PrEP Education for Youth-Serving Primary Care Providers Toolkit

In March 2016, the Sexuality Information and Education Council of the United States (SIECUS), supported in part by funding from Gilead Sciences, Inc., convened an Expert Work Group to address issues surrounding pre-exposure prophylaxis (PrEP) delivery and contribute to the development of an online resource to support primary care providers in offering PrEP to adolescents and young adults under age 25. Expert stakeholders from diverse disciplines convened to identify key concerns as well as barriers to greater primary care provider (PCP) engagement with PrEP. These robust discussions led to the development of the **PrEP Education for Youth-Serving Primary Care Providers Toolkit**.

The *PrEP Education for Youth-Serving Primary Care Providers Toolkit* is the only toolkit to date focused on supporting PCPs in providing PrEP to youth. Acknowledging that many excellent resources about PrEP and HIV already exist, SIECUS compiled some of these quality resources and developed new tools to address particular PCP needs in order to create this comprehensive resource.

Each section of the *PrEP Education for Youth-Serving Primary Care Providers Toolkit* has tools that PCPs can use in delivering PrEP care or in learning about particular aspects of PrEP delivery to youth at high risk of HIV acquisition. The Toolkit includes both original SIECUS tools and existing partner resources offering valuable information to assist youth-serving PCPs become better equipped at educating, counseling, and where appropriate, prescribing PrEP for young people. Review the toolkit section by section below.

Overview

Section 1: Clinical Tools

Sexual History

1.7 SIECUS Tool: Taking a Sexual History

Adolescent Development

1.8 Tool: **Adolescent Social, Psychosocial and Cognitive Development** (Sanders, Pediatrics in Review)

1.9 Tool: **Male Tanner Stages** (Family Practice Notebook)

1.10 Tool: **Female Tanner Stages** (Family Practice Notebook)

Section 2: Billing for PrEP

2.1 SIECUS Tool: PrEP Billing FAQs

2.2 Tool: **Getting Prepped** (Project Inform)

2.3 SIECUS Tool: Helping Insured Patients Estimate PrEP Costs

2.4 SIECUS Tool: PrEP-related ICD-10 and CPT Codes

2.5 Tool: **Medication Assistance and Co-pay Programs for PrEP** (Fair Pricing Coalition)

Section 3: HIV, Stigma, and Social Determinants of Health

Youth and Social Determinants of Health

3.1 Tool: **YMSM: The People Behind the Epidemiological Term** [Webinar]

(Contact Brandy Oeser at the YMSM + LGBT Center of Excellence, btoeser@ucla.edu to inquire about available CE)

3.2 Tool: **Our Health Matters: Mental Health, Risk and Resilience Among LGBTQ Youth of Color Who Live, Work, or Play in Boston** (Report by Fenway Institute, November 2015)

3.3 SIECUS Tool: Young Women, HIV, and PrEP

Building Cultural Competence

Check your bias

3.4 Tool: **Building Cultural Competence** (Advocates for Youth)

3.5 Tool: **Self-Assessment** (Advocates for Youth)

3.6 Tool: **Test Yourself for Hidden Bias** (The Southern Poverty Law Center)

3.7 SIECUS Tool: Creating a Welcoming Office

Understanding HIV Impact: Quick Reference

3.8 Tool: **HIV Among Various Groups—Gay and Bisexual Men, Gender, Race/Ethnicity, Age, Incarcerated Populations, Sex Workers, Economically Disadvantaged** (Centers for Disease Control and Prevention)

3.9 **Tool: HIV Among Young Men Who Have Sex with Men** (Centers for Disease Control and Prevention)

3.10 Tool: **Vital Signs HIV Among Youth in the US** (Centers for Disease Control and Prevention)

3.11 Tool: **Youth of Color-At Disproportionate Risk of Negative Sexual Health Outcomes** (Advocates for Youth)

3.12 Tool: **Black Americans and HIV/AIDS** (Kaiser Family Foundation)

3.13 Tool: **Trans HIV Testing Toolkit Module 1: Get the Facts About Trans People and HIV** (University of California San Francisco Center for Excellence in Transgender Health)

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PrEP Education for Youth-Serving Primary Care Providers Toolkit

Introduction

Four decades into the HIV/AIDS epidemic, there is finally a medication that individuals at high risk of HIV acquisition can take to protect themselves. Pre-exposure prophylaxis (PrEP) was approved by the United States Food and Drug Administration (FDA) as the first biomedical HIV prevention tool in 2012. With close to three-quarters of a million HIV-related deaths in the Unites States by the end of 2013,[1] one would expect that this breakthrough medication would find providers struggling to keep up with the demand from patients clamoring for this effective protection.

Yet nearly four years after FDA approval of Truvada as PrEP, its manufacturer, Gilead Sciences, estimates that just 40,000 U.S. residents—less than 4% of the 1.2 million individuals for whom the Centers for Disease Control and Prevention (CDC) estimates PrEP is indicated—are using it.[2] The medication has proven highly effective overall. Multiple randomized controlled trials have found that PrEP can reduce transmission in individuals at substantial risk of HIV infection by as much as 92% when used as indicated.[3] These findings have been replicated in multiple clinical trial settings. Despite PrEP's clinical success and its potential to change the course of the epidemic, there remains a gap between the efficacy of PrEP and the growing HIV epidemic among youth in the United States.

This toolkit aims to bridge that gap by increasing primary care providers' (PCP) capacity to work more effectively with young people at high-risk of HIV acquisition to provide targeted PrEP education and access and address HIV risk in culturally appropriate ways.

Youth under age 25 are among those most impacted by HIV. In 2014, youth aged 13–24 accounted for more than one in five new HIV infections in the United States. Gay, bisexual, and other men who have sex with men (MSM) accounted for most (80%) new infections among youth. Black/African American and Hispanic/Latino gay and bisexual men are especially affected.[4]

Young women accounted for about 20% of new cases.[5] Black/African American women in particular as well as Hispanic/Latina women continue to be disproportionately affected by HIV compared with women of other races and ethnicities.[6]

By the end of 2012, an estimated 57,200 youth ages 18–24 were living with HIV. Of these, nearly half (44%) were living with undiagnosed HIV—the highest rate of undiagnosed HIV in any age group.[7]

As with many groups disproportionately affected by HIV, multiple reasons for this health disparity in youth exist. Concerns regarding confidentiality, limited transportation, inconvenient hours, and lack of financial resources or insurance prevent some adolescents from accessing health care. Clinician-related barriers including discomfort serving adolescents, insensitive attitudes, and inadequate communication contribute as well.[8] While providing PrEP-related care involves having conversations around sexuality, many providers lack knowledge and skills regarding sexual and reproductive health care and are particularly uncomfortable discussing sexual behavior with adolescents.[9]

Lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) youth face additional barriers to care. Stigma and discrimination against LGBTQ persons increase stress on LGBTQ youth putting them at higher risk for depression, substance abuse, and sexual behaviors thereby placing them at higher risk of HIV and other sexually transmitted diseases (STDs).[10]

Youth who are rejected upon disclosure or discovery of their LGBTQ status, are sometimes thrown out of their homes or face physical, emotional, and/or sexual abuse.[11] Homeless youth often engage in survival sex (e.g., sex for food, shelter) thereby increasing their exposure to HIV. [12]

LGBTQ youth may also face discrimination in the health care setting. A 2009 survey by Lambda Legal found that almost 8% of LGB and 27% of transgender persons reported being denied care because of their identity and/or orientation and 11% reported that providers refused to touch them or used excessive precautions.[13]

Poverty, homelessness or marginal housing, low educational attainment, and lack of health insurance or quality health care are experienced at higher rates by some communities of color relative to whites and put youth of color at higher risk of HIV relative to white youth.[14] Studies have found that many low-income urban youth worry about HIV/AIDS but they worry more about food, housing, transportation, and child care.[15] Many of these youth also struggle with the impact of homophobia or transphobia, racism, or both.

Additionally, young women, and particularly young women of color may also face factors which affect their ability to negotiate safer sex,[16] intimate partner violence,[17] and a higher risk of HIV acquisition from heterosexual sex relative to their male partners.[18]

Despite its promise, PrEP has not changed the fact that the HIV epidemic has never been solely a medical epidemic. For health care providers, preparing to offer PrEP involves learning not only about the medication but also how to effectively reach and serve those who could benefit most from its use. The barriers to care—including the clinical barriers— described above need to be addressed to deliver care where it is needed. Learning to self-question and critique oneself around biases and interactions with other cultures in order to deliver care that is nonjudgmental and meets the individual patient are essential.[19]

According to the CDC, one in three primary care doctors and nurses does not yet know about PrEP. Some who are aware are not offering it.[20] The *PrEP Education for Youth-Serving Primary Care Providers Toolkit* offers resources so that all prescribing PCPs—physicians, nurse practitioners, physician assistants, nurse-midwives, nurses, pharmacists, and their staff—can effectively deliver PrEP care to youth at risk of HIV acquisition. The Toolkit seeks to provide solutions to empower providers and promote sexual health.

Toolkit Overview

Section 1: Clinical Tools

- Offers background information on PrEP, the CDC PrEP guidelines and other tools to help you in Getting Ready to Offer PrEP.
- The Clinical Reference Sheet breaks down the clinical components into a simple reference tool. Based on the CDC PrEP Guidelines, it is what you need to know for patient PrEP care in a quick and easy format.
- Taking a Sexual History guides clinicians who may not routinely conduct sexual histories in a culturally sensitive approach. Suggested questions are included.

Section 2: Billing for PrEP

- Provides resources and billing codes to help young people afford PrEP and allow you to capture maximum revenue.

Section 3: HIV, Stigma, and Social Determinants of Health

- Check Your Bias tools offer opportunities for self-reflection/education and increasing awareness about potential biases in working with high risk populations, among all staff in your office.

- Creating a Welcoming Office provides guidance in making your office welcoming and comfortable for all.
- Materials in this section provide an overview to familiarize staff with issues facing youth at high risk of HIV and resources to support you in serving in all patients who could benefit from PrEP.

Section 4: Youth and HIV Laws and Policies

- Provides information and direct source links about minors' consent, confidentiality, and HIV criminalization laws by state in the State Policy Table.

Section 5: Additional Resources

- While resources are provided throughout the toolkit, additional resources by topic are included for providers and patients alike.

Many additional resources are provided throughout this toolkit in an easy to access format to equip clinicians and office staff with the tools and knowledge needed to effectively serve young people who could benefit from PrEP. While far from an exhaustive compiling of available resources, these tools and resources are youth-specific though may also be useful in delivering PrEP care to other populations.

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PRIMARY CARE PROVIDERS AND PrEP: GETTING READY TO OFFER PrEP

As frontline providers, primary care providers (PCPs) are well situated to identify and serve youth who could benefit from pre-exposure prophylaxis (PrEP) for HIV. Yet studies suggest that lack of knowledge about PrEP, provider discomfort with issues surrounding PrEP delivery, and inexperience in conducting HIV risk assessments may represent missed opportunities for reaching youth at high risk of HIV acquisition.[1]

This resource is designed to support PCPs in identifying and effectively serving youth who could benefit from PrEP. In particular, this fact sheet addresses some common issues and concerns and directs providers to more detailed sources in the toolkit for additional information.

CONTENTS

- Daily PrEP can reduce the risk of acquiring HIV from sex by more than 90%.
- Daily PrEP can reduce the risk of acquiring HIV among people who inject drugs by more than 70%.
- Yet: 1 in 3 primary care doctors and nurses does not know about PrEP.

Source: Centers for Disease Control and Prevention

ABOUT PrEP

PrEP stands for **P**re-**E**xposure **P**rophylaxis. PrEP can be used by those at substantial risk of HIV exposure through sexual contact or injectable drug use to prevent acquisition of HIV infection.

To date, the FDA has approved one drug, Truvada, for PrEP in adults (18 and older) in 2012. Truvada is a combination of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) in one daily pill. It was FDA-approved for HIV treatment in 2004. In March 2016, the FDA approved low strength TDF-FTC for *treatment* for those under 18 years of age.

Evidence from clinical trials conducted among multiple high-risk populations suggests that oral TDF-FTC reduces the risk of HIV infection—by up to 92%—among those who regularly take their medications.[2, 3] When taken daily, TDF-FTC is safe and highly effective in preventing HIV infection.[4]

TDF-FTC should be used as part of a comprehensive prevention plan that also includes adherence and risk reduction counseling, HIV prevention education, and behavioral interventions such as drug abuse treatment and correct and consistent condom use.

TDF-FTC is for individuals who are at ongoing substantial risk of HIV infection. For those who need to prevent HIV after a single high-risk event of potential HIV exposure—such as condomless sex, sexual assault, or needle-sharing injection drug use—there is post-exposure prophylaxis (PEP). PEP must begin within 72 hours of exposure.

The important role of primary care providers in prescribing PrEP

All prescribing health care providers can deliver PrEP care. Infectious disease (ID) or HIV specialization is not needed. While ID providers are offering TDF-FTC to partners of some of their clients who are living with HIV, the primary care setting is the best setting for reaching youth that may benefit most from TDF-FTC and for preventive care. In fact, most youth who are HIV-negative could benefit from TDF-FTC are seen by community-based primary care providers (PCPs) for other reasons.

The concept behind PrEP is not new. Health care providers have long been prescribing malarial prophylaxis among those travelling to endemic areas. Contraception protects against unintended pregnancy in women of reproductive age. Bringing PrEP to more community settings and normalizing HIV prevention with PrEP, just as prevention of heart attacks is offered through prescription of statins to at-risk individuals, will bring this effective intervention where it can be accessed by those who would benefit from it.

Studies have found that some at-risk patients resist starting TDF-FTC because of their own perceived stigma as well as concerns that others may think they are HIV positive if they are taking medication traditionally associated with HIV care. Accessing TDF-FTC in a primary care office or clinic where multiple conditions are diagnosed and treated can help reduce the stigma for patients themselves. Particularly in small or rural communities, the PCP's office reduces the risk that a patient will be "discovered" in an HIV/AIDS setting and assumed to be HIV positive when they are actually seeking preventive care. This does not release society from the obligation to further de-stigmatize HIV care for individuals living with HIV.

PCPs who are willing to screen and prescribe TDF-FTC to youth at high risk and address the complexity of their lives as it impacts their health care are critical to curbing the HIV epidemic among youth. Yet providers who are comfortable serving all youth, including lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) youth and addressing sexual and drug use behaviors and environmental factors associated with HIV risk are in short supply.

This toolkit offers resources to address some of the concerns providers face in offering PrEP. In some cases, information about PrEP and the faces behind the epidemic may be all that's needed. In other cases, the guidance around Taking a Sexual History and having sensitive conversations around sexuality and gender identity may be most helpful. For others, examining individual biases (see **Check Your Bias**) and Creating a Welcoming Office can help increase efficacy as a clinician.

With more than 40,000 new HIV infections annually in the United States[5] and without an available HIV vaccination or cure, the need for bringing effective HIV prevention tools to primary care settings where they can be accessed by more who could benefit is critical.[6]

Why provide PrEP to youth

Many youth at substantial risk for HIV infection who would be good candidates do not know about and are not receiving TDF-FTC.

Youth are among those at the forefront of those at greatest risk of HIV acquisition. In 2014, youth ages 13–24 accounted for more than one in five new HIV infections in the United States. Gay, bisexual, and other men who have sex with men (MSM) accounted for most (80%) new infections among youth. Black/African American and Hispanic/Latino gay and bisexual men are especially affected.

Young women accounted for 19% of new cases in 2014.[7] Black/African American women in particular, as well as Hispanic/Latina women continue to be disproportionately affected by HIV compared with women of other races and ethnicities.[8]

Numerous factors contribute to this disparity. These range from an individual's low perceptions of risk, inconsistent condom use, high rates of sexually transmitted diseases (STDs) in youth, declining formal sexual health education and inadequate HIV prevention education, low rates of HIV testing, homelessness, substance abuse, and older sex partners who are more likely to be HIV positive.[9] See Section 3: HIV, Stigma, and Social Determinants of Health for further discussion.

By addressing these causes over time and by making prevention more available now, these high infection rates can be lowered. TDF-FTC, along with risk reduction counseling and other prevention measures, offers an effective tool to help to contain the spread of infection in youth at highest risk of HIV acquisition.

