National Native HIV/AIDS Awareness Day 2021: PrEP-ing Native Communities

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Mathiesen Memorial Health Clinic, Jamestown, Ca

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Disclaimer

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Disclosures

- Speaker - Gilead HCV Division
- Speaker - IHS
Learning Objectives

- How to start a PrEP program
- Define epidemiology, risk factors and screening for of HIV
- Define the difference between PEP and PrEP
- Learn how to talk to patients about PEP and PrEP
- Learn how to initiate and follow PrEP
- Identify resources for PrEP support
How did I get here?
Santa Clara University, BSC Marketing 1991
IF “Plan A” Didn’t Work. 
The alphabet has 25 more letters! Stay Cool.
Finding my inspiration
...in the smallest places
…and the most precious faces.
Plan B

- Case Western Reserve University BS Nursing 1995

- Case Western Reserve University MSN, ND 1997
  - Sigma Theta Tau Honor Society
  - Suma Cum Laude
  - Alumni Award for Clinical Excellence

- Sonoma State University Post Masters FNP 2000
Where am I?
Mathiesen Memorial Health Clinic

- Chicken Ranch Rancheria of MiWuk Indians
- Community/Tribal Primary Care Center
- Yoga, Acupuncture
- Diabetes Education group*
- Healthy Eating Group*
- Hepatitis C Group*
- Caregiver Support Group*
- Psychology Services
- MAT
- Pediatrics
- Allergy/Asthma
- Dermatology

*Prior to COVID
What am I doing?

- Treat Hepatitis B & C, and all fashion of Liver disease and GI diagnoses
- MAT
- HIV/PrEP
- Primary care
- Receive outside referrals as the specialist for liver care
- Transgender/Two Spirit support
The success of any program lies in the support of the administration allowing the provider time to build the skills necessary to care for patients. Critical to the success is a knowledgeable team in place to minimize errors, produce smooth workflow and effectively case manage patients.
What do you need?
Knowledge and Support!

Knowledge
• About your patient and how to use the knowledge
• About talking to patients
• About identifying eligible patients
  ▪ About what to prescribe
  ▪ About how to successfully prescribe
  ▪ About how to follow patients

Support
• In building systems that work to simplify monitoring and following patients
• For education of providers, staff and patients
OUTLINE

Epidemiology

PEP vs PrEP

nPEP

PrEP

Treatment as prevention

Talking to patients
OUTLINE

Epidemiology
HIV Prevalence and Incidence in the United States

- An estimated 1.04 million people aged 13 and older had HIV infection in 2018

HIV incidence rate per 100,000 people, 2018

<table>
<thead>
<tr>
<th>Year</th>
<th>Incidence Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>40,091</td>
</tr>
<tr>
<td>2014</td>
<td>40,796</td>
</tr>
<tr>
<td>2015</td>
<td>40,514</td>
</tr>
<tr>
<td>2016</td>
<td>40,201</td>
</tr>
<tr>
<td>2017</td>
<td>38,789</td>
</tr>
<tr>
<td>2018</td>
<td>37,881</td>
</tr>
</tbody>
</table>

*Data include diagnoses from the United States and six dependent areas.

Number of People Living with HIV by County for the State of Kansas as of December 31, 2018

This map reflects the number of persons living in Kansas who have been diagnosed with HIV. Last reported address was utilized to determine residency. If the last reported county variable was unknown, that individual will not be reflected in this map.
HIV Prevalence and Incidence by Age in the United States

HIV prevalence, by age, 2018*

Persons living with diagnosed HIV infection

Age

HIV incidence, by age, 2018*

Diagnoses of HIV infection

Age

*Data include diagnoses from the United States and six dependent areas.

The overall lifetime risk of HIV in the United States is 1 in 106, but the risk is higher in certain races and ethnicities. Racial disparities along the HIV care continuum might reflect differences in access to and use of health care and treatment.
**Estimated Per-Act Probability of Acquiring HIV, by Exposure Act***

