



Decision-Making Guide for the Provision of PrEP Services in Title X-Funded Family Planning Service Sites

HHS Office of Population Affairs



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Disclaimer

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Introduction

U.S. Office of Population Affairs and the Title X Family Planning Program

As the only federal program dedicated solely to providing family planning and related preventive health services, the Title X program serves approximately four million individuals each year. Title X service delivery is based on *Providing Quality Family Planning Services: Recommendations of the Centers for Disease Control and Prevention (CDC) and the U.S. Office of Population Affairs (OPA)* and includes a range of services related to preventing or achieving pregnancy, such as contraceptive services, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, and other preconception health services. Title X also funds activities to train family planning clinic personnel, conduct research and evaluation to improve service delivery within Title X and the broader reproductive health care field, and develop and disseminate information to communities.

Title X-funded agencies are also required to provide sexually transmitted disease (STD) services, including HIV/AIDS prevention education and testing. Pre-exposure prophylaxis (PrEP) has emerged as an effective HIV prevention strategy for individuals who are most at risk, and the inclusion of PrEP in the HIV prevention services provided at Title X sites is becoming an increasingly important method for protecting individuals of all ages from acquiring HIV. **The purpose of this resource guide is to help Title X-funded family planning service sites make evidence-informed decisions about their role in assuring access to PrEP services in their communities.**

Why PrEP?

PrEP has been advanced as a critical prevention strategy for people at substantial risk for HIV infection. The medication, a once-a-day pill (brand name Truvada), has been demonstrated to reduce the risk of HIV infection up to 92 percent, when taken as directed.¹

According to CDC, approximately 180,000 sexually active U.S. women of reproductive age (18 – 49 years) are potential candidates for PrEP.² **However, awareness and uptake of PrEP among women at risk for HIV has been limited.** Between 2012 and 2015, PrEP uptake in the U.S. increased significantly among men, while the number of women starting PrEP remained steady.³ Additionally, while HIV disproportionately affects African-American and Hispanic/Latina women, PrEP initiation among women of color has been significantly lower than among white women.⁴

CDC recommends PrEP counseling for individuals at substantial risk for HIV.⁷ Women at substantial risk for HIV are defined as those who are sexually active, not in a monogamous partnership with a recently tested HIV-negative partner, and at least one of the following:

- In an ongoing sexual relationship with an HIV-positive partner
- Recent bacterial sexually transmitted infection (syphilis and/or gonorrhea)
- History of inconsistent or no condom use with partners of unknown HIV status known to be at substantial risk for HIV
- Engage in exchange sex, injection drug use, or live in a high-prevalence area or network

Barriers to PrEP uptake among women in the U.S. include:^{5,6}



Limited knowledge about PrEP for HIV prevention



Stigma associated with HIV



Reluctance to discuss risk behaviors with providers to avoid judgment



Cost of PrEP

Title X family planning sites are a primary source of care for many women and served approximately 3.5 million women in 2017.⁸ Family planning providers have extensive experience providing sexual and reproductive health counseling, education, and services and are exceptionally qualified to provide HIV prevention services to women while incorporating clients' health goals into individual health care decisions.⁹ Studies also show that women consider family planning sites a preferred source for information about PrEP and access to PrEP services.¹⁰ Title X sites have a key opportunity to address gaps in PrEP awareness and access among women by integrating PrEP services into existing HIV prevention services, which often include HIV and STD prevention education, testing and referral, risk reduction counseling, and behavioral interventions, such as condom use promotion and post-exposure prophylaxis (PEP).

23%

Almost one-quarter of all people living with HIV in the U.S. are women.

20%

Women accounted for approximately 20% of new HIV infections in the U.S. in 2016; 77% of the women were African American or Hispanic/Latina.

68%

Of the approximately 258,000 heterosexually active U.S. adults who are eligible for PrEP, 68% are women.

Decision-Making Guide for the Provision of PrEP Services

Development of the Decision-Making Guide

To address the disparities in PrEP prescribing and uptake among women, OPA developed the *Decision-Making Guide for the Provision of PrEP Services in Title X-Funded Family Planning Service Sites* to assist in **organizational decision-making for leadership at Title X service sites who are considering beginning to offer PrEP services, considering offering a higher level of PrEP services, or unsure about offering PrEP services.** While this guide was initially intended to inform decision-making within Title X-funded agencies, the following considerations may also be applicable for other settings where family planning services are offered. Users of this guide are encouraged to revisit the *Decision-Making Guide* periodically to account for changes in organizational capacity and need for PrEP services within their service areas.

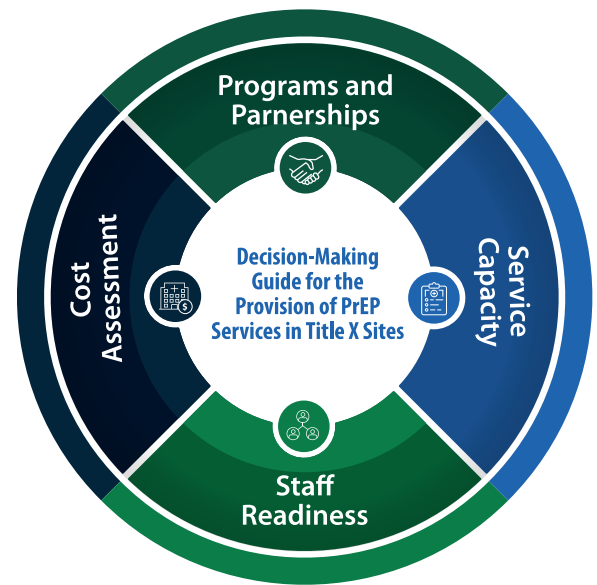
The *Decision-Making Guide* was informed by the best-available research and real-world experience in a 4-step process:

