIV transmission. The lack of laboratory capacity to perform advanced HIV tests locally means samples must be sent to Australia, causing significant delays. In 2024, only 36% of people living with HIV in Fiji were aware of their status. This is a significant gap. There is no national policy on HIVST. The lack of a clear, government-backed HIVST framework can hinder widespread, sustainable implementation and integration of HIV ST into the public health system.

8.3.2 Policy and programming barriers

This section includes the legal, administrative and political obstacles that hinder PrEP introduction and scaling.

- Conservative policy resurgence: There continue to be debates over PrEP, which are a growing issue in the Asia-Pacific. These discussions often focus on the tension between promoting condoms and adopting new biomedical prevention methods, fueled by moral arguments and rising STI rates.
    - Indonesia: A hostile environment is created by discriminatory policies that classify sexual orientation as a condition to be rehabilitated. This structural stigma and medical bias from some providers, coupled with police crackdowns, create a climate of fear that prevents key populations from seeking care.
    - Malaysia: Legal criminalization of same-sex relations and pervasive social stigma deter key populations from accessing PrEP out of fear of public exposure or arrest. Moral arguments and the perception of PrEP as encouraging "risky" behavior also serve as significant barriers.
    - Philippines: Conservative voices link the country's rising STI rates to "risk compensation" and PrEP use.
    - Thailand: Thailand still saw a conservative pushback in 2023 when a new regulation limited PrEP prescriptions to government doctors, essentially shutting down successful KP-led clinics. There is a concern among the policy community that PrEP may be contributing to rising STI rates.
    - Viet Nam: Though successful in PrEP rollout, Viet Nam faces a conservative concern over some clients dropping condom use. This highlights the need for public health messages to clarify PrEP as a powerful HIV tool, not a replacement for other prevention methods.

- Stigma and discrimination: Pervasive stigma and discrimination around HIV and key populations deter key population individuals at high risk of HIV from seeking PrEP services in all 8 countries.
    - Cambodia: PrEP users often conceal their PrEP use from partners due to fear of mistrust. Discomfort and fear of being perceived as HIV-positive arise when accessing PrEP at facilities co-located with ART services for people living with HIV. A desire exists among some key populations for PrEP to be universally available to help normalize use and reduce stigma. Criminalization, discrimination and stigmatization of key populations are overarching challenges.
    - Fiji: In a small island nation where "everyone knows each other," the stigma associated with HIV is exceptionally high. People with HIV often face gossip, social isolation and exclusion from their communities. This fear of being identified or judged as a person with HIV makes people fearful to seek out PrEP services. A cultural "tabu" or taboo prevents open discussion

about sex and HIV, complicating education and prevention efforts. This, coupled with widespread prejudice against key populations, makes people fearful of seeking care, even when they know their HIV status.

- Limited access to PrEP services: Limited access to PrEP services is a significant issue in many countries in the Asia-Pacific, particularly in places with growing epidemics. The barriers are often a combination of legal, social and structural factors.

    - Cambodia: PrEP services are concentrated in urban centers;
    - Indonesia: PrEP access remains limited due to significant structural and social barriers. Despite high levels of interest and awareness among key populations, PrEP is not yet included in the national health insurance scheme, nor is it widely available through the public health system. The cost of PrEP remains a major barrier. A one-month supply of oral PrEP can be extremely expensive, making it unaffordable for most. The criminalization of key populations and social stigma further hinder access. Some healthcare providers are also reluctant to prescribe PrEP and the fear of police harassment discourages people from seeking services.
    - Fiji: PrEP has historically been unavailable in the public health system. Despite the urgent need, PrEP has not been a priority for the government. Another major barrier is the fear of receiving care due to widespread prejudice. This social stigma makes it difficult for people to safely access the information and services they require.
    - Malaysia: There is limited access to PrEP services outside of the main urban centers. Clinics may have limited opening hours.
    - PNG: The country has a severe shortage of healthcare professionals and a very limited, often under-funded, public health system. Homosexuality is criminalized under an outdated penal code, which creates a hostile environment for key populations. The existence of this law, combined with widespread social stigma, makes people afraid to seek PrEP or other health services. PNG's rugged geography and remote communities make it difficult to establish a consistent supply chain and deliver services, including PrEP, to a large portion of the population.
    - Thailand: Accessing PrEP services is difficult in rural areas and distant provinces.

- Low levels of awareness and knowledge of PrEP: These are reported among men who have sex with men and transgender people in Malaysia. This includes poor perceptions of risk and concerns about potential side effects. Various misconceptions are reported in Cambodia including side effects of injectable PrEP. Low levels of knowledge about PrEP are reported in Fiji, Indonesia, Malaysia, Papua New Guinea, Philippines, Thailand and Viet Nam.

Gender-based violence: this is a significant issue in Fiji and PNG that severely undermines the ability of women to access HIV services.

- Fiji: GBV is a significant and widespread issue in Fiji that severely undermines women's ability to access HIV services, including PrEP. This is due to a complex web of social, cultural and structural barriers. It has some of the highest rates of GBV in the world. Studies show that 72% of women have experienced physical, emotional, or sexual violence from their intimate partners in their lifetime.
- PNG: The high prevalence of violence, coupled with deep-seated gender inequality, creates a complex web of social and structural barriers.

Part 6

A Pathway for the National Introduction and Scaling up of LA PrEP

Chapter 9: A Pathway for the National Introduction and Scaling up of LA PrEP

9.1 Conclusions

The Asia and the Pacific region are at risk of missing the 2030 goal to end AIDS and urgently needs to scale up its PrEP programming, including introducing new, effective options such as LEN. The 8 focus countries offer diverse experiences from basic oral PrEP introduction to scaling up multiple options, including LA PrEP. The successful rollout of LEN will need to follow the preparatory steps set out below:

1. **Price and procurement:** The current list price of LEN is prohibitively expensive for most low- and middle-income countries. The path forward relies on generic versions, with an agreed annual cost of US$40 USD for generic LEN, though it is not scheduled to be available until 2027.
2. **National regulatory approval:** No country has yet obtained regulatory approval for LEN. Gilead has identified the Philippines, Thailand and Viet Nam as priority countries for this first step. Lessons from oral PrEP approval should be applied, particularly to the Pacific Islands where this process is still incomplete.
3. **National PrEP guidelines:** No country has yet developed National PrEP Guidelines for LEN, though Thailand has a draft. A significant effort is needed to update all guidelines with detailed clinical guidance, potentially accelerated through regional cooperation mechanisms.
4. **Policy and strategic planning:** The diversity of PrEP options and delivery models necessitates the development of a comprehensive, costed national implementation plan for PrEP combined with a robust M&E framework, drawing lessons from successful plans in sub-Saharan Africa (e.g., Fiji's draft framework). There may also be advantages to developing a stand-alone policy document for PrEP, separate from broader National HIV Strategic Plans.

9.2 Recommendations

A pathway for the introduction and scaling up of LA PrEP

A critically important factor in accelerating the introduction of LA PrEP in the Asia-Pacific region is political will. Countries must build on existing political will by strategically engaging with key stakeholders to champion the cause of PrEP and ensure that the necessary resources are allocated to introduce, scale up and sustain LA PrEP service delivery.

To support this effort, a pathway has been developed for the accelerated introduction and scale-up of LA PrEP in the region. This pathway is structured around three key phases:

1) **Preparation**, which involves laying the policy and programmatic foundations; 2) **Introduction**, which focuses on testing service delivery models; and 3) **Scaling up**, which aims to achieve full integration and long-term sustainability.

For each component of the pathway, recommendations are made for: a) regional implementation; and b) country-level action.

Phase 1: Preparation – Creating the enabling environment for national LA PrEP programming within the national PrEP policy framework

Key components	Global/regional recommendations	Country-level recommendations
Price and Procurement	**Negotiate and pool resources:** Regional bodies to finalize regional procurement agreements and voluntary licensing for generic LEN and CAB-LA **Regional coordination of PrEP procurement and domestic finance:** Establish regional coordination to support more efficient procurement and strengthen domestic finance commitments	**Cost-effectiveness studies:** Conduct rapid national modeling to inform policy makers on LA PrEP benefits **Draft policy**: this should include who is eligible, delivery modalities, pricing etc. **Affordable pricing**: Negotiate affordable price of generic LEN **Funding:** Secure initial public/donor/private sector funding **Procurement**: Secure procurement arrangements for generic LEN
Regulatory approval	**Harmonize and expedite:** Establish a regional reliance pathway (e.g., using WHO PQ or Therapeutic Goods Administration (TGA)/Australian approval) to expedite national regulatory approval processes.	**Develop a strategy to fast-track national regulatory approval:** **Consider fast-track national registration:** Utilize a regional reliance pathway, including special import waivers if necessary; or **Use WHO Prequalification of Medicines Program (PQP):** Engage with manufacturers and involving civil society and community representatives
Normative guidance (National Guidelines)	**Strengthen regional collaboration:** to support countries that are lagging in guidelines development. Pacific Island countries need technical assistance. **Adapt WHO PrEP Guidelines:** Disseminate WHO PrEP guidelines focusing on a **choice-based prevention menu** and simplified testing protocols (HIV RDTs) for initiation.	**Develop National PrEP Guidelines for LEN:** Form national working groups to adapt WHO guidance into updated national PrEP guidelines and SOPs to incorporate LEN Tailor guidance to the needs of key populations, specifying LA PrEP for high-risk and those with adherence challenges to oral PrEP Disseminate National PrEP Guidelines

PrEP Policy and Planning	**Support cross-learning** on PrEP policy and guidelines development **Map out LA PrEP service delivery models** and lessons learned to maximize effectiveness of LA PrEP delivery across countries.	**Develop a standalone PrEP policy document**: Adopt PrEP as Choice Framework, integrating all PrEP options. Include LEN in national PrEP policy **Integrate planning and costings** for LA PrEP into the national HIV/AIDS strategic plans and operational plans **Develop a costed national PrEP implementation plan** including LEN, oral PrEP, CAB-LA and DVR as appropriate **Include M&E framework** in PrEP implementation plan

Phase 2: Introduction – Implementation and Programmatic Refinement

This phase focuses on testing and optimizing service delivery models. It focuses on logistical and human resources requirements for LA PrEP.

Key components	Global/regional recommendations	Country-level recommendations
Capacity building and training	**Develop Standardized Curricula:** Create certified training materials for injection technique, drug-resistance monitoring and adherence support. Job aids have been developed at the global level for use: Jhpiego & WHO – Provider Training Toolkit on Use of Oral and Long-acting PrEP WITS RHI and Unitaid - LEN provider Tools and Job Aids	**Develop costed medium-term training plan for LA-PrEP implementation** **Comprehensive training for LA PrEP providers:** Community system and primary health care strengthening **Task-shifting and training of trainers:** Formally authorize and train non-physician providers (nurses, community health workers) to administer LA PrEP in decentralized KPLHS
Service delivery models	**Facilitate Implementation Science:** Support multi-country research on the feasibility and acceptability of differentiated models (e.g., mobile clinics, integrated harm reduction)	**Develop costed service delivery models for LA PrEP and disseminate in a DSD framework** **Introduce LA PrEP in diverse settings** (KPLHS, mobile clinics, pharmacies) to test optimal scheduling and reminder systems for twice-yearly dosing

	Promote models for **Harm Reduction** and PrEP service integration to reach new risk groups	**Integrate LA PrEP injection services** directly into existing or new needle and syringe programs and opioid substitution therapy sites **Develop HIVST services** to support PrEP uptake
Demand creation/generation	**Shared Messaging Platform:** Develop regional, stigma-free communication frameworks that emphasize LA PrEP as **a convenient choice** for a healthy lifestyle and now affordable choice for HIV prevention **Share best practices** for LA PrEP demand creation and address injection hesitancy	**Develop strategy for demand generation involving LA PrEP:** **Develop community-led initiatives,** targeted and digital communications, empowering messaging and integration with service delivery
Stigma and GBV reduction	**Support cross-learning** on stigma reduction related to PrEP	**Develop a strategy to reduce stigma and GBV around HIV and PrEP:** **Invest in community engagement for stigma reduction:** Conduct targeted campaigns **Invest in provider training:** Training should be provided to healthcare professionals to ensure they can offer confidential, non-discriminatory and stigma-free services

Phase 3: Scaling Up – Integration and Sustainability

This phase focuses on making LA PrEP a standard, sustained component of national HIV prevention.

