



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

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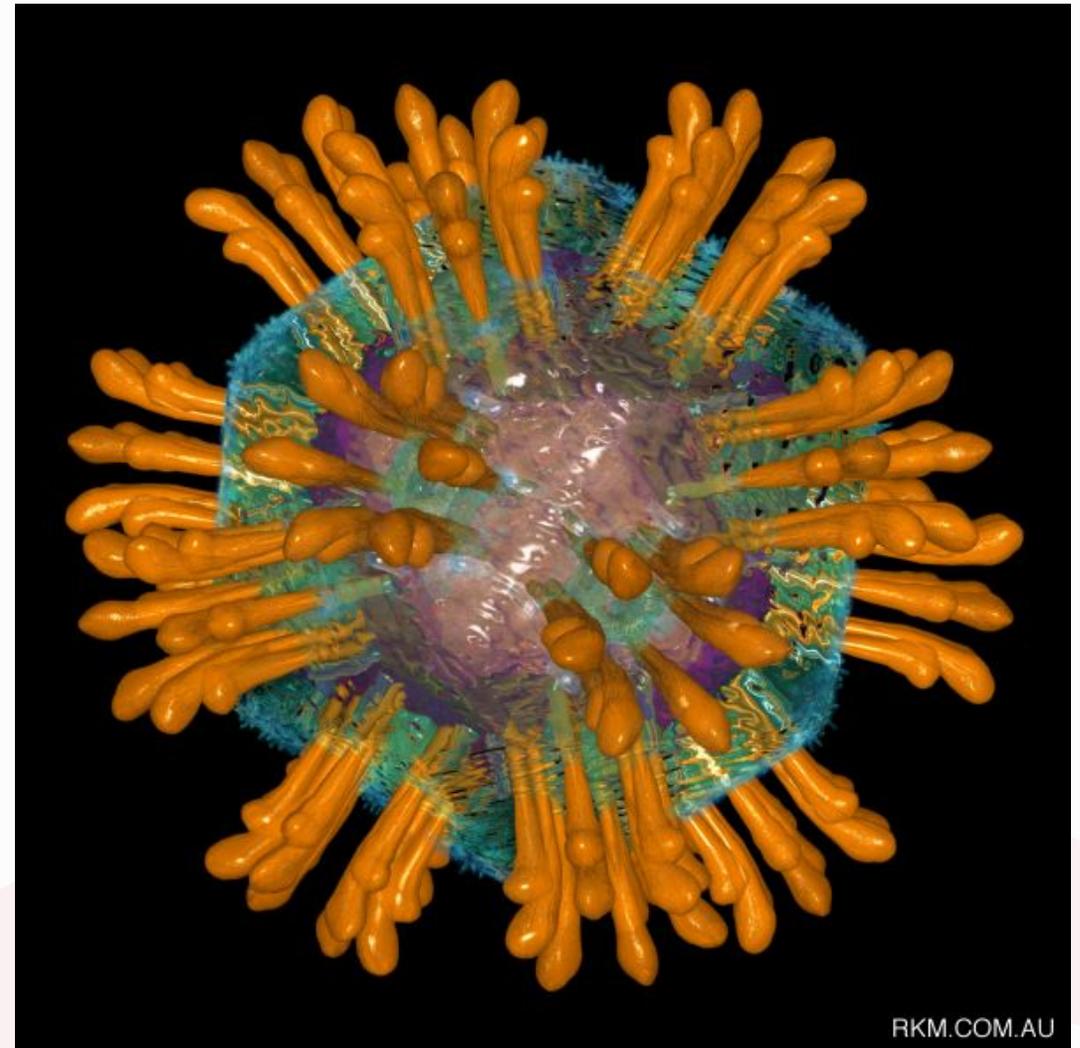
March 19, 2021

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?

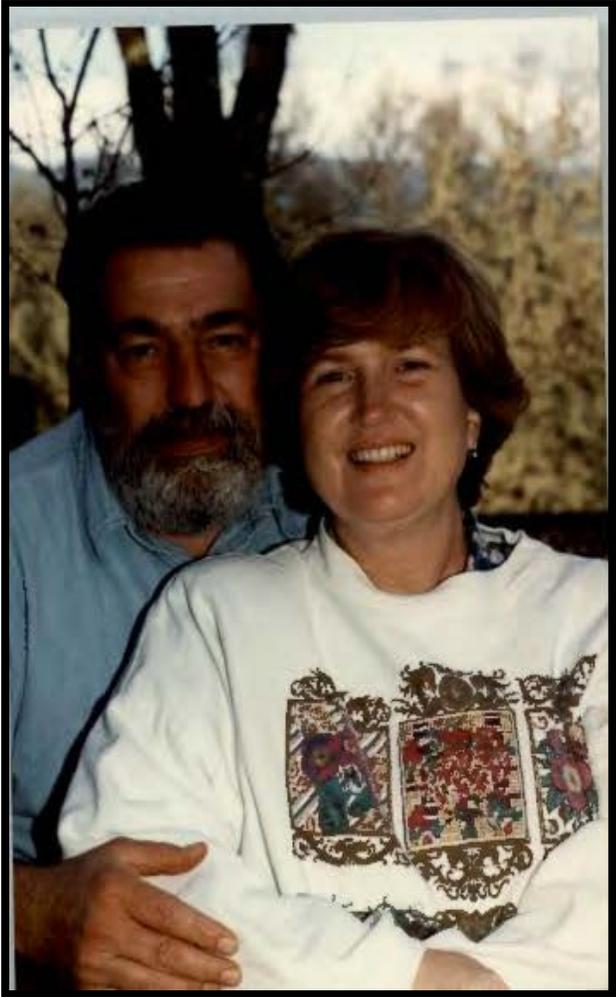


Santa Clara University, BSC Marketing 1991

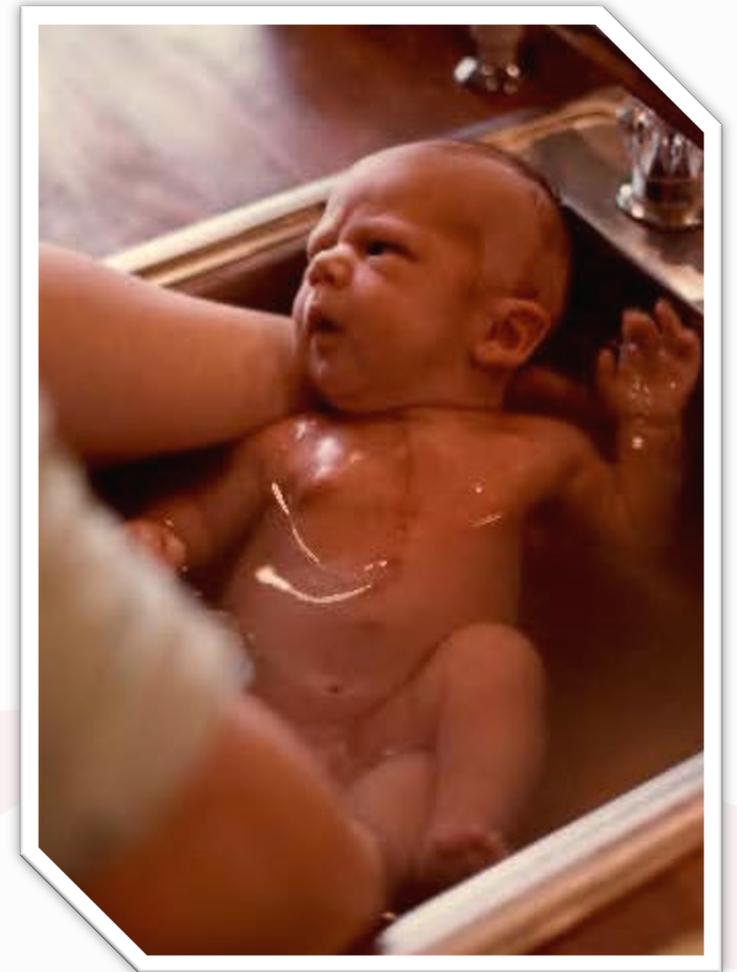
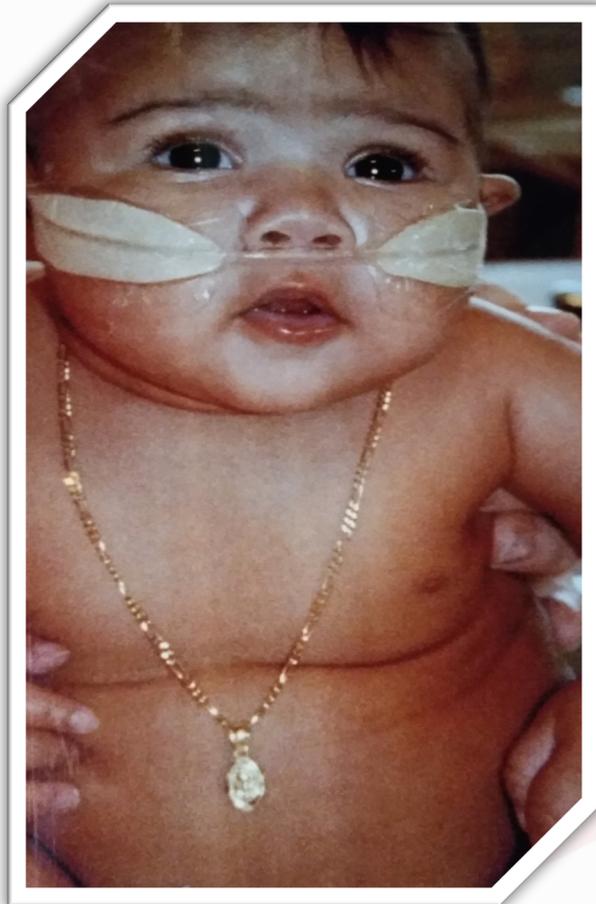
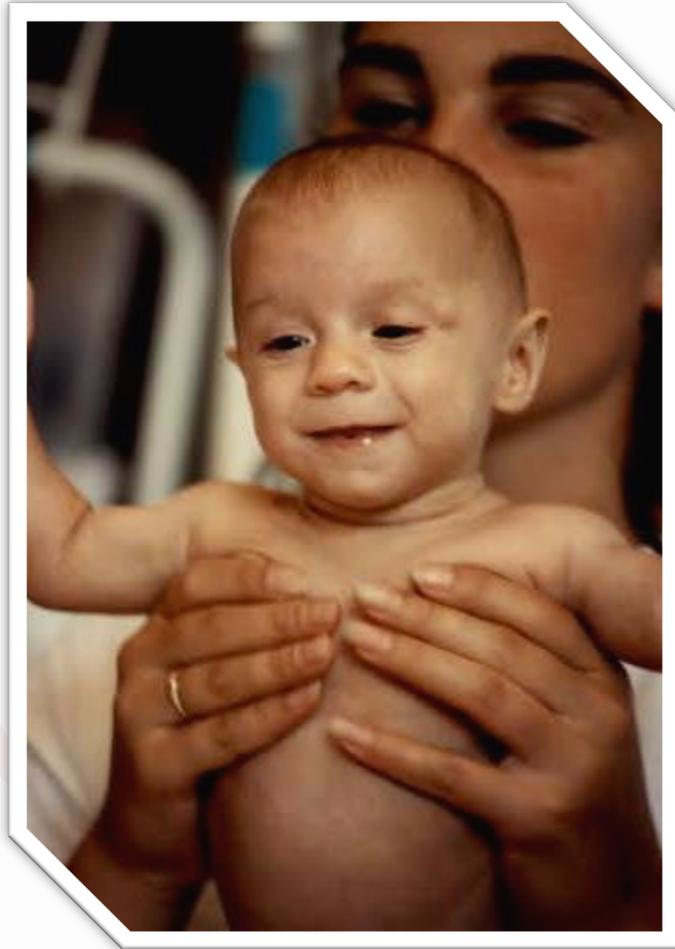