Indications for PrEP

Per the Centers for Disease Control and Prevention's (CDC) PrEP Guidelines,[10] PrEP may be appropriate for the following populations:

	Men who have sex with men (MSM)	Heterosexual women and men	Injection Drug Users (IDU)
Recommended Indicators for PrEP Use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use (with MSM, IDU, other high risk partner)	HIV+ injecting partners Sharing injection equipment or needles Risk of sexual acquisition (see columns on left)

Screening for HIV risk

PCPs have a lot of ground to cover with each patient squeezed into a tight timeframe dictated by insurance reimbursement schedules. Government agencies provide standards for care, which establish metrics for health services delivery. Since sexual health metrics are rarely measured, why would PCPs offer sexual health services? Consider that according to the CDC:

- 1 in 4 teens is believed to have an STD.[11] Having a STD increases the chance of seroconversion.[12]
- Only 44% of youth ages 18–24 living with HIV were aware they had HIV in 2012.[13]
- People at high risk of HIV acquisition who should be offered TDF-FTC include:
  - 1 in 4 gay or bisexual men
  - 1 in 5 who inject drugs
  - 1 in 200 heterosexual adults[14]

- **Providing risk assessment and prevention education and offering TDF-FTC as indicated can reduce the morbidity and mortality associated with HIV in youth and others at high risk of HIV acquisition.**
- **More than half of all people will have an STD at some point in their lifetime.**[15] Studies have shown that a significant portion of the sexually experienced population of all ages has risks associated with STDs yet many are unaware of potential risks associated with their sexual behaviors. Providers have the opportunity and responsibility to provide information and counseling that can reduce high risk behaviors and contribute to reducing STDs, including HIV, unintended pregnancies, and promote healthy sexual decisions in patients of all ages.
- **Sexual health is part of total health.** In the *Proactive Sexual Health History,* Nusbaum et. al. assert that "the most crucial deficit in sexual health care is a proactive and preventive approach in the primary care setting."[16] In high quality health care, sexual health would be integrated with all aspects of patient care on par with physical, spiritual, social, and emotional care. Asking about sexual orientation and sexual behaviors should be as natural as asking about risk factors for diabetes.[17]
- **Failing to take a sexual history may represent a risk management issue.** For example, a patient with repeated diagnoses of syphilis who is never asked about his sexual behaviors or advised that recurrent diagnoses may be associated with higher risks of HIV is not receiving optimal health care.[18]

Primary prevention of STDs, including HIV, includes performing an assessment of behavioral risk (i.e., assessing the sexual behaviors that may place persons at risk for infection) as well as biologic risk (i.e., testing for risk markers for HIV acquisition or transmission). A sexual and social history is vital to assessing risk behaviors and identifying indications for PrEP use.[19]

In order to obtain information about sexual health, clinicians must have conversations about sex that they may not be comfortable with or prepared to have. Thus, these conversations are often left to urologists or gynecologists. However, because people see PCPs more than other providers, PCPs are on the frontlines to address issues of sexual health.[20] Developing a routine way to take the patient's sexual history can help address discomfort and build competence. See Taking a Sexual History for guidance on how to have effective conversations around sensitive topics.

PrEP Safety

TDF-FTC has been used to treat HIV for over a decade with a good safety profile. In prevention studies to date, TDF-FTC for PrEP has not caused serious short-term safety concerns. TDF-FTC has caused renal toxicity and decreased bone mineral density when used for HIV treatment for months and years. TDF-FTC is considered safe for women of child-bearing age. Decisions about possible use during **pregnancy** must be individualized. While available data suggests that TDF-FTC does not increase the risk or birth defects, there are not enough data to exclude the possibility of harm (Pregnancy Class B). TDF-FTC is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high as in a serodiscordant partnership and because pregnancy itself is associated with an increased risk of HIV acquisition.

Since TDF-FTC is actively eliminated by the kidney, it should be co-administered with care in patients taking medications that are eliminated by active tubular secretion (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valganciclovir, aminoglycosides and high dose of multiple NSAIDs). Drugs that decrease renal function may also increase concentrations of TDF-FTC.

Adapted from: NYC Health, PrEP Provider FAQs[21]

PrEP safety in patients under 18 years of age

In March 2016, the United States Food and Drug Administration (FDA) updated the TDF-FTC tablet label to expand the indication to include treatment for pediatric patients weighing at least 12 kilograms and the addition of the following strength tablets (100/150 mg, 133/200 mg and 167/250 mg). See the **full changes** for more information.

The CDC PrEP guidelines suggest that prior to initiating TDF-FTC as PrEP for adolescents that clinicians consider:

- Lack of data on safety and effectiveness of TDF-FTC taken by patients under age 18;
- Possibility of bone or other toxicities among youth who are still growing; and
- Safety evidence available when TDC/FTC is used in treatment regimens for HIV-infected youth.

These factors should be weighed against the potential benefit of providing TDF-FTC for an adolescent at substantial risk of HIV acquisition.[22]

Unless contraindicated for an adolescent's safety, parent/guardian involvement is advised. In addition, the individual patient's ability to comply with daily dosing given developmental stage, family and social support, housing situation, and other life circumstances should also be considered.

PrEP effectiveness in young women

Both the FEM-PrEP and VOICE clinical studies failed to find efficacy in women at high-risk on daily TDF-FTC.[23] However, other studies of heterosexual populations including both women and men found higher efficacy where higher levels of adherence were achieved.[24]

Research indicates that adherence needs to be greater to achieve high levels of efficacy in women. Some studies have found that women need daily doses of TDF-FTC to prevent HIV acquisition while men need only two doses per week.[25] Furthermore, according to the CDC PrEP guidelines, data suggest that maximum intracellular concentrations of tenofovir diphosphate are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervico-vaginal tissues at approximately 20 days.[26]

Some research also suggests that PrEP may not be as effective in women younger than 25 and particularly younger than 21.[27] Further research is needed.

Supporting PrEP adherence

Research indicates that the efficacy of TDF-FTC depends upon patient adherence to the regimen as well as the benefits of the medication itself.[28] Therefore PrEP education, assessment of a patient's ability to adhere, follow up safety monitoring visits, and additional social supports as needed by individual patients given their life circumstances are all critical to successful TDF-FTC use.[29] Adherence is also critical to reducing the risk of developing a drug resistant virus.

Patients with chronic diseases have reported that the most important factors in medication adherence were incorporating medication into their daily routines, knowing that the medications work, believing the benefits outweigh the risks, knowing how to manage side effects, and low out-of-pocket costs.[30]

When initiating TDF-FTC, PCPs must educate patients to ensure they understand:

- How to take their medications (e.g., when, how many pills);
- What to do if they experience problems (e.g., what to do if they miss a dose, what constitutes a missed dose);

- What the most common side effects are and help patients develop a plan for handling them; and
- The importance of using condoms, especially if they decide to stop taking TDF-FTC.[31]

Additional tools such as providing reminder systems (e.g., texts, emails) have also proven effective. Furthermore, addressing financial, substance abuse, and mental health needs that may interfere with adherence and facilitating social supports are also recommended and may be key to maintaining adherence over time in high-risk youth. The Clinical Reference Sheet in this toolkit outlines key components of medication adherence counseling.

Research in this area continues to explore mechanisms for encouraging adherence, as well as novel formulations of PrEP that can help overcome adherence barriers such as long acting vehicles or intermittent PrEP.

Hormonal contraception and PrEP

Studies have found that TDF-FTC has no adverse impact on hormonal contraceptive effectiveness for pregnancy prevention.[32] Injectable contraceptives (Depo-Provera) have been associated with a 2–4 fold increased risk of HIV acquisition in some observational studies.[33] Research has demonstrated that TDF-FTC could mitigate the potential increased HIV-1 acquisition and transmission risks that have been associated with DMPA use.[34]

Conception, pregnancy and breastfeeding

Please refer to the CDC's **Provider Information Sheet-PREP During Conception, Pregnancy and Breastfeeding** for more information.

Transgender women and PrEP

Transgender women are at increased risk of HIV infection due to multiple factors, dominated by stigma and discrimination, including sex practices (vaginal and/or receptive anal sex), substance abuse, and possible sex work. Some limited studies demonstrated efficacy of PrEP in trans women who were adherent to PrEP.[35]

More research is needed to understand the interaction between feminizing hormones and PrEP and impact on the buildup of PrEP to protective levels in rectal tissue. It is advised to counsel patients on balancing possible PrEP efficacy with risk of HIV acquisition.[36]

Efficiently adding PrEP to your practice or clinic

So you want to add PrEP to your clinical practice. Here are some tools and ideas to make the transition smoother for you and your team:

- **Patient/Provider checklist.** The **CDC PrEP Guidelines Clinical Providers Supplement** offers resources to support delivery of PrEP care, including a Patient/Provider Checklist (pages 4–5) to help clinicians preparing to offer TDF-FTC to new patients.
- **Patient handouts.** The **CDC PrEP Guidelines Clinical Providers Supplement** includes a PrEP Information Sheet (pages 5–6) and Truvada Medication Information Sheet for Patients (pages 9–11). Additional patient education resources are provided throughout this toolkit.
- **Use technology to facilitate and streamline processes.**
  - Set up "***nudges***" **in your electronic health record** (EHR) to provide reminders to screen for HIV risk and indications for PrEP or to follow up negative HIV tests with a reminder to reassess risk practices and discuss prevention options including PrEP when appropriate.[37]

- **Order set.** To make prescribing PrEP easier in the clinical setting, work with IT staff to develop a drop down order set so all the baseline and follow lab tests are easy to order.

- **Create a team approach.** Involve nurses, pharmacists, counseling and other staff in managing the many steps needed for the safe use of TDF-FTC and to help increase TDF-FTC adherence.

- **Partner with community-based organizations (CBOs)**. Local CBOs can help provide ancillary services that can save your practice time and potentially save your low-income clients money, as they may be able to offer lower cost lab work and other services.

- **Use the tools in this toolkit.** Go to the PrEP Education for Youth-Serving Primary Care Providers Toolkit Section 5 to view available and additional resources.

1 Douglas Krakower, Kenneth H. Mayer, "Engaging Healthcare Providers to Implement HIV Pre-Exposure Prophylaxis," *Current Opinion in HIV and AIDS* 7, no. 6 (2012): 593-599, DOI: 10.1097/COH.0b013e3283590446; "Daily Pill Can Prevent HIV," *Centers for Disease Control and Prevention*, last modified November 24, 2015, www.cdc.gov/vitalsigns/hivprep/.

2 "CDC Supports New WHO Early Release HIV Treatment and PrEP Guidelines," *Centers for Disease Control and Prevention*, September 30, 2015, www.cdc.gov/media/releases/2015/s0930-hiv-prep.html.

3 "Pre-exposure Prophylaxis (PrEP) for HIV Prevention," *Centers for Disease Control and Prevention*, May 2014, www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf.

4 "Daily Pill Can Prevent HIV."

5 "HIV Surveillance Report: Diagnoses of HIV Infection in the United States and Dependent Areas, 2014," *Centers for Disease Control and Prevention*, 26 (2015), www.cdc.gov/hiv/pdf/library/reports/surveillance/cdc-hiv-surveillance-report-us.pdf.

6 "Strategy for an AIDS-Free Generation," *Centers for Disease Control and Prevention*, last modified November 27, 2013, www.cdc.gov/globalaids/global-hiv-aids-at-cdc/interventions.html.

7 "HIV Among Youth," *Centers for Disease Control and Prevention*, last modified April 27, 2016, www.cdc.gov/hiv/group/age/youth/index.html.

8 "HIV Among Women," *Centers for Disease Control and Prevention*, last modified March 16, 2016, www.cdc.gov/hiv/group/gender/women/.

9 "HIV Among Youth."

10 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline," *Centers for Disease Control and Prevention*, 2014, www.cdc.gov/hiv/pdf/prepguidelines2014.pdf.

11 "HIV Among Women," *Centers for Disease Control* and *Prevention, last modified March 16, 2016,* www.cdc.gov/hiv/group/gender/women/.

12 "Syphilis—CDC Fact Sheet (Detailed)," *Centers for Disease Control and Prevention,* last modified May 19, 2016*,* www.cdc.gov/std/syphilis/STDFact-Syphilis-detailed.htm.

13 "HIV Among Women."

14 "Daily Pill Can Prevent HIV."

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16 Margaret Nusbaum, Carol Hamilton, "The Proactive Sexual Health History," *American Family Physician* 66, no. 9, (2002): 1705-1713, www.aafp.org/afp/2002/1101/p1705.html.

17 Ibid.

18 Ibid.

19 "A guide to taking a sexual history," *US Department of Health and Human Services, Centers for Disease Control and Prevention*, www.cdc.gov/std/treatment/sexualhistory.pdf.

20 Margaret Nusbaum, "The Proactive Sexual Health History."

21 "PrEP Provider FAQs," *New York City Department of Health and Mental Hygiene,* www.nyc.gov/html/doh/downloads/pdf/csi/csi-prep-hcp-faq.pdf.

22 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline."

23 Mackenzie L. Cottrell et al., "A Translational Pharmacology Approach to Predicting HIV Pre-Exposure Prophylaxis Outcomes in Men and Women Using Tenofovir Disoproxil Fumarate With or Without Emtricitabine," *Journal of Infectious Diseases* 214, no. 1 (2016): 55-64, DOI: 10.1093/infdis/jiw077.

24 Jared M. Baeten, et al, "Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women," *New England Journal of Medicine* 367, (2012): 399-410, DOI: 10.1056/NEJMoa108524.

25 Mackenzie L. Cottrell et al., "A Translational Pharmacology Approach."

26 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline."

27 Sharon Hillier, "Macrobicides and PrEP: What have we learned?" (presentation, Office of AIDS Research Advisory Council meeting, Rockville, MD, April 7, 2016).

28 Amanda D. Castel, Manya Magnus, Alan E. Greenberg, "Pre-exposure Prophylaxis for Human Immunodeficiency Virus: The Past, Present, and Future," *Infectious Disease Clinics of North America* 24, no. 4 (2014): 563-583, DOI: 10.1016/j.idc.2014.08.001.

29 Ibid.

30 Ibid.

31 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline."

32 Pamela M. Murnane et al., "Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception." *AIDS* 28, no. 12 (2014) 1825-30. DOI: 10.1097/QAD.0000000000000290.

33 Craig Walter Hendrix, "The effect of Depo-Provera on HIV susceptibility, immune activation, and PrEP PK," *Grantome*, http://grantome.com/grant/NIH/R01-AI110371-01; Renee Heffron et al., "PrEP is Efficacious for HIV-1 prevention among Women using DMPA for Contraception," *AIDS* 28, no. 18 (2014): 2771-2776, DOI: 10.1097/QAD.0000000000000493.

34 "PrEP is Efficacious for HIV-1 prevention among Women using DMPA for Contraception."

35 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline."

36 Ibid.

37 Douglas Krakower, "Engaging Healthcare Providers to Implement HIV Pre-Exposure Prophylaxis."

Pre-exposure Prophylaxis (PrEP) Clinical Reference Sheet

General

- Pre-exposure prophylaxis (PrEP) is a medication taken daily which prevents HIV infection.
- PrEP is taken before (pre-) an exposure which is different than post-exposure prophylaxis (PEP), which is a medication regimen taken after exposure (e.g., after a needle stick).
- The medication used for PrEP for ≥18 years of age is a single pill comprised of 150 mg of tenofovir disoproxil fumarate (TDF) and 100 mg of emtricitabine (FTC).
- The medication was approved for ≥18 years of age by the United States Food and Drug Administration (FDA) in 2012 for PrEP.
- The brand name is Truvada (TDF-FTC).
- The medication has been approved for the treatment of HIV in adults since 2004. Low strength TDF-FTC for pediatric use was approved by the FDA in 2016 for HIV treatment only for patients weighing 17 kg to less than 35 kg who can swallow a pill. Please see full prescribing information below for pediatric dosing.

Indications for PrEP

Gay, Bisexual, and other Men Who Have Sex with Men (MSM), and Transgender Women: Any anal sex without condoms or sexually transmitted diseases (STDs) in the last six months, or in an ongoing relationship with an HIV+ partner, multiple sex partners.

Heterosexuals: Bisexual men, ongoing HIV+ partner, or condomless sex with 1+ partner(s) of unknown HIV status who are at increased risk of HIV such as an injection drug user or bisexual male partner, recent bacterial STD.

Injection Drug Users (IDU): HIV+ injection partner, sharing needles or risk of sexual acquisition as above.

Initial Efficacy Studies

iPrEx: In patients that had high levels of adherence, TDF-FTC reduced the risk of HIV in gay, bisexual, and other MSM by 92%.[1] *Brazil, Ecuador, Peru, S. Africa, Thailand, USA*

Partners PrEP Trial: In patients that had high levels of adherence, TDF-FTC reduced the risk of HIV in heterosexual patients by 90%, with efficacy being lower in women than men.[2] *Kenya, Uganda*

TDF2 Trial: TDF-FTC reduced the risk of HIV in heterosexual patients by 62%, but this may have included people who didn't always take the medication. Efficacy was lower in women.[3] *Botswana*

Bangkok Tenofovir Study: In patients that had high levels of adherence, TDF-FTC reduced the risk of HIV in IDUs by 49%.[4] *Thailand*

1 Robert M. Grant, et al., "Preexposure Chemoprophylaxis for HIV Prevention in Men who Have Sex with Men," *New England Journal of Medicine* 363, no. 27 (2010): 2587-99. DOI: 10.1056/NEJMoa1011205.

2 Jared M. Baeten, et al., "Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women," *New England Journal of Medicine* 367, (2012): 399-410, DOI: 10.1056/NEJMoa108524.

3 Michael C. Thigpen, et al., "Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana," *New England Journal of Medicine* 367, no. 5 (2012): 423-34, DOI: 10.1056/NEJMoa1110711.

4 Kachit Choopanya, et al., "Antiretroviral Prophylaxis for HIV Infection in Injecting Drug Users in Bangkok, Thailand (the Bangkok Tenofovir Study): A Randomized, Double-blind, Placebo-controlled Phase 3 Trial," *Lancet* 381, no. 9883 (2013): 2083-90, DOI: 10.1016/S0140-6736(13)61127-7.

