



Country policy  
development brief

July 2022

## Differentiated pre-exposure prophylaxis (PrEP) service delivery

Key considerations in developing policy guidance for differentiated PrEP service delivery

This brief is intended to support countries to develop and include differentiated PrEP service delivery in their national HIV operational guidance.

The brief provides:

- An introduction to differentiated PrEP service delivery
- Key policies for differentiated PrEP service delivery guidance
- A draft of the policy, for each key area, for consideration and country adaptation. Examples are based on a high HIV-burden setting.

### Introduction

#### What is differentiated service delivery?

Differentiated service delivery (DSD) is a client-centred approach that simplifies and adapts HIV services across the cascade in ways that both serve the needs of people living with HIV and reduces unnecessary burdens on the health system.

#### What is differentiated PrEP service delivery?

Differentiated PrEP service delivery is a client-centred approach that simplifies and adapts PrEP service provision in ways that both serve the needs of people and communities at substantial risk of acquiring HIV and reduces unnecessary burdens on the health system.

# Key policy areas for the development of guidance on differentiated PrEP service delivery

There are eight key policy areas to consider when developing differentiated PrEP service delivery operational guidance\*. Each policy area is outlined below, alongside the relevant World Health Organization (WHO) recommendations and guidance, followed by an example policy for consideration and country adaptation.

\* Based on the WHO 2022 [Technical brief: Differentiated and simplified pre-exposure prophylaxis for HIV prevention](#)<sup>1</sup> and [Guidelines on long-acting injectable cabotegravir for HIV prevention](#)<sup>2</sup>, the WHO 2021 [HIV consolidated guidelines](#)<sup>3</sup>, WHO 2017 [Technical brief: Preventing HIV during pregnancy and breastfeeding in the context of preexposure prophylaxis](#)<sup>4</sup>.

## 1. Recognize the importance of implementing differentiated PrEP service delivery

This section sets out the rationale for implementation. Differentiated PrEP service delivery increases person- and community-centredness, thereby increasing access, improving uptake and persistence, supporting effective use and reducing unnecessary burdens on the health system. Differentiated PrEP service delivery aims to:

- a. **Simplify and decentralize** – providing easier to collect, longer PrEP refills at more convenient locations
- b. **De-medicalize and task share** – reducing the clinical package at certain types of visits, enabling lay cadres to manage such visits and increasing utilization of virtual platforms
- c. **Integrate services** – screening for and managing common conditions within PrEP services and integrating PrEP services into other clinical and non-clinical services

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## 2. Define the criteria for PrEP access

This section sets out the country's suitability criteria for PrEP access.

Criteria could include:

- a. Definition of risk or substantial risk (individual/community)
- b. Target populations – specific populations and/or ages
- c. Clinical requirements (for example: HIV negative with no symptoms of acute HIV infection or specific to the PrEP product)



**Since 2015, the WHO recommends** that "oral pre-exposure prophylaxis (PrEP) containing tenofovir (TDF) should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (strong recommendation, high certainty evidence)"<sup>3,5</sup>. WHO also supports PrEP for pregnant and breastfeeding women<sup>4</sup>.

On "substantial risk of HIV acquisition", WHO says: "HIV acquisition risk varies considerably within populations and geographical locations. Population-level HIV incidence is an important determinant of individual-level risk of HIV acquisition. However, when considering who could benefit from PrEP, it is important to consider the characteristics and behaviours of individuals and their partners that could lead to HIV exposure. Even in locations with a low overall HIV incidence, there may be individuals at substantial risk who could benefit from PrEP services. Individuals requesting PrEP should be given priority to be offered PrEP since requesting PrEP indicates that there is likely to be a risk of acquiring HIV."<sup>2</sup>

PrEP country targets and focus populations (the estimated number of people who are intended to benefit from PrEP, their population group/s and their geographical location and concentration) have an impact on both the appropriate differentiated HIV testing and linkage service delivery models and the appropriate differentiated PrEP service delivery models.

For example, if a country's PrEP provision is focused on key populations (defined as gay men and other men who have sex with men, sex workers and their clients, trans people, people who inject drugs and people in prisons and other closed settings), differentiated PrEP service delivery could be prioritized in key population-focused models.

[Click to view Example policy 2](#)

### 3. Define and describe the approved PrEP methods for differentiated PrEP service delivery

This section outlines PrEP methods covered within country differentiated PrEP service delivery guidance.

