

# HIV Prevention and Treatment Challenges in Rural America

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# Disclaimer

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# Disclosures

- Clinical Research
  - Merck
  - ViiV
- Advisor/Consultant
  - Gilead
  - Janssen
  - ViiV

# Learning Objectives

- Discuss who should be offered HIV PrEP
- Identify current options in HIV treatment
- Recognize HIV care issues for people with HIV in rural areas



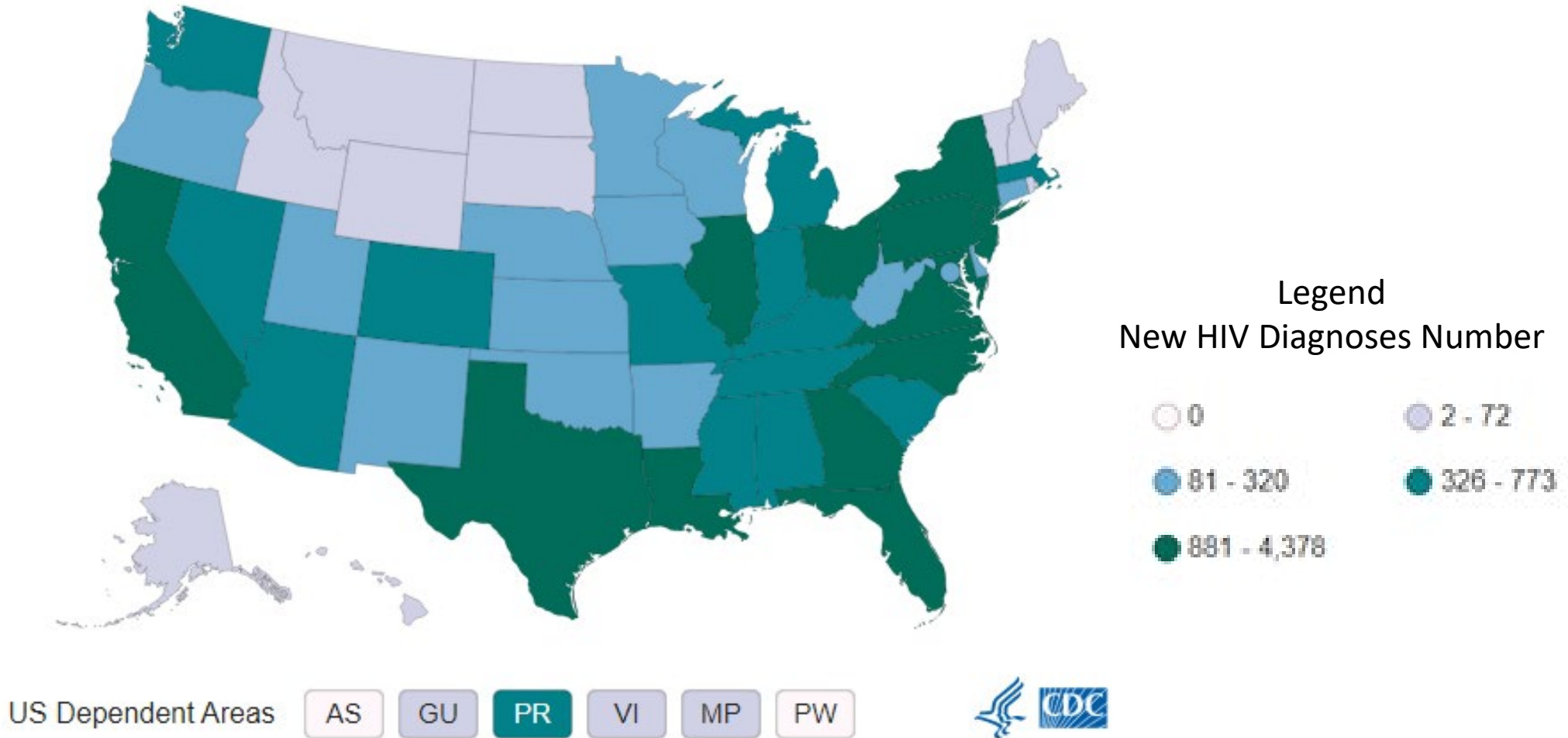
## ***How many people receive an HIV diagnosis each year in the United States and 6 dependent areas?***

- **36,801 people** received an HIV diagnosis in the United States and dependent areas in 2019.
- The annual number of new diagnoses decreased 9% from 2015 to 2019.

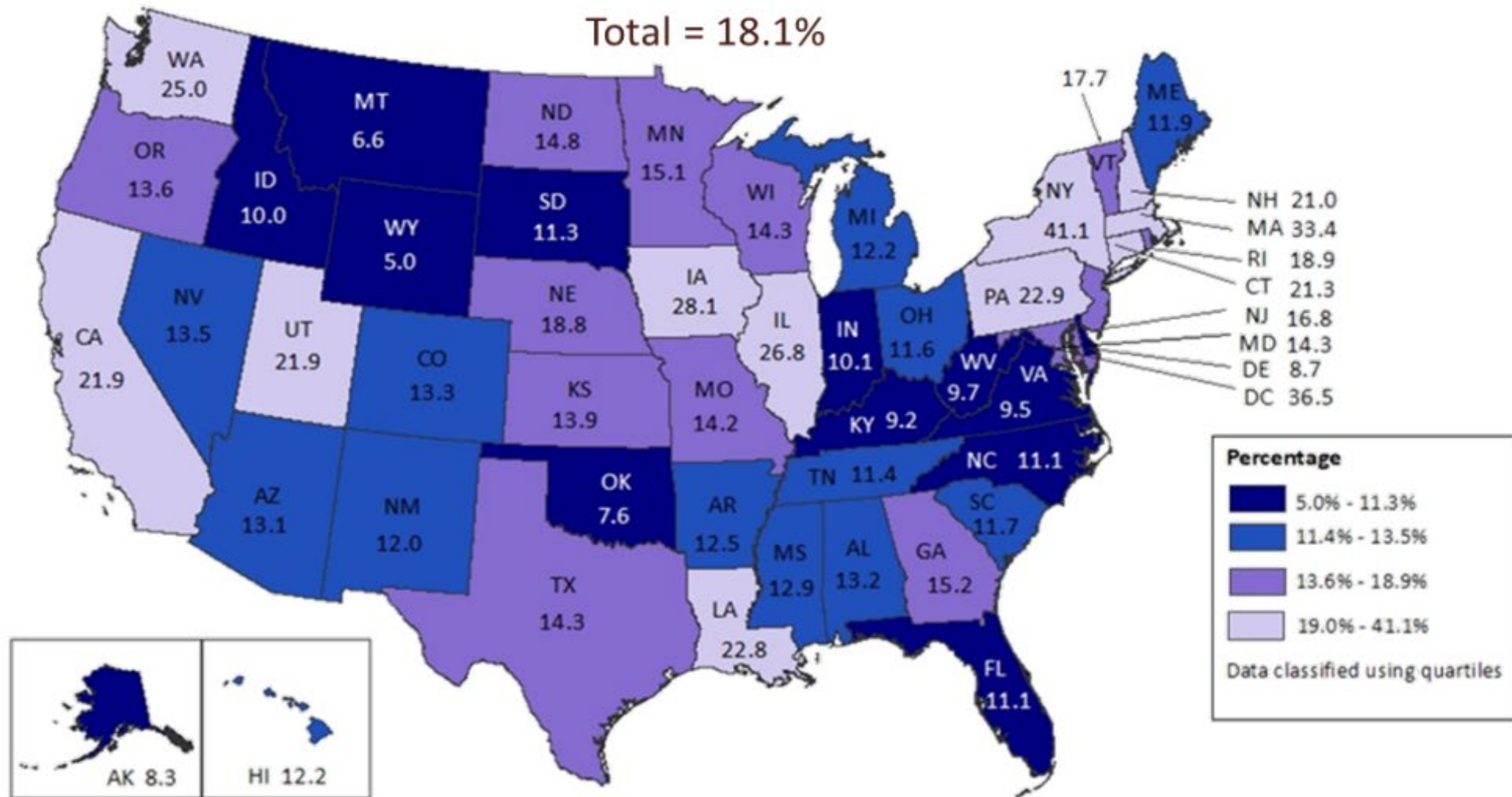
## ***How many people have HIV in the United States?***

- **1,189,700 people** were estimated to have HIV in the United States at the end of 2019, the most recent year for which this information is available.
  - Of those people, **about 87% knew they had HIV.**

# New HIV diagnoses and people with diagnosed HIV in the US and Dependent Areas by Area of Residence, 2019\*



# PrEP Coverage among Persons Aged ≥16 Years, by Area of Residence, 2018—United States



Abbreviation: PrEP, preexposure prophylaxis.

Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Different data sources were used in the numerator and denominator to calculate PrEP coverage.



# HIV In Rural America



- While the HIV/AIDS epidemic began in largely urban areas in the United States, it has become increasingly prominent in rural communities over the past decade.
  - In 2018, 21% of HIV/AIDS diagnoses occurred in rural areas.
  - There are regional disparities as well, with the highest rates (15.6 per 100,000) and most diagnoses (51%) occurring in the South.
  - Further, racial disparities in HIV/AIDS rates mean that the burden of this disease is borne disproportionately by Black Americans.



# Rural Residents Living with HIV/AIDS

- The more than 50,000 rural residents living with HIV/AIDS need consistent access to timely, high-quality health care in order to manage their symptoms and quality of life.
- Given the well-documented barriers in access to care for rural individuals, additional support systems may be needed for small, rural organizations to effectively provide health care services to those in their communities living with HIV/AIDS.

## “Rurality”



## ***“How rural is it?”***

This accounts for population size, density, distance to metropolitan areas

Extreme “rurality” is absent from most areas



# HIV/AIDS Is Not Just an Urban Issue

- Multiple definitions of “rural” used by different agencies may lead to varying estimates of HIV and AIDS incidence and prevalence, with implications for public policy and allocation of resources and services
- The effects of HIV in rural areas may be underestimated
- Statistics generated by the CDC are based on residence at time of diagnosis:
  - Persons diagnosed in urban areas may migrate to rural hometowns after diagnosis
  - Rural residents may go to urban testing locations for HIV screening and decline to provide their real residence to avoid stigma

# Rural Context

- Geographic estrangement from other men who have sex with men (MSM)
  - Estrangement from venues that serve gay and bisexual men
- Medical and mental health shortage areas
- Systemic homophobia
- Structural stigma



- May not identify as “gay” or “bisexual” and thus may not include themselves as a member of LGBT community

## Rural HIV populations...

- Experience numerous barriers to medical and mental health care
  - Less likely to be engaged than their urban counterparts
- Lack of access to affirming providers
- ↑ Substance use; ↓ mental health—including loneliness and isolation
- ↓ access to HIV testing

## New Options for Care

- Telemedicine
- At-home testing



A 3D rendering of a white puzzle piece with the word "GUIDELINES" in orange and red letters. The puzzle piece is set against a dark blue background. The word "GUIDELINES" is written in a bold, sans-serif font. The letters "G", "U", "I", "D", "E", "L", "I", "N", "E", and "S" are all in orange, while the letter "S" is in red. The puzzle piece has a slight shadow and a beveled edge, giving it a three-dimensional appearance.

**GUIDELINES**

# Grading of Strength of Recommendations and Quality of Evidence

Using the same grading system as the DHHS antiretroviral treatment guidelines 2021, these key recommendations are rated with a letter to indicate the strength of the recommendation and with a numeral to indicate the quality of the combined evidence supporting each recommendation.

**Table 10: Rating Scheme for Recommendations**

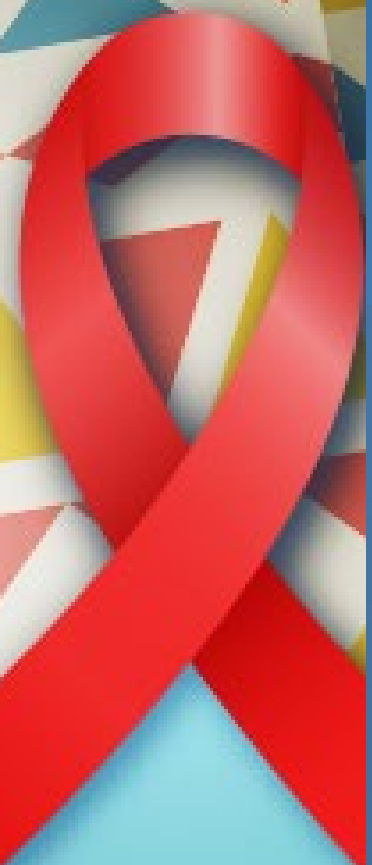
<b>Strength of Recommendation</b>	<b>Quality of Evidence Supporting a Recommendation</b>
<b>A. Strong recommendation for the statement</b>	<b>I.</b> One or more well-executed randomized, controlled trials with clinical outcomes, validated laboratory endpoints, or both
<b>B. Moderate recommendation for the statement</b>	<b>II.</b> One or more well-executed, nonrandomized trials or observational cohort studies with clinical outcomes
<b>C. Optional recommendation for the statement</b>	<b>III.</b> Expert opinion



Ending  
the  
HIV  
Epidemic

**JUNE 27**

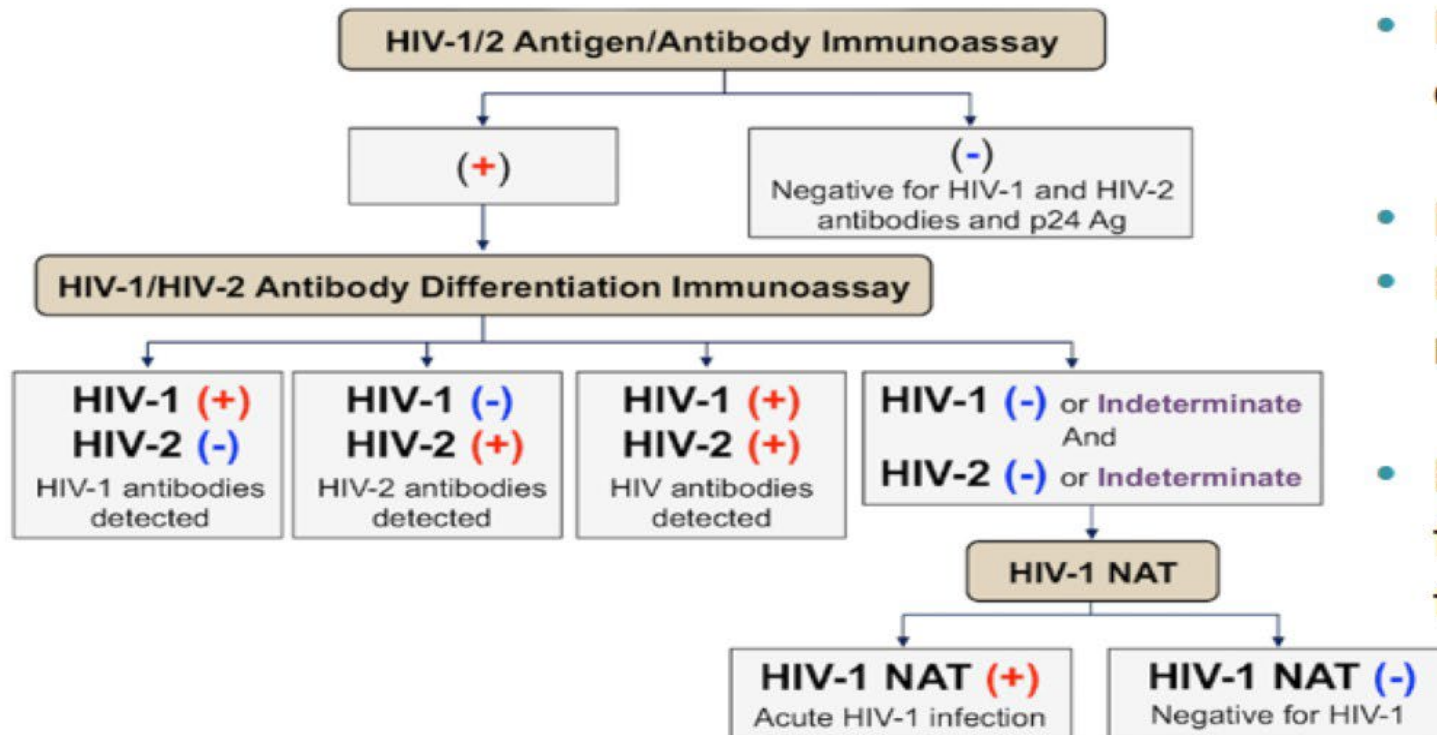
**NATIONAL HIV  
TESTING DAY**





# Screening Tests

## CDC and the APHL 2018 HIV Diagnostic Algorithm



- More accurate diagnosis of acute HIV-1
- More diagnosis of HIV-2
- Fewer indeterminate results
- Faster turnaround time for completion of the testing algorithm

