

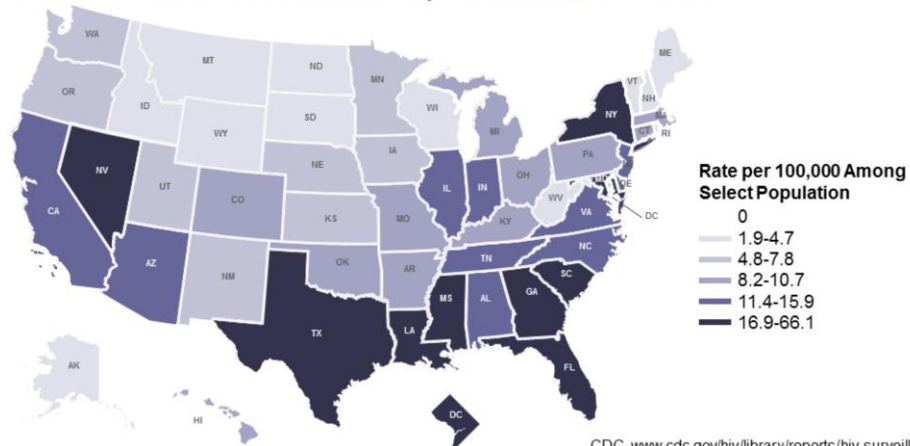


PrEP Basics:  
**A Patient-Centered Approach to Providing PrEP**

Developed by Med-IQ in collaboration with Project Inform



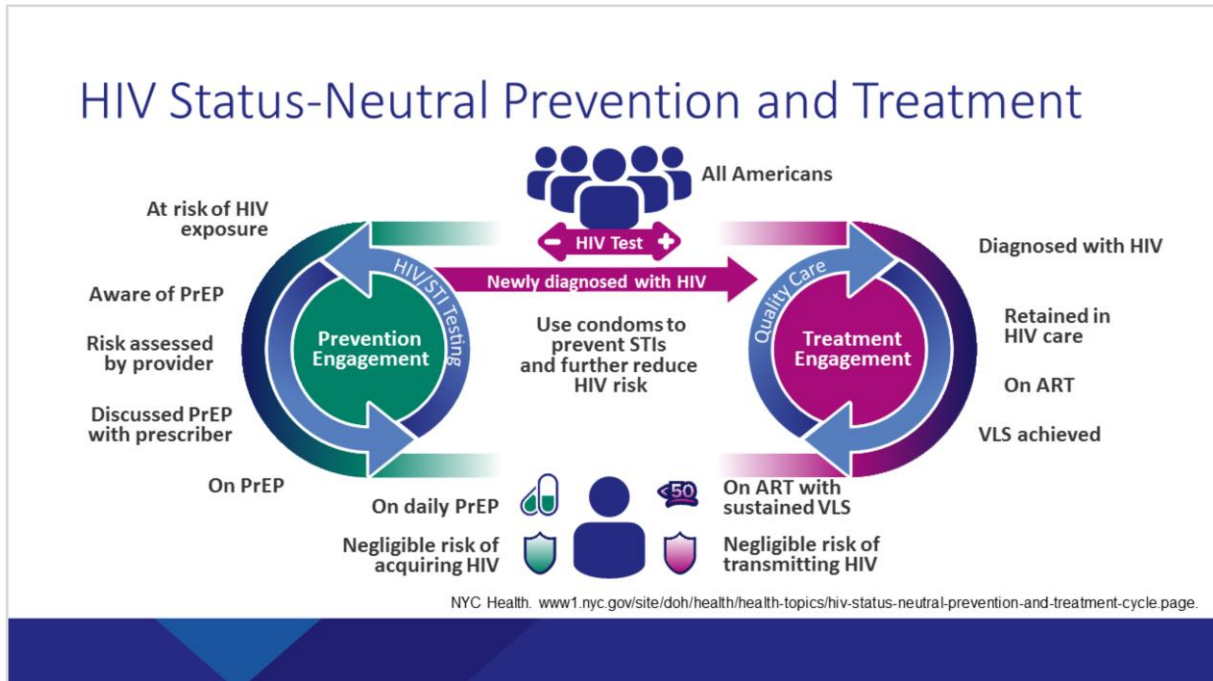
## Rates of New HIV Diagnoses Among Adults and Adolescents by State, 2015



