Objectives

• Background of PrEP
• Importance of PrEP in the Southeast
• Provider and patient barriers to PrEP
• PrEP eligibility
• Taking a sexual history
• PrEP prescribing
  • Counseling
  • Adverse effects
  • Lab monitoring
• Future directions of PrEP
Secondary Objectives

• Increase your confidence in providing PrEP!
• Improve your ability to take a sexual history!
PrEP is primary prevention

It is intended to PREVENT the onset of a disease in those who are AT RISK

It is a concept, fulfilled by medication that has been FDA-approved for this purpose
But what is PrEP, really?

- **Truvada®**
  - Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300mg/emtricitabine (FTC) 200mg
  - Developed by Gilead
  - FDA-approved for use as PrEP for adults on June 6, 2012
  - FDA-approved for use as PrEP for adolescents on May 15, 2018
- Generic TDF/FTC approved June 2017 (but not yet available)

For this talk: PrEP = Truvada® = TDF/FTC
## 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>
## Primary Prevention

### HIV Myocardial infarction or Stroke

#### Assess risk
- Take a sexual history
- Take a past medical, family, and social history
- Check cholesterol and screen for diabetes
- Calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines

#### Laboratory evaluation
- Serum creatinine
- Comprehensive metabolic panel, cholesterol profile, hemoglobin a1c

#### Further risk reduction
- Condom use, sexual health and substance use counseling, STI screening
- Lifestyle and diet modification counseling, treat comorbid conditions (hypertension, diabetes), smoking cessation

#### Medication options
- Truvada®
- Atorvastatin
- Rosuvastatin
- Pravastatin
- Pitavastatin
- Simvastatin
- Fluvastatin
- Aspirin
How well does PrEP work?
(spoiler alert: very well)
iPrEx

44% HIV risk reduction, but 92% risk reduction when taken consistently among MSM and transgender women
62.2% HIV risk reduction among heterosexual men and women
75% HIV risk reduction among heterosexual sero-discordant couples, 90% among those with detectable drug levels
Bangkok Tenofovir Study Group

THE LANCET

Volume 381, Issue 9883, 15–21 June 2013, Pages 2063–2090

Articles

Antiretroviral prophylaxis for HIV infection in injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomised, double-blind, placebo-controlled phase 3 trial

Kachit Choopanya, MD, Dr Michael Martin, MD, Pravan Suntharasai, MD, Udomsak Sangkum, MD, Philip A Mock, MAppStats, Manoj Leethchawalit, MD, Sithisat Chiamwongpaet, MD, Praphan Kitisin, MD, Pitinan Natrujirote, MD, Somyot Kittimunkong, MD, Ruft Chuachuwong, MD, Roman J Gvetadze, MD, Janet M McNicholl, MD, Lynn A Paxton, MD, Marcel E Curiin, MD, Craig W Hendrix, MD, Suphak Vanichseni, MD, for the Bangkok Tenofovir Study Group

48.9% risk reduction, but 74% HIV risk reduction when taken consistently, among IDUs (TDF only)
86% HIV risk reduction in MSM using on-demand PrEP
Dosing matters

Using drug concentrations in iPrEx and STRAND, pharmacokinetic models predict 76% risk reduction with 2 doses/week, 96% with 4 doses/week, and 99% with 7 doses/week.

### Studies Summary

<table>
<thead>
<tr>
<th>Study</th>
<th>Population</th>
<th>Dosing</th>
<th>Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEX</td>
<td>MSM</td>
<td>Daily</td>
<td>44% (92% with ideal adherence)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Heterosexual men and women</td>
<td>Daily</td>
<td>62.2% (100% in open-label extension with regular follow-up)</td>
</tr>
<tr>
<td>Partners</td>
<td>Sero-discordant heterosexual couples</td>
<td>Daily</td>
<td>75% (90% with ideal adherence)</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study Group</td>
<td>Intravenous drug users</td>
<td>Daily</td>
<td>48.9% (74% with ideal adherence)</td>
</tr>
<tr>
<td>IPERGAY</td>
<td>MSM</td>
<td>On-demand</td>
<td>86%</td>
</tr>
</tbody>
</table>
PrEP and adolescents

• Adolescent Trial Network
  • 78 HIV-negative MSM, ages 15-17, who reported HIV risk behavior during the previous 6 months received daily PrEP
  • Follow-up monthly for 12 weeks, then quarterly for the remainder of 48-week study
  • Adherence was high during monthly follow-up
    • 95% with detectable TDF drug levels at 12 weeks
  • After 12 weeks, adherence dropped dramatically (by more than half)
  • 32 discontinued before the end of the study
  • HIV acquisition rate: 3 new infections, 6.4 per 100 person-years
Safety and acceptability

- PrEP was well-tolerated
  - No discontinuations due to adverse effects
- BMD increased during treatment (as expected for age-appropriate increases in BMD)
  - Slight decline in z-score suggests BMD increase was lower than expected
    - Unclear if due to TDF or small sample size
Why the poor adherence?

Those without detectable TDF drug levels were:

- More likely to endorse the statement, “I worry others will see me taking pills and think I am HIV-positive”
- More likely to report missing doses due to:
  - Not being at home
  - Being too busy
  - Forgetting

Acceptability of pill size and taste decreased after 12 weeks

Those with seroconversion had absent TDF levels

Hosek SG, JAMA, 2017
Why PrEP matters
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.
HIV Risk by Race/Ethnicity and MSM

White women: 1 in 880
White men: 1 in 132
Hispanic women: 1 in 227
Hispanic men: 1 in 48
Black women: 1 in 48
Black men: 1 in 20

White MSM: 1 in 11
Hispanic MSM: 1 in 4
Black MSM: 1 in 2

PrEP Deserts

- Most MSM with reduced geographic access to PrEP providers (“PrEP deserts”) reside in the South.
- Over 50% of MSM in the South must drive >60 minutes to a PrEP provider.
- PrEP deserts are generally non-urban areas.

Tennessee
HIV risk and location of PrEP providers

https://aidsvu.org/state/tennessee/
https://getpreptn.com/get-prep/#map_top
Tennessee
HIV risk and location of PrEP providers

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

HIV risk and location of PrEP providers

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Nashville
HIV risk and location of PrEP providers

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

There were over 77,000 PrEP users in 2016.

