

Tool kit for the establishment of PrEP services in the Caribbean

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Introduction

In 2015 WHO recommended Pre-Exposure Prophylaxis (PrEP), a new and empowering prevention option for people at substantial risk of acquiring HIV, by prescribing ARVs to HIV negative persons, to protect against HIV infection. In general PrEP can protect an HIV negative partner in a serodiscordant relationship when the HIV partner is either not on ARVs or has not reached viral suppression. The World Health Organisation recommends PrEP to persons who had:

1. Vaginal or anal sexual intercourse without a condom with more than one partner, or
2. A sexually transmitted infection (STI) by laboratory testing or self-report or syndromic STI treatment, or
3. Used post exposure prophylaxis (nPeP) for sexual exposure in the past six months

Substantial risk of HIV infection includes someone in a high HIV prevalence population or geographical location who has had any of the following risk factors in the past

There are two types of options for PrEP which includes, daily PreP and Event Driven or PrEP on demand. The use of PrEP as part of combination HIV prevention approaches will support the reduction of HIV infections. PrEP is not taken for life, but if taken as prescribed, it can eliminate the risk of getting HIV infection. Persons taking PrEP are expected to continue to use a condom as it will not protect against other Sexually Transmitted infections (STIs) such as hepatitis C. As a result, condoms are still the best protection from STIs.

Among the biomedical interventions, PrEP is one that requires high adherence in order to be effective, needs on-going monitoring for safety through laboratory tests and repeated HIV testing and its more costly than options such as condoms¹.

In 2021 countries in the Caribbean region commenced implementing PEP services with support from the regional multi-country Global Fund Grants as well as through national grants. With the advances of the service in the region, this tool kit was developed by PAHO in collaboration with PANCAP, to support the standardization of services in the Caribbean region, aligned to WHO recommendations. It is anticipated that countries in the region will utilize the tool kit to support the implementation, scale-up and strengthening of PrEP services in the region.

Establishing PrEP Services at country level

When a country decides to include PrEP in its national HIV programme, a range of implementation issues have to be considered, such as cost-effectiveness, safety, and epidemiological impact. The WHO developed several training modules and technical guidance for different audiences. It includes a strategic planning module for public health officials and policymakers responsible for deciding to whom to offer PrEP for HIV prevention as a priority, where PrEP services could be provided, and how PrEP could be integrated into other health services (1). In this module, strategic decision-making practices are described on how to identify people at substantial risk of HIV who could benefit from being offered PrEP.

There are a number of important considerations for countries when making a decision to include PrEP as part of the national HIV response. Issues such as cost-effectiveness, safety and

¹ Model 5

epidemiological impact are important aspects that must be considered before setting up the service. The strategic planning process will need to maximize impact with available resources and based on the realities of the country. Information as to where PrEP services could be provided and how it can be integrated into other services, based on the health infrastructure are important issues for consideration. Prioritizing who should receive PrEP at the national level should take into consideration the epidemiological profile, geographical areas, population groups as well as individuals with HIV sexual and drug risk behaviours.

In order to support the planning process at the national level, PAHO has developed a [tool to estimate oral PrEP needs and implementation costs](#). The tool estimates the number of persons from the key populations that are projected to access PrEP services as well as the cost of implementing the high impact HIV prevention services. This tool makes it possible to estimate the total need for PrEP in a given geographical area or service and the cost of providing it in subsequent years to key population groups. The tool includes by default: i) gay men and other men who have sex with men (MSM); (ii) female sex workers (FSW); and (iii) transgender women (TGW). However, countries may decide to include other relevant populations in the analysis (e.g., indigenous populations or people in prisons and other closed settings). There are other key parameters and variables that are required to input into the tool for good estimation of the population in need of PrEP and the cost for PrEP delivery. The accuracy of the estimates provided by this tool will depend on the quality of the data entered. If some of the data required by the tool for the geographical area to be analyzed is unavailable, the information can be completed using, for example, proxy values from other geographical areas or available studies. Similarly, if behavioural data such as condomless act, PrEP acceptability and others that should be drawn from special studies is unavailable, then countries may choose to use, with critical assumptions, nation programme, regional or global data. Costing information has to also be considered including the prices for ARVs, testing, clinical consultations and counselling.

The steps for establishing a PrEP programme, include:

1. Determine the population who will require PrEP.
2. Determine where PrEP should be offered
3. Determine how to initiate PrEP services
4. Commence PrEP service delivery
5. Monitor and Evaluate PrEP programme.