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Risk per 10,000 Exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parenteral</strong></td>
<td></td>
</tr>
<tr>
<td>Blood Transfusion</td>
<td>9,250</td>
</tr>
<tr>
<td>Needle-sharing Injection Drug Use</td>
<td>63</td>
</tr>
<tr>
<td>Percutaneous Needle Stick</td>
<td>23</td>
</tr>
<tr>
<td><strong>Sexual risk</strong>*</td>
<td></td>
</tr>
<tr>
<td>Receptive Anal Intercourse (bottom)</td>
<td>138</td>
</tr>
<tr>
<td>Insertive Anal Intercourse (top)</td>
<td>11</td>
</tr>
<tr>
<td>Receptive Penile-Vaginal Intercourse</td>
<td>8</td>
</tr>
<tr>
<td>Insertive Penile-Vaginal Intercourse</td>
<td>4</td>
</tr>
<tr>
<td>Receptive or Insertive oral sex</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Other^</strong></td>
<td></td>
</tr>
<tr>
<td>Biting/Spitting</td>
<td>Negligible</td>
</tr>
<tr>
<td>Throwing Body Fluids (Including Semen or Saliva)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Sharing Sex Toys</td>
<td>Negligible</td>
</tr>
</tbody>
</table>

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and pre-exposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

^ HIV transmission through these exposure routes is technically possible but unlikely and not well documented.

Understanding the Link Between STIs and HIV-1 Risk

STIs are associated with increased acquisition and transmission of HIV

- Adolescents with STIs are at an increased risk of subsequent HIV infection and the risk increases with the number of STI diagnoses
  - For males and females, **HIV risk is doubled** in those who had an STI reported
  - In adolescent females, HIV risk is nearly **5 times as high** for those with 3 or more chlamydia episodes

- Higher HIV risk in adult MSM following an STI diagnosis
  - Those who have receptive anal sex are more susceptible to STIs due to thin lining of the rectal mucosa
  - **1 in 15** MSM with rectal chlamydia and/or gonorrhea were diagnosed with HIV within a year
  - **1 in 20** MSM with primary and secondary syphilis were diagnosed with HIV within a year

STI: sexually transmitted infection; MSM: men who have sex with men


MAT, HCV Treatment and PrEP as risk reduction

**MAT**
Medically Assisted Treatment for opiate use disorder
- Suboxone
- Decrease risk of re-exposure to blood borne pathogens
- Improved functionality

**HCV**
Hepatitis C Treatment/Cure
- Multiple treatment regimens
- Can cure HCV
- Improves overall morbidity and mortality

**PrEP/PEP**
Pre-Exposure Prophylaxis/Post Exposure Prophylaxis
- Prevention of HIV transmission/infection
Effectiveness of Prevention Strategies to Reduce the Risk of Acquiring or Transmitting HIV

The CDC provided updated best estimates of the effectiveness for various HIV prevention strategies when used optimally

- PrEP is 99% effective in MSM and heterosexual men and women with “optimal or consistent use” as defined by the CDC:
  - Taking PrEP medication daily or at least 4 days/week
- Only three cases of seroconversion have been confirmed to date worldwide while HIV-negative individuals were on PrEP medication with verified adherence
- TasP (U=U) is 100% effective
- The effectiveness of condom use is variable:
  - 63% MSM IAI
  - 72–91% MSM RAI
  - 80% heterosexual men and women
- On-demand dosing in MSM provided 86% effectiveness in IPERGAY randomized trial and 97% in open label extension

Oral daily PrEP is 99% effective when used optimally

*Efficacy data for prevention of sexual transmission and does not include injection drug use.

MSM, men who have sex with men; IAI, insertive anal intercourse; RAI, receptive anal intercourse; TasP: treatment as prevention; U=U, undetectable = untransmittable

1. Estimates likely underestimate the effectiveness of condoms when used consistently and correctly in practice due to measurement error regarding both consistent and correct use.

Mortality in the Highly Active Antiretroviral Therapy Era

AIDS-related death and disease rates have declined in the highly active antiretroviral therapy era and remain low.

Who Should be Screened for HIV Infection?

- CDC recommends everyone between the ages of 13 and 64 get tested for HIV at least once
- Most new diagnoses of HIV infection are attributed to male-to-male sexual contact; injection drug use is another important risk factor
- Additional risk factors include having anal intercourse without a condom, having vaginal intercourse without a condom and with more than 1 partner whose HIV status is unknown, exchanging sex for drugs or money (transactional sex), having other sexually transmitted infections or a sex partner with a sexually transmitted infection, and having a sex partner who is living with HIV or is in a high-risk category

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant persons</td>
<td>The USPSTF recommends that clinicians screen for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.</td>
<td>A</td>
</tr>
<tr>
<td>Adolescents and adults aged 15 to 65 years</td>
<td>The USPSTF recommends that clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened.</td>
<td>A</td>
</tr>
</tbody>
</table>


HIV Testing: Point-of-Care and At-Home

Specimen types most commonly used with FDA approved tests:

- Whole Blood
- Plasma/Serum
- Oral Fluid
- Urine
Recommendations for Repeat HIV Testing

- Testing should be repeated at least annually in persons who meet any of the following criteria\(^1\):
  - is a man who has sex with men (MSM)
  - has a sex partner who is living with HIV
  - has >1 partner since last HIV test
  - has shared needles
  - exchanged sex for money or drugs
  - diagnosed with another sexually transmitted disease
  - diagnosed with hepatitis or tuberculosis
  - for persons who live or receive medical care in a high-prevalence setting, such as a sexually transmitted disease clinic, tuberculosis clinic, correctional facility, or homeless shelter.\(^2\)

- Testing in sexually active MSM should be more frequent (every 3 to 6 months)\(^1\)

- The CDC and the American College of Obstetricians and Gynecologists recommend repeat prenatal screening for HIV during the third trimester of pregnancy in women with risk factors for HIV acquisition and in women living or receiving care in high-incidence settings.\(^2\)
  - repeat screening for HIV during the third trimester may be considered in all women.

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Ending HIV as an Epidemic: How Do We Get There from Here?

Modern HIV prevention efforts begin with HIV testing and focus on both the linkage and treatment of individuals living with HIV and identifying HIV-negative individuals at risk.
PEP vs PrEP
Fancy a PEP talk?
If you have taken a risk, PEP can stop HIV before it starts.
Ask us how.
PrEP vs. PEP

PrEP and PEP are methods for preventing HIV infection that involve taking HIV medicines. When you take steps to protect yourself against a disease, like HIV, it’s called prophylaxis.

PrEP and PEP are for people who don’t have HIV, but are at risk of getting it.

**What’s it called?**

<table>
<thead>
<tr>
<th>PrEP</th>
<th>PEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>stands for pre-exposure prophylaxis.</td>
<td>stands for post-exposure prophylaxis.</td>
</tr>
</tbody>
</table>

**Who’s it for?**

<table>
<thead>
<tr>
<th>PrEP</th>
<th>PEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>is for people who don’t have HIV and:</td>
<td></td>
</tr>
<tr>
<td>• have a sex partner with HIV</td>
<td></td>
</tr>
<tr>
<td>• have sex with people whose HIV status is unknown</td>
<td></td>
</tr>
<tr>
<td>• share injection drug equipment</td>
<td>is for people who don’t have HIV but may have been exposed:</td>
</tr>
<tr>
<td></td>
<td>• during sex</td>
</tr>
<tr>
<td></td>
<td>• at work through a needlestick or other injury</td>
</tr>
<tr>
<td></td>
<td>• by sharing injection drug equipment</td>
</tr>
<tr>
<td></td>
<td>• during a sexual assault</td>
</tr>
</tbody>
</table>

**When is it taken?**

<table>
<thead>
<tr>
<th>Before HIV exposure.</th>
<th>After HIV exposure.</th>
</tr>
</thead>
<tbody>
<tr>
<td>PrEP is taken every day, before possible exposure.</td>
<td>In emergency situations, PEP is taken within 72 hours (3 days) after possible exposure.</td>
</tr>
</tbody>
</table>

**How effective is it?**

<table>
<thead>
<tr>
<th>PrEP</th>
<th>PEP</th>
</tr>
</thead>
<tbody>
<tr>
<td>can reduce the risk of getting HIV from sex by more than 90% and from injection drug use by more than 70%.</td>
<td>can prevent HIV infection when taken correctly, but it is not always effective. Start PEP as soon as possible to give it the best chance of working.</td>
</tr>
</tbody>
</table>

Talk to your health care provider about whether a prescription for PrEP or PEP is right for you.
PEP vs PrEP

Exposure Event: Condom Breaks

PEP: 28-day ARV course started AFTER exposure

Days

No ARV Coverage

PEP: 28-day ARV course started AFTER exposure

Exposure Event: Condomless sex with undiagnosed HIV(+) partner who states they are HIV(-)

No ARV Coverage

Exposure Event: Condomless sex with undiagnosed HIV(+) partner who states they are HIV(-)