That's a 73% increase year over year since 2012.
PrEP use

Out of an estimated 1.2 million at high risk for HIV

The Southern U.S: 30% of all PrEP users, but 52% of all new HIV diagnoses in 2016
PrEP barriers

PrEP care cascade

- At-risk
- Aware and willing to use PrEP
- Able to access healthcare
- Receive PrEP prescription
- Adherent

https://www.aidsmap.com, Sept 9, 2016 [Accessed April 9, 2018]
Stigma

A preventative measure against the consequences of sexual activity

... condones sexual activity

... promotes sexual activity

... causes sexual activity
Sexual Risk Compensation

For patients believing they were on PrEP, the number of receptive anal intercourse partners decreased.

For patients believing they were on PrEP, condom use increased.

Syphilis incidence also decreased in both study arms.
Sexual Risk Compensation

- Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD)
  - UK randomized, open-label study
    - 275 MSM to start TDF/FTC immediately
    - 269 MSM to start TDF/FTC after 1 year
  - 86% HIV risk reduction
  - No difference between groups in STI incidence

Actually…

- Pre-Contemplation
- Contemplation
- Planning
- Action
- Maintenance
Actually…

- Pre-Contemplation
- Contemplation
- Planning
- Action
- Maintenance

Active commitment to health
Actually…

- Pre-Contemplation
- Contemplation
- Planning
- Action
- Active
- Confidence in sexual health
- Maintenance
Actually…

- Pre-Contemplation
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- Active
  - Confidence in
  - Stronger relationships

Confidence in sexual health
Stronger relationships
Active commitment to health
Actually…
Actually…

- Pre-Contemplation
- Contemplation
- Planning
- Maintenance
  - Active
  - Confidence in
  - Stronger
  - Fewer sexual
  - Further risk reduction
PrEP barriers - Providers

- Insufficient evidence of efficacy
- Inexperience with Truvada/lack of knowledge
- PrEP is cost-prohibitive
- PrEP is not a primary care activity ("not me")
- Unfamiliarity with PrEP candidates; inability to assess high HIV risk
- Sexual risk compensation (that use of PrEP will lead to increased high-risk behavior)
- Discomfort using a drug with potential adverse effects in an otherwise healthy person (primary prevention vs. treatment)
- Patients perceived as non-adherent, and risk HIV resistance mutation development
- Personal ideology

References:
As a society, we treat HIV-related health care activities differently.

As healthcare providers, we need to accept our responsibility to protect our patients.
The “cost” of Truvada®

- Out-of-pocket cost of TDF/FTC*
  - Per pill: $67.03
  - Per month: $1,876.84
  - Per year: $24,465.95

*Average Wholesale Price
Truvada® coverage

- Actually, Truvada® is very affordable for most patients
- All insurance plans cover TDF/FTC for the indication of HIV prevention
  - Variable copays
- Medicare/Medicaid cover TDF/FTC
- Gilead Advancing Access Program – Copay Assistance
  - $7,200/calendar year of copay assistance
  - No income limitation
- Gilead Advancing Access Program – Medication Access
  - Full drug coverage if income <500% federal poverty level
  - Primary option for uninsured patients
Copay Assistance

Gilead Advancing Access Co-pay Card
877-505-6986

copygileadcopay.com

- $7,200 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicaid, Medicare, VA or other state/federal prescription drug programs

If pharmacy is unable to process Gilead’s Co-pay Card, keep sales and pharmacy receipts. Call number on back of co-pay card. Submit paperwork for reimbursement for all refills. Some restrictions apply: terms, conditions at gileadcopay.com.

www.projectinform.org
## Copay Assistance

**Get Started with the Gilead Advancing Access® Program**

Advancing Access can provide you with information to help you find financial and insurance support every step of the way.

**Support by Phone**
Call 1-800-226-2056 to speak to an Advancing Access counselor directly. You can also leave a confidential message any time and day of the week.

**Hours:** Monday-Friday / 9am to 8pm ET

**Enroll Today**
The form requires some information from your healthcare provider, so you may want to fill it out with them. Download the Advancing Access Enrollment Form or Enroll Online.
Copay Assistance

Get Started with Gilead Access® Program

Co-Pay Coupon Card

FINANCIAL SUPPORT

INSURANCE SUPPORT

Requires some information from your healthcare provider so you may want to fill it out with them. Download the Advancing Access Enrollment Form or Enroll Online.
Gilead Advancing Access Program

- $7,200/calendar year benefit
  - Increased from $3,600 to $4,200 in January 2018
  - Increased from $4,200 to $7,200 in September 2018
- No income limitation
- Federal beneficiaries excluded
- Usually goes toward deductible
  - Beware of copay accumulator programs
    - Manufacturer copay assistance will no longer count toward deductible
Copay Assistance

Are you insured to cover your costs for PrEP?

No

U.S. Resident?

What's the date?

Nov 1 - Jan 31

Enroll in an insurance marketplace

obamacarefacts.com/state-health-insurance-exchange/

Avoid Bronze plans if you can; they generally have higher costs.

Silver plans will offer lower costs for people earning up to 250% FPL ($30,350).

Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

FEB 1 - OCT 31

below 138% FPL/yr

(<= $11,751)

above 138% FPL/yr

(> $11,751)

Check if you’re eligible for your state Medicaid plan. (medicaid.gov)

Enroll in the Gilead MAP.

www.truvada.com/truvada-patient-assistance

below $60,700

above $60,700

Retail cost of Truvada

What’s your income?

Check if you can get insurance through marketplace/employer.

Non-Resident/Undocumented?

FSA (Flexible Spending Account)

Employer FSAs can help cover up to $2,600 of out-of-pocket costs.

