How to be a PrEP Provider

Sean Kelly, MD
Assistant Professor of Medicine,
Vanderbilt Division of Infectious Diseases
Objectives

• Importance of PrEP in the Southeast
• Provider barriers for providing PrEP
• The Vanderbilt PrEP program, patient data
• Starting a PrEP clinic
• Logistical considerations of a PrEP clinic
  – Visits
  – Labs
  – Truvada® access
  – Advertising
• Cases of common PrEP patients
Have you provided PrEP?

A. Yes
B. No
C. Wait, what’s PrEP?
# Primary Prevention

<table>
<thead>
<tr>
<th>HIV</th>
<th>Myocardial infarction or Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assess risk</strong></td>
<td>Take a sexual history</td>
</tr>
<tr>
<td><strong>Laboratory evaluation</strong></td>
<td>Serum creatinine, HIV screen</td>
</tr>
<tr>
<td><strong>Further risk reduction</strong></td>
<td>Condom use, sexual health and substance use counseling, STI screening</td>
</tr>
<tr>
<td><strong>Medication options</strong></td>
<td>Truvada®</td>
</tr>
</tbody>
</table>
The Southeast remains the region with the highest HIV incidence, which can be markedly reduced with widespread use of pre-exposure prophylaxis (PrEP) among high-risk individuals.
Nashville

https://aidsvu.org/state/tennessee/
https://getpreptn.com/get-prep/#map_top
Memphis

https://aidsvu.org/state/tennessee/
https://getpreptn.com/get-prep/#map_top
VUMC PrEP Program

• Active patients: 101
  – 77 seen at Vanderbilt General Infectious Diseases Clinic
  – 24 seen at Vanderbilt Comprehensive Care Center
• Mean Age: 39.2 years
• No PCP: 36%
• MSM: 97%
  – 15% monogamous with HIV+ partner
  – 25% with any bacterial STI in past 6 months
    • 10% with gonorrhea
    • 13% with chlamydia
    • 10% with syphilis
  – 89% white, 5% black, 6% other
• 0 seroconversions
What are your barriers to providing PrEP?
Provider Barriers

• Based in review of 13 provider-based surveys 2014-2017 assessing PrEP practices and attitudes
  – 11 surveys of primary care providers
  – 1 survey of Internal Medicine residents
  – 1 survey of medical students
Provider barriers

Knowledge

- Inexperience with Truvada/lack of knowledge (60%-77.5%)\textsuperscript{3,6,8,10}
- Insufficient evidence of efficacy (22%-81%)\textsuperscript{5,6,7,11}
- PrEP is cost-prohibitive (29%-92%)\textsuperscript{4, 5, 6, 7, 10}
- Unfamiliarity with PrEP candidates (inability to assess high HIV risk) (61%)\textsuperscript{6}
Provider barriers
Perception/Attitudes

- Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior) (33%)\(^2,4\)
- Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment) (67%)\(^5,7\)
- Patients perceived as non-adherent, and risk HIV drug resistance selection (40%-77%)\(^4,5,7,11\)
- PrEP is not a primary care activity ("not me") (34%)\(^4,5\)
- Personal ideology\(^5\)
Provider barriers

Behavior

• Low number of providers reported providing PrEP (9%-35%)$^{5,8}$
Provider barriers

Behavior

• Provider factors associated with PrEP provision:
  – Higher patient caseload (2.2; 95% CI, 1.2–4.0)\(^1\)
  – Providing care for HIV+ patients (7.63, 95 \% CI 2.33–24.98)\(^2\)
  – Having previously prescribed PrEP (OR = 7.0, 95%CI = 1.4–34.6)\(^6\)
  – Taking a sexual history (p=0.004)\(^3\)
  – Male gender (1.5; 95% CI, 1.0–2.2)\(^1\)
  – LGBTQ self-identification (2.0; 95 % CI, 1.3–2.9)\(^1\)
  – Older age (>41)(p=0.004)\(^3\)
  – White race (p=0.026)\(^3\)
Provider Barriers
Needs for practice transformation

- Nursing support (92%)\textsuperscript{6}
- Social work support (90%)\textsuperscript{6}
- CME (90%)\textsuperscript{6}
- PrEP training event (OR 4.84, CI 1.77–13.21)\textsuperscript{8}
PrEP Clinic Needs

• Provider
• Nursing
  – Assistance in communicating with patient
  – Providing labs and other documents to pharmacy
  – Assisting in completing prior authorization
• Pharmacy
  – Specialty pharmacy partnership highly recommended
• Phlebotomy, blood draws
• Ability to provide treatment and counseling for STIs
Before prescribing