PrEP: Daily ARV use started BEFORE exposure

Days

0 10 20 30 40 50 60 70 80 90

Exposure Event: Condomless sex

Exposure Event: Condomless sex

Exposure Event: Condom Breaks

Exposure Event: Condom Breaks
Biomedical Interventions to Prevent HIV

<table>
<thead>
<tr>
<th>TIME OF EXPOSURE</th>
<th>PREVENT ACQUIRING INFECTION</th>
<th>TREAT HIV AND PREVENT TRANSMITTING INFECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PEP¹,²</strong></td>
<td>Use of a full regimen of ARV medications after an uninfected person has come into contact with bodily fluids that represent a substantial HIV risk</td>
<td>Use of ART by an HIV-positive individual to suppress viral load in bodily fluids, has effectively no risk of sexually transmitting HIV to HIV-negative partners</td>
</tr>
<tr>
<td><strong>PrEP³</strong></td>
<td>Use of daily ARV medications to reduce the risk of HIV infection in HIV-negative individuals at risk for acquiring HIV-1 before a sexual exposure occurs</td>
<td></td>
</tr>
<tr>
<td><strong>TasP⁴</strong></td>
<td>Two drugs, used along with regular HIV/STI testing, as well as periodic counseling and support around adherence and sexual behavior</td>
<td></td>
</tr>
</tbody>
</table>

OUTLINE

nPEP
What is PEP?

PEP (post-exposure prophylaxis) means taking medicine to prevent HIV after a possible exposure.

PEP Must Be Started Within 72 Hours of Possible Exposure to HIV

Talk right away (within 72 hours) to your health care provider, an emergency room doctor, or an urgent care provider about PEP if you think you’ve recently been exposed to HIV:
• during sex (for example, if the condom broke),
• through sharing needles, syringes, or other equipment to inject drugs (for example, cookers), or
• if you’ve been sexually assaulted.

The sooner you start PEP, the better. Every hour counts. If you’re prescribed PEP, you’ll need to take it daily for 28 days.

www.cdc.gov/hiv/basics/pep
PEP is for Emergency Situations
• PEP is given after a possible exposure to HIV.
• PEP is not a substitute for regular use of other HIV prevention.
• PEP is not the right choice for people who may be exposed to HIV frequently.
• If you are at ongoing risk for HIV, such as through repeated exposures to HIV, talk to your health care provider about PrEP (pre-exposure prophylaxis).

How well does PEP work?
If taken within 72 hours after possible exposure, PEP is highly effective (89%) in preventing HIV. But to be safe, you should take other actions to protect your partners while you are taking PEP. This includes always using condoms with sexual partners and not sharing needles, syringes, or other equipment to inject drugs.

Are there any side effects?
• PEP is safe but may cause side effects like nausea in some people.
• In almost all cases, these side effects can be treated and aren’t life-threatening.

• www.cdc.gov/hiv/basics/pep
PEP Regimens

- The preferred regimen for otherwise healthy adults and adolescents
  - Tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) with emtricitabine (200 mg) once daily
  - plus
  - Raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily.

- Alternative regimen for otherwise healthy adults and adolescents is
  - Tenofovir DF (300 mg) with emtricitabine(FTC) (200 mg) once daily
  - plus
  - Darunavir (DRV)(800 mg) and ritonavir (RTV) (100 mg) once daily

stacks.cdc.gov/view/cdc/38856
Transitioning from nPEP to PrEP*

- Possible nPEP to PrEP Candidates: Patients with repeated courses of nPEP (>2x) in 6 months
  
  Provide nPEP course if eligible

Evaluate:
- Is the patient eligible for nPEP? (Exposure within 72 hours)

At Conclusion of nPEP:
- Repeat rapid HIV test and assess for signs of acute HIV infection.
- Confirm HIV-negative status
- Complete baseline laboratory testing associated with PrEP initiation if not already performed
- Discontinue nPEP regimen and initiate PrEP regimen for patients at risk
- Provide adherence and risk reduction counseling
- Schedule follow up visits for HIV, STI, and other laboratory tests consistent with PrEP follow-up

*Please see USPHS Clinical Providers Supplement for complete recommendations on the transition of patient from nPEP to PrEP

nPEP, non-occupational post-exposure prophylaxis

Adapted from USPHS. Preexposure prophylaxis for the prevention of HIV infection in the United States, Clinical Providers Supplement. 2017
OUTLINE

PrEP
**What is PrEP?**

PrEP stands for “pre-exposure prophylaxis” and involves taking a pill once a day to help prevent you from becoming HIV-positive. Studies have shown that PrEP reduces the risk of HIV infection in men who have sex with men, as well as heterosexual men and women. In 2012, Truvada was approved by the U.S. Food and Drug Administration for use as PrEP among sexually active adults at risk for HIV infection.

**What is Truvada?**

Truvada is a combination of two anti-HIV medications: tenofovir disoproxil fumarate and emtricitabine, also called Viread and Emtriva. In addition to being used as PrEP, Truvada is also used with other medication to treat HIV and hepatitis B.