# USPSTF HIV Screening Recommendations

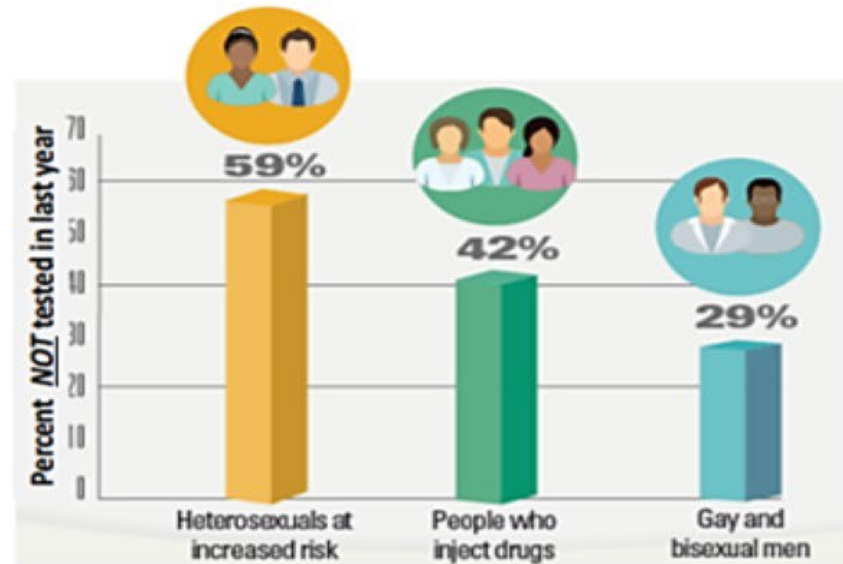
## Updated June 2019

Population	Recommendation	Grade (What's This?)
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.	<b>A</b>
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.	<b>A</b>

# Annual Testing for People at Risk for HIV

## Early Diagnosis Essential but Many People at Risk for HIV Not Tested Annually

**7 in 10** people at high risk who weren't tested for HIV in the past year saw a healthcare provider during that time. More than **75%** of them weren't offered a test.



In 2015, **nearly 40,000** people in the US received an HIV diagnosis

.....

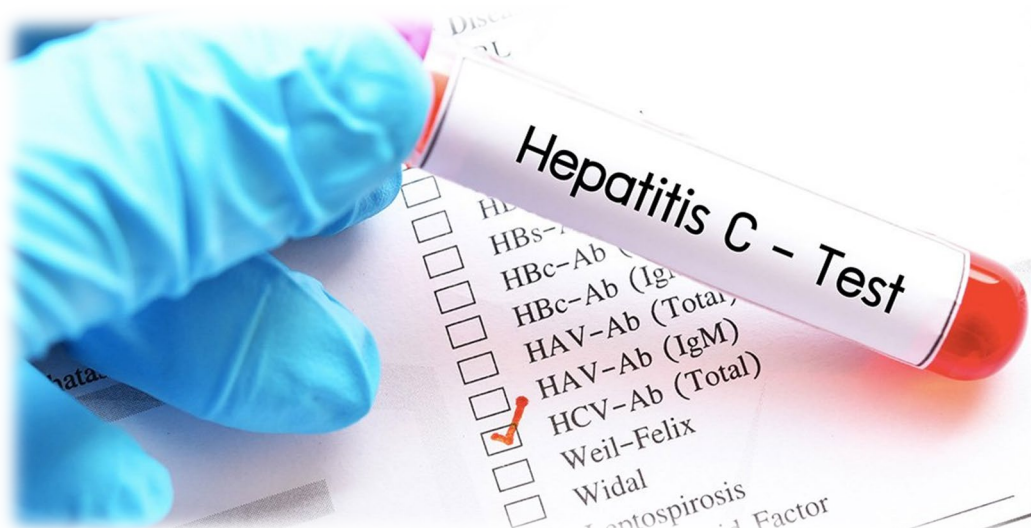
**1 in 2** had been living with HIV 3 years or more

.....

**1 in 4** had been living with HIV 7 years or more

.....

**1 in 5** already had the most advanced stage of HIV (AIDS)



## Hepatitis C - Test

- HBs-
- HBc-Ab (Ig)
- HBc-Ab (Total)
- HAV-Ab (Total)
- HAV-Ab (IgM)
- HCV-Ab (Total)
- Weil-Felix
- Widal
- Leptospirosis
- Acid Factor

# CDC Recommendations for Hepatitis C Screening Among Adults in the United States (1)

## Universal hepatitis C screening:

- Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%\*
- Hepatitis C screening for **all pregnant women during each pregnancy**, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%\*

\*Determining prevalence: In the absence of existing data for hepatitis C prevalence, health care providers should initiate universal hepatitis C screening until they establish that the prevalence of HCV RNA positivity in their population is less than 0.1%, at which point universal screening is no longer explicitly recommended but may occur at the provider's discretion.

# CDC Recommendations for Hepatitis C Screening Among Adults in the United States (2)

- **One-time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:**
  - People with HIV
  - People who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
  - People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis
    - people with persistently abnormal ALT levels
  - Prior recipients of transfusions or organ transplants, including:
    - people who received clotting factor concentrates produced before 1987
    - people who received a transfusion of blood or blood components before July 1992
    - people who received an organ transplant before July 1992
    - people who were notified that they received blood from a donor who later tested positive for HCV infection
  - Health care, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
  - Children born to mothers with HCV infection

# CDC Recommendations for Hepatitis C Screening Among Adults in the United States (3)

- **Routine periodic testing for people with ongoing risk factors**, while risk factors persist:
  - People who currently inject drugs and share needles, syringes, or other drug preparation equipment
  - People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis
- **Any person who requests hepatitis C testing** should receive it, regardless of disclosure of risk, because many persons may be reluctant to disclose stigmatizing risks

# HIV Prevention

PrEP

Condom Use



92%

**Efficiency**

80%

**Efficiency**



# USPSTF PrEP Guidelines

## Recommendation Summary

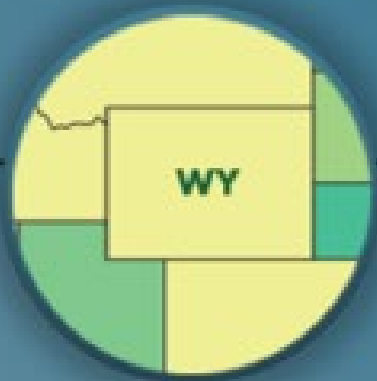
Population	Recommendation	Grade
Persons at high risk of HIV acquisition	The USPSTF recommends that clinicians offer preexposure prophylaxis (PrEP) with effective antiretroviral therapy to persons who are at high risk of HIV acquisition. See the Clinical Considerations section for information about identification of persons at high risk and selection of effective antiretroviral therapy.	<b>A</b>

