



PrEP

PrEP is DC's Key HIV Prevention Practice



PrEP is DC's Key HIV Prevention Practice



What is PrEP?

Pre-Exposure Prophylaxis or PrEP uses the medication Truvada® (Tenofovir Disporoxil Fumarate [TDF]/Emtricitabine [FTC] or) to prevent HIV infection. This is the first HIV prevention option since HIV was discovered. Prior to PrEP, effective HIV prevention included: condoms, abstinence, and clean needles. PrEP works because the medication blocks HIV from incorporating its genetic material into the host's genome thereby preventing HIV infection. It is a once daily pill. It is safe and tolerable with little or no side effects. It is for men and women. The District of Columbia wants all practitioners – including but not limited to primary care or family practice, internal medicine, OB/GYN, pediatric – to offer PrEP to patients who could benefit from its protection from HIV. Those patients include men and women who are straight, gay or bisexual.

PrEP is similar to other preventive health treatments from reproductive health to averting chronic conditions such as diabetes, hypertension and cardiovascular disease.

Guide to make PrEP easy

The District of Columbia Department of Health has prepared this handbook to guide you in advising some of your patients on the benefits of PrEP. It includes the recommendations of the *Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline* issued by the U.S. Centers for Disease Control and Prevention (CDC). The DC Department of Health has worked with DC medical providers to inform this handbook and will work with providers to successfully implement PrEP in their practices.

Why PrEP for DC?

Washington, DC has one of the highest rates of HIV in the nation. In 2017, the DC Department of Health reported that 1.9% of all District residents are currently living with HIV. The World Health Organization considers a rate exceeding 1% to be a significant health condition¹. In December 2016, Mayor Bowser issued the *90/90/90/50 Plan: Ending the HIV Epidemic in the District of Columbia by 2020*². The Plan aims to achieve 90% of persons with HIV to know their status, 90% of persons diagnosed on treatment, 90% of persons on treatment to achieve viral load suppression and a 50% reduction in new HIV infections by the year 2020. While the first three strategies contribute greatly to reducing new HIV infections, to reach the goal fully requires an increase in the number of residents using PrEP. The DC Department of Health estimates currently that less than 10% of the persons who could benefit from PrEP are using it. The DC Department of Health wants more clinicians to make PrEP available and support patients who ask for PrEP. This approach is supported by the CDC as an essential strategy to reduce HIV infection.

What is the Health Department doing to support medical providers?

While the essential component of PrEP is the prescription for the medication, patients may need extra support to keep taking the medication and advice on sexual health. The DC Department of Health is funding community-based organizations to provide that ongoing support. Like other preventive health approaches, i.e. reducing obesity or smoking cessation, medical providers can connect patients to

these organizations for sexual health support. This handbook includes the many resources available in DC. The DC Department of Health also has a team that can assist medical providers one-on-one in starting to provide PrEP in your office. In addition, the DC Department of Health offers a Continuing Medical Education (CME) credit for clinicians³. Call 202-671-4900.

The DC Department of Health is also educating residents about PrEP through the community-based organizations and advertising in the media. DC expects more persons will be asking their medical providers about PrEP.

Is PrEP covered by health insurance?

Yes, PrEP is covered by commercial health plans, DC Medicaid and Medicare. Gilead Sciences, the manufacturer of Truvada®, offers a patient assistance program. The DC Department of Health can help inform and navigate patients on insurance coverage and other financial support to use PrEP.



Questions?

Call (202) 671-5955

WEB SITES

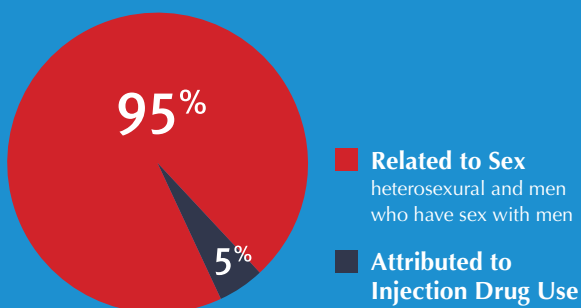
doh.dc.gov/hiv

dctakesonhiv.com/prep

Before Getting Started

New HIV Infection Estimates

According to the DC Department of Health estimates



Because there is such a high prevalence of HIV in DC, a single sexual encounter with someone of uncertain HIV status without a condom is a risky condition. It does not require multiple or anonymous partners.