• Risk Evaluation and Mitigation Strategies (REMS)
  – REMS is a safety strategy to manage risks associated with a drug and to enable continued access to the drug by managing its safe use.
  – REMS is a safety measure beyond the professional labeling to ensure the drug’s benefits outweigh its risks.
  – REMS requirements are different for different drugs.
Before prescribing

- Risk Evaluation and Mitigation Strategies (REMS)

https://www.truvadapreprems.com/truvadaprep-resources
Before prescribing

https://www.truvadapreprems.com/truvadaprep-resources
Patient Intake

• Most new PrEP patients will seek out PrEP
• Since many have no PCP, allow self-referrals
• Consider patient insurance status
  – Cost of medication
  – Cost of quarterly visits
  – Cost of labs
  – Cost of vaccination, parenteral antibiotics and their administrations
The First Visit

- Assess patient’s knowledge and attitudes about PrEP
- Assess patient’s HIV risk
- Medication counseling
PrEP Medication Counseling

• Dosing
  – One tab daily, with or without food
• Adherence, and its relationship to efficacy
• Time to effectiveness
  – 7-10 days for men, 21 days for women
  – Barrier protection especially needed during that time
• Adverse effects
  – Nausea, vomiting, diarrhea, loss of appetite, weight loss
  – Fatigue, headache
• Requirements for monitoring
• Refill process
  – “Call when you have 7-10 days left”
The First Visit

**Initial Visit:**
- Discuss PrEP with MD
- Provide labs
- Sign Truvada PrEP Agreement

PrEP is prescribed based on labs and your choice.

Pharmacist completes any necessary insurance requirements and sets you up with a copay card if possible.

PrEP is filled and shipped to you by Walgreens Specialty Pharmacy unless your insurance requires you to fill through a different pharmacy.
The First Visit

Agreement Form for Initiating Truvada® for Pre-exposure Prophylaxis (PrEP)

Instructions:
Review form with an HIV-negative person who is about to start or is taking TRUVADA for a PrEP indication at each visit. File form in the patient's medical record.

TRUVADA is indicated in combination with safer sex practices for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. The following factors may help to identify individuals at high risk:
- Has partner(s) known to be HIV-1 infected, or
- Engages in sexual activity within a high prevalence area or social network and one or more of the following:
  - Inconsistent or no condom use
  - Diagnosis of sexually transmitted infections
  - Exchange of sex for commodities (such as money, shelter, food, or drugs)
  - Use of illicit drugs, alcohol dependence
  - Incarceration
  - Partner(s) of unknown HIV-1 status with any of the factors listed above

Healthcare Provider Agreement
By signing below, I signify my understanding of the risks and benefits of TRUVADA for a PrEP indication and my obligation as a prescriber to educate the HIV-negative person about these risks, counsel the person on risk reduction, monitor the person appropriately, and report adverse events. Specifically, I attest to having done the following:
- Confirmed the negative HIV-1 status of this person prior to starting TRUVADA for a PrEP indication
- Read the Prescribing Information, including the BOXED WARNING
- Discussed with the HIV-negative person the known safety risks with use of TRUVADA for a PrEP indication
- Reviewed the importance of adherence with a comprehensive prevention strategy, including practicing safer sex
- Discussed the importance of regular HIV-1 testing (at least every 3 months) while taking TRUVADA for a PrEP indication
- Reviewed the TRUVADA Medication Guide with the HIV-negative person at high risk prior to prescribing TRUVADA for a PrEP indication
- Completed the Items on the Checklist for Prescribers: Initiation of TRUVADA for Pre-exposure Prophylaxis (PrEP)

Individual Label

HIV-Negative Person Agreement
By signing below, I acknowledge that I have talked with my healthcare provider about the risks and benefits of TRUVADA to reduce the risk of getting HIV-1 infection, and I understand them clearly. Specifically, I attest to the following:
- My healthcare provider talked with me about the importance of follow-up HIV-1 testing, and I agree to have repeat HIV-1 screening tests (at least every 3 months) as scheduled by my healthcare provider
- My healthcare provider talked with me about the safety risks involved with using TRUVADA to reduce the risk of getting HIV-1 infection
- My healthcare provider talked with me about a complete prevention strategy and always practicing safer sex by using condoms correctly
- I will talk with my healthcare provider if I have any questions
- I have read the TRUVADA Medication Guide