## Clinician Summary

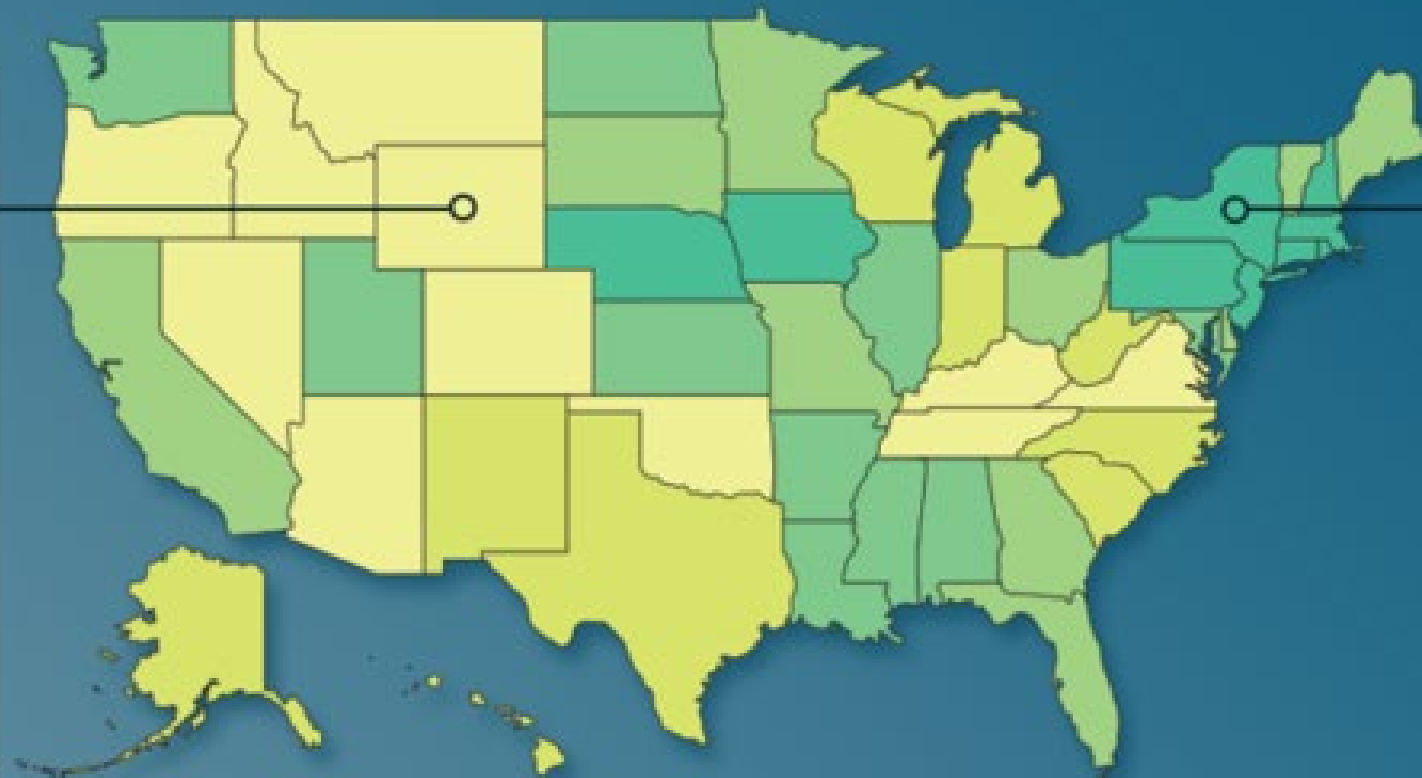
Population	Persons at high risk of HIV acquisition
Recommendation	Offer preexposure prophylaxis (PrEP). Grade: A

<https://uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>

PrEP use ranges widely among states, from...



...**16.9 male PrEP users** per 1,000 Gay and Bisexual Men in **Wyoming**...



...to **99.8 male PrEP users** per 1,000 Gay and Bisexual Men in **New York**.

The PrEP-to-MSM ratio is the ratio of the number of male PrEP users in 2018 to the number of Men who have Sex with Men (MSM) in 2018.