**Are there any side effects?**

Some people experience early side effects when taking Truvada for PrEP, including:

- Gas
- Bloating
- Softer stools
- More frequent stools
- Nausea
- Weight loss

These symptoms are usually mild and go away after the first month on PrEP. Strategies to deal with stomach-related symptoms include:

- Taking PrEP with food or snack
- Taking PrEP at night, before bedtime

Truvada can also cause kidney irritation and damage. It is important that your kidney function be followed by blood tests regularly while taking PrEP. Truvada can also cause weakening of bones (an early osteoporosis-like condition). Discuss with your healthcare provider what you can do to keep your bones strong and healthy.
Grade A recommendation means the USPSTF concluded with “high certainty” that there is a “substantial benefit” to using PrEP to decrease the risk of HIV infection in persons at high risk of HIV acquisition.

Adherence to PrEP is highly correlated with its efficacy in preventing the acquisition of HIV.

The USPSTF Grade A recommendation highlights the need to consider how best to identify and reach individuals at risk for HIV.
Taking PrEP – what does it take?

• Adherence! Taking the pill every day.
• Take 7 days before enough drug is “on board” to provide protection
  – Still must take Truvada every day
• Honest, open, and ongoing discussions with a medical provider about sexual activity and HIV risk
• HIV antibody test – before first prescription, and then every 3 months. Rx renewal tied to renewed HIV-negative test.
## PrEP for Prevention

### 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></td>
<td>· Sexual partner with HIV</td>
<td>· Sexual partner with HIV</td>
<td>· HIV-positive injecting partner</td>
</tr>
<tr>
<td></td>
<td>· Recent bacterial STD</td>
<td>· Recent bacterial STD</td>
<td>· Sharing injection equipment</td>
</tr>
<tr>
<td></td>
<td>· High number of sex partners</td>
<td>· High number of sex partners</td>
<td>· Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td></td>
<td>· History of inconsistent or no condom use</td>
<td>· History of inconsistent or no condom use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>· Commercial sex work</td>
<td>· Commercial sex work</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>· Lives in high-prevalence area or network</td>
<td></td>
</tr>
</tbody>
</table>

**Clinically eligible:**
- Documented negative HIV test before prescribing PrEP
- No signs/symptoms of acute HIV infection
- Normal renal function, no contraindicated medications
- Documented hepatitis B virus infection and vaccination status

**Prescription**
- Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90 day supply

**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
- Do oral/rectal STD testing
- Assess pregnancy intent
- Pregnancy test every 3 months
- Access to clean needles/syringes and drug treatment services

## Baseline Labs to Order For PrEP Candidates

<table>
<thead>
<tr>
<th>Baseline Lab/Assessment</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HIV</strong>&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>• Screen all individuals for HIV-1 infection immediately prior to initiating PrEP</td>
<td>At least every 3 months</td>
</tr>
<tr>
<td><strong>HBV</strong>&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td></td>
</tr>
</tbody>
</table>
| • Prior to or when initiating PrEP, test patients for hepatitis B virus infection  
  o HBV-uninfected & non-immune individuals should be offered vaccination  
  o If appropriate, anti-hepatitis B therapy may by warranted | Prior to Initiation or when initiating |
| **Renal Function**<sup>1,2</sup> |        |
| • Serum creatinine, estimated creatinine clearance, urine glucose and urine protein.  
  • In patients with chronic kidney disease, also assess serum phosphorous | At least every 6 months |
| **STIs**<sup>3</sup> |        |
| • Screen for genital, oropharyngeal, and rectal STIs | At least every 3 months |
| **Hepatitis C**<sup>3,4</sup> |        |
| • All sexually active individuals initiating PrEP should be tested for HCV infection | At Baseline |
| **Pregnancy Test** |        |
| • As appropriate |  |
HIV PrEP Medications Dosage and Administration

F/TAF for PrEP

- The dose of F/TAF for HIV-1 PrEP is one tablet once daily taken orally, with or without food in HIV-1 uninfected adults and adolescents weighing at least 35 kg, excluding individuals at risk from receptive vaginal sex. ¹ DESCOVY

F/TDF for PrEP

- The dose of F/TDF for PrEP in HIV-1 uninfected adults and adolescents weighing at least 35 kg is one tablet once daily taken orally with or without food.² TRUVADA