The DC Department of Health understands that for some medical providers conversations about sex can be uncomfortable. To reduce HIV in DC, medical providers must have a brief, candid and supportive conversation with their patients about sex. This handbook will help to make that conversation reasonable and practical.

What does this handbook contain?

This handbook will describe how to get started providing PrEP. It is meant to make the process easy to understand and contains contact information for questions, referrals for supports for your patients (adherence, sexual health education, insurance navigation) and links to additional detailed guidance.

Who should take PrEP?

While there can be multiple reasons why PrEP would make sense for many patients, there are three factors that the Department of Health consider crucial to encourage PrEP as an option:

- Not using condoms on a regular basis – this can be confirmed by your patient or by a recent sexually transmitted infection, such as chlamydia, gonorrhea or syphilis.
- Partner is HIV positive or unknown status – patient either confirms his or her partner is living with HIV or patient is uncertain or thinks the partner may have HIV.
- Patient asks for PrEP – your patient has made a self-assessment that he or she may have potential exposure to HIV and believes PrEP is a good option.

Getting Started

The following are five steps to help you initiate PrEP.



1 My patient asks about PrEP

Your patient is interested in PrEP or requests it directly.

You can ask what your patient knows about PrEP. If the patient knows about it, he or she is acknowledging that they are potentially at risk of acquiring HIV. You have the option to skip to step 4 to start the clinical tests to start PrEP.

2 A brief conversation about sexual health

To determine if PrEP is a good option, you can have a brief conversation about his or her sexual health.

While this has often been described as taking a patient's sexual history, the DC Department of Health encourages medical providers to focus less on what the patient did previously (the patient cannot undo what he or she did and may feel either ashamed or stigmatized and not be forthcoming) and instead on what the patient's sexual profile is today. Here is a suggested conversation introduction:

I am going to ask you a few questions about your sexual health today and how you see your sexual health in the future. I understand these questions are very personal, but they are important for your overall health. I ask these questions of all my patients, regardless of age, gender, sexual orientation or marital status. These questions help me help you stay healthy like other questions I ask about your health.

- *Are you currently having sex or expect to have sex?*
- *Do you have or contemplate having sex with men, women or both?*
- *Do you have or contemplate having have vaginal (penis in the vagina) and/or anal (penis in the anus) sex?*
- *How do you protect yourself or contemplate protecting yourself when you have sex? (the alternative is to ask directly about using condoms and frequency)*
- *How often do you use this protection with sex?*
- *Do you have or contemplate having sex with a person whom you know or think might be HIV positive?*
- *Have you been diagnosed with a sexually transmitted infection, such as chlamydia, gonorrhea or syphilis in the past 6 months?*

Here are some additional questions that can depend on the gender or relationship status of the patient:

- *When you have sex or contemplate sex with a man, do or will you have insertive (“top”) or receptive (“bottom”) sex or both?*
- *Are you currently trying or contemplate having a child?*

③ Has the patient considered PrEP?

Your patient should consider PrEP if he or she responds positively to these questions:

The patient sometimes does not use condoms, the patient has had a recent STI, and/or the patient may be having sex with a person who is or may be HIV positive.

The next step is ask if the patient is interested in PrEP as another way to prevent HIV. The basic description of PrEP is a single daily pill, taken according to directions, will help prevent HIV. Like other forms of sexual health protection, PrEP may fit the person's life circumstance at present or near future. This may change with a person's circumstances, such as a monogamous relationship, marriage, or childbirth. Your patient decides when PrEP is no longer necessary.

Taking any medication has its benefits and potential effects. Below is a quick rundown of benefits and effects.