If you’re a resident, these state plans may also help if you’re insured or uninsured:

- CALIFORNIA: truvada.com/ca/prepAP
- COLORADO: truvada.com/co/prepAP
- ILLINOIS: truvada.com/il/prepAP
- MASSACHUSETTS: truvada.com/mass/prepAP (cost of drug services)
- NEW YORK: truvada.com/nyc/prepAP (cost of drug services)
- VIRGINIA: truvada.com/va/prepAP
- WASHINGTON: truvada.com/wa/prepAP (cost of drug services)

Gilead Advancing Access, Co-pay Card

gileadcopay.com

877-505-6999

Patient Advocate Network Foundation

panapply.org
866-316-7263

• 7,200 max/calendar
• No income restrictions
• Covers co-pays, deductibles and co-insurance
• Re-applies annually as listed above
• US resident
• Not available for patients with Medicaid, Medicare, state/federal prescription programs

If pharmacy is unable to fill, patient can apply for Gilead’s Co-pay Card, or pharmacy receives on behalf of patient. Submit paperwork for re-appli-
cation and pharmacy receipt back to Gilead for authorization.

Medicare plans only

Covers co-pays, deductibles and co-insurance

US Resident

Pharmacies can bill PAN Foundation directly
Copay Assistance
Copay Assistance

Closed for new applications
Copay Assistance

ARE YOU INSURED TO COVER YOUR COSTS FOR PrEP?

YES

1. Gilead Advancing Access Co-pay Card
gileadcopay.com
877-505-6986
- $7,200 max/calendar year
- No income restrictions
- Covers co-pays, deductibles and co-insurance
- Re-apply annually as needed
- US resident
- Not available for persons with Medicare, Medicare Advantage or other state/federal prescription drug programs

2. Patient Advocate Foundation (PAF)
tinyurl.com/PAFhelp, or coays.org
- $7,500 max/year, re-apply
- Income <400% FPL ($48,560) + COLI (cost of living index) adjustments
- Based on taxable income (1040 line 7, 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 (800-532-5274)

3. Enroll in an insurance marketplace
Theobamacarefacts.com/state-health-insurance-exchange/
- Avoid Bronze plans if you can: they generally have higher costs.
- Silver plans will offer lower costs for people earning up to 250% FPL ($30,350). Gold & Platinum plans offer better coverage if you can afford them. Carefully select the right plan for you.

NO

U.S. RESIDENT?

What's the date?

NOV 1 – JAN 31
- Enroll in the Gilead MAP.
www.truvada.com/truvada-patient-assistance
- Check if you're eligible for your state Medicaid plan.
(shieldhealthcenter.org)

FEB 1 – OCT 31
- below 138% FPL/yr (< $14,751)
- Check if you can get insurance through marketplace/employer.

above 138% FPL/yr (> $14,751)
- Special enrollment
- For "qualifying life events" such as pregnancy, loss of job, change in household size, change in income, recent move, change in citizenship.
- California: tinyurl.com/g3pmap
- Colorado: tinyurl.com/k3pmap
- Illinois: tinyurl.com/l3pmap
- Massachusetts:online.gopdp.com/gopdp (cost of drug services)
- New York: tinyurl.com/n3pmap (cost of services)
- Virginia: tinyurl.com/v3pmap
- Washington: tinyurl.com/w3pmap (cost of drug)

NON-RESIDENT/UNDOCUMENTED?

below 60,700
- Enroll in the Gilead MAP.
www.truvada.com/truvada-patient-assistance
- 500% FPL ($112,430)
- Eligible: $4,330 per person and higher.
- 1040 line 7, 1040 EZ line 13
- (in Alaska & Hawaii, 1040 can have line 7, 1040 EZ line 13)
- only drug costs — tinyurl.com/FIncomes

above 60,700

Flexible spending account (FSA)
- Employer FSAs can help cover up to $2,600 of out-of-pocket costs.
Medication Assistance Program

We're Here to Help

The Gilead Advancing Access® program is committed to helping you afford your medication every step of the way.

FINANCIAL SUPPORT

- Co-pay Support
- Government Insurance Support
- Uninsured Support

https://www.gileadadvancingaccess.com
Medication Assistance Program
Medication Assistance Program
Medication Assistance Program

ENROLLMENT FORM

I understand that I must complete this enrollment form before I can receive assistance through Gilead Sciences, Inc.’s Advancing Access (“Program”) and the Patient Assistance Program/Medication Assistance Program ("PAP/MAP"). As part of this process, Gilead, the Program’s administrator and contractor (collectively, “Gilead”) will need to obtain, review, use, and disclose my personal and medical information as described below. I hereby authorize my healthcare providers and health plans to disclose my personal and medical information as described below to Gilead in connection with the Program and/or the PAP/MAP, all in accordance with this authorization, and I authorize Gilead to use and disclose the information in accordance with the authorization.

Information to Be Disclosed: Personal health information ("PHI"), including information about me (for example, my name, mailing address, financial information, and insurance information), my past, current and future medical condition (including information about my HIV status or treatment with this prescription medication and related medical condition), and all information provided on this enrollment form.

Persons Authorized to Disclose My Information: My healthcare providers, including any pharmacy that fills my prescription medication, and any health plans or programs that provide me healthcare benefits. I understand that my pharmacy providers may receive remuneration for disclosing my PHI pursuant to this authorization.

Purpose for Which My Information May Be Disclosed: Gilead, including the third party administrator responsible for the administration of the Program and the PAP/MAP.

Signatures and Acknowledgements of Medicine Agreement

By checking the box that indicates that you agree to receive marketing information, offers and educational materials related to my medical condition, treatment, and/or my prescription medication, including the customer relationship marketing program, you indicate that you have read and agree to this authorization.

