Pre-Exposure Prophylaxis (PrEP)

Clinic Resource Manual

2017

VDH VIRGINIA DEPARTMENT OF HEALTH

Promoting & Protecting the Health of All Virginians
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This document is a product of the Virginia Department of Health (VDH) and should only be used by entities associated with DDP-HIV Prevention and its PrEP programs. This manual is a resource for internal use only. Should questions about content or process arise, please contact, Eric S. Mayes, VDH PrEP Coordinator at eric.mayes@vdh.virginia.gov or (804) 864-7335.

PrEP Clinic Reference Manual
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I. Virginia Department of Health –Division of Disease Prevention: HIV PrEP Protocols for Local Health Departments

I. Summary: Purpose of PrEP

PrEP is indicated for individuals who have a documented negative HIV test result and are at substantial risk for HIV infection. A negative HIV test result needs to be confirmed as close to initiation of PrEP as possible. PrEP should only be prescribed to those who are able to adhere to the regimen and express a willingness to do so.

PrEP is not meant to be used as a lifelong intervention, but rather as an additional prevention tool during periods when people are at greatest risk of acquiring HIV. The length of use will depend on the individual's behaviors, which may change over time. **PrEP is intended to be a part of an individual's overall "prevention package" and not an individual's only prevention method.** Condoms, sterile injection equipment and other prevention measures should still be used correctly and consistently while the patient is on PrEP; however, the inability to practice these behaviors correctly and consistently does not exclude a person from being prescribed PrEP.

General Information:
In May 2014, the Centers for Disease Control and Prevention (CDC) released its guidelines for the use of daily pre-exposure prophylaxis (PrEP) for the prevention of HIV infection. The following CDC PrEP documents are available:

- *Preexposure Prophylaxis for HIV Prevention in the United States – 2014. A Clinical Practice Guideline* (http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf)
- *Preexposure Prophylaxis for the Prevention of HIV in the United States – 2014. Clinical Providers' Supplement* (http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf)
- Truvada Package Insert (http://www.gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf)

Daily use of emtrictabine/tenofovir (Truvada) is an effective and safe prevention method for reducing HIV acquisition in sexually active men and women and injection drug users.

These protocols are meant to serve as a guide for project personnel and providers administering PrEP under the VDH-DDP PrEP Program. These protocols are based on the CDC Guidance above along with NY City Health Department's Guidance

(http://www.hivguidelines.org/clinical-guidelines/pre-exposure-prophylaxis/guidance-for-the-use-of-pre-exposure-prophylaxis-prep-to-prevent-hiv-transmission/).

II. Program Eligibility:

PATIENT MUST BE:

- At least 18 years old.
- A Virginia resident if state funding is necessary for prescription and/or lab work funding assistance.
- Willing to participate in adherence/follow-up interventions and evaluation process.

AND

Determination of the prescribing medical provider based on best-evidence for use of PrEP as an HIV prevention tool for an HIV negative person practicing high-risk behaviors (defined below).

III. Behavioral Screening and Patient Education:

Please use the screening tool found in the Appendix A to obtain behavioral information.

Providers should obtain a thorough sexual and drug use history, and regularly discuss risk-taking behaviors with their patients to assess candidacy for PrEP, encourage safer-sex practices and safer injection techniques (if applicable), as well as assist in the decision of when to use PrEP and when to discontinue use.

Applicable High-Risk Behaviors Include:

- Unprotected vaginal or anal intercourse with individual(s) living with HIV or individual(s) of unknown HIV status.
- Needle Sharing.
- Sex while under the influence of drugs or alcohol with multiple partners.
- Engaging in commercial sex work (the exchange of sex for money, drugs, housing or other items of worth).

Clinicians should discuss PrEP with the following non-HIV infected individuals who have substantial ongoing behavioral risks:

- Men who have sex with men who engage in unprotected anal intercourse.
- Individuals who are in a serodiscordant sexual relationship with a known HIV-infected partner.

- Male to female and female to male transgender persons engaging in high-risk sexual behaviors and/or share injection equipment (i.e. share needles for silicon injections).
- Individuals engaging in transactional sex, such as sex for money, drugs or housing, or those working in the commercial sex industry, such as pornographic film actors/actresses.
- Injection drug users who report any of the following behaviors: sharing injection equipment and/or works, injecting one or more times daily, injecting methamphetamines, engaging in high-risk sexual behavior.
- Individuals diagnosed with at least one anogenital sexually transmitted infection in the last year, who engage high risk behaviors.
- Individuals who have been prescribed non-occupational post-exposure prophylaxis (nPEP) who continue to demonstrate high-risk behavior or have multiple courses of nPEP.

Identification of Participants:
Eligible participants can be identified by:

- HIV testing and prevention contractors, during HIV counseling and testing.
- HIV Care contractors, case managers, patient navigators primarily as identifiers of partners of HIV positive individuals.
- Health Department STI Clinic staff.
- Disease Intervention Specialist (DIS) during the partner notification process.

IV. Patient Education and Informed Decision Making Help

Once it is decided that the patient is a candidate for PrEP according to the criteria above, further assessments (listed in Appendix B) are needed to clearly understand the prevention needs of the individual patient and whether initiation of PrEP is an appropriate option. Patient education is critical to shared decision-making and the success of PrEP as part of the prevention plan. Tables 1 and 2 provide the basis from which shared decision-making about initiation of PrEP can occur, providing the clinician with the opportunity to educate the patient about risks, benefits, and options, while providing the patient with the opportunity to discuss preferences, needs, and individual circumstances. Medication adherence may be improved when patients participate in treatment decisions.

Patients need to understand how PrEP works, including risks and benefits, the need for strict adherence to maintain protective drug levels, and what it will and will not do for them. Explanations should be given in the patient's native language and should be easy to understand.

> For example: *The pill, Truvada, has two drugs in it that are commonly used to treat HIV in persons who are HIV-positive. When taken daily by people who are*

HIV-negative, they can block HIV from infecting the body. The pill needs to be taken every day in order for the body to build up sufficient drug levels to block HIV. It cannot be expected to work if it is only taken before or just after each time you have sex. PrEP reduces, but does not eliminate, HIV transmission risk. You should use condoms even if you are taking PrEP because PrEP does not protect against other sexually transmitted diseases.

Patient should be informed of: (see patient information brochure: Appendix C)

1. Limitations of PrEP
2. Potential side effects associated with Truvada.
3. Long term safety of PrEP
4. Symptoms of sero-conversion
5. How PrEP works
6. Importance of daily adherence
7. For those who may become pregnant, there is a lack of data that definitively states that PrEP causes no harm to developing fetuses

Useful Social Media for PrEP Patient Education:
All Audiences:

https://www.youtube.com/watch?feature=player_embedded&v=-Xx92whZS0o

https://vimeo.com/79717700

V. Clinical Screening

Medical History considerations for project exclusions:

(See Truvada package insert referenced above for full medical recommendations)

PrEP is not for use for patients with a history of renal or liver disease, osteoporosis or current HIV infection.

Patient use of other medications that reduce kidney renal function or compete for active renal tubular secretion should be considered before prescribing PrEP. Monitor these patients for dose-related renal toxicities.