- Incidence data help inform the need for local and state HIV services. However, individuals may be more vulnerable to HIV beyond what incidence data indicate.
- For example, those who travel, either for business or personal leisure, may engage in activities outside their areas of residence that increase their vulnerability, which may not be reflected in their residence incidence map.
- Social determinants of health can also affect a person's vulnerability to HIV and his/her ability to address that risk. These include socioeconomic status, education, physical environment, employment, food, social support, and access to healthcare.
- For example, modeling studies suggest that, without a greater investment in more equitable HIV prevention strategies, black men who have sex with men (MSM) have a 1 in 2 lifetime risk of HIV compared with their Latino (1 in 4) and white (1 in 11) counterparts. However, studies show that black (and perhaps Latino) MSM engage in fewer at-risk behaviors than white MSM, but these structural and social factors unequally influence their vulnerability to HIV.

### REFERENCE

CDC. [www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html](http://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html). Accessed November 9, 2017.



Successful HIV prevention for the full community (combination prevention) means offering multiple tools that can be used interchangeably as needed and appropriate for those at risk of and living with HIV. From this viewpoint, everyone is empowered to protect themselves and their partners.

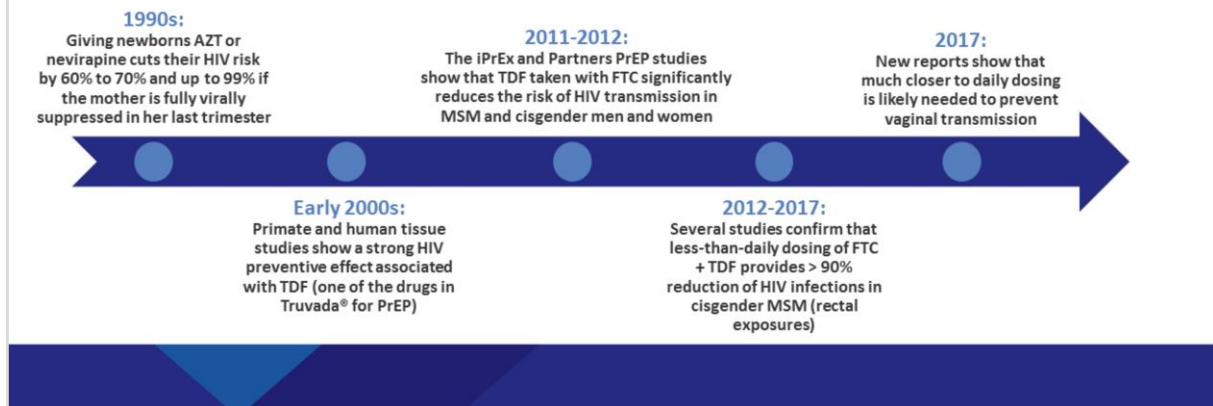
- It's important to discuss the prevention options that a person prefers, has access to, and is able to use consistently.
- It's common for individuals to move from one or more HIV prevention methods to others over time as their sex and/or drug use behaviors change.
- Combining 2 or more methods helps further reduce vulnerability to HIV.
- Many other prevention strategies are possible, such as knowing one's own or a partner's HIV status, using post-exposure prophylaxis (PEP, see below), reducing the number of sex partners, limiting sex while using substances that can impair safer sex decision making, etc. However, some strategies may offer greater protection than others. (For example, although some people "sero-sort," or have sex only with people who they believe have the same HIV status as they do, studies do not show that this method reliably reduces HIV infections.)
- PEP is a prevention method that starts HIV medications within 72 hours *after* a possible exposure to HIV through sex or syringes. Some people who seek PrEP may actually need PEP first—and right away. PrEP services have begun to move some people from PEP to PrEP over time.

## REFERENCES

1. New York City HIV Status Neutral Prevention and Treatment Cycle. [www.tinyurl.com/HIVneutralNYC](http://www.tinyurl.com/HIVneutralNYC). Accessed November 9, 2017.
2. US Non-Occupational PEP Guidelines. <https://stacks.cdc.gov/view/cdc/38856>. Accessed November 9, 2017.