Key components	Global/regional recommendations	Country-level recommendations
Supply chain management	Country support for supply chain management	**National Logistics Rollout:** Integrate LA PrEP into the national drug supply management and distribution system **Develop differentiated inventory system:** Oral PrEP can be managed with multi-month dispensing while LA PrEP requires a strict “just-in-time” delivery schedule

M&E	Country support to track LA PrEP uptake, persistence (retention in care) especially for the twice-yearly LEN schedule	**M&E system Strengthening and Data Integration:** Update national health information systems, ensuring disaggregated data to track LA PrEP use (including six-month appointment reminders and resistance data)
Long-term financing	**Advocacy for Domestic Investment:** Advocate for increased, sustainable domestic financing, highlighting the cost-savings of averted HIV infections	**Transition Planning:** Develop a clear, phased plan to transition all generic LEN-LA costs from donor to domestic government budgets, leveraging the US$ 40 price.

Annex 1: List of stakeholders consulted

#	Country	Organization	Last name	First name
1	Cambodia	Nation Center for HIV/AIDS, Dermatology and STDs (NCHADS)	Ouk	Vichea
2	Cambodia	NCHADS	Ngauv	Bora
3	Cambodia	NCHADS	Samreth	Sovannarith
4	Cambodia	FHI 360	Wignall	Steve
6	Cambodia	Men's Health Cambodia	Kem	Vichet
7	Cambodia	WHO Cambodia	Deng	Serongkea
8	Cambodia/Malaysia	UNAIDS Cambodia/Malaysia	Ung	Polin
9	Cambodia/Malaysia	UNAIDS Cambodia/Malaysia	Ongpin	Patricia
10	Cambodia/Malaysia	UNAIDS Cambodia/Malaysia	Shwe	Ye Yu
11	Fiji	UNAIDS Fiji	Ram	Renata
12	Indonesia	CCM / Technical Working Group (TWG) on HIV	Basri	Carmelia
13	Indonesia	Directorate for Communicable Disease Prevention and Control, Ministry of Health – Head of HIV & STIs Working Team	Junita	Tiersa Vera, M. Epid
14	Indonesia	World Health Organization (WHO) Indonesia	Arto	Budi
15	Indonesia	Spiritia Foundation (Global Fund Community Principal Recipient)	Marguari	Daniel
16	Indonesia	Indonesia AIDS Coalition (Global Fund Community Principal Recipient)	Laurents	Patrick
17	Indonesia	GWL-INA (National MSM & Transgender Network)	Nugraha	Irfani
18	Indonesia	Universitas Padjadjaran – Research Center for Clinical and Community HIV (RC3ID)	Wisaksana	Rudi
19	Indonesia	Universitas Udayana – Faculty of Medicine / Center of Public Health Innovation (CPHI)	Januraga	Pande Putu
20	Indonesia	RC3ID – Universitas Padjadjaran	Handayani	Miasari
21	Indonesia	RC3ID – Universitas Padjadjaran	Qifari	Sherli
22	Indonesia	UNAIDS Indonesia	Widen	Elis Kartina
23	Indonesia	UNAIDS Indonesia	Saleem	Muhammad
24	Indonesia	UNAIDS Indonesia	Hendry	Luis
25	Malaysia	WHO Malaysia	Gamage	Deepa
26	Malaysia	Malaysian AIDS Council	Chung	Han Yang
27	Malasia	University of Malaya	Azwa	Iskandar

28	Malaysia	Disease Control Division, Malaysia MOH	Yuswan	Fazidah Binti
29	PNG	UNAIDS PNG	Mogaba	Ignatius
30	PNG	UNAIDS PNG	Manova	Manoela
31	PNG	National Department Of Health (NDoH)	Gideon	Nano
32	PNG	National AIDS Council Secretariat (NACS)	Michelle	Ame-Nilkare
33	PNG	WHO PNG	Ruda	Challa
34	PNG	FHI 360	Nwaokoro	Pius
35	PNG	Key Population Advocacy Consortium (KPAC)	Bola	Lesley
36	PNG	KPAC	Ketepa	Cathy
37	PNG	Kirby Institute/Institute of Medical Research (IMR)	Kelly-Hanku	Angela
38	PNG	UNICEF	Safiyanu	Garba
39	PNG	FHI 360 (seconded to NDoH)	Moide	Iakuna
40	PNG	Pharmaceutical Standards and Services Board (PSSB)	Karo	Vali
41	Philippines	Global Fund PR	Norella	Loyd
42	Philippines	UNAIDS Philippines	De La Paz	Martha
43	Philippines	UNAIDS Philippines	Ocampo	Louie
44	Thailand	UNAIDS Thailand	Benjarattana porn	Patchara
45	Thailand	Institute of HIV Research and Innovation (IHRI)	Phanuphak	Nittaya
46	Thailand	Department of AIDS and STIs (DAS), MoPH	Chartpituck	Pongtorn
47	Thailand	SWING	Janyam	Surang
48	Thailand	SWING	Phangnongyang	Chamrong
49	Thailand	Mplus	Patpeerapong	Pongpeera
50	Thailand	Mplus	Apiputhipan	Rattawit
51	Viet Nam	Viet Nam Academy of Debate and Public Speaking, Division on HIV and Substance Abuse Treatment, focal point on PrEP	Mai	Nguyen Thi
52	Viet Nam	WeCare Centre	Anh	Quang
53	Viet Nam	WHO	Van	Nguyen Thi Thuy
54	Viet Nam	UNAIDS Viet Nam	Nguyen	Nga
55	Viet Nam	UNAIDS Viet Nam	Nguyen	Thi Bich Hue
56	Viet Nam	UNAIDS Viet Nam	Hailevich	Raman
57	Regional	FHI360	Mills	Stephen

58	Regional	APCOM	Poonkasetwattana	Midnight
59	Regional	Seven Alliance	Prabowo	Harry
60	Regional	Seven Alliance	Abdulghani	Fairy
61	Regional	Seven Alliance	Noviyanti	Ikka
62	Regional	Treat Asia	Khwairakpam	Giten
63	Regional	The Global Fund	Obermeyer	Christopher
64	Regional	The Global Fund	Dzokoto	Agnes
65	Regional	The Global Fund	Shrestha	Bhushan
66	Regional	The Global Fund	Villaman	Yira
67	Global	AVAC	Warren	Mitchell
68	Global/Regional	Gilead Sciences	Written response provided	
69	Global/United Kingdom (UK)	ViiV UK	Radcliffe	Anjali
70	Regional	ViiV Taiwan	Hwang	Ta-Fen

Annex 2: Country snapshots

1. Cambodia

- Initiated since 2019, the PrEP program has reached over 40,000 cumulative clients by Q2 2025.
- As of December 2024, 18,769 people were receiving PrEP. 31,006 individuals were reported to have ever been on PrEP.
- Over 9,000 new enrolments were recorded in the first half of 2025, indicating sustained momentum.

Cambodia has nearly achieved the UNAIDS 95-95-95 targets, but its HIV epidemic is concentrated among key populations. New infections are particularly high among young men who have sex with men and transgender women. The need for PrEP is high, and the country has been proactive, scaling up oral PrEP and becoming one of the first in the region to introduce CAB-LA as an option. Going forward, introducing LEN will require obtaining regulatory approval, integration in national PrEP guidelines, developing specific policy and implementation planning.

PrEP Foundations for national programming

Regulatory Approval	Oral PrEP –TDF+3TC (2019) and CAB-LA (2025)
PrEP Guidelines	Concept Note on HIV PrEP Implementation in Cambodia (Mar 2019) 2 SOPs for oral PrEP: i) SOP for PrEP implementation in Cambodia (Jan 2022), and ii) SOP for same-day PrEP delivery by CBO for key populations in Cambodia (Jan 2022) 1 SOP for Implementing CAB-PrEP in Cambodia (May 2025) 1 Concept Note for Implementing DVR PrEP (Aug 2025)
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and Planning
PrEP Planning	6th National Strategic Plan for a Comprehensive Multi-Sectoral Response to HIV/AIDs (2024-2028) Strategic Plan for HIV and STI Prevention and Care in Health Sector 2021-2025 which guides the health sector response to HIV.

Cambodia has successfully controlled its HIV epidemic, with prevalence falling from 1.05 % in 1998 to 0.5% in 2024. However, HIV prevalence has significantly increased in key populations, particularly among men who have sex with men and transgender women, with current figures showing worrying rises in the latest available data from 2023. While ART coverage is high, many key populations remain underserved by services, necessitating a shift in focus to expand testing and treatment access for these higher-risk groups.

PrEP strategies

PrEP is integrated into the country's Sixth National Strategic Plan for a Comprehensive, Multi-Sectoral Response to HIV/AIDS (2024-2028) and the Strategic Plan for HIV and STI Prevention and

Care in the Health Sector 2021-2025. PrEP is included in a strategy to expand differentiated services in HIV prevention. Scaling up will include CAB-LA and DVR. Efforts will be made to boost demand. PrEP is also included in community-led monitoring .

Cambodia employs a non-medicalized PrEP system, primarily leveraging CBOs for outreach and rapid testing, a distinction from traditional clinical settings. CBOs deliver PrEP with communication facilitated via Telegram to clinical hubs. This community-led approach accounts for the majority of PrEP uptake and is associated with better client retention rates compared to facility-based sites due to its patient-friendly nature. Fifteen CBO drop-in centres are active across 16 provinces, offering culturally competent and key population-friendly services.

PrEP services are integrated into various settings, including family health clinics (alongside STI services), ART sites (leveraging existing HIV care infrastructure and expertise) and CBO clinics (offering peer-led services with medical oversight). The National Center for HIV/AIDS, Dermatology and STD (NCHADS) have developed distinct SOPs for oral PrEP, community-based PrEP, CAB-LA and future DVR services. There is a plan for developing an SOP for LEN.

Cambodia is viewed as a regional leader in CAB-LA implementation in public health settings. The service delivery approach involves a collaborative model involving Ministry of Health facilities and CBOs. The CBOs are currently focused on demand creation.

Enabling factors

Strong government leadership: The leadership from NCHADS and the Ministry of Health, along with their commitment to adopting WHO recommendations, have facilitated rapid implementation. The Ministry of Health endorsement of PrEP was an important step and enabled an official launch in July 2019. Technical working groups have served to support guideline development and multi-partner collaboration. Multi-sectoral support involving different ministries has helped to create an enabling environment for PrEP programming.

Phased-implementation and decentralization: PrEP was rolled out in a phased approach. This started in Phnom Penh and Siem Reap and expanded gradually to more sites and provinces. Decentralization of services was strengthened through this approach. Starting with a single site in a facility-based setting in 2019 and expanding to 49 sites (34 facility-based sites/15 CBO sites) by March 2024 demonstrates the phased approach and significant scale-up of the program.