Finding my inspiration



...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

How can you do it?

- 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

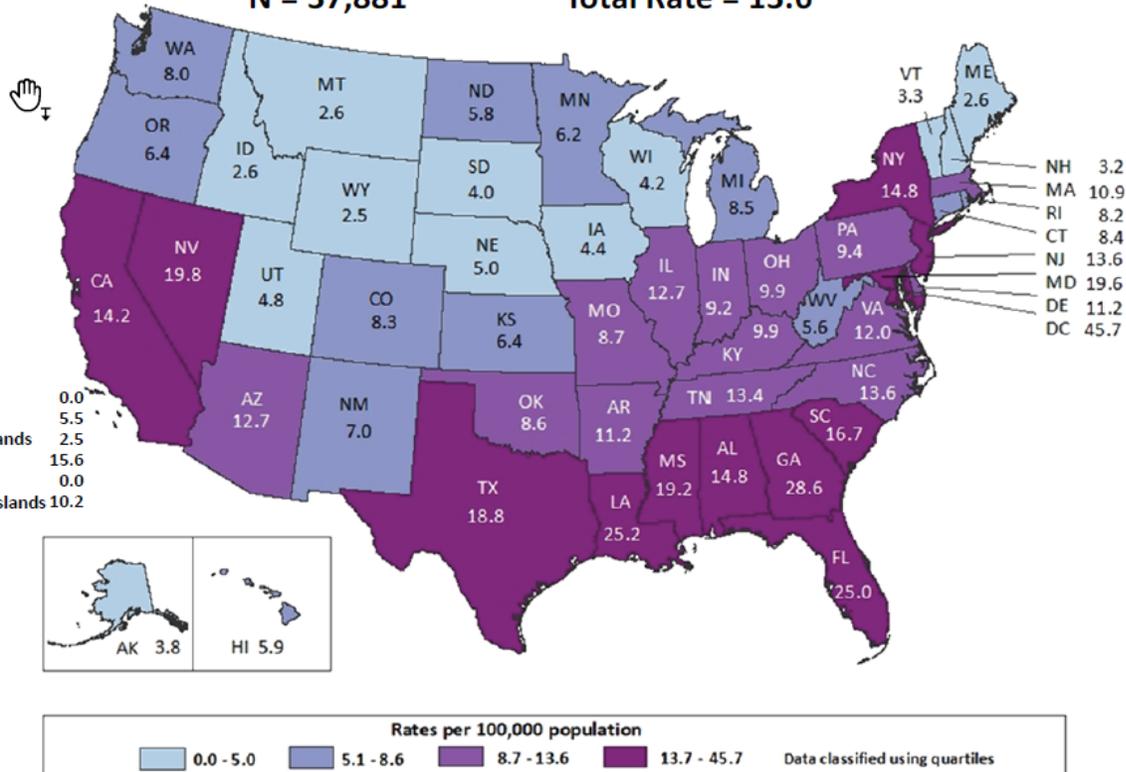
- Epidemiology
-
-
-
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HIV Prevalence and Incidence in the United States

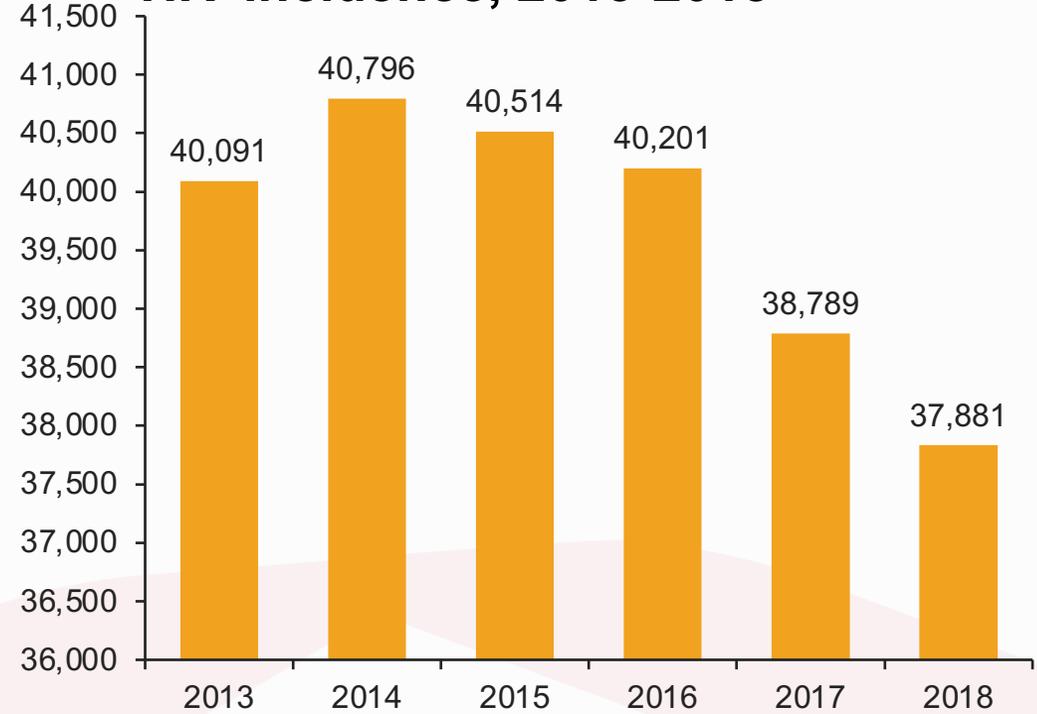
- An estimated 1.04 million people aged 13 and older had HIV infection in 2018