Patient Representative’s Name (if signing on behalf of patient):

Patient Representative’s Relationship to Patient:

FAX COMPLETED FORM TO ADVANCING ACCESS AT 1-800-216-6857

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State Plans

- Illinois - IDPH PrEP Assistance Program
  - PrEP Navigation, funding for cost assistance through IDPH
- Massachusetts - Massachusetts Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
  - Assistance for copays, co-insurance, full cost of Truvada®
  - Limited to <500% FPL
- Washington - Pre-Exposure Prophylaxis Drug Assistance Program (PrEP-DAP)
  - PrEP Navigation, assistance for medication and cost of labs/visits
  - No income limitation
- New York - Pre-exposure Prophylaxis Assistance Program (PrEP-AP)
  - Assistance for cost of labs and provider visits
  - Enrollment criteria based on AIDS Drug Assistance Program (ADAP)
- California - PrEP Assistance Program (PrEP-AP)
  - Launched early 2018
  - Assistance for cost of labs and provider visits
  - Limited to <500% FPL
Advice to patients

• Find out your deductible
• Find out your Truvada® copay
• Find out your estimated costs of visits and labs
• If you need an insurance plan from the marketplace, avoid Bronze Plans due to high out-of-pocket expenses
• Use Flexible Spending Account to offset any out-of-pocket expenses
# PrEP eligibility

## Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Detecting substantial risk of acquiring HIV infection:</th>
<th>Men Who Have Sex With Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Sexual partner with HIV</td>
<td>• Sexual partner with HIV</td>
<td>• HIV-positive injecting partner</td>
<td></td>
</tr>
<tr>
<td>• Recent bacterial STD</td>
<td>• Recent bacterial STD</td>
<td>• Sharing injection equipment</td>
<td></td>
</tr>
<tr>
<td>• High number of sex partners</td>
<td>• High number of sex partners</td>
<td>• Recent drug treatment (but currently injecting)</td>
<td></td>
</tr>
<tr>
<td>• History of inconsistent or no condom use</td>
<td>• History of inconsistent or no condom use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Commercial sex work</td>
<td>• Commercial sex work</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Lives in high prevalence area or network</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinically eligible:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• Documented negative HIV test before prescribing PrEP</td>
<td>• No signs/symptoms of acute HIV infection</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Normal renal function, no contraindicated medications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Documented hepatitis B virus infection and vaccination status</td>
<td></td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Prescription</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily, continuing, oral dosages of TDF/FTC (Truvada), ≤90 day supply</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other services:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Follow-up visits at least every 3 months to provide:</td>
</tr>
<tr>
<td>• HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STD symptom assessment</td>
</tr>
<tr>
<td>• At 3 months and every 6 months after; assess renal function</td>
</tr>
<tr>
<td>• Every 6 months test for bacterial STDs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Do oral/rectal STD testing</th>
<th>Assess pregnancy intent every 3 months</th>
<th>Access to clean needles/ syringes and drug treatment services</th>
</tr>
</thead>
</table>

## PrEP eligibility

### Summary of Guidance for PrEP Use

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<tr>
<td>Detecting substantial risk of acquiring HIV infection:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Sexual partners</td>
<td>- Recent HIV diagnosis</td>
<td>- History of drug use</td>
</tr>
<tr>
<td>- Recent HIV diagnosis</td>
<td>- High risk of partner involvement</td>
<td>- No condom use</td>
</tr>
<tr>
<td>- History of HIV diagnosis</td>
<td>- No condom use</td>
<td>- Comment</td>
</tr>
<tr>
<td>Clinically eligible:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Do not use PrEP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- No</td>
<td></td>
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<tr>
<td>- No</td>
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<tr>
<td>- Do</td>
<td></td>
<td></td>
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<tr>
<td>Prescription</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other services:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Follow up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- HIV prevention counseling</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- At risk screening</td>
<td></td>
<td></td>
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<tr>
<td>- Early intervention</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Do oral/rectal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### HIRI-MSM Risk Index*

<table>
<thead>
<tr>
<th>Question</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How old are you today (yrs)?</td>
<td>&lt;18 years: 0, 18-28 years: 8, 29-40 years: 5, 41-48 years: 2, ≥49 years: 0</td>
</tr>
<tr>
<td>2. How many men have you had sex with in the last 6 months?</td>
<td>&gt;10 male partners: 7, 6-10 male partners: 4, 0-5 male partners: 0</td>
</tr>
<tr>
<td>3. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man?</td>
<td>1 or more times: 10, 0 times: 0</td>
</tr>
<tr>
<td>4. How many of your male sex partners were HIV positive?</td>
<td>&gt;1 positive partner: 8, 1 positive partner: 4, &lt;1 positive partner: 0</td>
</tr>
<tr>
<td>5. In the last 6 months, how many times did you have insertive anal sex (you were the top) with a man who was HIV positive?</td>
<td>5 or more times: 6, 0 times: 0</td>
</tr>
<tr>
<td>6. In the last 6 months, have you used methamphetamines such as crystal or speed?</td>
<td>Yes: 5, No: 0</td>
</tr>
<tr>
<td>7. In the last 6 months, have you used poppers (amyl nitrate)?</td>
<td>Yes: 3, No: 0</td>
</tr>
</tbody>
</table>

Add down entries in right column to calculate total score.

**To identify sexually active MSM in their practice, we recommend clinicians ask all their male patients a routine question: “In the past (time) have you had sex? (if yes), with men, women, or both?”**

**If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.**


## PrEP eligibility

### Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Men Who Have Sex With Men</th>
<th>Heterosexual Women and Men</th>
<th>Injection Drug Users</th>
</tr>
</thead>
<tbody>
<tr>
<td>Detecting substantial risk of acquiring HIV infection:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Sexual partner is HIV-positive</td>
<td>• Recent or ongoing high-risk sexual activity</td>
<td>• History of needle-sharing no current injection drug use</td>
</tr>
<tr>
<td>• Recent diagnosis of HIV in a current or recent sexual partner</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• History of needle-sharing or recent injection drug use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Community outbreaks of HIV</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Clinically eligible:

- Do you have HIV-risk factors?
- No
- Do you have HIV-risk factors?
- No
- Do you have HIV-risk factors?
- No

### Prescription

### Other services:

- Follow-up care
- HIV testing
- STI testing
- At risk for overdose
- Evacuation protocol
- Do oral/oral

Source: US Public Health Service, Preexposure prophylaxis (PrEP) for the prevention of HIV-1 infection

---

**HIV-MSM Risk Index**

1. How old are you today? <18 years score 0
2. How many sexual partners have you had in the past 6 months? 2-4 score 1
3. In the last 6 months, how often did you use drugs for sex? Never score 0
4. How much were you using drugs for sex in the past 6 months? 2-4 score 1
5. In the last 6 months, how often did you use drugs in other settings? Never score 0
6. In the last 6 months, how often did you have sex with an HIV-positive partner? Never score 0
7. In the last 6 months, how often did you have sex with an HIV-positive (any) partner? Never score 0

---

**Medication Guide**  
TRUVADA (truh-VAD-uh)  
(emtricitabine and tenofovir disoproxil fumarate)

Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

This Medication Guide provides information about two different ways that TRUVADA may be used (see the Medication Guide section “What is TRUVADA?” for important information about how TRUVADA may be used):

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection, and
- to reduce the risk of getting HIV-1 infection in adults who are HIV-negative who are at high risk of acquiring HIV-1 through sexual contact with someone who has HIV-1.