Initiation of PrEP

- Negative HIV antibody test (within the last week; no oral rapid testing)
- Screen for acute HIV infection (recent "flu-like" symptoms. If concern, check an HIV viral load)
- Normal renal function, CrCl ≥60 ml/min (check creatinine)
- Negative for chronic hepatitis B infection (hepatitis B surface antigen negative)
- Screen for other STDs as needed (syphilis, gonorrhea, chlamydia)
- Negative pregnancy test (for women)
- Prescription for a three (3) month supply

Time to Achieving Protection

For MSM: Maximum concentration in rectal tissue at seven days

For Women: Maximum concentration in cervicovaginal tissue at 20 days

For Transgender Women: Maximum concentration in rectal tissue at seven days

For IDUs: Maximum concentration in the blood at 20 days

Potential Side-Effects

- No severe or life-threatening side-effects in the major trials [iPrEx].
- Mild gastrointestinal upset (e.g., nausea, flatulence) in 9% of individuals [iPrEx] which generally resolve in the first month.
- Other potential side-effects include fatigue, headache, and dizziness.
- TDF-FTC may cause a small decrease in bone mineral density (1%) but the clinical significance of this is unknown (i.e., does not appear to lead to fractures). In general, DEXA scans are not recommended.
- TDF-FTC is associated with renal dysfunction in <1 to 4.3% of individuals in North America.[1] Creatinine should be monitored periodically. Stopping TDF-FTC in these individuals generally leads to normalization of renal function.

1 Nishijima Takeshi et. al., "Impact of Small Body Weight on Tenofovir-Associated Renal Dysfunction in HIV-Infected Patients: A Retrospective Cohort Study of Japanese Patients," *PLoS ONE* 6, no. 7: e22661, DOI: 10.1371/journal.pone.0022661

Potential Drug Interactions

Caution should be taken when using other drugs that may reduce renal function (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valganciclovir, aminoglycosides and high doses of multiple NSAIDs) since TDF-FTC is actively eliminated by the kidney. Drugs that decrease renal function may also increase concentrations of TDF-FTC.

Drug Resistance

- No drug resistance generally found in patients who acquire HIV while on PrEP [iPrEx].
- Resistance identified in some patients who have HIV at baseline before PrEP is started [iPrEx].

Persons With a New HIV Diagnosis

- Confirm the diagnosis with subsequent testing (may be performed through local health department).
- Check CD4 lymphocyte count.
- Check HIV viral load.
- Check HIV genotype (for drug resistance).
- Linkage to care with an HIV provider.
- If the patient is on PrEP and diagnosed with HIV, urgent consultation with an infectious disease specialist is suggested. TDF-FTC may be continued, but a third drug should be added. A three-drug regimen is the standard treatment regimen for people living with HIV.

Treating Special Populations

PrEP During Conception, Pregnancy and Breast-feeding

See **PrEP Information Sheet: PrEP During Conception, Pregnancy, and Breastfeeding** (Centers for Disease Control and Prevention)

Adolescent Minors

- The CDC recommends routine HIV testing for those 13-65 years old. HIV screening is part of primary care and should be offered to all sexually active minors; those who are MSM or have a history of IDU should be screened more frequently as indicated.
- Discuss parent/guardian involvement in adolescent health care. Unless contraindicated for an adolescent's safety, parental/guardian involvement is advised.
- Be aware of consent, confidentiality, reporting, and parental disclosure laws and that these laws may also vary by local jurisdiction.
- None of the completed PrEP trials have included individuals below age 18. Consider:
  - the lack of data on safety and effectiveness of TDF-FTC taken by persons under 18 years of age, possibility of bone or other toxicities among youth who are still growing, safety data available when TDF-FTC is used in treatment regiments for youth living with HIV.
  - Weigh these factors against the potential benefit of providing TDF-FTC for an individual adolescent at substantial risk of HIV acquisition.

Transgender Women[1]

- Transgender women are at increased risk of HIV infection due to multiple factors dominated by stigma and discrimination, including sex practices (vaginal sex and/or receptive anal sex), and substance use.
- Some limited studies demonstrated efficacy of TDF-FTC in trans women who were adherent to TDF-FTC.
- More research is needed to understand the interaction between feminizing hormones and TDF-FTC and impact on the buildup of TDF-FTC to protective levels in rectal tissue.
- Counsel clients on balancing possible TDF-FTC efficacy with risk of HIV acquisition.

Patients with Chronic Active Hepatitis B Infection

- Refer to a clinician experienced in managing TDF-FTC.

Patients with Chronic Renal Failure

- Refer to a clinician experienced in managing TDF-FTC.

1 Samantha Marquez, Sean Cahill, "Transgender Women and Pre-exposure Prophylaxis: What We Know and What We Still Need to Know," *National Center for Innovation in HIV Care,* November 2015.

Medication Adherence Counseling

Establish trust and bidirectional communication

Provide simple explanations and education

- Medication dosage and schedule
- Management of common side-effects
- Relationship of adherence to the efficacy of TDF-FTC
- Signs and symptoms of acute HIV infection and recommended actions

Support adherence

- Tailor taking the medication to the patient's daily routine.
- Identify reminders and devices to minimize forgetting doses
- Identify and address barriers to adherence

Monitor medication adherence in a non-judgmental manner

- Normalize occasional missed doses, while ensuring patient understands importance of daily dosing for optimal protection
- Reinforce success
- Identify factors interfering with adherence and plan with patient to address them
- Assess side-effects and plan how to manage them

Behavioral Risk-Reduction Counseling

Establish trust and two-way communication

Provide feedback on HIV risk factors identified during sexual and substance use history taking

- Elicit barriers to, and facilitators of, consistent condom use
- Elicit barriers to, and facilitators of, reducing substance abuse

Support risk-reduction efforts

- Assist patient to identify one or two feasible, acceptable, incremental steps towards risk reduction
- Identify and address anticipated barrier to accomplishing planned actions to reduce risk

Monitor behavioral adherence in a non-judgmental manner

- Acknowledge the effort required for behavior change
- Reinforce success
- If not fully successful, assess factors interfering with completion of planned actions and assist patient to identify next steps

Adapted from Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States—2014 Clinical Practice Guideline *(Centers for Disease Control and Prevention)*

More Information

- Full prescribing information
- United States Public Health Service Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014: A Clinical Practice Guideline
- United States Public Health Service, Pre-exposure Prophylaxis for the Prevention of HIV Infection in the United States 2014: Clinical Providers' Supplement
- Taking a Sexual History
- To speak with a clinician experienced in managing PrEP, contact the University of California San Francisco Clinician Consultation Center, **(855) 448-7737** or **(855) HIV-PrEP**

38. PRE-EXPOSURE PROPHYLAXIS SAME-DAY INITIATION

POLICIES AND PROCEDURES

Purpose: Philadelphia FIGHT was founded on the principles of providing accessible, high-quality HIV care and HIV prevention during the early HIV healthcare crisis and is committed to ending the HIV epidemic. Truvada for HIV Pre-exposure Prophylaxis (PrEP) has been proven highly effective and safe for HIV prevention when initiated prior to exposure to HIV.

Policy: For patients at high risk of acquiring HIV with a history of inconsistent condom use, PrEP is a highly effective biomedical prevention option that if taken consistently will prevent an HIV infection. Patients who are at highest risk of new HIV infection need to be able to initiate PrEP immediately.

I. General

Philadelphia FIGHT Community Health Centers have patients who are often at highest risk of acquiring HIV. Some of the psychosocial risk factors for acquiring HIV are the same risk factors that might may a patient vulnerable to becoming lost to care or may make a patient disconnected from their healthcare. PrEP access is integral to harm reduction and patient empowerment; patients can engage in preventative healthcare and often initiating PrEP will empower people remain engaged in care.[1]

A typical PrEP initiation takes 1-2 weeks from the screening visit to the medication initiation visit. The potential loss-to-care and risk of acquiring HIV for our most vulnerable patients could be high during those 1-2 weeks and PrEP could, if initiated immediately PrEP will provide a highly effective protective factor.

II. Eligibility

Patients who have a documented negative HIV Rapid test in the office, and who meet at least one of the following criteria are eligible for same-day PrEP initiation:

1. are at high risk of exposure to HIV during the period from the PrEP screening visit (lab work, etc.) and initiation visit
2. have a documented positive STI (RPR or rectal gonorrhea) at current or last visit
3. are partnered with HIV positive individuals with detectable or unknown HIV viral loads, or history of inconsistent engagement in care or adherence to ARV medications

1 McCormack, Sheena. PROUD Study. CROI 2015, Seattle USA.

IV. Procedure

A. Patients will be seen for a medical visit by a clinician who will determine clinical eligibility for PrEP and assess with the patient the option of same-day PrEP initiation.

B. If patient is nPEP eligible based on clinical guidelines (including exposure within the last 72 hours), patient should initiate nPEP and transition to PrEP in 1 month.

C. If a patient meets both of the below criteria for possible acute seroconversion, they will not be candidates for same-day start. A clinician will draw a 4th generation HIV Ab/Ag test and bring the patient back for follow-up within one week.

1. Recent (within 2 to 6 weeks) high risk of exposure to HIV-1.[a]
2. Signs, symptoms, or recent laboratory findings may include but are not limited to one or more of the following: fever, lymphadenopathy, skin rash, myalgia/arthralgia, headache, diarrhea, oral ulcers, leukopenia, thrombocytopenia, transaminase elevation.

D. If patient is clinically eligible for and interested in same-day start PrEP, a clinician will order the required PrEP initiation labs per the Philadelphia FIGHT Community Health Center's HIV Pre-Exposure Prophylaxis Policy. If the clinician feels that a patient may have been exposed to HIV within the "window period" of the 4th generation HIV test (last 4 weeks) but not within the last 3 days (or they would be a nPEP candidate), then a 4th generation HIV test (Ab/Ag) will be repeated in 14 days from start of PrEP (Day 0).

E. Patients with medical insurance will be loaded with two doses of Truvada for PrEP in the office from their prescription and will then be given a pill pack with 7days of Prep. If uninsured or effectively uninsured, the patient will meet with Philadelphia FIGHT Community Health Center staff for medication access support and will receive temporary medications (2-pill load and 7-day supply) through 340B funds. Uninsured patients will need to meet with the Benefits Coordinator prior to leaving the office to both complete Gilead MAP application and apply for medical insurance, if eligible.

F. Patients will be counseled on safer sex practices and on the importance of medication adherence. They will complete an adherence plan that will be included in the patient's EMR and will be reassessed every 3 months.

G. Patients will pick up their medication weekly, biweekly or monthly at the Y-HEP Health Center and follow Philadelphia FIGHT's PrEP standard of care after it is determined that the person is HIV negative and outside the window for acute seroconversion after PrEP initiation.

Philadelphia FIGHT Medical Director Approved: 09.16.2015

37. PRE-EXPOSURE PROPHYLAXIS FOR MINORS

POLICIES AND PROCEDURES

Purpose: Philadelphia FIGHT was founded on the principles of providing accessible, high-quality HIV care and HIV prevention during the early HIV healthcare crisis and is committed to ending the HIV epidemic. Truvada for HIV Pre-exposure Prophylaxis (PrEP) has been proven highly effective and safe for HIV prevention.

Policy: Philadelphia FIGHT is committed to providing PrEP to young people under 18. If appropriate, we will try to obtain parental consent before prescribing PrEP. However, if it is not possible to obtain parental consent for logistical or safety reasons, we will prescribe PrEP , if there is a 1) a demonstrated need for PrEP as HIV prevention, 2) the patient is a clinically appropriate candidate for PrEP, and 3) we believe that the patient's health is at risk without PrEP. PrEP will only be provided to minors through the Y-HEP Health Center.

I. General

Truvada for PrEP was approved by the FDA on July 16, 2012 for use in adults at high risk of HIV acquisition. Truvada for the treatment of HIV was approved for use in persons over 12 years of age in 2004.[1]

Philadelphia FIGHT Community Health Centers is committed to offering needed medical treatment to all patients who present to our clinics. In some instances, young people may be unable to or unwilling to obtain parental consent to access treatment. Reasons for the aforementioned include, but are not limited to: ongoing emotional, physical, or mental abuses, the threat of abuse, having been kicked out of the home of their parent or guardian and are living on the street. Others are emancipated and do not require parental consent. Given the critical need to provide confidential health care to young people, the Commonwealth of Pennsylvania has created the following classes of minor where parental consent can be waived in order to provide the necessary care to the patient:

1. *If the patient is receiving sexual and reproductive health services (except abortion)*
2. *If the patient is receiving substance abuse treatment*
3. *If the patient is receiving mental health treatment*
4. *If the patient is receiving treatment and disclosure is not in the best interest if the patient because the disclosure would subject the minor to abuse and/or neglect*
5. *If the patient is receiving treatment and is a high school graduate*

1 http://gilead.com/~/media/files/pdfs/medicines/hiv/truvada/truvada_pi.pdf

6. *If the patient is receiving treatment and is or has ever been married*
7. *If the patient is receiving treatment and is pregnant (presently or previously)*
8. *If the patient is receiving treatment and is emancipated (has left parents/ guardians household by agreement or demand)*[2]

II. Eligibility

All patients of Philadelphia FIGHT Community Health Centers who may be at risk for HIV over the age of 13 are potentially eligible for PrEP. Patients under the age of 18 years of age are subject to the same eligibility criteria safety monitoring for PrEP as those patients over the age of 18 years of age.

The criteria set forth by the CDC outlines that a patient is eligible for PrEP if they have:

1. A documented negative HIV test result before prescribing PrEP
2. No signs/symptoms of acute HIV infection
3. Normal renal function; no contraindicated medications
4. Documented hepatitis B virus infection and vaccination status[3]

Patients who are prescribed PrEP will be monitored at least every 3 months to ensure that patients remain clinically eligible for PrEP.

III. Procedure

A. Patients under the age of 18 who seek to receive PrEP at Philadelphia FIGHT will complete all necessary intake paperwork, including:

   1. Philadelphia FIGHT Community Health Centers Consent for Treatment and Release of Health Information

      b. If a patient does not have parental consent, they must fall into one of the aforementioned categories that would allow the minor to seek care without parental consent.

      c. In addition, every attempt will be made to obtain parental consent prior to PrEP initiation even if a patient fits into one of the aforementioned categories, unless parental consent cannot be obtained either for logistical (no parent/guardian involved in patient's life and care) or safety reasons (risk of physical or emotional abuse, risk of neglect, etc, with disclosure of desire to start PrEP or discussion of sexuality with parent/guardian).

   2. Patient Information Forms
   3. Declaration of Income forms

B. Patients will be seen for a medical visit by a clinician who will determine clinical eligibility for PrEP

2 Philadelphia FIGHT Community Health Centers, Consent for Treatment and Release of Health Information. Board Approved 9/17/2015.
3 www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf

C. If patient is clinically eligible for PrEP and interested in PrEP, a clinician will order the required PrEP initiation labs and the patient will be sent for blood work in the laboratory. PrEP initiation labs include:

   1. Fourth generation HIV antibody/antigen test
   2. Complete Metabolic Panel (CMP)
   3. Hepatitis Panel (A,B,C)
   4. GC/CT Rectal, Pharyngeal and Urine
   5. Urine trichomonas
   6. RPR

D. If uninsured or effectively uninsured, the patient will meet with Philadelphia FIGHT Community Health Center staff for medication access support. If a patient is uninsured (or effectively uninsured) they will work with a Benefits Coordinator to apply for CHIP, and Philadelphia FIGHT will cover the cost of the medication for up to 2 months.

E. Patients will be counseled on safer sex practices and on the importance of medication adherence.

F. Patients will pick up their medication every week, every other week, or monthly (due to be determined by patient and provider) at the Y-HEP Health Center.

G. Patients will be monitored at least every 3 months to determine persistent eligibility for PrEP, to determine whether parental consent could feasibly and safely be obtained on an ongoing basis, to have repeat HIV and safety lab screening, and to access medication refills.

Philadelphia FIGHT Board Approved on: 05.20.2015

Taking a Sexual History

Assessing sexual health is an essential part of a comprehensive health exam. A sexual history needs to be taken during a patient's initial visit, routine preventive exams, and when a patient presents with signs or symptoms consistent with a sexually transmitted disease (STD).

A sexual history identifies patients at risk of HIV, and other STDs, clarifies pregnancy intentions, and reveals other sexual health-related concerns thereby giving providers the information needed to address these issues and conditions. The conversation that takes place helps build trust and provides opportunities for healthy behaviors counseling as well. *A sexual history is vital to assessing risk behaviors and identifying indications for PrEP use.* Ideally, a sexual history also provides guidance and addresses concerns around sexual pleasure and fulfillment as well.

Discussing sexuality with a provider may be awkward at any age. Youth and those who are sexual minorities may face additional sensitivities due to their age and/or society's heteronormativity. Some gender nonconforming youth have faced rejection and hostility from their families and bullying or violence in school or society related to their sexuality. They need to be assured that they will be safe if they disclose personal aspects of their lives and sexual behaviors.

This tool offers guidance for health care providers who care for adolescents and young adults as to how to take an inclusive sexual history to meet the needs of all youth including lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) youth. Many factors influence an individual's sexual life and expression. You are encouraged to adapt this guide to be culturally appropriate for your patients based on their age, gender identity and expression, sexual orientation, race, ethnicity, culture, and other factors.