For further information, consult the Truvada® medication guide⁴:

BENEFITS

- Prevents HIV when taken regularly
- Studies confirm that PrEP prevents most HIV infections when taken according to directions. One study found it 92% effective when taken daily⁵.
- A two-year study at a medical practice in the San Francisco bay area found that no patients on PrEP became infected⁶.

EFFECTS

According to FDA approved product labeling⁷, 2% or more of HIV-1 uninfected subjects (and more frequently by placebo subjects) in PrEP trials reported adverse reactions of headache, abdominal pain and decreased weight. Additional warnings and precautions include:

- A slightly greater decrease in bone mineral density and an increase in bone metabolism, suggesting increased bone turnover.

- Severe exacerbations of hepatitis B in patients co-infected with HBV and HIV-1 after Truvada is discontinued.
- New Onset or Worsening Renal Impairment

There has been a question of whether taking a medication that also treats HIV may result in resistance. To date, studies have not shown a significant increase in resistance⁸.

④ Let's get started with PrEP

The next step is to run some necessary tests under the CDC guidance⁹:

HIV – PrEP is only for persons who are HIV negative. CDC recommends the lab-based 4th generation HIV test algorithm. You can start with a rapid HIV test, but make sure to include a lab-based test on the panel. Note: the 4th generation HIV test can detect HIV antigens during the period after exposure to HIV and before the immune system has produced antibodies. This period is known as acute infection and between 40% to 90% of persons will manifest often flu-like symptoms¹⁰.

RENAL FUNCTION – there are documented decreases in renal function as measured by estimated creatinine clearance (CrCl) and Glomerular Filtration Rates (GFR) among some persons using Truvada®. CDC recommends a serum creatinine test to ensure that the person has a baseline kidney function $GFR \geq 60$ ml/min.

HEPATITIS – CDC recommends hepatitis B and C serology. Patients susceptible to hepatitis B should be vaccinated. Severe acute exacerbations of hepatitis B have been reported in patients co-infected with HBV and HIV-1 who discontinue Truvada®. Hepatic

function (clinical and laboratory follow-up) should be monitored closely for at least several months in these patients who discontinue Truvada®. See Endnote for more information on Truvada® for hepatitis B treatment¹¹.

PREGNANCY – Women should have a pregnancy test. PrEP is a viable option for women with HIV positive partners who want to have a child. PrEP provides an option for women to conceive naturally and reduce HIV acquisition. Both FDA labeling¹² and CDC guidelines¹³ permit this use. A study found in 46 HIV negative pregnant women that continued use of the medication did not result in adverse effects to the fetuses or HIV infection¹⁴. The medication is used regularly in HIV positive pregnant women with no adverse effects¹⁵. Providers can find more information at <http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf>.

5 Ready to start and maintain

With the HIV negative test result, you are ready to start your patient on PrEP.

You can start with a one-month prescription of Truvada® and see the patient in one month for a follow-up or a three-month prescription with a scheduled one-month appointment.

The medication becomes fully effective for men and women differently. Based on pharmacokinetic studies, the medication achieves full protection in men in approximately 7-14 days and 20 days for women¹⁶.

Some patients may experience headache, nausea or flatulence within the first two weeks of taking the medication. Providers can inform patients that over-the-counter medications will address those effects.

According to CDC guidelines, after the first month, the recommendation is visits at three-month intervals.

Here are the recommendations for the follow up visits:

ONE MONTH

- HIV test to confirm negative status
- Check in with the patient on side effects or any other difficulties with medication adherence.

THREE MONTH

- HIV test to confirm negative status
- Pregnancy test
- STI tests – chlamydia, gonorrhea, syphilis
- Hepatitis based upon patient profile
- Check in with patient on side effects and medication adherence

SIX MONTH

- HIV test to confirm negative status
- Pregnancy test
- STI tests – chlamydia, gonorrhea, syphilis
- Hepatitis based upon patient profile
- Check in with patient on side effects and medication adherence
- Add creatinine level check at ≥ 60 ml/min

Note: a rise in creatinine is not a reason to stop PrEP, however, decrease below 60 ml/min, stop PrEP and potentially consult on renal function if indicated.