- Thoroughly analyzed peer-reviewed literature on PrEP implementation, barriers and facilitators to PrEP adoption, and challenges for PrEP implementation within the family planning context.
- Conducted key informant interviews with family planning clinic administrators across the U.S.—both in urban and rural service areas—to assess the level of PrEP service provision, capacity, and resources for offering PrEP services and the challenges and benefits of PrEP implementation.
- Convened a Technical Expert Panel to review and provide critical external feedback on the *Decision-Making Guide*.
- Implemented a pilot project to test the usefulness and applicability of the *Decision-Making Guide* among Title X services sites across the U.S.

How to Use This Guide

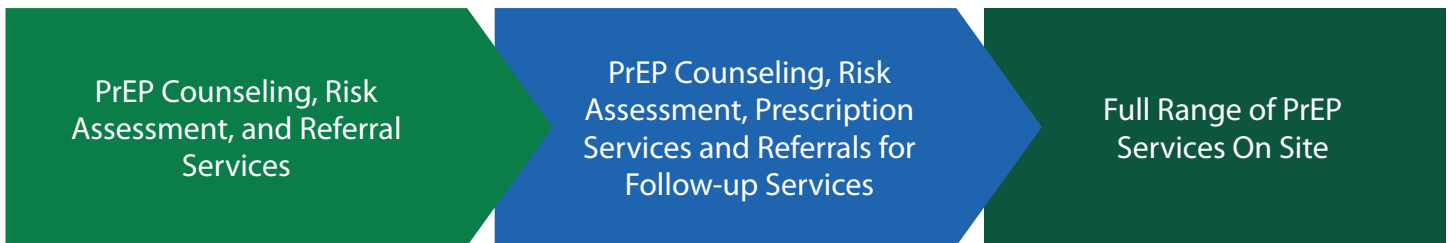
Key Decision-Making Factors

The guide enables Title X sites to consider the key factors for PrEP provision and allows flexibility for sites to make decisions based on their unique contexts. Each section of the guide is based on the four key decision-making factors—PrEP Programs and Partnerships, Service Capacity, Staff Readiness, and Cost Assessment—and features an interactive worksheet to document notes and action items. After reviewing each section of the guide, Title X sites should review the *Decision-Making Checklist*, an organizational assessment tool included in this guide for Title X sites to assess the appropriate level of PrEP service provision for their site. **Title X sites are encouraged to make PrEP service provision decisions that fit their specific context, capacity, and needs.**



Tiers of PrEP Service Provision

The *Decision-Making Checklist* suggests three tiers of PrEP service provision:



- **PrEP Counseling, Risk Assessment, and Referral Services:** Offering referral services for PrEP includes providing counseling to clients and conducting an initial assessment of clients' risk for HIV. Referral services may range from maintaining a resource list of PrEP providers in the area to offering a "warm-handoff" to a local PrEP provider. Title X sites offering PrEP referral services are a key link to services and ensure eligible clients know how and where to access additional PrEP-related care.
- **PrEP Counseling, Risk Assessment, Prescription Services, and Referrals for Follow-Up Services:** In this service model, a Title X site may start a client on PrEP by providing counseling to clients, assessing clients' risk for HIV, conducting baseline laboratory tests, and writing the prescription for the medication. The Title X provider then refers the client out for follow-up services, such as to a primary care provider.
- **Full Range of PrEP Services On Site:** The final service level is offering the full range of PrEP services on site, to include counseling, risk assessment, and baseline laboratory tests for PrEP as well as writing prescriptions and conducting follow-up visits on site. At both the second and third tiers, Title X sites should be prepared to also offer offsite referrals, based on client preferences for accessing services.

While reviewing this guide, **Title X sites should consider their current level of PrEP service provision, if any, and the resources required to provide a level of service that assures access to PrEP services in their communities.** For example, many Title X sites offer PrEP counseling and education services. For those sites, this guide may be a useful tool for considering how to offer add-on services, such as referrals for PrEP or onsite PrEP services.

PrEP Programs and Partnerships

Understanding the existing PrEP programs and organizational partners in a Title X site's service area is integral to understanding the local need for PrEP service provision.



Ask while reading this section: Do the existing local PrEP programs sufficiently meet the need of our family planning clients and the needs of the community?

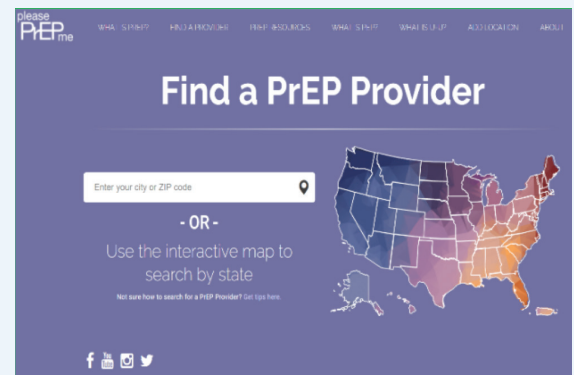
Existing PrEP Programs in the Service Area



Assessing the existing PrEP programs in the service area can help a Title X site understand whether there is a local need for PrEP service provision. In some areas, comprehensive PrEP service programs may already be in place. Neighboring family planning clinics, health centers, state or local health departments, and other community organizations may offer PrEP medication and other related services, including assessment of HIV risk, HIV and PrEP education services, HIV and STD testing, financial counseling for PrEP, or PrEP adherence counseling and risk reduction support. In areas where the existing PrEP service provision programs sufficiently meet the local need for PrEP, Title X sites may leverage partnerships to ensure PrEP services are available and accessible for all potential clients via referral services.

