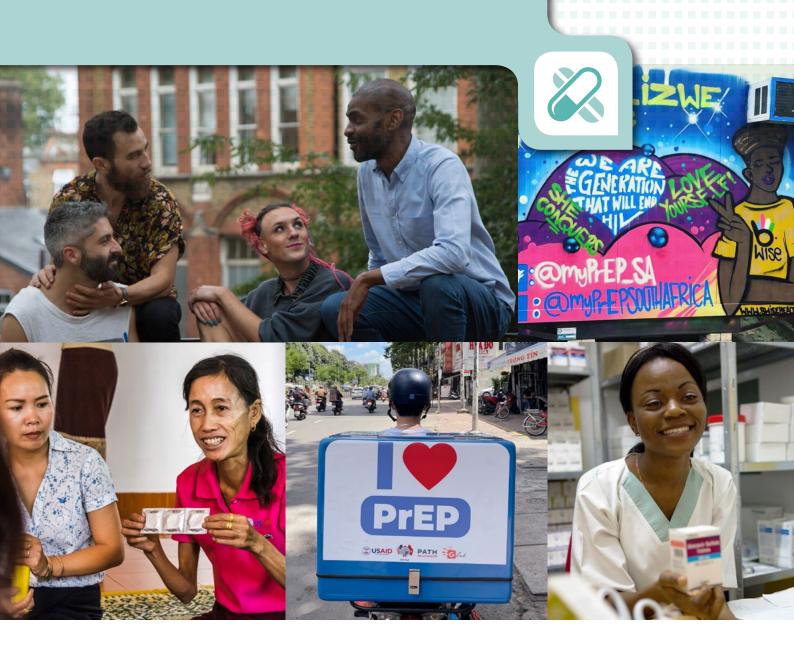
# WHO IMPLEMENTATION TOOL FOR PRE-EXPOSURE PROPHYLAXIS (PrEP) OF HIV INFECTION







WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection. Module 13. Integrating STI services

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# Introduction to the WHO PrEP implementation tool

Following the WHO recommendation in September 2015 that oral pre-exposure prophylaxis (PrEP) should be offered as an additional prevention choice for people at substantial risk of HIV infection<sup>1</sup> or who would benefit from PrEP as part of combination HIV prevention approaches (1), partners in countries expressed the need for practical advice on how to consider the introduction of PrEP for HIV infection and start implementation. In response, WHO has developed this series of modules to support the implementation of PrEP among a range of populations in different settings.

The modules in this tool provide suggestions for the introduction and implementation of PrEP based on the current evidence and experience at the time of publication. The modules will be periodically updated to reflect new evidence and recommendations. Several modules will be updated in 2022 and 2023 to incorporate new guidance on differentiated and simplified PrEP services (2) and WHO recommendations on the dapivirine vaginal ring (DVR) (3) and long-acting injectable cabotegravir (CAB-LA) (4).

PrEP should not replace or compete with other effective and well-established HIV prevention interventions, such as comprehensive condom programming for key populations and harm reduction for people who inject drugs. Many people who would benefit from PrEP belong to key population groups that may face legal, financial and social barriers in accessing health services overall. Efforts should be made to address some of these barriers to ensure access to PrEP. Although the public health approach underpins the WHO guidance on the provision of PrEP, the decision to use PrEP should always be made by the individual, and provision should follow national guidelines.

#### Audience and scope of the tool

The HIV PrEP implementation tool contains modules for a range of stakeholders to support them in the consideration, planning, introduction, implementation and roll-out of PrEP. The modules can be used on their own or in combination. In addition, there is a module for individuals interested in or already taking oral PrEP.

This module does not make any new recommendations. It compiles existing WHO recommendations, systematic scientific literature reviews and other relevant publications to provide suggested implementation approaches. It is the product of collaboration among many experts, community organizations and networks, providers, implementers, researchers and partners from all regions. The sexually transmitted infection (STI) service integration module is aligned with the recommendations of the WHO guidelines found in Annex 1.

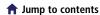
# **Guiding principles**

It is important to adopt an evidence-based public health, human rights, and people- and community-centred approach when offering PrEP. Such an approach is aligned with principles of universal health coverage, gender equality and health-related rights, including accessibility, availability, acceptability and quality of services for people who need PrEP. Placing the people and communities who could benefit from PrEP at the centre allows services to be adapted to their preferences and needs to attain sexual health.

According to WHO's definition (5), sexual health is:

"...a state of physical, emotional, mental and social well-being in relation to sexuality; it is not merely the absence of disease, dysfunction or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected and fulfilled."

<sup>&</sup>lt;sup>1</sup> 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 take into account 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 and other STIs (2).



# The module on PrEP and STI service integration

Many bacteria, viruses and parasites are known to be transmitted through sexual contact. Some have a major impact on sexual, reproductive and neonatal health and can result in severe or lifethreatening complications if not detected and treated in a timely manner (see Box 1).

This module is intended to complement the other modules in the WHO PrEP implementation tool. It focuses on the integration of STI services for people who may benefit from or use PrEP.

This module is divided into two parts: the first focuses on programme managers and other decision-makers, and the second on facility managers and health care workers. People who use PrEP will also benefit from this module.

# Box 1. Examples of infections that can be transmitted through sexual contact and can have serious consequences for sexual health and well-being

- Vertical transmission of syphilis can result in stillbirth, neonatal death, low birth weight, and prematurity and congenital deformities.
- Human papillomavirus (HPV) causes cervical cancer and is associated with anal and throat cancers. Cervical cancer is the fourth most common cancer among women globally.
- HIV continues to be a major global public health issue, having claimed 40.1 million lives so far.
- Gonorrhoea and chlamydia are major causes of pelvic inflammatory disease (PID), ectopic pregnancy and infertility.
- Most genital herpes simplex virus (HSV type 2) infections are asymptomatic, but symptoms include painful blisters or ulcers that can be severe and recurrent throughout people's lives
- Chronic hepatitis B and C can cause cirrhosis and primary liver cancer.

# **Epidemiology of STIs**

In 2020 there were approximately 374 million estimated incident cases of four curable STIs – syphilis, caused by *Treponema pallidum* (6 million cases); gonorrhoea, caused by *Neisseria gonorrhoeae* (87 million cases); *Chlamydia trachomatis* (127 million cases); and *Trichomonas vaginalis* (156 million cases) (6).

Globally, one million new cases of the four curable STIs are estimated to have occurred every day for over a decade, with no clear downward trends (6,7)

Syphilis during pregnancy caused an estimated annual 661 000 cases of congenital syphilis, including over 200 000 fetal and neonatal deaths (2016 estimate) (8). Almost 500 million adults were estimated to be living with genital herpes globally in 2016 (9); and HPV was responsible for an estimated 604 000 cases of cervical cancer and 342 000 deaths related to cervical cancer in 2020 (10).

Nearly 90% of all these cases and deaths are estimated to occur in low- and middle-income countries.

# High burden of STIs and associated factors among people on HIV PrEP

A systematic review of the STI burden among people accessing PrEP, predominantly men who have sex with men, showed that STI prevalence prior to starting PrEP was high (12% for gonorrhoea, 11% for chlamydia, 5% for active syphilis and 24% for any of the three). STI incidence remained high at follow-up visits for PrEP refills (11). For comparison, the estimated global prevalence in 2020 of these STIs among persons assigned male at birth, ages 15–49 years, was 0.7% for gonorrhoea, 2.5% for chlamydia and 0.6% for syphilis (6). For viral hepatitis, a global systematic review showed that among men who have sex with men on PrEP, the incidence rate of hepatitis C infection was 14.8 per 1000 person—years (12).

Similarly, prevalence at baseline and incidence of chlamydia and gonorrhoea were also found to be high among African women (18–25 years old) in three PrEP cohorts in Eastern and Southern Africa, ranging from 4–10% for gonorrhoea and 12–29% for chlamydia. Incidence varied from 11 to 20 cases and 27 to 53 cases per 100 person—years for *N. gonorrhoeae and C. trachomatis*, respectively (13). For comparison, WHO estimated 1.6% gonorrhoea prevalence and three incident cases per 100 person—years among women ages 15–49, and a chlamydia prevalence of 5.5% and five incident cases per 100 person—years in the WHO African Region (6).

The high prevalence and incidence of STIs among people who would benefit from or use PrEP are associated with synergist factors (Box 2).

#### Box 2. Synergistic factors affecting acquisition and transmission of STIs including HIV

**Biological factors:** STIs can cause inflammation and ulcers in the genital, oral and anal areas, as well as physiological and immunological responses, which create physical entry points for infection by other STIs through micro tears in the mucosa. Additionally, they can cause physiological and immunological responses that can increase susceptibility to other STIs (14,15,16).

**Behavioural factors:** Some behaviours have been associated with an increased risk of acquisition of HIV and other STIs: multiple sex partners, receptive anal sex, sexualized drug taking (chemsex), rectal and vaginal douching/cleansing, the use of saliva as a lubricant for anal sex, among others (17,18,19).

**Programmatic factors:** The lack of good-quality, accessible, acceptable and affordable sexual and reproductive health services is a major barrier to care, particularly for those already marginalized from society (20). This barrier is aggravated by discriminatory attitudes and behaviours of health care workers (21).

**Environmental factors:** Environmental factors such as criminalization, violence, stigma and discrimination, poverty, limited education, housing, forced immigration and internal displacement, and financial hardship also result in barriers for health-seeking behaviour and access to health care (22,23,24,25). As is well known for HIV, people who acquire other STIs also suffer stigma and discrimination, including internalized stigma, which affects the uptake of services, delaying treatment and increasing the risk of transmission (26,27).

**Background prevalence**: HIV and other STIs do not affect populations and geographic regions evenly. A higher prevalence of an STI in a region or specific population will lead to a higher risk of acquisition, all other factors being equal, than if the STI has a lower prevalence.

# Why integrate STI services?

Offering STI services to PrEP clients creates an important opportunity for people to benefit from such services who otherwise may not access STI testing and treatment, particularly those at high risk of infection and are asymptomatic (28,29). Integrating STIs services into PrEP services, as well as offering PrEP to people seeking STI and related services, fosters synergies and efficiencies in the public health response to HIV and STIs. Of equal importance, it also promotes a people-centred approach (30)<sup>1</sup> to improve sexual health and quality of care, and it creates opportunities to build the capacity of health care workers to address PrEP and STIs.

<sup>&</sup>lt;sup>1</sup> WHO defines people-centred care as follows: "All people should have access to health services that are equitable, safe, effective, efficient, timely and of acceptable quality, and that these services are provided in a way that responds to people's needs throughout their lives" (30).

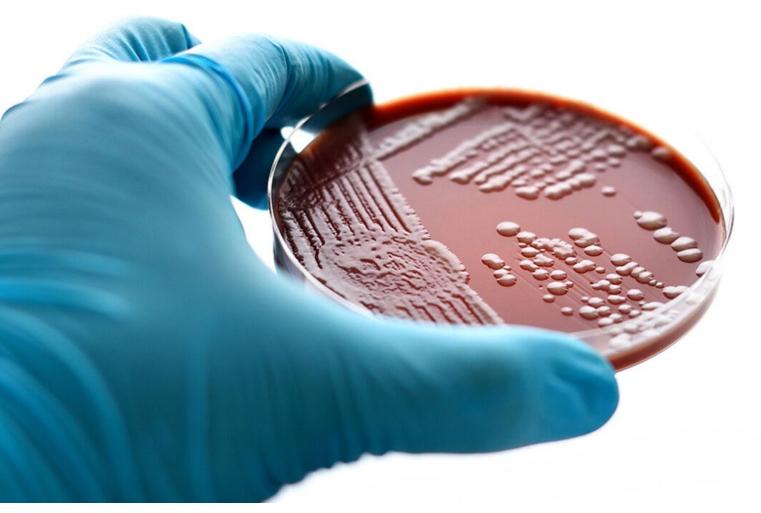


Furthermore, antimicrobial resistance (AMR) of STIs – in particular gonorrhoea and *Mycoplasma genitalium* – has increased rapidly in recent years and, thus, has significantly reduced treatment options. With the emerging resistance to extended-spectrum cephalosporins, a last-line treatment, gonorrhoea may soon become untreatable *(31,32)*. PrEP programmes can play an important role in informing treatment guidelines by systematically providing samples of urethral discharge to reference laboratories to monitor gonococcal AMR.<sup>1</sup>

Additionally, focusing on people at higher risk of STIs and increasing testing and treatment will support reaching the global commitment to end STIs as a public health problem by 2030 (33). Box 3 lists the agreed global impact targets for STIs.

