

Communicable Disease Branch NCPREP Program

Establishing a PrEP Clinic

Below are important steps and information for establishing a pre-exposure prophylaxis against HIV (PrEP) clinic. These will prove useful for our local health departments as well as partnering agencies.

Key points

- PrEP is:
 - A highly effective FDA approved prevention tool used to reduce the risk of HIV acquisition.
 - A service that can be incorporated into clinical practice like any other medical service.
 - An HIV prevention tool that can be used by anyone who is sexually active or injects drugs.
 - A program, not just medication.
 - A collaborative effort requiring involvement with local community-based organizations and other partners to create access to PrEP.
- 1. **Considerations in Planning PrEP provision:**
 - **Community Needs Assessment:**
 - Evaluate the need for PrEP Services in your area. Identify the priority population(s) who would benefit from PrEP.
 - Identify their special needs.
 - Evaluate for areas of high STI/HIV incidence.
 - [STI Statistics | STI Statistics | CDC \(cdc.gov/sti-statistics/index.html\)](https://www.cdc.gov/sti-statistics/index.html).
 - Identify existing PrEP providers in the area.
 - Assess need for educating providers who are not prescribing PrEP.
 - **Potential Patient Barriers to PrEP:**
 - Lack of patient HIV risk acknowledgement, e.g., condomless sex, transactional sex, sex partners with unknown HIV status or unknown viral loads.
 - Concerns about discrimination and stigma, both internally and externally.
 - Provider discomfort initiating sexual health conversations.
 - Concern about how to pay for PrEP.
 - Lack of access to medical care.
 - **Regulatory Requirements:**
 - Notify patients that PrEP has been available since July 2012, has an excellent safety record and is highly effective when taken as prescribed.
 - Understand that any medical prescriber can provide PrEP.
 - For more information on PrEP provision, visit: hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis
 - **Budgeting:**
 - Develop a budget that includes start-up costs, operational expenses, and funding sources – consider grants.

- Identify funding to support staffing needs such as:
 - Provider to see the patient and prescribe the medication.
 - Nurse to give the injection.
 - Case manager or social worker to assist in paperwork and other patient needs such as housing, food, transportation and medication assistance.
- See links to potential funding sources below:
 - [Rural Health Clinics \(RHCs\) – Funding & Opportunities - Rural Health Information Hub](https://ruralhealthinfo.org/topics/rural-health-clinics/funding) (ruralhealthinfo.org/topics/rural-health-clinics/funding)
 - [Federal Grant Funding - NACHC](https://nachc.org/policy-advocacy/health-center-funding/federal-grant-funding) (nachc.org/policy-advocacy/health-center-funding/federal-grant-funding)
 - [Giving in North America](https://gilead.com/responsibility/giving-at-gilead/corporate-giving/how-to-apply-for-funding/giving-in-north-america) (gilead.com/responsibility/giving-at-gilead/corporate-giving/how-to-apply-for-funding/giving-in-north-america).
 - [Positive Action AMP Grant](https://viivhealthcare.com/en-us/supporting-the-hiv-community/positive-action-amp-grant) (viivhealthcare.com/en-us/supporting-the-hiv-community/positive-action-amp-grant).

2. Consider Clinical Infrastructure Needs

- **Location and Facility Requirements:**

- Choose a location that is accessible and discreet and close to public transportation if possible.
- Ensure clinics can provide comprehensive care, including labs.

- **Staffing:**

- Hire/train medical staff which may include, physicians, physician associates, nurse practitioners, RNs, LPNs, MAs, peer counselors, peer navigators, and social workers.
- Clinics providing PrEP should consider the following staff at a minimum. If an already established clinic is adding PrEP, staff may be shared with other departments i.e.:
 - Front desk staff
 - LPN or MA
 - Phlebotomist
 - Prescribing provider
 - Billing clerk
 - Social worker or case manager
- Ensure staff are trained on PrEP administration, barriers to PrEP, adherence counseling, and patient management.

3. Develop Medical Protocols

- **PrEP Administration:**

- Use the link below for CDC established protocols for PrEP
 - cdc.gov/hivnexus/hcp/prep/index.html
- Tele-PrEP may be useful for oral PrEP.
- Self-injectable PrEP may become an option in 2025.
- There also may be an annual injection option for PrEP in the near future.