An assessment of the local existing PrEP programs may highlight a service gap and an opportunity for a Title X site to fill that gap in the community.

Local health centers may not offer PrEP medication, or the services may not be tailored to the needs of Title X clients. For example, in areas where PrEP services are available in HIV-related treatment centers or health centers tailored to LGBTQ clients, a service gap may still exist for clients who prefer accessing HIV prevention services within a family planning site where reproductive health services are integrated and clients are more comfortable discussing sexual risk behaviors in a familiar setting.¹¹ In areas where there are limited or no existing PrEP service programs, Title X sites may be ideal PrEP providers for their clients.





***PleasePrEPMe.org** and **PrEPLocator.org** are two searchable location-based PrEP provider directories for identifying local PrEP programs.*

Current and Potential Organizational Partnerships



Partnerships with outside organizations present valuable opportunities for collaboration, whether your site decides to offer PrEP services on site or via referral. Community partners, including local public health departments, community-based organizations, and other key stakeholder agencies, may offer PrEP services or serve as referral partners, help link high-risk clients to services at the Title X site, provide PrEP service training to Title X providers, or offer financial resources to support the clinic's PrEP activities. PrEP decision-making in Title X sites includes an evaluation of current and potential partners and their roles in maximizing the impact of local HIV prevention efforts.

Applying PrEP Programs and Partnerships at My Title X Site

 PrEP-ING FOR PrEP	 NOTES
<ul style="list-style-type: none"> ✓ Identify the local PrEP providers in your service area by visiting PleasePrEPMe.org and PrEPLocator.org. ✓ Ask the following questions at your site: <ul style="list-style-type: none"> • Do the local PrEP providers in the area meet the needs of our family planning clients? Are the programs in an accessible location for our clients? • Are the local PrEP providers accepting new clients? Are the programs friendly to all new clients, including women or uninsured clients? • Does our Title X site have partnerships with the local PrEP providers? For example, do any of the local health centers in our health system offer PrEP services? ✓ Reach out to local PrEP providers in your area to find an organization who is willing to “mentor” your site as you plan for PrEP services. ✓ List your current and potential partners who may provide assistance for your PrEP program by linking high-risk clients or offering financial resources, for example. 	
<p><i>Use the Decision-Making Checklist at the end of this Guide to assess your site's readiness for PrEP and find your suggested level of PrEP service.</i></p>	<div data-bbox="727 1472 789 1535"></div> SITE SPOTLIGHT <p>A Title X site partnered with the HIV Clinical Services Unit in their county health department to offer PrEP via electronic referrals. After providing PrEP counseling and risk assessment, the Title X clinician used the shared electronic medical record to communicate referral information with the HIV specialist. The service model enhanced coordination between clinics and streamlined care for clients.</p>

Service Capacity

Title X sites should assess their service capacity for offering PrEP services, including examining the site's unique structural and functional qualities that may influence PrEP service capacity.



Ask while reading this section: Does our Title X site have the **service capacity** to assess client's HIV risk, perform laboratory tests, prescribe PrEP and conduct follow-up visits?

PrEP Services Within a Framework of Comprehensive STD Services



PrEP is a part of comprehensive HIV and STD prevention services, including education, testing and treatment, and risk reduction counseling. Title X sites can build on the framework of services already in place to incorporate PrEP services. For example, your site may consider incorporating PrEP education into your current STD education and testing services or adapting your site's standard procedures for STD treatment referrals for referral services for PrEP. Title X sites may also consider building on, or beginning to offer, patient navigation services to assist with linking patients to financial resources for PrEP.

Engagement of Clients in PrEP Services



Title X sites should consider the site's ability to assess client risk for HIV, conduct appropriate laboratory tests to determine clinical eligibility for PrEP, prescribe PrEP medication or offer referrals, and provide follow-up services to clients. CDC publishes [comprehensive clinical practice guidelines for the use of PrEP](#) for HIV prevention. The link to the CDC guidelines is included at the end of this guide in the Resources List.

- **Assess client risk for HIV.** CDC recommends individuals at substantial risk of HIV be counseled on PrEP. In clinical decision-making, Title X sites should consider the HIV and STD prevention needs of the client population. A site's STD testing data, including the number of confirmed HIV cases in recent years, may serve as an indicator of the need for HIV prevention in the community. Local HIV and STD data may also be available through state and local data sources, such as a local health department. An additional helpful resource is AIDSVu.org, which features interactive county- and city-level HIV data, dynamic maps, and local health profiles.

Regardless of the HIV-related surveillance data, a site's client population may include individuals who are at substantial risk of HIV and may benefit from access to additional prevention services. It is important that family planning providers understand clients' individual HIV prevention needs and reproductive intentions, and counsel clients on risks and benefits of PrEP including the importance of medication adherence.