F/TAF’s availability in blister packaging may provide potential benefits

F/TDF’s small tablet size may be preferred by patients³

<table>
<thead>
<tr>
<th>TRUVADA</th>
<th>VS</th>
<th>DESCovy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Effectiveness</strong></td>
<td>&gt;99% effective</td>
<td>&gt;99% effective</td>
</tr>
<tr>
<td><strong>Regimen</strong></td>
<td>Daily use &amp;</td>
<td>Daily use</td>
</tr>
<tr>
<td><strong>Shown to be effective for</strong></td>
<td>Everyone, including: • Gay &amp; bisexual cis men • Trans women • Trans men • Heterosexuals • Cis women • People who inject drugs</td>
<td>Only: • Gay &amp; bisexual cis men • Trans women</td>
</tr>
<tr>
<td><strong>Safety: general</strong></td>
<td>Both medicines have very low rates of side effects overall. Some people experience “start-up” symptoms including diarrhea, nausea and vomiting, which usually resolve in the first three months of PrEP use.</td>
<td>Both medicines have very low rates of side effects overall. Some people experience “start-up” symptoms including diarrhea, nausea and vomiting, which usually resolve in the first three months of PrEP use.</td>
</tr>
<tr>
<td><strong>Bone health</strong></td>
<td>People with osteoporosis should avoid</td>
<td>Safer to take for people with osteoporosis</td>
</tr>
<tr>
<td><strong>Kidney health</strong></td>
<td>People with kidney issues or a strong family history of kidney disease should avoid</td>
<td>Safer to take for people with kidney issues or a strong family history of kidney disease, though monitoring still recommended</td>
</tr>
<tr>
<td><strong>Weight loss/gain</strong></td>
<td>May cause a small degree of weight loss¹</td>
<td>May cause a small degree of weight gain²</td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
<td>May cause small decreases in HDL, LDL and total cholesterol¹</td>
<td>May cause small increases in LDL cholesterol and triglycerides²³</td>
</tr>
<tr>
<td><strong>Cost</strong></td>
<td>Same cost ($1,845/month without insurance)</td>
<td>Same cost ($1,845/month without insurance)</td>
</tr>
<tr>
<td><strong>Insurance</strong></td>
<td>Covered by insurance</td>
<td>Likely covered by insurance</td>
</tr>
<tr>
<td><strong>Assistance programs</strong></td>
<td>Covered by assistance programs for medication and medical care costs</td>
<td>Covered by assistance programs for medication and medical care costs</td>
</tr>
<tr>
<td><strong>Pill size</strong></td>
<td>Larger pill than Descovy</td>
<td>Smaller pill than Truvada</td>
</tr>
</tbody>
</table>
Warnings Associated with PrEP Medications

US Prescribing Information

Considerations for those with hepatitis B

- Severe acute exacerbations of hepatitis B (HBV) have been reported in HBV-infected individuals who have discontinued emtricitabine and/or tenofovir disoproxil fumarate (F/TDF) and may occur with discontinuation of F/TAF

- Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in these individuals who discontinue F/TDF or F/TAF. If appropriate, initiation of anti-hepatitis B therapy may be warranted

HIV-Negative Status Must be Confirmed Prior to Initiation

- HIV-1 PrEP must only be prescribed to individuals confirmed to be HIV-negative immediately prior to initiating and at least every 3 months during use

- Drug-resistant HIV-1 variants have been identified with the use of F/TDF for HIV-1 PrEP following undetected acute HIV-1 infection

- Do not initiate F/TAF or F/TDF for HIV-1 PrEP if signs or symptoms of acute HIV infection are present unless negative infection status is confirmed

Effects of COVID on PrEP usage: My Experience

- Persons on PrEP have perceived a decreased risk of exposure
- Decreased adherence
- Decreased regular lab follow up
- Partners with HIV and at risk of COVID, decrease patient visits
- Cannot do labs in telehealth
- Increase in drug and alcohol use
OUTLINE

Treatment as prevention
## Treatment As Prevention

<table>
<thead>
<tr>
<th>Study</th>
<th>N=1,171 couples across Africa, Asia, North and South America</th>
<th>N=888 couples across 14 European countries</th>
<th>N= 343 MSM couples in Australia, Brazil, and Thailand</th>
<th>N= 783 MSM serodiscordant couples</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPTN 0521,2</td>
<td>2011</td>
<td>2015</td>
<td>2017</td>
<td>2018</td>
</tr>
<tr>
<td>8,494 PYFU</td>
<td>N=888 couples across 14 European countries</td>
<td>Median 35-42 condomless sex acts over 1.4 to 2.8 years of follow up per couple</td>
<td>N= 343 MSM couples in Australia, Brazil, and Thailand</td>
<td>1,596 CYFU</td>
</tr>
<tr>
<td><strong>Endpoint:</strong></td>
<td>Linked HIV transmission to negative partners</td>
<td>Linked HIV transmission to negative partners</td>
<td>591 CYFU (19% of CYFU consisted of negative partners on PrEP)</td>
<td>77,000 condomless sex acts with undetectable viral load</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>16,889 condomless sex acts</td>
<td>Endpoint: linked HIV transmission to negative partners</td>
</tr>
</tbody>
</table>

### Results: Suppressive ART† led to no HIV transmissions from the HIV-positive study participants to their HIV-negative partners.