## Why PrEP?

- Over the course of the HIV epidemic, data have continued to emerge that show how well HIV medications reduce the risk of transmission



- Kaiser Permanente of Northern California and other clinical cohorts that are following PrEP users find high levels of adherence and no HIV transmissions among those who regularly take PrEP.
- Data show very fast uptake among white MSM, but much lower rates among MSM of color, youth, and cisgender women.
- Data on PrEP uptake among transgender women and men are not available.
- The CDC estimates that 1.2 M Americans could benefit from PrEP, though only ~136,000 prescriptions have been written since July 2012.
- Data from 5 London clinics show a dramatic drop in new HIV infections in the past 2 years, which appears to be attributable to combination prevention efforts, including the uptake of PrEP.

## REFERENCES

1. Grant RM, et al. *N Engl J Med*. 2010;363:2587-99.
2. Baeten JM, et al. *N Engl J Med*. 2012;367:399-410.
3. Marcus JL, et al. *J Acquir Immune Defic Syndr*. 2016;73:540-6.
4. Ryan B. [www.poz.com/article/estimated-136000-people-prep-us](http://www.poz.com/article/estimated-136000-people-prep-us). Accessed November 9, 2017.

## What Is PrEP?

- Truvada was approved by the FDA for PrEP in July 2012
- Truvada is made up of 2 anti-HIV drugs: emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF)
- PrEP is highly effective at preventing HIV infection in clinical efficacy and implementation studies, which has helped provide information on best practices
- PrEP mirrors other successful prevention interventions, such as birth control and anti-malarial medications

- Truvada was approved by the FDA in 2004 for the treatment of HIV infection. Using it may cause some people anxiety, given the stigma that HIV carries in the US, and may cause personal hardships should others disapprove of friends/loved ones using PrEP or assuming they're HIV-positive.
- Truvada can also be prescribed to treat chronic HBV infection. A blood test to identify chronic HBV is recommended before starting PrEP. If chronic HBV is not present, the HBV vaccine is recommended if the person is not already immune to the virus. If chronic HBV disease is present while on PrEP, care must be taken when stopping PrEP, as flares of HBV can occur.

### REFERENCE

US Public Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Being Mindful of a Sex-Positive Medical Environment: Basic Principles

- The spectrum of sexual identity, expression, and activity is substantial and may differ greatly from your own experiences
- Everyone is entitled to receive medical care that affirms and supports their sexual health needs, sex, and gender
- “Cisgender” means that a person’s current gender is the same as the sex that was assigned to them at birth, whereas “transgender” means the current gender is different from what was assigned at birth

- Culturally affirming care starts the moment that a person seeking healthcare or social services walks in the door. Training for all staff and volunteers on these issues is critical.
- Implement the 2-step question affirming sex and gender of all patients: What is your current gender identity, and what sex were you assigned at birth?
- Review the COE for Transgender Health’s “Acknowledging Gender and Sex” module ([http://transhealth.ucsf.edu/video/story\\_html5.html?lms=1](http://transhealth.ucsf.edu/video/story_html5.html?lms=1)) to learn more about incorporating trans-affirming healthcare practices in your medical office.

### REFERENCE

Center of Excellence for Transgender Health. <http://transhealth.ucsf.edu/>. Accessed November 9, 2017.

## Fostering a Sex-Positive Medical Environment

- Consider how your opinions about the choices that others make could affect your interactions with them
- Create a safe space throughout the office by establishing sexual healthcare protocols that all staff use equally with each patient
- Avoid judgmental terms and language including nonverbal behavior that could be interpreted as judgmental or nonaffirming
- Admit and ask for clarification when you don't understand something, apologize when you make a mistake, and reassure that you'll do better in the future
- Use individuals' vernacular when discussing their sexual health