- **Conduct appropriate laboratory tests.** Clinicians should also conduct a series of laboratory tests to determine clinical eligibility for potential and returning PrEP candidates.



Local HIV data is a useful tool for making organizational decisions, gaining buy-in and informing processes for offering PrEP services.

Local STD data is also important for PrEP decision-making and understanding the local HIV risk. Recent data suggests that **women with a history of gonorrhea** are 5x as likely to acquire HIV; **Women with a history of syphilis** are 20x as likely to acquire HIV.¹² STD education and testing are key opportunities to talk about PrEP!

CDC Guidelines for PrEP-Related Laboratory Testing Capabilities (2017)

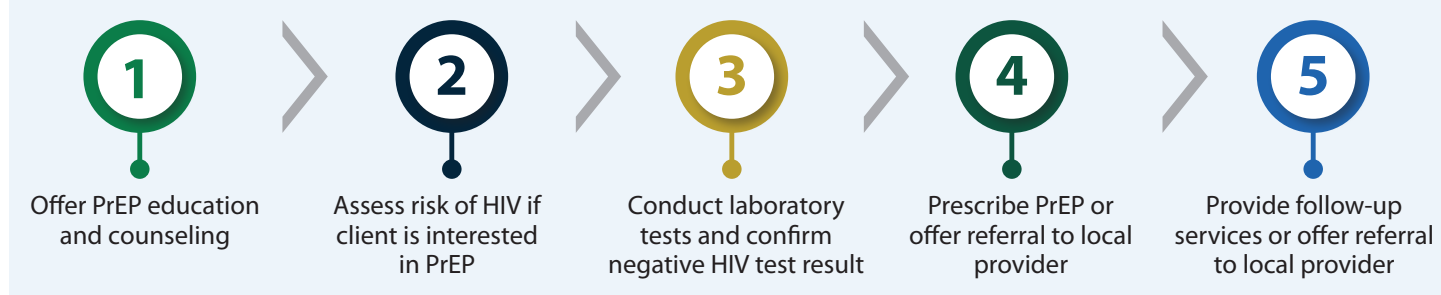
Laboratory Test	Timeframe	Additional Information
HIV test	Prior to prescribing PrEP and at least every three months after starting PrEP (and, before refilling a PrEP prescription)	<ul style="list-style-type: none"> HIV testing and the documentation of results are required to confirm that patients do not have HIV infection when they start taking PrEP medication. Clinicians should document a negative antibody test result within the week before initiating (or reinitiating) PrEP medications, ideally with an antigen/antibody test conducted by a laboratory. The required HIV testing can be accomplished by 1) drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test or antibody-only test or 2) performing a rapid, point-of-care, FDA-approved, finger stick blood test. Rapid tests that use oral fluid should not be used to screen for HIV infection when considering PrEP use because they can be less sensitive than blood tests. Clinicians should not accept patient-reported testing results or documented anonymous test results.
Renal function	Prior to prescribing PrEP and at least every six months after starting PrEP	<ul style="list-style-type: none"> A clinician should determine renal function and test for infection with hepatitis B virus (HBV) because both decreased renal function and active HBV infection are potential safety issues for the use of TDF/FTC (or Truvada®) as PrEP. For all persons considered for PrEP, a serum creatinine test should be done, and an estimated creatinine clearance (eCrCl) should be calculated using the Cockcroft-Gault formula. Any person with an eCrCl of <60 ml/min should not be prescribed PrEP with TDF/FTC.
Hepatitis serology	Prior to prescribing PrEP	<ul style="list-style-type: none"> HBV infection status should be documented by screening serology before TDF/FTC is prescribed as PrEP. Those patients determined to be susceptible to HBV infection should be vaccinated. Hepatitis C virus (HCV) infection testing is recommended for MSM and all sexually active persons starting PrEP.
Screening for sexually transmitted infections (STI)	<p>Prior to prescribing PrEP</p> <p>Every three months for sexually active persons with signs and symptoms of infection and MSM at high risk for recurrent bacterial STIs</p> <p>Every six months for sexually active adolescents and adults even if asymptomatic</p>	<ul style="list-style-type: none"> Tests to screen for syphilis are recommended for all adults prescribed PrEP, both at screening and at semi-annual visits. Tests to screen for gonorrhea are recommended for all sexually active adults prescribed PrEP, both at screening and at semi-annual visits. Tests to screen for chlamydia are recommended for all sexually active MSM prescribed PrEP, both at screening and at semi-annual visits. Because chlamydia is very common, especially in young women and does not strongly correlate with risk of HIV acquisition, regular screening for chlamydia is not recommended for all sexually active women as a component of PrEP care. Clinicians should refer to the 2015 STD guidelines for recommendations about chlamydia testing frequency for women regardless of PrEP use.
Baseline pregnancy test	Every three months for women who may become pregnant	<ul style="list-style-type: none"> If a woman is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss with her the known risks and benefits of continuing and discontinuing PrEP, and the effects of Truvada on a newborn.

