HIV Update: Epidemiology, Pathogenesis, Treatment and PrEp

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Professor of Medicine
Vanderbilt University School of Medicine
Objectives

• After this presentation the attendee should be able to:
  – Describe current epidemiological trends in the HIV epidemic;
  – Describe key points in HIV pathogenesis;
  – Describe current treatment standards;
  – Describe PrEP
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  – Describe key points in HIV pathogenesis;
  – Describe current treatment standards;
  – Describe PrEP

**Secret Objective:** convince you to start screening, testing for HIV and prescribing PrEP as appropriate.
The U.S. HIV Care Continuum

- 40,000 new infections per year

Number of Individuals:

- HIV-Infected: 100%
- HIV-Diagnosed: 87%
- Linked to HIV Care: 75%
- Retained in HIV Care: 57%
- Undetectable Viral Load: 55%
Testing, linkage to care, effective treatment and effective PrEP could stop the epidemic today.
Percentages of Diagnoses of HIV Infection among Adults and Adolescents, by Region and Population of Area of Residence, 2015—United States

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Data for the year 2015 are preliminary and based on 6 months reporting delay. Data exclude persons whose county of residence is unknown.
Percentages of Diagnoses of HIV Infection among Adults and Adolescents, by Population of Area of Residence and Age at Diagnosis, 2015—United States

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Diagnoses of HIV Infection among Men Who Have Sex with Men, by Age Group, 2010–2014—United States and 6 Dependent Areas

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting. Data on men who have sex with men do not include men with HIV infection attributed to male-to-male sexual contact and injection drug use.
United States and 6 Dependent Areas

Note.
Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. All displayed data have been statistically adjusted to account for reporting delays and missing transmission category, but not for incomplete reporting. Data on men who have sex with men do not include men with HIV infection attributed to male-to-male sexual contact and injection drug use.

* Hispanics/Latinos can be of any race.
There is a new epidemic among young MSM college students who have been aware of HIV all their lives.

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* Hispanics/Latinos can be of any race.
• HIV Pathogenesis
Opportunistic Infections in HIV Disease

This graph is idealized. Specific OIs can occur earlier/later and at higher/lower CD4 cell counts.
Primary infection
- Acute HIV syndrome,
  Wide dissemination of virus,
  Seeding of lymphoid organs

Clinical latency

Opportunistic diseases

Constitutional symptoms

Death

CD4+ T-Lymphocyte Count (cells/mm^3)

HIV RNA Copies/mL Plasma

Culturable Plasma Viremia (dilutional titer)
HIV Pathogenesis

• HIV infection disseminates quickly in the host and causes disease in almost all patients, if left untreated.
• Although thought of as an “Immune Deficiency “ disease, other critical factors are involved in generating poor outcomes for patients.
• Effective treatment of HIV ameliorates much of the damage done by the virus.
Treatment
Three Decades of Treatment Issues

• **1980’s**: AIDS described, PCP kills 90% of pts., clinicians develop skills in diagnosing, treating and preventing complications.

• **1990’s**: First effective treatments, patients respond, death rates drop.

• **2000’s**: New toxicities arise, resistance is critical, adherence issues emerge, limitations of therapy become apparent.

• **2007**: Second round of effective antiretroviral agents-integrase and CCR5 inhibitors.

• **2013**: Serious talk of “cure”.