Community engagement: Close collaboration with CBOs has been essential for developing demand generation. Trained peer educators are instrumental in providing education and support. Outreach workers from organizations such as Men's Health Cambodia (MHC) and Reproductive Health Association of Cambodia (RHAC) are vital sources of PrEP knowledge and motivation, actively targeting higher-risk populations and facilitating HIV testing. A number of CBOs are working on demand creation, notably KHANA, CWPD, MHSS and Friends International. Night time outreach specifically targets hotspots, freelance key populations and individuals who are typically busy during the day, providing education, testing (HIV/Syphilis) and referral linkages.

Demand creation: The strategies are multi-faceted and combine digital and on-the-ground efforts. These include: digital and social media campaigns; community-led and peer-based approaches; direct outreach; community-clinic linkages; online platforms and apps; and

multisectoral campaigns. Platforms such as Facebook and TikTok and the use of influencers are key in raising PrEP awareness and driving uptake. The national campaign "Kapea Klounneak" ("Protect Yourself") leverages online reservation applications ("TohTest") and social media to engage young and at-risk individuals in conversations about HIV and to encourage service access.

Differentiated service delivery (DSD): Cambodia's model for DSD PrEP is a strategic shift from a traditional, one-size-fits-all approach to a client-centered one. This model, guided by national policy, adapts services to meet the diverse needs of people at risk of HIV. The DSD model is characterized by: task-sharing; diverse service delivery; flexible service options, covering CAB-LA and exploring other new prevention tools, such as the dapivirine vaginal ring. The DSD model also includes: streamlined procedures through the "PrEP-direct" modality. The use of HIV self-testing is also recommended, allowing clients to test for HIV privately, which further enhances convenience and reduces the need for clinic visits.

Barriers

Low awareness and misinformation: PrEP awareness within key population communities remains low. There is confusion among clients due to the discrepancy between the "PrEP" label and the actual drug names (e.g., Tenofovir and Lamivudine) on medication bottles, leading to hesitancy. Some individuals perceive PrEP as a "luxury item" or believe it encourages unsafe sexual practices. Client misconceptions about new modalities, primarily center around its injectable nature, its relationship to other medications and the necessary clinical follow-up. Understanding and addressing these misconceptions is crucial for successful demand generation and uptake of these highly effective prevention options. Concerns about real or perceived side effects (e.g., fatigue, dizziness, nausea, skin rash) and a general "pill fatigue" or boredom with daily dosing contribute to discontinuation.

Low oral PrEP retention rate: The overall retention rate for the Oral PrEP program is 38%, with a 50% retention rate reported after six months of enrolment, indicating a need for improved adherence support strategies. Clients are most likely to discontinue PrEP within the first three months.

Accessibility and logistical challenges: Barriers include an insufficient number of PrEP sites, difficulties with transportation, travel costs and the distance to urban service areas, especially for those with rigid working hours. For CAB-LA, limited laboratory capacity at some facilities can lead to clients having to pay out-of-pocket for screening tests. Services are concentrated in urban areas.

Stigma and discrimination: This is a persistent and significant barrier to PrEP scale-up. PrEP users often conceal their PrEP use from partners due to fear of mistrust. Discomfort and fear of being perceived as HIV-positive arise when accessing PrEP at facilities co-located with ART services for people living with HIV. A desire exists among some key populations for PrEP to be universally available to help normalize use and reduce stigma. Criminalization, discrimination and stigmatization of key populations are overarching challenges.

Incentives and service support: An effective incentive system is crucial for provider engagement, but recent cutbacks have negatively impacted motivation. The Global Fund cuts have also affected client incentives, with support now largely limited to transportation for CAB-LA clients. The availability of PrEP is also constrained by a lack of ancillary services, technical assistance, staffing and training, even when drug stock is centrally available. Training gaps exist for healthcare staff

regarding CAB-LA, which is being implemented in 4 sites in Phnom Penh. The need to hire qualified healthcare providers for new PrEP options is also acknowledged.

Cost, affordability and funding: Cambodia's PrEP program relies heavily on external funding, facing sustainability challenges amidst recent changes in donor support. Cambodia currently funds 70% of antiretroviral drugs for treatment but provides zero prevention funding. This is a major sustainability concern, especially given the potential for a 40% reduction in Global Fund support. There is a recognized need for clear domestic funding strategies to ensure the sustainability of PrEP and broader HIV prevention efforts amidst these funding transitions.

The cost of CAB-LA is estimated at around US$ 30 per injection, which is considered accessible within public health budget constraints. However, regional cost-effectiveness analyses suggest that at current prices, CAB-LA is generally not cost-effective and would require a 50-90% price reduction to be so. The oral PrEP obtained from online pharmacies and private clinics is reported to cost much higher than the public sector price.

2. Fiji

- PrEP is not yet available in Fiji

Fiji has the fastest-growing HIV epidemic in the world, with a sudden surge in new cases linked to injecting drug use. The need for PrEP is urgent and widespread. The country recognizes the need to rapidly introduce and scale up oral PrEP and other prevention tools, including harm reduction programs as part of a comprehensive and rapid public health response.

PrEP Foundations for national programming

Regulatory Approval	Not yet obtained for any PrEP option
PrEP Guidelines	Draft Implementation Guidelines for PrEP (2025). This includes guidance on Oral PrEP, DVR and CAB-LA
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and HIV Planning
PrEP Planning	National HIV Surge Strategy 2024-2027

A critical development is the tripling of new HIV diagnoses from 2023 levels in 2024. Preliminary data for 2024 from the Ministry of Health indicate that half of people newly diagnosed with HIV who are currently receiving ART contracted HIV through sharing needles. This led the Government of Fiji to declare an HIV outbreak in January 2025. Fiji has the second fastest growing HIV epidemic in the Asia-Pacific region after the Philippines.

Sexual transmission remains an important mode of HIV transmission. This is driven by unprotected sex with multiple partners across different population groups including men who have sex with men, heterosexual men and women and young people. Chemsex practices have contributed to the rise in HIV infections. 70% of cases are among males and 73% among those less than 39 years of age.

PrEP is not yet available in Fiji. However, groundwork for PrEP delivery has been undertaken. It is aimed to have at least three sites where PrEP can be accessed by the end of 2025. Given the emphasis on "groundwork" and "feasibility and acceptability study", the approach currently appears to be in the planning and preparatory stages rather than active implementation.

PrEP strategies

The National HIV Surge Strategy 2024-2027 specifically includes PrEP for preventing HIV transmission among drug users and their partners. PrEP services will target key populations including men who have sex with men, sex workers, people who inject drugs and sero-discordant couples.

In 2025, the Ministry of Health and Medical Services developed draft Implementation Guidelines for PrEP. This includes guidance on Oral PrEP, DVR and CAB-LA. There are specific sections of starting PrEP, follow up scheduling and special considerations for specific situations and key populations. Roles and responsibilities are outlined including coordination, monitoring and evaluation. There are specific sections on community engagement, demand creation and capacity building.

Rollout of PrEP is on hold due to procurement and HIV testing challenges. CAB-LA is currently being considered for introduction. It is recognized that the HIV program needs to be revised in order to address the current HIV outbreak and the emerging factor of injecting drug use. HIV testing is reported to be a central challenge with inadequate levels of uptake, loss to follow up and long turnaround times for confirmatory tests due to centralized laboratory processing. Testing needs to be improved as a first step in PrEP programming.

There are significant data gaps that need to be addressed. These include data on new HIV cases and population size estimates. The last completed Integrated Bio-Behavioral Surveillance (IBBS) was conducted in 2012. IBBS for MSM and PWID is currently underway. Capacity building will be needed with priorities including training for health care workers and demand creation for key populations. NGOs/CBOs currently lack knowledge and skills for PrEP service delivery. M&E systems for PrEP service delivery are not yet in place.

Enabling factors

Political will and national response: The government of Fiji has declared an HIV outbreak and launched a HIV Outbreak and Cluster Response Plan. This has prompted a multi-sectoral, across government response, with key institutions such as the Fiji National University (FNU) stepping up as partners in public health. This high-level political commitment is a crucial enabler for accelerating PrEP implementation.

External partnerships and technical assistance: UNAIDS and the Australian Government's Indo-Pacific HIV Partnership are actively supporting Fiji in its response. UNAIDS, for instance, supports PrEP feasibility assessments and the development of national PrEP guidelines, working closely with stakeholders to facilitate PrEP roll-out

Growing awareness and demand: UNAIDS supported "Formative Assessment and PrEP Implementation Framework" to better understand feasibility and barriers of PrEP implementation and community demand. The goal is to introduce PrEP by the end of 2025. This indicates a proactive effort to build demand and address potential community barriers. Awareness is highest among men who have sex with men and concerning oral PrEP. Health professionals have some knowledge, but further education and training will be necessary for PrEP service introduction.

Existing combination prevention framework: The national response plan calls for a combination of prevention approaches, including condom distribution and PrEP. The Ministry of Health and Medical Services (MOHMS) has also stated that oral PrEP is to be offered as an "additional prevention choice" for people at substantial risk, indicating a policy openness to the method.

Community and partner-led initiatives: Organizations such as Medical Services in the Pacific (MSP) Fiji are already providing a broad range of sexual and reproductive health services and are prepared to implement harm reduction programs.[8] These non-profit organizations and their mobile clinic outreach teams can be critical partners in scaling up PrEP delivery, especially to hard-to-reach populations.

Barriers

Lack of regulatory approval: Fiji does not have regulatory approval for any PrEP products (both oral and injectable). This is a foundational barrier, as without it, PrEP cannot be legally procured or

distributed through national systems. Though under the outbreak period, approval can be fast tracked.

Health system challenges: The health system itself presents a number of significant obstacles. There is a severe shortage of healthcare professionals, including doctors, nurses and midwives, which limits the capacity to deliver a new service such as PrEP. This is compounded by a lack of specialized training for staff on PrEP. Shortages of essential medical supplies, such as HIV testing reagents and other diagnostics, are a persistent issue, leading to delays in confirming HIV status and impacting the continuity of care.

Inadequate HIV testing capacity: Uptake of HIV testing is low due to a lack of awareness and limited testing options. Undiagnosed cases in the population are driving HIV transmission. The lack of laboratory capacity to perform advanced HIV tests locally means samples must be sent to Australia, causing significant delays. In 2024, only 36% of people living with HIV in Fiji were aware of their status. This is a significant gap. There is no national policy on HIVST. The lack of a clear, government-backed HIVST framework can hinder widespread, sustainable implementation and integration into the public health system.

Financial constraints: Fiji faces significant financial barriers in its HIV response. These include: overall underfunding of HIV response and the cost of PrEP. The country has experienced a decade of underfunding and reduced international support for its HIV prevention strategies, which has undermined its ability to strengthen health services. As PrEP is not provided by the public health system, the cost of the medication is a major barrier for most individuals, restricting access to a privileged few who can afford it.

High levels of stigma and discrimination: In a small island nation where "everyone knows each other," the stigma associated with HIV is exceptionally high. People with HIV often face gossip, social isolation and exclusion from their communities. This fear of being identified or judged as a person with HIV makes people fearful to seek out PrEP services. A cultural "tabu" or taboo prevents open discussion about sex and HIV, complicating education and prevention efforts. This, coupled with widespread prejudice against key populations, makes people fearful of seeking care, even when they know their HIV status.

Lack of demand generation: This is currently at a preparatory stage.

Accessibility of PrEP: Accessing PrEP services will present a major challenge in remote rural areas and distant islands. Fiji is an archipelago of over 330 islands, of which approximately 110 are permanently inhabited. The two largest islands, Viti Levu and Vanua Levu, are home to about 87% of the total population.