PrEP-to-Men who have Sex with Men (MSM) Ratio, 2018

0 - 25.1

25.2 - 30.4

30.5 - 35.9

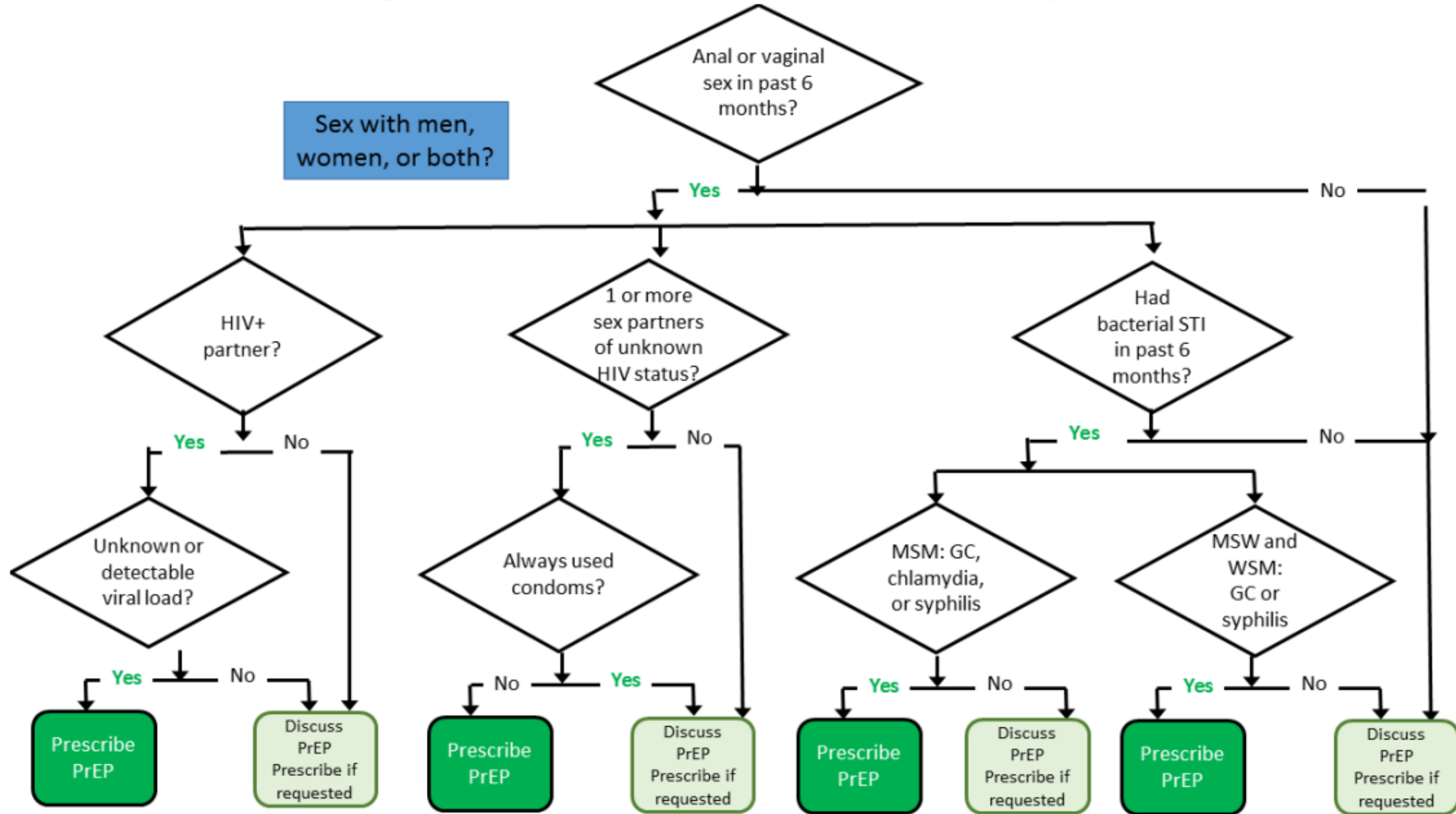
36.0 - 43.0

43.1+

# Who should be prescribed PrEP?

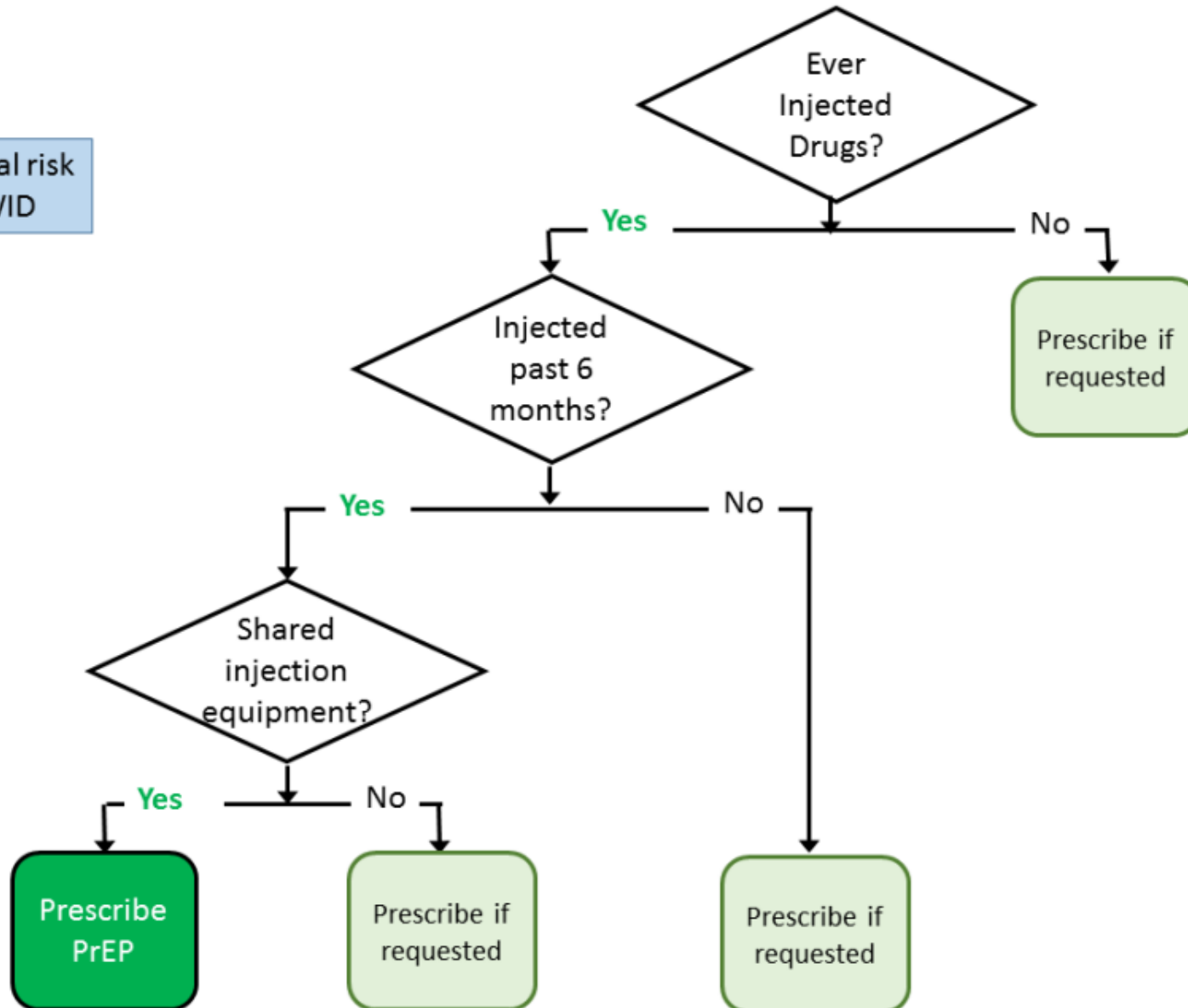
- All sexually active adult and adolescent patients should receive information about PrEP **(IIB)**
- For both men and women, PrEP with daily F/TDF is recommended for sexually-active adults and adolescents (>35 kg) who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- For both men and women, PrEP with daily F/TDF is recommended for persons who inject drugs (PWID) and report injection practices that place them at substantial ongoing risk of HIV exposure and acquisition **(IA)**
- PrEP should be prescribed in discordant couples
  - If the sexual partner with HIV has been inconsistently virally suppressed
  - If their VL is unknown
  - If the HIV-negative partner has other sexual partners
  - If the HIV-negative partner wants the additional reassurance of protection

# Assessing Indications for PrEP in Sexually Active Persons



# Assessing Indications for PrEP in Persons Who Inject Drugs

Assess sexual risk  
for all PWID



# Baseline HIV testing

- Document an HIV test within one week before PrEP
- Ideally lab-based Ag/Ab test
- Point-of-care Ag/Ab testing is acceptable when clinicians prescribe PrEP based solely on the results of point-of-care rapid tests, a laboratory antigen/antibody test should always be ordered at the time baseline labs are drawn
- Oral fluid tests should not be used

# How to prescribe PrEP?

- Same day PrEP

Same-day PrEP initiation **is not appropriate** for:

- Patients who express ambivalence about starting PrEP (e.g., need more time to think)
- Patients for whom blood cannot be drawn for laboratory testing
- Patients with signs/symptoms and sexual history indicating possible acute HIV infection
- Patients with history of renal disease or associated conditions (e.g., hypertension, diabetes)
- Patients without insurance or a means to pay when picking up the prescribed medication that day
- Patients who do not have a **confirmed** means of contact should laboratory test indicate a need to discontinue PrEP (e.g., HIV infection, unanticipated renal dysfunction)

Same-day PrEP initiation **may not be appropriate** for:

- Patients with a very recent possible HIV exposure but no signs and symptoms of acute infection (should be evaluated for nPEP before PrEP)
- Patients who may not be easily contacted for return appointments
- Patients with mental health conditions that are severe enough to interfere with understanding of PrEP requirements (adherence, follow-up visits)

- 2-1-1 dosing – clinicians may choose to prescribe F/TDF off label using 2-1-1 dosing for adult MSM who have sex less than once/week and can anticipate sex

## 2-1-1 Dosing

- The guideline now provides information on how to correctly use off-label 2-1-1 dosing for oral PrEP.
  - This means taking 2 pills 2 to 24 hours before sex, 1 pill 24 hours after the first dose, and 1 pill 24 hours after the second dose.
- This information may benefit gay, bisexual, and other men who have sex with men who choose to use 2-1-1 dosing.
- *This approach is not approved by the FDA and is not recommended by CDC.*



# What to prescribe as PrEP?

- For men only, daily oral PrEP with F/TAF is a recommended option for HIV prevention. PrEP with F/TAF has not yet been studied in women and so F/TAF is not recommended for HIV prevention for women or other persons at risk through receptive vaginal sex. **(IA)**
- For transgender women who have sex with men, daily oral PrEP with F/TAF is a recommended option for HIV prevention **(IIB)**
- The efficacy and safety of other daily oral antiretroviral medications for PrEP, either in place of, or in addition to, F/TDF or F/TAF, have not been studied extensively and are not recommended. **(IIIA)**
- Conditioned on a PrEP indication approved by FDA, PrEP with intramuscular cabotegravir (CAB) injections is recommended for HIV prevention in adults and adolescents who report sexual behaviors that place them at substantial ongoing risk of HIV exposure and acquisition. **(IA)**

# What to prescribe as PrEP? F/TDF v F/TAF

- For most patients, there is no need to switch from F/TDF to F/TAF.
- F/TAF is indicated for patients with eCrCl 30-60.
- Clinicians may prefer F/TAF for patients with previously documented osteoporosis or related bone disease.

# Long-acting Injectable PrEP Approved: Cabotegravir

- The FDA approved the use of an extended-release injectable formulation of the integrase inhibitor cabotegravir (CAB) for pre-exposure prophylaxis (PrEP) for adults and adolescents at risk for HIV infection.
- After two initial intramuscular (IM) injections given 1 month apart, it is administered every 2 months
- It is the first non-oral PrEP therapy to become available.
- Just before the FDA approval of IM CAB, the CDC published PrEP Guidelines, with recommendations for use of CAB plus important updates on oral PrEP.

# HIV PrEP: Present, Emerging, and Future

Present

Emerging

Future

Once-daily\* oral tablets

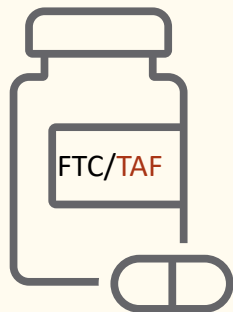
Long-acting options



INJECTABLE



Long-acting antiretroviral drug is injected into the body.



INTRAVAGINAL RING (IVR)



Polymer ring inserted into the vagina releases antiretroviral drug over time.

IMPLANT



Device implanted in the body releases antiretroviral drug over time.

ANTIBODY



Antibody is infused or injected into the body.

\*Off-label on-demand use of FTC/TDF supported by international guidelines.

# HIV PrEP: Present, Emerging, and Future

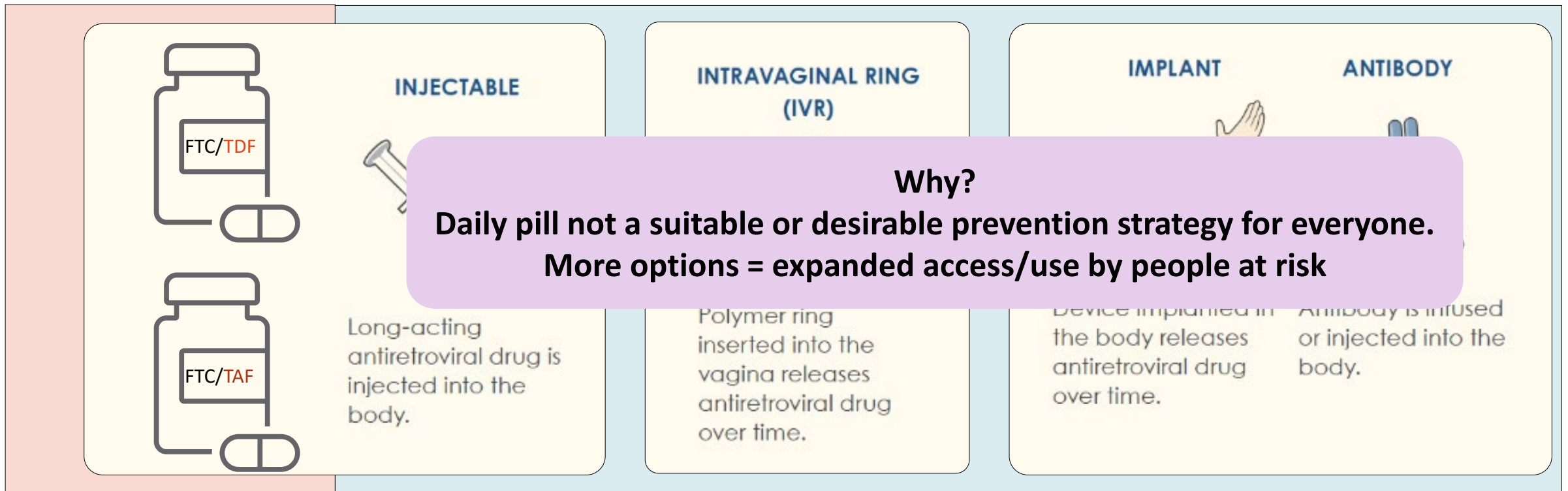
Present

Emerging

Future









Once-daily\* oral tablets

Long-acting options



\*Off-label on-demand use of FTC/TDF supported by international guidelines.