#### Box 3. Selected 2030 impact targets related to STIs in the Global Health Sector Strategies

- Annual new cases of four curable STIs (syphilis, gonorrhoea, chlamydia and trichomoniasis) among adults reduced from 374 million to fewer than 150 million by 2030 (33).
- Annual congenital syphilis cases reduced from 425 to <50 per 100 000 live births by 2030 (33).
- 300 000 HPV-related cervical cancer deaths averted from 2020 to 2030 (34).



Credit: Jarun Ontakrai

<sup>&</sup>lt;sup>1</sup> For step-by-step guidance on performing gonococcal AMR surveillance using sentinel sites, see *Neisseria gonorrhoeae* antimicrobial resistance surveillance: consolidated guidance (2020).

# Part 1. Integration of STI services for programme managers and other decision-makers

# **Planning for integration**

Differentiated service delivery (DSD) is a person-centred approach that simplifies and adapts PrEP and STI services to meet clients' needs and situations (2). DSD can ensure that the health system functions efficiently, enable the health system to focus resources on those most in need and, most importantly, enhance client outcomes.

Considering the WHO DSD framework (35) and its adaptation for the provision of PrEP (2), when planning for the integration of STI services, public health officials need to decide which STI services will be offered, how they will be offered, who will offer them and where they will be offered (Fig. 1).

Fig. 1. Differentiated service delivery framework adapted for the integration of STI services into services for people who use HIV PrEP



Source: WHO, 2021 (35)

#### How to integrate STI services?

A stepwise approach to the integration of STI services with PrEP services should be considered (<u>Fig. 2</u>). This approach should be informed by the local context, including epidemiology, availability of resources and acceptability to users and health care workers. When the information is available, the cost-effectiveness of the different levels of STI services provided should be considered.

Through this stepwise approach, programmes can transition from clinical management of STIs based on signs and symptoms to services based on etiologic management and can focus on enhancing access to STI interventions using various service delivery models.

#### What STI services to integrate?

Although it is not currently feasible to offer STI services to all people on PrEP everywhere, the gradual addition of services using a stepwise approach can encourage and advance integration of STI services. Particular STI services will need to be adapted to PrEP service delivery models (from digital health/virtual interventions (36,37) to facility-based models with laboratory infrastructure) as well as to the local context. See <u>Annex 2</u> for examples of STI services that might be offered with different models of PrEP delivery.

#### Where to integrate STI services?

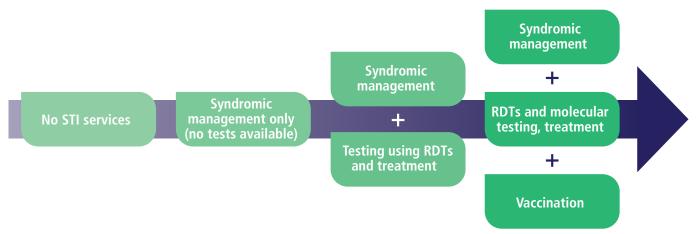
Currently, programmes offer PrEP through a variety of service delivery models. The STI services selected for integration should be feasible for the specific model of PrEP delivery as well as aligned with local resources, laws and regulations.

Annex 2 also provides examples of different combinations of STI services and where and how they can be offered to people who use PrEP.

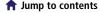
#### Who should offer integrated services?

As a range of health care workers may deliver PrEP, including trained peers and other lay providers, task shifting and task sharing are important to PrEP and STI service integration and scale-up (38). Along with increasing access, they may generate health system efficiencies and support models of service provision that are more acceptable to people on PrEP.

Fig. 2. Simplified programmatic stepwise approach to provide and improve STI services for people who access PrEP for HIV



**RDT Rapid diagnostic test** 



#### CAMBODIA

#### Integrating PrEP and STI services for key populations

Integrated PrEP and STI services were initiated in 2019, when the national HIV PrEP guidelines were developed. Fifteen facilities including family health, nongovernmental organization (NGO) and HIV treatment clinics provide integrated STI, HIV and PrEP services. Most PrEP enrolments occur in Phnom Penh, where nearly 50% of the country's key populations (men who have sex with men, transgender women, female entertainment workers and people who inject drugs) reside.

In Cambodia all people seeking PrEP receive STI services, and all STI clients are offered PrEP. PrEP clients are routinely screened for STI symptoms in line with the PrEP national guidelines, and those presenting with signs and symptoms are promptly treated. PrEP clients are tested with rapid diagnostic tests (RDTs) for syphilis and hepatitis B and C at PrEP enrolment and at refill visits. Syphilis treatment is offered immediately, as is treatment for hepatitis B and C. In case of urethral discharge and where a laboratory is available, Gram stain is used to identify gonococcal infection and guide treatment. Laboratory-based molecular testing for chlamydia and gonorrhoea is available but rarely used due to high cost. Sexual partners of clients diagnosed with HIV or other STIs are encouraged to come for treatment, and HIV self-tests (oral fluid) are offered to those whose partners are unwilling to come to the clinics.

The country recently initiated PrEP delivery by community-based organizations (CBO). CBO services include screening for STI symptoms and rapid testing for HIV, syphilis and hepatitis B and C conducted by trained lay providers. Clients with STI symptoms or positive RDTs are referred for clinical management in one of the facilities. With the approval of an offsite medical provider, eligible clients with no STI complaints and negative test results are initiated on PrEP in the CBO drop-in centre at the same visit.

The Toul Kork Government Health Centre (TKHC) in central Phnom Penh is Cambodia's most popular PrEP site, with the highest retention rate in the country. It has enrolled 1492 clients and retained 1284 (86%) on PrEP since 2020. The TKHC follows government guidelines, puts clients first, and is considered a PrEP government service of excellence. The TKHC offers:

- key population-friendly PrEP and STI services 24/7
- Telegram follow-up for missed appointments
- online counselling for questions and problems
- ensured privacy and confidentiality for clients.

Kret Setha, the TKHC Director, has been an extraordinary leader in providing client-focused PrEP and STI care to key populations in Cambodia.





PrEP and STI services at the Toul Kork Government Health Centre in central Phnom Penh, Cambodia Credit: Phou Maly

Source: Toul Kork Government Health Centre, Cambodia

# **Human resources and capacity building**

The human resources required to offer STI services to people who access PrEP will vary according to the characteristics of existing PrEP delivery models, including but not limited to the different cadres of health care workers, the possibility of task sharing and task shifting (38), engagement of peer and community health care workers, as well as local laws and regulations on the qualifications required to provide

Task sharing and task shifting are critical to facilitate the integration and scale-up of STI services for people who access PrEP.

specific services. It is likely that additional human resources may be needed. As with any health service provision, there will be a need to establish or include STI services in quality control procedures.

Depending on the personnel required to provide services, additional STI capacity building and training (for example, with job aids and tools) may be needed where STI services have not been routinely provided. This training may include:

- provision to clients of correct information on STIs
- diagnostic algorithms for certain STIs (such as syphilis) and interpretation of test results
- syndromic and pathogen-specific case management, 1 including antimicrobial resistance
- provision of virtual interventions/digital health, including case management and supervision (for example, via mobile phone messaging)
- provision of partner services, including expedited partner treatment
- referral for complicated STIs.

Examples of steps to increase capacity for STI services include provision and adaptation of job aids, tools and virtual interventions as well as support and supervision for PrEP providers from STI experts (for example, via mobile phone text message, email, instant messaging, voice mail, video messaging, etc.).

As with the provision of PrEP, a health care worker could mentor and supervise a team of peer and community lay providers.

Trained and supervised lay providers, including peers, may be best suited to provide certain STI services:

- provide information
- prompt for STI signs and symptoms (taking into account that several STIs are asymptomatic)
- · conduct rapid syphilis testing, including dual HIV/syphilis testing
- support self-care interventions, including self-collection of samples for STI testing (39)
- assist with partner services (40) and social network-based referral (41)
- help users navigate the health system when referral and linkage to care are needed
- support treatment adherence.

<sup>&</sup>lt;sup>1</sup> Syndromic case management is clinical decision-making based on a client's symptoms and signs.

#### Costs

Integrating the delivery of PrEP and STI services can increase efficiency in the use of national resources. Furthermore, considering that, historically, HIV programmes are fairly well-funded, offering integrated STI services to people on PrEP creates an opportunity to leverage additional funding and resources for the STI response, which typically is underfunded.

It is critical for PrEP programmes to consider a range of STI-related interventions, including, for example, testing and treatment of syphilis, despite the additional investment that integration often requires, particularly for personnel, training and supplies. Adding the dual HIV/syphilis test, however, can be cost-effective and cost-saving in some settings (42,43,44).

Additional costs to support implementing and scaling up of STI services for people who use PrEP must be budgeted and forecast appropriately, in line with the expected increase in PrEP demand. Costing tools, like that of the Pan American Health Organization/ Regional WHO Office for the Americas (Box 4), can help programme and service managers to make evidence-informed decisions for PrEP implementation and the integration of STI services using a stepwise approach, as illustrated in Fig. 2.

To increase efficiency, the dual HIV/syphilis test may have minimal budgetary impact and would help expand screening for syphilis.

Using costing tools, it is also possible to estimate commodity needs and schedules for equipment maintenance or replacement and to align them with local or national procurement cycles. This approach can support negotiating for extra funding with local authorities or donors.

#### Box 4. Needs estimation and costing tool for implementing PrEP from the Pan American Health Organization

The Pan American Health Organization has commissioned a user-friendly and practical Excel-based <u>tool</u> to help programmes estimate the needs and associated costs of introducing and scaling up PrEP over a five-year time frame (45). The tool also allows programmes to define the PrEP coverage that can be achieved with the available resources and the inclusion of testing and treatment for different STIs.

To generate costing and forecasting estimates, the tool requires:

- national population data (or assumptions, when national data are unavailable), including population size estimates and information about HIV prevalence, HIV infection risk profiles and PrEP acceptability among potential users;
- estimated cost of clinical visits for follow-up, according to available national data;
- estimated cost of medicines and laboratory tests, which are based on prices from procurement mechanisms available in the country and national protocols on required frequency of clinical follow-up of people on PrEP.

#### **BELIZE**

#### Making decisions informed by a costing and needs estimation tool

Belize applied the Pan American Health Organization Needs Estimation and Costing Tool to support decision-making for PrEP implementation and STI service provision. Data for the model were drawn from the 2013 Integrated Biological and Behavioural Surveillance Survey (IBBS), the Tracking Results Continuously (TRaC) survey (46) on condom availability and use among men who have sex with men and female sex workers, and the Belize 2018 Population Size Estimate Study. When national data were unavailable, assumptions were based on regional or international trends.

To estimate the costs of integrating STI services for people on PrEP, two scenarios were developed, and results are presented in Fig. 3:

- Scenario A: quarterly testing for active syphilis, biannual molecular testing for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) infection, treatment and follow-up;
- Scenario B: quarterly testing for active syphilis, treatment and follow-up.

Since this tool was used to inform decision-making on PrEP implementation, the costs of quarterly HIV testing, yearly hepatitis C testing, one-time testing for hepatitis B (as those with a negative result would be vaccinated) and pregnancy testing, when appropriate, where added to both scenarios (base package).

These two scenarios allowed the Belize Ministry of Health to prioritize STI services for people on PrEP according to available resources and plan the inclusion of molecular testing when possible.