**What is the most important information I should know about TRUVADA?**

If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.

**What are the possible side effects of TRUVADA?**

Other important information for people who take TRUVADA to help reduce their risk of getting HIV-1 infection:

Before taking TRUVADA to reduce your risk of getting HIV-1 infection:

- You must be HIV-negative to start TRUVADA. You must get tested to make sure that you do not already have HIV-1 infection.
- Do not take TRUVADA to reduce the risk of getting HIV-1 unless you are confirmed to be HIV-negative.
- Many HIV-1 tests can miss HIV-1 infection in a person who has recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you have had a flu-like illness within the last month before starting TRUVADA or at any time while taking TRUVADA. Symptoms of new HIV-1 infection include:
  - o fever
  - o fatigue
  - o sore throat
  - o rash

If score is 10 or greater, evaluate for PrEP or other intensive HIV prevention services; If score is 9 or less, provide indicated standard HIV prevention services.
# PrEP eligibility

## Summary of Guidance for PrEP Use

<table>
<thead>
<tr>
<th>Detecting substantial risk of acquiring HIV infection:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Men Who Have Sex With Men</td>
<td>Heterosexual Women and Men</td>
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</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual partners</td>
<td>History of no condom use</td>
<td></td>
</tr>
<tr>
<td>Recent HIV diagnosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High number of sexual partners</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of no condom use</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current injection drug use</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Clinically eligible:
- Do not know their HIV status
- Need to reduce risks of acquiring HIV

### Prescription
- Follow-up visits
- HIV counseling
- At least one negative HIV test
- Evidence of risk behavior

### Other services:
- Do oral/exercise

---

### HIRI-MSM Risk Index*

| 1 | How old are you today? | <18 years | score 0 |
| 2 | How many sexual partners have you had in the past year? |  |  |
| 3 | In the last 3 months, have you had rectal or vaginal sex anal sex without a condom? |  |  |
| 4 | How many times did you have sex with a new sex partner in the past month? |  |  |
| 5 | In the last 3 months, have you had sex with someone you have not met through a sexual networking site or app? |  |  |
| 6 | In the last 6 months, have you had sex with another man in the past 6 months? |  |  |
| 7 | In the last 6 months, have you had sex with someone you met through a sexual networking site or app? |  |  |

---

### Medication Guide

**TRUVADA** (tri-VAD-dah)
(emtricitabine and tenofovir disoproxil fumarate)

**WARNING**

Read this Medication Guide before you start taking TRUVADA and each time you get a refill. There may be new information. This document does not take the place of talking to your healthcare provider about your medical condition or your treatment.

This Medication Guide provides information about two different ways that TRUVADA may be used. (See the Medication Guide section “What is TRUVADA?” for important information about how TRUVADA may be used):

- to treat Human Immunodeficiency Virus-1 (HIV-1) infection,
- to reduce the risk of getting HIV-1 infection in adults who are HIV-negative

**HIV is the virus that causes AIDS (Acquired Immunodeficiency Syndrome).**

**What is the most important information I should know about TRUVADA?**

If you also have hepatitis B virus (HBV) infection and take TRUVADA, your hepatitis B may become worse if you stop taking TRUVADA.

**The USPSTF recommends the following persons be considered for PrEP:**

1. Men who have sex with men, are sexually active, and have one of the following characteristics:
   - A serodiscordant sex partner (i.e., a sex partner living with HIV)
   - A recent sexually transmitted infection (STI) with syphilis, gonorrhea, or chlamydia
   - Inconsistent use of condoms during receptive or insertive anal sex

2. Heterosexual women and men who are sexually active and have one of the following characteristics:
   - A serodiscordant sex partner (i.e., a sex partner living with HIV)
   - Inconsistent use of condoms during sex with a partner whose HIV status is unknown and who is at high risk (e.g., a person who injects drugs or bisexual partners)
   - A recent STI with syphilis or gonorrhea

3. Persons who inject drugs and have one of the following characteristics:
   - Share drug injection equipment
   - Are at risk of sexual acquisition of HIV (see above)

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PrEP eligibility

Anyone with high risk for HIV acquisition, as determined by the patient’s and/or provider’s assessment, in which the risk of Truvada® does not outweigh the benefit.
Recommendation comparisons

- 300 high risk young, black MSM (age 16-29) in Chicago
- 33 HIV acquisitions over 3 years
  - 52% met CDC eligibility for PrEP
  - 85% met HIRI-MSM eligibility for PrEP
  - 94% met drug company eligibility for PrEP

- CDC guidelines: Low sensitivity, specificity (52%)
- Drug company guidelines: High sensitivity, low specificity (15%)
What about U=U?
**U=U**

- Those who have an undetectable viral load have effectively no risk of transmitting the virus.
- This is a consensus of HIV experts worldwide, CDC, NIH, IDSA/HIVMA, common knowledge in the medical community.
- Combined data from 4 studies (HPTN 052, OPPOSITES ATTRACT, PARTNER and PARTNER2)
  - Among sero-discordant couples where the partner living with HIV had a durably undetectable viral load:
    - zero transmission among over a hundred thousand condomless sex acts
    - Results similar in both male-female and male-male partnerships
• Is PrEP necessary in this situation?
  • Consider *durable* viral suppression
    • Contributing factors include adherence, history of virologic failure, follow-up interval of the HIV-positive person
  • Consider non-monogamous sex
    • In U=U studies, HIV transmissions **DID** occur, but were linked to sex between HIV-negative participant and HIV-positive individual not involved in the study
  • *Always* weigh risks and benefits
HIV risk is behavioral, individual, transitional

The only way to know is to ask (and listen)!
PrEP is a PROGRAM

• Not only HIV prevention
• Involves comprehensive sexual healthcare
  • Screening and treatment for STIs
  • Hepatitis A and B vaccination
  • Counseling on STI prevention strategies
The Sexual History

• Patients have sex, *in lots of different ways*.
• Patients may not want to discuss this.
• Providers may not feel comfortable discussing this.