Diagnostic Baseline Screening test required:

Baseline Tests:	***Name of Test and Cost:***	***Comments and Rationale***
HIV Test: 4th Generation or RNA PCR testing		Test for acute HIV infection in ALL patients initiating PrEP with a 4th Generation combination HIV Ag/AB assay. Screen for acute HIV infection symptoms. If patient has chronic HIV infection, Truvada alone is not sufficient treatment and the risk of developing resistance to this classification of drugs (nucleoside analog reverse transcriptase inhibitor) is high.
Creatinine		CrCl should be ≥ 60 ml/min (Cockcroft Gault) to safely use tenofovir.
Hepatitis B surface antigen		Truvada is active against hepatitis B virus (HBV). Patients with chronic HBV **can** use Truvada for PrEP, but should have regular liver function tests monitoring while using PrEP. Also, caution the patient rebound viremia may occur after discontinuing PrEP. Patients who are HBsAg negative should be offered HBV vaccination if not previously infected or immunized.
STDs (based on patient's self-reported sexual history)		Participants should be tested for syphilis, urethral, rectal and pharyngeal GC and CT unless contraindicated by risk profile.
Pregnancy test (if applicable)		PrEP should be coordinated with pre-natal care.

Other important considerations when prescribing PrEP:

- **Is the patient pregnant or attempting to conceive?** PrEP may be one of several options to help protect the HIV seronegative partner from acquiring HIV infection in serodiscordant couples during attempts to conceive.

  - If a patient is pregnant when starting PrEP or becomes pregnant while on PrEP, discuss the known risks and benefits of taking TDF/FTC during pregnancy
  - Providers should report information regarding use of PrEP during pregnancy to the Antiretroviral Pregnancy Registry

- **Is the patient an adolescent?**

  - If PrEP is indicated for/or requested by an adolescent contact DDP for guidance on a case by case basis.

- **Is the patient taking concomitant nephrotoxic drugs or drugs that have interactions with TDF/FTC?**

  - Obtain a thorough medication history and consult the medication package insert for additional information on drug interactions.

- **Does the patient have osteopenia/osteomalacia/osteoporosis?** There may be a risk of bone loss associated with tenofovir.

  - Discuss risk of bone loss with individuals with pre-existing risk factors or demonstrated osteoporosis/osteomalacia/osteopenia.

VI. PrEP Management

Pre-Prescription Visit:
- Discuss PrEP use; clarify misconceptions
- Perform following laboratory tests:
  - HIV test (4th generation)
  - Serum creatinine
  - Hepatitis B, and C serology
  - STI screening
  - Pregnancy test (if applicable)

To reduce wastage and ensure adherence, medication from Central Pharmacy is only dispensed 30 days at a time. After initial appointments, there is a 30 day and 90 day in-person follow-up, with in-person visits required every 90 days thereafter. For patients who report poor adherence or intermittent use, schedule more frequent follow-ups. Contact CBO or DDP for adherence intervention support.

For individuals over 40, consider testing bone density at 90-day intervals

After confirmation of negative HIV test:
Prescribe 30-day supply of PrEP (Prescriptions may include with more refills, but patient follow-up schedule must be followed)
Follow up in 2 weeks to assess side effects (in person or by phone)

30-day visit:
Assess:
- Side effects
- Serum creatinine or, for patients with borderline renal function or at increased risk for kidney disease, calculated creatinine clearance (>65 years of age, black race, hypertension, or diabetes)
- Discuss risk reduction and provide condoms

Prescribe 60-day refill; patient must come in for 3-month visit for HIV test and follow-up assessments, then 90-day schedule can begin. ***For patients accessing medication through Virginia's PrEP DAP program, PrEP is dispensed for 30 days at a time.***

3-month visit
- HIV test • Serum creatinine • Obtain STI screening tests
- Pregnancy test • Discuss risk reduction and provide condoms

6-month visit
- HIV test • Pregnancy test
- Obtain STI screening tests • Discuss risk reduction and provide condoms

9-month visit
- HIV test • Serum creatinine and calculated creatinine clearance
- Obtain STI screening tests • Pregnancy test
- Discuss risk reduction and provide condoms

12-month visit
- HIV test • Pregnancy test • Obtain STI screening tests • Urinalysis
- HCV serology for IDUs, and those with multiple sexual partners
- Discuss risk reduction and provide condoms

Adherence Counseling

PrEP only is useful as a prevention tool if the patient takes the medication as prescribed, daily.

Since PrEP is a long term commitment for some, helping the patient form strategies that ensure adherence may be useful. Strategies may include formulation of a patient-centered adherence plan, which accounts for time of day to take the drug, storage of the drug, what to do if the patient misses a dose, what to do if side-effects occur, etc. Adherence is often compromised by other factors such as mental illness, substance abuse, lack of stable housing and interpersonal violence. In addition, adherence has been shown to vary widely according to age. Younger patients may need more adherence counseling to ensure a successful outcome.

Clinical staff and the patient should discuss barriers to adherence and possible means of overcoming these barriers prior to patient being prescribed PrEP.

Some community-based organizations (CBOs) provide interventions that may help increase adherence. If the clinical staff feels these would be useful to the patient, a referral can be made to these CBOs (see resource list). DDP's HIV/STD/Hepatitis Hotline is also available to provide adherence counseling and resources for patients on PrEP.

VIII. Prescription and Financial Qualifications

Prescriptions may be written to include multiple refills; however each fill will be for 30 days only. After the initial 30 days' worth of medication, patients will need to follow-up in person and complete a medical evaluation. After 30 day evaluation, a medical evaluation will not be needed until for another 60 days, although prescription refills will continue to only be made for 30 days at a time. At the end of 60 days (which will mark 3 months after the initial prescription), another medical evaluation will occur, at which point patients will only need medical evaluation every 90 days thereafter, unless a client indicates possible issues with drug adherence. Medication will continue to be dispensed for 30 days at a time. Follow-up appointment planning is necessary to ensure that patient does not run out of medication waiting for medical evaluation.

The patient has 10 business days to pick up medication. For the first fill, the window period begins from the day the medication arrives to the partner site. For subsequent fills, the pick-up period is based on date of previous pick-up (30+5 days). If a patient does not pick up medication within 10 days of the medication arriving at the partner site, the patient may need to undergo medical evaluation in order to receive medication.

If a patient cannot be reached to arrange an evaluation, or is no longer interested in the program, return the medication to Central Pharmacy and notify the eligibility specialist of the withdrawal. It is recommended that unclaimed medication be returned to Central Pharmacy as soon as possible, but cannot 60 days at partner locations unclaimed by clients.

In the event that a patient will be out of state for an extended period and unable to arrange medication pick-up from a Virginia-based partner site, a request for an additional 30 day fill can be made. This request can only be made once within a 12 month period, and the decision to provide additional fill is made on a case-by-case basis by VDH-DDP, Central Pharmacy and PrEP navigator.

DDP will handle the financial eligibility screenings for this project, if the patient is uninsured. If insured, the LHD should proceed with billing the patients' insurance carrier.

For uninsured patients: consult the financial eligibility section beginning on page 24.