HIV incidence rate per 100,000 people, 2018*

N = 37,881 Total Rate = 13.6



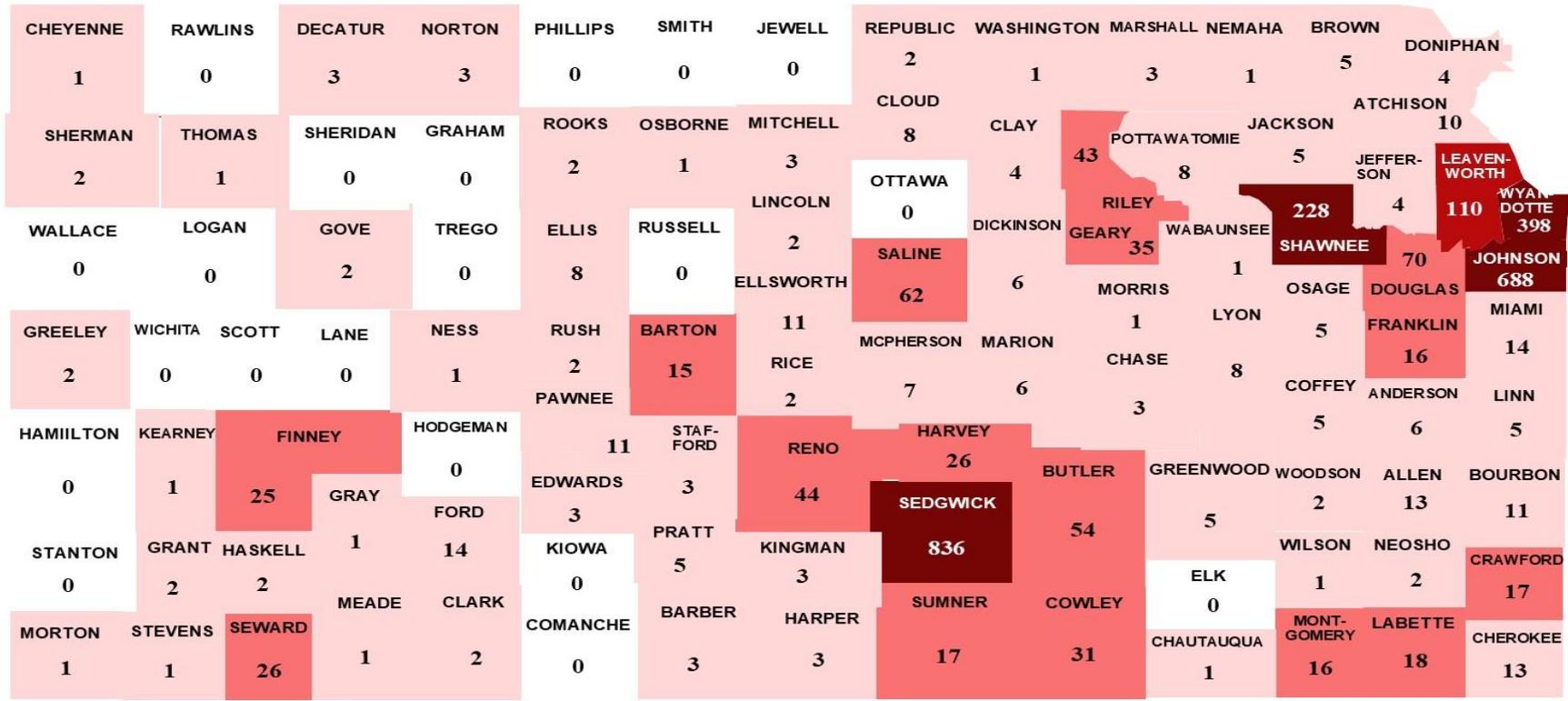
HIV incidence, 2013-2018*



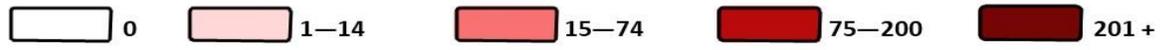
*Data include diagnoses from the United States and six dependent areas.

Centers for Disease Control and Prevention. *HIV Surveillance Report, 2018 (Updated)*; vol. 31. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 7, 2020. Accessed May 9, 2020.

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



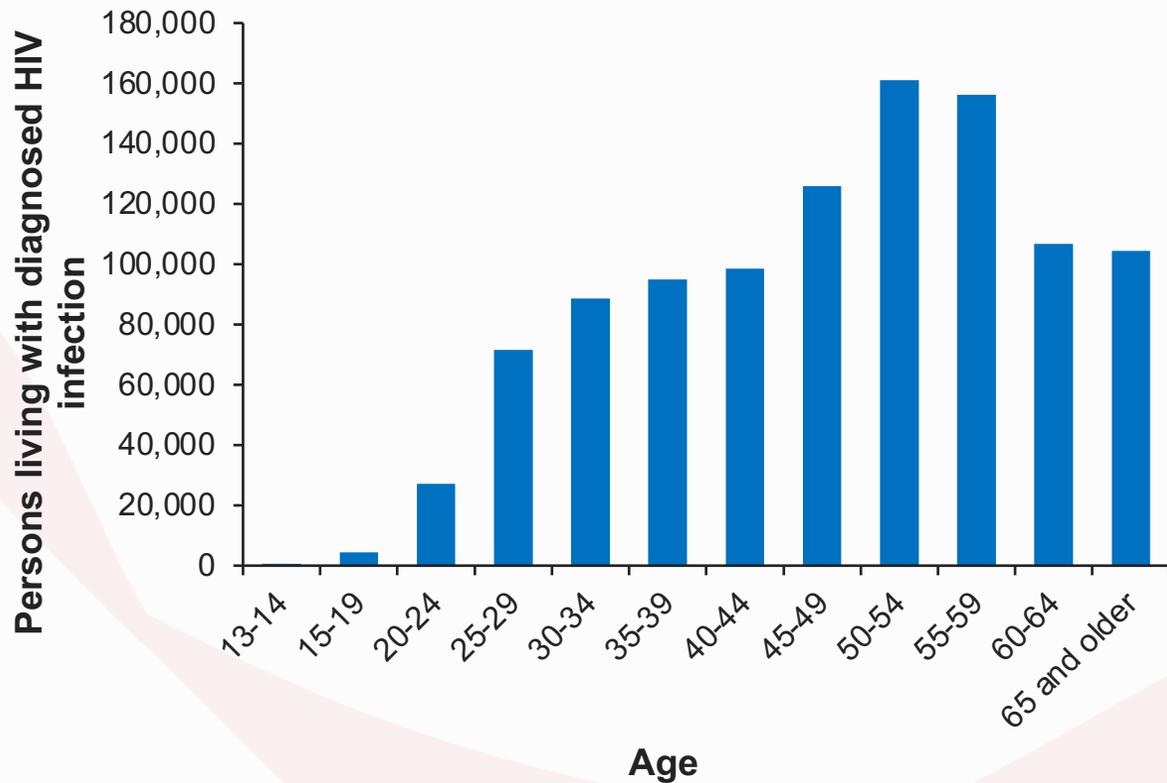
Total: 3,047



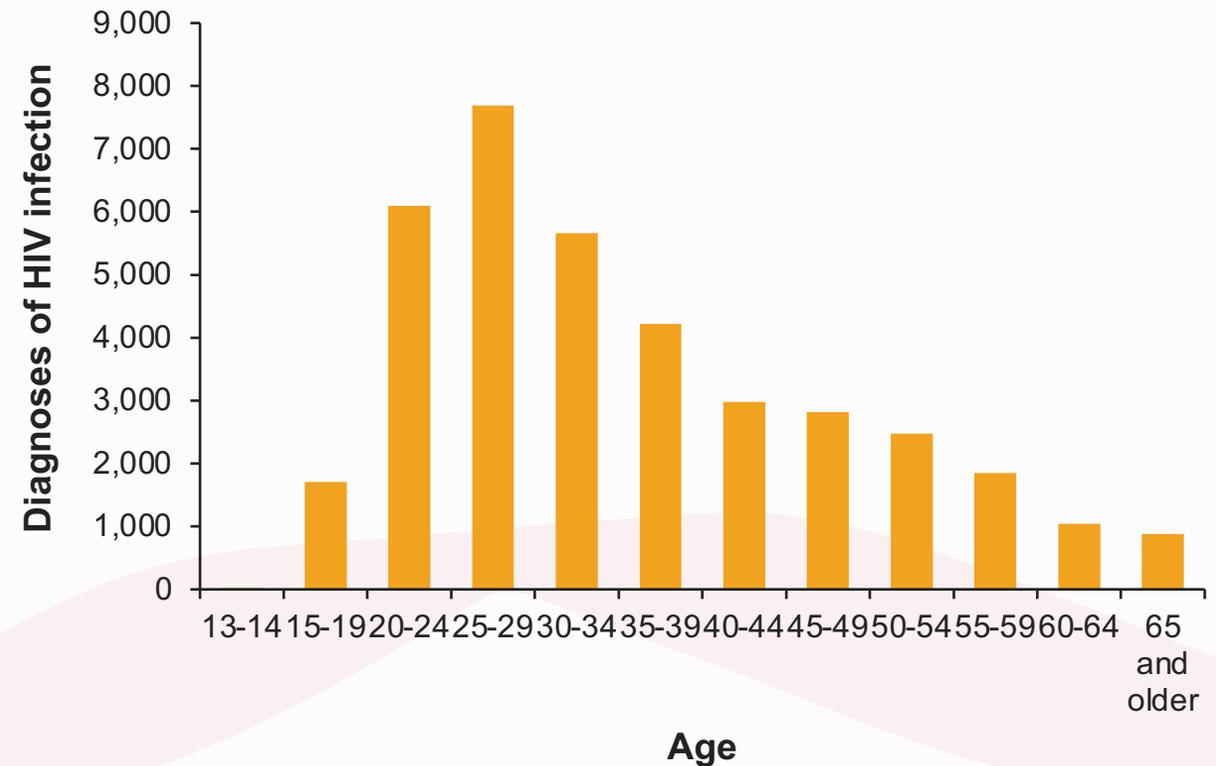
This map reflects the number of persons living in Kansas who have been diagnosed with HIV. Last reported address was utilized to determine residency. If the last reported county variable was unknown, that individual will not be reflected in this map.