It draws attention to potential constraints or limitations of different PrEP methods on the "building blocks" of differentiated PrEP service delivery including storage and administration requirements. The "building blocks" are:

- WHEN (service frequency)
- WHERE (service location)
- WHO (service provider)
- WHAT (package of services)

**All PrEP methods approved in a country should be considered when adapting or building differentiated PrEP service delivery models.**

With an increasing number of PrEP methods available to support different needs and

population groups, it is important to specify the method/s covered by each differentiated PrEP service delivery model and consider the impact of the method on the service component building blocks.

For example, frequency of visits (the WHEN building block) should be considered beyond daily oral PrEP, which can be supplied for multiple months at a time. Oral event-driven PrEP could also be supplied to cover a number of expected, but infrequent, events over a longer period. Dapivirine vaginal rings are inserted by the person using PrEP, allowing for the dispensing of more than one ring at a time. In contrast, long-acting injectable cabotegravir has to be injected every second month by an authorised provider, limiting the ability to further space service frequency.



**The WHO recommends** three methods of PrEP: oral PrEP containing TDF; the dapivirine vaginal ring for cis-gender women; and long-acting injectable cabotegravir as additional prevention choices for people at substantial risk of HIV infection. Oral PrEP can be used either daily or as event-driven PrEP by people assigned as male at birth who are not using oestradiol-based exogenous hormones.

2015: "Oral pre-exposure prophylaxis (PrEP) containing TDF should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches (strong recommendation, high-certainty evidence)."<sup>3</sup>

2021: "The dapivirine vaginal ring may be offered as an additional prevention choice for women<sup>i</sup> at substantial risk of HIV infection as part of combination prevention approaches (conditional recommendation, moderate-certainty evidence)."<sup>3</sup>

2022: "Long acting injectable cabotegravir may be offered as an additional prevention choice for people at substantial risk of HIV infection<sup>1</sup>, as part of combination prevention approaches (conditional recommendation; moderate-certainty evidence)."<sup>2</sup>

[Click to view Example policy 3](#)

<sup>i</sup> "For the recommendation on the dapivirine vaginal ring, the term women applies to cisgender women, meaning women assigned female at birth. There is no research at this time to support the dapivirine vaginal ring for other populations."<sup>3</sup>

## 4. Consider and define the duration of intended PrEP use to assess suitability for differentiated PrEP service delivery models

This section defines:

- a. Short-term PrEP use
- b. Moderate-term PrEP use
- c. Prolonged PrEP use (only appropriate if a country plans to support a differentiated PrEP service delivery model that specifically provides for prolonged use)

PrEP should be used effectively during periods of substantial HIV risk. Periods of substantial risk differ for each individual PrEP user, from a single episode to a short or moderate length period of potential exposure to HIV or a prolonged

period extending for the foreseeable future. Differentiated PrEP service delivery considers an individual's intended duration of PrEP use when adapting and building differentiated PrEP service delivery models (accepting that the initial intention could change).

For example, when an individual intends to use PrEP for a short duration or remains uncertain of their period of risk and requires regular follow-up for discontinuation assessment, a differentiated PrEP service delivery model built to support on-going daily oral use (multi-month PrEP refills or home delivery) may not be appropriate.



**The WHO 2021 guidance recognizes** that "PrEP should be used effectively – during periods of substantial HIV risk – but is unlikely to be for life. PrEP can be discontinued if a person taking PrEP is no longer at risk. It is not unusual for people to start and stop PrEP repeatedly depending on periods of higher and lower HIV risk".<sup>3</sup>

[Click to view Example policy 4](#)



## 5. Define the suitability assessments for differentiated PrEP delivery models during the PrEP continuation phase

People intending to use PrEP for more than a short duration should be considered for less intensive differentiated PrEP service delivery models during the continuation phase (beyond the initial phase). Differentiated PrEP service delivery models can support effective PrEP use for the longer term (beyond the first few months). Such models consider separate building blocks for PrEP refill-only collection (or injection administration), clinical consultations and, where appropriate, psychosocial support. This separation enables PrEP refill collection (and psychosocial support) closer to home or school or work and limits unnecessary clinical consultations.

People using PrEP should be assessed for suitability for a less intensive differentiated PrEP service delivery model as soon as it is feasible. For example, this should happen at the first in-person follow-up visit following PrEP initiation. Timely referral to an appropriate differentiated PrEP service delivery model reduces the burden on the client and provider while maintaining and supporting quality of care.

Suitability for less intensive differentiated PrEP service delivery for the continuation phase should consider:

- a. **Intended duration of PrEP use**  
An example is use for longer than three months.
- b. **PrEP method**  
Some differentiated PrEP service delivery models may only be feasible for oral PrEP.
- c. **Concurrent risks or health conditions that may require more frequent clinical care**  
Identify any clinical indicators that require more regular clinical follow-up (such as frequent STIs) and clearly specify any clinical indicators that are NOT a contra-indication to eligibility (such as specified co-morbidity, pregnancy or breastfeeding)
- d. **Any additional adherence-related considerations**  
An example is having no psychosocial concerns that may impact use effectiveness.