• **2015**: PREP
Targets for HIV Inhibition

**Reverse Transcriptase Inhibitors**
- ZDV, d4T, ddl, 3TC, FTC, ABC, TDF, EFV, NVP, DLV, RLPV, ETRV

**Entry Inhibitors**
- T-20

**Integrase Inhibitors**
- Ralt, Dolut, Elvit

**Protease Inhibitors**
- NFV, SQV, IDV, APV, r/LPV, ATV

Current drugs: More in development
Current Available Medications

- **NRTI’s**: zidovudine, didanosine, stavudine, lamivudine, abacavir, emtricitabine, tenofovir, TAF
- **NNRTI’s**: efavirenz, nevirapine, delavirdine; etravirine, rilpivirine, doravirine
- **PI’s**: indinavir, ritonavir, saquinavir, nelfinavir, fosamprenavir, lopinavir, tipranavir, darunavir
- **Fusion I’s**: enturvidine
- **CCR5 I’s**: maraviroc
- **Integrase I’s**: raltegravir, dolutegravir, elvitegravir, bictegravir
Current Available Medications

• **NRTI’s**: zidovudine, didanosine, stavudine, lamivudine, abacavir, emtricitabine, tenofovir, TAF

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• **Fusion I’s**: enfuvirtide

• **CCR5 I’s**: maraviroc

• **Integrase I’s**: raltegravir, dolutegravir, elvitegravir, bictegravir

Currently most patients can be treated with one or two pills a day. New treatment modalities may include long acting injectables and immune enhanced therapies.
Benefits of Treatment

• Treating people with AIDS greatly improves survival and quality of life.
• Treating people with advanced HIV (200-350 CD4 count) may delay disease progression and improve quality of life.
• Treating people with early HIV (>350 CD4 count) may delay progression of disease and preserve immune function.
• Treating HIV may have important benefits independent of immune function preservation.
Benefits of Treatment

- Treating people with AIDS greatly improves survival and quality of life.
- Treating people with advanced HIV (CD4 count 200-350) may delay disease progression and improve quality of life.
- Treating people with early HIV (CD4 count >350) may delay progression of disease and preserve immune function.
- Treating HIV may have important benefits independent of immune function preservation.

Why Treat all patients?

1) Medications are much less toxic.
2) Treating HIV slows the inflammatory process.
3) Treating HIV decreases the risk of transmission.
PrEP: What about never getting infected in the first place?
James

- 19 year old college freshman, presents to ED with fever, slight headache, some rash and cough.
  - Slightly elevated LFT’s, CXR clear.
    - Sent home with OTC recs for fluids and antipyretics.
- Back to the ED 48 hours later, continued fever, severe malaise and myalgias.
  - HIV serology indeterminant, HIV-1 RNA 2,466,303 copies/ml
James

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James grew up in a small town in East TN. His family PCP knew him well but when James asked him to consider prescribing PrEP, he declined, saying he did not feel comfortable prescribing it.
# Primary Prevention

<table>
<thead>
<tr>
<th>HIV</th>
<th>Myocardial infarction or Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess risk</td>
<td>Take a sexual history</td>
</tr>
<tr>
<td>Laboratory evaluation</td>
<td>Serum creatinine, HIV screen</td>
</tr>
<tr>
<td>Further risk reduction</td>
<td>Condom use, sexual health and substance use counseling, STI screening</td>
</tr>
<tr>
<td>Medication options</td>
<td>Truvada®</td>
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</tbody>
</table>
# Primary Prevention

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<td>Family, social</td>
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<td>history, check cholesterol and</td>
<td>cholesterol and</td>
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<td>diabetes, calculate 10-year</td>
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<td>ASCVD risk by 2013 ACC/AHA</td>
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<td><strong>Laboratory evaluation</strong></td>
<td>Serum creatinine, HIV screen</td>
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<tr>
<td>Comprehensive metabolic panel,</td>
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<td>cholesterol profile, hemoglobin a1c</td>
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<td><strong>Further risk reduction</strong></td>
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<td>Counseling, STI screening,</td>
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<td>Lifestyle and diet modification</td>
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<td>Counseling, treat comorbid</td>
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<td>diabetes), smoking cessation</td>
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<tr>
<td><strong>Medication options</strong></td>
<td>Atorvastatin, Aspirin</td>
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<td>Rosuvastatin</td>
<td>Rosuvastatin, Aspirin</td>
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<td>Pitavastatin</td>
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<td>Simvastatin</td>
<td>Simvastatin, Aspirin</td>
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<td>Fluvastatin</td>
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</tbody>
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**PrEP IS EASY**
Who benefits from PrEP