HIV Prevalence and Incidence by Age in the United States

HIV prevalence, by age, 2018*



HIV incidence, by age, 2018*

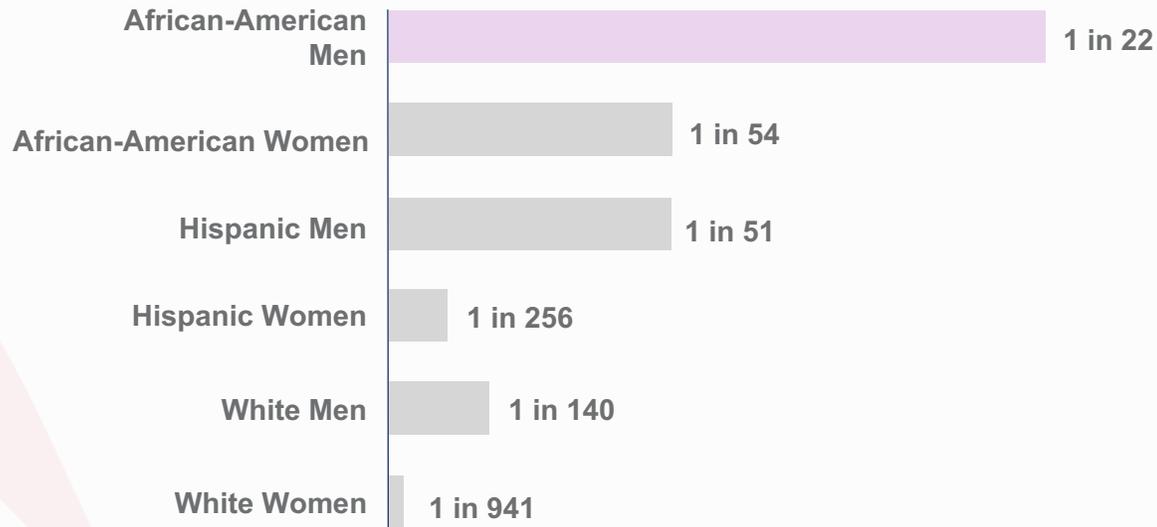


*Data include diagnoses from the United States and six dependent areas.

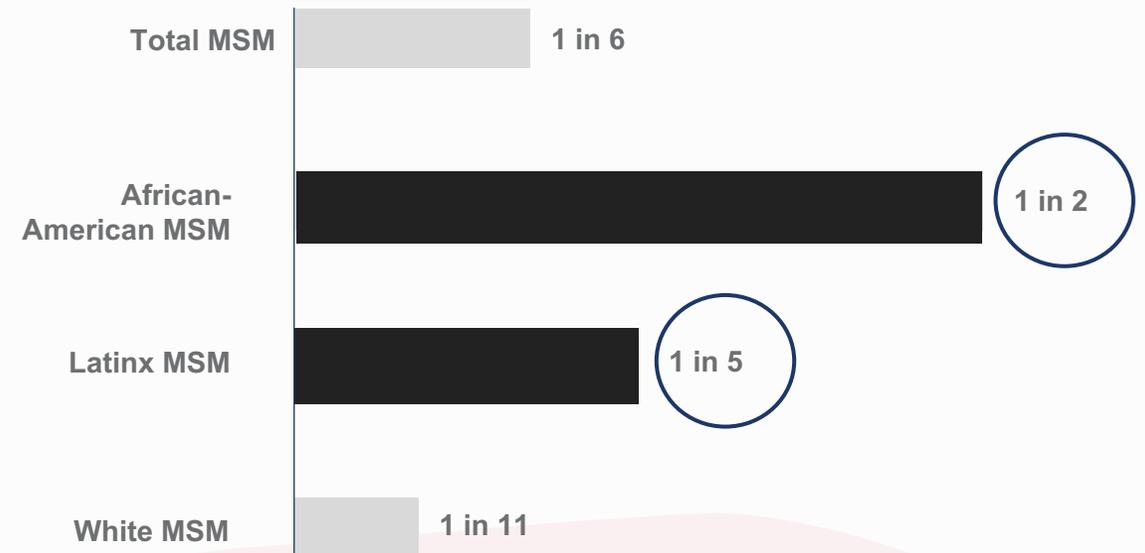
Centers for Disease Control and Prevention. *HIV Surveillance Report, 2018 (Updated)*; vol. 31. <http://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 7, 2020. Accessed May 9, 2020.

Lifetime Risk of HIV Diagnosis* by Gender and Race/Ethnicity in the U.S.

Lifetime Risk of HIV Diagnosis



Lifetime Risk of HIV Diagnosis Among MSM



- The overall lifetime risk of HIV in the United States is 1 in 106¹, 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 treatment²

Estimated Per-Act Probability of Acquiring HIV, by Exposure Act* ‡

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

* 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
<https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html> accessed May 5, 2020



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

Newbern EC, et al. Adolescent sexually transmitted infections and risk for subsequent HIV. *Am J Public Health*. 2013;103(10):1874–1881. doi:10.2105/AJPH.2013.301463

Pathela, P. HIV Incidence Among Men With and Those Without Sexually Transmitted Rectal Infections: Estimates From Matching Against an HIV Case Registry, *Clinical Infectious Diseases*, Volume 57, Issue 8, October 2013, <https://doi.org/10.1093/cid/cit437>

Pathela P, et al. The High Risk of an HIV Diagnosis Following a Diagnosis of Syphilis: A Population-level Analysis of New York City Men, *Clinical Infectious Diseases*, Volume 61, Issue 2, July 2015. <https://doi.org/10.1093/cid/civ289>

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

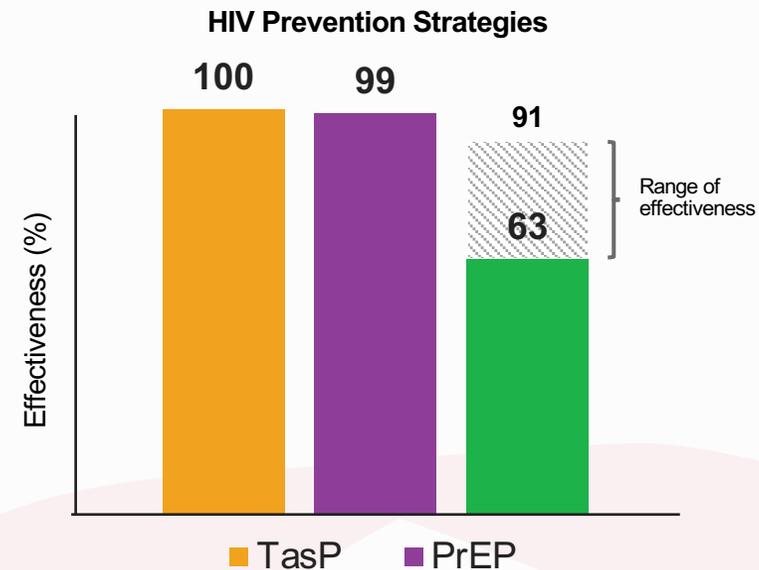
Pre-Exposure Prophylaxis/Post Exposure Prophylaxis

- 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 variable¹:
 - **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.

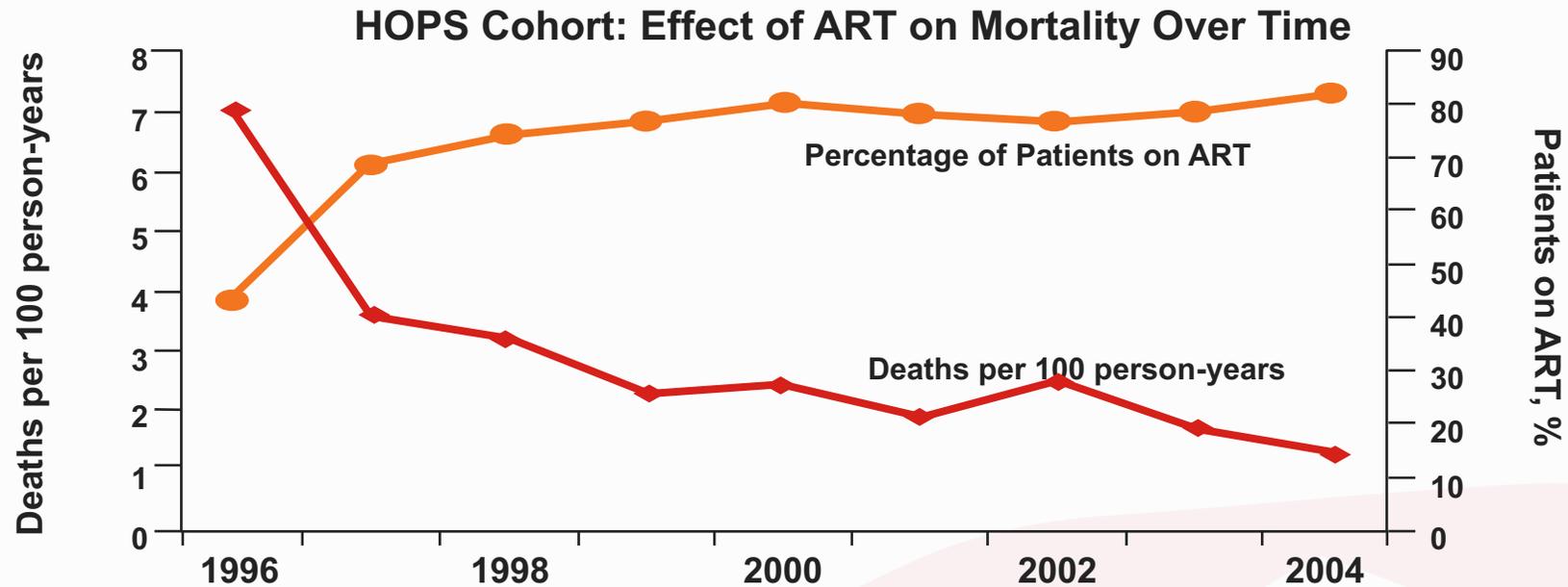
MSM, men who have sex with men; IAI, insertive anal intercourse; RAI, receptive anal intercourse; TasP: treatment as prevention; U=U, undetectable = untransmittable

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.