Taking a sexual history is a potentially life-saving intervention.

• Recognize that this is our duty as physicians
• It’s a learnable skill (like all things in medicine)
• With experience comes comfort
Barriers to the Sexual History

• Lack of understanding of relevance of sexual health to overall health
• Uneasiness of clinicians and patients with a difficult and sensitive subject
• Belief it is irrelevant
• Belief it is someone else’s job
• Lack of time
• Fear of offending the patient
• Medical/nursing school curricula design
Sexual History Misconceptions

• The problems with labeling
  • “Married persons do not acquire STIs”
  • “Persons who identify as “straight” only have sex with those of the opposite gender”
  • “Persons who identify as “gay” or “lesbian” only have sex with those of the same gender”

• Persons will an STI will have symptoms
• Persons will voice sexual concerns without prompting
Principles of a comprehensive sexual history

- Ensure privacy and confidentiality.
- Be professional.
- Be open minded and non-judgmental.
- Recognize non-verbal cues.
- Explain procedures and treatments thoroughly.

Effective Communication Skills

- Consider prefacing the sexual history with a short introduction.
- Start with open-ended questions
- Use closed-ended questions to elicit specific information
The Sexual History

• Preface
  • “The rates of sexually transmitted infections continue to increase, especially here in the South. In order to screen you correctly, prevent STIs and keep you healthy, it’s important for me to know how you have sex and with whom.”

  • “Gonorrhea and chlamydia can also live in our rectums and throats, so it’s important for us to test anywhere you might have had an exposure.”
The Sexual History

• “About how many partners have you had in the past 6 months?”
• “Do you have sex with men, women or both?”
• “Are you a top, bottom, or vers?”
  • Top = anal insertive
  • Bottom = anal receptive
  • Vers/versatile = both insertive and receptive
• “Do you have oral sex?”
• “What do you do to prevent STDs?”
• “Are you trying to prevent pregnancy? What do you use for contraception?”
• “Do you use condoms? What percentage of the time would you say you use condoms?”
The Sexual History

• “Are any of your partners HIV-positive?”
  • If so, “do you know if they’re undetectable?”
• “Have any of your partners recently had an STD?”
• “Have you ever had an STD”
• “Have you ever had HIV or STD testing?”
The Sexual History

• “Do you ever use drugs, like poppers or meth, when you have sex?”
• “Do any of your partners make you scared or feel unsafe?”
• “Do you ever have to use sex for things you need, like food or to pay pills?”
The Sexual History

• Also a great time to discuss travel!
• Many people meet sexual partners, or have sex with partners other than long-term partner, during travel
Ready, set, PrEP!
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”
## Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>FTC–TDF (N = 1251)</th>
<th>Placebo (N = 1248)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of patients (%)</td>
<td>no. of patients (%)</td>
<td>no. of events</td>
</tr>
<tr>
<td>Any adverse event</td>
<td>867 (69)</td>
<td>877 (70)</td>
<td>2630</td>
</tr>
<tr>
<td>Any serious adverse event</td>
<td>60 (5)</td>
<td>67 (5)</td>
<td>76</td>
</tr>
<tr>
<td>Any grade 3 or 4 event</td>
<td>151 (12)</td>
<td>164 (13)</td>
<td>248</td>
</tr>
<tr>
<td>Grade 3 event</td>
<td>110 (9)</td>
<td>117 (9)</td>
<td>197</td>
</tr>
<tr>
<td>Grade 4 event</td>
<td>41 (3)</td>
<td>47 (4)</td>
<td>51</td>
</tr>
<tr>
<td>Elevated creatinine level</td>
<td>25 (2)</td>
<td>14 (1)</td>
<td>28</td>
</tr>
<tr>
<td>Headache</td>
<td>56 (4)</td>
<td>41 (3)</td>
<td>66</td>
</tr>
<tr>
<td>Depression</td>
<td>43 (3)</td>
<td>62 (5)</td>
<td>46</td>
</tr>
<tr>
<td>Nausea</td>
<td>20 (2)</td>
<td>9 (&lt;1)</td>
<td>22</td>
</tr>
<tr>
<td>Unintentional weight loss (±5%)</td>
<td>27 (2)</td>
<td>14 (1)</td>
<td>34</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>46 (4)</td>
<td>56 (4)</td>
<td>49</td>
</tr>
<tr>
<td>Bone fracture</td>
<td>15 (1)</td>
<td>11 (&lt;1)</td>
<td>16</td>
</tr>
<tr>
<td>Death</td>
<td>1 (&lt;1)‡</td>
<td>4 (&lt;1)</td>
<td>1</td>
</tr>
<tr>
<td>Discontinuation of study drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanently</td>
<td>25 (2)</td>
<td>27 (2)</td>
<td>26</td>
</tr>
<tr>
<td>Permanently or temporarily</td>
<td>79 (6)</td>
<td>72 (6)</td>
<td>99</td>
</tr>
</tbody>
</table>

* A listing of all laboratory abnormalities and clinical adverse events of grade 2 or higher that were reported in 25 or more subjects (1%) is provided in Tables S9 and S10 in the Supplementary Appendix. FTC–TDF denotes emtricitabine and tenofovir disoproxil fumarate.

† P values were calculated by the log-rank test.