# Who benefits from PrEP

## 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>
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<tbody>
<tr>
<td>• Sexual partner with HIV</td>
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<td>• Recent bacterial STD</td>
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<td>• History of inconsistent or no condom use</td>
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<td>• Commercial sex work</td>
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<tr>
<td>• Lives in high-prevalence area or network</td>
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<thead>
<tr>
<th>Clinically eligible:</th>
<th>Daily, continuing, oral doses of TDF/FTC (Truvada), &gt;90 day supply</th>
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</thead>
<tbody>
<tr>
<td>• Documented negative HIV test before prescribing PrEP</td>
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<tr>
<td>• No signs/symptoms of acute HIV infection</td>
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<tr>
<td>• Normal renal function, no contraindicated medications</td>
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<tr>
<td>• Documented hepatitis B virus infection and vaccination status</td>
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</tbody>
</table>

## Other services:

- Follow-up visits at least every 3 months to provide:
  - HIV test, medication adherence counseling, behavioral risk reduction support,
  - side effect assessment, STD symptom assessment
- At 3 months and every 6 months after, assess renal function
- Every 6 months test for bacterial STDs

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


## Summary of Guidance for PrEP Use

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<td>• Sexual partner recently diagnosed with HIV or unknown HIV status</td>
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<td>• Recent bacterial STI</td>
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<td>• History of inconsistent condom use</td>
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<td>• Commercial sex</td>
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<tr>
<td>• Documented diagnosis of HIV</td>
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<tr>
<td>• No symptoms of HIV</td>
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<tr>
<td>• Normal CD4 count</td>
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<tr>
<td>• Documented treatment for HIV</td>
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<thead>
<tr>
<th>Prescription</th>
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<td>Date</td>
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<th>Other services:</th>
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<td>Follow-up check-up</td>
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<tr>
<td>HIV test, side effects</td>
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<td></td>
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<tr>
<td>At 3 months</td>
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<td></td>
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<tr>
<td>Every 6 months</td>
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<tr>
<td>Do oral/rectal Sex</td>
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### HIRI-MSM Risk Index*

| 1. How old are you today (yrs)? | 0-17 years | score 0 |
| 18-28 years | score 8 |
| 29-40 years | score 5 |
| 41-48 years | score 2 |
| ≥49 years | score 0 |

| 2. How many men have you had sex with in the last 6 months? | >10 male partners | score 7 |
| 6-10 male partners | score 4 |
| 0-5 male partners | score 0 |

| 3. In the last 6 months, how many times did you have receptive anal sex (you were the bottom) with a man? | 1 or more times | score 10 |
| 0 times | score 0 |

| 4. How many of your male sex partners were HIV positive? | >1 positive partner | score 8 |
| 1 positive partner | score 4 |
| <1 positive partner | score 0 |

| 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? | 5 or more times | score 6 |
| 0 times | score 0 |

| 6. In the last 6 months, have you used methamphetamine such as crystal or speed? | Yes | score 5 |
| No | score 0 |

| 7. In the last 6 months, have you used poppers (amyl nitrate)? | Yes | score 3 |
| No | score 0 |

Add down entries in right column to 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.