Gender-based violence (GBV): GBV is a significant and widespread issue in Fiji that severely undermines women's ability to access HIV services, including PrEP. This is due to a complex web of social, cultural and structural barriers. It has some of the highest rates of GBV in the world. Studies show that 72% of women have experienced physical, emotional, or sexual violence from their intimate partners in their lifetime.

Lack of service delivery models: Planning is needed to develop appropriate service delivery models for PrEP. This should include consideration of integration with existing SRH services, community leadership and participation together with partnerships across organizations. Developing effective collaboration between health hubs and NGO clinics will be important.

3. Indonesia

- As of December 2024, the current number of people on oral PrEP in Indonesia is 40,044, with 31,038 newly initiated in 2024.
- Indonesia's PrEP program continues to expand, targeting 46,280 men who have sex with men and 24.432 female sex workers targets by the end of 2025, in line with the National HIV Strategic Plan.

Indonesia has one of the highest numbers of new infections in the region. As of 2024, the estimated number of people living with HIV in Indonesia is between 520,000 and 620,000, an increase from 380,000-460,000 in 2010. The HIV incidence per 1000 adults (15-49) was 0.15 [0.13 - 0.18] in 2024, down from 0.34 [0.3 - 0.39] in 2010.

The PrEP program is heavily dependent on international donor funding and services. Expansion of service delivery has reached 146 districts in 36 provinces (Q3 2025). The need is to secure domestic funding and integrate PrEP into the national health insurance system (JKN) to ensure the sustainability of the program and expand access beyond urban centers.

PrEP Foundations for national programming

Regulatory Approval	Generic oral PrEP (TDF/FTC and TDF/3TC is BPOM registered, while Truvada is not. TDF/3TC has replaced TDF/FTC in the National PrEP Program since 2024.
PrEP Guidelines	Guidelines for oral pre-exposure prophylaxis (2023).
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and Planning.
PrEP Planning	National Strategic Plan on HIV/AIDS and STI 2021-2030.
PrEP Implementation	As of December 2024, the current number of people on oral PrEP in Indonesia is 40,044.

(*BPOM = Badan Pengawas Obat dan Makanan / National Agency of Drug and Food Control*)

PrEP strategies

The National Strategic Plan on HIV/AIDS and STI 2021-2030 promotes the scaling up of PrEP for HIV-negative individuals at increased risk, alongside integrated HIV services, community-led approaches and partnerships to improve access, quality and affordability of prevention services, including PrEP, for key populations - men who have sex with men, female sex workers and transgender women.

Indonesia began PrEP implementation later than its regional peers but has achieved rapid scale-up and significant geographic expansion in recent years. The initial policy regulation for PrEP was delayed until 2020, with full pilot implementation occurring in 2022-2023. The pilot phase focused on testing delivery models and operational feasibility within the Indonesian healthcare context.

Indonesia initially planned for PrEP implementation in 5 provinces and 12 districts, but this has expanded to 146 districts as of Q3 2025. National implementation priorities include strengthening policy frameworks for daily and event-driven PrEP regimens expanding access through community clinics and sustained demand generation.

Indonesia also plans to build on its oral PrEP rollout for future Lenacapavir (LEN) introduction by 2027. Discussions are ongoing to explore differentiated service delivery (DSD) models for oral PreP, including nurse-led and pharmacy-based distribution channels. Training and capacity building will be important for oral PrEP scale up and LEN introduction.

Enabling factors

Differentiated service delivery (DSD): Indonesia is in the process of adopting a DSD model for PrEP, moving beyond a one-size-fits-all approach to make services more accessible and client-centered. This shift is a response to the country's fast-growing HIV epidemic and aims to address the significant barriers that have historically limited PrEP uptake. The NSP encourages the provision of differentiated PrEP services tailored to the specific needs and preferences of different key population groups, emphasizing convenience and choice.

Strengthening health infrastructure: Efforts continue improve PrEP service delivery by expanding the network of health facilities including public hospitals, community clinics (Puskesmas), private providers and community-led clinics capable of providing PrEP services.

Integrated service delivery: The strategy emphasizes integrating HIV services into broader health and social protection systems to ensure a comprehensive approach for people at risk of and affected by HIV. PrEP services have been integrated into existing HIV care, support and treatment. PrEP has become a routine component of HIV service delivery.

Public-private partnerships: Strengthening public-private partnerships is a focus to support comprehensive HIV prevention efforts, including PrEP.

Improving PrEP affordability: The plan includes investigating mechanisms to improve the affordability of PrEP, such as exploring regional price negotiations and facilitating the approval of generic versions of PrEP medications.

Community engagement: The NSP promotes community-led services and monitoring to increase access and improve quality of HIV and PrEP services for key populations. Peer educators and outreach workers have been key in recruiting participants from HIV communities, sex work venues and digital platforms.

Demand generation: Demand generation campaigns have been a crucial component of the PrEP scale-up in Indonesia, particularly since the launch of the pilot program in 2021. The primary goal of these campaigns is to increase awareness of PrEP and drive uptake among eligible populations, which are predominantly key populations, including men who have sex with men, female sex workers, transgender people and people who inject drugs. Key aspects include: community-Led efforts; targeted digital platforms, using online platforms such as Tanya Marlo and Saya Berani; and Multi-partner collaboration, involving the Ministry of Health, local community organizations, academic institutions and international donors.

Barriers

Conservative culture: Sexual orientation can be considered negatively in parts of Indonesia, and homophobia remains a barrier to service uptake and participation. While no LAI-PrEP (long-acting injectable) pilot projects have been implemented in Bali, early discussions and feasibility studies for

DVR (Dapivirine Vaginal Ring) and future LAI-PrEP introduction highlighted sensitivities requiring careful community engagement and advocacy.

Stigma and discrimination: These pose significant, multi-level barriers to PrEP access in Indonesia, hindering the country's HIV prevention efforts. These barriers exist at the societal, healthcare and policy levels. PrEP itself is sometimes stigmatized as a "pill for promiscuity" or as an alternative to condoms, which are culturally associated with responsible sexual behavior.

Lack of national policy and licensing for PrEP: Oral PrEP implementation has national programmatic approval, but formal BPOM (Badan Pengawas Obat dan Makanan / National Agency of Drug and Food Control) registration is still pending. This has led to a limited access through the national health system and dependence on donor-supported procurement. Other PrEP regimens recommended by WHO (CAB-LA, DVR and LEN) are not yet licensed in Indonesia and no formal regulations for their distribution exist.

Barriers to HIV testing: These include stigma and discrimination; low awareness about HIV and the benefits of testing; and lack of training of health care providers. Access to HIV testing is often concentrated in urban areas, with limited services in remote, island or rural communities. In some cases, logistical barriers, such as shortages of HIV test kits or delayed reagent supply chains can lead to interruptions in testing and diagnosis.

High cost: Under the national program, oral PrEP is provided free of charge at MoH and community sites. However, for individuals purchasing privately, a one-month supply costs around USD 60-130 when ordered online, often without prescription oversight. Lack of insurance coverage under JKN continues to be a barrier to long-term sustainability.

Low awareness of PrEP: This is found among the general population and health care providers. Awareness among key populations, such as men who have sex with men and transgender women is observed and has improved since 2021 but remains uneven. A 2017-2018 study in Bali found that only 16.4% of participants had heard of PrEP.

Limited access and community capacity for service delivery: PrEP implementation is sometimes constrained by uneven provincial readiness and limited numbers of trained providers. Drug stock-outs are rare under the national rollout, but challenges persist in PrEP-STI integration and laboratory linkage. Community-based STI services remain limited in many areas and conservative attitudes in certain regions may also limit access to PrEP at high volume key population (KP) -focused clinics.

Donor dependence: There is significant dependence on Global Fund financing, with no confirmed funding beyond 2026. This raises serious sustainability concerns, heightened by the complete dependence on donor funding without a clear pathway for government or private sector engagement. The current financial landscape underscores the importance of integrating PrEP commodities and service delivery costs into national and sub-national health budgets to ensure program continuity as external funding gradually tapers.

4. Malaysia

- As of December 2024, the current number of people on oral PrEP in Malaysia is 6,714.
- From January to June 2025, there were around 5,000 active PrEP users including all key populations:
  - 2,639 men who have sex with men;
  - 448 transgender women;
  - 608 female sex workers; and
  - 73 people who inject drugs.
- The cumulative total of PrEP users (2022-2025) is:
  - 12,408 men who have sex with men;
  - 666 transgender women;
  - 4,778 female sex workers; and
  - 244 people who inject drugs.

**Source: Ministry of Health Malaysia, Malaysia Global AIDS Monitoring (GAM) Report 2025*

Malaysia's HIV epidemic is concentrated among men who have sex with men. Despite a growing number of people on PrEP, issues such as social stigma and a conservative legal environment deter many from seeking services. The need is for **community-led initiatives** that can provide discreet and stigma-free access to PrEP, bypassing traditional healthcare settings that may not be welcoming to key populations.

PrEP Foundations for national programming

Regulatory Approval	Truvada (2016) and generic TDF/xTC; CAB-LA (2024)
PrEP Guidelines	National Guidelines for PrEP Program Implementation (2025)
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and Planning
PrEP Planning	National Strategic Plan to End AIDS 2016-2030

HIV is concentrated among key populations, accounting for 88% of total new HIV infections in 2024. HIV prevalence among all key populations was declining between 2017 and 2022. Men who have sex with men are expected to account for three-quarters of all cases by 2030. HIV prevalence among transgender people was 5.9% in 2022.

The pattern of HIV transmission in Malaysia has shifted significantly over the years. There has been a transition from HIV transmission through sharing injection equipment to being spread through sexual contact. Young adults (20-39 years old) comprised the majority of new HIV cases reported in 2024. Sexual transmission accounted for 96% of all diagnosed HIV cases. Of these, 64% involved homosexual or bisexual contact, while 32% were heterosexual.

Estimated sizes of key populations are available for female sex workers (22,000), men who have sex with men (220,000), transgender (15,000) and people who inject drugs (60,000). The current target of 25,000 people on PrEP represents only 10% of key population targets in total 270,000: 220,000 men who have sex with men and 50,000 transgender people. There are no targets set for sex workers and people who inject drugs[40 41].

PrEP strategies

The National Strategic Plan to End AIDS 2016-2030 contains limited investment in PrEP. It is stated that it will include consideration of the newly available PrEP and PEP tools for prevention in specific key populations and situations. There will a study of the feasibility and the programmatic introduction of PrEP.

Current PrEP policy emphasizes a community-clinic partnership model, beginning in 2023, with clinic-based PrEP navigators and community-led outreach to engage key populations in primary healthcare. This framework supports the integration of PrEP into national HIV prevention efforts, complementing other strategies e.g. condom use and harm reduction.

Enabling factors

Integrated service delivery: PrEP services have been introduced into primary care clinics to improve access in public healthcare settings. Malaysia's PrEP program began with a pilot project in January 2023 at 18 health clinics and has expanded to 35 clinics nationwide. Currently there are 109 health facilities across 26 provinces providing oral PrEP services. The service delivery model involves a clinic partnership and PrEP navigator network in the public sector.

Malaysia's integration of PrEP into its UHC system began in 2023, focusing on community-clinic partnerships within primary healthcare to make PrEP accessible and reduce stigma for key populations, especially men who have sex with men. Key initiatives include the introduction of PrEP in public clinics, the use of PrEP navigators and community outreach to increase demand and facilitate access. Efforts are underway to expand PrEP services through pharmacies, increasing access by providing non-stigmatizing, convenient care.