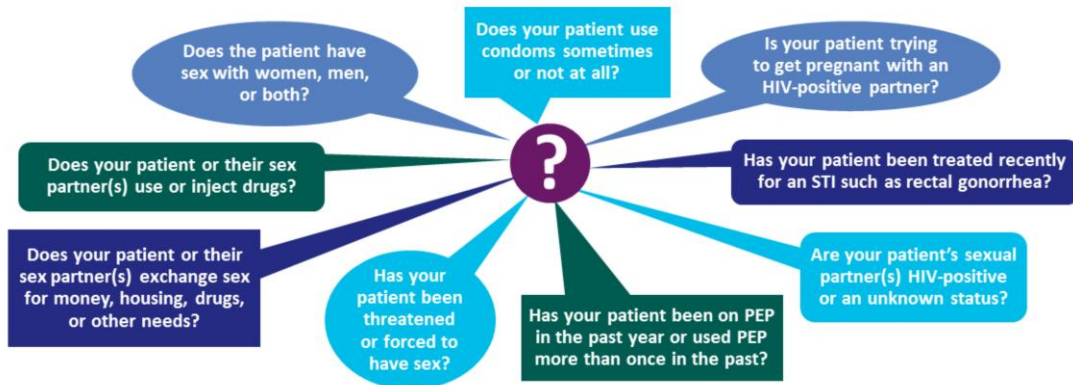
- Having all staff wear name badges or adhesive stickers stating their preferred pronouns signals that staff and volunteers respect their transgender, non-binary, and gender-queer clients.
- Paperwork and electronic medical records that include a client's preferred name and pronoun preferences, which may be different than their birth or legal name, should be included. Calling out a male name in front of others for someone who physically presents as a woman can create an unsafe environment for that patient.

### REFERENCE

Center of Excellence for Transgender Health. <http://transhealth.ucsf.edu/>. Accessed November 9, 2017.

## Screening Patients for Vulnerability to HIV

**Key Point:** Let your patient know that you ask the same sexual health questions of everyone



- The USPHS guidelines offer brief screening tools (pages 26 to 29, [www.tinyurl.com/PrEPCDCGuidelines](http://www.tinyurl.com/PrEPCDCGuidelines)).
- People may initiate a PrEP discussion during their medical visits. However, anecdotally, many don't approach their PCPs about PrEP or sexual health issues out of fear of judgment around their sexual activity, orientation, or gender identity.
- Establishing routine and affirming sexual health screening that's initiated by the medical team can help you identify those who could benefit from the use of PrEP.

### REFERENCE

US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.



## Candidates for PrEP: USPHS Guidelines

- Sexually active MSM, including African American and Latino men
- Sexually active heterosexual men and women at significant risk
- People who inject/use drugs
- HIV-negative partners in mixed-status couples, including heterosexual couples seeking natural conception

- The number of transgender women in PrEP studies has been small, and very limited data exist on transgender men and PrEP. However, experts believe that at-risk transgender individuals are good candidates for PrEP.
- People who inject or use drugs or who share injection equipment (for drugs or hormones) often have other risk factors such as sexual risk.
- Patients who may not obviously fit within these groups may still be candidates for PrEP. If a person requests PrEP, they may be at risk but do not feel comfortable disclosing risk behaviors.

### REFERENCE

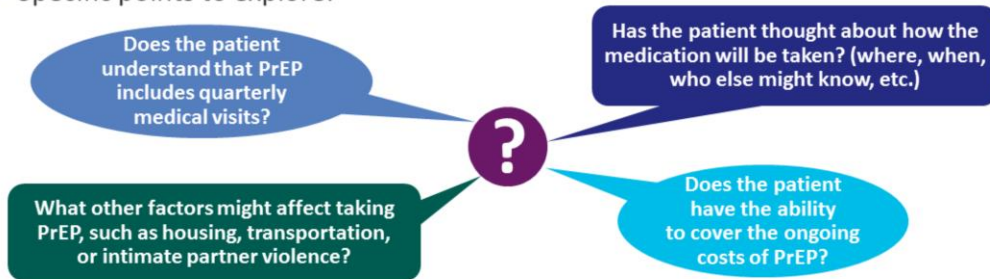
US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Additional Factors That Contribute to Vulnerability to HIV

- Stigma
- Less-stable access to routine healthcare
- High HIV incidence areas of the city or state
- Poverty level
- Unstable housing or lack of housing
- Criminalization issues
- Intimate partner violence

## Assessing Patient Readiness for PrEP

- Assess the person's understanding of PrEP and provide additional education as needed
- Consider whether your patient is regularly engaged in care or new to it
- Specific points to explore:



## Protection Against Rectal HIV Transmission

- USPHS guidelines recommend 7 daily lead-in doses to achieve protective levels in rectal tissue
- In clinical studies of MSM, no infections occurred in people with drug blood levels equal to 4 or more doses per week
- Some infections occurred in people who took fewer than 4 doses, and higher infection rates were seen in those who took 2 or fewer doses per week
- More-recent data from the Ipergay study show that sex-based dosing (2 doses taken 24 hours before sex, and 1 dose taken 24 hours and 48 hours after sex) greatly reduces HIV transmission, even when sex is infrequent\*
- Occasional missed doses are more “forgiving” for rectal exposures