# Summary of guidance for daily oral PrEP

	Sexually-Active Adults and Adolescents <sup>1</sup>	Persons Who Inject Drug <sup>2</sup>
Identifying substantial risk of acquiring HIV infection	<p>Anal or vaginal sex in past 6 months AND any of the following:</p> <ul style="list-style-type: none"> <li>• HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)</li> <li>• Bacterial STI in past 6 months<sup>3</sup></li> <li>• History of inconsistent or no condom use with sexual partner(s)</li> </ul>	<p>HIV-positive injecting partner OR Sharing injection equipment</p>
Clinically eligible 	<p><b><u>ALL OF THE FOLLOWING CONDITIONS ARE MET:</u></b></p> <ul style="list-style-type: none"> <li>• Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP</li> <li>• No signs/symptoms of acute HIV infection</li> <li>• Estimated creatinine clearance <math>\geq 30</math> ml/min<sup>4</sup></li> <li>• No contraindicated medications</li> </ul>	
Dosage 	<ul style="list-style-type: none"> <li>• Daily, continuing, oral doses of F/TDF (Truvada®), <math>\leq 90</math>-day supply OR</li> <li>• For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), <math>\leq 90</math>-day supply</li> </ul>	
Follow-up care      	<p><b><u>Follow-up visits at least every 3 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support</li> <li>• Bacterial STI screening for MSM and transgender women who have sex with men<sup>3</sup> – oral, rectal, urine, blood</li> <li>• Access to clean needles/syringes and drug treatment services for PWID</li> </ul> <p><b><u>Follow-up visits every 6 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for patients aged <math>\geq 50</math> years or who have an eCrCl <math>&lt; 90</math> ml/min at PrEP initiation</li> <li>• Bacterial STI screening for all sexually-active patients<sup>3</sup> – [vaginal, oral, rectal, urine- as indicated], blood</li> </ul> <p><b><u>Follow-up visits every 12 months to provide the following:</u></b></p> <ul style="list-style-type: none"> <li>• Assess renal function for all patients</li> <li>• Chlamydia screening for heterosexually active women and men – vaginal, urine</li> <li>• For patients on F/TAF, assess weight, triglyceride and cholesterol levels</li> </ul>	

**What has  
changed  
in HIV  
Care?**





# Stage 1: Acute HIV Infection

- ✓ People have a large amount of HIV in their blood. They are very contagious.
- ✓ Some people have flu-like symptoms. This is the body's natural response to infection.
- ✓ But some people may not feel sick right away or at all.
- ✓ If you have flu-like symptoms and think you may have been exposed to HIV, seek medical care and ask for a test to diagnose acute infection.
- ✓ Only [antigen/antibody tests or nucleic acid tests \(NATs\)](#) can diagnose acute infection.





Stage 2:  
Chronic HIV  
Infection

# Stage 2: Chronic HIV Infection

- ✓ This stage is also called asymptomatic HIV infection or clinical latency.
- ✓ HIV is still active but reproduces at very low levels.
- ✓ People may not have any symptoms or get sick during this phase.
- ✓ Without taking HIV medicine, this period may last a decade or longer, but some may progress faster.
- ✓ People can transmit HIV in this phase.
- ✓ At the end of this phase, the amount of HIV in the blood (called *viral load*) goes up and the CD4 cell count goes down. The person may have symptoms as the virus levels increase in the body, and the person moves into Stage 3.
- ✓ People who take HIV medicine as prescribed may never move into Stage 3.



# Stage 3: Acquired Immunodeficiency Syndrome (AIDS)

- ✓ The most severe phase of HIV infection.
- ✓ People with AIDS have such badly damaged immune systems that they get an increasing number of severe illnesses, called [opportunistic infections](#).
- ✓ People receive an AIDS diagnosis when their CD4 cell count drops below 200 cells/mm, or if they develop certain opportunistic infections.
- ✓ People with AIDS can have a high viral load and be very infectious.
- ✓ Without treatment, people with AIDS typically survive about 3 yrs.

# Current Recommendations for Same-Day ART Initiation

- Rapid start or initiating ART on same day as HIV is diagnosed is an emerging strategy to **reduce loss to follow-up and decrease time to viral suppression**
- Evidence base limited but growing, and outcomes favorable thus far

## DHHS<sup>[1]</sup>

- **Recommended** at time of diagnosis (when possible) or soon afterward
  - Resource intensive
  - US experience from observational trials

## WHO<sup>[2]</sup>

- **Recommended** for all PWH, including same day, if patient is ready\*

## IAS-USA<sup>[3]</sup>

- Start ART as soon as possible, **including immediately after diagnosis**, if patient is ready

\*Rapid initiation defined as within 7 days of diagnosis. Priority should be given to patients with advanced disease.



# Patient Information Before Initiating Rapid ART

## Need prior to start

- Patient prepared for ART and interest in rapid initiation
- Physical examination
  - Active cryptococcal meningitis or TB infection could increase risk for IRIS and *may warrant a short ART delay*
  - Other AIDS-defining conditions could increase risk of morbidity/mortality in the setting of rapid ART initiation
- Counsel on medication adherence

## Not needed prior to start

- CD4+ cell count
- HIV viral load
- HIV genotype
- Resistance test results
- Hepatitis A/B/C status
- HLA-B\*5701 status
- STI screening results
- Pregnancy test results

# Recommended Regimens for Rapid ART

## DHHS<sup>1</sup>

### Recommended Regimens

BIC/FTC/TAF

DTG + (TAF or TDF) + (3TC or FTC)

**(DRV/RTV or DRV/COBI) + (TAF or TDF) +  
(3TC or FTC)**

## EACS<sup>2</sup>

### Recommended Regimens

BIC/FTC/TAF

DTG + TDF/FTC, TAF/FTC, TDF/3TC, or ABC/3TC

**Boosted PI + TDF/FTC, TAF/FTC, TDF/3TC, or  
ABC/3TC**



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# Licensure of Antiretroviral Agents by Year

1987: zidovudine (Retrovir)

# LICENSURE OF ANTIRETROVIRAL AGENTS BY YEAR

1987: zidovudine (Retrovir)  
 1991: didanosine (Videx)  
 1992: zalcitabine (Hivid)  
 1994: stavudine (Zerit)  
 1995: lamivudine (Epivir)  
 saquinavir (Invirase)  
 1996: ritonavir (Norvir)  
 indinavir (Crixivan)  
 nevirapine (Viramune)  
 1997: nelfinavir (Viracept)  
 delavirdine (Rescriptor)  
 1998: efavirenz (Sustiva)  
 abacavir (Ziagen)  
 1999: amprenavir (Agenerase)  
 2000: lopinavir/ritonavir (Kaletra)  
 2001: tenofovir (Viread)  
 2003: enfuvirtide (Fuzeon)  
 6/03: atazanavir (Reyataz)  
 7/03: emtricitabine (Emtriva)  
 8/04: lamivudine/abacavir sulfate (Epzicom)  
 6/05: tipranavir (Aptivus)  
 6/06: darunavir (Prezista)  
 7/06: efavirenz/emtricitabine,  
 tenofovir DF (Atripla)  
 8/07: maraviroc (Selzentry)  
 10/07: raltegravir (Isentress)  
 1/08: etravirine (Intelence)  
 5/20/11: rilpivirine (Edurant)  
 8/11/11: rilpivirine/ tenofovir/ emtricitabine (Complera)  
 7/16/12: emtricitabine/tenofovir disoproxil fumarate (Truvada)  
 8/28/12: emtricitabine/ tenofovir/elvitegravir/cobicistat. (Stribild)  
 8/12/13: dolutegravir (Tivicay)