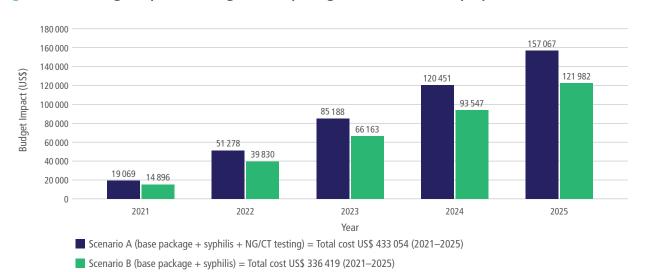


Fig. 3. National budget impact of adding different packages of STI services for people on PrEP

Source: Pan American Health Organization, 2021.

# **Documentation, monitoring and evaluation**

Documentation, monitoring and evaluation of the provision of STI services for people on PrEP are essential to assess service performance and adjust interventions in a timely manner. For countries that do not have a system that can capture STI data, monitoring questions related to STIs can be incorporated into existing PrEP-related reporting systems (for example, sexual history taking) and do not need to be developed independently. This will allow the longitudinal follow-up of users diagnosed with an STI and tracking of regular check-ups.

It is critical to ensure the confidentiality of clients' clinical records in both paper and electronic formats and to inform clients about such procedures.



A suggested set of data elements and indicators to monitor STIs in either aggregate or individual formats (individual is preferable) can be found in <u>Annex 3</u> and in the new <u>WHO Consolidated HIV Strategic Information Guidelines</u> (2022) (47).

#### NAMIBIA

#### Using an online platform to promote testing and manage and monitor services for HIV and other STIs

To help Namibia's Ministry of Health rapidly accelerate the coverage of systematic, data-driven, key population-focused HIV interventions, IntraHealth Namibia (IHN), a local NGO, is leading the KP-STAR Project. The project takes a comprehensive approach to HIV programming, ensuring clients access to a spectrum of sexual health services, including STI testing and treatment. The Walvis Bay Corridor Group and several civil society organizations led by key populations actively lead community engagement and service delivery as part of the project.

The KP-STAR project uses an online reservation app (ORA), marketed as QuickRes,\* which was developed by FHI 360, funded by the United States Agency for International Development (USAID), and used in 23 countries. QuickRes empowers clients to book their own appointments and receive system-generated reminders and virtual support. QuickRes is intuitive in design and easy to learn.

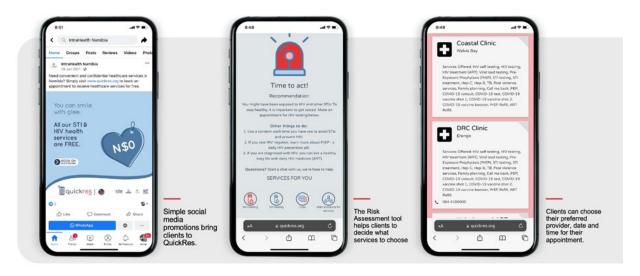
Clients using this online platform for the first time are encouraged to use the self-guided HIV risk assessment tool to prioritize and recommend services. When the tool recommends that clients get an HIV test, they are also encouraged to book STI testing. Returning clients and those opting to skip the risk assessment can still book STI services themselves on the platform.

The provider-facing functions of the app enable staff to keep track of appointments and use enhanced clinic and case management functions to report services administered (including STI testing and treatment), record and follow referrals and support client adherence to treatment. Clinic and program staff use data export functions and visualizations to routinely review the number of appointments booked, those arriving for services and the number and type of services provided. This monitoring information is used to improve services and program quality.

Currently, 68 facilities and 44 case managers in Namibia are using QuickRes. Between January 2021 and June 30, 2022, a total of 5659 appointments were made for PrEP, and 84% of these clients arrived for their appointments and were routinely screened for HIV and STIs.

In Namibia demand generation for HIV services, which makes use of social media and peer-led activities, also includes promotion of STI testing, whether or not members of key populations are seeking or qualify for PrEP.

#### Using QuickRes to book appointments for STI services in Namibia



\*Learn more about FHI 360's QuickRes and other virtual health interventions here: https://fhi360.org/goingonline. Source: IntraHealth Namibia

# Demand generation for STI services among people accessing PrEP

Like demand generation for HIV PrEP (see WHO PrEP implementation tool Module 2: community educators and advocates (48)), creating demand for STI services is critical. It can raise awareness of STI signs and symptoms and potential exposure to an STI, as well as promote care-seeking behaviours such as regular STI testing and notifying partners of an STI diagnosis. This is particularly relevant as most STIs do not present signs or symptoms and can be easily cured.

It also is critical to engage with communities when planning demand generation activities so that messaging is based on their needs and preferences. In addition, any demand generation activities need to be sensitive, inclusive and based on local cultural context. A range of effective demand generation approaches has been used for HIV testing and PrEP and could be adapted and used for integrated PrEP and STI services (49,50).

There is little public awareness that most STIs are asymptomatic and easily cured.

#### **BRAZIL**

#### Using social media to create demand for HIV PrEP and STI services

Project PrEP1519 is a demonstration cohort study, co-funded by Unitaid and the Brazilian National Health System and implemented in the large cities of Salvador, Belo Horizonte and São Paulo. This project assesses effective ways to provide HIV PrEP for adolescent men who have sex with men and transgender adolescent girls. Project strategies for demand creation and provision of services were discussed and decided by the adolescents engaged in the project.

In the three cities, the project includes a friendly sexual health clinic where condoms, lubricants, HIV self-tests, PrEP and STI services are provided, among other interventions. In the Salvador clinic, STI services include diagnostic tests for syphilis, gonorrhea, chlamydia and *M. genitalium*, and treatment following national guidelines. Clients have the choice of oropharyngeal, anorectal or (urethral) self-sampling or provider collection of samples.

Demand creation is a key component of the project, which uses face-to-face and various online strategies, including text messaging, online social media (for example, Instagram and Facebook), peer profiles in popular dating apps and an innovative artificial intelligence chatbot called Amanda Selfie. The chatbot was designed to talk to young people from key populations about positive sexuality and sexual health in addition to providing support information and linkage to PrEP and STI services.

Study results showed that online demand creation strategies were less effective than face-to-face peer recruitment, and they tend to reach adolescents from key populations of higher socioeconomic background. However, online interventions can be more cost-effective and easily scaled-up to increase service coverage. On the other hand, face-to-face recruitment can reach proportionally more underserved adolescents from key populations but require trained peers. In combination, online and peer-driven face-to-face strategies can provide a critical balance between offering wide coverage and equitable sexual health services for adolescents of key populations from different socioeconomic backgrounds (51).



Amanda Selfie, the chatbot used by the PrEP1519 project to create demand for PrEP and STI services among Brazilian adolescents from key populations (see https://prep1519.org/en/amanda-selfie/).

Source: PrEP1519 Brazil Study, funded by Unitaid and supported by the Brazilian Ministry of Health (https://prep1519.org/en/), 2022.

# **Preparing for upcoming innovations**

Upcoming innovations may make the provision of integrated PrEP and STI services more efficient and acceptable and support scale-up. Currently, WHO does not have recommendations on these innovations. As evidence becomes available, WHO guidelines will be released.

#### • Innovations in STI testing

 Syphilis self-test and HIV/syphilis self-test. Self-tests have proved highly acceptable to both health care workers and clients, and WHO recommendations already exist for HIV and hepatitis C. WHO is currently working towards having recommendations also for self-tests for syphilis and for dual HIV/syphilis.

Preparing for effective innovations could make integrated PrEP and STI services more acceptable to clients and may accelerate scale-up and response.

- **Rapid tests for active syphilis diagnosis**. These tests, which are already available, combine both a treponemal and non-treponemal test in a single cartridge. They can be used to support health care workers in diagnosing those with active infection.
- Near point-of-care (POC) multiplex diagnostic platforms. These platforms can simultaneously detect or identify biomarkers of multiple pathogens in a single diagnostic test. Several are in the pipeline; however, affordability is likely to be a challenge for most countries.

#### • Innovation in STI prevention

- Pre- and post-exposure prophylaxis for STIs. A recent randomized controlled trial with men who have sex with men and transgender women demonstrated the effectiveness of a single dose of 200 mg doxycycline, taken within three days of having sex without a condom, to prevent chlamydia, gonorrhoea and, possibly, syphilis (52).
  - Other than the prophylactic use of antibiotics after sexual violence, the regular use of STI post-exposure prophylaxis (PEP) or PrEP is not yet recommended, as there is not yet enough information regarding the effects on antimicrobial resistance. Thus, there is no current consensus on whether the benefits of using STI PEP and PrEP outweigh the risks from a public health perspective (53,54).
- Gonorrhoea vaccine. There is mounting evidence that the vaccine to prevent meningococcal meningitis caused by the bacteria *Neisseria meningitis* serogroup B (MenB) offers cross-protection against *N. gonorrhoeae* (55,56,57).
   Results of ongoing randomized controlled trials are expected within the next two to three years. The offer of MenB vaccination for people on PrEP could be rapidly implemented, as many countries already have this vaccine approved and available.

Other medium- to long-term innovations that WHO is supporting include, but are not limited to, a rapid lateral-flow test for gonorrhoea, molecular testing for gonococcal resistance, therapeutic vaccines for HPV and vaccines for genital herpes.

# Part 2. STI service delivery for facility managers and health care workers

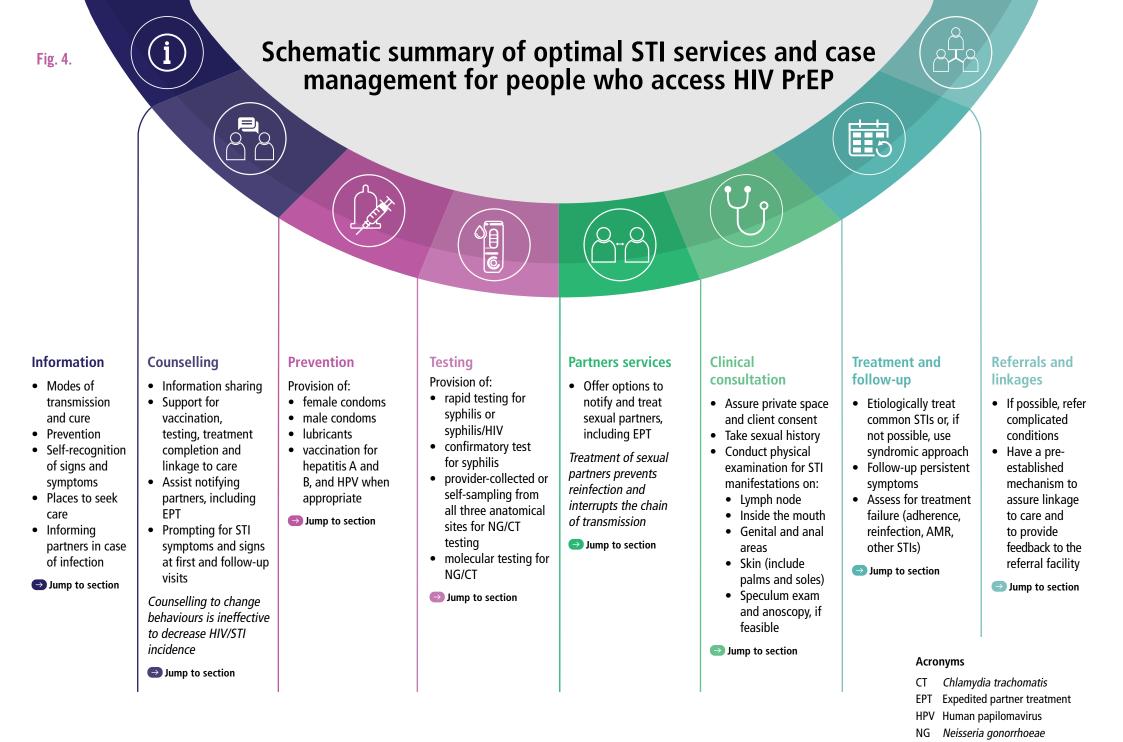
As mentioned in Part 1, different STI services can be integrated with PrEP services depending on how and where PrEP is offered and on local resources. Fig. 4 summarizes an optimal package of STI services that could be integrated at the facility level with laboratory support. In all contexts, however, inability to offer STI services should never delay or be a barrier to the provision of PrEP nor to adopting strategies to simplify access to PrEP, such as making it available through pharmacies or home delivery.