Source: US Public Health Service, Preexposure prophylaxis

Who benefits from PrEP

**Summary of Guidance for PrEP Use**

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<td>- Sexual partner of a person known to have, or believed to have, HIV</td>
<td>- Recent bacterial sexually transmitted infection (STI)</td>
<td>- High number of sex partners</td>
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<tr>
<td>- Recent injection drug use</td>
<td>- History of inconsistent condom use</td>
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<td>- Commercial sex work</td>
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**Clinically eligible:**

- Documented HIV infection in sexual partner
- Documented HIV infection in recent sexual partner
- Documented HIV infection in sex partner
- Documented HIV infection in recent sexual partner
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- Documented HIV infection in sex partner
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- Documented HIV infection in sex partner

**Prescription Data:**

- Follow-up laboratory test
- HIV test
- Sexual transmitted infection (STI) test
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months
- At least 6 months

**Other services:**

- Do oral/rectal Sex

Source: US Public Health Service. Preexposure prophylaxis

**HIV-MSM Risk Index**

1. How old are you today (ys)?
   - <18 years: score 0
   - 18-28 years: score 8
   - 29-40 years: score 5
   - 41-48 years: score 2
   - ≥49 years: score 0

2. How many men have you had sex with in the last 6 months?
   - >10 male partners: score 7

3. In the last 6 months, how many times did you have receptive anal sex (you were on the bottom) with a man?
   - score 8

4. How many of your male sex partners were HIV positive?
   - score 0

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?
   - score 5

6. In the last 6 months, have you used methamphetamine, such as crystal or speed?
   - score 2

7. In the last 6 months, have you used poppers (amyl nitrate)?
   - score 0

*To identify sexually active MSM, their male patients a routine question: men, women, or both?"**

**Medication Guide**

TRUVADA® (tru-VAD-a)
(emtricitabine and tenofovir disoproxil fumarate)

**Table**

Read this Medication Guide before you start taking TRUVADA and each time you get a refil. 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 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 HIV is the virus that causes AIDS (Acquired Immune Deficiency 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.

- Don’t stop taking TRUVADA without talking to your healthcare provider.
- Do not stop taking TRUVADA while taking other hepatitis B medicines.
- If your healthcare provider stops TRUVADA, you may need to take hepatitis B medicine for several weeks to control the hepatitis B virus infection.

**Side effects**

- Read the side effects section “What are the possible side effects of TRUVADA?” in this Medication Guide.
- 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 infection unless you are confirmed to be HIV-negative.
    - Many people with HIV-1 infection in people who have recently become infected. If you have flu-like symptoms, you could have recently become infected with HIV-1. Tell your healthcare provider if you had a flu-like illness within the last month before starting TRUVADA or if any time while taking TRUVADA. Symptoms of HIV-1 infection include:
      - Headache
      - Fatigue
      - Muscle or joint pain
      - Shortness of breath
      - Sweating while sleeping
      - Fever
      - Chest pain
      - Nausea
      - New or worsened sores in your mouth or on your lips
      - Rash
      - Color vision changes

Who benefits from PrEP

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.
How well does PrEP work?
iPrEx

44% HIV risk reduction, but 92% risk reduction when taken consistently among MSM and transgender women
TDF2 Study Group

62.2% HIV risk reduction among heterosexual men and women
Partners PrEP Study Team

75% HIV risk reduction among heterosexual sero-discordant couples, 90% among those with detectable drug levels
48.9% risk reduction, but 74% HIV risk reduction when taken consistently, among IDUs (TDF only)
On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection

Jean-Michel Molina, M.D., Catherine Capitant, M.D., Bruno Spire, M.D., Ph.D., Gilles Pialoux, M.D., Laurent Cotte, M.D., Isabelle Charreau, M.D., Cécile Tremblay, M.D., Jean-Marie Le Gall, Ph.D., Eric Cua, M.D., Armelle Pasquet, M.D., François Raffi, M.D., Claire Pintado, M.D., Christian Chidiac, M.D., Julie Chas, M.D., Pierre Charbonneau, M.D., Constance Delaugerre, Pharm.D., Ph.D., Marie Suzan-Monti, Ph.D., Benoî de Loze, B.S., Julien Fonsart, Pharm.D., Gilles Peytavin, Pharm.D., Antoine Cheret, M.D., Ph.D., Julie Timsit, M.D., Gabriel Girard, Ph.D., Nicolas Lorente, Ph.D., Marie Préau, Ph.D., James F. Rooney, M.D., Mark A. Wainberg, Ph.D., David Thompson, B.C.L., LL.B., Willy Rozenbaum, M.D., Veronique Doré, Ph.D., Lucie Marchand, B.S., Marie-Christine Simon, B.S., Nicolas Etiën, B.S., Jean-Pierre Aboulker, M.D., Laurence Meyer, M.D., Ph.D., and Jean-François Delvailly, M.D., for the ANRS IPERGAY Study Group.