<https://www.cdc.gov/hiv/risk/estimates/preventionstrategies.html> Accessed July 2019

Centers for Disease Control and Prevention (CDC)

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.

Palella FJ, et al. *J Acquir Immune Defic Syndr.* 2006;43:27-34



Who Should be Screened for HIV Infection?

| Population | Recommendation | Grade |
|--|--|-------|
| Pregnant persons | 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. | A |
| Adolescents and adults aged 15 to 65 years | 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. | A |

- 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

US Preventative Services Task Force. Screening for HIV infections: US Preventative Services Task Force recommendation statement [published online June 11, 2019]. JAMA. Doi:10.1001/jama.2019.6587

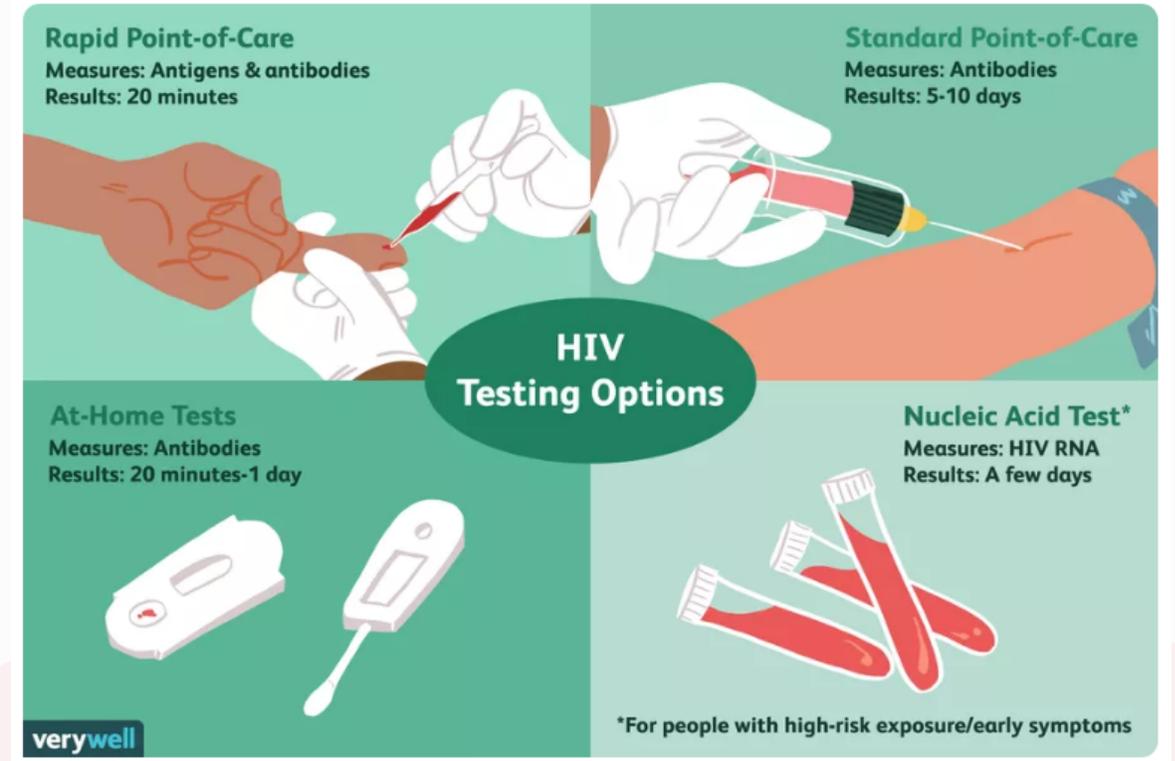
<https://www.cdc.gov/HIV/BASICS/HIV-Testing/getting-tested.html>



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 criteria¹:
 - 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.

1. <https://www.cdc.gov/HIV/BASICS/HIV-Testing/getting-tested.html> Accessed 7/29/20

2. US Preventative Services Task Force. Screening for HIV infections: US Preventative Services Task Force recommendation statement [published online June 11, 2019]. JAMA. Doi:10.1001/jama.2019.6587



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

Ending the HIV Epidemic: A Plan for America

GOAL: HHS will work with each community to establish local teams on the ground to tailor and implement strategies to:

75% reduction in new HIV infections in 5 years and at least **90%** reduction in 10 years.

- Diagnose** all people with HIV as early as possible.
- Treat** people with HIV rapidly and effectively to reach sustained viral suppression.
- Prevent** new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).
- Respond** quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

The Initiative will target our resources to the 48 highest burden counties, Washington, D.C., San Juan, Puerto Rico, and 7 states with a substantial rural HIV burden.

Geographical Selection: Data on burden of HIV in the US shows areas where HIV transmission occurs more frequently. More than 50% of new HIV diagnoses* occurred in only 48 counties, Washington, D.C., and San Juan, Puerto Rico. In addition, 7 states have a substantial rural burden - with over 75 cases and 10% or more of their diagnoses in rural areas.

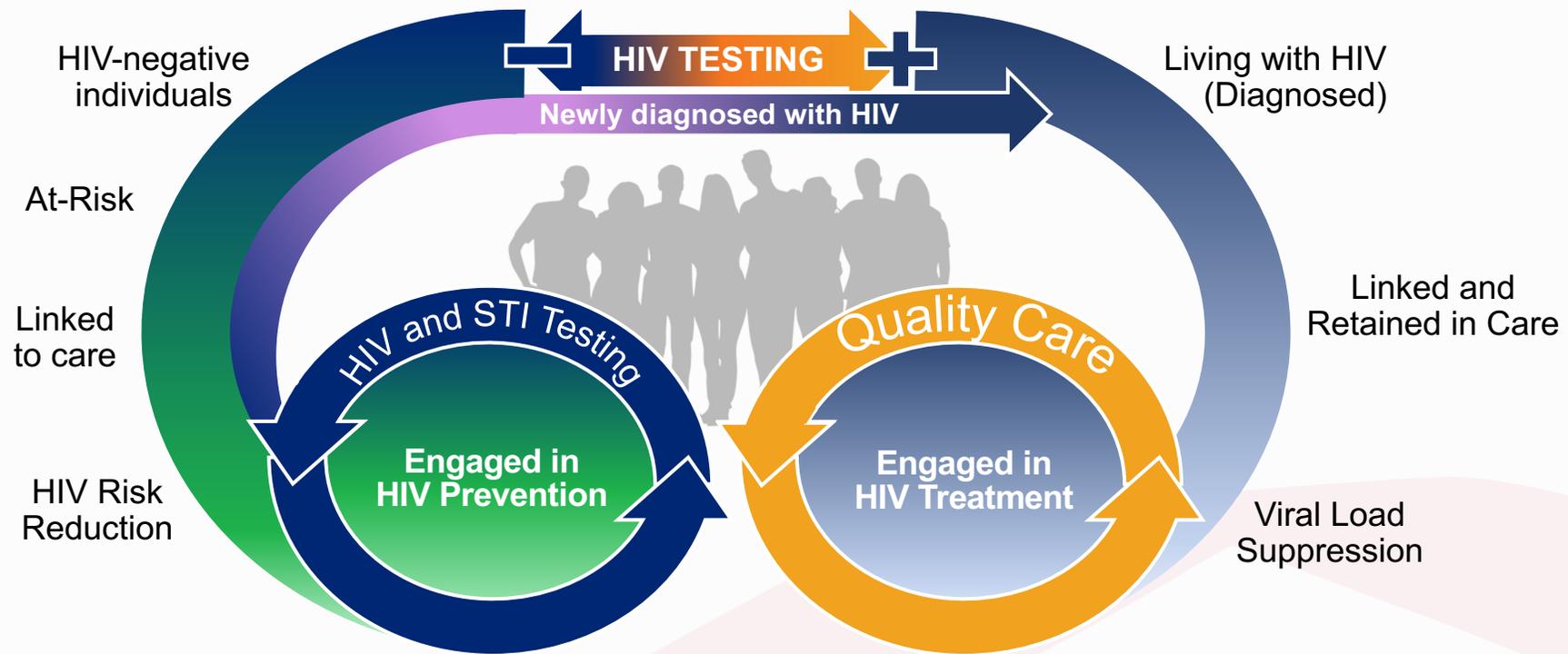
*2016-2017 data

Ending the HIV Epidemic
www.HIV.gov

CDC. Ending the HIV Epidemic: A Plan for America. Feb 2020. Available at: <https://www.cdc.gov/endhiv/index.html>. Accessed 17 Mar 2020



Testing, Treatment, and Prevention: A Status Neutral HIV Continuum of Care



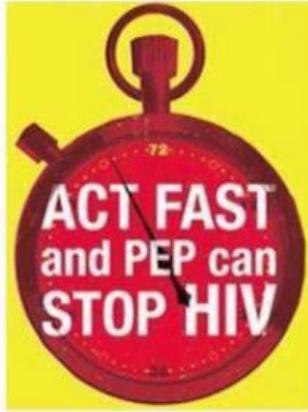
Modern HIV prevention efforts begin with HIV testing and focus on both the linkage and treatment of individuals living with HIV and identifying HIV-negative individuals at risk

Adapted from Myers J, et al. Redefining Prevention and Care: A Status-Neutral Approach to HIV. OFID. 2018



OUTLINE

- [Redacted]
- PEP vs PrEP
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]



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.