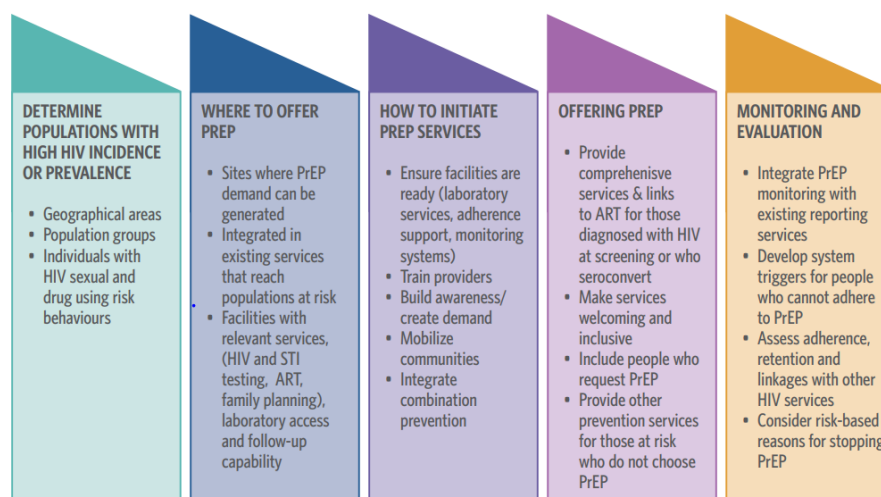


Figure 1: Steps for establishing PrEP services

In addition, WHO has developed a series of modules to support the implementation of PrEP among a wide range of populations in different settings. The following are WHO links with materials to support the detail planning for the implementation of PrEP at the national level.

1. [Clinical Module](#): This module seeks to provide an overview of relevant information for clinicians, including physicians, nurses and clinical officers, who are providing PrEP in clinical settings. It describes important considerations when starting PrEP in an individual and monitoring PrEP use.
2. [Community Educators and Advocates Module](#): For PrEP services to reach populations in an effective and acceptable way, community educators and advocates are needed to increase awareness about PrEP in their communities. This module provides up-to-date information on PrEP that should be considered in community-led activities that aim to increase knowledge about PrEP and generate demand and access.
3. [Counselors Module](#): This module is for staff who counsel people as they consider PrEP or start taking PrEP and support them in addressing issues around coping with side-effects and adherence strategies. Those who counsel PrEP users may be lay, peer or professional counsellors and healthcare workers, including nurses, clinical officers and doctors.
4. [Leaders Module](#): This module aims to inform and update leaders and decision-makers about PrEP. It provides information on the benefits and limitations of PrEP so that they can consider how PrEP could be most effectively implemented in their own settings. It also contains a series of frequently asked questions about PrEP, with related answers.
5. [Monitoring and Evaluation Module](#): This module is for people responsible for monitoring PrEP programmes at the national and site levels. It provides information on how to monitor PrEP for safety and effectiveness, suggesting core and additional indicators for site-level, national and global reporting.

6. [Pharmacist Module](#): This module is for pharmacists and people working in pharmacies under a pharmacist's supervision. It provides information on the medicines used in PrEP, including the optimal storage conditions. It also gives suggestions for how pharmacists and pharmacy staff can monitor PrEP adherence and support PrEP users to take their medication regularly.
7. **Regulatory Officials Module**. This module is for national authorities in-charge of authorizing the manufacturing, importation, marketing and or control of antiretroviral medicines used for HIV prevention. It provides information on the safety and efficacy of PrEP medicines. ***This module is currently under development.***
8. [Site Planning Module](#) : This is for individuals engaged in the planning process, organizing PrEP services at specific sites. It outlines the steps to be taken in planning for the roll out of the service and gives suggestions for personnel, infrastructure and commodities that could benefit from PrEP, and in which settings PrEP services would not be the most-cost-effective.
9. [Strategic Planning Module](#): A public health approach is emphasized in this module to offer PrEP to those that are at substantial risk for HIV. It provides guidance to policy makers on how to prioritize services in order to reach those who could benefit from PrEP and in settings that are most cost-effective.
10. [Testing Providers Module](#): This module is for those who are providing testing services at PrEP sites and laboratories. The module offers guidance in selecting testing services, including screening of individuals before PrEP is initiated and monitored.
11. [PrEP User Module](#): This module provides information for people who are interested in taking PrEP to reduce the risk of acquiring HIV and people who are already on PrEP.
12. [Adolescent and Young People Module](#): This is for persons who are interested in providing PrEP services to older adolescents and young adults who are at substantial risk of HIV. It provides information on factors that influence HIV susceptibility among young people.

Identification of Sites & Site Assessment

Given the context of the Caribbean, the following are some key characteristics for considerations of sites when setting up PrEP services. This may support increased access to service without hesitation by the target population. Some key consideration when identifying sites:

- Type of service- stand alone or integrated?
- Does the site facilitate access by key populations ?
- Does it offer HIV/STI testing (Particularly Syphilis, hepatitis B & C)?

Types of services to be considered within the context of PrEP

PrEP services are implemented within the combination HIV prevention combination approach.

The approach promotes a combination of biomedical, behavioral and structural interventions to meet the HIV prevention needs of specific people and communities with the overall aim which is to reduce the new HIV infection. Therefore, PrEP services should be delivered using a differentiated approach and focused on different interventions to reduce the HIV infection. Key recommended services to be implemented within the context of PrEP are:

- a. Diagnosis and treatment of other STIs such as syphilis, Chlamydia, Gonorrhoea, and hepatitis B & C. The diagnosis and treatment of these STIs can be integrated into a phase approach given the realities and function of the health system.
- b. Provide Post-Exposure Prophylaxis (nPeP) for sexual exposure with condomless intercourse (receptive or insertive, anal or vaginal) which is consensual or not or percutaneous exposure to blood (or body fluids contaminated with bloods).