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 (2499)</td>
<td>Daily</td>
<td>44% (92% with ideal adherence)</td>
</tr>
<tr>
<td>TDF2</td>
<td>Heterosexual men and women (1219)</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 (4758 couples)</td>
<td>Daily</td>
<td>75% (90% with ideal adherence)</td>
</tr>
<tr>
<td>Bangkok Tenofovir Study Group</td>
<td>Intravenous drug users (2413)</td>
<td>Daily</td>
<td>48.9% (74% with ideal adherence)</td>
</tr>
<tr>
<td>IPERGAY</td>
<td>MSM (400)</td>
<td>On-demand</td>
<td>86%</td>
</tr>
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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.
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.

Low PrEP Uptake

• Based on the most recent CDC estimates, only 27% of providers who care for HIV+ AND HIV-patients have ever prescribed PrEP.

• Among other recent national surveys, low numbers of primary healthcare providers reported providing PrEP (9%-35%).


Provider Barriers to PrEP

- Insufficient evidence;
- Inexperience;
- Cost Prohibitive;
- Not a primary care activity;
- Sexual history taking issues;
- Fear of non-adherence, resistance and sexual risk compensation.
...Ready for it?

- Inquiring about a sexual history and sexual health counseling are part of primary care.
  - You already do that!
- The most important tool for assessing HIV risk is your clinical sense.
  - You already have that!
- Basic labs are required for Truvada® prescriptions.
  - You already do that!
- Most common medications, like Truvada®, require follow-up and monitoring.
  - You already do that!
Ready, set, PrEP!
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”
## 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>
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<tbody>
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<td>no. of patients (%)</td>
<td>no. of events</td>
<td>no. of patients (%)</td>
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<td>867 (69)</td>
<td>2630</td>
<td>877 (70)</td>
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<tr>
<td>Any serious adverse event</td>
<td>60 (5)</td>
<td>76</td>
<td>67 (5)</td>
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<tr>
<td>Any grade 3 or 4 event</td>
<td>151 (12)</td>
<td>248</td>
<td>164 (13)</td>
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<tr>
<td>Grade 3 event</td>
<td>110 (9)</td>
<td>197</td>
<td>117 (9)</td>
</tr>
<tr>
<td>Grade 4 event</td>
<td>41 (3)</td>
<td>51</td>
<td>47 (4)</td>
</tr>
<tr>
<td>Elevated creatinine level</td>
<td>25 (2)</td>
<td>28</td>
<td>14 (1)</td>
</tr>
<tr>
<td>Headache</td>
<td>56 (4)</td>
<td>66</td>
<td>41 (3)</td>
</tr>
<tr>
<td>Depression</td>
<td>43 (3)</td>
<td>46</td>
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<tr>
<td>Nausea</td>
<td>20 (2)</td>
<td>22</td>
<td>9 (&lt;1)</td>
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<tr>
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<td>27 (2)</td>
<td>34</td>
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</tr>
<tr>
<td>Diarrhea</td>
<td>46 (4)</td>
<td>49</td>
<td>56 (4)</td>
</tr>
<tr>
<td>Bone fracture</td>
<td>15 (1)</td>
<td>16</td>
<td>11 (&lt;1)</td>
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<tr>
<td>Death</td>
<td>1 (&lt;1)‡</td>
<td>1</td>
<td>4 (&lt;1)</td>
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<tr>
<td>Discontinuation of study drug</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Permanently</td>
<td>25 (2)</td>
<td>26</td>
<td>27 (2)</td>
</tr>
<tr>
<td>Permanently or temporarily</td>
<td>79 (6)</td>
<td>99</td>
<td>72 (6)</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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<td>66</td>
<td>41 (3)</td>
</tr>
</tbody>
</table>