Medications provided by through Gilead's Patient Assistance Program will be mailed directly to the LHD for distribution to patient.

Medications provided by VDH-DDP will be sent to the local health department of the patient's choice. However, if a patient proves adherent, the patient may be eligible to have medication sent to their home after consultation with the PrEP navigator. The decision to allow home delivery is made collaboratively the site PrEP navigator, VDH-DDP and Central Pharmacy, and is based on patient's prior adherence, accessibility, and possible barriers. A patient must provide a physical address for shipment by Central Pharmacy. For patients without a physical shipping address, DDP will work with the patient and Central Pharmacy to determine a solution. Patients who are eligible to have their medications delivered must confirm the successful delivery with the PrEP navigator who will in turn complete the PrEP Medication Order Form. If a patient does not confirm delivery within 5 days of shipping, the PrEP coordinator will attempt to contact the patient. If the patient does not respond to call with 24 hours, the patient will no longer be eligible for home delivery. If a patient does not receive the medication within 7 days of delivery, notify Central Pharmacy immediately. An appointment for the patient to have a medical evaluation will be necessary for the client, and home delivery will be suspended unless a resolution is reached which satisfies VDH-DDP, Central Pharmacy and partner site to ensure safe and timely deliveries.

IX: Evaluation and Client Consent

DDP will evaluate the PrEP program in order to determine program effectiveness and to assist in similar future projects. Patients receiving DDP funded medications must consent to be involved

in the evaluation process. Other participants should be encouraged to participate in evaluation as well. This process involves:

1. Permission for LHD to share information on behavioral risks, HIV/STD/Hepatitis status, and drug adherence with VDH-DDP PrEP project staff.
2. Completion of short patient satisfaction surveys (paper or online) at 3 months and at end of patient participation in project.
3. Permission to contact patient if they withdraw from the without notification to ascertain their reason for stopping PrEP.

X: Patient Withdrawal from Program

Patients may withdrawal from the program at any time.

DDP would like to monitor why clients withdrawal for program planning purposes. DDP requests that clinicians ask patients to contact the clinic or DDP if they chose to withdrawal from the program. The local health department may also choose to stop providing PrEP services for a patient if said patient fails to return for the 30 day follow-up appoint or any subsequent appointment required for PrEP maintenance. Before discontinuing services, the agency should try to contact the patient by telephone with three total attempts, one of which must be outside of regular business hours. These attempts should be documented in the patient's records. A new set of calls is made if new telephone contact information is obtained.

Once withdrawal has been determined, the provider site will complete a PrEP DAP withdraw form, and fax said form to both the PrEP eligibility specialist and Central Pharmacy.

XI. Resources

a. **PrEP:** The Virginia Department of Health's PrEP page with clinic locator.

http://www.vdh.virginia.gov/disease-prevention/disease-prevention/prep-and-npep/

DDP HIV STD HEPATITIS Hotline: 800-533-4148

Social service and other resources:

Access a complete list of resources through the Virginia Department of Health website at:

http://www4.irissoft.com/IFTWSQL4/vdhh/public.aspx

Provider Training:

University of California, San Francisco Clinician Consultation Warmline
(855)-448-7737
11 a.m. to 6 p.m., Monday – Friday

Virginia HIV/AIDS Resource and Consultation Center- Virginia Commonwealth University
Johanna McKee
804-828-2430
jmckee2@mcvh-vcu.edu

Virginia HIV/AIDS Resource and Consultation Center – Eastern Virginia Medical School
Tanya Kearney
757-446-6170
kearneTK@evms.edu

VDH-DDP Contact Information:

General Project Support and Financial Qualification: Eric Mayes
PrEP Eligibility Specialist: Julie Karr
Central Pharmacy Support: Stephanie Wheawill
HIV Prevention Director: Elaine Martin
Social Media Coordinator: Chris Barnett
Other Support Staff: Bruce Taylor

APPENDIX A: Behavioral Screening Tool

GENERAL INFORMATION

1. What is your current gender?
□ Male □ Transgender (male to female)
□ Female □ Transgender (female to male)
□ Transgender- unspecified:_____
2. What is your current age? _____ Years
3. Are you . . . *(mark all that apply)*
□ Black □ American Indian/Alaska Native
□ White □ Pacific Islander/Hawaiian
□ Asian □ Another race not listed above
4. Are you Hispanic or Latino? □ Yes □ No
5. Were you born outside of the United States? □ Yes □ No
5a. If yes, in what country were you born?_____
6. What is the highest grade or level of education that you have completed?
□ Less than high school/GED □ Some college
□ High school graduate/GED □ 4 yr. college or more
7. Are you a student at this time?
□ Not a student □ Yes, full-time student
□ Yes, part-time student
8. What is your employment status at this time?
□ Employed □ Out of work more than one year
□ Self-employed □ Out of work less than one year
□ Homemaker □ Retired
□ Unable to work
9. What is your current marital status?
□ Currently married □ Divorced
□ Married but separated □ Widowed
□ Living with partner □ Never married
10. Do you have any type of health care coverage or medical insurance? *(Note: Your response to this question will not be used to bill you for any services today.)*
□ Yes □ No
10a. If yes, what type of insurance do you have?
□ Private health insurance *(individual or through an employer)*
□ Public health insurance *(such as Medicaid or CHIP)*
□ Don't know □ Not applicable
11. How did you know about this STD clinic? *(Mark all that apply)*
□ I've been here before □ Flier or news advertisement
□ From a friend or relative □ From the internet / website
□ From a sex partner □ Other: _____

MEDICAL HISTORY

12. What is the main reason you came to the clinic today?
□ Because of symptoms □ Follow-up to previous visit
□ STD/HIV testing only □ Family planning
□ For treatment/medication □ PrEP: □ Other: _____
13. Are you seeking care today because a sex partner told you that he/she has an STD? □ Yes □ No
14. Do you have any STD symptoms today? □ Yes □ No