- **Lab Testing:**
 - Set up procedures for routine HIV Testing to include Fourth Generation Ag/AB, HIV Viral load or RNA, kidney function monitoring, liver function monitoring, and STI testing every 3 months.
 - Labs should be obtained every 3 – 4 months for oral PrEP.
 - Labs should be obtained every 2 months for injectable PrEP.
 - Consider mobile lab services provided by agencies such as Mako and LabCorp for rural areas or for patients without transportation.
 - Tele-PrEP may be a useful option in conjunction with mobile lab services.
- **Emergency Situations**
 - Develop a plan for managing adverse reactions or emergencies related to PrEP. Adverse reactions are rare. How to handle adverse reactions is discussed in the package insert for each PrEP medication.

4. **Ensure Patient Education and Support**

- **Educational Materials:**
 - Develop protocols for prescribing and monitoring PrEP, including its benefits, potential side effects, and adherence requirements.
 - Consider the branded and unbranded materials available for free from Gilead and ViiV Healthcare. Both companies provide free education to clinics and patient groups. See below for other educational material resources:
 - hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis
 - [What is DESCOVY for PrEP®? \(descovy.com/what-is-descovy-for-prep?utm_source=bing&utm_medium=cpc&utm_campaign=US_SEM_D4P_DTP_Prep_MA_NB_PH_Learn+About+A+Gilead+Medication+Standard&utm_content=PrEP+General&utm_term=drug+prep&gclid=1a9a9d3702fa17faaf01fa66bfa87eef&gclsrc=3p\)](https://descovy.com/what-is-descovy-for-prep?utm_source=bing&utm_medium=cpc&utm_campaign=US_SEM_D4P_DTP_Prep_MA_NB_PH_Learn+About+A+Gilead+Medication+Standard&utm_content=PrEP+General&utm_term=drug+prep&gclid=1a9a9d3702fa17faaf01fa66bfa87eef&gclsrc=3p)
 - [FAQs | APRETUDE \(apretude.com/getting-started/faqs/?cc=ps_P6G6FRE8YJEXEOU2119296&gclid=af15b0e64b3e10c63951d7b7f6b862c6&gclsrc=3p.ds&msclkid=af15b0e64b3e10c63951d7b7f6b862c6&utm_source=bing&utm_medium=cpc&utm_campaign=MB~APRE_CN~UNBRANDED-MEDICATION-ALL_CA~UB_MT~E\)](https://apretude.com/getting-started/faqs/?cc=ps_P6G6FRE8YJEXEOU2119296&gclid=af15b0e64b3e10c63951d7b7f6b862c6&gclsrc=3p.ds&msclkid=af15b0e64b3e10c63951d7b7f6b862c6&utm_source=bing&utm_medium=cpc&utm_campaign=MB~APRE_CN~UNBRANDED-MEDICATION-ALL_CA~UB_MT~E)
 - [Pre-exposure Prophylaxis \(PrEP\) Fact Sheets for Patients - HIV \(hiv.va.gov/products/prep-patient-factsheets.asp\)](https://hiv.va.gov/products/prep-patient-factsheets.asp)
 - [HIV PrEP Medications | Healthysexual \(healthysexuals.com/about-prep?utm_source=bing&utm_medium=cpc&utm_campaign=US_SEM_HSX_DTP_Prep_MA_NB_PH_Prep+Standard&utm_content=PrEP&utm_term=pre+exposure+prophylaxis&gclid=471778b0040f1d69e9cb1fe1ba97e1da&gclsrc=3p.ds&msclkid=471778b0040f1d6\)](https://healthysexuals.com/about-prep?utm_source=bing&utm_medium=cpc&utm_campaign=US_SEM_HSX_DTP_Prep_MA_NB_PH_Prep+Standard&utm_content=PrEP&utm_term=pre+exposure+prophylaxis&gclid=471778b0040f1d69e9cb1fe1ba97e1da&gclsrc=3p.ds&msclkid=471778b0040f1d6)
 - [PrEP Brochure \(cdc.gov/hiv/media/pdfs/2024/04/cdc-hiv-stsh-prep-brochure-english.pdf\)](https://cdc.gov/hiv/media/pdfs/2024/04/cdc-hiv-stsh-prep-brochure-english.pdf)