| Nausea                               | 20 (2)             | 22                 | 9 (<1)    | 10          | 0.04     |

| Unintentional weight loss (≥5%)     | 27 (2)             | 34                 | 14 (1)    | 19          | 0.04     |
| Diarrhea                             | 46 (4)             | 49                 | 56 (4)    | 61          | 0.36     |
| Bone fracture                        | 15 (1)             | 16                 | 11 (<1)   | 12          | 0.41     |
| Death                                | 1 (<1)‡            | 1                  | 4 (<1)    | 4           | 0.18     |
| Discontinuation of study drug       |                    |                    |          |             |          |
| Permanently                          | 25 (2)             | 26                 | 27 (2)    | 33          | 0.82     |
| Permanently or temporarily          | 79 (6)             | 99                 | 72 (6)    | 92          | 0.49     |

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<td>Discontinuation of study drug</td>
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<td>Permanently</td>
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<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TDF-FTC (N=611)</th>
<th>Placebo (N=608)</th>
<th>P Value†</th>
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<tr>
<td></td>
<td>no. of</td>
<td>no. of</td>
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<td></td>
<td>participants (%)</td>
<td>events</td>
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<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>
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<tr>
<td>Headache</td>
<td>227 (37.2)</td>
<td>390</td>
<td>226 (37.2)</td>
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<tr>
<td>Dizziness</td>
<td>92 (15.1)</td>
<td>109</td>
<td>67 (11.0)</td>
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<tr>
<td>Abdominal pain</td>
<td>155 (25.4)</td>
<td>215</td>
<td>156 (25.7)</td>
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<td>Nausea</td>
<td>113 (18.5)</td>
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<td>43 (7.1)</td>
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<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>
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<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>Hyperuricemia</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 2. Adverse Events, According to Treatment Group.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>TDF-FTC (N=611)</th>
<th>Placebo (N=600)</th>
<th>P Value†</th>
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<td>no. of participants (%)</td>
<td>no. of events</td>
<td>no. of participants (%)</td>
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<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>
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<td>385</td>
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</tr>
</tbody>
</table>

Dizziness: 92 (15.1) 109 67 (11.0) 82 0.03

Abdominal pain: 155 (25.4) 215 156 (25.7) 217 0.78
Nausea: 113 (18.5) 132 43 (7.1) 48 <0.001
Vomiting: 69 (11.3) 87 43 (7.1) 47 0.008
Diarrhea: 76 (12.4) 93 65 (10.7) 76 0.22
≥5% Weight loss: 75 (12.2) 113 61 (10.0) 72 0.13
Back pain: 57 (9.3) 72 68 (11.2) 90 0.37
Rash: 39 (6.4) 44 42 (6.9) 48 0.81
Fracture: 7 (1.1) 7 6 (1.0) 8 0.74
Elevated creatinine: 1 (0.2) 1 0 0 1.00
Hypophosphatemia: 142 (23.2) 239 159 (26.2) 245 0.65
Hyperamylasemia: 315 (51.6) 997 302 (49.7) 1017 0.45
Elevated AST: 36 (5.9) 43 38 (6.2) 42 0.90
Elevated ALT: 38 (6.2) 48 43 (7.1) 66 0.57
Death: 2 (0.3) 2 4 (0.7) 4 0.45

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# Adverse Events

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<tr>
<td>Fracture</td>
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<tr>
<td>Elevated creatinine</td>
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<tr>
<td>Death†</td>
<td>2</td>
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<td>4</td>
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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.
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

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
  – (with the recent hepatitis A outbreak, consider hepatitis A IgM/IgG)
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
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+
PrEP resources for patients
PrEP resources for patients

About Truvada

Truvada (tenofovir and emtricitabine) is a medicine used to treat human immunodeficiency virus (HIV) and hepatitis B virus infection. It is also used to prevent HIV infection. When you take Truvada to prevent HIV infection, this is called “pre-exposure prophylaxis” or “PrEP.”