Inability to offer STI services should never be a barrier to offering PrEP.

Certain populations, such as adolescents and trans and gender diverse people, among others, will benefit from provision of additional services and support. Adolescents are in a unique stage of human development, with rapid physical, cognitive and psychosocial growth. This stage of life needs to be recognized, and health facilities need to adapt to encourage appropriate access to and use of PrEP and STI services.

For trans and gender diverse people, the use of the name and pronoun of choice needs to be respected as well as the use of gender-inclusive language for body parts when performing a physical examination.







# Providing information and promoting health-seeking behaviours

During the first encounter with health services, clients should be provided with basic information on STIs (see <u>Annex 4</u>), including self-assessment for signs and symptoms (see example in <u>Box 5</u>) and prevention strategies (see <u>section on STI Prevention</u>).

Additionally, due to the intense stigma associated with STIs, clients should know that some symptoms associated with STIs can be caused by other, non-STI-related pathogens or conditions (Box 6). Also, reminding users that STI infection can be asymptomatic is critical.

People who use PrEP should be aware that it will reduce the risk of acquiring HIV, but it will NOT reduce the risk of getting other STIs.

#### Box 5. Example of self-assessment for signs and symptoms of an STI

# If you have any of the following symptoms, you may have an STI:

- □ ulcers or sores on the genitals or anal areas or in the mouth\*
- ☐ discharge from the penis or vagina
- ☐ unusual or odorous vaginal discharge
- □ bumps or warts on the genitals, anal area, or in the mouth
- ☐ painful or burning urination
- ☐ unusual vaginal bleeding
- ☐ pain during sex
- □ sore, swollen lymph nodes, particularly in the groin
- □ lower abdominal pain

Some of these symptoms may not be caused by an STI. Seek care as soon as possible and refrain from sex until you receive a diagnosis and treatment, if appropriate.

\* Some STIs can cause ulcers and sores in the mouth when anal sex is performed on a person with infection, but there are many other causes of oral ulcers that are not related to sex.

Credit image: iStock/invincible\_bulldog



STI-related information, such as that in <u>Annex 4</u> and <u>Box 5</u>, can be provided via online interventions and tools such as social media and dating platforms, printed material (for example, posters and leaflets), peer/community groups and consultations with health care providers.

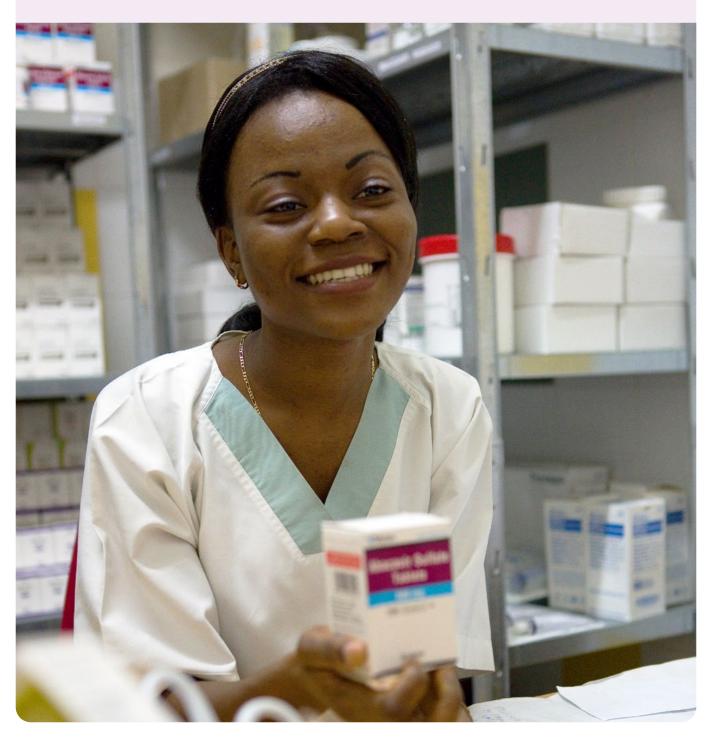
For materials and messaging to be appropriate to culture, age, sexual orientation and gender, their development should always involve members of the community.

#### Box 6. Common vaginal infections that may not be sexually transmitted

Vaginal discharge may be caused by some STIs such as trichomoniasis. However, the most common vaginal infections usually are due to an overgrowth of organisms normally present in the vagina, which may or may not be sexually transmitted.

The most common of these vaginal infections are candidiasis (also called yeast infection or thrush) and bacterial vaginosis. In most areas these infections are much more common than STIs. Between 5% and 25% of women have bacterial vaginosis, and between 5% and 15% have candidiasis at any given time.

- **Candidiasis** is not usually transmitted through sex. It can be easily cured with antifungal medications such as fluconazole. Without treatment, the bacteria that causes candidiasis can be transmitted to an infant during delivery.
- **Bacterial vaginosis** can develop after sexual intercourse and is a result of microbiome imbalance. It is not easily treated and is often recurrent (as is candidiasis). Although it is rare, those who have never had sex can develop bacterial vaginosis.





# Counselling

Quality counselling is an essential component of client-centred care. Counselling is defined here as a non-judgemental interactive process between a trained health care worker or lay provider and a client during which information is exchanged and support is provided so that clients can make informed decisions, design a plan and take action to improve their health (58). For example, some behaviours associated with increased risk for HIV and STIs, such as use of sex dating apps and chemsex, particularly among men who have sex with men, are becoming more frequent. It is important for those providing counselling to raise awareness of the risks of such practices (Box 7).

Counselling may enhance relationships between providers and clients and may encourage access to services. It is important to note, however, that WHO does not recommend counselling to try to change people's behaviours, as it has proved ineffective to reduce HIV/STI incidence (59).

WHO does not recommend counselling to change people's behaviours as it has been shown to be ineffective to reduce HIV/STI incidence.

#### Box 7. Increasingly common high STI risk practices among some people who would benefit from PrEP

- **Chemsex.** In chemsex, a seemingly growing phenomenon, people engage in sexual activity while taking stimulant drugs such as methamphetamine or mephedrone. Chemsex typically involves several or many participants, the use of multiple drugs at the same time (including injecting drug use) and over a prolonged time for example, at group sex parties. Chemsex is also known by other names, such as "slam sex", "party and play", and sexualized drug use, and it is increasingly reported in some communities of high risk-taking men who have sex with men, mostly in high-income countries (59). Chemsex can be associated with unsafe (condomless) sex, which increases the risk of transmission of HIV, hepatitis A, B and C viruses and other STIs, as well as drug dependence and adverse mental health outcomes (60,61).
- **Virtual dating apps.** The use of smartphones is rapidly increasing globally and, with them, dating apps offer an efficient and discreet way to find sexual partners. A 2018 systematic review and meta-analysis showed that dating app users were more likely than nonusers to engage in casual and unsafe sex and to use recreational drugs. The review also found a greater prevalence of syphilis, chlamydia and gonorrhoea among men who have sex with men who used online dating applications than among those who did not (62).

#### **Prompting for signs and symptoms of STIs**

Prompting clients to notice STI signs and symptoms they may have is essential to promote health-seeking behaviours and to provide appropriate STI services, and it can be conducted as a self-assessment (see example in <u>Box 5</u>).

<sup>&</sup>lt;sup>1</sup> The definition for counselling used in this module is adapted from WHO's Counselling for maternal and newborn health care: a handbook for building skills (58).

#### **SOUTH AFRICA**

#### **Prompting youth for STI symptoms**

In South Africa the standard of care for STI management set forth in national guidelines is a syndromic approach. In a PrEP implementation science project in South Africa (the Wits RHI Unitaid-funded Project PrEP), symptomatic screening of clients for STIs was incorporated into the standard of care for all clients presenting for PrEP, which is offered as part of sexual and reproductive health services. In addition, a sub-study to assess the feasibility of integrating etiological testing for STIs within PrEP services was undertaken. This approach was supported through the provision of updated guidelines to sites, training and on-site mentoring of health care providers on STI screening and management, and improved monitoring of routinely collected programme data on STI symptom screening.

Data routinely collected between December 2018 and December 2021 showed that 92.2% of the 25 100 male and female clients presenting for PrEP services for the first time at project sites were screened for STI symptoms. Of these, 8.7%, or 2019, had an STI symptom detected. Among females screened, 6.5% (1259/19 324) had vaginal discharge syndrome. In the sub-study urine samples of participants were tested for chlamydia, gonorrhoea and trichomoniasis using a polymerase chain reaction (PCR) assay performed at an off-site laboratory. Of those tested, 33.5% (144/430) had at least one positive STI result, and, of these, 19.4% (28/144) had more than one STI.

The high prevalence of STIs diagnosed through etiological screening in PrEP services highlights the need to consider it as an additional intervention for this population. However, for countries or sites where etiological screening is not feasible, STI symptom screening and management for clients presenting for PrEP has the ability to identify those in need of STI care who otherwise might have been missed.



Credit: Wits RHI

Source: Wits RHI, Project PrEP, funded by Unitaid and in collaboration with the South Africa National Department of Health, STAR HIV self-screening - Initiative Africa (funded by Unitaid), Optimizing Prevention Technology on Schedule (OPTIONS, Technical assistance program for PrEP), 2022.



Vaccines and condoms are the primary STI prevention tools (<u>Table 1</u>). In settings where voluntary medical male circumcision (VMMC) is recommended for HIV prevention, it also provides protection against some other STIs (63,64,65). Currently, WHO recommends post-exposure prophylaxis (PEP) for bacterial STIs only in the case of sexual assault/rape (66,67).

#### Table 1. WHO recommendations for STI prevention

#### **Vaccines**

- **Hepatitis A:** WHO recommends vaccination for people at higher risk of contracting hepatitis A virus in low-endemicity settings, which includes men who have sex with men and people who inject drugs (68).
- **Hepatitis B:** WHO recommends vaccination for people at high risk of infection, including those with multiple sexual partners, persons in prisons and other closed settings, people who inject drugs, men who have sex with men and other people at risk of HIV infection.
  - Routine pre-vaccination or post-vaccination testing is not recommended. Where laboratory or testing facilities are available and pre-vaccination testing is considered cost-effective, serological testing may reduce the number of unnecessary vaccinations of people who are already immune to the hepatitis B virus (69).
- **HPV:** Current HPV vaccines are effective in protecting against high-risk HPV types known to be carcinogenic and low-risk HPV types known to cause genital warts (70,71). Both the quadrivalent and nonavalent HPV vaccines cover both high- and low-risk HPV types. The HPV bivalent vaccine offers protection only against the HPV virus types that cause cancer.

#### **STI PEP**

• **PEP for other STIs** is recommended by WHO for use only following sexual violence/abuse, together with emergency contraception and PEP for HIV (66,67).

# Barrier methods

- All condoms provide a high degree of protection against many STIs when used correctly and consistently
  with all partners and at every act of penetrative sex, starting before intercourse and continuing
  throughout. Condoms also have the advantage of offering protection against pregnancy.
- External condoms (male condoms) used during penetrative oral, anal or vaginal sex.
- **Internal condoms** (female condoms) used internally during vaginal or anal sex.

Internal and external condoms and lubricants should always be available for people who use PrEP, as they are at greatest risk of STIs.

- A dental dam is a square, stretchy sheet made from latex or polyurethane plastic that can be used during oral sex to keep the mouth from touching genitals and body fluids.
  - O Placing the dental dam over the vulva or anus makes transmission less likely.
  - O In the case of mouth—penis oral sex, an external condom offers better protection.