14a. If yes, do you have:
Penile discharge or burning with urination? □ Yes □ No
Vaginal discharge, odor or itching? □ Yes □ No
Sore throat? □ Yes □ No
Rectal / anal symptoms or bleeding? □ Yes □ No
Sores or ulcers in the genital area? □ Yes □ No
Rashes or bumps in the genital area? □ Yes □ No
Stomach/belly pain or cramping? □ Yes □ No
14b. How many days have you had symptoms before coming to the STD clinic today? _____ Days
15. Have you ever been infected with:
Chlamydia? □ Yes □ No
Gonorrhea? □ Yes □ No
Trichomoniasis (Trich)? □ Yes □ No
Genital warts? □ Yes □ No
Syphilis? □ Yes □ No
Herpes? □ Yes □ No
Hepatitis B (HBV)? □ Yes □ No
Hepatitis C (HCV) □ Yes □ No
16. Have you ever been tested for HIV/AIDS? □ Yes □ No
16a. When were you last tested for HIV? ____ / ____
(*leave blank if unknown*) *mm yyyy*
16b. What was your last HIV test result?
□ Negative □ Positive □ Indeterminate
□ Unknown/Did not receive results/Not Applicable
17. Have you ever been vaccinated for Human Papilloma Virus (HPV), which can cause cervical cancer and rectal cancer?
(Available vaccines include Gardasil and Cervarix)
□ Yes (received all 3 shots) □ No
□ Yes, partially (received 1 or 2 shots) □ Unsure
18. Have you ever been tested for Hepatitis B (HBV)?
□ Yes □ No □ Don't know
19. Have you ever been vaccinated for Hepatitis B (HBV)?
□ Yes □ No □ Don't know
20. In your lifetime, have you ever had sex with:
□ Men □ Women □ Transgender or non-binary person(s) □ Multiple genders □ None
21. In the past 3 months, have you had sex with:
□ Men □ Women □ Transgender or non-binary person(s) □ Multiple genders □ None
22. How many sex partners have you had in the last 3 months?
_____ partner(s)
23. Have you had any new sex partners in the last 3 months?
□ Yes □ No
24. Did you use a condom the last time you had sex?
□ Yes □ No
24a. If no, what were your reasons for not using a condom?
(Please check all that apply)
□ I don't like them □ I wasn't sure how to use one
□ I didn't think I needed one □ My partner refused to use one
□ I didn't have one □ I didn't have money to buy one
□ I was drunk/high □ Other:**_____**
25. Which (if any) of the following types of sex have you had in the last 3 months?
Penis in vagina □ Yes □ No
Vagina to vagina □ Yes □ No
Penis in rectum / anal sex (given) □ Yes □ No
Penis in rectum / anal sex (received) □ Yes □ No
Mouth to penis / oral sex (given) □ Yes □ No

Mouth to penis / oral sex (received) □ Yes □ No
Mouth to vagina (given or received) □ Yes □ No
26. Do you think, or know, that your recent sex partner has been having sex with anyone else?
□ Yes □ No □ Don't know
27. In the last 12 months, have you been in jail or prison?
□Yes □ No
28. In the last 12 months, have you had sex with anyone who you had never met before and who you would not be able to contact again? □ Yes □ No
29. In the last 12 months, have you met any sex partners through the internet or a mobile app? □ Yes □ No
30. In the last 12 months, has a sex partner ever hit, slapped, kicked, pushed or hurt you in any way? □ Yes □ No
30a. In the last 12 months, have you experienced unwanted sex by a current or former sex partner? □ Yes □ No
31. Are you currently homeless or likely to become homeless in the next 3 months? □ Yes □ No

SUBSTANCE ABUSE/MENTAL HEALTH
32. Have you used any of the following in the last 12 months?
Marijuana (pot) □ Yes □ No
Cocaine / Crack □ Yes □ No
Nitrates / Poppers □ Yes □ No
Heroin □ Yes □ No
Methamphetamines (meth, crystal) □ Yes □ No
Mollies / Ecstasy □ Yes □ No
Prescription drugs (recreational use) □ Yes □ No
Injection drugs □ Yes □ No
33. In the last 12 months, have you given or received drugs or money for sex? □ Yes □ No
34. In the last 3 months, did you drink any alcohol, such as beer, wine, or liquor? □ Yes □ No
34a. In the last 3 months, how often did you drink . . .
If you are male . . . 5 or more drinks in one sitting?
If you are female or transgender . . . 4 or more drinks in one sitting?
□ Never □ More than once a month
□ Once a day □ Once a month
□ More than once a week □ Less than once a month
□ Once a week □ Don't know
35. Before or during the last time you had sex, did you use:
Alcohol? □ Yes □ No
Drugs? □ Yes □ No
36. Have you ever been told by a medical or psychological professional that you have a mental health disorder or illness? □Yes □ No
36a. Have you been depressed, down, anxious, unable to think clearly, extremely moody for more than the 10 out of the last 30 days? or had suicidal thoughts in the past 30 days? □Yes □ No

ONLY FOR THOSE ABLE TO BECOME PREGNANT:
37. Are you currently pregnant?
□ Yes □ No □ Don't know
38. Which, if any, of the following methods are you currently using to prevent pregnancy? *(Check all that apply)*
□ Birth control pills (oral contraceptives)
□ Intra-uterine device (IUD) or other implant
□ Condoms (male or female)
□ Natural, such as the rhythm method
□ Other method, please specify:
□ None / not applicable

FOR PERSONS REQUESTING PrEP:

39. Have you ever been told by a medical professional that you have any type of kidney, liver or bone disease(s) or disorder(s)?
□ Yes □ No if yes, what disease(s) or disorder(s)? _____
40. Is one of your primary sex partners or injection partners HIV positive that you know of? □ Yes □ No

APPENDIX B: Educational and Psychosocial Tools

Pre-Prescription: Education and Counseling:

Patients need to understand how PrEP works, including risks and benefits, the need for strict adherence to maintain protective drug levels, and what PrEP will and will not do for them. Explanations should be given in the patient's native language and should be easy to understand.

For example: *PrEP is a pill that if taken once a day by people who are HIV negative may prevent HIV infection. It has to be taken consistently – daily, preferably at the same time each day – because it does not work if it is only taken just before or just after (sex, shooting up, sharing works). PrEP reduces, but does not eliminate, the risk of getting HIV. You still need to (use condoms, clean your works) even if you are taking PrEP because PrEP does not protect against (other sexually transmitted diseases, Hepatitis C).*

Checklist 1: Patient Education and Assessment

1. **How PrEP works:**
   - **a.** Explain how PrEP works in language that is easy to understand.

     (PrEP is one pill with the brand name Truvada, which is two drugs in one tablet that when taken once a day may prevent HIV infection.)

   - **b.** PrEP works as part of a comprehensive prevention plan.

     (PrEP does not prevent other STI's and it is recommended that you still use condoms and/or get regular STI screenings.)

2. **Limitations of PrEP:**
   - **a.** Efficacy is dependent on adherence.

     (PrEP works ONLY when taken consistently – daily, preferably at the same time each day – to maintain levels of the drug in your blood.)

   - **b.** PrEP reduces but does not eliminate HIV transmission risk.

     (PrEP is still being studied and though a number of studies have shown that it prevents infection long term risks remain unknown. When taken correctly and consistently PrEP has been shown to be 90 percent effective in preventing HIV infection.)

3. **PrEP use:**

a. Dosing and need for daily adherence:

(PrEP is a one pill, once a day regimen, which must be taken consistently to be effective. Taking PrEP incorrectly could lead to resistance, which means that PrEP will no longer prevent HIV infection, so it's important that you take the pills as prescribed.)

b. Number of sequential doses to achieve protective effect:

(PrEP is not effective immediately. Research suggests that it's not fully effective for 30 days, though it may reach an acceptable level of effectiveness in rectal tissue after seven days and in vaginal tissue after 20 days.)

c. When doses are missed:

(If doses are accidentally missed there is no need to double up doses the following day. Just take one pill the following day at the usual time and maintain your pill schedule after that.)

d. Common side effects: Headache, abdominal pain, weight loss; side effects usually resolve or improve after first month.

(PrEP does come with some side effects but they are typically tolerable and diminish or disappear after a few weeks. Common side effects are: headache, abdominal pain, and weight loss.)

e. Baseline tests and schedule for monitoring.