PrEP stands for pre-exposure prophylaxis.

What's it called?

PEP stands for post-exposure prophylaxis.

Before HIV exposure.

PrEP is taken every day, before possible exposure.

When is it taken?

After HIV exposure.

In emergency situations, PEP is taken within 72 hours (3 days) after possible exposure.

PrEP is for people who don't have HIV and:

- have a sex partner with HIV
- have sex with people whose HIV status is unknown
- share injection drug equipment

Who's it for?

PEP is for people who don't have HIV but may have been exposed:

- during sex
- at work through a needlestick or other injury
- by sharing injection drug equipment
- during a sexual assault

PrEP can reduce the risk of getting HIV from sex by more than 90% and from injection drug use by more than 70%.

How effective is it?

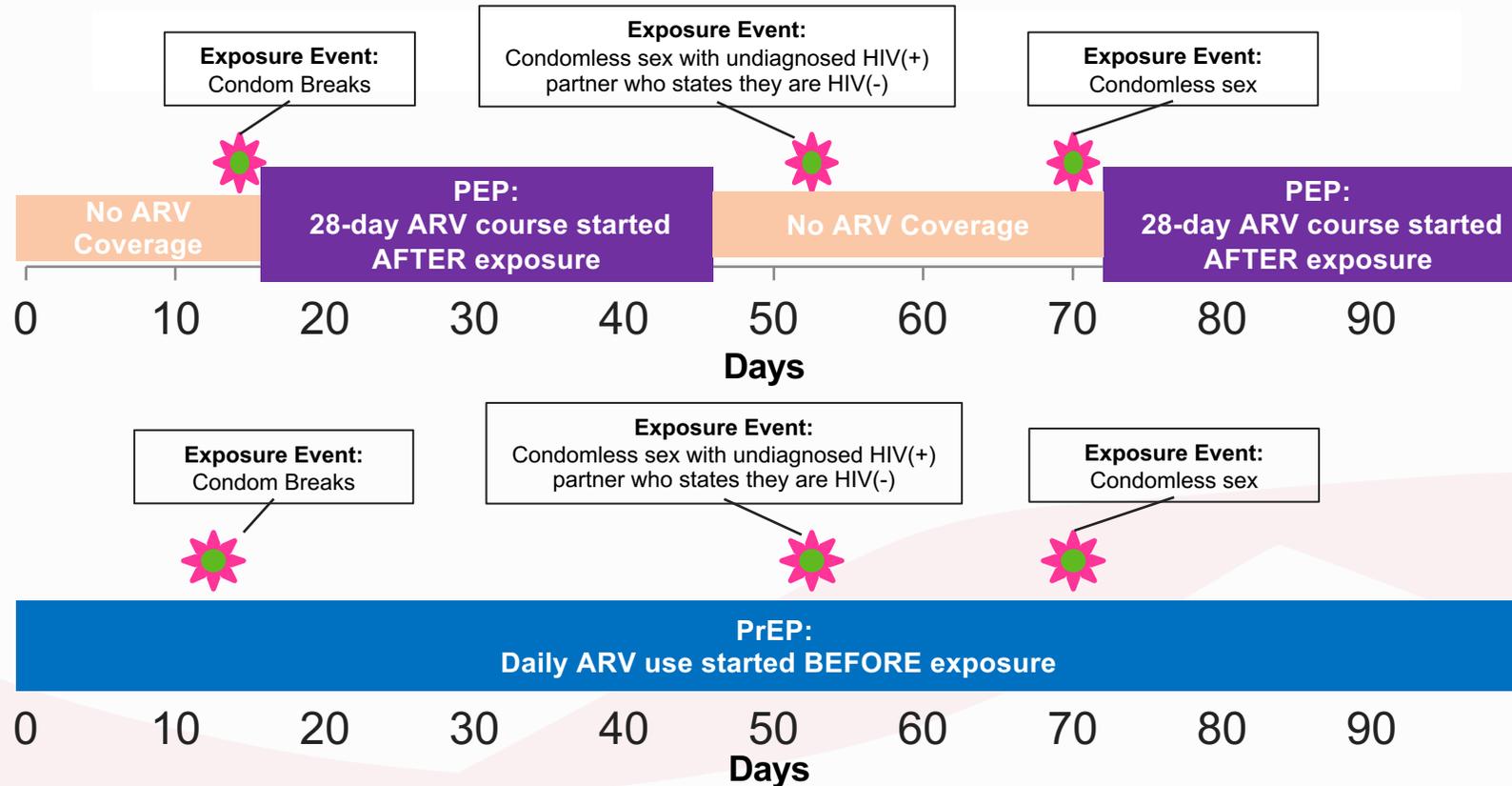
PEP can prevent HIV infection when taken correctly, but it is not always effective.

Start PEP as soon as possible to give it the best chance of working.

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

AIDSinfo

PEP vs PrEP



Biomedical Interventions to Prevent HIV



Prevent Acquiring Infection



Treat HIV and Prevent Transmitting Infection

PEP^{1,2} (Post-Exposure Prophylaxis) TIME OF EXPOSURE

- 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
- Need for PEP is a **medical emergency** and **must be initiated within 72 hours** of the exposure

PrEP³ (Pre-Exposure Prophylaxis) PRIOR TO EXPOSURE

- 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**
- **Two drugs**, used along with regular HIV/STI testing, as well as periodic counseling and support around adherence and sexual behavior

TasP⁴ (Treatment as Prevention) AFTER INFECTION

- 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

1. World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach—second edition. 2. Centers for Disease Control and Prevention. Updated guidelines for antiretroviral post-exposure prophylaxis after sexual, injection drug use, or other non-occupational exposure to HIV—United States, 2016. 3. Centers for Disease Control and Prevention. Pre-exposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. 4. Centers for Disease Control and Prevention. Prevention benefits of HIV treatment. <https://www.cdc.gov/hiv/risk/art/index.html/>. Accessed May 6, 2020..

OUTLINE

- [Redacted]
- [Redacted]
- nPEP
- [Redacted]
- [Redacted]
- [Redacted]



ABOUT PEP



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



ABOUT 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^a

- 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

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

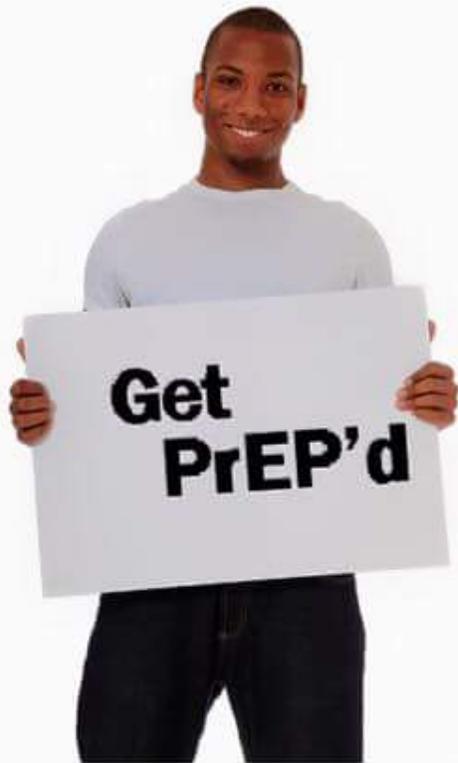
nPEP, non-occupational post-exposure prophylaxis

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

OUTLINE

- [Redacted]
- [Redacted]
- [Redacted]
- PrEP
- [Redacted]
- [Redacted]

HIV Negative? Stay that way.



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.

United States Prevention Services Task Force (USPSTF) Recommendation for PrEP

| Population | Recommendation Summary | Grade |
|---|--|-------|
| Persons at high risk of HIV acquisition | The USPSTF recommends that clinicians offer pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition | A |

- **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.

Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement, *JAMA*. 2019;321(22):2203-2213.
doi:10.1001/jama.2019.6390.

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

| | Men Who Have Sex With Men | Heterosexual Women and Men | Injection Drug Users |
|---|---|---|--|
| Detecting substantial risk of acquiring HIV infection: | <ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work | <ul style="list-style-type: none"> Sexual partner with HIV Recent bacterial STD High number of sex partners History of inconsistent or no condom use Commercial sex work Lives in high-prevalence area or network | <ul style="list-style-type: none"> HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting) |
| Clinically eligible: | <ul style="list-style-type: none"> 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: | <ul style="list-style-type: none"> 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 | | |
| | <ul style="list-style-type: none"> Do oral/rectal STD testing | <ul style="list-style-type: none"> Assess pregnancy intent Pregnancy test every 3 months | <ul style="list-style-type: none"> Access to clean needles/syringes and drug treatment services |

Source: US Public Health Service. Preexposure prophylaxis for the prevention of HIV infection in the United States —2014: a clinical practice guideline.