- **Prescribe PrEP medication or offer referral.** After assessing HIV risk, conducting appropriate laboratory tests, and confirming that clients starting PrEP do not have HIV infection, clinicians can prescribe PrEP for clients or offer referral for PrEP, depending on the Title X site's PrEP service model. The medication currently approved by the FDA for PrEP is a single daily dose of tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC) (brand name: Truvada). Identifying clinic staff to act as case managers or patient navigators is especially useful for linking uninsured and underinsured clients to resources for accessing PrEP. Title X sites should also consider partnering with pharmacies to ensure that clients have access to the PrEP medication. In some cases, a local pharmacy may regularly stock PrEP medication and therefore may understand the financing mechanisms for PrEP. In other cases, Title X sites should consider developing a working relationship with a local pharmacy to ensure client access to the medication.

- **Provide follow-up services:** PrEP efficacy is highly dependent on adherence. Title X sites should consider their ability to provide follow-up services at least every three months to support PrEP adherence, assess client HIV status, and promote risk reduction. PrEP providers should also be able to advise clients when to discontinue PrEP use (e.g., lowered risk for HIV infection, continual nonadherence, signs and symptoms of seroconversion, personal client choice).⁷ Activities to promote proper use of PrEP medication include:
 - » Engaging with client's primary care provider.
 - » Scheduling frequent follow-up visits.
 - » Assigning clinic staff person(s) to act as case manager or patient navigator to actively remind clients of follow-up.
 - » Providing condoms at every clinic visit and discussing use of effective contraception.
 - » Contacting the pharmacy to confirm PrEP medication is regularly stocked and does not need a prior authorization.
 - » Referring clients to relevant support groups.
 - » For serodiscordant couples, recommending treatment for the HIV-infected partner.
 - » For injection drug users, offering referrals to substance use treatment and needle-exchange programs.

Process for Offering PrEP Services

Many components of offering PrEP may be integrated into a client's family planning visit or STD testing visit.






Performance Measures for PrEP Services



Prior to implementing PrEP services, Title X sites should consider adopting performance measures to assess the success of service implementation. These may include process, quality, or outcome-related measures. Performance measures may also help sites identify service gaps and opportunities to move along the PrEP service continuum. For example, a Title X site may find a high percentage of its at-risk clients who received PrEP counseling ultimately started PrEP at another health center. This may indicate an opportunity for the Title X site to establish referral partnerships with local PrEP providers or consider prescribing PrEP medication on site. The following organizational, clinical, and patient-level indicators are a sample of measures your site may consider using:^{7,13}

- » Percentage of clients who received PrEP counseling and education services.
- » Percentage of clients screened for PrEP services and at significant risk for HIV who began medication.
- » Percentage of PrEP clients who attended scheduled follow-up visits at 3, 6, 9, and 12 months.
- » Percentage of PrEP clients reporting proper adherence to medication and duration of PrEP use.
- » Percentage of PrEP clients (taking the medication for more than one month) who seroconvert.
- » Percentage of PrEP clients choosing to discontinue medication.

Applying Service Capacity at My Title X Site

 PrEP-ING FOR PrEP	 NOTES
<ul style="list-style-type: none"> ✓ Review the local HIV and STD data within your Title X site and service area to understand the risk of HIV and need for PrEP. ✓ Identify existing opportunities to incorporate PrEP services at your Title X site. For example, consider incorporating PrEP education into your HIV and STD education and testing services. ✓ Ask the following questions at your site: <ul style="list-style-type: none"> Is our Title X site able to: <ul style="list-style-type: none"> • Assess clients risk for HIV? • Conduct appropriate laboratory tests for potential and returning PrEP clients? • Prescribe PrEP medication on site or offer referrals for PrEP prescriptions to a local PrEP provider? • Provide regular follow-up services for PrEP clients at least every three months or offer referrals for follow-up services? 	
<p>✓ Consider the performance measures your Title X site will use to evaluate your PrEP program.</p> <p><i>Use the Decision-Making Checklist at the end of this Guide to assess your site's readiness for PrEP and find your suggested level of PrEP service.</i></p>	<div data-bbox="732 1388 1024 1444">  SITE SPOTLIGHT </div> <p>A Title X site used performance measures to identify gaps in PrEP awareness and access among its clients. Using demographic information, the site determined that the majority of clients offered and prescribed PrEP identified as male. This prompted staff trainings on PrEP for women and transgender individuals. It also presented an opportunity for clinic leadership to identify and assess additional barriers to PrEP services among clinicians, in the health centers, and in the community.</p>

Staff Readiness

Staff readiness factors are related to leadership, clinicians and staff within the clinic and involve identifying and understanding the level of readiness for PrEP service implementation.



Ask while reading this section: Does our site have adequate **staff capacity** for PrEP service implementation? How can our site access training resources for PrEP?

Support of Clinic Leadership



Leadership support within Title X sites is vital to successful PrEP service implementation and sustainability. Engaged and supportive leadership influences agenda-setting, reinforces priorities, and promotes readiness for implementation and integration across services.^{14,15} Leadership must be committed to planning and implementation activities for providing services, directing resources (e.g., staff resources, including training and financial resources) to PrEP service programs, and overcoming initial barriers to service implementation. Pointing to other health centers and organizations who have successfully implemented PrEP programs may be helpful in garnering leadership support.¹⁵

Staff Resources for PrEP Service Provision



Staff capacity. Title X sites must have adequate staffing and sufficient staff time to implement PrEP services. Linking PrEP programs to existing HIV prevention services at your Title X site can help providers and staff who are accustomed to counseling and testing for HIV skillfully offer PrEP as an additional service for clients.¹⁶ Title X sites may also consider various service models and types of staff who may be involved, including clinicians, counselors, health educators, patient navigators, financial counselors, and pharmacists, as a way to reduce clinician burden and costs.¹⁶ For example, ancillary staff can serve as PrEP patient navigators by assisting with initial PrEP counseling, lab work, financial paperwork, or other non-provider specific tasks.