(Prior to being prescribed PrEP, your doctor will run a series of medical tests including: an HIV test and liver and renal function tests. Truvada can impact liver and kidney function and your eligibility depends on those test results. A positive HIV test is an automatic disqualifier.)

f. Elements of, and schedule for, follow-up monitoring, including HIV testing at least every 3 months.

(Though an individual prescription may be written for an initial fill and subsequent refills, if you are prescribed PrEP, Central Pharmacy will only provide medication for 30 days at a time. At the end of the first 30 days, you will be required to come in so we can make sure you're taking your meds and everything is going ok. After that, and at the end of 60 days, you'll come in so we can do a follow-up HIV test and other assessments. From then on you'll only have come in every three months for medical evaluation.)

4. **Criteria for discontinuing PrEP**

a. Positive HIV test result:

(If at any time while you're on PrEP you have a positive HIV test result, PrEP will be discontinued immediately.)

b. Development of renal disease

(PrEP may also be stopped if you develop kidney disease or your kidneys show signs of distress.)

c. Non-adherence to medication or appointments

(Taking PrEP incorrectly or not attending follow-up appointments could result in PrEP being stopped.)

d. Change in risk behaviors (ie, PrEP is no longer needed)

(If anything in your life changes – you break up with an HIV positive partner, you start a monogamous relationship with an HIV negative partner or your patterns of sexual behavior change – let us know and we'll discuss whether PrEP is still right for you. Please notify us if you plan to discontinue PrEP yourself.)

For Those Who May Become Pregnant: Potential Benefits/Risks if Pregnancy Occurs During Use of PrEP

a. Effects on pregnant

(If you're pregnant or plan on becoming pregnant while on PrEP please discuss the risks and benefits of PrEP with your physician.)

Checklist 2: Psycho-Social Wellness

Review patient Behavioral Risk Assessment (Appendix A)

Assess if Questions 30-30a require referral for abuse/assault.
Assess if Questions 32-35 require referral for substance abuse treatment.
Access if Questions 36-36a requires referral for Mental Health treatment.
Access if Question 31 requires referral to housing/shelter.
Access how each of these factors may impact PrEP adherence.

II. Initiating PrEP in Local Health Departments – Financial Eligibility

PrEP Program
Financial Eligibility Overview

Purpose: To provide clear parameters for financial eligibility for PrEP program.
Objective: To ensure that PrEP-eligible clients have financial access to the medication.

To be eligible for the PrEP program, applicants/clients must:

1. Show proof of Virginia residency
2. Apply through the Central Eligibility Office located at the Virginia Department of Health by calling 804-864-7938.
3. Have an individual or family income no greater than 700% of the federal poverty level
4. Provide proof of income
5. Provide proof of insurance (private or government assisted):
    a. If Medicaid eligible, must apply for Medicaid within 90 days. (Lack of Medicaid at the time of financial determination does not mean client will not be eligible for the program.) Once approved, Medicaid will be billed for medical and prescription services.
    b. If no insurance, must be given information on or assisted with completing application for insurance through the Health Marketplace. Client may access health insurance information and enrollment at www.healthcare.gov. (Lack of insurance does not mean client will not be eligible for the program.) The PrEP program intake staff will assist client with determining eligibility through the Advancing Access Patient Support Program by calling 800-226-2056 or click https://www.gileadadvancingaccess.com/.
    c. If client has insurance, but requires assistance with co-pays, the PrEP program intake staff will assist client with accessing the Gilead PrEP (Truvada) Co-pay application at **www.GileadCoPay.com** or call 800-226-2056 for more information to see if client is eligible. Restrictions do apply.

d. If client has government assisted insurance, they will not be eligible for Gilead Co-pay program. This program requires commercial/private insurance. However the client or PrEP program intake staff may still contact Gilead at 800-226-2056 to determine other patient assistance eligibility options.
e. If client has government assisted insurance, cannot afford co-pays, and does not qualify for other assistance programs, then client will be financially eligible for the Virginia PrEP DAP program.

6. Have a documented HIV-negative test result as close to the initiation of PrEP as possible, ideally on the same day the prescription is given.
7. Agree to follow the protocols and procedures of the PrEP program.

III. Initiating PrEP in Local Health Departments – Forms

PrEP Client Forms

a. PrEP Assessment Form –

i. This one-page form is used to evaluate a client's potential risk that would support their uptake of PrEP and /or prevention education materials or interventions and can be viewed and printed by clicking here (will hyperlink document here).

b. New Patient Checklist

i. The New Patient Checklist accompanies the initial VA PrEP DAP Application and ensures that all necessary documentation and information has been collected prior to a client's uptake of PrEP from either the VA DAP or other available programs for PrEP. This form can be found here:

c. PrEP Agreement

i. This is a one-page consent form that is signed by client and provider and stored in client file. This form certifies that client understand PrEP enrollment requirements and adherence and can be found here:

d. VA PrEP DAP Application

i. This form serves as the first step in the process to begin a client's eligibility for the VA PrEP DAP program. This form should be completed on or before the initial clinic visit and initiates the PrEP uptake process for each client. The VA PrEP DAP Application can be viewed and printed by clicking here:

e. PrEP Withdrawal Form

i. There are several reasons for which a client can be removed from the PrEP program. In the event that withdrawal occurs this form should be completed by PrEP clinic representative and signed by client, if possible. A copy should be given to client and the original stored in client file. This form can be found by clicking here:

f. VDH STI Confidential Health History

i. The VDH STI Confidential Health History should be completed for every client enrolled in the PrEP program. This form gathers medical

information specific to patient history of medical treatment for STI and any other risk behavior that a client may present. This form can be found by clicking here:

g. Approval Letter

i. Used for PrEP DAP patients, at the discretion of the clinician or PrEP navigator at each individual site. It is the intent of the Virginia PrEP program that no one who meets the medical eligilibity qualifications be turned away. This form can be found here:

h. No income Letter:

i. The attached letter is intended as verification of no income for patients seeking assistance through the PrEP DAP program. This form can be found here:

i. PrEP Medication Order Form:

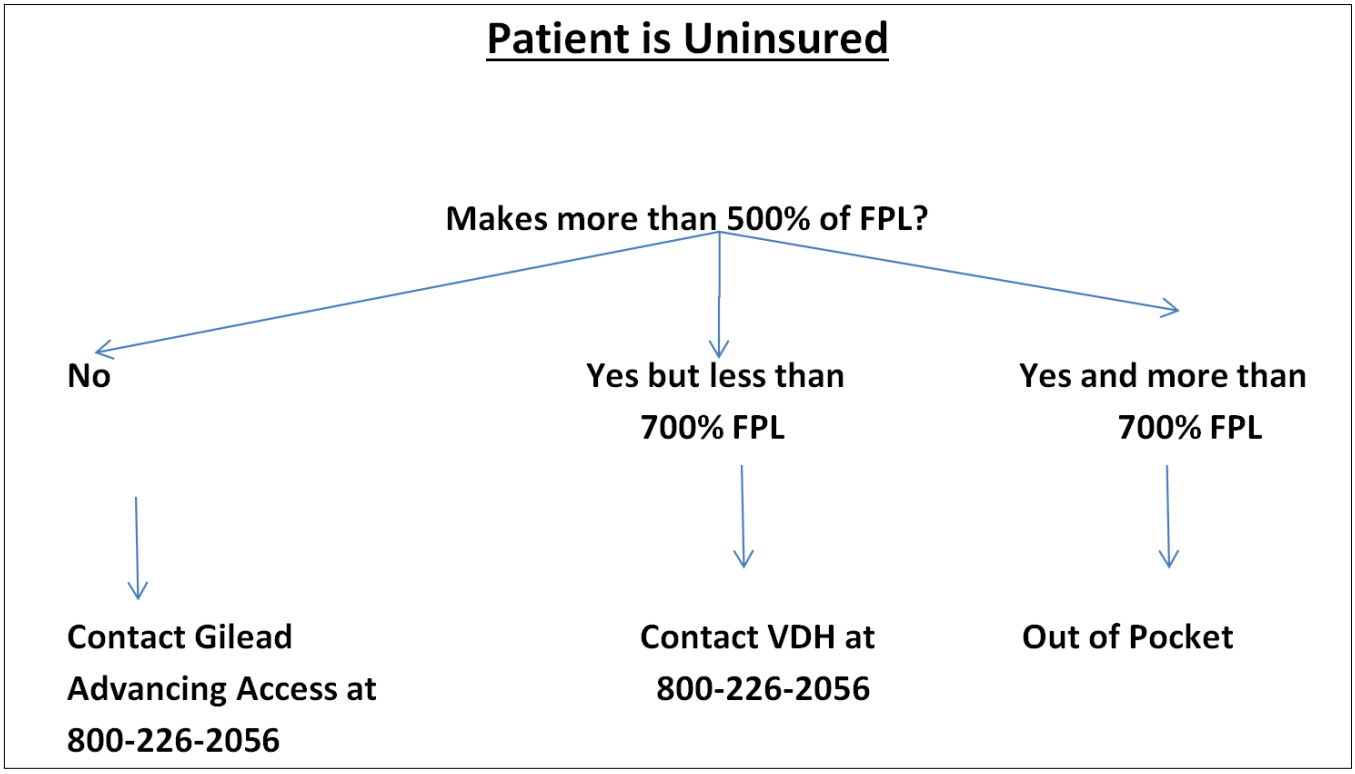
i. This form is used to fill a patient's PrEP prescription. See form for instructions. This form can be found here:

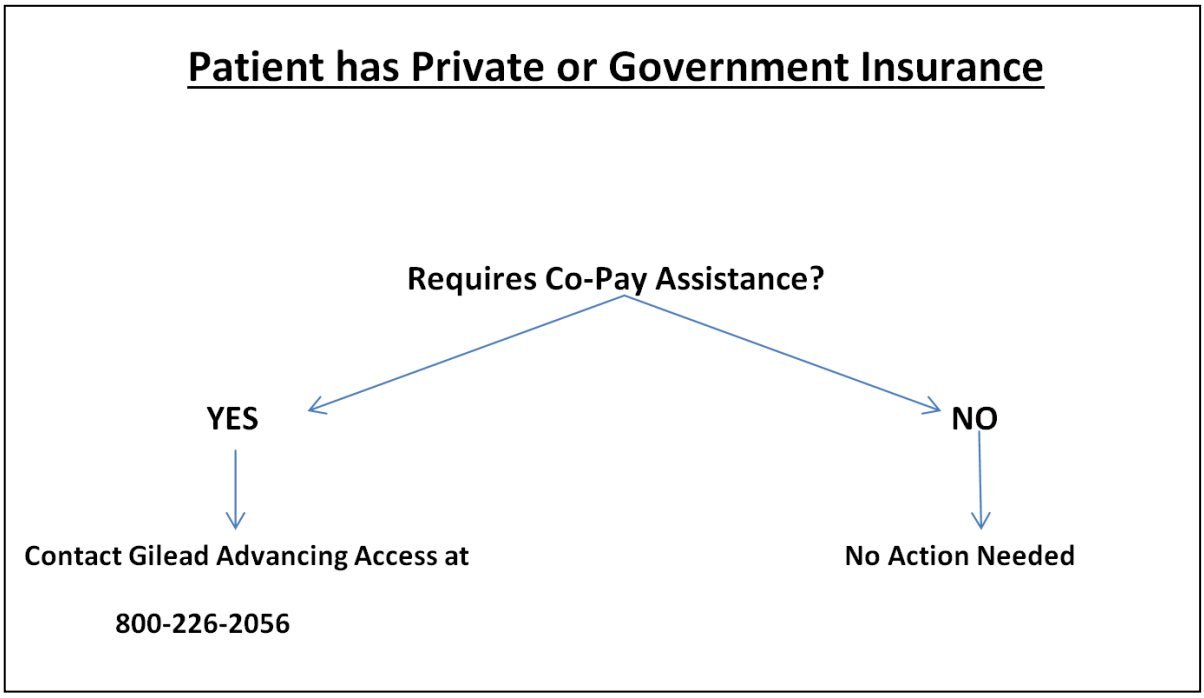
IV. Initiating PrEP in Local Health Departments – Financial Eligibility Chart & Algorithms

The following chart above is for reference in determining if the patient meets criteria for Gilead at up to 500% above FPL or VDH Assistance at up to 700% above FPL.

To be qualified for family status the patient's income has to be supporting the family size shown, refer to Gilead or VDH if there are questions regarding eligibility.

Federal Poverty Level Index for PrEP Program Qualifications								
	Individual	Family of 2	Family of 3	Family of 4	Family of 5	Family of 6	Family of 7	Family of 8
Federal Poverty Level	$11,880.00	$16,020.00	$20,160.00	$24,300.00	$28,440.00	$23,580.00	$36,730.00	$40,890.00
Gilead Qualification (500%)	$59,400.00	$80,100.00	$100,800.00	$121,500.00	$142,200.00	$117,900.00	$183,650.00	$204,450.00
VDH Qualification (700%)	$83,160.00	$112,140.00	$141,120.00	$170,100.00	$199,080.00	$165,060.00	$257,110.00	$286,230.00




Patient has Private or Government Insurance
Requires Co-Pay Assistance?
YES
NO
Contact Gilead Advancing Access at
800-226-2056
No Action Needed

V. PrEP Pharmacy Procedures

Central Pharmacy Phone Number: **804-786-4326**
Central Pharmacy Fax Number: **804-371-0236**

1. Fill out the PrEP DAP application form
2. Fax application form to PrEP eligibility specialist at Central Office Richmond 804-864-8050
3. After the application form is received at Central Office, the eligibility specialist will review the application and ensure that all needed documentation is present and sufficient to approve application. Once the application is approved, the eligibility specialist will inform the PrEP navigator, at which point the eligibility specialist will fax the approved application. Upon approval, the provider will fax the prescription, along with the corresponding completed PrEP Medication Order Form to Central Pharmacy: 804-371-0236.