HIV-Negative Person’s Signature Date

Healthcare Provider’s Signature Date

Truvada
emtricitabine 200 mg and
tenofovir disoproxil fumarate 300 mg tablets

© 2019 Gilead Sciences, Inc. The contents of this booklet are not intended to constitute medical advice. This booklet is intended for healthcare providers, patients, and caregivers in the United States. Please see full Prescribing Information and Patient Guide for complete information about TRUVADA.

https://www.truvadapreprems.com/truvadaprep-agreement-form#
The First Visit

• Labs:
  – HIV Ag/Ab
  – Basic Metabolic Panel
  – Hepatitis B sAg, sAb
  – Hepatitis C Ab
  – Treponemal IgG
  – Gonorrhea/chlamydia PCR
The First Visit

• Tips
  – If a specialty pharmacy will be used, make sure to document the patient’s preferred pharmacy
    • Provides more efficient prescription for azithromycin if +chlamydia!
  – Get contact information!
  – Taking a sexual history is an excellent opportunity to discuss substance use
  – High risk behavior often occurs during travel, so ASK!
  – Use patient-friendly terms
PrEP resources for patients

• PrEP welcome packet
  1. CDC PrEP medication information sheet for patients
  2. Patient/Provider Agreement
  4. Walgreens Specialty Pharmacy contact information
  5. Additional PrEP resources
PrEP resources for patients
Prescribing process

• Specialty Pharmacy may complete all prior authorization and copay assistance requirements and connect with the patient.

• May also send the prescription and prior authorizations to another pharmacy if the patient requests this.
Prescribing process

• Send prescription electronically to Specialty Pharmacy
  – 30 tabs, 2 refills (total 90-day supply)
• When HIV Ag/Ab and serum creatinine are available, send message to clinic RN to fax lab results to pharmacy
• Pharmacy contacts patient for further counseling and to arrange PrEP delivery
• Pharmacy contacts patient intermittently over 6 months to assess tolerability and adherence
Prescribing Process
No Specialty Pharmacy

• Send prescription to pharmacy
• Fax HIV Ag/Ab, serum creatinine when available
• Complete PA if required
  – Information requested: last date of screening and sometimes PrEP Agreement form
• Copay card
  – Gilead copay card: $3600/year benefit
  – https://www.gileadadvancingaccess.com/copay-coupon-card
  – Federal beneficiaries not eligible
## Prior Authorization

**Drug Prior Authorization**

temtricitabine/tenofovir (TRUVADA)

###STEP 1: CLEARLY PRINT AND COMPLETE TO EXPEDITE PROCESSING

<table>
<thead>
<tr>
<th>Date</th>
<th>Preparer First &amp; Last Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/28/2017</td>
<td>Sean Kelly</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient First &amp; Last Name</th>
<th>Preparer NPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1832477177</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriber Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>1211 21st Ave # Suite 102A Nashville TN 37222</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescriber Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/5-936-1174</td>
</tr>
</tbody>
</table>

###STEP 2: COMPLETE REQUIRED CRITERIA: COMPLETE ONE OF THREE

**DIAGNOSIS A: Coverage for Human Immunodeficiency Virus (HIV) or Hepatitis B Virus (HBV) infected patients (Approve for Lifetime)**

- [ ] Prescribed for the active treatment of HIV or HBV

**DIAGNOSIS B: Post-Exposure Prophylaxis (Approve for 1 Month)**

- [ ] Prescribed for post-exposure prophylaxis following suspected or confirmed Human Immunodeficiency Virus (HIV) exposure

**DIAGNOSIS C: Pre-Exposure Prophylaxis (Initial Coverage) (Approve for 3 Months)**

- [ ] Patient is at high risk for contracting Human Immunodeficiency Virus (HIV) due to sexual transmission and receiving TRUVADA for pre-exposure prophylaxis. If not due to sexual transmission, please explain other reason patient is at high risk for contracting HIV:

- [ ] Patient is ≥ 18 years of age
- [ ] Patient is HIV negative: Please provide date of last test:
- [ ] Prescriber has completed the REMS Prescriber Checklist:
- [ ] Patient and prescriber have signed the REMS Agreement Form and it is saved in the patient’s medical chart:
  http://www.truvadaannex.com/Content/pdf/Agreement_Form.pdf

Please provide expected duration of treatment:

**DIAGNOSIS D: Pre-Exposure Prophylaxis (Continuing Coverage) (Approve for 3 Months)**

- [ ] Patient is Human Immunodeficiency Virus (HIV) negative

Please provide date of last test: 12/30/2018

###STEP 3: SIGN AND FAX TO: NAVITUS PRIOR AUTHORIZATION AT: 855-564-8591

<table>
<thead>
<tr>
<th>Prescriber Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sean Kelly</td>
<td>2-28-17</td>
</tr>
</tbody>
</table>

If patient meets criteria, allow 2 business days for processing.
Other Cost Options

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

YES

1. Gilead Advancing Access Co-pay Card
gileadcopay.com 877-505-5985
- $3,600 max/annual
- No income restrictions
- Covers co-pays, deductibles and co-insurance

2. Patient Access Network Foundation
panfoundation.org/avertreatment-and-prevention 866-316-7763
- $8,000 max/year, reapply
- Income <300% FPL ($50,300)
- Based on taxable income (1040 line 2, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays, deductibles and co-insurance
- US resident
- Pharmaceuticals can bill PAN Foundation directly

3. Patient Advocate Foundation (PAF)
https://www.paf.org/diseases/htv-aids-and-prevention
- $7,500 max/year, reapply
- Income <400% FPL ($64,240)
- Based on taxable income (1040 line 2, 1040 EZ line 1)
- Must be insured (as listed under "YES" above)
- Covers co-pays only
- Proof of US residence (utility bill, etc.)
- Case managers available to help resolve medical cost issues (800-831-7274)

NO

U.S. RESIDENT?

1. Enroll in an insurance marketplace
obamacarefacts.com/state-health-insurance-exchange/
Avoid Bronze plans if you can, generally have higher costs.
Silver plans will offer lower costs for people earning up to 250% FPL ($30,150). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

2. Check if you’re eligible for your state Medicaid plan.

3. What’s the date?
   - NOV 1 – JAN 31
   - FEB 1 – OCT 31
   - below 138% FPL/yr (<$11,440)
   - above 138% FPL/yr (>=$11,440)

NON-RESIDENT/UNDOCUMENTED?

1. Enroll in the Gilead MAP
www.truvada.com/truvada-patient-assistance

2. Retail cost of Truvada
3. Special enrollment
   You can get insurance during the year if you’re "qualifying life events" such as pregnancy, loss of coverage, loss of job, change in household size, change in income, new marriage, change in citizenship.

FSAs (flexible spending accounts)

If employer offers an FSA, it can help cover up to $5,500 of out-of-pocket costs.

On Medicaid?
Medicaid should cover all medical costs related to PrEP if you encounter barriers to coverage, consult a legal advocate.

If you’re a resident, these state plans may also help:
- CALIFORNIA: https://www.iams.com/OpenFPF
- ILLINOIS: https://www.IFP.com/Ilpfp
- MARYLAND: https://myhealth.maryland.gov/affordablecare/ (In English)
- WASHINGTON: http://www.gov.wa.gov/affordablecare (In English)
- WISCONSIN: http://www.gov.wi.gov/afp (In English)

UPDATED AS OF FEBRUARY 10, 2017

340B Drug Pricing Program

• Federal program that requires manufacturers to provide reduced drug prices for eligible outpatient centers

• Centers can purchase and dispense the medication through internal or external (contract) pharmacies
Billing/coding

• While ICD-10 does not provide specific codes for PrEP, the following codes have been discussed with billing and used for PrEP visits:
  – Z20.6 “Contact with and (suspected) exposure to HIV”
  – Z17.1 “Human immunodeficiency virus [HIV] counseling”
  – Z11.3 “Encounter for screening for infection with a predominantly sexual mode of transmission”
  – Z79.2 “Long-term (current) use of antibiotics”

• Note: Can also bill by time, >25 minutes = level 4

• Not suggested
  – Z72.52 – High risk homosexual behavior
Billing/coding

• While ICD-10 does not provide specific codes for PrEP, the following codes have been discussed with billing and used for PrEP visits:
  – Z20.6 “Contact with and (suspected) exposure to HIV”
  – Z17.1 “Human immunodeficiency virus [HIV] counseling”
  – Z11.3 “Encounter for screening for infection with a predominantly sexual mode of transmission”
  – Z79.2 “Long-term (current) use of antibiotics”

• Note: Can also bill by time, >25 minutes = level 4

• Not suggested:
  – Z72.52 – High risk homosexual behavior
The Second Visit

• Repeat HIV screen, repeat serum creatinine
• Assess adherence
• Reassess eligibility
• Assess for side effects
• Provide behavioral risk reduction support
• Assess pregnancy intention (test if could be pregnant)
• If HIV-negative and eligible, refill PrEP
Every 3 months