\*Non-daily dosing is not approved by the FDA

- Don’t assume you know the sexual activity of your patients. Not all MSM engage in anal sex, and many heterosexual men and women do.
- Some people call anal sex by different names, such as “bottoming,” “topping,” “back-end sex,” “booty call,” or other phrases.
- Rarely, HIV infections have been reported in MSM with rectal exposures despite very high levels of adherence. In one case, the person was exposed to a multi-drug resistant virus. In another, the person reported multiple sex and drug-using partners (not injection use), and explanations for the infection are incomplete.
- No data are available to guide daily lead-in doses needed to reach maximum protective levels in penile tissue.

### REFERENCES

1. US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.
2. Aidsmap.com. [www.tinyurl.com/IpergayInfrequent](http://www.tinyurl.com/IpergayInfrequent). Accessed November 9, 2017.
3. Guillemette A. <http://programme.ias2017.org/Abstract/Abstract/3629>. Accessed November 9, 2017.
4. Newman E. [www.tinyurl.com/PrEPtransmission1b](http://www.tinyurl.com/PrEPtransmission1b). Accessed November 9, 2017.
5. Aidsmap.com. [www.tinyurl.com/PrEPtransmission2](http://www.tinyurl.com/PrEPtransmission2). Accessed November 9, 2017.

## Protection Against Vaginal/Frontal HIV Transmission

- USPHS guidelines recommend 20 daily lead-in doses to achieve protective levels in vaginal/cervical tissue
- In clinical studies, no infections occurred in cisgender women with drug blood levels equal to taking 6 or 7 doses per week
- Some infections occurred in those who took 4 or 5 doses per week
- No completed clinical studies have so far included transgender men
- Occasional missed doses are less forgiving for vaginal/frontal exposures

- Many transgender men do not refer to their front genitals as vaginas and may prefer to use “front,” “front sex,” “frontal sex,” or other phrases to describe their sexual activity.
- Feminizing, masculinizing, and other hormones do not appear to interact with Truvada for PrEP, but studies are now exploring this.

### REFERENCES

1. US Preventive Health Service. [tinyurl.com/PrEPCDCguidelines](http://tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.
2. Grant R. <http://programme.ias2017.org/Programme/Session/9>. Accessed November 20, 2017.

## Protection Against Parenteral HIV Transmission

- USPHS guidelines recommend 20 daily lead-in doses to achieve protective levels in blood tissue
- In the Bangkok TDF study, taking daily TDF resulted in a 49% reduction in HIV infections
- Those with more persistent daily adherence (primarily among those with directly observed therapy) had a 74% reduction
- Encouraging patients to not share syringes or directing them to clean syringe programs can further reduce risk

- People who share injection equipment, take hormones, or have diabetes may have other risk exposures to HIV, such as sexual risk.

### REFERENCES

1. US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.
2. Choopanya K, et al. *Lancet*. 2013;381:2083-90.

## When to Start PrEP

| Laboratory Tests  | Patient Readiness  | Patient Understanding  | Financial Considerations   |
|---|--|--|--|
| <ul style="list-style-type: none"><li>• Confirmed negative HIV status</li><li>• eCrCl <math>\geq</math> 60 mL/min (marker of kidney health)</li></ul> | <ul style="list-style-type: none"><li>• Engaged in stable healthcare</li><li>• Aware he/she is currently at risk of HIV (ie, this is a “season of risk”)</li></ul> | <ul style="list-style-type: none"><li>• PrEP is highly protective, but not 100% preventive</li><li>• Adherence to daily doses and quarterly medical visits is critical</li></ul> | <ul style="list-style-type: none"><li>• Able to cover the costs of ongoing PrEP care</li></ul> |

- People may start PrEP for a time to test whether it’s right for them.
- Since FDA approval, 3 HIV infections have occurred in individuals who were highly adherent to PrEP. Continued testing is necessary.
- People may need support to engage with stable healthcare over time and cover the financial aspects of PrEP care. It is critical to connect clients to resources for insurance and financial support.