   Orders faxed to Central Pharmacy before 1 p.m. will ship the same day. Orders received after that will ship the following day. **NEVER e-mail patient information to Central Pharmacy.**
4. Central Pharmacy will fill and ship the medication, along with the PrEP Medication Order Form to the pick-up site designated for the client. The medication will be in a brown paper bag with a "**P**" on it so that it is easily distinguishable from other medications stored at the pick-up site.
5. When the client picks up the medication, the site must obtain the client signature and date on the PrEP Medication Order Form that accompanied the medication. If the pickup site is different than the program site, the PrEP Medication Order Form will need to be faxed back to the program site fax number, found at the top of the form, so that the program site knows when to reorder medication from Central Pharmacy. Completed PrEP Medication Order Forms are to be sent to be faxed to Eric Mayes, PrEP Coordinator at 804-864-7335, no later than the end of each month.
6. All refills need to be tracked and submitted by the program site PrEP Navigator. If the prescription sent to Central Rx contains multiple refills, after the initial fill, only the completed PrEP Medication Order Form is required to be faxed to Central Pharmacy. If there are no remaining fills, a prescription will need to accompany the PrEP Medication Order Form. Medication will not be filled earlier than 14 days from the date that it is due. Central Pharmacy will only fill a 30 day supply at a time.

   If a patient withdraws, or is otherwise deemed ineligible, after a prescription has been filled by Central Pharmacy, please fax a completed withdrawal form to both the PrEP eligibility specialist and Central Pharmacy.

CDC FACT SHEET

PrEP: A New Tool for HIV Prevention

Pre-exposure prophylaxis, or PrEP, is a new HIV prevention method in which people who do not have HIV infection take a pill daily to reduce their risk of becoming infected. The pill contains medicines that prevent HIV from making new virus as it enters the body. In this way PrEP medicines can help keep the virus from establishing a permanent infection.

Providing a preventive medication before exposure to a germ or virus is not a new practice and has been used to prevent other diseases. For example, when individuals travel to an area where malaria is common, they are advised to take malaria medication before and during travel to prevent getting infected if bitten by a mosquito carrying the malaria parasite. However, the use of medication to prevent HIV infection has only recently been evaluated. When used consistently, PrEP has been shown to reduce the risk of HIV infection among adults at very high risk for HIV infection through sex, including men who have sex with men and heterosexually-active men and women. CDC is also evaluating PrEP's effectiveness in preventing HIV infection among individuals exposed to HIV through injecting drugs, but those results are not yet available.

For some individuals at very high risk for sexual exposure to HIV, PrEP may represent a much-needed additional prevention method — but it will not be right for everyone. PrEP is an intensive approach that requires strict adherence to daily medication and regular HIV testing. It is not intended to be used in isolation, but rather in combination with other HIV prevention methods. If it is used effectively and by persons at very high risk, PrEP may play a role in helping to reduce the number of new HIV infections in the United States.

PrEP Medications

Most PrEP efficacy trials have tested a combination of the antiretroviral drugs tenofovir disoproxil fumarate (also called TDF, or tenofovir) and emtricitabine (also called FTC), taken in a single pill daily for HIV prevention. This combination pill (brand name Truvada®) was approved by the U.S. Food and Drug Administration (FDA) for use as an HIV treatment in 2004, and was approved as PrEP in July 2012. Some clinical studies have also evaluated the use of tenofovir on its own as a preventive drug, but this drug alone is not FDA-approved as PrEP.

PrEP Proven Safe and Effective in Preventing Sexual HIV Acquisition

Strong research evidence indicates that PrEP, when used consistently, is safe and effective for reducing the risk of acquiring HIV sexually.

Research among Men Who Have Sex with Men

In November 2010, the multinational iPrEx study showed that a once-daily pill containing tenofovir plus emtricitabine was safe and provided an average of 44 percent additional protection against HIV infection among men who have sex with men (MSM) who were also provided with a comprehensive package of prevention services. These services included provision of condoms, monthly HIV testing, counseling to reduce risk behavior and encourage adherence to the daily pill regimen, and management of other sexually transmitted infections.

The level of protection varied widely depending on how consistently participants used PrEP, with significantly greater levels of protection among those who adhered well to the daily dosing regimen. Among MSM with detectable levels of the medication in their blood, the risk of HIV acquisition was reduced by more than 90 percent.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AUGUST 2012

The iPrEx study followed an earlier study by CDC that examined safety and adherence among MSM in the United States who were using daily tenofovir alone. The study found that the regimen was safe and did not lead to increases in risk behavior.

Research among Heterosexually-active Men and Women

In July 2011, researchers announced the results of two PrEP studies finding strong evidence that PrEP is effective and safe among heterosexually-active men and women.

- The TDF2 study found that a once-daily tablet containing tenofovir plus emtricitabine reduced the risk of acquiring HIV infection by roughly 62 percent overall in the study population of uninfected heterosexually-active men and women.
- The Partners PrEP study found that that daily doses of tenofovir plus emtricitabine or daily doses of tenofovir alone reduced HIV transmission among heterosexual serodiscordant couples (in which one partner is infected with HIV and the other is not) by 75 percent and 67 percent, respectively. The trial found that PrEP was equally effective among men and women, and that there was no statistically significant difference in efficacy between the two medication regimens.

As with the iPrEx study, both TDF2 and Partners PrEP showed that the level of protection offered by PrEP is strongly related to the level of adherence to the daily medication doses.

- In Partners PrEP, participants in the tenofovir-plus-emtricitabine group with detectable levels of the medication experienced a 90 percent reduction in risk for HIV infection; in the tenofovir- only group, the presence of medication in the blood was associated with an 86 percent reduction in risk.
- In TDF2, only half of the participants in the tenofovir-plus-emtricitabine group who became infected with HIV had any detectable medication in their blood, and even those participants had very low levels of medication present. This suggests that they had not taken PrEP consistently. In contrast, over 80 percent of matched participants who remained uninfected had detectable medication in their blood and the average medication level was substantially higher.

Two other research studies also reported results in 2011: a study called FEM-PrEP examining PrEP with tenofovir plus emtricitabine and a single group of participants in the VOICE trial examining PrEP with oral tenofovir alone did not show a protective effect among heterosexually-active women. Further sub-analysis of a sample of women in the FEM-PrEP trial showed that fewer than half of women assigned to take tenofovir plus emtricitabine were actually taking the drug, indicating that lack of adherence was likely a major factor contributing to the lack of efficacy in that trial.

Other than low adherence, no factors have yet been identified that appear to influence the efficacy of PrEP in reducing sexual transmission of HIV. The VOICE trial, which is still evaluating daily oral tenofovir plus emtricitabine in women, remains underway and may provide additional insight once those results are available.

CDC Interim Guidance on PrEP Use

MSM: Following the publication of the iPrEx trial results, CDC published interim clinical guidance for physicians electing to provide PrEP for HIV prevention among MSM in January 2011. CDC guidance stressed the importance of targeting PrEP to MSM at very high risk for HIV acquisition; delivering PrEP as part of a comprehensive set of prevention services; providing counseling regarding risk reduction and the importance of PrEP medication adherence; ensuring MSM who are prescribed PrEP are confirmed to be HIV negative prior to use; and providing regular monitoring of HIV status, side effects, adherence, and risk behaviors.