#### Lubricants

 Lubricants are commonly used, particularly during anal sex, with or without condoms, and improve sexual health and well-being (72). Even when used without condoms, lubricants can provide some degree of protection by reducing the risk of microtrauma during penetrative sex.

When condoms are used with lubricant during both anal and vaginal sex, they offer extra protection against HIV and other STIs.

- Water-based or silicone-based lubricants should always be provided with condoms. Using lubricant with condoms during both anal and vaginal sex offers extra protection against HIV and other STIs because lubricants help prevent condom breakage and reduce the risk of microtrauma to the mucosa during penetrative sex.
- **Oil-based lubricants** (for example, butter, mineral or vegetable oil, or skin hydration creams) **cannot** be used with condoms, as they damage the latex.



# **STI** testing

Some STIs can be diagnosed using etiologic laboratory methods, such as molecular tests. Etiologic diagnosis of syphilis is feasible in almost all settings. However, for other pathogens, etiologic diagnosis remains limited due to high costs. Alternatively, some STIs require the collection of samples and the culture of the pathogen under specific laboratory conditions, which also are not widely available.

On the other hand, rapid tests allow people to be tested at the point of care and be treated for STIs in a single visit, greatly decreasing the risk of loss to follow-up. Furthermore, rapid tests can be performed by trained lay providers or by self-testing. Inexpensive rapid tests are currently available and are recommend by WHO for HIV, syphilis, and hepatitis B and C (including self-tests for HIV and HCV).

Rapid tests allow people with a positive STI result to start treatment immediately, avoiding the risk of loss to follow-up.

Suggested types of tests and testing strategies for common pathogens are described in the <u>WHO laboratory manual for the diagnosis of STIs</u> (73) and summarized in <u>Annex 5</u>. WHO also provides a <u>list of in-vitro diagnostic tests</u> that have been evaluated and meet WHO standards of quality (pre-qualification process).<sup>1</sup>

#### Frequency of testing

Optimal frequencies of STI testing vary by pathogen, population and epidemiologic context. Considering the WHO guidance for differentiated and simplified PrEP services, PrEP follow-up visits may vary between people on PrEP (2). For STIs, self-testing and self-sampling can be used between or in place of some clinic visits. For example, services that require PrEP clients to return every three months for a PrEP refill and for HIV and STI testing could provide PrEP for six months in addition to HIV self-test and kits for the self-collection of samples for STI testing.

A recent systematic review and meta-analysis suggests that increasing the frequency of syphilis testing from every six months to every three months for people on PrEP did not have additional benefit. For gonorrhoea and chlamydia, although more cases were identified when testing every three months, the acceptability to clients and adherence by providers decreased (74). The same study concluded that insufficient evidence currently exists for a general recommendation on the frequency of STI testing for different STI pathogens in specific populations and settings. The increased costs and unfeasibility of testing for STIs more frequently than six monthly (in many resource-limited settings) needs to be balanced against possible benefits.

WHO is currently working on a practical tool to help countries find the optimal frequency of STI testing, which includes considerations of cost-effectiveness and local epidemiologic context. This tool is expected to be available soon and will be posted on the <a href="https://www.who.ncb.nih.gov/who.n



It is strategic to prioritize resources to provide regular testing for people at higher risk of STIs, such as those accessing PrEP.

Credit photo: WHO/Tomislav Georgiev

<sup>&</sup>lt;sup>1</sup> Certain products and suppliers are not included in the list because their products have not been assessed by WHO. If these were assessed, evaluated and tested, they might be found to comply with the WHO standards for pre-qualification.

#### Considerations for syphilis testing and diagnosis

Many people with syphilis do not have any symptoms or signs of infection, or health care providers may not notice signs and symptoms. Syphilis diagnosis is complex, usually requiring clients' clinical and sexual history, physical examination and laboratory testing.

The most widely available tests for syphilis are based on serology. These can be of two types: treponemal and non-treponemal tests.

- **Treponemal tests**, which encompass laboratory tests, rapid single syphilis tests and rapid dual HIV/syphilis tests, are highly sensitive. However, they do not distinguish between active infection and past infection that has been previously treated. Positive results on these tests remain positive for life in about 85% of cases.
- **Non-treponemal tests**, such as the Venereal Disease Research Laboratory (VDRL) test or a rapid plasma reagin (RPR) test, detect anti-lipid immunoglobin M or G (IgM or IgG) antibodies. Since these antibodies can also be produced in other diseases or conditions, non-treponemal tests are not highly specific for syphilis and can give false-positive results. Additionally, these tests may be negative for up to four weeks after the lesion of primary syphilis first appears and in late latent syphilis, and false-negative results can also be due to the prozone phenomenon.<sup>1</sup>

Depending on which assays are available and used in a particular setting, different diagnostic algorithm strategies are needed (75,76). When one of the above tests is reactive, the other is used as a confirmatory test. A positive result in both tests is considered indicative of active infection.<sup>2</sup>

Rapid syphilis tests (alone or combined with HIV testing) expedite treatment initiation, significantly decrease loss to follow-up and can be cost-saving.

Using only one type of test (treponemal or non-treponemal) for treatment initiation will lead to overtreatment but also to a decrease in loss to follow-up, particularly when using rapid tests. Programmes with available treponemal and non-treponemal test need to make a decision whether to start treatment based on the first syphilis-positive test result or to wait for the confirmation of active syphilis. This decision should be based on the risk of loss to follow-up when sending clients or their blood sample for confirmatory lab testing and scheduling a return visit to decide on treatment initiation.

In an antenatal care setting, if both a rapid test and an on-site RPR test are available and results are given in the same visit, treatment should be initiated based on two positive results (independently of titre). If only an RPR or a rapid syphilis test is available, and the confirmatory test result cannot be provided during the same visit, WHO recommends starting treatment immediately, in the same visit, if the test result is positive (75).

A dual, combined rapid treponemal and non-treponemal test is available. Use of this type of test could facilitate the diagnosis of active syphilis, thus decreasing and preventing loss to follow-up (77). WHO has guidance for the use of such tests for the diagnosis of yaws when affordable by the programme (78), and guidance should also be available soon for syphilis testing.

#### Considerations for the diagnosis of gonorrhoea and chlamydia

The costs of high-performance molecular POC tests for *N. gonorrhoeae* and *C. trachomatis* remain prohibitive for many low- and middle-income countries posing an important barrier to increase testing coverage. Still, POC platforms for molecular testing are increasingly available in these countries for the diagnosis of tuberculosis (TB) and could be used for some STIs to optimize use of resources and increase testing coverage.

The use of self-collected samples can be an additional strategy to overcome the high cost of molecular testing when it is feasible to transport samples to a central laboratory for testing.

*N. gonorrhoeae* and *C. trachomatis* infection can occur at the oropharynx, anorectum and urethra. For people at high risk of infection, it is important to collect samples from all three sites. For example, one study among female sex workers showed that 40% of chlamydia and 60% of gonorrhoea infections would have been missed if only genital samples had been tested *(79)*. Similarly, another study, conducted mostly among men who have sex with men, noted that 85% of gonorrhoea and 82% of chlamydia cases would be missed if only urine samples had been tested *(80)*.

<sup>&</sup>lt;sup>1</sup> The prozone phenomenon is a false-negative result that occurs because a higher than optimal amount of antibody in the tested sera prevents the flocculation reaction typifying a positive result in reagin tests.

<sup>&</sup>lt;sup>2</sup> For disease notification and surveillance purposes, if only one type of test is available, WHO considers a case of syphilis to be reportable when either a treponemal or non-treponemal test is positive. For countries with the capacity to confirm active syphilis, both tests are recommended and confirmed cases should be reported instead of the result of individual tests.

One way to decrease the cost and increase the efficiency of molecular tests for the diagnosis of gonorrhoea and chlamydia is to pool samples collected from the oropharynx, anorectum and urethra of an individual and run one diagnostic test. WHO recommends this practice (59,81).

For people at high risk of infection, it is critical to collect samples from all three anatomic sites. These samples can be pooled and one diagnostic test be used.

Current WHO first-line treatment recommendations for chlamydia (82) and gonorrhoeae (83) are the same for any site of infection. For countries with national guidelines that differentiate treatment by anatomic site, positive samples will need to be opened and tests rerun separately by site or, alternatively, the highest dose recommended for oropharyngeal infection may be considered. However, due to increasing antimicrobial resistance to azithromycin by *N. gonorrhoeae* and reduced susceptibility to cephalosporins, WHO is revising the current treatment guidelines.

#### **GEORGIA**

#### Improving accessibility of testing and treatment for bacterial STIs in PrEP services

In Georgia most HIV infections occur among members of key populations and their partners. Roll-out of the PrEP programme in the country started in 2019. The programme is currently implemented in national and several regional HIV treatment and care clinics and in community-based settings serving mostly men who have sex with men.

Based on the national protocol, people accessing PrEP should be offered a package of services that includes STI testing and treatment. However, implementation of STI services faces some barriers as, historically, these services have been provided only in specialized STI clinics. Currently, it is possible to offer testing for syphilis to all clients at PrEP enrolment at the community centres. However, in case of positive syphilis test results, as well as for regular testing for gonorrhoea and chlamydia, clients are referred from PrEP services to the STI clinic at a different location. Although STI services are free of charge, acceptability and accessibility of this referral system among people on PrEP is suboptimal. The main barriers are the centralization of STI services, the need to travel to additional locations, key populations' perception of stigma and discrimination resulting from the need to disclose key population status and concerns about confidentiality.

Recognizing these barriers and taking advantage of the availability of molecular POC testing platforms used for TB and hepatis C, Georgia is moving towards a one-stop shop approach to STI testing for people who would benefit from PrEP. In 2023 PrEP clients will be offered the options of self-collection or provider-collected samples of the three

anatomic sites. They will also be able to have gonorrhoea and chlamydia diagnosis at the HIV clinic, with results provided in the same visit. Additionally, to increase efficiency, samples from the same individual will be pooled for testing. While those who need treatment will still be referred, the next step will be full integration of STI diagnostic services with PrEP provision to optimize the accessibility of STI services for members of key populations who would benefit from PrEP.

Credit: Lasha Nonikashvili Source: Equality Movement





# Partner services

WHO recommends that providers offer assistance to clients who test positive for HIV to notify their partners and link them to care (40). Partner services' strategies (such as assisted partner notification services) (see <u>Box 8</u>) are proven to be highly efficient and effective in detecting new cases and have already been adopted by several low- and middle-income countries. These strategies can also be used for STIs (84).

Furthermore, combining partner service strategies with dual rapid HIV/syphilis testing could yield a greater number of previously undetected and untreated syphilis infections. It can also be cost-saving and help to break the chain of transmission (42,43,44).

#### Box 8. Effective strategies for partner services

- **User referral partner notification:** A client who tests positive for HIV or other STIs (the index case) can be issued a contact-tracing card for sex partners along with an invitation to attend the clinic for assessment and, if necessary, treatment.
- Provider referral partner notification: The health care provider obtains contact details from the index case and
  then attempts to contact the sex partners in person or by telephone, through SMS messages, or other ways, with the
  agreement of the index case.
- **Contractual partner referral:** The index case and service provider agree that the index case will contact the sex partners and the partners will present for examination and treatment within a certain amount of time, after which the health care provider will try to contact the sex partners.
- Social network-based referral: In an extension of partner services, a trained provider asks all clients at high risk of
  infection, independently of test results, to encourage and invite individuals in their sexual, drug-injecting or social
  networks to participate in voluntary testing services.
- **Expedited partner therapy (EPT):** The client diagnosed with a bacterial STI is given a prescription or medicines to give to sex partners without examination by the health care provider.

Details on implementing these strategies can be found in WHO's <u>Guidelines on HIV self-testing and partner notification: supplement to consolidated guidelines on HIV testing services</u> (40), the WHO policy brief, <u>WHO recommends social network-based HIV testing approaches for key populations as part of partner services package</u> (41), and in the <u>WHO's Guidelines for the management of symptomatic sexually transmitted infections</u> (84).



# **Consultation and physical examination**

To establish a correct diagnosis, the health care provider needs to ensure that there is a conducive environment to enable people to discuss their sexual history freely.