Staff buy-in. Like other clinical services, clinician and staff support for PrEP services is a key factor for service provision. Knowledgeable providers and staff with favorable attitudes are integral to a clinic's successful service implementation. For example, try gauging provider and staff attitudes toward PrEP by asking whether they believe HIV prevention and PrEP education are essential parts of a family planning visit.¹⁷ Staff training and standardized PrEP screening tools to identify PrEP candidates may also help mitigate implementation challenges.⁷

Staff training. Title X sites should consider staff training needs for PrEP service provision. Clinical staff should be aware of the importance of PrEP for HIV prevention, indications for PrEP use, prescribing considerations (e.g., when to initiate treatment, awareness of toxicity concerns), and culturally appropriate ways to approach risk reduction counseling. All non-clinical staff should also receive training on PrEP, with a tailored approach to individual job functions. For example, billing staff should be provided information



Do you have a **PrEP champion** at your site?

A PrEP champion, who is passionate and committed to the cause, may be a powerful advocate who engages other clinic staff around service provision and helps articulate the benefits of setting up a PrEP program.

on the financial considerations on PrEP, and front-desk staff should be aware that PrEP is offered in the clinic and trained on culturally competent ways of interacting with potential and returning PrEP clients.

Training topics may include:

- » Identification of clients who may benefit from PrEP.
- » Culturally sensitive HIV risk reduction and PrEP counseling.
- » Initial and follow-up visit protocols for clients using PrEP to monitor for adherence and side effects.
- » Common comorbidities and other prescribing considerations.
- » Billing procedures and any internal policies regarding referrals or prescription.

Clinicians at your Title X site who are knowledgeable about PrEP services may be a resource for in-house trainings.

Additionally, local PrEP providers in your area, state or local health departments, and other community organizations and partners may be willing to offer in-person PrEP trainings at your site. Several online training resources also exist for PrEP service implementation, such as webinars, pamphlets, and fact sheets. Review the Resources List to find links to helpful training resources.



*The **AIDS Education and Training Center Program**, funded by the Health Resources and Services Administration (HRSA), provides clinical consultation and technical assistance to integrate HIV care along the continuum, including PrEP services. This training resource, along with several other helpful tools, may be found in the Resources List.*



Medical Assistants or Nursing Assistants may:

- Provide PrEP education and counseling
- Assist with lab screenings for new and returning PrEP clients
- Offer risk reduction counseling and resources



Patient Navigators or Health Educators may:

- Provide PrEP education and counseling
- Assist PrEP clients in identifying a local pharmacy to fill a prescription
- Link clients to financial resources to cover the costs of PrEP






Clinical Pharmacists may:

- Conduct laboratory screenings for new and returning PrEP clients
- Prescribe PrEP medication
- Provide follow-up services for PrEP clients
- Offer in-house PrEP trainings

Various clinicians and staff may play an important role in your Title X site's PrEP program.

Applying Staff Readiness at My Title X Site

 PrEP-ING FOR PrEP	 NOTES
<ul style="list-style-type: none"> ✓ Talk to clinic leadership about interest in offering PrEP services. ✓ Identify a PrEP champion to engage leadership, clinicians and staff around PrEP services. ✓ Consider innovative service delivery models that involve various staff. ✓ Ask the following questions at your site: <ul style="list-style-type: none"> – Who are the clinicians at my site who would be involved in implementing PrEP services? What training would they need? – Who are the staff at my site who would be involved in implementing PrEP services? What training would they need? ✓ Identify training opportunities for clinicians and staff to learn about PrEP service delivery. Potential resources for training include: <ul style="list-style-type: none"> – In-house trainings, if there is a clinician who can provide training. – State and local health departments. – Existing PrEP providers in your area. – Online training resources, including the Family Planning National Training Center and National Clinical Training Center for Family Planning. <p><i>Use the Decision-Making Checklist at the end of this Guide to assess your site's readiness for PrEP and find your suggested level of PrEP service.</i></p>	<div data-bbox="792 1381 1524 1457">  SITE SPOTLIGHT </div> <p>A Title X site implemented PrEP on site by involving family physicians and clinical pharmacists in service implementation. Clients interested in PrEP establish care with a family physician, who sends an electronic referral to the clinical pharmacists. The pharmacists determine the appropriateness of PrEP for the client, conduct labs, help with financial assistance navigation, provide the drug, and complete 3-month follow-up visits with clients.</p>

Cost Assessment

PrEP is a cost-effective HIV prevention strategy at the population level, especially when directed toward the populations at highest risk and in areas with high HIV prevalence.¹⁸⁻²² Nonetheless, the costs of PrEP services for the client and the site are important for Title X sites to consider.



Ask while reading this section: Is our Title X site able to **access resources to assess and manage PrEP service costs** for the site and clients?

Considering Costs to the Client



Coverage for client costs is an important consideration for Title X sites offering PrEP services.