Contents

Create a Safe Environment

Creating a safe environment for discussion of sensitive topics is critical to establishing trust and open communication. All adolescents and LGBTQ youth may be particularly sensitive. When taking an adolescent's sexual history:

Establish rapport

Set expectations for the clinical encounter. Speak to the parent or guardian (if present) and minor adolescent together and let them know what to expect, including that the adolescent will have some time alone with you. If you will talk alone with the parent as well, do so before you talk to the adolescent alone, so the adolescent does not worry that you are sharing what you have discussed. This will also provide you and the parent or guardian an opportunity to share any concerns.

In a private interview with the (adolescent) patient:

- **Normalize the discussion.** State that all patients are asked the same questions. By asking personal questions you can provide the best possible care.
- **Minimize note-taking, particularly during sensitive questions.**

- **Sexual history should be part of a broader risk assessment.** For minor adolescents, the sexual history can be part of a broader risk assessment which asks about issues relating to home, school, drug and alcohol use, smoking, etc.
- **Provide assurance of confidentiality and establish limits of confidentiality.** Patients—especially young patients—are more likely to disclose sensitive information if consent and confidentiality are clearly explained. Clarify the laws and limits of confidentiality, explaining where confidentiality may need to be breached, such as when there is reported abuse or suicidal thoughts. Ensure that confidentiality will be maintained as allowable throughout the billing process. Some adolescents up to age 26 may still be on their parents' health plans so arrangements may need to be made regarding where the Explanation of Benefits will be sent. Know your state's minor consent laws and communicate parameters as needed. See Section 4 PrEP and Young People: Laws and Policies for more information.

Avoid assumptions of heteronormativity or behaviors

Do not assume a patient's gender identity, sexual orientation, sexual behaviors, or number of partners.

- **Understand the difference between gender and sexuality and how it may apply to your patients.**
  - **Gender identity** is a person's internal sense of gender: man/male, woman/female, both, neither, or another gender.
  - **Gender expression** is the ways in which a person acts, presents themselves, and communicates. Gender expression may or may not correspond to assigned gender at birth or gender identity.
  - **Sexuality** encompasses **sexual orientation** (how a person characterizes their emotional and sexual attraction to others, e.g., heterosexual, lesbian, gay, bisexual), **sexual attraction** (who one loves and/or is attracted to) and **sexual behaviors.**
  - Note that youth who may be questioning their sexual orientation and/or gender identity may have changing responses to questions in this area over time.
  - See **Glossary of LGBT Terms for Health Care Teams** (National LGBT Health Education Center) for more information.
- **Use gender-neutral language.** Ask your patients—especially those who are gender nonconforming—which pronouns they prefer. Some may prefer the pronouns you and they, rather than he and she. Some sexual minority youth prefer non-traditional pronouns to describe themselves such as yo, ze, zhe, hir, they. Instead of asking "What do you and your girlfriend do together?" ask "Tell me about your partner." Or, "What do the two of you do together?"
- **Be familiar with colloquial terminology your patients might use.** See **Gender & Sexuality Terminology** (LGBT Resource Center, University of California, Riverside) for suggestions.

Be nonjudgmental and supportive

Talking about sensitive topics such as sexual behavior, gender identity, and coming out can be risky for LGBTQ youth in particular. Keep an open mind and seek to understand what youth need from this medical encounter in terms of risk reduction and medical care. It is also important that all office staff be nonjudgmental and welcoming.

- **Offer open-ended encouragement.** For LGBTQ youth and for particularly sensitive topics: ask questions to understand their current situation. "Tell me your story." Ask about feelings, preferences, thoughts, and behaviors.
- **Ask developmentally appropriate questions.** Talk in terms adolescents will understand, taking note of the adolescent's age as well as developmental stage.
- **Ask open-ended questions**. Practice listening skills. Watch for nonverbal cues as well.
- **Avoid the surrogate parent role.** Instead, look for opportunities to offer relevant and appropriate risk reduction information. Don't lecture.
- **Be concrete and specific with your questions.** See examples in the following pages.
- **Describe how screening tests and results will be delivered.** Make sure clinic staff are also aware of how results will be delivered so that patient confidentiality will be maintained.
- **And remember, it's a conversation…not a lecture or an interrogation!**

Taking the History

Introduction

- ✔ Some of my patients your age have started having sex. Have you had sex?

  Or

- ✔ Are you sexually active?

Partners

- ✔ In the past 6 months, how many sex partners have you had?
- ✔ Are your sex partners men, women, both, transgender?
- ✔ Were any partners known to be HIV positive? How many partners were known to be HIV positive?

Practices

- ✔ What kind of sexual contact do you have or have you had? Genital (penis in the vagina)? Anal (penis in the anus)? Oral (mouth on penis, vagina or anus)? Other (e.g. digital/finger in vagina or anus)?
- ✔ For men who have sex with men, are you the receptive partner ("the bottom"), the insertive partner (the "top") or both ("versatile")?

Protection from STDs

- ✔ Do you use condoms consistently? If not, in which situations are you most likely to use or not to use a condom?
- ✔ How many times did you have vaginal or anal sex without a condom?
- ✔ Did you use a condom at your last sexual encounter? (This last question provides an opportunity to gauge condom use and assess the need for emergency contraception in women and possible risk of acute HIV infection in all patients.)

Past History of STDs

- ✔ Have you ever been diagnosed with a STD, such as HIV, herpes, gonorrhea, chlamydia, syphilis, genital warts, HPV, or trichomoniasis? When? How were you treated? Did you take all of your medicine?
- ✔ Have you had any recurring symptoms or diagnoses?
- ✔ Have you ever been tested for HIV? When was your last HIV test? What was the result?
- ✔ Has your current partner or any former partners ever been diagnosed or treated for an STD? Were you tested for the same STD(s)? If yes, when were you tested? What was the diagnosis? How was it treated?

Prevention of Pregnancy

- ✔ Are you currently trying to conceive a child?
- ✔ Are you concerned about getting pregnant or getting your partner pregnant?
- ✔ Are you using contraception or practicing any form of birth control? Do you need any information on birth control (or a referral)?
- ✔ Have you used emergency contraception in the past year? If so, how many times?

Note: Repeated use of emergency contraception (EC) is a flag for unprotected sex. Use of EC twice or more in six months may warrant screening for intimate partner violence (IPV) as partners may be sabotaging or prohibiting their partner's use of contraception. See resources for IPV screening at the end of this form.

Additional questions to identify HIV and hepatitis risk

- ✔ Have you or any of your partners been diagnosed with HIV or hepatitis B or C?
- ✔ Have you or any of your partners ever injected drugs?
- ✔ Have you used methamphetamines/crystal meth, crack, MJ, or any other drugs? Which one(s)?
- ✔ Do you have sex when you have been using drugs or after drinking alcohol?
- ✔ Have you had the hepatitis B vaccine (all three doses)?
- ✔ Have you had the hepatitis A vaccines (two doses)? (Recommended for men who have sex with men and injection drug users)
- ✔ Have you ever taken pre-exposure prophylaxis (a medication to prevent against HIV)? Or used a partner's medication to avoid getting HIV?
- ✔ Have you ever taken post-exposure prophylaxis (a medication taken within 72 hours after sex to prevent against HIV)?

Completing the History

- ✔ Is there anything else about your sexual practices that I need to know about to ensure your good health care?
- ✔ Are you or your partner having any sexual difficulties at this time?
- ✔ Do you have any sexual concerns you would like to discuss?

After taking the sexual history, thank the patient for being open and honest and commend any protective practices. For patients at risk of STDs, encourage testing and offer praise for protective practices. For patients at risk of pregnancy, offer praise for consistent contraceptive use. After reinforcing positive behavior, address specific high risk practices. Discuss PrEP if appropriate.

Adapted from **A Guide to Taking a Sexual History** *(Centers for Disease Control and Prevention)*

Additional Resources

1. Talking to Patients about Sexuality and Sexual Health (Association of Reproductive Health Professionals)
2. Taking an Adolescent Sexual History (Bolan, Director of the Centers for Disease Control and Prevention's Division of STD Prevention)
3. A Clinician's Guide to Sexual History Taking (California Department of Public Health STD Branch)
4. Bright Futures Previsit Questionnaires (Early Adolescent, 15–17 Years, and 18–21 Years) (American Academy of Pediatrics)
5. Office-based Care for Lesbian, Gay, Bisexual, Transgender and Questioning Youth (Levine and Committee on Adolescence, American Academy of Pediatrics)
6. Adolescent Friendly Health Services [PowerPoint and video] (Physicians for Reproductive Health, Adolescent Reproductive and Sexual Health Education Program)
7. Caring for Transgender Adolescents [PowerPoint and video] (Physicians for Reproductive Health, Adolescent Reproductive and Sexual Health Education Program)
8. Lesbian, Gay, Bisexual, Transgender, Questioning Youth [PowerPoint and video] (Physicians for Reproductive Health, Adolescent Reproductive and Sexual Health Education Program)
9. Sexual History-Taking: Essential Questions [PowerPoint and video.] (Physicians for Reproductive Health, Adolescent Reproductive and Sexual Health Education Program)
10. Preexposure prophylaxis for the prevention of HIV infection in the United States-2014: A clinical practice guideline (US Public Health Service)

Resources for Intimate Partner Violence Screening

1. IPV Screening and Counseling Toolkit (Futures Without Violence)
2. National Coalition of Antiviolence Programs
3. National Domestic Violence Hotline 800-799-SAFE (7233), 800-787-3224 TYY

FAQs Billing for PrEP

Does private insurance cover PrEP and related costs?

Commercial plans cover PrEP, however coverage varies by plan. Individuals should contact their plans directly to find out about coverage. Helping Insured Patients Estimate PrEP Costs can help your patients determine their insurance coverage, not only for the medication but also for office visits, lab work, copays, deductibles, etc. Patient assistance programs are available to help offset high out-of-pocket costs for insured individuals. (See below)

Do Federally-Facilitated and State Marketplaces cover PrEP?

Individuals with coverage purchased through the Federally-Facilitated Marketplace or State Marketplace in your state should check with their individual plans as coverage varies.

Does Medicaid cover PrEP?

Medicaid should cover medical costs related to PrEP. Check with an individual's health plan for specific coverage information. For those states which have not expanded Medicaid, single men are among those most impacted. Patient assistance options (see below) and partnerships with community based organizations can support you in helping patients navigate the payment system. (See below)

Does Medicare cover PrEP?

The coverage varies by plan and by state. Patients should contact their insurance plans for coverage details. Helping Insured Patients Estimate PrEP Costs can help them in discussions with their insurance plans.

What patient assistance programs are available?

A few patient assistance available options are available although most of them help with payment for TDF-FTC and not for copays, deductibles, lab work and other associated costs. Please see **Getting Prepped** for more information on these and other patient assistance options. Also check with your state health department about possible patient assistance programs in your state.

Does the Ryan White AIDS Program pay for PrEP?

No, the Ryan White AIDS Program does not cover PrEP.

How can I guarantee minor patients' confidentiality in the billing process?

Some adolescent patients may have private insurance, but do not want their parents or guardians to know they are receiving PrEP. As you know, this is an issue with ramifications beyond insurance. Young people should be encouraged to involve their parents or guardians in the decision to start PrEP if possible; this could also help address the confidentiality issue. Section 4 of this toolkit addresses PrEP and Young People: Laws and Policies. The State Policy Table provides further guidance as to your state's minors' access and confidentiality laws.

How can I help my patients navigate PrEP costs?

Getting Prepped provides a detailed overview of the insurance process for PrEP. Helping Insured Patients Estimate PrEP Costs provides guidance to patients in researching their insurance coverage.

What are ways to capture revenue and control costs while offering PrEP?

There are some ways to capture revenue and control costs when offering PrEP within a small practice and/or when many of your patients may be uninsured or underinsured. Hiring a full- or part-time Benefits Counselor or PrEP Navigator who can help your patients assess their eligibility for public or private insurance and patient assistance programs could help your patients afford PrEP and maximize the revenue you capture.

Also, some community-based organizations (e.g., Federally Qualified Health Centers, community and free clinics, and public health clinics) can help with caring for low-income or uninsured patients. They may also be partners in serving your clients by coordinating benefits. For example, they might provide some ancillary services at reduced charge for your low-income or uninsured patients. Reach out to them and see how you might work together to serve your local community. Greater Than AIDS provides a **state directory of PrEP providers**.

Helping Insured Patients Estimate PrEP Costs

Nearly all insurance plans cover PrEP, but out-of-pocket costs vary. Your insurance plan can give you the most accurate estimate of your out-of-pocket costs. Call your plan and ask about your PrEP coverage.

Ask the following questions to get an accurate estimate:

- ✔ Ask for an estimate of the out-of-pocket costs for PrEP.
- ✔ Is Prior Authorization needed to see a specialist, such as an infectious disease physician? If so, how can I obtain Prior Authorization?
- ✔ Is my PrEP provider contracted with my insurance plan? Is my PrEP provider considered "in" or "out" of network? In-network providers will have lower out-of-pocket costs.
- ✔ What is the difference in copayment (copay) between a specialist visit and a primary care physician visit?
- ✔ What is my deductible for medical care and medications? How much of the deductible(s) have I met to date?
- ✔ Does my plan have an out-of-pocket maximum amount I have to pay in one year for medical care and medications? If so, what is this amount? How much have I spent to date?
- ✔ Will I have to pay any out-of-pocket costs for lab work?
- ✔ What is the monthly copay for Truvada?

There are patient assistance options that can greatly reduce or eliminate this out-of-pocket cost. Please see **Getting Prepped** by Project Inform for more information on these options.

If you have trouble with insurance coverage, contact local HIV advocates. Some national organizations can also provide assistance such as Lambda Legal (**www.lambdalegal.org/help**) and My PREP Experience (**www.MyPrEPexperience.org**).

PrEP-related ICD-10 and CPT Codes

PrEP-related International Classification of Disease and Related Health Problems (ICD) and Current Procedural Terminology (CPT) codes are available on pages 29–31 in the **Clinical Providers Supplement**, *Preexposure Prophylaxis for Prevention of HIV Infection in the United States 2014* (Centers for Disease and Control Prevention).

Additional CPT Prevention Counseling Codes are provided below.

CPT	Description
99401	Prevention Counseling (15 minutes)
99402	Prevention Counseling (30 minutes)
99403	Prevention Counseling (45 minutes)
99404	Prevention Counseling (60 minutes)

HIV and PrEP among Young Women in the United States

In 2014, women accounted for nearly one in five (19%) new HIV infections in the United States.[1] Women of color, especially young women, have been especially impacted and comprise the majority of women living with the disease. Women at risk of HIV face challenges to getting needed prevention education and services. Systemic inequities perpetuate health disparities of youth; low HIV testing rates and high rates of sexually transmitted diseases (STDs) contribute to this imbalance. While multi-faceted approaches are needed to address these factors and disparities, PrEP provides another prevention option that can benefit women at high-risk of HIV acquisition.

Contents

Women and HIV

Approximately 1 in 4 people living with HIV are women age 13 and up.[2] Of women living with HIV, about 11% do not know they are infected.[3]

In 2014, approximately 13% of new HIV diagnoses among youth aged 13–24 were young women.[4]

Women accounted for 25% (5,168) of the estimated 20,792 AIDS diagnoses among adults and adolescents in 2014 and represent 20% (246,372) of the approximately 1.2 million cumulative AIDS diagnoses from the beginning of the epidemic through the end of 2014.[5]

Among all women diagnosed with HIV in 2014, about 62% (5,128) were Black/African American, 18% (1,483) were white and 16% (1,350) were Hispanic/Latina.[6] Newly infected Black/African American women and Hispanic/Latina women are likely to be younger than white women: 23% of new infections among Black/African American women and 21% among Hispanic/Latina women were in 13–24 year olds, compared to 16% in white women.[7]

In 2014, 87% of new HIV diagnoses among women were attributed to heterosexual sex and 13% were attributed to injection drug use.[8]

Black/African American women in particular, as well as Hispanic/Latina women, continue to be disproportionately affected by HIV compared with women of other races/ethnicities.[9]

While the number of HIV diagnoses among African American women declined from 2010-2014,[10] it is still high compared to women of other races and ethnicities.[11]

PrEP and young women

As with all at-risk populations, young women can benefit from accurate HIV prevention education and condom use. Some young women at highest risk could benefit from risk reduction counseling and pre-exposure prophylaxis (PrEP). The CDC recommends that all individuals ages 13-65 be tested for HIV.