The PrEP study of the medical practice in the San Francisco bay area found an increase in bacterial STIs¹⁷. You may diagnose one of these STIs with your patient. While the efficacy studies on PrEP found no reduction in condom use¹⁸, implementation studies

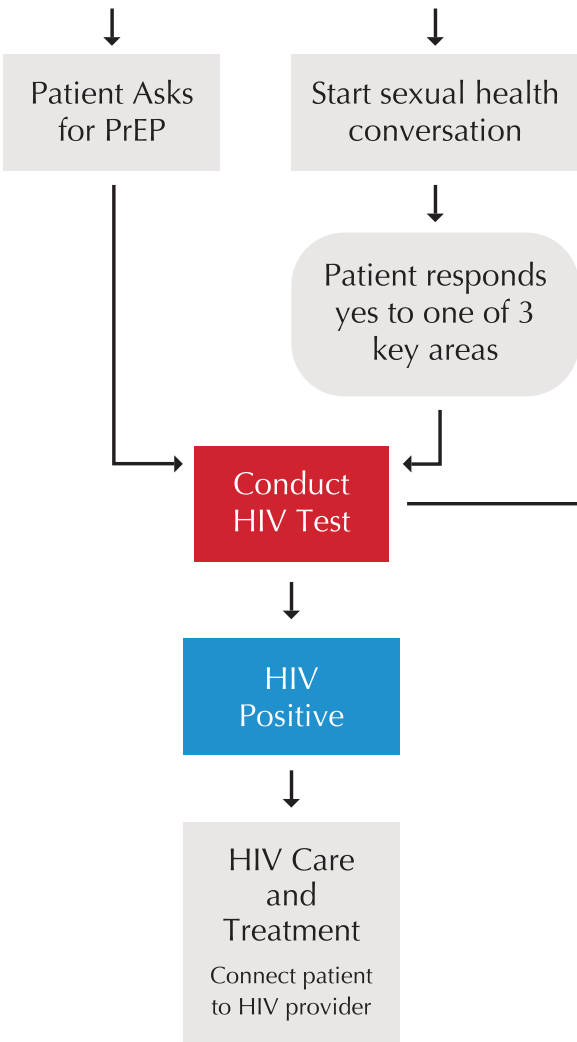
have evidenced a decrease¹⁹. Diagnosing a STI in a patient on PrEP is not a reason to discontinue PrEP. However, while PrEP protects against HIV, patients need to know that it does not protect against curable bacterial infections, such as chlamydia, gonorrhea and syphilis. **The DC Department of Health has weighed the potential risk of potential STD exposure and fully recommends PrEP as an essential HIV prevention treatment for your patients.**

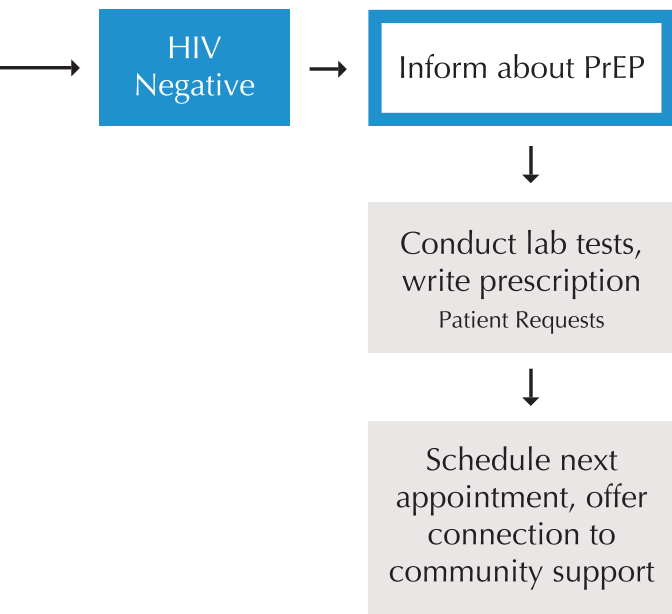
The CDC and the DC Department of Health recommends that medical providers continue to have conversations with their patients about their sexual health, including discussion of protection and risk factors. The DC Department of Health supports multiple community-based organizations to provide ongoing support for patients on PrEP. Professional staff at the organizations will talk with PrEP participants about sexual health practices, condom use, risk reduction and self-confidence in negotiating and managing healthy relationships. The DC Department of Health encourages medical providers to offer these resources to their patients. A list of the organizations are listed under Resources in this handbook.