Heterosexuals: Following the publication of final results from the TDF2 and Partners PrEP trials, in August 2012 CDC published interim guidance to help clinicians safely and effectively provide PrEP for heterosexually-active adults. This guidance included recommendations similar to those for MSM, as well as new recommendations relevant to women who may become pregnant while taking PrEP and to couples in which one partner is HIV-positive and the other is HIV-negative.

CDC is also leading the development of comprehensive U.S. Public Health Service (PHS) guidelines on the use of PrEP for the prevention of sexually-acquired HIV infection. These guidelines will include more detailed recommendations for PrEP use with adults at very high risk for HIV infection, including MSM as well as heterosexually-active men and women. They are being developed in partnership with other PHS agencies and will incorporate input from providers, HIV prevention partners, and affected communities. The guidelines will be updated as information from additional trials and studies about factors affecting efficacy and safety for all transmission risk groups becomes available.

CDC Interim Guidance on HIV Pre-Exposure Prophylaxis

Before initiating PrEP

Determine eligibility:

- Document negative HIV antibody test immediately before starting PrEP medication.
- Test for acute HIV infection if patient has symptoms consistent with acute HIV infection or reports unprotected sex with an HIV-positive person in the preceding month.
- Determine if women are planning to become pregnant, are currently pregnant, or are breastfeeding.
- Confirm that patient is at ongoing, very high risk for acquiring HIV infection.
- If any sexual partner is known to be HIV-infected, determine whether receiving antiretroviral therapy; assist with linkage to care if not in care or not receiving antiretroviral therapy.
- Confirm that calculated creatinine clearance is ≥60 mL per minute (Cockcroft-Gault formula).

Other recommended actions:

- Screen for hepatitis B infection; vaccinate against hepatitis B if susceptible, or treat if active infection exists, regardless of decision regarding prescribing PrEP.
- Screen and treat as needed for sexually transmitted infections (STIs).
- Disclose to women that safety for infants exposed during pregnancy is not fully assessed but no harm has been reported.
- Do not prescribe PrEP to women who are breastfeeding.

Beginning PrEP medication regimen:

- Prescribe tenofovir disoproxil fumarate 300 mg (TDF) plus emtricitabine 200 mg (FTC) (i.e., one Truvada [Gilead Sciences] tablet) daily.
- In general, prescribe no more than a 90-day supply, renewable only after HIV testing confirms that patient remains HIV-uninfected. For women, ensure that pregnancy test is negative or, if pregnant, that the patient has been informed about use during pregnancy.
- If active hepatitis B infection is diagnosed, consider using TDF/FTC, which may serve as both treatment of active hepatitis B infection and HIV prevention.
- Provide risk-reduction and PrEP medication-adherence counseling and condoms.

Follow-up while PrEP medication is being taken:

- Every 2–3 months, perform an HIV antibody test (or fourth generation antibody/antigen test) and document negative result.
- At each follow-up visit for women, conduct a pregnancy test and document results; if pregnant, discuss continued use of PrEP with patient and prenatal-care provider.
- Evaluate and support PrEP medication adherence at each follow-up visit, more often if inconsistent adherence is identified.
- Every 2–3 months, assess risk behaviors and provide risk-reduction counseling and condoms. Assess STI symptoms and, if present, test and treat for STIs as needed.
- Every 6 months, test for bacterial STIs even if asymptomatic, and treat as needed.
- Three months after initiation, then every six months while on PrEP medication, check serum creatinine and calculate creatinine clearance.

On discontinuing PrEP (at patient request, for safety concerns, or if HIV infection is acquired):

- Perform HIV test(s) to confirm whether HIV infection has occurred.
- If HIV positive, order and document results of resistance testing, establish linkage to HIV care.
- If HIV negative, establish linkage to risk reduction support services as indicated.
- If active hepatitis B is diagnosed at initiation of PrEP, consider appropriate medication for continued treatment of hepatitis B infection.
- If pregnant, inform prenatal-care provider of TDF/FTC use in early pregnancy and coordinate care to maintain HIV prevention during pregnancy and breastfeeding.

Recommendations in black apply to both adult MSM and heterosexually-active men and women; items in blue are specific to heterosexual women.

Ongoing and Planned PrEP Trials

Injection Drug Users

CDC is sponsoring the only clinical trial of PrEP among injection drug users (IDUs), the Bangkok Tenofovir Study. The study, being conducted in Thailand, is assessing the efficacy of PrEP with daily oral tenofovir alone to prevent HIV infection among 2,400 male and female IDUs. Like other PrEP trials, this study is also examining the effects of taking a daily pill on HIV risk behaviors, adherence to and acceptability of the regimen, and in cases where participants become HIV-infected, the resistance characteristics of the acquired virus. Results are anticipated in late 2012.

Other PrEP Studies

Other trials are underway or planned to examine the safety, adherence, acceptability, and feasibility of other PrEP regimens and dosing strategies. For detailed information on the full range of PrEP trials, visit **www.avac.org**.

Next Steps in Assessing and Maximizing the Benefits of PrEP

PrEP offers a new tool to help combat the HIV epidemic among the hardest-hit populations in the United States and around the world, but its overall impact on the epidemic will depend on many things that at this point remain unknown, including access and acceptability among the populations at highest risk. Impact will also depend upon whether programs implemented in community settings can achieve the key requirements for success, including ensuring regular HIV testing, maintaining high levels of medication adherence, and preventing increases in risk behavior.

CDC and its partners are working to assess many of these key questions to determine how PrEP can most effectively be used in the United States.

- "Open-label extension" studies of the iPrEx, Partners PrEP, and TDF2 trials — in which all participants in those trials are provided PrEP knowing that they are taking medication with proven efficacy — are planned or underway, and will provide additional valuable information in research settings about acceptability, adherence to PrEP, and risk behavior.
- Demonstration research projects to evaluate PrEP use among MSM are planned in several California cities and Miami to provide similar information in "open-label" studies conducted with new research participants.
- CDC is working with federal, state, local, and private partners to identify additional ways to evaluate key PrEP implementation questions at community sites providing PrEP as a clinical HIV prevention service.

With limited resources available to combat the HIV epidemic, we will have to carefully consider how to most effectively use this tool in combination with other proven approaches to have the greatest possible impact on the HIV epidemic. Other key strategies such as HIV testing and treatment of individuals with HIV infection are critical, and will need to be expanded to reach the substantial number of Americans who are either unaware of their HIV status or not being effectively treated. CDC estimates indicate that only one-quarter of Americans with HIV currently have their virus suppressed to the levels needed to maintain their own health and prevent transmission to others.

Nevertheless, while expanded HIV treatment for those with HIV infection is essential, it will not be sufficient to end the epidemic. Even if we can improve treatment outcomes for all of those diagnosed with HIV, individuals who do not know they are infected are likely to continue to unknowingly transmit HIV infection to others.

With 2.7 million people becoming infected annually worldwide, including approximately 50,000 in the United States, we must capitalize on every available prevention tool. While the most appropriate uses of PrEP as part of these efforts is yet to be determined, available data suggest that this prevention method, if used strategically and effectively, could be cost-effective and may help reduce the continuing toll of HIV infection in this nation.