Guidelines and other materials

PAHO has supported in 2019 the development of a generic PrEP and nPeP guidelines that are aligned to the WHO recommendations. PAHO has also supported the revision and summary of key WHO recommendations for priority STIs (Syphilis, chlamydia, Gonorrhoea, herpes, Trichomonas,) as well as hepatitis B and C.

With the support of the Global Fund multi country grant, several documentations were developed to support countries in setting up PrEP services. These and others listed below are available for adaptations based on the realities of the country and the health system.

- [Counselling checklist](#)
- [PrEP register](#)
- [Procedures when initiating PrEP](#)
- [HIV Testing Algorithm](#)
- [Cascade worksheet](#)
- [List of medications that interact with ARVs for PrEP](#)
- [Record form for PrEP screening](#)
- [Clinic follow up form](#)

In addition to programme and clinical site specific tools, [Social Media Cards](#) and [Brochures](#) are available to adapt and use at the country level. These are aimed at increasing knowledge of and creating demand for PrEP among the key populations.

Monitoring and evaluation of PrEP Services

Routine monitoring of PrEP programmes is essential to assess the quality of the service, uptake, effective use and safety, as well as to forecast demand and to ensure a sufficient, uninterrupted supply of required commodities.

In the Caribbean the experience with PrEP is limited and the monitoring of the services, utilizing a standardized approach and tools developed by PAHO will allow for the availability of data to monitor and evaluate the service in the region. As health services in the region expands PrEP services and integrates HIVST, it is critical for the surveillance, monitoring and reporting systems to be able to capture appropriate information that is useful to support programmatic improvements.

A monitoring and reporting strategy should maximize data quality and minimize the burden on health care workers by collecting and reporting only data and indicators at site (including CSO), sub-national and national levels that are necessary for decision-making at each of those levels. Within the region programme performance may differ and as a result it is useful to develop a monitoring framework that can be used across a range of implementing countries. This will facilitate consistent reporting and comparisons of effectiveness outcomes monitoring across sites, at the national and regional levels.

Monitoring of PrEP can be done within national systems. However, it is critical to ensure that PrEP monitoring should be able to track the services provided to individuals through the cascade from initial screening through regular follow-up as defined in national protocols. Systems to monitor PrEP will need to avoid inadvertent duplicate reporting of indicators at sites, sub-national and national levels. Kindly refer to the [PrEP register](#) and the [Cascade worksheet](#) which track the continuum of service to key populations. PAHO has developed a [monitoring and evaluation tool](#) to assist countries to define and streamline their monitoring evaluation aspects of PrEP programmes.

Capacity Building for PrEP

PAHO and PANCAP has put together a standardize training that will allow for countries to initiate PrEP services. The training package include with materials that can be adapted and utilized by national facilitators in country that are planning on rolling out the services. The training package includes:

- [Generic Caribbean PrEP guidelines](#)
- [Proposed training agenda](#)
- Training Power Point Presentations
 - [Management of STIs and Viral Hepatitis in the context of PrEP](#)
 - [The Future of PrEP Newer PrEP modalities](#)
 - [Monitoring of HIV/STI Prevention Services for Key Populations HIV Prevention Cascade within the PrEP context](#)
 - [Management of PrEP and nPEP](#)

References

1. What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: Update to WHO's recommendation on oral PrEP. Technical brief:
<https://www.who.int/hiv/pub/prep/211/en/>
2. Prevention and control of sexually transmitted infections (STIs) in the era of oral pre-exposure prophylaxis (PrEP) for HIV. Technical brief: <https://www.who.int/hiv/pub/prep/prevention-sti-prep/en/>
3. WHO implementation tool for pre-exposure prophylaxis of HIV infection:
<https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/>
4. Update of recommendations on first- and second-line antiretroviral regimens. Policy brief:
<https://www.who.int/hiv/pub/arv/arv-update-2019-policy/en/>
5. Updated recommendations on first-line and second-line antiretroviral regimens and post-exposure prophylaxis and recommendations on early infant diagnosis of HIV. Interim guidance:
<https://www.who.int/hiv/pub/guidelines/ARV2018update/en/>
6. ¹ The PAHO Monitoring Framework is available at:
https://iris.paho.org/bitstream/handle/10665.2/51682/9789275121061_eng.pdf?sequence=4&isAllowed=y
7. WHO/JHPIEGO e-learning course on the PAHO Virtual Campus: <https://www.campusvirtualesp.org/en/course/oral-pre-exposure-prophylaxis-prep-hiv-infection-elearning-tool-clinicians>
8. ¹ The WHO/JHPIEGO Oral PrEP Tool is available at: <https://www.who.int/hiv/mediacentre/news/oral-prep-app/en/>