START HERE

Patient Presents for Medical Appointment





More Information

This section provides additional guidance and information sources.



Can adolescents take PrEP?

It is important to note that DC public health law enables minors (persons less than 18 years old) to access sexual health services without parental or guardian notification or approval.

The services include testing and treatment. The DC Department of Health currently provides STI and HIV testing in the public high schools and in community settings. Adolescents in DC have low rates of HIV (the prevalence rate is 0.1%). However, adolescents have high rates of chlamydia and gonorrhea. The incidence rate of chlamydia is more than 5% among young people under 19 years old. In some settings, the DC Department of Health has found incidence rates as high as 20%. These rates and behavior indicate the significant potential for HIV exposure.

The current FDA labeling for Truvada® for PrEP is above 18 years old²⁰. The CDC recognizes that there are adolescents at substantial risk of HIV acquisition and PrEP has the potential to prevent infection²¹.

The International AIDS Society has encouraged expansion of PrEP to older adolescents (ages 15 to 19)²².

Limitations to offering PrEP to adolescents include:

- Current PrEP trials have not concluded or presented complete data.
- Adolescents can be inconsistent in adherence.
- There are potential effects on bone density.
- There are issues related to insurance coverage

and notification. Some insurance plans send Explanation of Benefits (EOBs) that could disclose the adolescent to the parent or guardian. There are exceptions. The DC Medicaid program does not send EOBs.

The DC Department of Health has consulted with other health departments and several are supporting and directly providing PrEP to adolescents. The DC Department of Health will be starting to offer PrEP to adolescents at its new DC Health and Wellness Center. Contact Dr. Travis Gayles at 202-671-4900 for specific questions on PrEP for adolescents.

PrEP for non-sexual transmission

This handbook has focused primarily on sexual transmission of HIV based on nearly all new HIV infections are from sex. However, persons who inject drugs remain at risk of HIV exposure through sharing needles. PrEP is a good option to avert HIV infection for individuals willing to take daily medication. The DC Department of Health has a community-based organization partner that works with persons who inject drugs to support them benefiting from PrEP, and serves as a referral site for PrEP initiation for their clients.

Insurance coverage

As noted previously, commercial insurance plans, DC Medicaid and Medicare cover the medication for PrEP, the clinical visits and laboratory tests. Some plans do require prior authorization for Truvada® for PrEP. Some patients may have plans with varied co-pays for the medication. Gilead Sciences has a patient assistance program that will cover the entire cost of the medication for persons without insurance. It covers covers some co-pays and deductibles for persons with insurance. In addition,

the Patient Access Network Foundation will cover some medication costs. Both Gilead and the Foundation have eligibility for patients up to 500% of the Federal Poverty Level or \$59,400 for a single individual.

Post-Exposure Prophylaxis (PEP)

Some persons may not be interested or prepared for the daily medication regimen comprising PrEP. Another option is Post-Exposure Prophylaxis or PEP. PEP has been mostly used in occupational settings for persons accidentally exposed through needle sticks or other work-related exposure. PEP is a valid HIV prevention course for a person who experienced an isolated incident of sexual or injection-related HIV exposure. PEP is a 28-day regimen of antiretroviral medications based on the level of exposure. It is effective within 72 hours of the exposure. Some persons who utilize PEP may become interested in PrEP from repeated instances. Due to the low uptake of PEP, the DC Department of Health expects a small number of persons to recognize PEP. The DC Department of Health is currently offering PEP at its new DC Health and Wellness Center (former STD Clinic) and intends to promote PEP as an option through separate provider education and media.