8/30/14 abacavir/dolutegravir/lamivudine (Triumeq)  
 1/29/15 atazanavir 300 mg and cobicistat /150 mg (Evotaz)  
 11/5/15 elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide.(Genvoya)  
 3/1/16 rilpivirine+emtricitabine+tenofovir alafenamide (Odefsey)  
 4/6/16 emtricitabine+tenofovir alafenamide (Descovy)  
 11/21/17 dolutegravir sodium / rilpivirine hydrochloride (Juluca)  
 2/7/18 bicitgravir 50 mg /emtricitabine 200 mg/tenofovir alafenamide 25mg (Biktarvy)  
 3/6/18 ibalizumab-uiyk IV 2,000mg/800mg (Trogarzo)  
 2/5/2018 efavirenz, lamivudine, and tenofovir disoproxil fumarate (Symfi)  
 2/5/18 efavirenz, lamivudine, and tenofovir disoproxil fumarate (Symfi Lo)  
 2/28/18 lamivudine and tenofovir disoproxil fumarate (Temixys, 3TC/TDF)  
 2/28/18 lamivudine/tenofovir disoproxil (Cimduo)  
 7/17/18 darunavir 800 mg/cobicistat 150mg/emtricitabine 200mg/tenofovir alafenamide 10 mg (Symtuza)  
 8/30/18 doravirine (Pifeltro)  
 8/30/18 doravirine/lamivudine/ tenofovir disoproxil fumarate (Delstrigo)  
 11/28/18 lamivudine and tenofovir disoproxil fumarate; (Temixys; Celltrion)  
 4/8/2019 dolutegravir and lamivudine (Dovato)  
 7/2/2020 fostemsavir (Rukobia)  
 2/1/2021 cabotegravir (Cabenuva) – First long acting injectable

Highlighted yellow: generic available in U.S.  
 Highlighted grey: generic available, but rarely/never used  
 Blue: Fixed dose combinations of existing drugs

# DHHS, IAS-USA Guidelines: Recommended First-line ART Regimens for Most PWH

DHHS <sup>1</sup>	IAS-USA <sup>2</sup>
<p><i>Recommended (rating A1, unless otherwise specified) initial regimens for most PWH:</i></p> <ul style="list-style-type: none"><li>▪ BIC/FTC/TAF</li><li>▪ DTG/3TC/ABC <i>if HLA-B*5701 negative and without chronic HBV coinfection</i></li><li>▪ DTG + (FTC or 3TC) + (TAF or TDF)</li><li>▪ DTG/3TC<sup>†</sup></li></ul>	<p><i>Recommended (rating A1a) initial regimens for most PWH:</i></p> <ul style="list-style-type: none"><li>▪ BIC/FTC/TAF</li><li>▪ DTG + FTC/(TAF or TDF)</li><li>▪ DTG + 3TC/TDF</li><li>▪ DTG/3TC<sup>†‡</sup></li></ul>

<sup>†</sup>Except for individuals with baseline HIV-1 RNA >500,000 copies/mL, with HBV, or for whom results of HIV genotypic resistance testing or HBV testing are not yet available.

<sup>‡</sup>Possibly not suitable for individuals with baseline CD4+ cell count <200 cells/mm<sup>3</sup>.



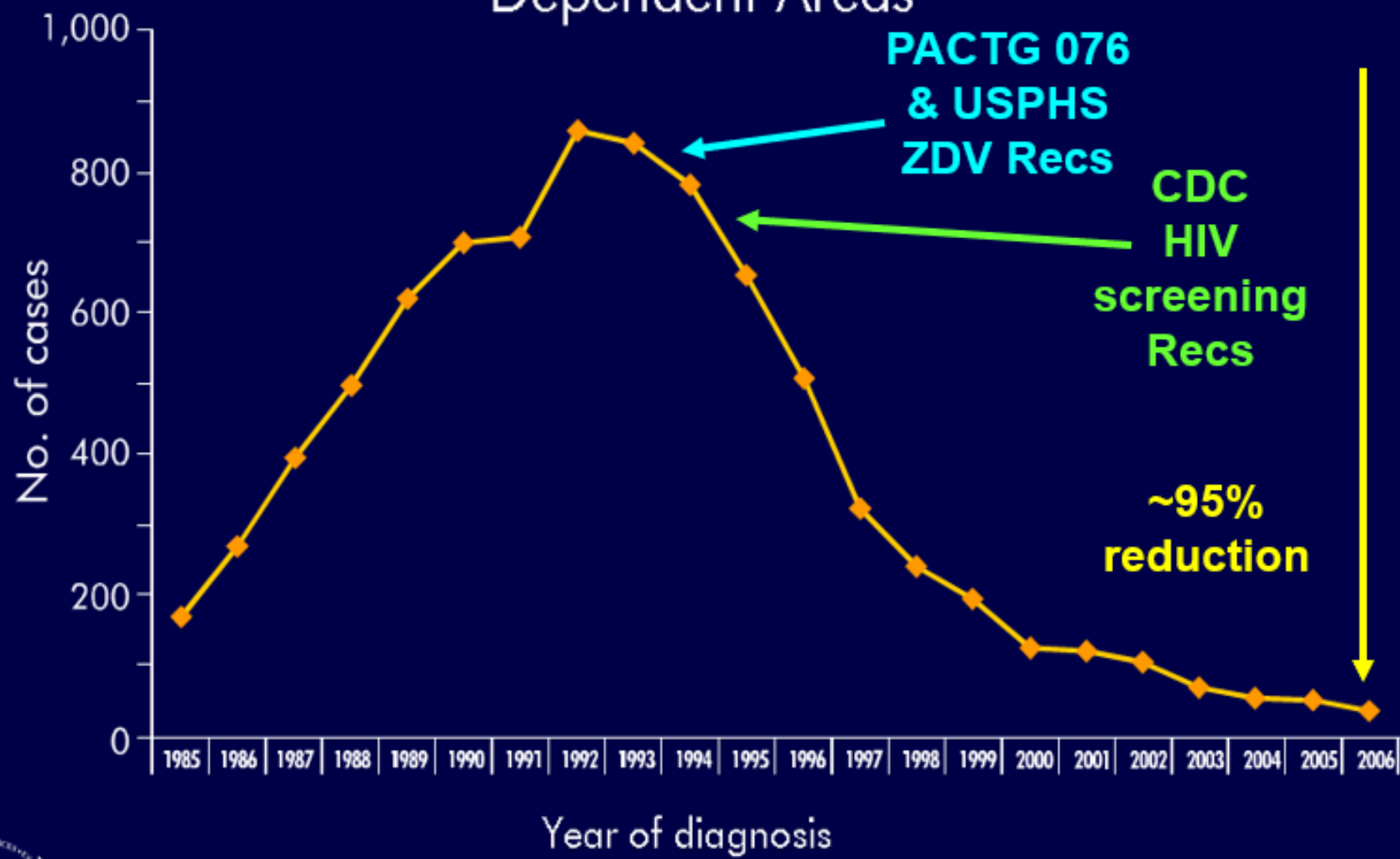
# Available Single-Tablet Regimens for Treatment-Naive Patients

Class	Agent	Components	Caveats <sup>1</sup>
INSTI	BIC/FTC/TAF	INSTI + dual NRTI	
	DTG/3TC	INSTI + single NRTI	Do not use if HIV-1 RNA >500,000 c/mL, HBV coinfection, or without resistance testing results
	DTG/ABC/3TC	INSTI + dual NRTI	Only if HLA-B*5701 negative
	EVG/COBI/FTC/(TAF or TDF)	Boosted INSTI + dual NRTI	
NNRTI*	DOR/3TC/TDF	NNRTI + dual NRTI	
	EFV (400 or 600 mg)/3TC/TDF	NNRTI + dual NRTI	
	EFV/FTC/TDF	NNRTI + dual NRTI	
	RPV/FTC/(TAF or TDF)	NNRTI + dual NRTI	Only if HIV-1 RNA <100,000 c/mL and CD4+ cell count >200 cells/mm <sup>3</sup>
<b>Boosted PI*</b>	DRV/COBI/FTC/TAF	Boosted PI + dual NRTI	

\*Recommended initial regimens in certain clinical situations.



# Estimated Number of Perinatally Acquired AIDS Cases by Year of Diagnosis, 1985–2006—United States and Dependent Areas



Note. Data have been adjusted for reporting delays and cases without risk factor information were proportionally redistributed.