‡ This death was due to a motorcycle accident.
# Adverse Events

## Table 2. Adverse Events

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<tr>
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<th>FTC–TDF (N = 1251)</th>
<th>Placebo (N = 1248)</th>
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</tr>
<tr>
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<td>56 (4)</td>
<td>66</td>
<td>41 (3)</td>
</tr>
<tr>
<td>Nausea</td>
<td>20 (2)</td>
<td>22</td>
<td>9 (&lt;1)</td>
</tr>
<tr>
<td>Unintentional weight loss (≥5%)</td>
<td>27 (2)</td>
<td>34</td>
<td>14 (1)</td>
</tr>
<tr>
<td>Death</td>
<td>1 (&lt;1)‡</td>
<td>1</td>
<td>4 (&lt;1)</td>
</tr>
<tr>
<td>Discontinuation of study drug</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Permanently</td>
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### Table 2. Adverse Events, According to Treatment Group. *

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TDF–FTC (N = 611)</th>
<th>Placebo (N = 608)</th>
<th>P Value†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>no. of participants (%)</td>
<td>no. of events</td>
<td>no. of participants (%)</td>
</tr>
<tr>
<td>Any</td>
<td>557 (91.2)</td>
<td>4357</td>
<td>536 (88.2)</td>
</tr>
<tr>
<td>Any serious</td>
<td>63 (10.3)</td>
<td>68</td>
<td>66 (10.9)</td>
</tr>
<tr>
<td>Grade 3 or 4 only</td>
<td>19 (3.1)</td>
<td>21</td>
<td>29 (4.8)</td>
</tr>
<tr>
<td>At least possibly related to study drug</td>
<td>20 (3.3)</td>
<td>21</td>
<td>27 (4.4)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>231 (37.8)</td>
<td>385</td>
<td>241 (39.6)</td>
</tr>
<tr>
<td>Headache</td>
<td>227 (37.2)</td>
<td>390</td>
<td>226 (37.2)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>92 (15.1)</td>
<td>109</td>
<td>67 (11.0)</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>155 (25.4)</td>
<td>215</td>
<td>156 (25.7)</td>
</tr>
<tr>
<td>Nausea</td>
<td>113 (18.5)</td>
<td>132</td>
<td>43 (7.1)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>69 (11.3)</td>
<td>87</td>
<td>43 (7.1)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>76 (12.4)</td>
<td>93</td>
<td>65 (10.7)</td>
</tr>
<tr>
<td>≥5% Weight loss</td>
<td>75 (12.3)</td>
<td>113</td>
<td>61 (10.0)</td>
</tr>
<tr>
<td>Back pain</td>
<td>57 (9.3)</td>
<td>72</td>
<td>68 (11.2)</td>
</tr>
<tr>
<td>Rash</td>
<td>39 (6.4)</td>
<td>44</td>
<td>42 (6.9)</td>
</tr>
<tr>
<td>Fracture</td>
<td>7 (1.1)</td>
<td>7</td>
<td>6 (1.0)</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>1 (0.2)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>142 (23.2)</td>
<td>219</td>
<td>159 (26.2)</td>
</tr>
<tr>
<td>Hyperamylasemia</td>
<td>315 (51.6)</td>
<td>997</td>
<td>302 (49.7)</td>
</tr>
<tr>
<td>Elevated AST</td>
<td>36 (5.9)</td>
<td>43</td>
<td>38 (6.2)</td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>38 (6.2)</td>
<td>48</td>
<td>43 (7.1)</td>
</tr>
<tr>
<td>Death‡</td>
<td>2 (0.3)</td>
<td>2</td>
<td>4 (0.7)</td>
</tr>
</tbody>
</table>

* ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.
† All P values were calculated with the use of a time-to-first-event analysis (regression analysis of survival data on the basis of the Cox proportional-hazards model), with the exception of the P values for weight loss of 5% or more and death, which were calculated with the use of Fisher’s exact test.
‡ The causes of death in the TDF–FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).
# Adverse Events

<table>
<thead>
<tr>
<th>Adverse Event</th>
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<tbody>
<tr>
<td>Any</td>
<td>557 (91.2)</td>
<td>536 (88.2)</td>
<td>0.003</td>
</tr>
<tr>
<td>Any serious</td>
<td>63 (10.3)</td>
<td>66 (10.9)</td>
<td>0.90</td>
</tr>
<tr>
<td>Grade 3 or 4 only</td>
<td>19 (3.1)</td>
<td>21 (4.8)</td>
<td>0.17</td>
</tr>
<tr>
<td>At least possibly related to study drug</td>
<td>20 (3.3)</td>
<td>27 (4.4)</td>
<td>0.35</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>233 (37.8)</td>
<td>385</td>
<td>0.84</td>
</tr>
<tr>
<td>Dizziness</td>
<td>92 (15.1)</td>
<td>109</td>
<td>0.03</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>155 (25.4)</td>
<td>155 (25.7)</td>
<td>0.72</td>
</tr>
<tr>
<td>Nausea</td>
<td>113 (18.5)</td>
<td>132</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vomiting</td>
<td>69 (11.3)</td>
<td>87</td>
<td>0.008</td>
</tr>
<tr>
<td>Back pain</td>
<td>57 (9.3)</td>
<td>72</td>
<td>0.37</td>
</tr>
<tr>
<td>Rash</td>
<td>39 (6.4)</td>
<td>44</td>
<td>0.81</td>
</tr>
<tr>
<td>Fracture</td>
<td>7 (1.1)</td>
<td>7</td>
<td>0.74</td>
</tr>
<tr>
<td>Elevated creatinine</td>
<td>1 (0.2)</td>
<td>1</td>
<td>1.00</td>
</tr>
<tr>
<td>Hypophosphatemia</td>
<td>142 (23.2)</td>
<td>219</td>
<td>0.65</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>315 (51.6)</td>
<td>997</td>
<td>0.45</td>
</tr>
<tr>
<td>Elevated AST</td>
<td>36 (5.9)</td>
<td>43</td>
<td>0.90</td>
</tr>
<tr>
<td>Elevated ALT</td>
<td>38 (6.2)</td>
<td>48</td>
<td>0.57</td>
</tr>
<tr>
<td>Death‡</td>
<td>2 (0.3)</td>
<td>2</td>
<td>0.45</td>
</tr>
</tbody>
</table>

*ALT denotes alanine aminotransferase, and AST aspartate aminotransferase.
†All P values were calculated with the use of a time-to-first-event analysis (regression analysis of survival data on the basis of the Cox proportional-hazards model), with the exception of the P values for weight loss of 5% or more and death, which were calculated with the use of Fisher’s exact test.
‡The causes of death in the TDF–FTC group were motor vehicle accident (one participant) and suicide (one); the causes of death in the placebo group were motor vehicle accident (two), homicide (one), and cerebrovascular accident (one).
Adverse Events
Adverse Events