How does Truvada help prevent HIV infection?
If you take Truvada daily, it can sometimes stop the virus from spreading through your body. It does not work all the time, so you should still use condoms during sex to get the most protection from HIV infection.

How should Truvada be used?
- You must take one Truvada tablet by mouth every day.
- Follow the directions on your prescription label carefully. Ask your doctor or pharmacist to explain any part you do not understand.
- Do not stop taking Truvada without talking to your doctor. When you stop to miss doses, contact your doctor or pharmacist to get more.
- You may be at higher risk of getting infected with HIV if you miss doses or stop taking Truvada than if you take it every day.

Is there anything I should do before I start taking Truvada?
Tell your doctor and pharmacist:
- If you are allergic to tenofovir, emtricitabine, or any other medicines
- About all the medicines and herbal products you take, including vitamins, nutritional supplements, and herbal products.

Tell your doctor:
- If you have or ever had kidney or liver disease.
- If you become pregnant or you are breastfeeding.

What should I eat while taking this medicine?
Eat your normal diet unless your doctor tells you something else.

What should I do if I forget a dose?
Take the missed dose as soon as you remember it. It is almost time for the next dose, skip the missed dose and keep to your normal dosing schedule. Do not take a double dose to make up for a missed dose.

(continued)
PrEP resources for patients

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How should Truvada be used?

• You should take one Truvada tablet each day.

• Follow the directions on your prescription label carefully. Ask your doctor or pharmacist to explain any part you do not understand.

• Do not stop taking Truvada without talking to your doctor. When you start to take Truvada, follow your doctor’s instructions about how to get Truvada for the first time.

• You may have a higher risk of getting infected with HIV if you start Truvada or stop taking Truvada than if you take it every day.

Vanderbilt University Medical Center

HIV Pre-Exposure Prophylaxis (PrEP)

Action Plan

Welcome to the Comprehensive Care Center at Vanderbilt University Medical Center. Our dedicated team of physicians are here to guide you through getting started on Pre-Exposure Prophylaxis (PrEP) to reduce your risk of acquiring HIV. While you are on PrEP, we will be working together to make sure you receive the best care and access to medication.

We are here to answer any questions or concerns during your treatment.

What's next?

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

PrEP is prescribed based on labs and your choice

- Pharmacist completes any necessary insurance requirements and sends you up with a copy card if possible.

PrEP is filled and shipped to you by the Specialty Pharmacy (your insurance may require you to fill through a different pharmacy).

Contact information:
Vanderbilt Comprehensive Care Center: (615) 935-5311
Wigmore Specialty Pharmacy: (855) 631-888
PrEP resources for patients
PrEP resources for patients

About Truvada

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You must take one Truvada tablet every day.

Follow the directions on your prescription label carefully. Ask your doctor or pharmacist if you do not understand any of them.

Do not stop taking Truvada without talking to your doctor. When you start to take Truvada, your condition may get worse. You may be at higher risk of getting sick if you stop taking Truvada than if you take it every day.

HIV Pre-Exposure Prophylaxis (PrEP) Action Plan

Welcome to the Comprehensive Care Center at Vanderbilt Medical Center. Our dedicated team of physicians through getting started on Pre-Exposure Prophylaxis (PrEP) can help reduce your risk of acquiring HIV. While you are on PrEP, we are here together to make sure you receive the best care.

What’s next?