HIV prevention challenges for young women

Biological factors affect a young woman's risk for HIV infection. Most women are infected by heterosexual sex and the risk of getting HIV during vaginal sex is higher for women than for men. Anal sex is also riskier for getting HIV than vaginal sex and more so for the receptive than the insertive partner.[12] Young women are also more vulnerable to infection due to their less mature reproductive tract.[13]

Low rates of testing. Only 22% of high school students who have ever had sexual intercourse had been tested for HIV.[14] Early detection and treatment keeps people living with HIV healthy and living longer. People who know they are HIV positive can also take action to protect their sex partner(s) and drug injection partner(s) as appropriate. People who know their HIV status can take antiretroviral medications for their own health that can also reduce the spread of HIV infection by 96%.[15]

High rates of sexually transmitted diseases (STDs). Half of all STDs are in young women and men ages 15–24 even though they represent only 25% of the sexually experienced population.[16] HIV seroconversion is higher among women with STDs.[17] Furthermore, research shows that there are higher rates of STDs in some communities of color relative to whites due to social and economic conditions, posing additional risks for young people in those communities.[18]

Older male partner. Young women may be at higher risk of HIV when they have an older male sex partner. As opposed to adolescent partners, older male partners are more likely to have had multiple partners and STD, HIV, and drug exposures.[19] Furthermore, power differentials in the relationship may make it more difficult for young women to negotiate condom and contraceptive use.[20]

Intimate partner violence (IPV). More than one-third (36%) of US women have experienced rape, physical violence, or stalking by an intimate partner in her lifetime. Of these women, 69% reported experiencing IPV at age 25 or younger and 22% experienced IPV for the first time between ages 11 and 17. Women with a history of IPV are more likely to report HIV risk factors, including unprotected sex, injection drug use, and alcohol abuse, compared to women who have not experienced violence.[21]

Stigma, fear, discrimination and negative perception about HIV testing may also place young women at higher risk and discourage HIV testing and prevention efforts such as condom use.[22]

Lack of awareness of HIV status. Diagnosis late in the course of HIV infections is common in African American communities which also contributes to higher transmission rates. Later diagnosis also impacts opportunities to get early medical care.[23]

Poverty contributes to the health disparities in HIV prevalence in the US. About 46% of Blacks and 40% of Hispanics live in high poverty urban areas with high HIV prevalence compared to 10% of whites.[24] Limited access to health care including sexual and reproductive health care, housing, and HIV prevention education—among other socioeconomic factors—directly and indirectly increase the risk for HIV infection.

One study found that urban minority female adolescents living in poverty reported high levels of worry about AIDS, but also reported equal or greater concerns about having enough money to live on, general health, doing well in school, getting pregnant, and getting hurt in a street fight. These women may prioritize taking care of their housing, food, child care, and transportation needs ahead of HIV risk reduction behaviors.[25]

Prevalence of HIV in Black/African American communities may affect a young woman's risk of infection. The higher prevalence of HIV in Black/African American communities and the fact that African Americans tend to have sex with partners of the same race/ethnicity mean that Black/African American women face a greater risk of HIV infection with each new sexual encounter.[26]

Historic injustices. Unethical experimentation, such as the Tuskegee syphilis study, have affected the Black/African American community's, and other communities of color's, trust of public health messages and may contribute to an unwillingness for some to be tested or treated for HIV.[27]

About PrEP

PrEP stands for **Pr**e-**E**xposure **P**rophylaxis. PrEP can be used by those at substantial risk of HIV exposure through sexual contact or injectable drug use to prevent acquisition of HIV infection.

To date, the FDA has approved one drug, Truvada, for PrEP in adults (18 and older) in 2012. Truvada is a combination of tenofovir disoproxil fumarate and emtricitabine (TDF-FTC) in one daily pill. It was FDA-approved for HIV treatment in 2004. In March 2016, the FDA approved low strength TDF-FTC for *treatment* for those under 18 years of age.

Evidence from clinical trials conducted among multiple high-risk populations suggests that oral TDF-FTC reduces the risk of HIV infection—by up to 92%—among those who regularly take their medications.[28] When taken daily, TDF-FTC is safe and highly effective in preventing HIV infection.[29]

TDF-FTC should be used as part of a comprehensive prevention plan that also includes adherence and risk reduction counseling, HIV prevention education, and behavioral interventions such as drug abuse treatment and correct and consistent condom use.

TDF-FTC is for individuals who are at ongoing substantial risk of HIV infection. For those who need to prevent HIV after a single high-risk event of potential HIV exposure—such as condomless sex, sexual assault, or needle-sharing injection drug use—there is post-exposure prophylaxis (PEP). PEP must begin within 72 hours of exposure.

Indications for PrEP use for women

Per the CDC PrEP Guidelines,[30] PrEP may be appropriate for the following populations:

	Men who have sex with men (MSM)	Heterosexual women and men	Injection Drug Users (IDU)
Recommended Indicators for PrEP Use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use	HIV+ sex partner Recent bacterial STD Multiple sex partners Inconsistent condom use (with MSM, IDU, other high risk partner)	HIV+ injecting partners Sharing injection equipment or needles Risk of sexual acquisition (see columns on left)

Advantages of PrEP for women

TDF-FTC is the first HIV prevention tool that women can fully control. A woman does not have to negotiate or rely on her partner's condom use. Also, women in abusive relationships may be able to discreetly take PrEP to protect themselves as needed.

PrEP effectiveness in young women

Both the FEM-PrEP and VOICE clinical studies failed to find efficacy in women at high-risk on daily TDF-FTC.[31] However, other studies of heterosexual populations including both women and men found higher efficacy where higher levels of adherence were achieved.[32]

Research indicates that adherence needs to be greater to achieve high levels of efficacy in women. Some studies have found that women need daily doses of TDF-FTC to prevent HIV acquisition while men need only two doses per week.[33] Furthermore, according to the CDC PrEP guidelines, data suggest that maximum intracellular concentrations of tenofovir diphosphate are reached in blood after approximately 20 days of daily oral dosing, in rectal tissue at approximately 7 days, and in cervico-vaginal tissues at approximately 20 days.[34]

Some research also suggests that PrEP may not be as effective in women younger than 25 and particularly younger than 21.[35] Further research is needed.

PrEP safety

TDF-FTC has been used to treat HIV for over a decade with a good safety profile. In prevention studies to date, TDF-FTC for PrEP has not caused serious short-term safety concerns. TDF-FTC has caused renal toxicity and decreased bone mineral density when used for HIV treatment for months and years. TDF-FTC is considered safe for women of child-bearing age. Decisions about possible use during **pregnancy** must be individualized. While available data suggests that TDF-FTC does not increase the risk or birth defects, there are not enough data to exclude the possibility of harm (Pregnancy Class B). TDF-FTC is often used in pregnancy if the risk of ongoing HIV transmission is sufficiently high as in a serodiscordant partnership and because pregnancy itself is associated with an increased risk of HIV acquisition.

Since TDF-FTC is actively eliminated by the kidney, it should be co-administered with care in patients taking medications that are eliminated by active tubular secretion (e.g., acyclovir, adefovir dipivoxil, cidofovir, ganciclovir, valganciclovir, aminoglycosides and high dose of multiple NSAIDs). Drugs that decrease renal function may also increase concentrations of TDF-FTC.

Adapted from: NYC Health, PrEP Provider FAQs[36]

PrEP safety for women under 18 years of age

In March 2016, the United States Food and Drug Administration (FDA) updated the TDF-FTC tablet label to expand the indication to include treatment for pediatric patients weighing at least 12 kilograms and the addition of the following strength tablets (100/150 mg, 133/200 mg and 167/250 mg). See the **full changes** for more information.

The CDC PrEP guidelines suggest that prior to initiating TDF-FTC as PrEP for adolescents that clinicians consider:

- Lack of data on safety and effectiveness of TDF-FTC taken by patients under age 18;
- Possibility of bone or other toxicities among youth who are still growing; and
- Safety evidence available when TDF-FTC is used in treatment regimens for HIV-infected youth.

These factors should be weighed against the potential benefit of providing TDF-FTC for an adolescent at substantial risk of HIV acquisition.[37]

Unless contraindicated for an adolescent's safety, parent/guardian involvement is advised. In addition, the individual patient's ability to comply with daily dosing given developmental stage, family and social support, housing situation and other life circumstances should also be considered.

Supporting PrEP adherence

Research indicates that the efficacy of TDF-FTC depends upon patient adherence to the regimen as well as the benefits of the medication itself.[38] Therefore PrEP education, assessment of a patient's ability to adhere, follow up safety monitoring visits, and additional social supports as needed by individual patients given their life circumstances are all critical to successful TDF-FTC use.[39] Adherence is also critical to reducing the risk of developing a drug resistant virus.

Patients with chronic diseases have reported that the most important factors in medication adherence were incorporating medication into their daily routines, knowing that the medications work, believing the benefits outweigh the risks, knowing how to manage side effects, and low out-of-pocket costs.[40]

When initiating TDF-FTC, PCPs must educate patients to ensure they understand:

- How to take their medications (e.g., when, how many pills);
- What to do if they experience problems (e.g., what to do if they miss a dose, what constitutes a missed dose);
- What the most common side effects are and help patients develop a plan for handling them; and
- The importance of using condoms, especially if they decide to stop taking TDF-FTC.[41]

Additional tools such as providing reminder systems (e.g., texts, emails) have also proven effective. Furthermore, addressing financial, substance abuse, and mental health needs that may interfere with adherence and facilitating social supports are also recommended and may be key to maintaining adherence over time in high-risk youth. The Clinical Reference Sheet in this toolkit outlines key components of medication adherence counseling.

Research in this area continues to explore mechanisms for encouraging adherence, as well as novel formulations of PrEP that can help overcome adherence barriers such as long acting vehicles or intermittent PrEP.

Hormonal contraception and PrEP

Studies have found that TDF-FTC has no adverse impact on hormonal contraceptive effectiveness for pregnancy prevention.[42] Injectable contraceptives (Depo-Provera) have been associated with a 2–4 fold increased risk of HIV acquisition in some observational studies.[43] Research has demonstrated that TDF-FTC could mitigate the potential increased HIV-1 acquisition and transmission risks that have been associated with DMPA use.[44]

Conception, pregnancy and breastfeeding

Please refer to the CDC's **Provider Information Sheet-PREP During Conception, Pregnancy and Breastfeeding** for more information.

HIV and intimate partner violence

Women with a history of intimate partner violence (IPV) are more likely to report HIV risk factors, including unprotected sex, injection drug use, and alcohol abuse, relative to women who have not experienced violence.[45]

The National Domestic Violence Hotline (**www.thehotline.org/help/**) is available to all who suffer from intimate partner violence.

As of April 29, 2015, survivors of domestic violence may apply for health insurance under the Affordable Care Act at any time. They do not need to wait for Open Enrollment.

Exposure to IPV can increase a woman's risk for HIV infection through:

- forced sex with an HIV positive partner
- limited or compromised negotiation of safer sex practices
- increased sexual risk-taking[46]

Source: Suzanne Maman, et al., "The intersections of HIV and violence: directions for future research and interventions," Social Science and Medicine 50, no. 4 (2000):459-478, DOI: 10.1016/S0277-9536(99)00270-1.

As survivors of domestic violence, they qualify for a Special Enrollment Period (SEP). Survivors can contact the call center at 1-800-318-2596 and explain, "I am a survivor of domestic violence. I want a Special Enrollment to apply for health care." The call center will grant the SEP and the survivor will have 60 days to choose a health care plan. More details are available at **healthcare.gov** or the **Health Cares About IPV: Intimate Partner Violence Screening and Counseling Toolkit** (Futures Without Violence).

Other PrEP methods being studied

A number of studies are underway to look at different delivery mechanisms as well as medications for use as PrEP, including:

- multipurpose technologies (MPT) which would deliver contraception and PrEP, such as a vaginal ring;
- microbicides; and
- long acting antiretrovirals delivered by implant or injection.

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2 "HIV Among Women," *Centers for Disease Control and Prevention*, last modified March 16, 2016, www.cdc.gov/hiv/group/gender/women/.

3 Ibid.

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7 "Women and HIV/AIDS in the United States," *The Henry J. Kaiser Family Foundation*, last modified March 6, 2014, http://kff.org/hivaids/fact-sheet/women-and-hivaids-in-the-united-states/.

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19 Nyounti Tuan, "Young African American Women and HIV." www.advocatesforyouth.org/index.php?option=com_content&task=view&id=499&Itemid=177.

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21 "Addressing the Intersection of HIV/AIDS, Violence against Women and Girls, & Gender-Related Health Disparities," *The President's Working Group on the Intersection of HIV/AIDS, Violence again Women and Girls, and Gender-Related Health Disparities*, September 2013, www.whitehouse.gov/sites/default/files/docs/vaw_master_report.pdf.

22 "HIV Among African Americans."

23 Ibid.

24 Paul Denning, Elizabeth DiNenno, "Communities in Crisis: Is There a Generalized HIV Epidemic in Impoverished Urban Areas of the United States?" *Centers for Disease Control and Prevention*, June 23, 2015, www.cdc.gov/hiv/group/poverty.html.

25 Jennifer Augustine, "Young Women of Color and the HIV Epidemic."

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38 Amanda D. Castel, Manya Magnus, Alan E. Greenberg, "Pre-exposure Prophylaxis for Human Immunodeficiency Virus: The Past, Present, and Future," *Infectious Disease Clinics of North America* 24, no. 4 (2014): 563-583, DOI: 10.1016/j.idc.2014.08.001.

39 Ibid.

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41 "Pre-Exposure Prophylaxis for the Prevention of HIV Infection in the United States: A Clinical Practice Guideline."

42 Pamela M. Murnane et al., "Pre-exposure prophylaxis for HIV-1 prevention does not diminish the pregnancy prevention effectiveness of hormonal contraception." *AIDS* 28, no. 12 (2014) 1825-30. DOI: 10.1097/QAD.0000000000000290.

43 Craig Walter Hendrix, "The effect of Depo-Provera on HIV susceptibility, immune activation, and PrEP PK," *Grantome*, http://grantome.com/grant/NIH/R01-AI110371-01; Renee Heffron et al., "PrEP is Efficacious for HIV-1 prevention among Women using DMPA for Contraception," *AIDS* 28, no. 18 (2014): 2771-2776, DOI: 10.1097/QAD.0000000000000493.

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46 Suzanne Maman, et al., "The intersections of HIV and violence: directions for future research and interventions," *Social Science and Medicine* 50, no. *4 (2000):459-478, DOI:* 10.1016/S0277-9536(99)00270-1.

Creating a Welcoming Office

Imagine an African-American gay man walking into a waiting room full of brochures that show images of heterosexual white couples but none of same-sex couples or people of color. Then he sits down to complete a registration form that only has options for single or married. He is in a long-term relationship in a state where he cannot get legally married. Which box should he check? It is unlikely that he feels included, affirmed, or even safe to disclose his sexual orientation to his provider. For a transgender patient there is the further humiliation of being called the wrong name or wrong pronoun in the waiting area because intake forms don't capture current gender identity and preferred names.

Adapted from: Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health

Many lesbian, gay, bisexual, transgender, queer, and questioning (LGBTQ) people experience invisibility in the health care setting. Yet health professionals' knowledge of patients' sexual and gender identity may be critical to receiving necessary preventive care or a correct diagnosis. Societal homophobia, as well as fear of discrimination based on past experiences, contributes to LGBTQ discomfort in disclosure, thus contributing to health disparities in the LGBTQ population. Furthermore, members of racial or ethnic minorities may experience additional barriers due to racism and/or cultural biases. Youth also have particular confidentiality and other concerns that need to be addressed with sensitivity so that they feel comfortable disclosing sexual and social behaviors relating to their health care needs.

Homophobia in medical practice still exists.[1] More than half of LGB respondents in a 2009 survey reported that they had experienced at least one of the following: health care professionals refusing to touch them or using extra precautions; health care professionals using harsh or abusive language; being blamed for their health status or health care professionals being physically rough or abusive. Among transgender and gender non-conforming respondents, 70% reported such discrimination.[2] Respondents who were persons of color and/or low income reported higher rates of discrimination.[3]

While parts of country have become more accepting in recent years, these issues have not disappeared entirely. Health care providers can take steps to affirmatively let their LBGTQ patients of all backgrounds and ages know that they are welcome and will be treated respectfully. By modifying office spaces, practices, policies, and staff training—often with simple steps—health care providers can improve access to quality health care for LGBTQ people, youth, and members of various racial and ethnic backgrounds in their communities.

The majority of youth, including LGBTQ youth, are healthy and well-adjusted. High risk behaviors exhibited by some LGBTQ adolescents are often reactions to social stigma and victimization by family, peers, and/or society.[4] Effectively serving all youth, including LGBTQ youth, may require staff education as well as modifications in the medical office. Become familiar with adolescent sexuality development for all adolescents (see Section 1), mental health issues related to the coming out process for LGBTQ youth, and related physical and sexual victimization. Additional resources are found throughout the *PrEP Education for Youth-Serving Primary Care Providers Toolkit*.

Contents

Create an inclusive culture

Train all staff to be welcoming and nonjudgmental. Provide training opportunities to teach employees about the different populations you serve or seek to serve. Training for all staff is critical to creating and maintaining spaces that feel safe for LGBTQ and youth populations. Training should be periodic to keep staff up-to-date; train all new staff within 30 days of hire. Be sure to teach appropriate standards of respect towards transgender individuals including referring to them by their preferred name and using appropriate pronouns.

Create an environment of accountability. Appoint a staff person responsible for providing guidance and fielding complaints. Encourage office staff to politely correct colleagues who use wrong names or pronouns or make insensitive comments. Create a safe space where people feel comfortable supporting one another in having an inclusive environment.

Hire diverse staff. Hiring staff with different racial/ethnic, age, ability, and other cultural backgrounds helps to bring valuable knowledge and perspectives to the practice and signals an open environment. Openly gay, lesbian, bisexual, transgender, and queer staff can help LGBTQ patients feel comfortable.

Share these guidelines with all staff. The guidelines will reinforce training and provide a reminder of expected standards of care in the office.