Small (2%) but significant decline in estimated creatinine clearance was observed in the TDF/FTC group after taking the drug for, on average, 81 weeks.
Table 3. Bone Mineral Density Scores.*

<table>
<thead>
<tr>
<th>Assessment</th>
<th>T score</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>-0.75</td>
<td>-0.58</td>
<td>0.44</td>
<td>0.53</td>
<td>-0.72</td>
<td>-0.59</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6 mo</td>
<td>-0.77</td>
<td>-0.50</td>
<td>0.33</td>
<td>0.57</td>
<td>-0.84</td>
<td>-0.45</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 mo</td>
<td>-0.79</td>
<td>-0.48</td>
<td>0.33</td>
<td>0.54</td>
<td>-0.77</td>
<td>-0.56</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>18 mo</td>
<td>-0.93</td>
<td>-0.27</td>
<td>0.17</td>
<td>0.77</td>
<td>-0.92</td>
<td>-0.43</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>24 mo</td>
<td>-0.92</td>
<td>-0.13</td>
<td>0.21</td>
<td>0.74</td>
<td>-1.11</td>
<td>-0.37</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>z Score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment</td>
<td>-0.70</td>
<td>-0.54</td>
<td>0.45</td>
<td>0.54</td>
<td>-0.67</td>
<td>-0.54</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6 mo</td>
<td>-0.73</td>
<td>-0.45</td>
<td>0.35</td>
<td>0.58</td>
<td>-0.80</td>
<td>-0.41</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12 mo</td>
<td>-0.72</td>
<td>-0.42</td>
<td>0.34</td>
<td>0.55</td>
<td>-0.74</td>
<td>-0.53</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>18 mo</td>
<td>-0.88</td>
<td>-0.21</td>
<td>0.18</td>
<td>0.78</td>
<td>-0.88</td>
<td>-0.41</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>24 mo</td>
<td>-0.87</td>
<td>-0.13</td>
<td>0.20</td>
<td>0.76</td>
<td>-1.09</td>
<td>-0.28</td>
<td>&lt;0.001</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.
### Significant decline in T scores and z scores for BMD at the forearm, hip, and lumbar spine in participants who received TDF/FTC, as compared with those who received placebo

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Forearm</th>
<th></th>
<th>Hip</th>
<th></th>
<th>Lumbar Spine</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>T score</td>
<td>0.004</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enrollment</td>
<td>-0.75</td>
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Adverse Events

**Table 3. Bone Mineral Density Scores.**

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<tr>
<th>Assessment</th>
<th>Forearm</th>
<th>P Value</th>
<th>Hip</th>
<th>P Value</th>
<th>Lumbar Spine</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
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<td>&lt;0.001</td>
<td></td>
<td>&lt;0.001</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**BUT THIS CAN RECOVER!**

Bone mineral density recovered after 6 months of stopping TDF/FTC in both young and older adults.

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The First Visit

- Labs:
  - HIV Ag/Ab (but if symptoms of acute HIV, get HIV RNA)
  - Basic Metabolic Panel
  - Hepatitis B sAg, sAb
  - Hepatitis C Ab
  - Treponemal IgG
  - Gonorrhea/chlamydia PCR (oral, rectal and urethral)
  - Consider Hepatitis A IgM/IgG given recent outbreak
The Second Visit

- Repeat HIV screen, repeat serum creatinine
- Assess adherence
- Reassess eligibility
- Assess for side effects
- Provide behavioral risk reduction support
- STI screen, if necessary
- 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
- STI screen, if necessary
- 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
## A year of PrEP

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

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

**Prescriptions/Refill authorizations:** 5

**Discussions:** 5+
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”

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

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  • 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”

• Not suggested
  • Z72.52 – High risk homo sexual behavior
Special considerations

- **Pregnant or breastfeeding women**
  - Pregnancy Category B (No known risk)
  - Minimally secreted in breastmilk, not contraindicated in breastfeeding

- **Chronic HBV**
  - TDF and FTC are active against HBV
  - Abrupt withdrawal of TDF/FTC could cause HBV flare
  - Stopping TDF/FTC requires careful monitoring and observation

- **Chronic Renal Failure (eGFR <60mL/min)**
  - Don’t use TDF/FTC; safety has not been adequately determined
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
Descovy®

- Similar to Truvada®
  - Truvada® = tenofovir disoproxil fumarate (TDF) + emtricitabine
  - Descovy® = tenofovir alafenamide (TAF) + emtricitabine
    - Currently approved for HIV treatment, but not PrEP

- TAF achieves high intracellular concentrations, but lower (>10-fold) plasma and tissue concentrations than TDF
  - Lower risk of BMD loss and reduced creatinine clearance
  - Can be used in chronic kidney disease (eGFR >30 mL/min)

Does the lower plasma/tissue concentration affect efficacy as PrEP?
DISCOVER trial - Update

- 5400 MSM and transgender women
- Randomized to Truvada® vs Descovy®
- Descovy® is non-inferior to Truvada® at 48 weeks
- Adverse events similar

Conclusion

• PrEP is a component of primary care
• PrEP is an extremely effective preventive strategy for both HIV and STIs
• Understand PrEP prescribing guidelines
• There are some adverse effects, but PrEP is generally very well-tolerated
• PrEP requires an ongoing patient-doctor relationship
• Sexual history is essential to comprehensive health care
• Ask for help! sean.g.kelly@vumc.org
PrEP Locator

Vanderbilt Infectious Disease Clinic
1211 26th Avenue S
Medical Arts Building
Nashville, TN 37212
615-321-7216
Distance from your location: 0.3 miles

Planned Parenthood Nashville Health Center
412 Dr. D.B. Todd Jr. Blvd
Nashville, TN 37203
615-321-7216
Distance from your location: 1.4 miles

Meharry Community Wellness Center
1005 Dr. D.B. Todd Jr Blvd
Suite 333
Nashville, TN 37209
615-327-5481
Distance from your location: 2 miles

Middle Tennessee Internal Medicine Associates - Tracy Osbourne MD
510 Recovery Road
Suite 201
Nashville, TN 37212
615-803-7080
Distance from your location: 6 miles

Neighborhood Health @ MyHouse
42 Metropolitan Drive
Building 4
Nashville, TN 37211

https://preplocator.org
Questions?