Contact Information:
Vanderbilt Comprehensive Care Center: (615) 343-1151
Vanderbilt Specialty Pharmacy: (615) 322-1622

Agreement Form

For Initiating Truvada® for Pre-exposure Prophylaxis (PrEP)

Instructions:

Review form with an HIV-negative person who is interested in discussing PrEP. An HIV-negative person should be taking Truvada for PrEP at each visit. Form is in the patient’s medical record.

Truvada is indicated in prophylaxis (PrEP) to reduce the risk of HIV infection. The following factors may increase risk:

- Patients who are inconsistent about taking the drug
- Diagnosis of sexually transmitted infections
- Exchange of sex for money
- Use of illicit drugs (specifically methamphetamine and other drugs)
- Incest
- Partner(s) of unknown HIV status

Healthcare Provider Agreement

By signing below, I certify that I have reviewed the guidelines for the use of Truvada in PrEP and the risks and benefits of Truvada and the appropriate management of Truvada for PrEP and have discussed these with the patient.

Healthcare Provider’s Signature

Date

Learn More About PrEP

AIDS.gov – PrEP information page: https://www.aids.gov/pre-exposure-prophylaxis-prеп

AIDSInfo (https://www.aidsinfo.nih.gov/ContentFiles/PrEP.pdf)

AVAC (https://www.avac.org/prevention/aids-prevention/learn)


CDC (https://www.cdc.gov/mmwr/volumes/62/wr/mm6219e1.htm)


PrepTalk (https://www.preptalk.org)

Preventing for HIV Prevention (https://www.preptalk.org)

PrEPWatch (https://www.preptalk.org)

Project Inform (https://www.projectinform.org/preep)

SAP – City of San Francisco Department of Public Health’s PrEP Information page (https://sfgov.org/sap/preepprogram)

Talk PrEP (http://www.sfgov.org/sap/preepprogram)

Guideline for Use of PrEP in Practice and Research Settings

WAC – Women’s AIDS Coalition (https://www.wacff.org/public/seasons_article/)

CDC – Centers for Disease Control and Prevention (https://www.cdc.gov/hiv/diagnosis/prep/prep.html)

From the Makers of Truvada

https://www.truvada.com – Information about Truvada for healthcare providers, consumers and educators

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

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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"

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

• Not suggested:
  – Z72.32 High risk homosexual behavior
PrEP Conclusions

• PrEP is an extremely effective preventive strategy
• Many PrEP barriers exist, but can *easily* be overcome
• Understand PrEP prescribing guidelines
• Evaluate individual clinic needs
• Identify individual beliefs and perceptions
• Ask for help!
  sean.g.kelly@vanderbilt.edu
• steve.raffanti@vanderbilt.edu
AIDS 1985- One Patient’s Experience

- 322 IV insertions
- 14 hospital admissions
- 11 months of hospital stay
- 60 phlebotomies
- 32 chest x-rays
- 5 CT scans of head
- 3 abdominal ct scans
- 6 bronchoscopies
- 8 intubations
- 4 lumbar punctures
- 3 bone marrows
- 5 cycles of chemo
- 2 lymph node bx
AIDS 1985- One Patient’s Experience

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- 14 hospital admissions
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- 32 chest x-rays
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- 3 abdominal CT scans
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- 5 cycles of chemo
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If Pablo were to present with his HIV infection today, he would have labs drawn, be started on a pill to treat HIV and his wife would be started on PrEP. He would raise his kids and live out his life.
Useful HIV Websites

www.seatc.com
www.vanderbilthealth.com/vccc
www.aidsinfonet.org
www.aidsetc.org
www.hivatis.org (DHHS, USPHS/IDSA Guidelines)
www.cdc.gov/nchstp/hiv_aids.htm
www.hiv-web.lanl.gov (Resistance mutations)
www.niaid.nih.gov
www.AIDS.medscape.com
www.hopkins-aids.edu
www.iapac.org
www.igm.gov
www.ucsf.edu/medical
www.virology.net
Questions?