Financial counseling and other client resources for accessing low- or no-cost PrEP medication may help minimize barriers to care and increase patient adherence to the medication. Private insurance companies often cover PrEP medication, clinic visits, and lab work; some plans may require co-payments or other cost-sharing mechanisms. Publicly funded programs, such as Medicaid, Medicare, and state and local government programs, may also offer financial assistance to cover expenses associated with PrEP. There are several resources available to help Title X sites evaluate the cost of PrEP services and potential coverage scenarios for clients found in the Resources List at the end of this guide.

Prescription assistance programs can help reduce the cost of PrEP for clients.

The Gilead Advancing Access Program assists clients without insurance or prescription drug coverage to offset PrEP medication costs. For eligible commercially insured individuals, Gilead offers a co-pay assistance program to offset out-of-pocket costs up to \$7,200 annually. Clients enrolled in government health care programs, such as Medicaid, Medicare (except those without prescription coverage), or other federal and state prescription drug programs, are not eligible for the co-pay program. For uninsured individuals, the Gilead Medication Assistance Program provides free medication for those who qualify based on financial need. The Patient Advocate Foundation's Co-Pay Relief Program assists clients with private insurance living below 400% of the Federal Poverty Level (FPL) with out-of-pocket co-pays for PrEP medication up to \$7,500 per year. Title X sites may find it useful to identify staff who can assist clients with accessing the available financial resources for PrEP.

State and local prescription assistance programs can help reduce the cost of PrEP for clients, such as the Washington State PrEP Assistance Program, the New York Department of Health PrEP-AP, and the Illinois PrEP Assistance Program.






Considering Costs to the Site



Costs to the site may include staff time for training and service delivery, as well as medication and lab services not covered by the client.

Innovative service delivery models and free training resources may help offset costs to the site. The **340B Drug Pricing Program** may assist with discounted medication and related medical supplies. Certain qualifying safety-net providers, including FQHCs and specialized clinics, such as STD clinics and Title X-funded family planning clinics, are eligible to participate and receive discounts on eligible outpatient medications, and subsequently provide medications to eligible clients, regardless of payer status. National Alliance of State and Territorial AIDS Directors (NASTAD) also offers a **Billing Coding Guide for HIV Prevention: PrEP, Screening, and Linkage Services**, which describes various scenarios for PrEP provision and the corresponding CPT and ICD-10 diagnosis codes for filing a claim with the client's insurance company or government payer. This resource and others may be found in the **Resources List** at the end of this guide.

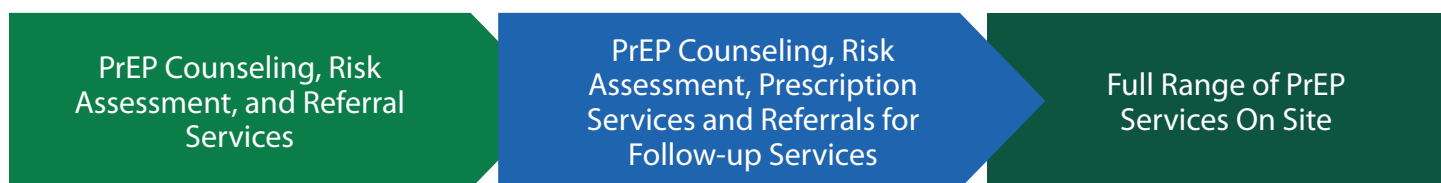
Applying Cost Assessment at My Title X Site

 PrEP-ING FOR PrEP	 NOTES
<ul style="list-style-type: none"> ✓ Assess the cost of PrEP services for your Title X site and clients. Available resources are listed at the end of this guide in the Resources List. ✓ Talk to billing staff, or others at your Title X site familiar with funding, about existing grants or financing programs for PrEP. ✓ Identify state and local PrEP financing mechanisms for your site. Identify state and local prescription assistance programs for your clients. ✓ Ask the following questions at your site: <ul style="list-style-type: none"> – Who at our site can assist clients with accessing available financial resources for PrEP? What training would staff need to help clients apply for financial assistance or enroll in insurance programs? – What resources does our site need to provide to clients to help them access financial resources for PrEP? 	
<p><i>Use the Decision-Making Checklist at the end of this Guide to assess your site's readiness for PrEP and find your suggested level of PrEP service.</i></p>	 SITE SPOTLIGHT
	<p>A Title X site placed strong emphasis on the availability of financial counselors within their onsite PrEP service model. The robust financial counseling program to assist and counsel clients through options for covering the medication was described as integral to their PrEP service implementation.</p>

Decision-Making Checklist for the Provision of PrEP Services in Title X Sites

The *Decision-Making Checklist* is an organizational assessment tool to determine your Title X site's position as it relates to the key decision-making factors covered in this guide: PrEP Programs and Partnerships; Service Capacity; Staff Readiness; and Cost Assessment. **Now that you have read the Decision-Making Guide, complete the Decision-Making Checklist to assess your site's readiness for PrEP services. Review each criteria in the checklist and select the appropriate readiness level (Low, Medium, or High) for your site.** Total the number of checkmarks for each readiness level and use the tips below to find the suggested level of PrEP service provision for your site.

Criteria	Low	Medium	High	Additional Considerations
PrEP Programs and Partnerships				
Need for PrEP services unmet by existing local PrEP programs				
Service Capacity				
Ability to offer full range of PrEP services on site (i.e., counseling, risk assessment, laboratory tests, prescription and follow-up visits)				
Staff Readiness				
Leadership and staff buy-in for in-house PrEP implementation				
Staff capacity to provide PrEP services				
Cost Assessment				
Access to resources to assess and manage PrEP service costs for the site and clients				
Total				n/a



Title X sites are encouraged to make PrEP service provision decisions that fit the specific needs of the site.