### REFERENCES

1. Aidsmap.com. [www.tinyurl.com/PrEPtransmission2](http://www.tinyurl.com/PrEPtransmission2). Accessed November 9, 2017.
2. Aidsmap.com. [www.tinyurl.com/PrEPtransmission3](http://www.tinyurl.com/PrEPtransmission3). Accessed November 9, 2017.
3. CDC. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Ensure Negative Status Before Starting PrEP

- The USPHS recommends that adults who are vulnerable to HIV get an HIV test at least annually
  - A combination antibody-antigen test is recommended to confirm HIV-negative status
  - Oral rapid tests should not be used
- Clinical studies have shown that a few people were incorrectly identified as HIV-negative before starting PrEP
- Possible HIV exposures within 2 weeks of starting PrEP may indicate the need for additional HIV screening
- Screen for possible symptoms of acute HIV infection and retest when indicated

- Same-day PrEP is being implemented in some parts of the US in people who have the highest risk of HIV. A negative rapid test result will allow individuals to start on PrEP the same day. A follow-up antibody/antigen test should be done 14 days after starting PrEP to further rule out HIV.

### REFERENCES

1. US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.
2. Philadelphia FIGHT Same-Day PrEP Protocol. [www.tinyurl.com/SIECUSSameDayPrEP](http://www.tinyurl.com/SIECUSSameDayPrEP). Accessed November 9, 2017.



## Starting and Monitoring PrEP Care

|   | Baseline | 1 month after starting PrEP | 3 months after starting PrEP | Quarterly thereafter |
|---|----------|-----------------------------|------------------------------|----------------------|
| HIV antibody test                         | X        | X                           | X                            | X                    |
| Assessment for acute HIV infection        | X        | X                           | X                            | X                    |
| STI screening, treatment <sup>a</sup>     | X        | X                           | X                            | X                    |
| eCrCl                                     | X        | X                           | X                            | X <sup>b</sup>       |
| Urinalysis                                | X        | X                           | X                            | X                    |
| Hepatitis A, B, C serologies <sup>c</sup> | X        |                             |                              |                      |
| Pregnancy test <sup>d</sup>               | X        | X                           | X                            | X                    |
| Assessment for side effects               |          | X                           | X                            | X                    |
| Risk-reduction counseling                 | X        | X                           | X                            | X                    |
| Assess/address adherence                  | X        | X                           | X                            | X                    |
| PrEP prescription                         | 30 days  | 60 days                     | 90 days                      | 90 days              |
| Evaluate PrEP continuation                |          |                             |                              | At 12 months         |

<sup>a</sup>Consider: urine tests (gonorrhea, chlamydia), blood test (syphilis), or swabs (rectal, vaginal, and throat for gonorrhea, chlamydia). More frequently if needed.

<sup>b</sup>Kidney health may be assessed every 6 months if stable, or refer to a nephrologist for consultation if declining.

<sup>c</sup>Vaccinate against HAV and HBV if not immune. Consider treatment options in the context of chronic HBV disease. Discuss repeated HCV testing based on risk.

<sup>d</sup>PrEP appears to be safe to use in HIV-negative women during pregnancy.

### REFERENCES

1. US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.
2. CDC. Provider Information Sheet on PrEP During Conception. [www.cdc.gov/hiv/pdf/prep\\_gl\\_clinician\\_factsheet\\_pregnancy\\_english.pdf](http://www.cdc.gov/hiv/pdf/prep_gl_clinician_factsheet_pregnancy_english.pdf). Accessed November 9, 2017
3. Mofenson LM, et al. *AIDS*. 2017;31:213-32.

## Factors Influencing Patient Adherence

- Those who perceive themselves at risk of HIV tend to maintain/improve adherence
- Those aged 40 years or older are more likely to adhere to medication
- Younger people tend to have poorer adherence and their adherence may wane more quickly
- Socioeconomic status, health literacy level, and access to care may influence adherence

- For some, taking daily PrEP at the same time as other daily routines can help adherence.
- Suggest reminder systems and tools, such as pill boxes, cell phone alerts, or online reminder services.
- Address financial, substance use, or mental health needs that can complicate adherence.

### REFERENCE

US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Supporting Patient Adherence

- Monitor adherence quarterly in a nonjudgmental manner
- Focusing solely on adherence to daily dosing can inadvertently minimize other factors, such as ensuring that refills are ordered, maintaining continuous healthcare coverage, and attending medical visits
- Adherence to medications and medical visits is highly variable among individuals; allow patients to lead discussions on what would work for them

- For some, taking daily PrEP at the same time as other daily routines can help adherence.
- Suggest reminder systems and tools, such as pill boxes, cell phone alerts, or online reminder services.