Differentiated Service Delivery (DSD): This involves adapting service models beyond traditional facility-based care to improve access for key populations. These include pharmacy-led PrEP services and mobile clinics in the Klang Valley, to decentralize and de-medicalize care, making PrEP more accessible by addressing barriers related to cost and stigma. This model leverages the accessibility of community pharmacies and incorporates HIV self-test kits available at pharmacies to support PrEP initiation and continuation, simplifying the delivery of PrEP services in a non-clinical setting. The pharmacists collaborate with physicians through a telemedicine platform to enable same-day PrEP via electronic prescription.

Demand generation: Demand generation for PrEP involves community-led initiatives, peer outreach and advocacy by PrEP navigators to raise awareness and facilitate access within key populations. Strategies focus on culturally appropriate targeted messaging, engaging end-users in program design and leveraging online platforms for outreach and counseling. Universities have developed JomPrEP app and chatbot for men who have sex with men and transgender populations using implementation science research approaches. The website www.testnow.com.my and MySejahtera application provide information on HIV and the mHealth Model focuses on self-tests and referrals. Qualitative research is being conducted on long-acting injectable PrEP barriers and facilitators among key populations.

Capacity building: Malaysia has actively built its PrEP capacity by integrating the service into primary care and pharmacies, training healthcare professionals, developing community-led outreach programs and utilizing PrEP navigators and peer support to overcome stigma and stigma barriers for key populations. The aim is to expand access by addressing policy and geographic

barriers in rural areas and strengthening regional collaboration and knowledge exchange to sustain and scale up PrEP services nationwide.

Cost subsidies: Government subsidies for PrEP services help make it more affordable for those in need. Since January 2023, the Malaysian Ministry of Health (MOH) and the Malaysian AIDS Council (MAC) have collaborated to dispense free PrEP at selected public health clinics in states with high HIV prevalence, including Selangor, Kuala Lumpur, Johor, Penang and Sabah. This program is aimed at scaling up PrEP use for an estimated 9,000 to 10,000 key population members.

Barriers

Conservative culture: This is rooted in both social norms and religious beliefs, significantly affects PrEP access by creating a complex web of legal, social and healthcare-related barriers. This environment of stigma and criminalization disproportionately impacts key populations, particularly gay, bisexual and other men who have sex with men and transgender people, who are the primary beneficiaries of PrEP. PrEP is sometimes stigmatized as a "pill for promiscuity," with oppositional groups arguing that its availability will "condone or normalize" LGBTQ identities.

The cost of PrEP outside selected public health clinics: This varies depending on the brand, clinic and whether generic versions are available. Some clinics may offer special pricing or packages that include PrEP medication, follow-up HIV tests and doctor consultations. The cost of injectable PrEP remains a significant barrier, with retail prices of over 2,000 ringgits for CAB-LA compared to 50-90 ringgit for oral PrEP.

PrEP supply chain policy: It involves national efforts to integrate PrEP into the HIV response, but management has faced challenges such as inaccurate forecasting and stock-outs due to insufficient national logistics, a lack of digital tools for monitoring and inconsistent procedures. Limitations in national electronic data repositories have hindered effective monitoring and evaluation of PrEP uptake, adherence and outcomes, making it difficult to track progress and manage inventory.

Access to PrEP: This is a primary concern in Malaysia where it is limited, particularly outside urban areas. Equitable access to a wider area is critical in prevention efforts to allow high-risk individuals to protect themselves from potential transmission.

HIV testing barriers: HIV testing for PrEP faces significant barriers in Malaysia, particularly for men who have sex with men. Issues include limited access, lack of awareness and stigma and discrimination. Many individuals are concerned about the confidentiality of their medical records, especially in government-run clinics, which may deter them from getting tested.

Limited awareness and knowledge: Low levels of awareness and understanding of PrEP are found in both the general public and among health care providers. This issue is amplified by a perceived low risk of HIV among some providers and concerns about risk compensation, where they believe PrEP use may lead to a decrease in other prevention methods.

5. Papua New Guinea

- As of December 2024, the current number of people on oral PrEP in Papua New Guinea (PNG) is 604.
- This represents critically low uptake, less than 10% of the potential target population. This low uptake is attributed to limited access (deployed in only two provinces) and insufficient demand creation.

PNG has a significant HIV epidemic with high prevalence among key populations. The country faces unique challenges due to its complex geography and limited health infrastructure. The need is for differentiated service delivery models that can overcome these geographical barriers, making PrEP accessible in remote and rural areas.

PrEP Foundations for national programming

Regulatory Approval	Oral PrEP is approved for use and listed in the essential medicines list of the National Department of Health.
PrEP Guidelines	A National Guideline for Oral PrEP is in place. PrEP is also covered under the National HIV Care and Treatment Guidelines
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Planning
PrEP Planning	National STI and HIV Strategy 2024-2028

In 2024, the estimated number of adults and children living with HIV in Papua New Guinea was 120,000, an increase from 54,000 in 2010. The HIV incidence per 1000 adults (15-49) in 2024 was 1.4 [1.2 – 1.8], an increase from 0.98 [0.84 – 1.2] in 2010. The HIV prevalence among 15–49-year-olds in 2024 was 1.5% [1.3 – 1.7%], up from 1.0% [0.9 – 1.2%] in 2010. ART coverage in PNG was 49.7%.

PrEP strategies

PNG's 2024-2028 National STI and HIV Strategy aims to end AIDS by reducing new infections by 50% by 2030 and includes plans to integrate PrEP as a key prevention method. The strategy emphasizes strengthening health systems, improving access to quality services and implementing people-centered, community-involved interventions to address the growing HIV crisis in PNG. While the strategy outlines the framework, significant work remains to be done to overcome implementation challenges and achieve broader PrEP scale-up across the country. There is a need for a dedicated PrEP strategic planning document with targets, objectives, activities, timeline and costing.

PNG initiated oral PrEP implementation in late 2022. PrEP services primarily target men who have sex with men, sex workers and serodiscordant couples.

Current implementation scope covers three provinces with oral PrEP services established through donor-funded pilot programs. Two provinces (National Capital District and Eastern Highlands Province) have been fully operational since 2022-2023 with USAID and DFAT funding support and a third province (Morobe) commenced services recently after training completion. One additional province (Western Highlands) is planned for expansion in 2025-2026, with Global Fund financing already secured. The National HIV Program is committed to supporting implementation across all 22 provinces beyond the currently covered areas.

The Dapivirine Vaginal Ring (DVR) acceptability and feasibility study showed encouraging results[42]. This found that there is very low awareness of the DVR among demand and supply participants but communicated strong interest post initial introduction. Target users indicated a high level of acceptance of the DVR. Initial exposure to the DVR through research engagements, including its usage and benefits, has resulted in strong interest from women to try it out. The DVR was perceived to be an empowering tool to protect themselves against HIV in high-risk environments and seen as highly acceptable to the target audience. The ongoing PrEP delivery channels are likely the most suitable for DVR provision. However, staff shortages and lack of funding to HIV programs need to be addressed for a successful rollout.

Injectable LEN PrEP discussions are at an early stage. Healthcare worker capacity exists for injectable product management, though the workforce is currently overstretched. Global Fund price negotiations with Gilead are ongoing, though final pricing unknown. Generic alternatives are projected 2-3 years away from market availability. Government cost absorption capacity is severely limited given current economic constraints and historical resistance to HIV prevention intervention costs.

A key issue is integration of LEN service delivery in current HIV services in phased implementation. There are several entry points for integration and one of the promising approaches is integrating LEN into the national prevention of mother-to-child transmission of HIV (PMTCT) program in selected provinces. This would be a highly strategic move, allowing the program to utilize existing clinics, trained staff (or newly trained) and patient flow, rather than building an entirely new service delivery system. Integrating STI services will be critical for a successful PMTCT/LEN PrEP program. There will also be a need to strengthen linkages with community services to enhance demand generation and accessibility for other key populations. Moreover, there are significant structural and social barriers to PMTCT programming that must be addressed before effective integration of LEN, can begin. Healthcare worker capacity exists for injectable product management, though the workforce is currently overstretched.

Enabling factors

Government leadership: The National Department of Health (NDoH) and the National AIDS Council Secretariat (NACS) are committed to broader support across all provinces in PNG for HIV prevention initiatives, aligning with government emergency response plans. Identified critical success factors include strong community engagement, government backing and a focused need for population-specific interventions to enhance prevention efforts.

International donor support: Current funding sources include USAID commodity procurement and technical assistance, DFAT implementation support, UNAIDS technical assistance and Global Fund expansion financing. There is free service delivery to end users through donor-supported programming. Government procurement transition is planned under Global Fund arrangements. Commodity pricing information is not readily available to program implementers.

Strong coordination infrastructure: The HIV Technical Working Group with a dedicated Prevention sub-technical working group is effective in coordination and provides oversight for PrEP implementation. This has high-caliber representation from government, partners and community organizations ensuring quality decision-making. There is government leadership of coordination mechanisms with partners' technical support. Robust technical infrastructure supports quality program implementation and decision-making.

Community and key population engagement: Experienced CSO partners and church-run organizations have proven HIV service delivery capacity. Community sensitization is achieved with willingness to support and drive demand for PrEP services. Provincial health authorities are actively engaged in service delivery oversight and expansion planning. Key population programs operate strategically under an HIV prevention umbrella with strong government support from the NACS and NDoH. Community readiness for PrEP has been highlighted through province-wide consultations by the Key Population Advocacy Consortium (KPAC), establishing a basis for scaling up services with community involvement.

Community-based delivery model: In response to the low uptake, PNG is planning to decentralize PrEP delivery from a facility-based to include community-based delivery model to improve the accessibility and uptake of PrEP services. A strategic shift toward community-based PrEP delivery is underway to tackle slow facility-based uptake, utilizing second-generation saliva-based testing for easier HIV screening. Community members are being trained beyond demand generation to support actual PrEP dispensing across multiple provinces, starting with NCD. Community-based service delivery involves community-based platforms such as drop-in centers, outreach services and mobile services.

Barriers

Insufficient resources in the health system: The limited financial and human resources of the health system including a shortage of health care professionals impede the delivery of PrEP. PNG's initial oral PrEP implementation, which began in late 2022, utilized a health facility-focused approach. This strategy, however, proved ineffective as health facilities primarily focused on HIV-positive patients receiving ART.

Geographical barriers: This is a major barrier to the implementation and delivery of PrEP. The country's landscape, coupled with its underdeveloped infrastructure, severely limits the reach of health services, particularly to the 85% of the population living in rural and remote areas. The highland epidemic concentration is a significant factor. While the epidemic is found across the country, it is concentrated in the five Highlands provinces. This is one of the most geographically difficult regions to access.

HIV testing barriers: HIV testing as a critical step for accessing PrEP is a major bottleneck in the country's HIV prevention efforts. Overall HIV testing coverage in PNG is low, especially among young people. Studies show that a large percentage of young men (82.7%) and young women have never been tested for HIV. While HIV testing is available in all 22 provinces, access is often limited by geographical barriers and the lack of functioning health facilities. The supply chain for HIV test kits is often strained, with occasional stockouts, poor quality of services and weak referral linkages for PrEP services.

Low level of PrEP awareness and knowledge: Among key populations, this contributes to misconceptions, such as PrEP being perceived as a luxury item, encouraging unsafe sex, or being unaffordable. There is low awareness of PrEP among health care providers.

Socioeconomic barriers: Socioeconomic barriers, particularly the high cost of PrEP and the limited financial resources of clients, are a primary reason for low retention and adherence to PrEP in PNG. These financial challenges often lead to clients discontinuing the medication after just one or two months, undermining the effectiveness of the prevention program. These are identified as a primary

challenge with clients dropping off after 1-2 months due to the cost of transportation for adhering to monthly refill requirements.