After completing the checklist for your Title X site, if you:

- **Answered mostly lows**→ Consider offering PrEP services via **referrals to a partnering service provider** and begin planning and implementation activities for referral services.
- **Answered mostly mediums**→ Consider offering **PrEP counseling, risk assessment, and prescription services on site with offsite referrals for follow-up services** and begin planning and implementation activities for service provision.
- **Answered mostly highs**→ Consider offering the **full range of PrEP services onsite** and begin planning and implementation activities for service provision.

Conclusion

As leaders in sexual and reproductive health care, Title X sites play a key role in assuring access to PrEP services in their communities and are in a prime position to address the disparities in PrEP awareness and access among women. Given PrEP's effectiveness as an HIV prevention tool, many Title X sites have already begun to integrate PrEP services into their existing HIV prevention strategies. This *Decision-Making Guide* is a key resource for those Title X sites contemplating the appropriate level of PrEP services to offer in their sites to consider the key decision-making factors:

- **PrEP Programs and Partnerships:** Do the existing PrEP programs sufficiently meet the need of the site's family planning clients, and the larger community?
- **Service Capacity:** Does the site have the service capacity to assess HIV risk, perform laboratory tests, prescribe PrEP, and conduct follow-up visits?
- **Staff Readiness:** Does the site have adequate staff capacity for PrEP service implementation? How can the site access training resources for PrEP?
- **Cost Assessment:** Is the site able to access resources to assess and manage PrEP service costs for the site and clients?

Throughout the *Decision-Making Guide*, Title X sites are prompted to consider their current level of organizational readiness across the four key decision-making factors to decide on the appropriate level of PrEP service provision: offer PrEP counseling, education, and referral services; offer PrEP counseling, education, and PrEP prescription services with referrals for follow-up services; and offer the full range of PrEP services on site. Suggested resources, tools, and solutions to increase the site's capacity to offer PrEP services are offered throughout the *Decision-Making Guide*, and additional resources are included in the **Resources List** on the following page.



**Ready to
Decide on
PrEP!**

Now that you have read the *Decision-Making Guide*, **complete the *Decision-Making Checklist*** (found on page 15) to assess your site's readiness for PrEP service in each of the four key areas and find the suggested level of PrEP service for the site! Title X sites are encouraged to make PrEP service provision decisions that fit the specific needs of their sites.

When your site is ready to begin planning and implementing your PrEP program, remember to visit the [Family Planning National Training Center](#) website, the [National Clinical Training Center for Family Planning](#) website, and the [Family Planning Provider PrEP Toolkit](#) for additional PrEP training and implementation resources!

Resources List

The following resources may help inform decision-making and implementation of PrEP services in Title X-funded agencies.

Clinical Guidelines for PrEP

- [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States - 2017 Update Clinical Practice Guideline](#): U.S. Public Health Service and Centers for Disease Control and Prevention
- [Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2017 Update Clinical Providers' Supplement](#): U.S. Public Health Service and Centers for Disease Control and Prevention

Implementation and Training Resources

- [Family Planning Provider PrEP Toolkit](#): San Francisco Department of Health Center for Public Health and Innovation in coordination with University of California San Francisco's Hub of Positive and Reproductive Sexual Health (HIVE)
- [AIDS Education and Training Centers](#)
The AIDS Education and Training Centers, the training arm of the Ryan White HIV/AIDS Program, is a national network of HIV experts who provide locally based, tailored education, clinical consultation and technical assistance along the HIV care continuum.
- [Clinician Consultation Center PrEPline](#)
The CCC PrEPline provides free, expert consultations on all aspects of PrEP management to clinicians across the country. Monday - Friday 9am - 8pm EST at (855) 448-7737 or (855) HIV-PREP
- [San Francisco Department of Public Health Capacity Building Assistance](#)
The San Francisco Department of Public Health provides free, customized, peer-to-peer Capacity Building Assistance in high-impact HIV prevention to health departments.
- [Minors' Consent Laws for HIV and STI Services](#)
In 2018, the Food and Drug Administration (FDA) approved PrEP use among adolescents who weigh at least 35 kg (77 lb). This CDC resource summarizes state statutes and regulations regarding HIV prevention for minors.

PrEP Financing Resources

- [Paying for PrEP Fact Sheet](#): Centers for Disease Control and Prevention
General overview of how the costs associated with PrEP care may be covered.
- [Getting PrEPped Flow Chart](#): Project Inform
Flowchart to help consumers and patient navigators understand how to access services and cover medical costs for PrEP
- [Gilead Advancing Access® Program](#): Gilead Sciences
Additional information about the Advancing Access® Program, including the enrollment process.
- [Billing Coding Guide for HIV Prevention: PrEP, Screening and Linkage Services](#): NASTAD
Example scenarios for PrEP provision and the corresponding CPT and ICD-10 diagnosis codes for filing a claim with the client's insurance company or government payer.
- [PrEPCost.org](#): NASTAD
PrEPCost.org is an online health plan finder for PrEP. PrEPCost.org can assist navigators by searching across plans in the Marketplace and evaluating PrEP coverage to find the best options available. This resource will be relaunched in early November 2018.

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