### REFERENCE

US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Managing Side Effects

- In clinical studies, short-term side effects occurred in about 10% of participants
  - Most were mild and resolved within the first month on PrEP
- If serious side effects occur, patients should contact their medical provider
- TDF negatively affects kidney health in about 1% of patients
  - PrEP should not be started if eCrCl is < 60mL/min and should be stopped if eCrCl declines below that level
- Minor bone loss was seen in clinical studies, but the bone loss did not increase the risk of fractures or breaks
  - Bone loss is generally recovered over months after stopping PrEP

- OTC medications can help ease transitional side effects such as headache, nausea, and flatulence.
- Kidney health may also be affected by the use of NSAIDs, acyclovir, valacyclovir, and creatine or protein supplements.
- Some people remark that they wonder if PrEP is working at all because of the lack of side effects.
- Many people report a range of emotional and sexual health changes while on PrEP, including increasing discussion of sexual activity and risk with partners, increasing use of condoms or other prevention methods, enjoying sex without fear of the virus, and being more discerning of partners. Some state that their level of intimacy has increased and their level of anxiety has decreased.

### REFERENCE

US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Troubleshooting Administrative Issues

- Some commercial insurance plans, Medicaid, and Medicare cover PrEP, although copays and deductibles can vary widely
- Prior authorizations are often required at baseline to differentiate Truvada for PrEP from treatment
- PrEP-related ICD, CPT, and LOINC codes are found in the USPHS guidelines and other resources
- Insurers may require different codes for Truvada for PrEP
- Insurance denials can occur, and many are reversed on additional challenges and corrected paperwork

- The service at [covermymeds.com](http://covermymeds.com) provides integration of prior authorization processes with EHR systems.
- A PrEP flow chart infographic is available at [www.projectinform.org/prep-chart](http://www.projectinform.org/prep-chart).
- Available patient assistance programs are also listed at [www.tinyurl.com/FPCprep](http://www.tinyurl.com/FPCprep).
- Project Inform provides a PrEP navigation manual at [www.projectinform.org/prep-manual](http://www.projectinform.org/prep-manual).

### REFERENCES

1. US Public Health Service. [www.tinyurl.com/PrEPCDCsupplement](http://www.tinyurl.com/PrEPCDCsupplement). Accessed November 9, 2017.
2. UCSF National PrEPline. [www.tinyurl.com/CCCprepline](http://www.tinyurl.com/CCCprepline). Accessed November 9, 2017.

## When to Stop PrEP

- The person decides PrEP is no longer desired or needed at that time
- eCrCl declines toward or falls below 60 mL/min (marker of kidney health)
- Side effects or other factors prevent PrEP from being taken daily
- HIV acquisition: patients should undergo resistance testing and be linked to HIV care, as PrEP is not a full HIV treatment regimen

- Many clinical study participants who stopped PrEP due to kidney dysfunction were able to restart PrEP later after kidney health had returned to normal without negatively affecting renal function.
- Severe side effects were rare in clinical studies and did not occur more frequently than in those who received placebo. Mild, transient side effects usually resolved within 2 to 4 weeks of starting PrEP.

### REFERENCE

US Preventive Health Service. [www.tinyurl.com/PrEPCDCguidelines](http://www.tinyurl.com/PrEPCDCguidelines). Accessed November 9, 2017.

## Stopping PrEP: Practical Considerations

- USPHS guidelines recommend 30 daily doses after the last possible HIV exposure when stopping PrEP
- People with chronic HBV need to have a plan for monitoring after stopping Truvada to detect a flare (eg, symptom tracking, lab testing)

### KEY QUESTION:

**What HIV prevention strategies will be in place after stopping PrEP?**

## Key Take-Home Messages

- PrEP, when used separately or together with other prevention strategies, can greatly reduce a person's risk of HIV
- When necessary, addressing a person's structural barriers to healthcare can maintain and improve their adherence to PrEP and medical visits and can improve their chances of staying HIV-negative
- Different numbers of daily lead-in doses and different levels of daily adherence are needed for maximum levels of protection depending on the route of exposure
- For some, getting PrEP is the first time they've regularly engaged in healthcare and offers opportunities to discuss health issues that may be missed beyond screening for and treating STIs



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