- **Counseling Services:**
 - Provide one-on-one counseling by medical staff, peer navigators, social workers, etc., to address any concerns or questions a patient may have. Screen for mental health and substance use disorders frequently.
 - **Consider Support Groups:**
 - Facilitate support groups or peer networks to help patients stay motivated and connected. Most AIDS Service Organizations (ASO's) as well as many houses of worship provide these support groups.
5. **Develop Community Outreach and Marketing**
- **Community Collaborations and Partnerships:**
 - Collaborate with local organizations and community leaders to raise awareness about PrEP and your clinical services. Build relationships with other health care providers and advocacy groups.
 - **Advertising:**
 - Create flyers and social media content to inform potential patients about available clinic services.
6. **Ensure Data Management and Quality Assurance**
- **Medical Records:**
 - Obtain a secure electronic health record (EHR) system to manage information.
7. **Consider Legal and Ethical Considerations**
- **Confidentiality:**
 - Ensure that patient information is kept confidential and handled in accordance with the Health Insurance Portability and Accountability Act (HIPAA).
 - **Informed Consent:**
 - Make sure patients are fully informed about PrEP and provide informed consent before starting treatment.
8. **Develop Evaluation and Feedback Processes**
- **Performance:**
 - Track patient adherence rates, outcomes, and clinic utilization.
 - **Patient Feedback:**
 - Use Patient Satisfaction Surveys to collect feedback from patients to identify areas for improvement and ensure high quality care.

Available PrEP Delivery Models

- **Traditional Models**
 - Traditional PrEP models are primarily clinic-based, which may not work in some areas of North Carolina for many reasons. Although still important, traditional models have evolved to include approaches that provide more ways in which patients can access PrEP as a sexual health option, including in STI clinics, family planning clinics, and as part of regular preventative checkups.

- **Telemedicine**

- The onset of the COVID-19 pandemic [accelerated the use of telemedicine](https://thebodypro.com/article/coronavirus-elevates-telehealth-for-prep) (thebodypro.com/article/coronavirus-elevates-telehealth-for-prep) for health care services including PrEP.
- Telemedicine services also known as Telehealth, use technology to provide health care remotely through video calls, phone calls, secure messaging, EHR/EMR health portals, and remote monitoring.
- Telemedicine allows patients to see their providers from home or another secure location leading to a faster, less stressful and less expensive patient experience. Other benefits include:
 - Use as telemedicine when in-person visits are not possible.
 - Use as a bridge between in-person visits.
 - Can be coupled with at home HIV and STI testing.
 - Increase access to “PrEP mentors” who provide expert guidance.
 - Reduces need for transportation

Lab services must still be arranged either through an in-person visit to a local LabCorp, Mako, Qwest, etc., or through a mobile phlebotomist that travels to the patient’s home or through self-obtained swabs and Dried Blood Spot (DBS) if available.

- **Pharmacy-Based**

- Pharmacists can provide PrEP via MD/DO approved protocols which include HIV and STI screening and dispensing oral or injectable PrEP.
- Pharmacy-based settings allow pharmacists to optimize medication therapy, provide education on their medications, preventive care, and medication monitoring.
- Pharmacy-based clinics already use in-person, telemedicine and hybrid models.

- **Multi-disciplinary and other models**

- Nursing-led programs
 - May be an option for clinic, Tele-Health, and onsite home care via MD/DO approved protocols
 - Nursing-led clinics can be managed by a MD/DO, nurse practitioner, or clinical nurse specialist.
 - Nursing-led clinics can provide patients with more face-to-face time than standard care and can lead to improved patient outcomes and better patient experience.
- Peer-navigators or PrEP navigators via CBOs can test and facilitate linkage to care to any of the service models listed above.

Reference to any specific commercial product, process, or service, or the use of any trade, firm or corporation name is for the information and convenience of the public, and does not constitute endorsement, approval, recommendation, or favoring by Communicable Disease Branch of the North Carolina Department of Health and Human Services, Division of Public Health.