Baseline Labs to Order For PrEP Candidates

Per US Prescribing Info

Per Guidelines*

Per PrEP US Labeling

| Baseline Lab/Assessment | | Timing |
|-------------------------------|---|--|
| HIV ^{1,2} | <ul style="list-style-type: none"> Screen all individuals for HIV-1 infection immediately prior to initiating PrEP | At least every 3 months |
| HBV ^{1,2} | <ul style="list-style-type: none"> Prior to or when initiating PrEP, test patients for hepatitis B virus infection <ul style="list-style-type: none"> HBV-uninfected & non-immune individuals should be offered vaccination If appropriate, anti-hepatitis B therapy may be warranted | Prior to Initiation or when initiating |
| Renal Function ^{1,2} | <ul style="list-style-type: none"> 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 ³ | <ul style="list-style-type: none"> Screen for genital, oropharyngeal, and rectal STIs | At least every 3 months |
| Hepatitis C ^{3,4} | <ul style="list-style-type: none"> All sexually active individuals initiating PrEP should be tested for HCV infection | At Baseline |
| Pregnancy Test | <ul style="list-style-type: none"> As appropriate | |

*References are for HIV-1 PrEP, as there are currently no clinical guidelines on the use of F/TAF for PrEP.
1. FITAF USPI 2018.3 2. FITAF USPI 2018.3 3. USPHS CDC PrEP Guidelines 2017.4. AASLD HCV Guidance



HIV PrEP Medications Dosage and Administration

F/TAF for PrEP¹

- 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/TAF's availability in blister packaging may provide potential benefits

F/TDF for PrEP²

- 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**



767 mm³



249 mm³



340 mm³

*Pills shown are not actual size. Size comparison to illustrate relative width and height of the pills to a US dime, and not depth

F/TAF's small tablet size may be preferred by patients³

1. F/TAF Prescribing Information, Gilead Sciences Inc., 2019. 2. F/TDF Prescribing Information, Gilead Sciences Inc., 2020. 3. Fields, et al. Curr Ther Res Clin Exp. 2015 Dec; 77: 79–82.

TRUVADA

VS

DESCOVY

Effectiveness

>99% effective

Regimen

Daily use &

Shown to be effective for

Everyone, including:

- Gay & bisexual cis men
- Trans women
- Trans men
- Heterosexuals
- Cis women
- People who inject drugs

Safety: general

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.

Bone health

People with osteoporosis should avoid

Kidney health

People with kidney issues or a strong family history of kidney disease should avoid

Weight loss/gain

May cause a small degree of weight loss¹

Cholesterol

May cause small decreases in HDL, LDL and total cholesterol¹

Cost

Same cost (\$1,845/month without insurance)

Generic version may be available in 2020

Insurance

Covered by insurance

Assistance programs

Covered by assistance programs [for medication](#) and [medical care costs](#)

Pill size

Larger pill than Descovy

Effectiveness

>99% effective

Regimen

Daily use

Shown to be effective for

Only:

- Gay & bisexual cis men
- Trans women

(No clinical data to support use in people who may be exposed to HIV through injection drug use or vaginal sex)

Safety: general

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.

Bone health

[Safer to take for people with osteoporosis](#)

Kidney health

[Safer to take for people with kidney issues](#) or a strong family history of kidney disease, though monitoring still recommended

Weight loss/gain

May cause a small degree of weight gain²

Cholesterol

May cause small increases in LDL cholesterol and triglycerides^{2,3}

Cost

Same cost (\$1,845/month without insurance)

Insurance

Likely covered by insurance

Assistance programs

Covered by assistance programs [for medication](#) and [medical care costs](#)

Pill size

Smaller pill than Truvada

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

1. F/TAF Prescribing Information, Gilead Sciences Inc., 2019.
2. F/TDF Prescribing Information, Gilead Sciences Inc., 2018.

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

- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- Treatment as prevention
- [Redacted]

Treatment As Prevention

| HPTN 052 ^{1,2} 2011 | PARTNER ³ 2015 | Opposites Attract ⁴ 2017 | PARTNER 2 ⁵ 2018 |
|--|--|--|--|
| <ul style="list-style-type: none"> ▪ N=1,171 couples across Africa, Asia, North and South America ▪ 8,494 PYFU ▪ Endpoint: Linked HIV transmission to negative partners | <ul style="list-style-type: none"> ▪ N=888 couples across 14 European countries ▪ Median 35-42 condomless sex acts over 1.4 to 2.8 years of follow up per couple ▪ Endpoint: Linked HIV transmission to negative partners | <ul style="list-style-type: none"> ▪ N= 343 MSM couples in Australia, Brazil, and Thailand ▪ 591 CYFU (19% of CYFU consisted of negative partners on PrEP) ▪ 16,889 condomless sex acts ▪ Endpoint: linked HIV transmission to negative partners | <ul style="list-style-type: none"> ▪ N= 783 MSM serodiscordant couples ▪ 1,596 CYFU ▪ 77,000 condomless sex acts with undetectable viral load ▪ Endpoint: linked HIV transmission to negative partners |

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

[†]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

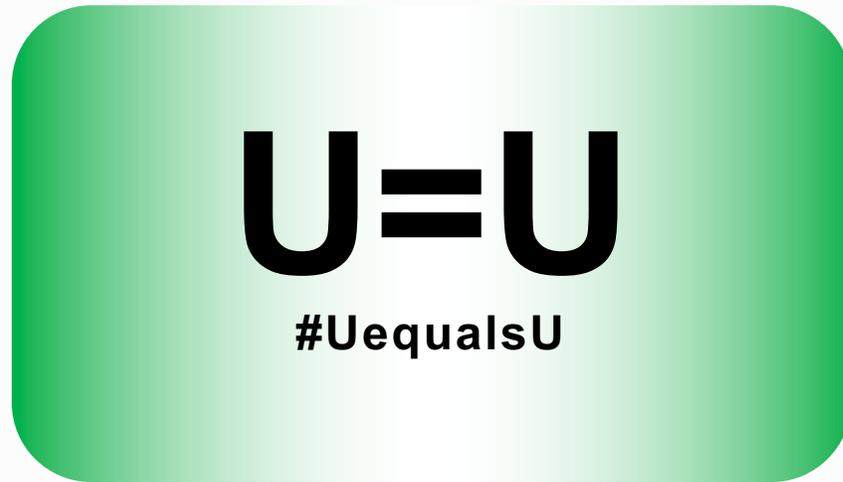
1. Cohen MS, et al. IAS 2015, Vancouver, Canada. Oral # MOAC0101LB
 2. Eshleman S, et al. IAS 2015, Vancouver, Canada. Poster # MOLBPE18
 3. Rodger A, et al. JAMA. 2016;316(2):171-181

4. Grulich A, et al. IAS 2017. Paris, France. Oral # TUAC0506LB
 5. Rodger A, et al. IAS 2018, Amsterdam, Netherlands #WEAX0104LB.
 6.. <https://www.hiv.gov/iasp>. Accessed April 7, 2020



Undetectable = Untransmittable

Prevention Access Campaign



- **U=U** signifies that achieving and maintaining HIV RNA levels <200 copies/mL with ART prevents HIV transmission through sex¹
- 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 documented¹
- **To maintain U=U** status, continue to take your medicines every day to help your viral load remain undetectable²

1. DHHS, December 2019. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. <http://aidsinfo.nih.gov/guidelines>. Accessed January 2020

2. Prevention Access Campaign. Undetectable = Untransmittable (U = U). <http://www.preventionaccess.org>. Accessed October 2019.



OUTLINE

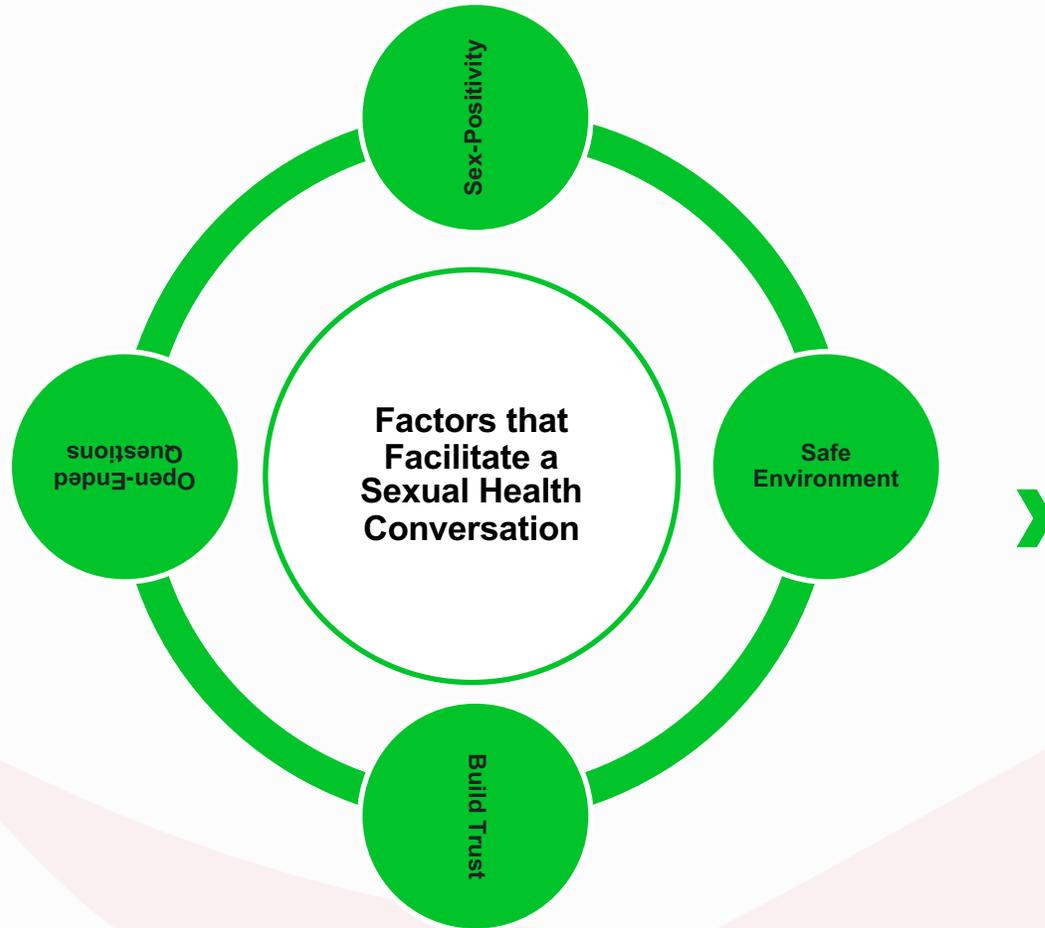
-
-
-
-
-
- Talking to patients

**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



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

Adapted from: Centers for Disease Control and Prevention. Pre-exposure prophylaxis for the prevention of HIV infection in the United States—2014: a clinical practice guideline. <http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf>. Accessed July 2017.
Adapted from: Centers for Disease Control and Prevention. A guide to taking a sexual history. <https://www.cdc.gov/std/treatment/sexualhistory.pdf>. Accessed July 2017.