Taking a sexual and medical history is also central to providing quality PrEP and STI care, and it is an important component of people-centred care. Obtaining clients' sexual history will help providers to gauge a person's likelihood of being infected with an STI. Sexual history taking is described in detail in Module 3 of the PrEP implementation tool (85).

As with counselling, taking a sexual history should not be a requirement for clients to access PrEP or to be tested and treated for STIs.

#### **Physical examination**

Prior to the physical examination, the user should:

- be informed about the examination procedure (exposure of abdomen, genitals and thighs);
- give consent for the examination.

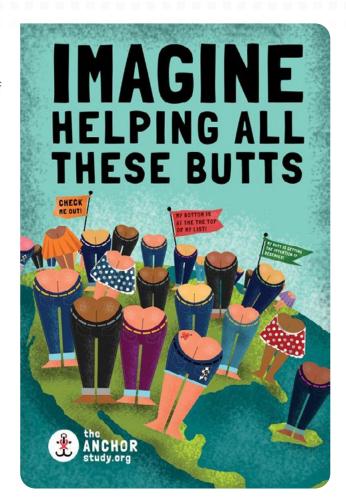
During the examination, the user should be:

- examined in a private space with the presence of a chaperone; if a chaperone is not available, the health care provider should ask the user's consent to be examined without a chaperone;
- covered with a drape or draw sheet to maintain dignity and respect;
- · asked to expose only the area to be examined;
- offered and informed about options for self-collection of samples or provider collection for *N. gonorrhoeae* and *C. trachomatis* testing.

Box 9 presents a summary of a physical examination for STIs.

Credit: AIDS Malignancy Consortium (NCI award number 2 UM1 CA121947)

Source: Learn more about the ANCHOR study here: https://anchorstudy.org/



#### Box 9. Physical exam for signs and symptoms of STIs

During the physical exam, the provider should look for:

- lymph nodes: swelling/buboes
- inside the mouth: thrush, sores, other lesions
- skin over the abdomen: swelling
- palms of hands and sole of feet, thighs and buttocks: rashes, ulcers
- external genitals: discharge, sores, ulcers, warts, parasites, excoriations
- penis: look at glans and at the urethra for discharge
- · vagina: manual exam for abnormal masses, tenderness
- anal area: discharge, rashes, ulcers, warts.

In settings where speculum exam and/or anoscopy is available, the provider should also examine the:

- vaginal mucosa and cervix
- rectal mucosa.

For a step-by-step guide to performing a clinical examination, see the 2021 <u>WHO Guidelines for the management of symptomatic sexually transmitted infections</u> (84).

#### **NIGERIA**

#### Visual examination and facility-level treatment for anogenital warts

With support from the Key Population Investment Fund (KPIF), which was distributed through the United States Centers for Disease Control and Prevention (CDC) to local implementing partners and key population-led/competent community-based organizations, cryotherapy equipment and supplies were provided to 13 one-stop-shop clinics in Nigeria where members of key populations access HIV prevention, treatment, care and other ancillary services. Thirty providers received hands-on training on the management of anogenital warts.

To ensure service uptake, messaging for anogenital warts treatment was integrated into routine HIV prevention messaging for members of key populations. These messages were delivered in peer-led educational sessions, was highlighted during outreach and moonlight activities, leveraged on social events organized by men who have sex with men, discussed in social media chat groups, as well as by direct referral from treated clients. Concurrently,

meetings alerted community opinion leaders, gatekeepers and other stakeholders to the availability of services. As a result, programme implementation and uptake of services for anogenital warts were facilitated by buy-in from the key population community and key population-led civil society organizations. The programme also engaged with local companies that produce and supply liquid nitrogen for cryotherapy.

The integration of visual screening and cryotherapy treatment for anogenital warts into PrEP services led to the diagnosis and treatment of cases that otherwise would have been missed. Also, those who were treated for warts and tested HIV-negative were offered PrEP.

Barriers to service implementation included the high upfront cost of cryotherapy equipment and its maintenance and the sporadic availability and challenges with storage of liquid nitrogen. These are important challenges for the sustainability of anogenital warts management services. Cost—effectiveness analyses could inform advocacy for funding after donor support ends.

Credit: Vincent Emmanuel Chidera. Source: U.S. CDC Nigeria





# Syndromic approach

The syndromic approach identifies consistent groups of symptoms and easily recognized signs (syndromes –for example, vaginal discharge, urethral discharge, genital ulcers, abdominal pain) and treats for the most likely organisms producing the syndrome.

WHO recommends that countries enhance syndromic management by gradually incorporating laboratory testing to support diagnosis.

Syndromic case management can result in both overtreatment, because there are other causes of syndromes not related to an STI, and undertreatment, as the majority of STIs are asymptomatic. Despite these shortcomings, syndromic case management remains an essential component for treating people with symptoms of STIs in settings without laboratory diagnosis or where results from laboratory diagnosis take several days.

In 2021 WHO released a guideline to optimize syndromic diagnosis and to support countries moving from a syndromic to an etiological approach based on local laboratory capability (84). In settings where quality-assured molecular assays are available, WHO recommends treating STIs based on laboratory test results. In settings where initiating treatment based on molecular assay results is not feasible in one visit, or in settings that have limited or no molecular testing, WHO suggests treatment based on syndromic management (84).

Click on the WHO guideline cover for updated flow charts to help with the diagnosis and management of five STI syndromes — urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome and anorectal discharge.





# **Specific treatment for common STIs**

Correct and effective STI treatment should be provided and taken, ideally, on the day of first contact between clients and health care providers. Rapid treatment of sexual partners is also critical to avoid reinfection and to break the chain of transmission, which could include expedited partner treatment.

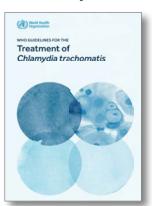
The correct, effective and timely treatment of STIs will cure the infection and reduce the risk of developing complications and antimicrobial resistance.

A client who is prescribed treatment for an STI should be counselled on medication information, risks and benefits, adverse reactions, dosing and adherence.

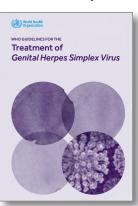
Standardized treatment protocols for STIs ensure appropriate treatment at all levels of health care services and help reduce the risk of developing resistance to antimicrobials.

For detailed information on treatment regimens recommended by WHO for specific STIs,<sup>1</sup> click on the following guideline cover pages:

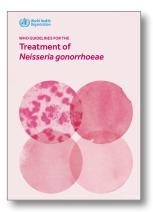
#### Chlamydia



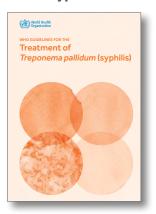
#### **Genital herpes**



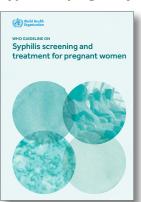
Gonorrhoea<sup>1</sup>



**Syphilis** 



Syphilis in pregnancy



**HPV** and cervical cancer





# Clinical follow-up

Follow-up is generally limited to those with persistent symptoms after a stipulated period after the recommended treatment. Clients may return for further assessment if the condition has not resolved or it has recurred. The health care provider will need to determine the reason for the user's return to guide next steps (see <u>Box 10</u>).

#### Box 10. Reasons for STI treatment failure that need to be assessed to guide further treatment

- **Adherence:** such as a client failing to complete a 7-day or 21-day course of doxycycline for the treatment of chlamydia, including for lymphogranuloma venereum (LVG).
- Reinfection: perhaps because sex took place without a condom with an untreated sex partner or a new partner.
- **Antimicrobial resistance:** of particular importance in gonococcal and *M. genitalium* infections.
- Other untreated infection: such as *T. vaginalis* and/or *M. genitalium* when urethral discharge was treated only for *N. gonorrhoeae* and *C. trachomatis* at the first visit.

<sup>&</sup>lt;sup>1</sup> WHO does not have specific guidelines for the treatment of trichomoniasis or other STIs, but treatments can be found in the WHO guideline for the management of symptomatic STIs (84).

WHO is currently revising its treatment recommendations and dosages for gonorrhoea due to increasing antimicrobial resistance to azithromycin and reduced susceptibility to cephalosporins.



# Referrals and linkage to care

Sometimes people diagnosed with an STI will need to be referred to another level of care. For example, someone with an abnormality in the anorectal area may need to be referred to a colorectal surgeon or oncologist or for diagnostic tests. Health care workers should be provided with clear and easily accessible information on referral and counter-referral mechanisms.<sup>1</sup>

However, when referring someone to another facility, it is critical to consider loss to follow-up due to individual, programmatic and environmental factors (see <u>Box 2</u>). Loss to follow-up results in poorer outcomes such as longer-term consequences of the infection and missed opportunities to stop the chain of transmission.

Before assuming that routine referral is needed, providers should consider that most STIs can be dealt with routinely at the facility level and during one visit.

Treatment given on the same visit is especially relevant in settings where users' return rates are low for reasons such as distance to the clinic, clinic fees, transport fees, among others. This will reduce costs for both the user and the health care system.

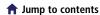
Some effective strategies to support linkage to HIV care can also be applied to when clients must be referred to another services for STI testing or treatment as listed in Box 11.

#### Box 11. Suggested strategies to support linkage care that could be applied to STI referrals

- **Friendly services** that are inclusive and non-judgemental increase acceptability and access to care. Stigma and discrimination related to STIs constitute important barriers to health care-seeking behaviour.
- Flexible services regarding opening hours and days.
- Adoption of self-care services, such as self-collection of samples at home or at the facility.
- Services that are free of cost to users and financial support to access other referral facilities if needed.
- Availability of peer and community support and follow-up, including client navigators and linkage escorts.
- **Digital platforms**, including social media, videos, text messaging and other digital applications, are promising for improving linkage to care and may be less costly than intensive in-person approaches.
- **National policies** need to help sites and health care workers support linkage to care. Programme managers should consider adopting and implementing a clear linkage strategy and policy, including specific approaches, interventions and designation of cadres supporting linkage to care and monitoring its effectiveness.

Source: Adapted from the WHO Consolidated guidelines on HIV testing services, 2019 (86)

<sup>&</sup>lt;sup>1</sup> Referral and counter-referral is an established communication mechanism between health facilities to assure client continuation of care. A facility without the means to provide a specific type of care to attend the client's needs (for example, diagnosis, treatment, vaccines) uses this mechanism to refer the client to another facility that can provide such services. The counter-referral is the communication back to the original facility with the outcome of the service provided and indications for further assistance if necessary.



#### **SOUTH AFRICA**

#### Values and preferences of youth for STI services

Although the burden of STIs among young women receiving PrEP in South Africa is high (87), STI services have remained relatively unchanged since PrEP introduction. Limited knowledge of STIs, long clinic waiting times, limited accessibility of services, poor integration and services that are not oriented to youth are barriers to obtaining STI and other sexual and reproductive health services (88).

The standard of care for STI management in South Africa is a syndromic approach, with treatment provided according to national algorithms. A quantitative discrete choice experiment (89) with a sample of approximately 500 individuals indicated that health care users:

- have a strong preference for self-sampling to test for STIs over provider sampling;
- do not want to wait for four hours at a clinic to receive results;
- equally prefer receiving results within a week through an SMS or online and receiving results within two hours at the clinic;
- may prefer same-day clinic treatment over clinic follow-up for treatment;
- have equal preferences for receiving treatment at a local pharmacy or same-day clinic treatment;
- have a strong preference for expedited partner treatment (EPT) over the use of contact slips or provider notification.

Modelling of the data identified two distinct groups of users. The majority (68%) preferred a more self-care service model, with strong preferences for self-sampling and not waiting at the clinic for results or having to come back for a follow-up appointment for treatment, and a strong preference for EPT. The other group (32%) preferred a more provider-led model; they favoured provider sampling, showing a willingness to wait for results, gave some indication that they would not mind returning to the clinic for treatment, and preferring provider-initiated partner notification.