Address prejudices. Some employees may have longstanding negative feeling about LGBTQ populations due to ignorance or lack of familiarity with LGBTQ issues. Some may feel their religious beliefs require condemnation of LGBTQ persons. Some employees may need individual training and counseling.[5]

Create a welcoming physical space

Greet and interact with patients using gender-neutral terms. Front line staff plays a critical role in helping patients feel welcome and get the services they need both in person and over the phone. For transgender persons who are often discriminated against or misunderstood, every interaction counts in creating a welcoming environment. A person's gender is not always apparent by name or appearance. Address people without using terms that indicate gender. You can avoid using Mr./Mrs./Ms./Miss by using first names or by using the first and last name together or by saying, "Excuse me, we are ready for you."

Also avoid gender terms when talking about a patient to a third party. For example, instead of saying, "She is here for a follow up appointment," you can say "Dr. Aron's 1:00 patient is here," or, "The patient is in the waiting room." You can also use "they" as a gender-neutral pronoun. *Never* refer to a patient as "it."

Present inclusive visual signs. Include pictures of people of varying races and ethnicities, same-sex as well as opposing gender couples, youth, transgender individuals, and people of different abilities on posters, brochures, and videos and other educational materials and media in the waiting spaces. A rainbow flag, pink triangle, or another LGBTQ-friendly symbol will signal that you welcome LGBTQ patients. Include brochures on LGBTQ health concerns including breast cancer, safe sex, hormone, therapy, mental health, substance use, and sexually transmitted infections such as HIV/AIDS, syphilis, and Hepatitis A and B. Youth might be more comfortable picking up brochures if they are in the examination rooms. Be sure to include materials and signage in the languages commonly used in your service area.

Post or disseminate a nondiscrimination statement in the waiting area. State that equal care will be provided to all patients regardless of age, race, ethnicity, physical ability or attributes, religion, sexual orientation, or gender identity and expression.

Have at least one, clearly marked, universal gender-inclusive restroom. Many transgender persons as well as others not conforming to physical gender expectations have been harassed for entering the "wrong" bathroom. At least one universal restroom would help create a safer atmosphere.

Connect with community resources. Be aware of community and national resources for LGBTQ persons, youth, racial and ethnic minorities, and others in your care. Make connections with groups that can provide resources to enhance the care you provide to your patients.

Develop LGBTQ-sensitive forms

Electronic or paper patient intake forms which are sensitive to the needs of LGBTQ patients can contribute to patient comfort and ultimately lead to disclosure of information needed to deliver quality health care services.

Consider these additions or modifications:

- **Name:** Develop a system that allows patient to put their **preferred name, gender, and pronouns** into intake and other relevant forms. Staff can then see and use patient preferences. This is helpful for multiple reasons. Many transgender people change their name and gender to match their gender identity. These changes are not always made on their legal documents for various reasons. This new system will also help cisgender (self-identity conforms with the gender that corresponds to biological sex) patients who prefer to use nicknames or middle names. It is important to respect patients' gender identity by always using their preferred pronouns as indicated on the forms.

- **Gender:** Offer options for female, male, transgender female to male, transgender male to female, and other (leave a space for patient to fill in).

- **Relationship status:** Offer options such as single, married, domestic partnership, partnered, involved with multiple partners, separated from spouse/partner, divorced/permanently separated from spouse/partner, and other (leave space for patient to fill in). Alternatively, leave a blank line next to Relationship Status.

- **Sexual orientation identity:** Offer options for gay, lesbian, bisexual, heterosexual/straight, queer, and other, not sure, don't know, or please feel free to explain (leave space for patient to fill in).
  Note: youth may be going through a questioning process whereby they explore their sexual identity, gender identity, and sexual expression. This process takes place over a period of years. Health care providers need to be aware of and sensitive to this process and to ask these questions again over time in order to deliver appropriate care as needed at any given time.

- **Gender identity/expression:** Do you have any concerns related to your gender identity/expression or sex of assignment?
- **Hormones:** Do you currently use or have you used hormones (i.e., testosterone, estrogen, etc.)? Do you need any information about hormone therapy?

Sample recommended questions for an LGBTQ-friendly intake form can be found in the **Guidelines for Care of LGBT Patients** (Gay and Lesbian Medical Association). For more information on taking a sexual history, please see Taking a Sexual History.

Provide inclusive care

Approach the patient interview with empathy and a nonjudgmental attitude. Practicing the tips below will make this process easier for you and your office staff over time.

Reaffirm confidentiality. Explain that provider-patient dialogue is confidential. Encourage openness by explaining that you need to ask some sensitive questions in order to understand and best meet their health care needs.

Developing a written confidentiality policy that is distributed to all patients (and possibly signed) will encourage youth, LGBTQ, and all patients of their confidentiality. Your HIPAA policy will cover most elements. You may also want to post the confidentiality policy in plain language in the waiting area.

Additionally, youth in particular need to be told the parameters where maintaining confidence is not possible by law—if there is abuse or a possibility of self-harm. Familiarize yourself with your state laws regarding minor consent and confidentiality as found in the State Policy Table and inform your patients accordingly.

Listen to your patient's language and mirror it. Listen to how they describe their relationships, partners, sexual orientation, and gender identity and follow their lead about their self-descriptions. This will help to build trust and respect. Caveat: Be careful about using words such as "queer," "dyke," and "fag" which have been used derogatorily. While your patients may use them to describe themselves, they are not appropriate for health providers' use. If you are not sure how to refer to a patient, ask what term or phrase they prefer. The **Glossary of LGBT Terms for Health Care Teams** (National LGBT Health Education Center) provides definitions and may provide some guidance as to generally acceptable terms.

Avoid using the term "gay" with patients. Unless the patient has used this term, don't assume it is appropriate even if patients have discussed a same-sex or same gender sexual partner. Some men who have sex with men (MSM)—particularly Black/African American and Latino/Hispanic—do not consider themselves gay. If your patient has not indicated a specific identity or indicated a sexual orientation other than gay, the term may cause alienation or mistrust. Again, listen to your patient's language and reflect back as appropriate. Proper and respectful language helps build trust.

Avoid labels. Youth in particular, and adults as well, may not self-identify using traditional orientation labels such as gay or lesbian. Some may not choose a label at all.

Ask open-ended questions. Use gender-neutral terms to describe relationships and sexual behaviors.

Do not make assumptions about the gender of a patient's partner or about sexual behaviors. If a female patient identifies as a lesbian, do not assume that she has never had a male sex partner, a pregnancy, a child, or has little risk of sexually transmitted diseases (STDs).

Likewise don't assume that a male patient who identifies a male sexual partner or identifies as gay has never had a female sexual partner and does not have children.

Ask only the questions needed for health care delivery. People are often curious about transgender people and thus sometimes want to ask questions. However, like everyone else, transgender people want to keep their medical and personal affairs private. Before asking a transgender person a question, think about "What do I need to know to best serve this patient? How can I ask for this information appropriately and sensitively?"

Be aware of differences in socioeconomic status, racial/ethnic discrimination, age, cultural norms, physical and mental ability, and geography and how they may affect health status and behaviors. Do not make assumptions about literacy or language ability.

Apologize if you make a mistake. If you make a mistake, acknowledge it and state that you did not mean to disrespect your patient. If you used the wrong pronoun or term, ask for the preferred term.

Discuss issues specific to LGBTQ patients

Mental health and depression. While most LGBTQ youth are quite resilient and emerge from adolescence as healthy adults, homophobia, biphobia, transphobia and related discrimination, stigma and harassment can contribute to depression, anxiety, and stress for LGBTQ youth.

Youth of color may also struggle with the effects of racism and/or cultural biases. Conduct screening for mental health and depression as indicated.

- Discuss to what extent LGBTQ patients are "out" to family, peers, friends and the extent of support they experience. Strong community support correlates with improved mental health and decreased risk of sexually transmitted diseases (STDs).
- Explore whether youth are using alcohol or drugs to deal with social stress. Studies indicate increased tobacco and substance use among LGBTQ youth who experience a high degree of discrimination and stigma.[6]
- Use Taking a Sexual History in this toolkit as a launching point to discuss safer sex strategies and to introduce PrEP as indicated. Be prepared to answer questions about STDs and HIV transmission risk for sexual activities of all youth.

Screen for STDs. Sexually active gay, bisexual, and other men who have sex with men (MSM) have higher rates of syphilis and more than half of all new HIV infections occur among MSM.[7] Sexually active youth are also at higher risk of STDs. Nearly half of the 20 million new STDs diagnosed each year in the US are among youth 15 to 24.[8] It is therefore important to provide prevention education and screen these patients for STDs including HIV as indicated. Please see the **Centers for Disease Control and Prevention's 2015 Sexually Transmitted Diseases Screening Guidelines**. The Taking a Sexual History in Section 1 can provide guidance on taking a sexual history that helps puts patients at ease and sensitively addresses issues facing various populations. See **sample provider-patient interview videos developed** by Physicians for Reproductive Health for additional guidance. Have referral networks in place for follow up care as needed.

Screen for intimate partner violence. LGBTQ persons are not exempt from intimate partner violence. Abusers may also threaten "outing," that if they report the violence, the abuser will tell others that about their sexual orientation or gender identity. According to 2001-2009 Youth Behavior Surveys in seven sites and six large urban school districts, 19%-29% of gay and lesbian students experienced dating violence in the prior year and 14% to 31% of gay and lesbian students across the sites had been forced to have sexual intercourse at some point in their lives.[9]

The National Domestic Violence Hotline is available to all who suffer from intimate partner violence and has an LGBTQ page to identify local resources to support patients who may need them.

Sources and Additional Resources

- I AM: Trans People Speak
- LGBT Youth (Centers for Disease Control and Prevention)
- Sexual Risk Behaviors: HIV, STD and Teen Pregnancy Prevention (Centers for Disease Control and Prevention)
- Syphilis & MSM (Men Who Have Sex With Men)-CDC Fact Sheet (Centers for Disease Control and Prevention)
- What Gay, Bisexual and Other Men Who Have Sex with Men Need to Know About Sexually Transmitted Diseases (Centers for Disease Control and Prevention)
- National LGBT Health Education Health Center (The Fenway Institute)
- National Consensus Guidelines on Identifying and Responding to Domestic Violence Victimization in Health Care (Futures Without Violence)
- A Provider's Handbook on Culturally Competent Care: Lesbian, Gay, Bisexual, and Transgender Population (Kaiser Permanente National Diversity Council)
- When Health Care Isn't Caring (Lambda Legal)
- Office-Based Care for Lesbian, Gay, Bisexual, Transgender, and Questioning Youth (Levine and the Committee on Adolescence)
- Fenway Guide to Lesbian, Gay, Bisexual, and Transgender Health, 2nd Edition (Makodon et. al.)
- Variations in Sexual Identity Milestones Among Lesbians, Gay Men, and Bisexuals (Martos, et al.)
- Affirmative Care for Transgender and Gender Non-Conforming People: Best Practices for Front-line Health Care Staff (National LGBT Health Education Center)
- Barriers to Health Care (National LGBT Cancer Network)
- Recommendations for Promoting the Health and Well-being of Lesbian, Gay, Bisexual, and Transgender Adolescents: A Position Paper of the Society for Adolescent Health and Medicine (Society for the Adolescent Health and Medicine)
- Trans HIV Testing Toolkit (University of California San Francisco Center of Excellence on Transgender Health)
- The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care: A Blueprint for Advancing and Sustaining CLAS Policy and Practice (United States Department of Health and Human Services, Office of Minority Health)

1 Kaiser Permanente National Diversity Council. *A Provider's Handbook on Culturally Competent Care: Lesbian, Gay, Bisexual and Transgendered Population*, 2nd ed., (Oakland, CA, Kaiser Permanente; 2004).

2 "When Health Care Isn't Caring," *Lambda Legal*, 2010, www.lambdalegal.org/publications/when-health-care-isnt-caring.

3 Ibid.

4 "Recommendations for Promoting the Health and Well-being of Lesbian, Gay, Bisexual, and Transgender Adolescents: A Position Paper of the Society for Adolescent Health and Medicine," *Society for the Adolescent Health and Medicine* 52, no. 4:506-510, DOI: 10.1016/j.jadohealth.2013.01.015.

5 "Guidelines for Care of LGBT Patients." *Gay and Lesbian Medical Association*. 2006. http://glma.org/_data/n_0001/resources/live/GLMA%20guidelines%202006%20FINAL.pdf.

6 "LGBT Youth," *Centers for Disease Control and Prevention*, last modified November 12, 2014, www.cdc.gov/lgbthealth/youth.htm.

7 "CDC Fact Sheet: What Gay, Bisexual and Other Men Who Have Sex with Men Need to Know About Sexually Transmitted Diseases," *Centers for Disease Control and Prevention*, last modified November 17, 2015, www.cdc.gov/std/life-stages-populations/stdfact-msm.htm.

8 "Sexual Risk Behaviors: HIV, STD and Teen Pregnancy Prevention," *Centers for Disease Control and Prevention,* last modified April 15, 2016, www.cdc.gov/healthyyouth/sexualbehaviors/index.htm.

9 "LGBT Youth."

Youth and HIV Laws and Policy Considerations

While it is good practice for Primary Care Providers (PCPs) to be aware of the laws and policies in place that affect their patients and the provision of care, serving young people encompasses additional considerations. Laws, policies, and/or regulations in place relating to minor consent, confidentiality, and HIV criminalization may influence whether or not a young patient will be able to access pre-exposure prophylaxis (PrEP) for HIV prevention. It is important for PCPs to be versed on the laws in their state so that they can dutifully inform their young patients of what legal barriers they may encounter throughout their healthcare experience. The State Policy Table in this section is intended to indicate if states have applicable statutes and regulations and includes direct links to the relevant text in order to guide PCPs through the laws and policies that exist in each state to better help minors access PrEP as appropriate.

Contents

Consent

There are no state or federal laws that explicitly allow or prohibit minors to consent to pre-exposure prophylaxis (PrEP), but rather an assortment of laws surrounding their ability to consent to sexually transmitted disease (STD) and/or communicable disease testing, treatment, and prevention. Some states' statutes expressly include testing, prevention, and treatment; others are more vague regarding which aspect of care a minor can consent. Still other states unambiguously include HIV in these laws, while others are unclear.

A minor's ability to consent to PrEP is important for a variety of factors. Many adolescents are unwilling to receive sensitive healthcare services if they need to involve their parent or guardian.[1] This can be an impediment to a minor's willingness to get tested for HIV or accept a prescription for a medication such as PrEP. Given continued stigma surrounding the behaviors that transmit HIV, as well as HIV itself, minors may not want to include their parents and/or guardians in their HIV-related decisions for this reason. Furthermore, minors that come from unsafe homes may fear violence if discovered to be taking an HIV preventive pill. Each state has a combination of statues and regulations that try to address these issues. Though PrEP is not explicitly mentioned in any of the laws, their interpretation may provide several legal pathways for minor consent.

Confidentiality

Even if a minor may consent to his or her own healthcare, there might be state laws in place that breach the confidentiality of the receipt of these services. In Iowa, for example, a minor can consent to HIV testing, but if the test result is positive, a parent or guardian must be notified.[2] Even in states in which confidentiality of services is expressly written into law, it may be breached in the health insurance claims and notification process. Many states require that explanation of benefits (EOBs), denial of claims, or processing of claims be sent to the policyholder, rather than the beneficiary.[3] Few states have laws in place that protect minors from unintended breaches in this way.[4]

It is important to review the various confidentiality laws—including HIPAA requirements and exceptions—that impact a minor's ability to receive healthcare services privately, and to delineate them to the minor before services are given, as these provisions may influence whether or not a minor wishes to proceed.

Criminalization

There are a variety of notification requirements on the part of the healthcare provider regarding an HIV positive test result. PrEP is an HIV prevention medication but because an HIV test is required before prescribing it, there is a chance that providers will be faced with an HIV positive test result. It is therefore important to know what the law requires in these instances. Many states require providers to notify their state's department of health of all HIV positive results. Some go further in requiring providers to put in a good-faith effort to notify their patient's previous partners that they may have been infected with HIV, either with confidentiality provisions or without. There are varying degrees of liability attached to these statutes, as well as liability exemptions.

People living with HIV/AIDS (PLWHA) are subject to a variety of criminalizing statutes, many of which were written into law before treatment was available, that could diminish viral load and outlaw acts that pose no risk of transmitting the virus.[5] These laws further stigmatize PLWHA through provisions related to sentence enhancement, prostitution, organ, blood, and semen donation, having sex or sharing needles without disclosure of HIV positive status, and even spitting. States may classify these acts as misdemeanors or felonies, and many of these laws are applicable to STDs more generally.