- HIV screen
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- Assess pregnancy intention (test if could be pregnant)
- If HIV-negative and eligible, refill PrEP
Every 6 months

- Screen for other STIs
- Repeat serum creatinine
STOP PrEP

• The patient doesn’t want it
• Behavior or life situations have changed that lower risk for HIV infection
• Intolerable adverse events/toxicities
• Nonadherence despite attempted interventions to improve
• HIV-infection
A year of PrEP

<table>
<thead>
<tr>
<th>Encounter</th>
<th>To do</th>
</tr>
</thead>
</table>
| Month 0   | • Screen for HIV  
          | • Confirm HBV and HCV status  
          | • Check serum creatinine  
          | • Screen for STIs  
          | • Counseling  
          | • Prescribe |
| Month 3   | • Screen for HIV  
          | • Check serum creatinine  
          | • Counseling  
          | • Prescribe |
| Month 6   | • Screen for HIV  
          | • Screen for STIs  
          | • Counseling  
          | • Prescribe |
| Month 9   | • Screen for HIV  
          | • Check serum creatinine  
          | • Counseling  
          | • Prescribe |
| Month 12  | • Screen for HIV  
          | • Screen for STIs  
          | • Counseling  
          | • Prescribe |

Labs:
- HIV screen: 5
- Serum creatinine: 3
- STI screen: 3

Prescriptions/Refill authorizations: 5

Discussions: 5+
Pre-Exposure Prophylaxis (PrEP) at the Vanderbilt Comprehensive Care Center

If you have a partner who is not HIV-infected, the Vanderbilt Comprehensive Care Center now offers pre-exposure prophylaxis (PrEP) to reduce his or her risk of HIV infection.

PrEP is an HIV-prevention strategy. It is a pill, taken once daily, containing some of the same medicines used to treat HIV. If taken by an HIV-uninfected person who has a high risk of getting HIV, PrEP may reduce that person's risk by more than 90%.

If your partner is interested in starting PrEP, he or she may set up an appointment with a Vanderbilt Comprehensive Care Center PrEP provider by calling 615-875-5111.

Combination therapy PrEP offers effective way to prevent HIV infection

by Bill Snyder | Thursday, Sep. 7, 2017, 9:44 AM

Infectious disease experts Katie White, M.D., Ph.D., and Sean Kelly, M.D., are working to raise awareness of effective ways to prevent HIV infection, including the combination drug therapy called pre-exposure prophylaxis, or PrEP. (Photo by Daniel Delenay)

Rates of new HIV infections in the United States are declining — except among men who have sex with men. Rates are particularly high among African-American and Hispanic men and especially in the South.
PrEP Locator

https://preplocator.org
Walgreen’s

- As of 7/2017, select sites offer PrEP counseling, STI screening, and Truvada® provision
- Sites are those with existing Walgreens Healthcare Clinics with APNs, PAs
- Sites include:
  - Cincinnati, Cleveland, Columbus, Dallas, Denver, Kansas City, Knoxville, Las Vegas, Louisville, Memphis, Nashville, Orlando, Philadelphia, Phoenix, Tucson, Washington D.C., and Wichita.
- [https://www.walgreens.com/topic/scheduler/hiv-prep.jsp](https://www.walgreens.com/topic/scheduler/hiv-prep.jsp)
Let’s start seeing patients...
Patient 1

- A 24-year-old African American man presents to Internal Medicine clinic as an urgent visit. He reports mild dysuria and requests STI screening. He is MSM, has had 5 partners in the past 6 months, uses condoms inconsistently, and has anal insertive, receptive and oral sex. He has never had a known STI, but has only been screened once before (2 years ago).
Case 1

• Your patient says he has heard of PrEP, but doesn’t know anyone taking it. He asks if it really works.
Case 1

• After discussing PrEP, your patient is interested.

What just happened?
Taking a sexual history promotes comprehensive STI risk reduction counseling

Condom use
Knowing HIV status
Knowing partner’s HIV status
PrEP
How often do you discuss sexual history with your patients?

B. Almost always
C. Occasionally
D. Not often at all
What are your barriers to discussing your patients’ sexual histories?
Patient 2

A 27-year-old man presents for a routine health maintenance exam. You notice he was seen by another provider 3 months ago and diagnosed with gonorrhea by rectal swab. He also has a history of syphilis, treated 2 years ago. He is MSM, has anal receptive sex and uses condoms “80 percent” of the time. He has had 10-15 partners in the past 6 months and gets HIV screens consistently every 6 months. You initiate a conversation about PrEP...
Patient 2
Case 2

Your patient has heard about PrEP and tells you he is absolutely not interested. You ask him why not.