People who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner6

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2. Eshleman S, et al. IAS 2015, Vancouver, Canada. Poster # MOLBPE18

†viral load was undetectable in 95.2% of CYFU in Opposites Attract

ART, antiretroviral therapy, CYFU, couple years of follow up; MSM, men who have sex with men; PYFU, patient years of follow up
Undetectable = Untransmittable
Prevention Access Campaign

- **U=U** signifies that achieving and maintaining HIV RNA levels <200 copies/mL with ART prevents HIV transmission through sex\(^1\).
- Persons starting ART should use another form of prevention with sexual partners for at least the first 6 months of treatment and until an HIV RNA level of <200 copies/mL has been documented\(^1\).
- **To maintain U=U** status, continue to take your medicines every day to help your viral load remain undetectable\(^2\).

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Talking to patients
I’VE LEARNED THAT PEOPLE WILL FORGET WHAT YOU SAID, PEOPLE WILL FORGET WHAT YOU DID, BUT PEOPLE WILL NEVER FORGET HOW YOU MADE THEM FEEL.

-Maya Angelou
Having Sexual Health Conversations Can Help Identify HIV Risk

Factors that Facilitate a Sexual Health Conversation

- Safe Environment
- Open-Ended Questions
- Safe-Positivity

Build Trust

- Use a sensitive and nonjudgmental tone
- Avoid making assumptions based on the individual’s personal factors
- If unaware of the individual’s gender identity, use gender-neutral language


What's up Doc?

Ask me about...

- COVID | VACCINE
- CANCER SCREENINGS
- Your hepC | HIV test
- PrEP | PEP for HIV prevention
- Addiction treatment
- FLU | Pneumonia | Hepatitis shots
The 5 P’s of Sexual History

- Partners
  - Do you have sex with women, men, and/or transgender partners? In the past year, who have you had sex with? • Do you currently have a main sex partner? Do you have more casual “hook-ups”?

- Pregnancy
  - Are you trying to have a child or trying to avoid pregnancy?

- Practices

- Protection Against STIs
  - How do you protect yourself from HIV and other STIs?

- Past History of STIs
  - Have you ever been diagnosed with HIV or another STI? When were you last tested? Have you had any recent symptoms?
Don’t judge a situation you’ve never been in.
Taking a Sexual History

Dialogue

- Be mater of fact.
- Make it part of your routine history. Do you have a history of surgeries, cardiac disease, STD’s, IV or nasal drug use even one time, blood transfusion?
- Do you have sex with men, women or both?
- How do you have sex? For example receptive oral, anal or vaginal sex?
- How many partners have you engaged within the last year?
- Have you had your lifetime screening for HIV/HCV?
- What do you use for protection from STD now? What do you know about PrEP?
- What are your concerns about pregnancy?
- Which pronoun accurately reflects you, him, her, they?
- Do you identify as transgender or Two Spirit?
WELCOMING LGBTQ PATIENTS AND THEIR PARTNERS

To welcome and engage patients of all sexual orientations and gender identities:

- Display posters and literature in different languages that promote lesbian, gay, bisexual, transgender, and queer (LGBTQ) health with models illustrating racial and ethnic diversity.
- Display policy statements that prohibit discrimination in your office.
- Ask patients for their gender identity, sex assigned at birth, and the genders of sexual partners as a standard part of their patient records.
- Ask patients for the name they use (if different from the name on their insurance), and the pronouns they use and enter the information into the electronic health record.
- Ensure that staff address and refer to the patient with the correct name and pronouns.
- Refer to the patient’s medical record before each encounter so that LGBTQ patients do not have to “come out” at every visit.
- Assure patients that all the information you collect will be kept confidential and shared only on a need-to-know basis—for example, for billing or disease reporting.
- Train all staff in how to welcome and serve LGBTQ patients, including all of the above practices.
Summary