Additional Resources

Consent

1. State Policies in Brief: Minors' Access to STI Services (Guttmacher Institute, Updated March 2016)
2. PrEP and Our Youth: Implications in Law and Policy (Burda, 2016)
3. State Adolescent Consent Laws and Implications for HIV Pre-Exposure Prophylaxis (Culp and Caucchi, January 2013)

Confidentiality/Insurance

1. Confidentiality for Individuals Insured as Dependents: A Review of State Laws and Policies (English et. al, July 2012)
2. Confidentiality, Third-Party Billing, & the Health Insurance Claims Process: Implications for Title X (English et. al, April 2015)
3. More Evidence Supports the Need to Protect Confidentiality in Adolescent Health Care (English and Ford, 2007)
4. Unintended Consequences: How Insurance Processes Inadvertently Abrogate Patient Confidentiality (Gold, 2009)
5. State Policies in Brief: Protecting Confidentiality for Individuals Insured as Dependents (Guttmacher Institute, Updated March 2016)
6. Confidentiality Protections for Adolescents and Young Adults in the Health Care Billing and Insurance Claims Process (The Society for Adolescent Health and Medicine and the American Academy of Pediatrics, 2016)
7. Protecting Adolescent Confidentiality Under Health Care Reform: The Special Case Regarding Explanation of Benefits (Tebb, et. al, June 2014)

Criminalization/Partner notification

1. **Partner notification in the context of HIV: an interest-analysis** (Laar et. al, January 2015)
2. **Discretion to Warn: Balancing Privacy Rights with the Need to Warn Unaware Partners of Likely HIV/AIDS Exposure** (Burke, April 2015)
3. **Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States** (Lehmen, et. al, June 2014)

1 Diane M. Reddy, Raymond Fleming, Carolyne Swain, "Effect of Mandatory Parental Notification on Adolescent Girls' Use of Sexual Health Care Services," The Journal of the American Medical Association 288, no. 6 (2002): 710-714, DOI: 10.1001/jama.288.6.710.

2 "State Policies in Brief: Minors' Access to STI Services," Guttmacher Institute, March 2016, www.guttmacher.org/sites/default/files/pdfs/spibs/spib_MASS.pdf.

3 Abigail English, et al., "Confidentiality, Third-Party Billing, and the Health Insurance Claims Process: Implications for Title X," National Family Planning and Reproductive Health Association, April 2015, www.confidentialandcovered.com/file/ConfidentialandCovered_WhitePaper.pdf.

4 "State Policies in Brief: Protecting Confidentiality for Individuals Insured as Dependents," Guttmacher Institute, March 2016, www.guttmacher.org/sites/default/files/pdfs/spibs/spib_CMII.pdf.

5 J. Stan Lehmen, et al., "Prevalence and Public Health Implications of State Laws that Criminalize Potential HIV Exposure in the United States," AIDS and Behavior 18, no. 6 (2014): 997-1006, DOI: 10.1007/s10461-014-0724-0.

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Alabama	Ala. Code § 22-8-6 Ala. Code § 22-11A-19	Ala. Code § 22-8-4	Ala. Code § 22-11A-19	Ala. Admin. Code r. 482-1-124-.04 Ala. Admin. Code r. 482-1-079-.18 Ala. Code § 27-21B-10	Ala. Code § 22-11A-21	Ala. Code § 22-11A-38
Alaska	Alaska Stat. § 25.20.025	Alaska Stat. § 25.20.025		Alaska Stat. § 21.36.125 Alaska Stat. § 21.36.495 Alaska Admin. Code tit. 3, § 26.040 Alaska Admin. Code tit. 3, § 26.110 Alaska Stat. § 21.54.050	Alaska Stat. § 12.55.155	Alaska Admin. Code tit. 7, § 27.005
Arizona	Ariz. Rev. Stat. § 44.-132.01	Ariz. Rev. Stat. § 44-132		Ariz. Rev. Stat. § 20-841.05 Ariz. Rev. Stat. § 20-1057.02 Ariz. Admin. Code § 20-6-801		Ariz. Rev. Stat. § 36-664 Ariz. Rev. Stat. § 32-2556 Ariz. Rev. Stat. § 32-1457 Ariz. Admin. Code § 9-6-202 Ariz. Admin. Code § 9-6-341
Arkansas	Ark. Code § 20- 16-508	Ark. Code § 20-9-602	Ark. Code § 20-16-508	Ark. Code § 23-66-206 Ark. Code § 23-86-104	Ark. Code § 5-14-123 Ark. Code § 20-15-903	Ark. Code § 20-15-904
California	Cal. Fam. Code § 6926(a)-(b)	Cal. Fam. Code § 6922		Cal Ins Code § 10123.13 Cal Health & Saf Code § 1371 Cal Health & Saf Code § 1371.35 Cal Ins Code § 790.03 Cal Ins Code § 10133.66 Cal. Code Regs. tit. 10, § 2695.7 Cal. Code Regs. tit. 28, § 1300.71	Cal. Health & Safety Code § 120290 Cal. Health & Safety Code § 120291 Cal. Penal Code § 12022.85 Cal. Health & Safety Code § 1621.5 Cal. Penal Code § 647f	Cal. Health & Safety Code § 121015 Cal. Health & Safety Code § 121022
Colorado	Colo. Rev. Stat. § 25-4-402	Colo. Rev. Stat. § 13-22-103	Colo. Rev. Stat. § 25-4-1405	3 Code Colo. Regs. 702-4 Colo. Rev. Stat. § 10-3-1104 Colo. Rev. Stat. § 10-16-113 Colo. Rev. Stat. § 10-16-106.5	Colo. Rev. Stat. § 18-3-415.5 Colo. Rev. Stat. § 18-7-201.7 Colo. Rev. Stat. § 18-7-205.7	Colo. Rev. Stat. § 25-4-1402 6 Code Colo. Regs. 1009-9

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Connecticut	Conn. Gen. Stat.§ 19a-216			Conn. Gen. Stat. § 38a-816 Conn. Gen. Stat. § 38a-497 Conn. Gen. Stat. § 46b-84 Conn. Gen. Stat. § 19a-216		Conn. Gen. Stat. § 19a-584
District of Columbia	D.C. Mun. Regs. tit. 22, § B600.7			D.C. Code § 1–307.41 D.C. Code § 31–2231.16 D.C. Code § 31–2231.17		D.C. Mun. Regs. tit. 22, §B206.3 D.C. Code § 7–1605
Delaware	Del. Code tit. 13, § 710		Del. Code tit. 13, § 710	Del. Code tit. 18, § 2304 CDR 18-1400-1408 CDR 18-900-902 CDR 18-1300-1310 Del. Code tit. 18, § 3543 Del. Code tit. 16, § 710	Del. Code tit. 16, § 2801	CDR 16-4000-4202 Del. Code tit. 16 § 702
Florida	Fla. Stat. § 384.30	Fla. Stat. § 743.067		Fla. Stat. § 626.9541 Fla. Stat. § 627.613 Fla. Stat. § 641.3155 Fla. Stat. § 641.3903 Fla. Stat. § 627.426 Fla. Stat. § 384.30	Fla. Stat. § 384.24 Fla. Stat. § 775.0877 Fla. Stat. § 381.0041 Fla. Stat. § 796.08	Fla. Stat. § 456.061
Georgia	Ga. Code. § 31-17-7		Ga. Code § 31-17-7	Ga. Code § 33-24-59.5 Ga. Code § 33-24-59.14 Ga. Code § 33-6-34 Ga. Code § 20-2-890 Ga. Code § 20-2-917 Ga. Code § 45-18-11 Ga. Code § 33-30-9	Ga. Code § 16-5-60 Ga. Code § 31-22-9.1	Ga. Code § 24-12-21
Hawaii	Haw. Rev. Stat. § 577A-2	Haw. Rev. Stat. § 577D-2	Haw. Rev. Stat. § 577A-3	Haw. Rev. Stat. § 431:13-103 Haw. Rev. Stat. § 431:13-108 Haw. Rev. Stat. § 576E-17 Haw. Rev. Stat. § 577D-2		Haw. Rev. Stat. § 325-101 Haw. Rev. Stat. § 325-2
Idaho	Idaho Code. § 39-3801	Idaho Code § 39-4503.		Idaho Code § 41-1329 Idaho Code § 41-5602 Idaho Code § 32-1214C	Idaho Code § 39-601 Idaho Code § 39-608	Idaho Code § 39-610 Idaho Admin. Code r. 16.02.10.020 Idaho Admin. Code r. 16.02.10.360

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Illinois	410 Ill. Comp. Stat. § 210/4	410 Ill. Comp. Stat. § 210/1.5	410 Ill. Comp. Stat. 210/5	215 Ill. Comp. Stat. 5/143.31 215 Ill. Comp. Stat. 5/154.6 Ill. Adm. Code tit. 50, pt. 919.50 Ill. Adm. Code tit. 50, pt. 5420.70 215 Ill. Comp. Stat. 5/357.9 215 Ill. Comp. Stat. 5/367a 215 Ill. Comp. Stat. 125/4-2 215 Ill. Comp. Stat.165/15.12 215 Ill. Comp. Stat. 5/356i	720 Ill. Comp. Stat. § 5/12-5.01	410 Ill. Comp. Stat. 305/9
Indiana	Ind. Code § 16-36-1- 3	Ind. Code § 16-36-1-3		Ind. Code § 27-8-5.5-2 Ind. Code § 5-10-8.1-6 Ind. Code § 27-4-1-4.5 Ind. Code § 27-8-5.7-5 Ind. Code § 27-13-36.2-3 Ind. Code § 27-8-5-15 Ind. Code § 27-8-23-6	Ind. Code § 16-41-7-1 Ind. Code § 35-42-2-1 Ind. Code § 16-41-14-17 Ind. Code § 16-41-12-15	Ind. Code § 35-38-1-10.5 Ind. Code § 16-41-2-3 Ind. Code § 16-41-7-3
Iowa	Iowa Code § 139A.35		Iowa Admin. Code r. 641-11.3	Iowa Code § 507B.4 Iowa Admin. Code r. 191-15.32	Iowa Code § 709D.3 Iowa Code § 709D.2	Iowa Code § 141A.5
Kansas	Kan. Stat. § 65-2892	Kan. Stat. § 38-123B	Kan. Stat. § 65-2892	Kan. Stat. § 40-2404 Kan. Stat. § 40-2442 Kan. Stat. § 23-3003	Kan. Stat. § 21-5424	Kan. Stat. § 65-6004
Kentucky	Ky. Rev. Stat. § 214.185		Ky. Rev. Stat. § 214.185	806 Ky. Admin. Regs. 12:092 Ky. Rev. Stat. § 304.12-230 Ky. Rev. Stat. § 304.17A-702 Ky. Rev. Stat. § 304.17A-706 Ky. Rev. Stat. § 304.17A-704 Ky. Rev. Stat. § 304.17A-150	Ky. Rev. Stat. § 311.990(24)(b) Ky. Rev. Stat. § 529.090	Ky. Rev. Stat. § 214.181

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Louisiana	La. Stat. § 40:1121.8(A)	La. Stat. § 40:1079.1	La. Stat. § 40:1121.8	La. Stat. § 22:1873 La. Stat. § 22:1834 La. Stat. § 22:1964 La. Admin. Code tit. 37, § 13.6013 La. Stat. § 22:1832 La. Stat. § 22:1833 La. Admin. Code tit. 37, § 13.6007 La. Admin. Code tit. 37, § 13.6009	La. Stat. § 14:43.5	La. Stat. § 40:1171.4
Maine	Me. Stat. tit. 32, § 2595 Me. Stat. tit. 32, § 3292 Me. Stat. tit. 22, § 1823	Me. Stat. tit. 22, § 1503	Me. Stat. tit. 32, § 2595 Me. Stat. tit. 32, § 3292 Me. Stat. tit. 22, § 1505	Me. Stat. tit. 24-A, § 4303 Me. Stat. tit. 24-A, § 2164-D Me. Stat. tit. 24-A, § 2436 Me. Stat. tit. 24-A, § 7110 Me. Stat. tit. 24-A, § 4317 Me. Stat. tit. 24-A, § 2814 Me. Stat. tit. 24-A, § 2713-A Me. Stat. tit. 24-A, § 2823-A		Me. Stat. tit. 5, § 19203
Maryland	Md. Code, Health-Gen. § 20-102	Md. Code, Health-Gen. § 20-102	Md. Code, Health-Gen. § 20-102	Md. Code, Ins. § 15-1007 Md. Code Regs. 31.10.41.07 Md. Code, Ins. § 14-136 Md. Code, Ins. § 15-1005 Md. Code, Ins. § 15-1006 Md. Code, Ins. § 27-304 Md. Code Regs. 31.10.18.04 Md. Code Regs. 31.15.08.03 Md. Code, Ins. § 27-303 Md. Code, Ins. § 15-405	Md. Code, Health-Gen. § 18-601.1	Md. Code, Health-Gen. § 18-337

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Massachusetts	Mass. Gen. Laws ch. 112, § 12F	Mass. Gen. Laws ch. 112, § 12F		Mass. Gen. Laws ch. 176D, § 3 Mass. Gen. Laws ch. 32A, § 11A Mass. Gen. Laws ch. 32B, § 9H Mass. Gen. Laws ch. 175, § 110I Mass. Gen. Laws ch. 176A, § 8F Mass. Gen. Laws ch. 176B, § 6B Mass. Gen. Laws ch. 176G, § 5A		Mass. Gen. Laws ch. 111 § 70F
Michigan	Mich. Comp. Laws § 333.5127(1)		Mich. Comp. Laws § 333.5127	Mich. Comp. Laws § 550.1405 Mich. Comp. Laws § 550.1402 Mich. Comp. Laws § 550.940 Mich. Comp. Laws § 550.1211a Mich. Comp. Laws § 500.2026 Mich. Comp. Laws § 500.2006 Mich. Comp. Laws § 550.1419a Mich. Comp. Laws § 550.1807	Mich. Comp. Laws § 333.5210 Mich. Comp. Laws § 333.11101	Mich. Comp. Laws § 333.5114a Mich. Comp. Laws § 333.5119 Mich. Comp. Laws § 333.5131
Minnesota	Minn. Stat. § 144.343	Minn. Stat. § 144.341	Minn. Stat. § 144.346	Minn. Stat. § 62J.581 Minn. Stat. § 72A.20 Minn. Stat. § 72A.201	Minn. Stat. § 609.2241	
Mississippi	Miss. Code § 41-41-13			Miss. Code § 73-21-155 Miss. Code § 25-15-17 Miss. Code § 83-9-47	Miss. Code § 97-27-14	
Missouri	Mo. Rev. Stat. § 431.061	Mo. Rev. Stat. § 431.056	Mo. Rev. Stat. § 191.656 Mo. Rev. Stat. § 431.062	Mo. Rev. Stat. § 376.1400	Mo. Rev. Stat. § 191.677 Mo. Rev. Stat. § 567.020	Mo. Rev. Stat. § 191.656 Mo. Code Regs. tit.19, § 20-20.020

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Missouri (cont.)				Mo. Rev. Stat. § 375.1007 Mo. Rev. Stat. § 376.383 Mo. Code Regs. tit.20, § 100-1.050 Mo. Code Regs. tit.20, § 100-5.010 Mo. Code Regs. tit.20, § 400-6.400 Mo. Code Regs. tit.20, § 100-1.030 Mo. Rev. Stat. § 454.624 Mo. Rev. Stat. § 454.700		
Montana	Mont. Code § 41- 1-402	Mont. Code § 41-1-402	Mont. Code § 41-1-403	Mont. Code § 33-18-201 Mont. Code § 33-18-232	Mont. Code § 50-18-112 Mont. Code § 50-18-101	Mont. Code § 50-16-1009 Mont. Admin. R. 37.114.201 Mont. Admin. R. 37.114.503
Nebraska	Neb. Rev. Stat. § 71-504			210 Neb. Admin. Code, ch. 61 Neb. Rev. Stat. § 44-1540 Neb. Rev. Stat. § 44-8004		173 Neb. Admin. Code, ch. 1, § 007.02 173 Neb. Admin. Code, ch. 1, § 006 173 Neb. Admin. Code, ch. 1, § 003 173 Neb. Admin. Code, ch. 1, § 004.06 Neb. Rev. Stat. § 71-503
Nevada	Nev. Rev. Stat. § 441A.310 Nev. Rev. Stat. § 129.060	Nev. Rev. Stat. § 129.030		Nev. Rev. Stat. § 683A.0879 Nev. Rev. Stat. § 686A.310 Nev. Rev. Stat. § 689A.410 Nev. Rev. Stat. § 689B.0295 Nev. Rev. Stat. § 689B.255 Nev. Rev. Stat. § 695G.230 Nev. Rev. Stat. § 689A.450 Nev. Rev. Stat. § 689A.755	Nev. Rev. Stat. § 441A.180 Nev. Rev. Stat. § 201.205 Nev. Rev. Stat. § 201.358	Nev. Admin. Code § 441A.230 Nev. Admin. Code § 441A.450

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Nevada (cont.)				Nev. Rev. Stat. § 689B.100 Nev. Rev. Stat. § 689B.320 Nev. Rev. Stat. § 695A.155 Nev. Rev. Stat. § 695B.2505 Nev. Rev. Stat. § 695B.360 Nev. Rev. Stat. § 695C.167 Nev. Rev. Stat. § 695C.185 Nev. Rev. Stat. § 695D.215		
New Hampshire	N.H. Rev. Stat. Ann. § 141-C:18			N.H. Rev. Stat. Ann. § 420-B:8-n N.H. Rev. Stat. Ann. § 420-H:4 N.H. Rev. Stat. Ann. § 415-A:4-a N.H. Rev. Stat. Ann. § 415:10 N.H. Rev. Stat. Ann. § 417:4 N.H. Rev. Stat. Ann. § 161-H:2		N.H. Rev. Stat. Ann. § 141-F:7 N.H. Rev. Stat. Ann. § 141-F:9
New Jersey	N.J. Stat. § 9:17A-4		N.J. Stat. § 9:17A-5	N.J. Stat. § 17:29B-4 N.J. Stat. § 17:48-8.4 N.J. Stat. § 17:48A-7.10 N.J. Stat. § 17:48A-7.12 N.J. Stat. § 17:48E-10.1 N.J. Stat. § 17:48E-32.1 N.J. Stat. § 17:48H-33.1 N.J. Stat. § 17B:26-9.1 N.J. Stat. § 17B:27-30.1 N.J. Stat. § 17B:27-30.3 N.J. Stat. § 17B:27-44.2	N.J. Stat. Ann. § 2C: 34-5	N.J. Stat. Ann. § 26:5C-6