Resources



DC-Based Services and Support



The District of Columbia offers medical providers and their patients many resources to be successful on PrEP. The DC Department of Health is available to answer questions, provide consultations and offer technical assistance to providers to include PrEP in their practices.

List of DC resources

ANDROMEDA TRANSCULTURAL HEALTH

1400 Decatur Street NW

Washington, DC 20011

(202) 291-4707

Note: Multi-lingual service provider

CHILDREN'S NATIONAL MEDICAL CENTER

111 Michigan Avenue NW

Washington, DC 20010

(202) 476-5000

Note: Adolescents and Young Adults

DC DEPARTMENT OF HEALTH HAHSTA

DC Health and Wellness Center

77 P Street NE

Washington, DC 20002

(202) 741-7692

DC DEPARTMENT OF HEALTH HAHSTA

HIV/AIDS, Hepatitis, STD and TB Administration

899 North Capitol Street NE

Washington, DC 20002

(202) 671-5955

doh.dc.gov/hiv

www.dctakesonhiv/prep

HIPS

906 H Street NE

Washington, DC 20002

(202) 232-8150

Note: Substance-use expertise

MARY'S CENTER

2333 Ontario Road, NW

Washington, DC 20009

(202) 483-8196

METROHEALTH

1012 14th Street NW, Suite 700

Washington, DC 20005

(202) 638-0750

PLANNED PARENTHOOD – CAROL WHITEHILL MOSES CENTER

1225 4th Street, NE

Washington, DC 20002

(202) 347-8500

US HELPING US

3636 Georgia Ave NW

Washington, DC 20010

(202) 446-1100

WHITMAN-WALKER HEALTH

1525 14th Street NW

Washington, DC 20005

(202) 745-7000

THE WOMEN'S COLLECTIVE

3230 Pennsylvania Avenue SE, Suite 312

Washington, DC 20020

(202) 483-7003

CDC Materials

CDC Clinical Practice Guideline:
www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf

CDC Clinical Practice Guideline Supplement:
www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement201414.pdf

CDC PrEP Basics:
www.cdc.gov/hiv/basics/prep.html

Insurance Billing

Currently, there is no official ICD-10 code specifically for PrEP. However, based on surveys of providers across the country providing PrEP there are several common diagnosis codes:

ICD-10	Description
Z20.2	Contact with and (suspected) exposure to infections with a predominantly sexual mode of transmission
Z11.4	Encounter for screening for human immunodeficiency virus [HIV]
Z11.3	Encounter for screening for infections with a predominantly sexual mode of transmission
Z72.5	High-risk sexual behavior
Z20.82	Contact with and (suspected) exposure to other viral communicable diseases

The five steps described previously to assess and start a patient on PrEP are covered generally under preventive medicine CPT codes. Here are the most relevant:

Evaluation and management (E/M) services	
Code	Description
99201-99205	New patients
99211-99215	Established patients

Preventative medicine counseling and/or risk-factor-reduction intervention(s) provided to an individual (separate procedure)	
Code	Time duration
99401	Approximately 15 minutes
99402	Approximately 30 minutes
99403	Approximately 45 minutes
99404	Approximately 60 minutes

Preventative medicine counseling and/or risk-factor-reduction intervention(s) provided to an individual in a group setting (separate procedure)	
Code	Time duration
99411	Approximately 30 minutes
99412	Approximately 60 minutes

The National Alliance of State & Territorial AIDS Directors (NASTAD) has published a helpful guide on billing codes associated with PrEP. They include those mentioned above, laboratory tests, and Medicare-specific codes. Go to www.pleaseprepme.org/wp-content/uploads/2015/10/BillingCodingGuide_v4_Final_2016.pdf.