SIGN UP FOR OUR PATIENT PORTAL!



YOUR MEDICAL HOME ON THE WEB.
CONNECT WITH YOUR PROVIDER
THROUGH A CONVENIENT, SAFE, AND
SECURE ENVIRONMENT

24/7 ACCESS TO:

- MEDICAL RECORDS
- MEDICATION LISTS
- PRESCRIPTION REFILLS
- MESSAGES REGARDING LAB & X-RAY RESULTS
- UPCOMING APPOINTMENTS
- E-MAILING TO & FROM OUR PROVIDERS & STAFF

ASK OUR FRIENDLY STAFF TO SIGN YOU UP TODAY

AT-A-GLANCE FEBRUARY 2021

| SUN | MON | TUE | WED | THU | FRI | SAT |
|-----|-----|-----|-----|-----|-----|-----|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |

FEBRUARY

WHAT'S UP DOC?

ASK ME ABOUT...

- COVID / VACCINE
- CANCER SCREENINGS
- Your hep C / 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
 - What types of sex do you have? Oral? Vaginal? Anal? Digital penetration?
- 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 matter 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.

www1.nyc.gov



PIEP 101

What is PIEP?

Is PIEP Right For You?

Call Your Healthcare Provider

How Can You Get Help Paying For PIEP?

Indigenous Great Health

1.8 million people in the U.S. are of Indigenous descent.

Increased Risks

HEP IN INDIGENES?

SCREENING GUIDELINES/RECOMMENDATIONS

CDC RECOMMENDS ANYONE BORN FROM 1945-1965 GET TESTED FOR HEPATITIS C

| Genotype 1 | Genotype 2 | Genotype 3 | Genotype 4 | Genotype 5 | Genotype 6 |
|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|----------------------------------|
| Sovaldi, Daklinavir, Velpatasvir |
| Harvoni | Harvoni | Harvoni | Harvoni | Harvoni | Harvoni |

Therapeutic Yoga

Offered at no cost for Midwestern patients.

- Improve your health & well-being
- Learn skills to cope with stress
- Improve balance, strength & mobility
- Manage chronic pain and illness

Tuesdays:
Mat yoga therapy: 2:30-3:30 AND 5:30-6:30pm
Chair yoga therapy: 4:30pm

Call clinic to schedule. No experience necessary!

When we put the young kindness and compassion of our children next to our parents...

Happy Home Appearance Services
In Chicago

HOW WELL DOES BIRTH CONTROL WORK?

Infographic showing effectiveness rates for various birth control methods.



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

| | |
|--|--|
|  | <p>U.S. PHS/CDC Clinical Practice Guidelines for PrEP</p> <p>http://www.cdc.gov/hiv/risk/prep/index.html</p> |
|  | <p>HIV Prevention Capacity Building Assistance Providers</p> <p>www.cbaproviders.org</p> |
|  | <p>HRSA-funded AIDS Education and Training Centers</p> <p>aidsetc.org</p> |
|  | <p>National PrEPLine @ UCSF Clinical Consultation Center</p> <p>HIV 800-933-3413, PrEP 855-448-7737, HCV 844-437-4636, Substance Use 855-300-3595</p> <p>https://nccc.ucsf.edu/2014/09/29/introducing-the-ccc-prepline/</p> |
|  | <p>NACCHO's PrEP for Local Health Departments Educational Series</p> <p>https://www.naccho.org/programs/community-health/infectious-disease/hiv-sti/prep-1/prep</p> |
| <p>Kansas Department of Public Health-PrEP</p> <ul style="list-style-type: none"> www.kdheks.gov/sti_hiv/PrEP.htm | |
| <p>GILEAD</p> | <p>Advancing access 800-226-2056</p> <ul style="list-style-type: none"> https://www.gileadadvancingaccess.com/hcp |
| <p>GILEAD</p> | <p>Gilead HIV Prevention and Treatment Medical Scientist can also do a more in-depth training on implementation of services in your area in Kansas</p> <ul style="list-style-type: none"> For Prevention contact Patty Martin, PharmD patty.martin@gilead.com. For treatment the medical scientist is Brittany Mills, PharmD Brittany.mills@gilead.com |

PrEP Resources

| | |
|--|---|
|  | NASTAD PrEP Cost Calculator https://www.nastad.org/prepcost |
|  | Ready, Set, PrEP Program https://www.getyourprep.com/ |
|  | PleasePrEPMe http://pleaseprepme.org Prep resources for Kansas <ul style="list-style-type: none">• www.pleaseprepme.org/kansas Includes Tools to help estimate and pay PrEP costs: <ul style="list-style-type: none">• Gilead Sciences - Truvada PrEP Access and Assistance Programs www.truvada.com/how-to-get-truvada-for-prep/truvada-cost• Patient Advocate Foundation - Copay Relief copays.org/funds/hiv-aids-and-prevention/• Project Inform - Getting Yourself Prepared for PrEP Flow Chart www.pleaseprepme.org/sites/default/files/file-attachments/PrEP_Flow_Chart_eng.pdf• PrEPCost.org nastad.checkbookhealth.org/prepcost/2020/ |
|  | PrEP Locator http://preplocator.org |
| GILEAD | Gilead Copay support for HIV treatment and prevention medications <ul style="list-style-type: none">• www.gileadadvancingaccess.com/hcp/financial-assistance/copay-support |

Resources

Pep Consultation service for Clinicians 888-448-4911

www.hivinfo.nih.gov

www.hivguidelines.org

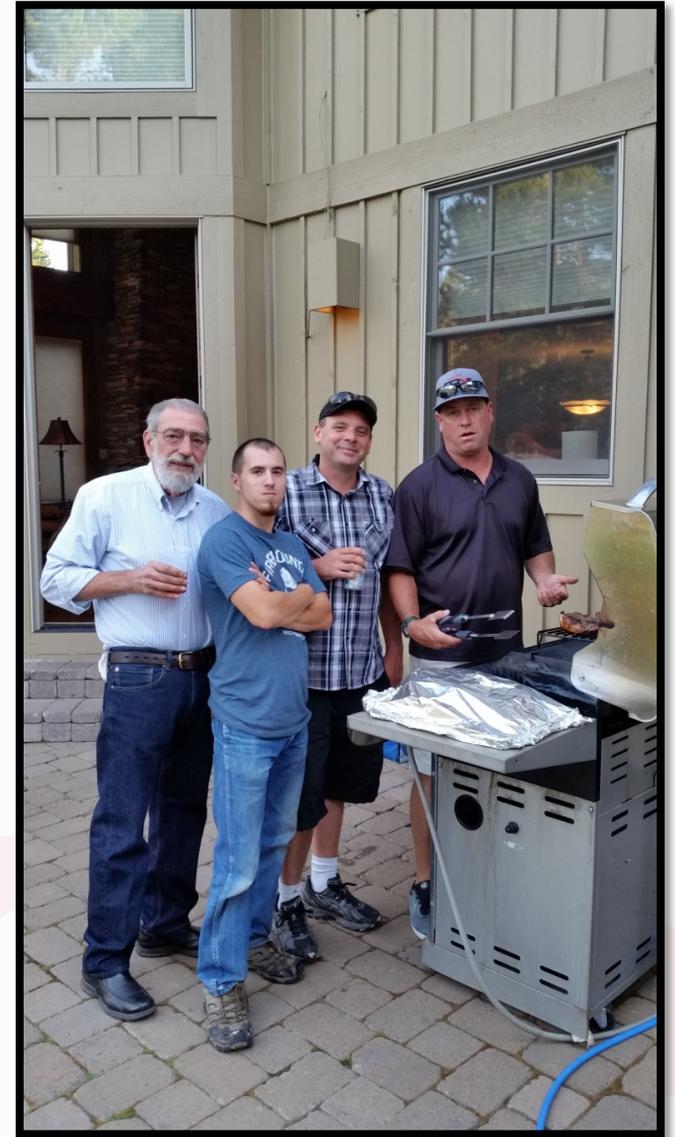
www1.nyc.gov

cdc.gov

QUESTIONS?



I think a hero
is any person
really intent
on making this
a better place
for all people.
MAYA ANGELOU



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