“You know what they say about PrEP, it will make me have more sex and get STDs,” he responds.
PrEP Stigma
Patient 3

32-year-old white man taking TDF/FTC for the past year presents for routine follow-up. He is MSM, has one long-term partner and 4 other partners over the past 3 months. He remains HIV-negative, but his renal function has declined (serum creatinine 0.9 mg/dL three months ago, now is 2.3 mg/dL with eGFR mL/min).
Nephrotoxicity

• Tenofovir disoproxil fumarate (TDF)
  – Proximal tubulopathy due to mitochondrial toxicity
    • May occur with or without decline in eGFR
    • Fanconi syndrome
      – Generalized proximal tubulopathy
        » renal tubular acidosis
        » glycosuria
        » hypophosphatemia
        » hypouricemia
        » Proteinuria
  • Tubular dysfunction may precede loss of renal function
  • Underlying CKD increases risk

Patient 3

Your patient reveals that his partner, a physician, has been providing him with IM testosterone. The patient subsequently developed hypertension, for which his partner provided lisinopril. The patient has also been taking daily ibuprofen for headaches.
Patient 3

You stopped TDF/FTC and counseled extensively on HIV risk reduction strategies. The patient stopped taking testosterone, ibuprofen and, eventually, lisinopril. Three months later, his serum creatinine was 1.5 mg/dL, eGFR 82 mL/min.
Nephrotoxicity

- Tenofovir disoproxil fumarate (TDF) is contraindicated if CrCl <60 mL/min
- In the absence of HIV infection, renal toxicity due to tenofovir disoproxil fumarate (TDF) is generally reversible after TDF discontinuation.

Case 5

82-year-old white man presents to discuss PrEP initiation. He has a new partner, a 78-year-old woman with HIV-infection, undetectable for many years. Your patient has a history of prostate cancer s/p TURP, coronary artery disease, and well-controlled hypertension. He reports falling once in the past year while raking his yard, denies any injuries.
**Table 3. Bone Mineral Density Scores.**

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Forearm</th>
<th>Hip</th>
<th>Lumbar Spine</th>
</tr>
</thead>
<tbody>
<tr>
<td>T score</td>
<td>0.004</td>
<td>&lt;0.001</td>
<td>-0.72</td>
</tr>
<tr>
<td>Enrollment</td>
<td>-0.75</td>
<td>-0.58</td>
<td>0.44</td>
</tr>
<tr>
<td>6 mo</td>
<td>-0.77</td>
<td>-0.50</td>
<td>0.33</td>
</tr>
<tr>
<td>12 mo</td>
<td>-0.72</td>
<td>-0.42</td>
<td>0.34</td>
</tr>
<tr>
<td>18 mo</td>
<td>-0.88</td>
<td>-0.21</td>
<td>0.18</td>
</tr>
<tr>
<td>24 mo</td>
<td>-0.87</td>
<td>-0.13</td>
<td>0.20</td>
</tr>
</tbody>
</table>

*In the TDF–FTC group, 58 participants completed bone mineral density testing at the 6-month visit, 45 at the 12-month visit, 36 at the 18-month visit, and 23 at the 24-month visit. In the placebo group, 66 participants completed bone mineral density testing at the 6-month visit, 44 at the 12-month visit, 33 at the 18-month visit, and 35 at the 24-month visit.*
Sero-discordant partners

• Effective ART use by the HIV+ partner can significantly reduce, if not eliminate, transmission risk
  – 1238 sero-discordant couples, representing 58,000+ condomless sex acts over ~2 years
    • No transmissions observed
  – 343 gay sero-discordant couples, representing 12,000+ condomless sex acts over ~1.5 years
    • No transmissions observed

• Long-term follow-up studies are needed to precisely determine risk reduction by effective ART


Case 4

BENEFIT

• Further reduction in HIV risk (which is already extremely low)

RISK

• Bone mineral density loss
• Increased fracture risk
• Nephrotoxicity
• Medication interactions
Conclusion

• PrEP is an extremely effective preventive strategy
• Many PrEP barriers exist, but can be overcome
• Understand PrEP prescribing guidelines
• Evaluate individual clinic needs
• Identify individual beliefs and perceptions
• Ask for help! sean.g.kelly@vanderbilt.edu
References


Thank you!

Questions?