Other Patient Assistance Programs

Gilead Sciences and the Patient Access Network offer supplemental financial assistance for PrEP. Contact information:

GILEAD ADVANCING ACCESS PROGRAM

800-226-2056

www.gileadadvancingaccess.com

Patient Access Network (PAN)

866-316-7263

www.panapply.org



References

A photograph of a modern conference room. In the foreground, a long, bright yellow conference table is partially visible. Several black mesh office chairs with red seats are arranged around the table. In the background, a whiteboard on a stand is positioned against a blue wall. The room has a drop ceiling with recessed lights and a glass partition on the left side.

1. World Health Organization Consolidated ARV Guidelines, June 2013
2. Mayor's 90/90/90/50 Play: Ending the HIV Epidemic in the District of Columbia by 2020 (December 2016), <https://doh.dc.gov/page/90909050-plan-ending-epidemic-district-columbia-2020>
3. D.C. Code § 3-1205.10 details license requirements for clinicians and continuing education requirements, which shall include 3 credits of instruction on the Human Immunodeficiency Virus ("HIV") and the Auto Immune Deficiency Syndrome ("AIDS") for the following practices: medicine, registered nursing, practical nursing, nursing assistive personnel and physician assistants.
4. Truvada® Medication Guide, http://www.gilead.com/~media/Files/pdfs/medicines/hiv/truvada/truvada_medication_guide.pdf
5. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men, Grant et al, NEJM December 2010
6. No New HIV Infections With Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting, Volk et al, Clinical Infectious Diseases, September 2015
7. Nucleoside/Nucleotide Analog Human Immunodeficiency Virus-1: Reverse Transcriptase Inhibitors, <https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatients/PostmarketDrugS/UCM312304.pdf>
8. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline, <https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf> (see page 25 for study citations)
9. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline, <https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf>
10. Considerations for Antiretroviral Use in Special Patient Populations: Acute and Recent (Early) HIV Infection, <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-treatment-guidelines/20/acute-hiv-infection>
11. Truvada® is not FDA-approved for treatment of chronic Hepatitis B (HBV) infection, and the safety and efficacy of Truvada® has not been established in patients co-infected with HBV and HIV-1. Both components of Truvada®, Tenofovir Disporoxil Fumarate (TDF)

and Emtricitabine (FTC), are active against both HBV and HIV infections. Use of Truvada® may prevent the development of significant liver disease by suppressing the replication of HBV. However, only TDG is currently FDA-approved for the treatment of HBV. The CDC recommends individuals at substantial risk of both HBV and HIV infections may benefit from daily prophylactic Truvada®.

12. Gilead Sciences. Truvada® Package Insert. 2013, http://www.gilead.com/pdf/truvada_pi.pdf.
13. Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission. Recommendations for use of antiretroviral drugs in pregnant HIV-1-infected women for maternal health and interventions to reduce perinatal HIV transmission in the United States. 2014, <http://aidsinfo.nih.gov/contentfiles/lvguidelines/perinatall.pdf>.
14. Preexposure Prophylaxis and Timed Intercourse for HIV-discordant Couples Willing to Conceive a Child, Vernazza et al. AIDS 2011.
15. Antiretroviral Pharmacology: Special Issues Regarding Pregnant Women and Neonates. Mirochnick, et al. Clin Perinatal 2010.
16. Penetration of Tenofovir and Emtricitabine in Mucosal Tissues: Implications for Prevention of HIV-1 Transmission. Patterson et al. Sci Transl Med 2011; Pharmacological considerations for tenofovir and emtricitabine to prevent HIV infection. Anderson et al. Journal of Antimicrob Chemother 2011; Pharmacology considerations for HIV prevention. Anderson. 13th International Workshop on Clinical Pharmacology of HIV 2012; Barcelona, Spain.
17. See note 6
18. See note 5
19. See note 6
20. See note 12
21. See note 8 (see page 42 for guidance on adolescents)
22. Empowering Adolescents with PrEP, <http://www.iasociety.org/The-latest/Blog/ArticleID/49/Empowering-adolescents-with-PrEP>