Countries may consider further reductions in service intensity (for example, six-monthly dispensing with six-monthly or annual clinical consultations) for specific populations using PrEP

for prolonged durations, such as people in long-term sero-different partnerships. In this case, further suitability assessment considerations can also be defined.

[Click to view Example policy 5](#)

## 6. Define the building blocks that can be utilized for building differentiated PrEP service delivery models for i) PrEP assessment; ii) PrEP initiation (and re-initiation); iii) early follow-up; and iv) PrEP continuation with PrEP refills and clinical consultations.

The following are provided to support this process: (a) a template for differentiated PrEP service delivery; and (b) an explanation of each building block within the template.

**Table 1: Building blocks for differentiated PrEP service delivery**

	PrEP assessment, initiation (re-initiation) and early follow-up (0-3 months)			PrEP continuation (>3 months)	
	Assessment (after negative HIV test result)	PrEP initiation/re-initiation*	Initial clinical follow-up	PrEP refill (or injection) only	Clinical consultation
WHEN Service frequency	Timing of PrEP assessment and offer	Timing of PrEP initiation or re-initiation*	Frequency of initial follow-up	Frequency of PrEP refill collection/injection administration visits (length of PrEP product supply)	Frequency of maintenance clinical consultations
WHERE Service location	Locations for PrEP assessment and offer	Locations for PrEP initiation or re-initiation*	Locations for initial follow-up visit/s (including virtual)	Locations where PrEP refills can be collected/injections administered (no clinical consultation required)	Locations where maintenance clinical consultations can be provided
WHO Service provider	Service provider/s who can assess for and offer PrEP	Service provider/s authorized to initiate or re-initiate* PrEP	Service providers who can carry out initial follow-up visit/s	Service provider/s who can distribute PrEP refills/administer injection (considering HIV testing requirements and method)	Service provider/s who may conduct PrEP maintenance clinical consultations
WHAT Service package**	Service package for PrEP assessment and offer	Service package for PrEP initiation or re-initiation*	Service package at initial follow-up visit/s	Service package at PrEP refill collection/ injection administration visit/s	Maintenance clinical consultation service package

\* Re-initiation visit can further simplify the service package as it is not necessary to repeat all services and some services could be abbreviated (for example, counselling).

\*\* HIV testing may or may not form part of each component's service package. If HIV testing is required, the type of HIV testing (HIV self-testing, rapid testing or laboratory required testing) and its impact on the WHERE and the WHO building blocks should be considered.

**Under PrEP continuation phase:** A separate psychosocial support component (column) can be added, defining the building blocks for additional psychosocial support (beyond counselling already reflected in the service delivery package for refill-only and clinical consultation visits). However, as this is not required for all PrEP clients, this is not routinely reflected.

[Click to view Example policy 6](#)

## 7. Define differentiated PrEP service delivery models, including by method

This section defines the differentiated PrEP service delivery models for different PrEP methods and to support specific target populations. It also considers both facility-based and community-based models of PrEP delivery.

Defining specific differentiated PrEP delivery models provides guidance, but does not limit service providers from adapting or building new models using the building blocks defined above.

[Click to view Example policy 7A \(by model\)](#)

[Click to view Example policy 7B \(by PrEP method\)](#)

## 8. Define how to support the transition to differentiated HIV treatment services

This section provides guidance on enablers and facilitators to support the transition to HIV treatment services.

People using PrEP are eligible for PrEP due to a substantial risk of HIV acquisition. Regular and frequent HIV testing helps ensure timely identification and/or diagnosis of HIV and supports the transition to HIV treatment services. To ensure the effective transition to and rapid initiation of HIV treatment, the building blocks for linkage to treatment should be defined.

[Click to view Example policy 8](#)

## References

- 1 WHO. [Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical Brief, 2022](#)
- 2 WHO. [Guidelines on long-acting injectable cabotegravir for HIV prevention](#), 2022.
- 3 WHO. [Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach](#), 2021.
- 4 WHO. [Technical brief: Preventing HIV during pregnancy and breastfeeding in the context of preexposure prophylaxis \(PrEP\)](#), 2017.
- 5 WHO. [Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach, 2nd ed.](#), 2016.

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Download a word version of an example differentiated PrEP service delivery policy at <https://bit.ly/DSDpreppolicy>