Gender-based violence (GBV): GBV is a significant and widespread issue in PNG that severely undermines women's ability to access HIV prevention services, including PrEP. The high prevalence of violence including intimate partner violence, coupled with deep-seated gender inequality, creates a complex web of social and structural barriers.

Stigma and discrimination: There is social stigma associated with HIV and related services including PrEP. This deters people from seeking services. PrEP's use is often associated with having HIV, or engaging in "promiscuous" behavior, which compounds the existing stigma. This misperception is a barrier for potential users, as they may worry that taking PrEP will cause others to assume they are HIV-positive or promiscuous, leading to social repercussions.

Punitive laws on sex work and same-sex relationships hinder service access However, community representatives report successful navigation around these legal barriers through strategic HIV-focused programming and strong partner support.

Donor dependence: PNG's HIV response is characterized by low ART coverage (below 50%). Globally, HIV prevention programs are heavily reliant on donor funding, with 11 of 16 reporting countries relying on international sources for over 75% of their prevention financing. USAID/FHI 360 technical assistance, previously available for PrEP implementation in PNG, is no longer available.

6. Philippines

- As of December 2024, a total of 55,284 individuals in the Philippines had initiated PrEP, which is approximately 40% short of the national PrEP target for 2025.

The Philippines has the second fastest-growing HIV epidemic in the Asia-Pacific region. The vast majority of new infections are among men who have sex with men. Community-based organizations have been instrumental in leading the PrEP rollout, but services are still highly concentrated in major urban centers.

PrEP Foundations for national programming

Regulatory Approval	Oral PrEP: Truvada (2016) and generic (2023): CAB-LA 2024
PrEP Guidelines	Interim Guidelines for PrEP (2021)
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and Planning
PrEP Planning	7th AIDS Medium Term Plan (2023-2028)

The adult HIV prevalence rate (aged 15-49) is estimated at 0.3%. As of the end of 2024, an estimated 215,400 people are living with HIV (PLHIV) in the Philippines, with approximately 55 new cases diagnosed per day as of March 2024. New HIV infections and AIDS-related deaths in the Philippines continue to rise rapidly. There has been a 550% rise in new HIV infections since 2010. There were 31,000 new infections in 2024.

The HIV Epidemic is largely among men who have sex with men and transgender women. Youth (18-24 years) are the drivers of new infections with 47% of new infections in 2023. Sexual transmission, primarily among men who have sex with men, accounts for the vast majority of new HIV cases. As of January 2023, approximately 70% of all HIV cases were among men who have sex with men. By December 2024, men who have sex with men accounted for 94% of total cases. The population size estimate for men who have with men in 2024 was 1,384,400, with an HIV prevalence of 17%.

PrEP strategies

The Seventh AIDS Medium Term Plan (AMTP) 2023-2028 includes PrEP. PrEP is specifically included under Objective 1: Prevent new HIV infections among Key Populations, including young key populations in the HIV Prevention and Control Costed Operational Plan 2018-2020. National PrEP guidance states that oral PrEP (containing TDF + 3TC) is to be offered as an additional prevention choice for people at substantial risk of HIV. The guidelines are being revised to include telePrEP as a person-centered service delivery option.

Enabling factors

Strong political will: There is strong political support from the Secretary of Health who recognizes the need for additional HIV prevention options given low condom usage.

Availability of domestic and international funding for PrEP: PrEP services in the Philippines are supported through both domestic and international funding. Domestic funding comprises support from the national government (Department of Health, PhilHealth) and other national government agencies, local government units and the private sector. From 2007 to 2017, HIV spending

progressively increased, with domestic funding comprising a larger share, though overall funding remains insufficient. The Philippines committed to funding PrEP using domestic resources and in 2024, the country's PrEP supply began to include government purchase in addition to Global Fund donations. The government is exploring purchasing HIV services through social contracting.

The KPLHS model: PrEP service delivery is built on CBOs which initiated oral PrEP services before government involvement, establishing a community-led precedent. There is a strong community presence but a funding vulnerability due to the shifting donor landscape. A social contracting mechanism is being advocated to enable CBO access to government funding. Key population-led organizations play key roles in PrEP advocacy and implementation, including social media campaigns, digital health tools and integration with HIV self-testing. Project PrEPPY involved community members as PrEP navigators and life coaches. A National PrEP Network in the Philippines serves as a hub for PrEP service providers.

Integrated service delivery: PrEP is being integrated into HIV services in the Philippine public health system through a multi-pronged approach that combines supportive policies with innovative, community-led service delivery models. The government, led by the DOH, has made significant strides in shifting from a centralized, hospital-based system to a more accessible, patient-centered framework.

Local evidence to inform policy and programming: A study on PrEP preferences among Filipino men who have sex with men found that the most important attributes were PrEP type, access location and cost. Men who have sex with men showed a preference for daily oral PrEP over other forms such as implants and a strong preference for free PrEP over paid options. They preferred CBO-led clinics as access points. There is high interest in long-acting PrEP options.

Differentiated Service Delivery (DSD): The Philippines has adopted DSD models that move beyond traditional hospital settings. Key approaches include community-based clinics which are run by and for key populations, TelePrEP, decentralization and simplified care. The DOH has endorsed a patient-centered approach, including providing a three-month supply of PrEP at the initial visit to reduce the burden of frequent clinic visits and improve adherence.

Demand generation: Demand generation for PrEP in the Philippines involves a multi-pronged, community-led approach that leverages digital platforms and strategic partnerships to overcome stigma and increase awareness among key populations. The country's demand generation efforts have proven highly effective in boosting PrEP uptake. CBOs are at the forefront of PrEP demand generation. These groups, e.g. LoveYourself Inc., are trusted by key populations. More than 60% of PrEP initiations in the country by the end of 2022 were facilitated by CBOs.

HIV self-testing (HIVST): The introduction of HIV self-testing has enabled more people to know their HIV status which is a prerequisite for accessing PrEP. The Philippine Department of Health (DOH) has recognized this and included HIVST in its 2022 Guidelines for Implementing Differentiated HIV Testing Services to increase coverage. For an individual to start PrEP, they must first have a confirmed HIV-negative status. By making HIV testing more accessible and acceptable, HIVST serves as a crucial entry point to the PrEP continuum of care. The DOH's guidelines explicitly include HIVST as a strategy to "maximize options" for prevention and increase points of access to services.

Barriers

Low awareness and knowledge of PrEP: Despite rising interest, overall awareness of PrEP remains low among at-risk populations. A lack of comprehensive and targeted public education campaigns means many individuals simply do not know PrEP exists or that they are eligible for it. Misconceptions about PrEP are common. Some believe that PrEP is only for the LGBTQ+ community, others confuse it with emergency contraception, and a widespread myth is that taking PrEP eliminates the need for condom use, leading to potential risk-taking behavior.

HIV testing: This is a foundational step for accessing PrEP. The country has made significant strides in its legal framework to improve testing access, but significant barriers remain, particularly for key populations. Stigma and discrimination affect people at every level, from their own fear and reluctance to get tested to their interactions with healthcare providers.

Limited access to PrEP services: Less than 50% of public HIV facilities are dispensing PrEP despite national guidance that all facilities should do so to reach the targets set. Most HIV and PrEP services are concentrated in major urban centers, for example, Metro Manila. This creates significant geographic and travel barriers for people living in rural or suburban areas who may have to travel long distances, sometimes without access to affordable transportation. There is insufficient outreach of PrEP services. There is a lack of culturally sensitive PrEP programming that addresses the needs of key populations.

Logistics management: PrEP logistics management faces significant challenges primarily due to the country's geography. It is an archipelago with over 2,000 inhabited islands which make efficient and reliable delivery difficult. Complicating factors include poor and aging infrastructure, urban traffic congestion, inefficient customs processes and a lack of real-time visibility into the supply chain. These result in delivery delays and higher costs. Natural disasters disrupt transportation.

GBV as a barrier to PrEP access and adherence: GBV is a significant and interconnected issue with PrEP access and uptake in the Philippines. While much of the data on PrEP has focused on men who have sex with men, studies from other contexts show how GBV can act as a powerful barrier to both HIV prevention and adherence.

Stigma and discrimination: HIV is heavily stigmatized due to conservative, Catholic social values that often associate it with immorality and sin. This leads to fear of judgment and social rejection within communities and even families, which deters people from seeking out HIV services. Men who have sex with men, in particular, face a dual stigma related to their sexual orientation and their HIV status, creating a profound barrier to accessing PrEP. Discrimination may be experienced from healthcare workers. Many individuals fear that healthcare workers will be judgmental or discriminatory. A lack of trained and culturally competent providers in health facilities further discourages key populations from seeking care, even if services are available.

Unfamiliarity with PrEP among service providers. Many healthcare providers may be unfamiliar with PrEP or uncomfortable discussing sexual health. The system for accessing PrEP can be overwhelming for providers without the support of PrEP navigators.

Cost and affordability: While the government has made progress by including PrEP in the national formulary, the cost of PrEP can still be a prohibitive financial burden for many Filipinos, particularly those from lower socioeconomic backgrounds. In some cases, out-of-pocket costs for the medication and associated lab tests prevent consistent use and adherence.

7. Thailand

- As of December 2024, the current number of people on oral PrEP in Thailand is 32,991 – 46% of the national target (UNAIDS Data 2024).

Thailand is a regional leader in HIV prevention, having successfully integrated oral PrEP into its universal health coverage. The epidemic is highly concentrated among men who have sex with men, with alarmingly high incidence rates. The need is to scale up and sustain services and continue to innovate with new PrEP products to reach those who may not adhere to a daily pill regimen.

PrEP Foundations for national programming

Regulatory Approval	Oral PrEP -Truvada (2016) and generic (2023); CAB-LA (2024)
PrEP Guidelines	Guidelines for PrEP for Clinical Sites and CBO (2023)
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines and Planning
PrEP Planning	National Operational Plan 2023-2026 (Thailand National Strategy to End AIDS 2017-2030):

In 2024, the estimated number of adults and children living with HIV in Thailand was 570,000. The HIV incidence per 1000 adults (15-49) in 2024 was 0.23 [0.19 - 0.29], a decrease from 0.46 [0.4 - 0.53] in 2010. The HIV prevalence rate among adults aged 15-49 was 1.0% [0.8 - 1.2] in 2024, down from 1.6% [1.4 - 1.9] % in 2010. Male-to-male sexual transmission accounts for more than 44% of all newly reported HIV cases. The annual HIV incidence among Thai men who have sex with men is 6.0 cases per 100 person-years

The national PrEP target for Thailand in 2024 was 71,000 users. The reported PrEP coverage as of that period was 46%, with 32,991 users actively using the service. The majority of these users (76%) were located in Bangkok and the surrounding metropolitan area.

Thailand's oral PrEP program is one of the leaders in the region, with 32,991 users recorded as of 2024, an increase from 26,619 in 2023, though only reaching a fraction of the national target[43]. The vast majority of users are men who have sex with men and transgender women, who are prioritized due to high HIV incidence[44]. PrEP distribution is achieved through a differentiated service delivery model, with trained staff at 561 hospitals in 74 provinces establishing a unified monitoring system, but with the KPLHS model historically accounting for the majority of users (up to 82% in 2022)[45] [46].