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
New Jersey (cont.)				N.J. Stat. § 17B:27-75 N.J. Stat. § 17B:27A-18.1 N.J. Stat. § 17B:27A-4.1 N.J. Stat. § 17B:30-13.1 N.J. Stat. § 26:2J-10.1 N.J. Stat. § 26:2J-8.1		
New Mexico	N.M. Stat. § 24-1-9	N.M. Stat. § 24-7A-6.2		N.M. Stat. § 59A-16-20 N.M. Stat. § 59A-22-34.2 N.M. Stat. § 59A-23-7.2 N.M. Stat. § 59A-46-38.1 N.M. Stat. § 59A-47-37		N.M. Stat. § 24-2B-6
New York	N.Y. Pub. Health Law § 2305(2)			N.Y. Ins. Law § 3234 N.Y. Ins. Law § 2601 N.Y. Comp. Codes R. tit. 11, § 216.4 N.Y. Comp. Codes R. tit. 11, § 216.5 N.Y. Comp. Codes R. tit. 11, § 216.6 N.Y. Ins. Law § 2608-a	N.Y. Pub. Health Law § 2307	N.Y. Pub. Health Law § 2130
North Carolina	N.C. Gen. Stat. § 90- 21.5			N.C. Gen. Stat. § 58-3-172 N.C. Gen. Stat. § 58-3-225 N.C. Gen. Stat. § 58-63-15 N.C. Gen. Stat. § 58-51-120	10A N.C. Admin. Code 41A.0202	10A N.C. Admin. Code 41A .0202 N.C. Gen. Stat. § 130A-143.
North Dakota	N.D. Cent. Code § 14-10-17			N.D. Cent. Code § 26.1-04-03 N.D. Cent. Code § 26.1-36.5-04	N.D. Cent. Code § 12.1-20-17	N.D. Cent. Code § 23-01.3-02 N.D. Cent. Code § 23-01.3-04 N.D. Admin. Code 33-06-04-10
Ohio	Ohio Rev. Code § 3709.241			Ohio Rev. Code § 3901.381 Ohio Admin. Code § 3901-1-07 Ohio Admin. Code § 3901-8-11 Ohio Rev. Code § 3924.47	Ohio Rev. Code § 2903.11 Ohio Rev. Code § 2927.13 Ohio Rev. Code § 2907.24 Ohio Rev. Code § 2907.25 Ohio Rev. Code § 2907.241	Ohio Rev. Code § 3701.243

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Oklahoma	Okla. Stat. tit. 63, § 2601 Okla. Stat. tit. 63, § 2602	Okla. Stat. tit. 63, § 2602	Okla. Stat. tit. 63, § 2602	Okla. St. tit. 36, § 6055 Okla. St. tit. 36, § 1219 Okla. St. tit. 74, § 1328 Okla. St. tit. 36, § 6058A Okla. St. tit. 43, § 118.2	Okla. Stat. tit. 21, § 1192.1 Okla. Stat. tit. 21, § 1031	
Oregon	Or. Rev. Stat. § 109.610	Or. Rev. Stat. § 109.640		Or. Rev. Stat. § 746.230 Or. Rev. Stat. § 743B.450 Or. Rev. Stat. § 743.543 Or. Rev. Stat. § 743B.470		Or. Admin. R. 333-022-0210
Pennsylvania	35 Pa. Cons. Stat. § 10103			40 Pa. Cons. Stat. § 1171.5 31 Pa. Code § 146.7 31 Pa. Code § 146.5	18 Pa. Cons. Stat. § 5902	35 Pa. Cons. Stat. § 7609
Rhode Island	R.I. Gen. Laws § 23-11-11 R.I. Gen. Laws § 23-6.3-3			R.I. Gen. Laws § 27-9.1-4 R.I. Gen. Laws § 27-18-61 R.I. Gen. Laws § 27-19-52 R.I. Gen. Laws § 27-20-47 R.I. Gen. Laws § 27-41-64 02 030 R.I. Code R. 013 R.I. Gen. Laws § 15-29-10	R.I. Gen. Laws § 23-11-1	R.I. Gen. Laws § 23-6.3-10
South Carolina		S.C. Code § 63-5-350		S.C. Code § 38-59-20 S.C. Code § 38-59-230 S.C. Code § 38-71-260	S.C. Code § 44-29-60 S.C. Code § 44-29-145	S.C. Code § 44-29-90 S.C. Code § 44-29-146 S.C. Code § 44-29-250 S.C. Code § 44-29-70
South Dakota	S.D. Codified Laws § 34-23-16			S.D. Codified Laws § 58-33-67 S.D. Codified Laws § 58-12-20 S.D. Codified Laws § 58-33-88	S.D. Codified Laws § 22-18-31 S.D. Codified Laws § 22-24B-1	S.D. Admin. R. 44:20:02:08 S.D. Admin. R. 44:20:01:01 S.D. Admin. R. 44:20:02:01
Tennessee	Tenn. Code § 68-10-104			Tenn. Code § 56-8-105 Tenn. Code § 56-32-126 Tenn. Code § 56-7-109 Tenn. Code § 56-7-2302	Tenn. Code § 68-10-107 Tenn. Code § 39-13-109 Tenn. Code § 39-13-516	Tenn. Code § 68-10-115

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Texas	Tex. Fam. Code § 32.003	Tex. Fam. Code § 32.003		28 Tex. Admin. Code § 21.2009 28 Tex. Admin. Code § 21.203 28 Tex. Admin. Code § 21.2804 28 Tex. Admin. Code § 21.2805 28 Tex. Admin. Code § 21.2807 28 Tex. Admin. Code § 21.2808 28 Tex. Admin. Code § 21.5020 Tex. Ins. Code § 1204.251 Tex. Ins. Code § 1251.005 Tex. Ins. Code § 1251.114 Tex. Ins. Code § 1301.103 Tex. Ins. Code § 1301.1054 Tex. Ins. Code § 1456.003 Tex. Ins. Code § 1504.055 Tex. Ins. Code § 541.060 Tex. Ins. Code § 542.003 Tex. Ins. Code § 542.055 Tex. Ins. Code § 843.338 Tex. Ins. Code § 843.3385		Tex. Health & Safety Code § 81.051 Tex. Health & Safety Code § 81.103
Utah	Utah Code § 26-6-18(1)-(3)			Utah Code § 31A-26-301.6 Utah Code § 31A-26-303 Utah Code § 31A-26-301.5 Utah Code § 31A-22-610.5	Utah Code § 76-10-1309	Utah Code § 26-6-3.5 Utah Admin. Code r. 388-803-4
Vermont	Vt. Stat. tit. 18, § 4226		Vt. Stat. tit. 18, § 1099	CVR 21-040-023 Vt. Stat. tit. 8, § 4724 Vt. Stat. tit. 18, § 9418 Vt. Stat. tit. 8 § 4082 Vt. Stat. tit. 8 § 4100b		Vt. Stat. tit. 18, § 1001

State	Minor Consent		Confidentiality		Criminalization of HIV	
	Laws related to HIV/STDs	Laws related to general medical care	Laws related to HIV/STDs	Insurance regulations	Laws related to exposure/transmission	Notification/reporting requirements
Virginia	Va. Code § 54.1-2969			Va. Code § 2.2-2818 Va. Code § 38.2-514 Va. Code § 38.2-3407.4 Va. Code § 38.2-3407.13:2 Va. Code § 38.2-510 14 Va. Admin. Code § 5-400-70 14 Va. Admin. Code § 5-400-50 14 Va. Admin. Code § 5-400-60 Va. Code § 38.2-3407.2	Va. Code § 18.2-67.4:1 Va. Code § 32.1-289.2	Va. Code § 32.1-36 Va. Code § 32.1-36.1
Washington	Wash. Rev. Code § 70.24.110			Wash. Admin. Code § 284-30-330 Wash. Admin. Code § 284-30-380 Wash. Admin. Code § 284-30-360 Wash. Rev. Code § 48.44.026 Wash. Rev. Code § 48.01.235 Wash. Admin. Code § 284-04-510	Wash. Rev. Code § 9A.36.011	Wash. Admin. Code § 246-100-072 Wash. Admin. Code § 246-100-209
West Virginia	W. Va. Code §16-4-10			W. Va. Code § 33-11-4 W. Va. Code R. § 114-14-6 W. Va. Code R. § 114-14-5 W. Va. Code § 33-45-2 W. Va. Code § 33-15-16 W. Va. Code § 33-16-11 W. Va. Code § 48-12-113	W. Va. Code § 16-4-20 W. Va. Code § 16-4-1	W. Va. Code, § 16-3C-3
Wisconsin	Wis. Stat. § 252.11			Wis. Stat. § 632.725 Wis. Stat. § 632.857 Wis. Adm. Code Ins. § 6.11	Wis. Stat. § 973.017	Wis. Stat. § 252.15
Wyoming	Wyo. Stat. § 35-4-131	Wyo. Stat. § 14-1-101		Wyo. Stat. § 26-13-124 Wyo. Stat. § 26-40-201 Wyo. Stat. § 26-15-135		Wyo. Stat. § 35-4-133

Additional Resources by Topic

Contents

PrEP basics

1. **PrEP Kit: A Resource Guide about Pre-Exposure Prophylaxis** (Aids United, May 2014)
2. **Pre-exposure Prophylaxis for the Prevention of HIV in the United States: Clinical Providers' Supplement** (Centers for Disease Control and Prevention, May 2014)
3. **PrEP Information Sheet: PrEP During Conception, Pregnancy, and Breastfeeding** (Centers for Disease Control and Prevention)
4. **Truvada** (Gilead Sciences)
5. **Truvada Prescribing Information** (Gilead Sciences)
6. **PrEP Provider Directory by State** (Greater Than AIDS)
7. **Clinician Consultation Center** (University of California, San Francisco)
8. **PrEP for Women** (The Well Project, March 2016)

PEP basics

1. **PEP** (Centers for Disease Control and Prevention, Updated April 2016)
2. **Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV** (Centers for Disease Control and Prevention, 2016)

Serving adolescents

1. **Bright Futures Reference Table-Adolescent Visits** (American Academy of Pediatrics)
2. **Bright Futures Screening Guidelines** (American Academy of Pediatrics)
3. **Adolescent-Friendly Health Services** (Physicians for Reproductive Health)

PrEP adherence

1. **High Impact HIV Prevention** (Centers for Disease Control and Prevention, Updated November 2016)

Sexually transmitted diseases

1. A Clinician's Resource for Sexually Transmitted Diseases (STDs) in Gay Men and Other Men Who Have Sex with Men (MSM)—The MSM Toolkit (California Department of Public Health and the California STD/HIV Prevention Training Center, Revised July 2015)
2. 2015 Sexually Transmitted Diseases Treatment Guidelines [Summary Wall Chart] (Centers for Disease Control and Prevention)
3. 2015 Sexually Transmitted Diseases Screening Recommendations (Centers for Disease Control and Prevention)
4. Reported STDs in the United States, 2014 National Data for Chlamydia, Gonorrhea, and Syphilis (Centers for Disease Control and Prevention, November 2015)
5. Sexually Transmitted Diseases, Adolescents and Young Adults (Centers for Disease Control and Prevention, Updated December 2015)
6. Sexually Transmitted Diseases: Tools and Materials (Centers for Disease Control and Prevention, Updated October 1, 2015)
7. STD Prevention Infographics (Centers for Disease Control and Prevention, Reviewed March 28, 2013)
8. National Network of STD Clinical Prevention Training Centers

For patients

1. My PrEP Experience (AIDS Foundation of Chicago)
2. #LetsTalkAboutPrEP (Black Women's Health Imperative)
3. Know Your Rights: Pre-Exposure Prophylaxis (Lambda Legal)
4. Do Ask, Do Tell: Talking to Your Provider about Being LGBT (National LGBT Health Education Center, Fenway Institute)
5. From Health Care Provider to Teen: What You Need to Know about Sex and Sexuality [Power Point] (Physicians for Reproductive Health)
6. Sexual Health for Transwomen (University of California San Francisco Center of Excellence in Transgender Health)
7. Salud sexual para mujeres transgenero (University of California San Francisco Center of Excellence in Transgender Health)

HIV and social determinants of health

1. Young African American Women and HIV (Advocates for Youth)
2. Youth of Color-At Disproportionate Risk of Negative Sexual Health Outcomes (Advocates for Youth, August 2010)
3. Young People and HIV in the United States (Advocates for Youth, July 2012)
4. Young Women of Color and Their Risk for HIV and Other STIs (Advocates for Youth)
5. Trans Populations and HIV: Time to End the Neglect (amfAR, March 2014)
6. YMSM + LGBT (ATTC Center of Excellence)
7. HIV and AIDS in the United States of America (Avert, Last reviewed May 2015)
8. Social Determinants of Health and HIV (National Network of STD Clinical Prevention Training Centers)
9. Communities in Crisis: Is there a generalized HIV Epidemic in Impoverished Urban Areas of the United States? (Centers for Disease Control and Prevention, Last updated June 2015)

10. **Intersection of Intimate Partner Violence and HIV in Women** (Centers for Disease Control and Prevention, February 2014)
11. **The Health of Lesbian, Gay, Bisexual and Transgender People: Building a Foundation for Better Understanding** (Institute of Medicine, March 2011)
12. **Improving the Health of Lesbian, Gay, Bisexual and Transgender People: Understanding and Eliminating Health Disparities** (Lard and Makadon, 2012)
13. **Transgender Women and PrEP: What We Know and What We Still Need to Know** (Marquez and Cahill, December 2015)
14. **Injustice at Every Turn: A Report of the National Transgender National Transgender Discrimination Survey, Executive Summary** (National Center for Transgender Equality and National Gay and Lesbian Task Force, 2011)
15. **Transgender Issues in HIV** (Sevelius, December 2013)

Creating a welcoming practice

1. **Posters** (Advocates for Youth)
2. **Reaching Teens: Strength-Based Communication Strategies to Build Resilience and Support Healthy Adolescent Development** (*Chapter 61: Sexual and Gender Minority Youth*) (American Academy of Pediatrics, 2014)
3. **Guidelines, Creating a Safe Clinical Environment for Lesbian, Gay, Bisexual, Transgender, and Intersex (LGBTI) Patients** (Gay and Lesbian Medical Association, 2003)
4. **Update Your Provider Directory Listing** (Gay and Lesbian Medical Association)
5. **Connect: Community Leaders in Transgender Health** (University of California San Francisco Center of Excellence in Transgender Health)

Building cultural competence

1. **Frequently Asked Questions About Sexual Orientation and Gender Identity** (Advocates for Youth)
2. **Tips and Strategies for Creating a Safe Space for LGBT Youth** (Advocates for Youth)
3. **Tips and Strategies for Meeting the Needs of GLBTQ Youth of Color** (Advocates for Youth)
4. **Tips and Strategies for Meeting the Needs of Transgender Youth** (Advocates for Youth)
5. **Tips and Strategies for Taking Steps to Cultural Fairness** (Advocates for Youth)
6. **Primary Care Protocol for Transgender Patient Care** (Center of Excellence for Transgender Health, April 2011)
7. **Working with GLBTQ Youth** (Gilliam, June 2002)
8. **A Youth Leader's Guide to Building Cultural Competence** (Messina, 1994)
   - Chapter 1: **Cultural Components**
   - Chapter 4: **Cultural Background for HIV/AIDS Prevention**
9. **BESAFE: A Cultural Competence Model for African Americans** (National Minority AIDS Education and Training Center, Updated 2005)
10. **Cultural Competency and Adolescent Health** (Physicians for Reproductive Health)
11. **Lesbian, Gay, Bisexual, Transgender, and Questioning Youth** (Physicians for Reproductive Health)

Culturally competent care: online courses, webinars and videos

1. **Supporting LGBTQ Youth: Providing Affirmative and Inclusive Care across the Spectrum of Gender and Sexual Identity** (Dowshen and Garofalo, November 2015)
2. **Learning Modules** (National LGBT Health Education Center, Fenway Institute)
3. **Online Publications and Training Materials** (National LGBT Health Education Center, Fenway Institute)
4. **Optimizing Transgender Health: A Core Course for Health Care Providers** (National LGBT Health Education Center, Fenway Institute)
5. **Webinars and Video Training** (National LGBT Health Education Center, Fenway Institute)
6. **A Physician's Practical Guide to Culturally Competent Health Care** (Office of Minority Health, US Department of Health and Human Services)
7. **Standardized Case Videos: Adolescent Sexual and Reproductive Health** (Physicians for Reproductive Health)