Although these findings highlight that most clients prefer self-led STI services, there remains a group that would prefer provider-led services. Models of service provision cannot be a one-size-fits-all approach; they need to be client-centred and offer choices.



Credit: Wits RHI Source: Wits RHI, 2022.



# Outbreaks of STIs and other infections that can be sexually transmissible

There has been an increase in outbreaks of syphilis, gonorrhoea (including extensive drug resistance (XDR)<sup>1</sup> by gonococci), LVG and HIV, as well as other pathogens not classified as STIs but that are transmissible through sexual contact, reported mostly by high-income countries among men who have sex with men. The most recent outbreaks include those by *Shigella flexneri*, *Shigella sonnei* (including multidrug resistance<sup>2</sup> and XDR), verocytotoxin-producing *Escherichia coli*, hepatitis A, B and C, and monkeypox (Box 12).

Although these outbreaks have been mostly reported among men who have sex with men, all efforts should be made not to stigmatize them or any other affected population.

#### Box 12. Monkeypox

Monkeypox is an infection caused by the monkeypox virus that may lead to a range of medical complications. During human monkeypox outbreaks, close personal contact is the most significant risk factor for infection (for example, face-to-face, skin-to-skin, mouth-to-skin, mouth-to-mouth contact, including oral, vaginal, or anal sexual contact). It has been commonly reported among men who have sex with men with multiple and/or anonymous sexual partners and who engage in sexualized drug use (chemsex), but the risk is not limited to men who have sex with men.

Monkeypox is usually a self-limited disease, with symptoms lasting from two to four weeks, but severe cases can occur. Symptoms and signs of a suspected case are headache, acute onset of fever (>38.5°C), swollen lymph nodes, muscle and body aches, back pain and/or profound weakness, and acute rash and lesions not fully explained by their common causes. People may experience all or only a few of these symptoms. Clinical differential diagnosis includes other rash illnesses, such as chickenpox, measles, bacterial skin infections, scabies, syphilis and medication-associated allergies. The full case definition as well as clinical management information can be found in the monkeypox outbreak toolbox on the WHO website.

Contact tracing (see <u>Partner services section</u>) should start immediately after a suspected case is identified, and a vaccine should be offered to those exposed, ideally (but not exclusively) within four days of first exposure to prevent onset of disease and to interrupt the chain of transmission.

A vaccine against monkeypox virus has been approved and recommended by WHO (90). Also, new and safer vaccines for smallpox have been demonstrated to be about 85% effective in preventing monkeypox and should be given to anyone at high risk of exposure. However, the availability and accessibility of both smallpox and monkeypox vaccines are currently limited.

Information on monkeypox is rapidly evolving. Please check for the most recent information on the WHO website.

Surveillance and rapid identification of new cases are critical for outbreak response. To support countries, WHO has developed a <u>disease outbreak toolbox</u> that can be used for any outbreak, including those related to sexual transmission. The latest WHO <u>disease outbreak news</u> is also available, which includes information on confirmed acute public health events or potential events of concern. Additionally, the <u>WHO health topics</u> webpage provides links to technical documents, reports, guidelines, WHO position papers, press releases and news updates.

Services that offer PrEP play a critical role in detecting surges of infections that can be transmitted through sex and reporting them through existing surveillance mechanisms.

Currently, WHO has issued disease-specific guidance documents and tool kits for outbreak responses for several pathogens, including monkeypox virus, ebola virus, hepatitis A virus, zika virus and Shigella sonnei. Clear, targeted and intense efforts are needed to inform people most at risk, which includes communities who would benefit from PrEP.



<sup>&</sup>lt;sup>1</sup> Defined as non-susceptibility of a bacteria to at least one agent in all but two or fewer antimicrobial categories.

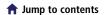
<sup>&</sup>lt;sup>2</sup> Defined as acquired non-susceptibility of a bacteria to at least one agent in three or more antimicrobial categories.

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# Annex 1. WHO guidance and guidelines relevant to integrating STI services into PrEP

This STI service integration module is aligned with the recommendations of the following WHO guidance and guidelines.

#### **Key populations**

 Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations (2022) (1)

#### STIs

- Guidelines for the management of symptomatic sexually transmitted infections (2021) (2)
- WHO recommendations on self-care interventions: Self-collection of samples for sexually transmitted infections (STIs) (2020) (3)
- Guideline on syphilis screening and treatment for pregnant women (2019) (4)
- Guidelines for the treatment of Chlamydia trachomatis (2016) (5)
- Guidelines for the treatment of genital herpes simplex virus (HSV) (2016) (6)
- Guidelines for the treatment of Neisseria gonorrhoeae (2016) (7)
- Guidelines for the treatment of Treponema pallidum (syphilis) (2016) (8)

#### **Cervical cancer**

• Guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention (2021) (9)

### Viral hepatitis

- Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection (2022) (10)
- Updated recommendations on treatment of adolescents and children with chronic HCV infection (2022) (11)
- Recommendations and guidance on hepatitis C virus self-testing (2021) (12)
- Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection (2018) (13)
- Guidelines on hepatitis B and C testing (2017) (14)
- Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection (2015) (15)

### Strategic information

• Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact (2022) (16)

- Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240052390)
- 2. WHO Guidelines for the management of symptomatic sexually transmitted infections. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240024168)
- 3. Self-collection of samples for sexually transmitted infections (STIs). Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/WHO-SRH-20.10)
- 4. WHO guideline on syphilis screening and treatment for pregnant women. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241550093)
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- 9. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention. Geneva: World Health Organization; 2021 (https://www.who.int/publications-detail-redirect/9789240030824, accessed 8 August 2022).
- 10. Updated recommendations on simplified service delivery and diagnostics for hepatitis C infection. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240052697, accessed 8 August 2022)
- 11. Updated recommendations on treatment of adolescents and children with chronic HCV infection. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240052710, accessed 29 July 2022).
- 12. Recommendations and guidance on hepatitis C virus self-testing. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031128, accessed 29 July 2022).
- 13. Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection. Geneva: World Health Organization; 2018 (https://www.who.int/publications/i/item/9789241550345, accessed 29 July 2022).
- 14. Guidelines on hepatitis B and C testing. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241549981, accessed 29 July 2022).
- 15. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva: World Health Organization; 2015 (https://www.who.int/publications/i/item/9789241549059, accessed 29 July 2022).
- Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240055315, accessed 8 August 2022).

# Annex 2. Examples of possible PrEP service delivery models and potential integration of STI services.

PrEP service delivery models can be combined to increase the range of STI services provided, such as digital health platforms with home delivery. All the examples provided of PrEP service delivery models and STI service integration to be implemented will depend on local context and on national norms and regulations.

PrEP delivery platforms STI services	Virtual intervention platforms (1)	Home delivery (post/courier)	Home delivery (community members/peers)	Pharmacies	Mobile units	Facilities without laboratory <sup>a</sup>	Facilities with laboratory
Information	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Counselling <sup>b</sup>	Yes	No	Yes	Yes	Yes	Yes	Yes
Prompting <sup>b</sup> or self-assessment for signs and symptoms	Yes	Yes <sup>c</sup>	Yes	Yes	Yes	Yes	Yes
Partner services <sup>b</sup>	Yes	No	Yes	No	Yes	Yes	Yes
ЕРТ	Yes <sup>d</sup>	Yes	Yes	Yes	Yes	Yes	Yes
Condoms & lubricants	Yes	Yes	Yes	Yes	Yes	Yes	Yes
RDTs <sup>b,e</sup>	No <sup>f</sup>	Nof	Yes <sup>f</sup>	Yes	Yes	Yes	Yes
Provider or self-sampling for NG/CTb,h	Yes	Yes <sup>c</sup>	Yes	Yes	Yes	Yes	Yes
Laboratory-based syphilis testing (T/NT)	No	No	No	No	No	No	Yes
POC NAAT	No	No	No	Yes	Yes	Yes	Yes
Laboratory-based NAAT	No	No	No	No	No	No	Yes
Visual physical examination <sup>b</sup>	Yes	No	Yes	Yes	Yes	Yes	Yes
Vaccination	No	No	Yes	Yes	Yes	Yes	Yes
Treatment	Yes <sup>d</sup>	Yes	No	Yes	Yes	Yes	Yes
Referral and linkage <sup>i</sup> to care	Yes	No	Yes	Yes	Yes	Yes	Yes

Notes: CT: Chlamydia trachomatis; EPT: expedited partner therapy; NAAT: nucleic acid amplification test; NG: Neisseria gonorrhoeae; POC: point-of-care test; RDT: rapid diagnostic test; T/NT: treponemal/non-treponemal test.

<sup>a</sup>Community-based or not.

<sup>b</sup>If space is available or privacy can be assured.

<sup>c</sup>Self-assessment /self-sampling only.

<sup>d</sup>By prescription.

eRDTs are available for syphilis, dual syphilis/HIV, hepatitis B and C; self-tests are available for HIV and hepatitis C.

fRapid lateral-flow syphilis self-tests, dual HIV/syphilis self-tests and rapid treponemal/non-treponemal tests are available but none are yet recommended by WHO. WHO guidance is planned for and quality-assured self-test for syphilis and HIV/syphilis should be available soon and could be home-delivered.

<sup>9</sup>By trained lay provider.

hSamples should be collected from the urethra, oropharynx and anorectum and can be pooled and run using one diagnostic test.

<sup>i</sup>Referrals and linkage to care can be offered for vaccination, testing, treatment and complicated infections.

#### References

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## **Annex 3. STI priority indicators**

### **Core STI indicators**

Short name	Indicator definition	Numerator	Denominator
Syphilis testing coverage	% of people tested for syphilis during the reporting period	Number of people tested for syphilis during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period <sup>a</sup>
Syphilis test positivity	% of people who tested positive for syphilis during the reporting period	Number of people who tested positive for syphilis during the reporting period (tested positive on both nontreponemal and treponemal tests or tested positive on either nontreponemal or treponemal test)	Number of people tested for syphilis during the reporting period
Syphilis treatment coverage	% of people tested positive for syphilis who were treated based on national guidelines in the reporting period	Number of people who tested positive for syphilis and were treated based on national guidelines in the reporting period	Number of people who tested positive for syphilis during reporting period <sup>b</sup>
Gonorrhoea testing coverage	% of people tested for gonorrhoea during the reporting period	Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period <sup>a</sup>
Gonorrhoea test positivity	% of people who tested positive for gonorrhoea during the reporting period	Number of people who tested positive for gonorrhoea during the reporting period	Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period
Gonorrhoea treatment coverage	% of people tested positive for gonorrhoea who were treated based on national guidelines during the reporting period	Number of people who tested positive for gonorrhoea and were treated based on national guidelines during the reporting period	Number of people who tested positive for gonorrhoea (using a molecular test, culture or POC test) during the reporting period
Presence of STI syndrome	% of people diagnosed with a particular STI syndrome during the reporting period <sup>c</sup>	Number of people diagnosed with a particular STI syndrome during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period
Repeat diagnosis of STI syndrome	% of people diagnosed with a particular STI syndrome who were diagnosed with the same STI syndrome two or more times during the reporting period <sup>c</sup>	Number of people who were diagnosed with a particular STI syndrome two or more times during the reporting period	Number of people diagnosed with a particular STI syndrome during the reporting period

Source: WHO, 2022 (1).

WHO has treatment guidelines for the management of symptomatic infections related to five syndromes: urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome and anorectal discharge (2).

<sup>&</sup>lt;sup>a</sup>All unique individuals who have accessed an HIV service (including STI clinics, PrEP services, key population services, HIV testing services, antenatal care clinics, or HIV treatment). These indicators should be disaggregated by service type.

<sup>&</sup>lt;sup>b</sup>Denominator to reflect country guidelines. For some countries, treatment may be offered to those who are suspected of having syphilis, while in others only to those who test positive on both non-treponemal and treponemal tests.