Persistence rates are significantly higher at KPLHS/private clinics, with a median duration of PrEP use persistence at 268 days, compared to 148 days at public clinics, highlighting the importance of client-centered models[47]. Impact studies confirm the program's effectiveness: a large-scale study among high-risk youth reported zero HIV seroconversions when PrEP was being used, with infections occurring only in those who had discontinued[48]. Furthermore, modeling projects KPLHS-delivered PrEP as the most cost-effective model, demonstrating the greatest epidemiological impact by averting 58% of new infections compared to a scenario without PrEP[47].

Despite the established infrastructure, very low oral PrEP uptake persists, indicating a gap between policy and actual service utilization. A modelling study indicated that increasing oral PrEP coverage to 80% from 31% (for suitable men who have sex with men) would decrease new HIV diagnoses by

14.5% over a 40-year period. However, current PrEP uptake among men who have sex with men remains suboptimal at 31%.

PrEP strategies

The National Operational Plan 2023-2026 for the Thailand National Strategy to End AIDS 2017-2030 includes PrEP as a key prevention strategy, aiming to reduce new HIV infections to under 1,000 per year, by integrating it into comprehensive prevention programs: "Reach-Recruit-Test-Treat-Retain" (RRTTPR) for key populations. The strategy focuses on expanding service packages and establishing a sustainable financing system to support community-led PrEP programming, though challenges remain in achieving consistent PrEP usage and comprehensive coverage for all key populations.

Thailand has updated its PrEP guidelines (2021) to adopt a "status neutral" approach, recognizing that individuals presenting for PrEP are typically at high risk of HIV infection and should not be dissuaded from using it. This moves away from categorization of key populations as the sole basis for PrEP prescription, aiming to eliminate stigmatization of both PrEP and key populations.

Enabling factors

Political will and free access through UHC: Since October 2020, PrEP has been provided through the UHC free of charge. This has significantly increased PREP use for key populations. Supported by the National Health Security Office, discussions have been initiated for inclusion of LEN in the UHC.

HIV testing: HIV testing is a highly developed and integrated part of the national HIV response. The country's approach has evolved from initial pilot projects and clinical trials to a comprehensive, publicly funded system that prioritizes accessibility and confidentiality. HIVST is a key component of Thailand's strategy to expand PrEP access and achieve its goal of ending the AIDS epidemic by 2030.

Integration with existing HIV services: PrEP is integrated into existing HIV and STI prevention services, resulting in a more comprehensive approach to HIV care.

The KPLHS model: CBOs run by key populations deliver a range of health and HIV services including PrEP programming. The model is KP-friendly and accessible with flexible working hours. A substantial portion of the country's PrEP users access their services through KPLHS. The success has led to its integration into the national health security system, with the government piloting its inclusion in its overall universal health care budget.

Accessible service delivery: Community-based services such as KPLHS are central to PrEP uptake. CBOs provide a trusted and accessible entry point to PrEP services, especially young key populations who constitute the majority of PrEP users in the country. The services include awareness and support activities which are regarded as effective in reaching and retaining individuals taking PrEP.

Implementation science: Thailand has been a global leader in using implementation science to effectively scale up PrEP, particularly for key populations. Its success is rooted in a strategic and multi-faceted approach that moved from efficacy trials to real-world demonstration projects, with continuous monitoring and evaluation. The Institute of HIV Research and Innovation (IHRI) with KP-led organizations such as Caremat, Mplus, RSAT and SWING have played a key role in implementation science research and policy development through small-scale pilot studies and

demonstration projects to test the feasibility and acceptability of diverse PrEP service modalities in different settings.

Demand generation: Diverse demand creation activities have helped increase PrEP uptake. These include social media campaigns. Men who sex with men-focused demand creation has involved social media influencers and platforms including LINE, Twitter, Facebook and Hornet. The "TestBKK" experience in Thailand informed APCOM's "Get PrEP Done" toolkit, which promotes sex-positive activities to increase HIV service uptake." Implementation science has played an important role in advancing demand for PrEP providing evidence to inform the development of demand creation messaging.

Differentiated Service Delivery (DSD): DSD has involved the integration of community-based and KPLHS approaches to PrEP service delivery resulting in improved convenience and reach for key populations. It has also supported the decentralization and simplification of service delivery.

Multi-channel education: PrEP is integrated into existing information services using digital platforms. Peer education is another effective strategy for enabling increased PrEP uptake. Accurate information is available for many eligible PrEP users.

Barriers

Poor perception of risk: A significant barrier to PrEP uptake is poor perception of risk, especially among men who have sex with men. They may not perceive themselves as being at risk for HIV.

Inadequate knowledge about PrEP: There are low levels of PrEP knowledge among key populations, contributing to misconceptions, such as PrEP being perceived as a luxury item, encouraging unsafe sex, or being unaffordable. Fear of side effects is a significant barrier.

Limited accessibility of PrEP delivery: Accessing PrEP services is often difficult for those living in the provinces or rural areas. Services may also be inconvenient in terms of appointment scheduling, HIV testing or obtaining refills. Healthcare providers may be overburdened, limiting their capacity to deliver services effectively.

Stigma and discrimination: Stigmatization of PrEP use as well as HIV services continues to be a significant barrier to PrEP scale-up. This makes people reluctant to seek or openly use PrEP services. Lack of support for disclosure can lead to fear of stigmatization by partners family or employers resulting in secretive PrEP use.

Limitations with the current PrEP implementation model: Stakeholder consultations from key populations identified limitations with the current implementation model. The requirement to have medical supervision can lead to delays if the assigned doctor is unavailable e.g. on leave and the medication cannot be dispensed. CBOs cannot stock PrEP medication which has to be requested from the hospital on a daily basis which can lead to shortages if numbers exceed the requested quantity resulting in service delays. With regard to data, community inputs are credited to hospital codes and not formally recognized.

Cost of CAB-LA: Access barriers and private sector limitations regarding CAB-LA due to high pricing and lack of voluntary licensing have been identified. Private clinic exclusivity is limiting availability and creating cost barriers. Price reduction strategies are needed for broader access and public sector integration. Technical support is needed in demand creation and quality assurance.

Gender-based violence (GBV): GBV is a significant barrier to PrEP access and uptake in Thailand, particularly for women and transgender people. The link between GBV and HIV vulnerability is well-documented.

Sustainability Challenges. Challenges in integrating PrEP into UHC include a limited quota (2,000 PrEP users in 2020) and reimbursement channels restricted to health facilities, while the majority of PrEP users access services outside these facilities. Telehealth approaches for PrEP service delivery are also not yet reimbursed. New rules preventing PrEP from being issued to people excluded from the country's main health insurance system also pose a challenge.

8. Viet Nam

- As of December 2024, the current number of people on oral PrEP in Viet Nam was 74,950.

Viet Nam has a successful oral PrEP program, but it remains heavily reliant on international funding. The epidemic has shifted from people who inject drugs to sexual transmission, particularly among men who have sex with men. The need is to transition to domestic funding for PrEP and other services to ensure sustainability and independence from external donors.

PrEP Foundations for national programming

Regulatory Approval	Oral PrEP (2015) and generic (2019): CAB-LA under review
PrEP Guidelines	PrEP is included in the MOH 2021 Decision for issuing the national guidelines on HIV/AIDS care and treatment
PrEP Policy	No specific policy paper. PrEP policy is contained in PrEP Guidelines
PrEP Planning	Decision No. 5154/QĐ-BYT, issued on 11 December 2020, by the Minister of Health, on the Issuance of the Plan for Pre-Exposure Prophylaxis (PrEP) with Antiretroviral drugs for HIV, period 2021-2025

The estimated number of new infections in 2024 (all ages) was 6,100. This is a 56% reduction compared to 2010.

PrEP services in Viet Nam primarily target key populations at substantial risk of HIV acquisition. These include men who have sex with men, transgender women, female sex workers, people who inject drugs, and serodiscordant couples.

PrEP strategies

Viet Nam's National Strategy to End AIDS by 2030 prioritizes PrEP programming by expanding service delivery through a mix of public, private, and community-led clinics, leveraging both conventional and digital/TelePrEP models to reach key populations, and developing national policies and guidelines to support rapid scale-up and widespread access to PrEP services. The Decision No. 5154/QĐ-BYT was a key factor guiding the rapid scale up and widespread access to PrEP, which had very ambitious and clear annual targets for 5 years, by key populations and by province.

HIV testing is a prerequisite for determining an individual's eligibility to use PrEP services. The Ministry of Health has a clear strategy to diversify and scale up testing to ensure that people at high risk of HIV can access PrEP. The country has made significant strides in PrEP scale-up through innovative service delivery models. The current PrEP service delivery models include fixed-site models located at medical examination and treatment facilities as well as hybrid models that combine fixed and outreach (mobile) service delivery. A remote (tele-PrEP) model has also been piloted; however, it has not yet been scaled up due to the absence of full compliance with the legal and technical requirements for telemedicine services. According to the Government's Decree No. 63/2021/NĐ-CP, PrEP service providers must be licensed medical examination and treatment facilities, not pharmacies.

Enabling factors

Strong political commitment: Since the introduction of PrEP in Viet Nam in 2018, the Government of Viet Nam has demonstrated a strong political commitment by clearly defining coverage targets for the PrEP program through 2025 and 2030 in the National Strategy to End the AIDS Epidemic by 2030.

This commitment has been further institutionalized as part of the National Target Program on Health Care, Population and Development for the period 2026–2035, under which certain PrEP-related services—including testing and referral costs—are financed by the state budget. In addition, efforts are ongoing to advocate for PrEP drugs to be covered by the Social Health Insurance Fund and the Disease Prevention Fund. Furthermore, PrEP services have now been integrated into the service package of commune health stations.

Differentiated Service Delivery (DSD): Key populations were engaged at the outset in creating the service delivery model and demand creation activities. Private service providers play a critical role, using the key population led health services (KPLHS) model to make PrEP accessible to thousands of key populations, primarily men who have sex with men and female sex workers. Public services, mostly located in government-run healthcare facilities, contribute almost 60% of total PrEP clients.

Innovative service delivery models: The current PrEP service delivery models in Viet Nam include fixed-site models located at medical examination and treatment facilities, as well as hybrid models that combine fixed and outreach (mobile) service delivery. Viet Nam has also piloted a remote (tele-PrEP) model; however, it has not yet been scaled up due to the absence of full compliance with the legal and technical requirements for telemedicine services.

Private sector engagement. Viet Nam has strategically leveraged the private sector through a "total market approach" to move away from donor dependence and build a sustainable national HIV response. The involvement of private pharmacies and clinics has contributed to increased PrEP coverage. One of the most significant success stories in Viet Nam's private sector engagement is the transformation of community-based organizations into professional, private "social enterprise" clinics owned and led by key populations (members of the LGBTQI+ community). Clinics such as Glink, Galant, and My Home in major cities like Hanoi and Ho Chi Minh City have become the preferred providers for many clients. These private clinics offer a stigma-free, friendly and flexible environment. They operate as "one-stop shops," integrating PrEP consultation and dispensing with HIV testing, STI screening and treatment, mental health counseling, and gender-affirming care. As part of diversifying service delivery channels, Viet Nam is also integrating private pharmacies into the PrEP ecosystem to increase convenience. These have resulted in a highly effective public-private partnership model where private entities play an outsized role in expanding PrEP coverage.

Demand Creation: Viet Nam has actively employed client-centered approaches to increase demand and awareness for PrEP, utilizing targeted media campaigns, social media, and dating apps. Communications play an important role in generating demand. Key populations were engaged from the outset in designing the service delivery model and demand creation activities. Viet Nam has successfully used implementation science to advance demand generation for PrEP, with assessments on acceptability, accessibility, and affordability providing evidence to strengthen messaging.