- Identify individuals at risk for HIV who may be candidates for PrEP
  - Provide a safe environment to have open and non-judgmental sexual health conversations
  - Learn how to talk to patients
- Order appropriate baseline labs and screen for STIs
  - Note the differences in minimum eCrCl requirements between F/TAF and F/TDF in implementing same-day or rapid PrEP
- Prescribe a PrEP medication option tailored to the individual at risk
  - Note the key differences between F/TAF and F/TDF, including indications, renal and bone considerations, and PrEP user preferences such as pill size and availability of blister packaging
  - Counsel on adherence to daily dosing, as it highly correlates to efficacy
- Provide appropriate follow-up monitoring and labs
  - Regularly assess medication adherence and continued HIV risk
## PrEP Resources

<table>
<thead>
<tr>
<th><strong>U.S. PHS/CDC Clinical Practice Guidelines for PrEP</strong></th>
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<table>
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<tr>
<th><strong>HIV Prevention Capacity Building Assistance Providers</strong></th>
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<tbody>
<tr>
<td><a href="http://www.cbapropviders.org">www.cbapropviders.org</a></td>
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<tr>
<th><strong>HRSA-funded AIDS Education and Training Centers</strong></th>
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<tr>
<td>aidsetc.org</td>
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<thead>
<tr>
<th><strong>National PrEPLine @ UCSF Clinical Consultation Center</strong></th>
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<tbody>
<tr>
<td>HIV 800-933-3413, PrEP 855-448-7737, HCV 844-437-4636, Substance Use 855-300-3595</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>NACCHO’s PrEP for Local Health Departments Educational Series</strong></th>
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### Kansas Department of Public Health-PrEP
- [www.kdheks.gov/sti_hiv/PrEP.htm](http://www.kdheks.gov/sti_hiv/PrEP.htm)

### GILEAD
- Advancing access 800-226-2056
  - [https://www.gileadadvancingaccess.com/hcp](https://www.gileadadvancingaccess.com/hcp)

GILEAD
- Gilead HIV Prevention and Treatment Medical Scientist can also do a more in-depth training on implementation of services in your area in Kansas
  - For Prevention contact Patty Martin, PharmD [patty.martin@gilead.com](mailto:patty.martin@gilead.com)
  - For treatment the medical scientist is Brittany Mills, PharmD [Brittany.mills@gilead.com](mailto:Brittany.mills@gilead.com)
## PrEP Resources

<table>
<thead>
<tr>
<th>NASTAD PrEP Cost Calculator</th>
<th><a href="https://www.nastad.org/prepcost">https://www.nastad.org/prepcost</a></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready, Set, PrEP Program</td>
<td><a href="https://www.getyourprep.com/">https://www.getyourprep.com/</a></td>
</tr>
<tr>
<td>PleasePrEPMe</td>
<td><a href="http://pleaseprepme.org">http://pleaseprepme.org</a></td>
</tr>
<tr>
<td>Prep resources for Kansas</td>
<td><a href="http://www.pleaseprepme.org/kansas">www.pleaseprepme.org/kansas</a></td>
</tr>
<tr>
<td>Includes Tools to help estimate and pay PrEP costs:</td>
<td></td>
</tr>
<tr>
<td>• Gilead Sciences - Truvada PrEP Access and Assistance Programs <a href="http://www.truvada.com/how-to-get-truvada-for-prep/truvada-cost">www.truvada.com/how-to-get-truvada-for-prep/truvada-cost</a></td>
<td></td>
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<tr>
<td>• Patient Advocate Foundation - Copay Relief copays.org/funds/hiv-aids-and-prevention/</td>
<td></td>
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<tr>
<td>• PrEPCost.orgnastad.checkbookhealth.org/prepcost/2020/</td>
<td></td>
</tr>
<tr>
<td>GILEAD</td>
<td>Gilead Copay support for HIV treatment and prevention medications</td>
</tr>
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## Resources

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<tr>
<th><strong>Pep Consultation service for Clinicians</strong> 888-448-4911</th>
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<tr>
<td><a href="http://www.hivinfo.nih.gov">www.hivinfo.nih.gov</a></td>
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<tr>
<td><a href="www.hivguidelines.org">www.hivguidelines.org</a></td>
</tr>
<tr>
<td>www1.nyc.gov</td>
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<tr>
<td>cdc.gov</td>
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</tbody>
</table>
QUESTIONS?
I think a hero is any person really intent on making this a better place for all people.

MAYA ANGELOU
Contact Information

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valentgm1967@gmail.com
209-743-9234 Cell
209-984-4820 Office