### **Additional STI indicators**

Short name	Indicator definition	Numerator	Denominator
Time to syphilis treatment	Median time between syphilis test (screening test or confirmatory) and treatment	Median number of days between syphilis screening date (or confirmatory test date if confirmatory test performed) and date treatment prescribed or dispensed	n/a
Gonorrhoea repeat test positivity	Percentage of people tested positive for gonorrhoea who tested positive again during the reporting period	Number of people who tested positive for gonorrhoea two or more times during the reporting period	Number of people who tested positive for gonorrhoea (molecular test, culture or POC test) during the reporting period
Time to gonorrhoea treatment	Median time between gonorrhoea test and treatment	Median number of days between gonorrhoea test date and date treatment prescribed or dispensed	n/a

Source: WHO, 2022 (1).

## Additional STI indicator for people on PrEP

Ref No	Short name	Indicator definition	Numerator	Denominator
Prv.22 (NEW)	STIs in PrEP users	Incident STI cases per 100 person- years of follow-up on PrEP	Number of PrEP-recipients identified through syndromic or etiologic approaches as STI cases during reporting period while using PrEP	Total person-years of PrEP during reporting period. <i>Option:</i> Person-time on PrEP contributed by individuals who are lost-to-follow-up can be excluded from the denominator.

Source: WHO, 2022 (1).

- 1. Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240055315, accessed 8 August 2022).
- 2. WHO Guidelines for the management of symptomatic sexually transmitted infections. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240024168, accessed 8 August 2022).

# Annex 4. Main types of pathogens of relevance for people accessing PrEP: ability to treat and modes of transmission

STI	Туре	Curable <sup>a</sup>	Vaginal sex	Anal sex	Oral sex	Skin-to skin	Blood-to- blood	Vertical transmission
Chlamydia trachomatis	Bacteria	Yes	Yes	Yes	Yes	No	Yes, rarely	Yes
Genital herpes simplex virus (HSV)	Virus	No <sup>b</sup>	Yes	Yes	Yes	Yes	No	Yes
Genital mycoplasmas <sup>c</sup>	Bacteria	Yes	Yes, rarely	Yes	No	No	No	Yes <sup>d</sup>
Hepatitis A	Virus	Yes <sup>e</sup>	No	Yes	Yes <sup>f</sup>	No	No	No
Hepatitis B	Virus	Nog	Yes	Yes	Yes, rarely	No	Yes	Yes
Hepatitis C	Virus	Yes	No	Yes	No	No	Yes	Yes
Human papillomavirus (HPV)	Virus	No	Yes	Yes	Yes	Yes	No	Yes
Lymphogranuloma venereum (LGV)	Bacteria <sup>h</sup>	Yes	Yes	Yes	Yes	No	No	No
Neisseria gonorrhoeae	Bacteria	Yes	Yes	Yes	Yes	No	Yes, rarely	Yes
Treponema pallidum (syphilis)	Bacteria	Yes	Yes	Yes	Yes	No	Yes, rarely	Yes
Trichomonas vaginalis	Parasite	Yes	Yes	Yes, rarely	Yes, rarely	No	No	Yes, Rarely

<sup>&</sup>lt;sup>a</sup>See Annex 5 for STI diagnostics and treatment.

- WHO guidelines for the treatment of genital herpes simplex virus. Geneva: World Health Organization; 2016 (https://www.who.int/publications/i/item/978924154987, accessed 29 July 2022).
- 2. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva: World Health Organization; 2015 (https://www.who.int/publications/i/item/9789241549059, accessed 29 July 2022).

bSuppressive therapy for HSV is available (1).

<sup>&</sup>lt;sup>c</sup>M. genitalium, M. hominis and Ureaplasma spp.

dClinical significance unclear.

<sup>&</sup>lt;sup>e</sup>Does not require treatment to be cured.

fDuring oral-anal sex.

<sup>9</sup>For acute hepatitis B there is no specific treatment, and for chronic hepatitis B, suppressive treatment is available (2).

hCaused by a different serovar of C. trachomatis.

# Annex 5. Summary of WHO guidance for testing and treatment for selected pathogens that can be transmitted through sex

Pathogen	Diagnostic tests <sup>a</sup>	WHO recommended first line treatment	Notes
Chlamydia trachomatis	<ul> <li>NAAT (gold standard)</li> <li>Provider-collected or self-sampling of oropharynx; anorectum; and urethra (penis) by swabs or urine (1,2)</li> </ul>	Azithromycin 1 gm orally or Doxycycline 100 mg 2 times/day for 7 days (3)	<ul> <li>Samples for three anatomical sites may be pooled and one diagnostic test run to decrease testing costs (4)</li> <li>For anorectal infection, doxycycline is recommended over azithromycin (3)</li> <li>Doxycycline is contraindicated in pregnancy (3)</li> </ul>
Genital herpes simplex virus (HSV)	• NAAT (gold standard) (2,5)	First clinical episode Acyclovir 400 mg orally 3 times/day for 10 days  Recurrent clinical episodes <sup>b</sup> Acyclovir 400 mg orally 3 times/day for 5 days or Acyclovir 800 mg 2 times/day for 5 days or Acyclovir 800 mg 3 times/day for 2 days (5)	Recurrent clinical episodes that are frequent, severe or cause distress (suppressive therapy) Acyclovir 400 mg orally twice daily (5)
Mycoplasma genitalium	• NAAT (2)	Doxycycline 100 mg orally 2 times/day for 7 days (if resistance testing is not available) (6)	WHO does not have treatment guidelines for infections by genital mycoplasmas
Hepatitis B (HBV)	HBsAg (RDT or lab-based immunoassay) <sup>c</sup> (7)	Considering the complexity of suppressive therapy, please check: WHO Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection (2015) (8)	
Hepatitis C (HCV)	<ul> <li>HCV-antibodies (RDT), including self-testing<sup>c</sup> or lab-based immunoassay</li> <li>Confirmatory testing for presence of active infection (NAAT<sup>c</sup> or core-antigen)</li> <li>(7,9,10)</li> </ul>	WHO recommends the use of the following pangenotypic DAA regimens in adults (18 years and older) and adolescents (12–17 years) with chronic hepatitis C infection:  • Sofosbuvir/daclatasvir for 12 weeks (In those without cirrhosis. Treatment for 24 weeks in those who are treatment-experienced or with compensated cirrhosis)  • Sofosbuvir/velpatasvir 12 weeks  • Glecaprevir/pibrentasvir 8 weeks  (9,11,12)	Pangenotypic regimens as those leading to a rate of sustained virological response >90-95% across all six major hepatitis C genotypes

Pathogen	Diagnostic tests <sup>a</sup>	WHO recommended first line treatment	Notes
Human papillomavirus (HPV)	NAAT <sup>c</sup> Lab-based or near POC test      If NAAT test is not available, use VIA or cytology for the detection of cervical-uterine lesions (pre-cervical cancer)  (13)	No treatment is currently available for HPV infection For lesions, the methods of treatment may be ablative (destroying abnormal tissue by heating it with thermal coagulation or freezing it with cryotherapy) or excisional (surgically removing abnormal tissue with LLETZ or CKC) <sup>d</sup> (13)	<ul> <li>HPV is vaccine preventable</li> <li>VIA should be replaced by NAAT as soon as possible.</li> <li>WHO recommends two approaches for cervical-uterine lesions: <ul> <li>screen-and-treat approach: the decision to treat is based on a positive primary screening test only.</li> <li>screen, triage and treat approach: the decision to treat is based on a positive primary screening test followed by a positive second test (a "triage" test), with or without histologically confirmed diagnosis.</li> </ul> </li> </ul>
Lymphogranuloma venereum (LVG) <sup>e</sup>	NAAT     Provider-collected or self-sampling of anorectum and urethra (penis) by swabs or urine     (2,3)	Doxycycline 100 mg orally 2 times/day for 21 days (3)	When doxycycline is contraindicated, azithromycin 1g orally weekly for 3 weeks is indicated (3).
Neisseria gonorrhoeae	<ul> <li>NAAT (gold standard)         <ul> <li>Provider-collected or self-sampling of oropharynx, anorectum and urethra (penis) by swabs or urine</li> </ul> </li> <li>Culture</li> <li>Gram stain (only for urethral discharge) (2,14)</li> </ul>	Dual Therapy <sup>f</sup> Ceftriaxone 250 mg intramuscularly, single dose PLUS azithromycin 1 g orally, single dose or Cefixime 400 mg orally, single dose PLUS azithromycin 1 g orally, single dose (14)	<ul> <li>Samples for 3 anatomical sites may be pooled to decrease test costs (4).</li> <li>WHO is revising current treatment recommendations and dosages for gonorrhoea due to increasing antimicrobial resistance to azithromycin and reduced susceptibility to cephalosporins.</li> </ul>
Treponema pallidum (syphilis)	Non-treponemal antibody tests:  RPR or VDRL  Treponemal tests:  RDT (single or with HIV) <sup>c</sup> TPPA, FTPA, FTA-ABS, EIA, CIA  Treponemal/Non-treponemal RDT (same platform)  Dual HIV/syphilis RDT <sup>c</sup> Direct detection from lesions (2,15)	Early syphilis <sup>9</sup> Benzathine penicillin G, 2.4 million units, intramuscularly, single dose  Late syphilis or unknown duration <sup>h</sup> Benzathine penicillin G, 2.4 million units, intramuscularly, weekly for 3 weeks (interval not to exceed 14 days)  (15)	<ul> <li>Syphilis in pregnancy</li> <li>Because oral medications against syphilis either do not cross the placenta or are contraindicated (tetracyclines), infection during pregnancy must be treated with parenteral penicillin to avoid adverse pregnancy outcomes, including death or disability</li> <li>Both treponemal and non-treponemal tests should be used to support the diagnosis of active infection</li> <li>Use non-treponemal test to monitor cure (i.e., a four-fold decrease in titres)         <ul> <li>(15)</li> </ul> </li> </ul>
Trichomonas vaginalis	<ul> <li>NAAT</li> <li>Culture (from urethral or vaginal discharge)</li> <li>RDT</li> <li>(2)</li> </ul>	• For men: Metronidazole 500 mg 2 times/day for 7 days • For women: Metronidazole 2 g orally in a single dose (6,16)	There is insufficient evidence for testing extragenital sites

Notes: CIA: treponemal chemiluminescence immunoassay; CKC: conization of cervix; DAA: Direct acting antivirals; EIAs: enzyme immunoassays; FTA-ABS: fluorescent treponemal antibody absorption test: direct immunofluorescence assay; FTPA: *T. pallidum* hemagglutination; HBsAg: hepatitis B surface antigen; LLETZ: large loop excision of the transformation zone; NAAT: nucleic acid amplification test; POC: point-of-care; RDT: rapid diagnostic test; RPR: rapid plasma reagin; TPPA: *T. pallidum* passive particle agglutination VDRL: Venereal Disease Research Laboratory; VIA: visual inspection with acetic acid.

<sup>a</sup>Only most used tests are listed. For information on other tests, check WHO laboratory manual for the diagnosis of STIs (2).

<sup>b</sup>Treatment should be given within the first 24 hours of the onset of symptoms or during the prodromal phase (i.e., prodromal symptoms can include feelings of a tingling or itching sensation in the oral or genital regions between 30 minutes to two days before the next outbreak occurs).

These tests are prequalified by WHO. See: https://extranet.who.int/pqweb/vitro-diagnostics/prequalification-reports/whopr.

dBefore treatment of cervical—uterine lesions, a positive screen test with any test other than VIA should be visually inspected with acetic acid by a trained health care worker to determine eligibility for ablative therapy.

<sup>e</sup>Caused by a different serovar of *C. trachomatis*.

fRecommended by WHO for countries without an antimicrobial resistance (AMR) surveillance system in place to guide national treatment guidelines.

gEarly syphilis: primary, secondary and early latent syphilis of not more than two years' duration.

<sup>h</sup>Late syphilis: infection of more than two years' duration.

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#### For more information, contact:

World Health Organization Global HIV, Hepatitis and STIs Programmes 20, avenue Appia 1211 Geneva 27 Switzerland

E-mail: hiv-aids@who.int

www.who.int/hiv