Barriers

Critical funding disruption: 70% of PrEP support previously came from PEPFAR before a stop-work order, creating a massive coverage gap. The remaining 30% comes from Global Fund and national program sources. The freeze on PEPFAR funding has significantly impacted the expansion of PrEP coverage, leading to disruptions in access and reduced capacity for HIV prevention services. This has caused multiple CBOs to stop providing PrEP services due to a lack of free medication and service support funding.

Low levels of PrEP knowledge: Many individuals are unaware of PrEP as an HIV prevention method. Low knowledge of PrEP among key populations has been observed. Studies among key populations including men who have sex with men in Ho Chi Minh City found that only 24.7% had heard of PrEP. Although this number is higher in some studies, it still highlights a major information gap.

Poor perception of risk: Poor perception of HIV risk in Viet Nam is largely due to stigma, misinformation and a lack of targeted public health messaging, which makes many people, particularly those in key populations, underestimate their personal risk.

Costs: Affordability is a barrier particularly for those with lower socio-economic status. HIV prevention services, including PrEP, are not yet financed by the National Health Insurance (NHI) and other government funds. This can be a significant barrier for those who cannot afford the cost of the medication and associated medical care.

Stigma and discrimination: There is a fear of being stigmatized as a person engaging in high-risk sexual behaviors by partners, family or friends. For example, behaviors that increase the risk of HIV, such as sex work, injecting drug use and same-sex relationships, have historically been labelled by the government and society as "social evils." Because PrEP is a tool for HIV prevention, taking it can be seen as a tacit admission of engaging in these stigmatized behaviors. An individual may fear that by taking PrEP, they are effectively "outing" themselves as engaging in activities that their family and community view as shameful or criminal. The result is that many remain vulnerable to HIV infection rather than risk the consequences of disclosure.

References

[1] UNAIDS. *The urgency of now: AIDS at a crossroads. Regional Profile. Asia and the Pacific*. 2025. Geneva: UNAIDS.
[2] UNAIDS. *Regional Profile. Asia and the Pacific*. 2024. Geneva: UNAIDS.
[3] UNAIDS. *The urgency of now: AIDS at a crossroads. Regional Profile. Asia and the Pacific*. 2025. Geneva: UNAIDS.
[4] UNAIDS. *The urgency of now: AIDS at a crossroads. What the data tells us. Projections for the HIV epidemic in Asia and the Pacific in 2030*. 2025. Geneva: UNAIDS.
[5] UNAIDS. *Regional Profile. Asia and the Pacific*. 2024. Geneva: UNAIDS.
[6] UNAIDS. *Regional Profile. Asia and the Pacific*. 2024. Geneva: UNAIDS.
[7] UNAIDS. *Regional Profile. Asia and the Pacific*. 2025. Geneva: UNAIDS.
[8] Injectable PrEP - APCOM. 2021. Available from: https://www.apcom.org/wp-content/uploads/2021/12/Factsheets-APCOM_UNAIDS-PreP_v3.pdf
[9] World Health Organization; 2020 May 20. Available from : https://www.who.int/news/item/20-05-2020-exciting-new-results-from-long-acting-prep-study-show-it-to-be-effective-in-preventing-hiv-acquisition-in-msm-and-transgender-women
[10] CATIE; 2022. Safety and effectiveness of long-acting cabotegravir for prevention in men and transgender women. Available from : https://www.catie.ca/treatmentupdate-250/safety-and-effectiveness-of-long-acting-cabotegravir-for-prevention-in-men-and
[11] World Health Organization. Guidelines on long-acting injectable cabotegravir for HIV prevention [Internet]. Geneva: World Health Organization; 2022. Available from: https://iris.who.int/bitstream/handle/10665/361817/9789240054325-eng.pdf.
[12] World Health Organization. Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis [Internet]. Geneva: World Health Organization; 2025. Available from: https://www.who.int/publications/i/item/9789240111608.
[13] Centers for Disease Control and Prevention. Preexposure Prophylaxis (PrEP). Atlanta: CDC; 22. Available from: https://www.cdc.gov/hiv/basics/prep/index.html. (Supports the availability of daily pills, on-demand pills and long-acting injectables).
[14] UNAIDS. Global AIDS Strategy 2021–2026: End Inequalities. End AIDS. Geneva: UNAIDS; 2021. Available from: https://www.unaids.org/sites/default/files/media_asset/global-AIDS-strategy-2021-2026_en.pdf. (Supports the principle of providing choice and combination prevention for diverse key populations).
[15] *From Clinical Trial to Public Health Impact: A plan for Accelerating Access to Injectable Lenacapavir for PrEP*. October 2024. AVAC.
[16] Carlisle S, Ayling K, Jia R, Buchanan H, Vedhara K. The effect of choiceinterventions on retention-related, behavioural and mood outcomes: a systematic review with meta-analysis. Health Psychol Rev. 2022;16(2):220–56.
[17] Naidoo NP et al. Journal of the International AIDS Society 2025, 28(S2):e26512http://onlinelibrary.wiley.com/doi/10.1002/jia2.26512/full | https://doi.org/10.1002/jia2.26512
[18] Cáceres CF, Borquez A, Klausner JD, Baggaley R, Beyrer C. Implementation of pre-exposure prophylaxis for human immunodeficiency virus infection: progress and emerging issues in research and policy. J Int AIDS Soc. 2016;19(Suppl7)(6):21108; Calabrese SK. Understanding, contextualizing and addressing PrEP stigma to enhance PrEP implementation. Curr HIV/AIDS Rep.

2020;17(6):579–88. Haberer JE, Mujugira A, Mayer KH. The future of HIV pre-exposure pro-phylaxis adherence: reducing barriers and increasing opportunities. Lancet HIV. 2023;10(6):e404–11.
[19] The Global Fund. 2025. Mapping country-level activities for PrEP product introduction and scale. Adapated from MOSAIC Situation Analysis 2022
[20] Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis (PrEP). Geneva: World Health Organization; 2025.
[21] IAS 2025. PrEP: WHO Guidelines on lencapavir.
[22] World Health Organization. Guidelines on long-acting injectable cabotegravirfor HIV prevention. Geneva: World Health Organization; 2022.
[23] IAS. 2025. First experiences of long-acting cabotegravir in Zambia
[24] Clinton Health Access Iniatitve (CHAI). 2023. *Cost of Goods Sold (COGS) Analysis. Generic Long Acting Injectable Cabotegravir (CAB-LA)*.
[25] World Health Organization. Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization; 2015.
[26] World Health Organization. What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men. World Health Organization; 2019
[27] UNAIDS. 2025. *The Prices of Antiretroviral Medicines to Treat and Prevent HIV in Asia and the Pacfic*. *A Scoping Study*. *Draft Report*. Bangkok: UNAIDS.
[28] IAS. 2025. MK-8527 once monthly oral PrEP
[29] AVAC. *Getting PrEP Rollout Right this Time*. *Lessons from the field*. 2025.
[30] Guimarães, N.S., Magno, L., Monteiro, G.M.B. *et al. Demand creation and retention strategies for oral pre-exposure prophylaxis for HIV prevention among men who have sex with men and transgender women: a systematic review and meta-analysis*. BMC Infect Dis 23, 793 (2023). https://doi.org/10.1186/s12879-023-08693-z
[31] To KW, Lee SS. *HIV pre-exposure prophylaxis in South East Asia: A focused review on present situation*. Int J Infect Dis. 2018 Dec;77:113-117. doi: 10.1016/j.ijid.2018.10.027. Epub 2018 Nov 3. PMID: 30395980.
[32] McCoy K, Mantell JE, Deiss R, Liu A, Bauman LJ, Bonner CP, Vinson J, Buchbinder S. Pre-Exposure Prophylaxis Awareness and Demand Creation: Overlooked Populations and Opportunities to Move Forward. J Acquir Immune Defic Syndr. 2025 Apr 15;98(5S):e170-e180. doi: 10.1097/QAI.0000000000003626. PMID:
[33] WHO and AVAC, 2024. HIV Self-Testing and PrEP: Opportunities for Scale Up. A guide for Implementers and Ministries of Health.
[34] Consolidated guidelines on differentiated HIV testing services. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.
[35] *Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact*. Geneva: World Health Organization; 2022.
[36] Oliveri, C. *et al.* (2024) 'High PrEP acceptability and need for tailored implementation in Cambodian key populations: results from a qualitative assessment', *AIDS Care*, 36(sup1), pp. 109–116. doi: 10.1080/09540121.2024.2308029.
[37] Cabotegravir + Rilpivirine Long-Acting: Overview of Injection Guidance, Injection Site Reactions and Best Practices for Intramuscular Injection Administration | Open Forum Infectious Diseases | Oxford Academic [Internet]. 2024. Available from: https://academic.oup.com/ofid/article/11/6/ofae282/7681611
[38] The Global Fund. 2022. *Technical Brief: Community Systems Strengthening*. Allocation Period 2022-2023. Geneva: The Global Fund.

[39] Barriers to Uptake of Long-Acting Antiretroviral Products for Treatment and Prevention of HIV in Low- and Middle-Income Countries (LMICs) - Oxford Academic [Internet]. 2022. Available from : https://academic.oup.com/cid/article/75/Supplement_4/S549/6835713

[40] Malaysia National Strategic Plan for Ending AIDS (NSPEA) 2016–2030 (or the subsequent Action Plans 2021-2025).

[41] UNAIDS Country Factsheets/Reports for Malaysia (specifically those detailing HIV prevention targets and key population size estimates).

[42] ThinkPlace. 2024. Acceptability and Feasibility Study for the Dapivirine Vaginal Ring in Papua New Guineas. A qualitative study on the Dapivirine Vaginal Ring for use amongst Cisgender Women at Substantial HIV risk in Papua New Guinea.

[43] Centers for Disease Control and Prevention (CDC). CDC in Thailand: August 2021. Atlanta: Centers for Disease Control and Prevention; 2021. Available from: https://stacks.cdc.gov/view/cdc/111937.

[44] Thai Ministry of Public Health. Thailand's National Guidelines on HIV/AIDS Treatment & Prevention, 2021–2022. Bangkok: Thai Ministry of Public Health; 2024 Feb 26.

[45] Aidsmap. Thailand has exceeded its target for people accessing PrEP, but is lagging on HIV diagnosis. London: Aidsmap; 2022 Dec 19. Available from: https://www.aidsmap.com/news/dec-2022/thailand-has-exceeded-its-target-people-accessing-prep-lagging-hiv-diagnosis. *(**Note:** This news report, while not a primary academic source, is frequently the first public citation for the **82% KPLHS utilization figure** and other program updates reported at international conferences around that time.)*

[46] Frontiers. Chautrakarn S, Rayanakorn A, Intawong K, Chariyalertsak C, Khemngern P, Stonington S, et al. PrEP stigma among current and non-current PrEP users in Thailand: A comparison between hospital and key population-led health service settings. Front Public Health. 2022 Oct 25;10:1019553.

[47] Versteegh L, Amatavete S, Chinbunchorn T, Thammasiha N, Mukherjee S, Popping S, et al. The epidemiological impact and cost-effectiveness of key population-led PrEP delivery to prevent HIV among men who have sex with men in Thailand: a modelling study. Lancet Reg Health Southeast Asia. 2022;7:100097.

[48] Mayer KH, Anekthananon T, Anekthananon T, Bhakeecheep S, Balthazar K, Chokphaibulkit K, et al. High PrEP Uptake, Adherence, Persistence, and Effectiveness Outcomes among Young Thai Men and Transgender Women Who Sell Sex in Bangkok and Pattaya, Thailand: Findings from the Open-Label Combination HIV Prevention Effectiveness (COPE) Study. J Acquir Immune Defic Syndr. 2023 Feb 1;92(2):167–75.