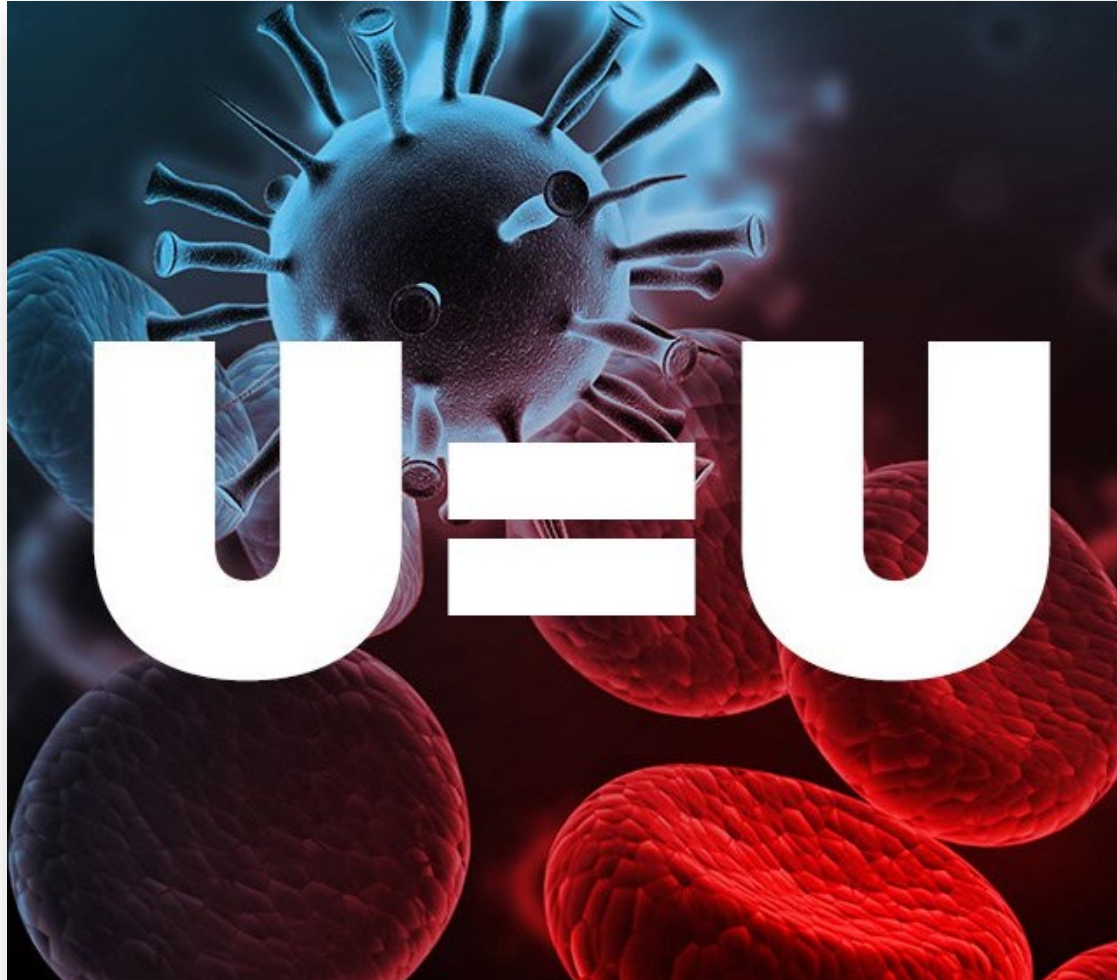
# DHHS Recommendations for Initial ART During Pregnancy

Guideline Status	NRTIs	INSTIs	PIs	NNRTIs
<b>Preferred</b>	3TC/ABC* FTC/TDF 3TC + TDF	DTG <sup>†</sup> RAL	ATV/RTV DRV/RTV <sup>‡</sup>	
<b>Alternative</b>	3TC/ZDV		LPV/RTV <sup>‡</sup>	EFV RPV <sup>§</sup>
<b>Insufficient data to recommend</b>	TAF	BIC		DOR
<b>Not recommended</b>		EVG/COBI	ATV/COBI DRV/COBI	

\*Only if HLA-B\*5701 negative. <sup>†</sup>Use of DTG at conception/very early pregnancy has been associated with small but statistically significant increase in the risk of NTDs; this information should be discussed with patients to ensure informed decision-making.

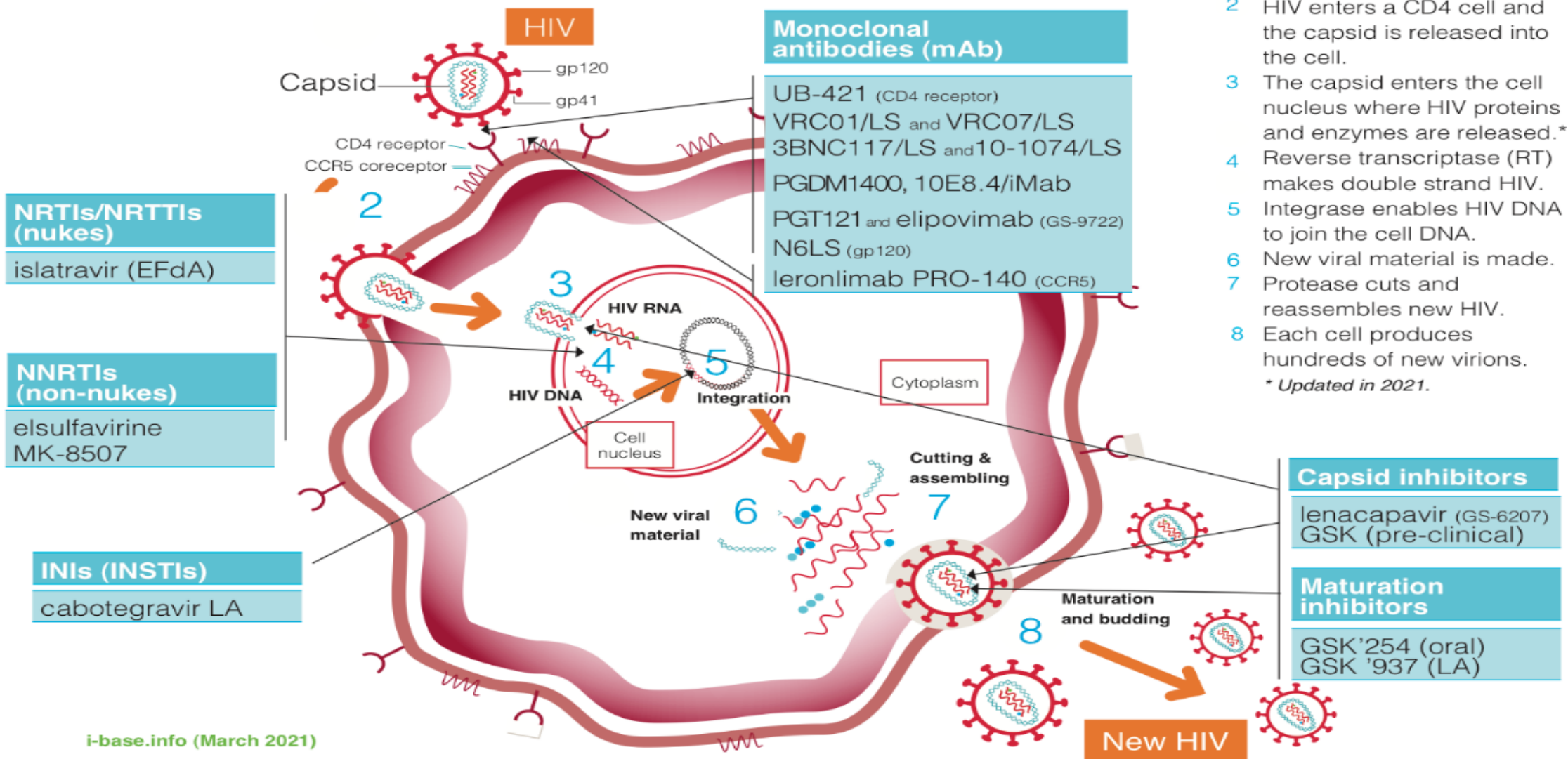
<sup>‡</sup>Must be used twice daily in pregnancy. <sup>§</sup> Only if pretreatment HIV-1 RNA ≤ 100,000 copies/mL and CD4+ cell count ≥ 200 cells/mm<sup>3</sup>.

# Treatment as Prevention: *Undetectable means Untransmittable*

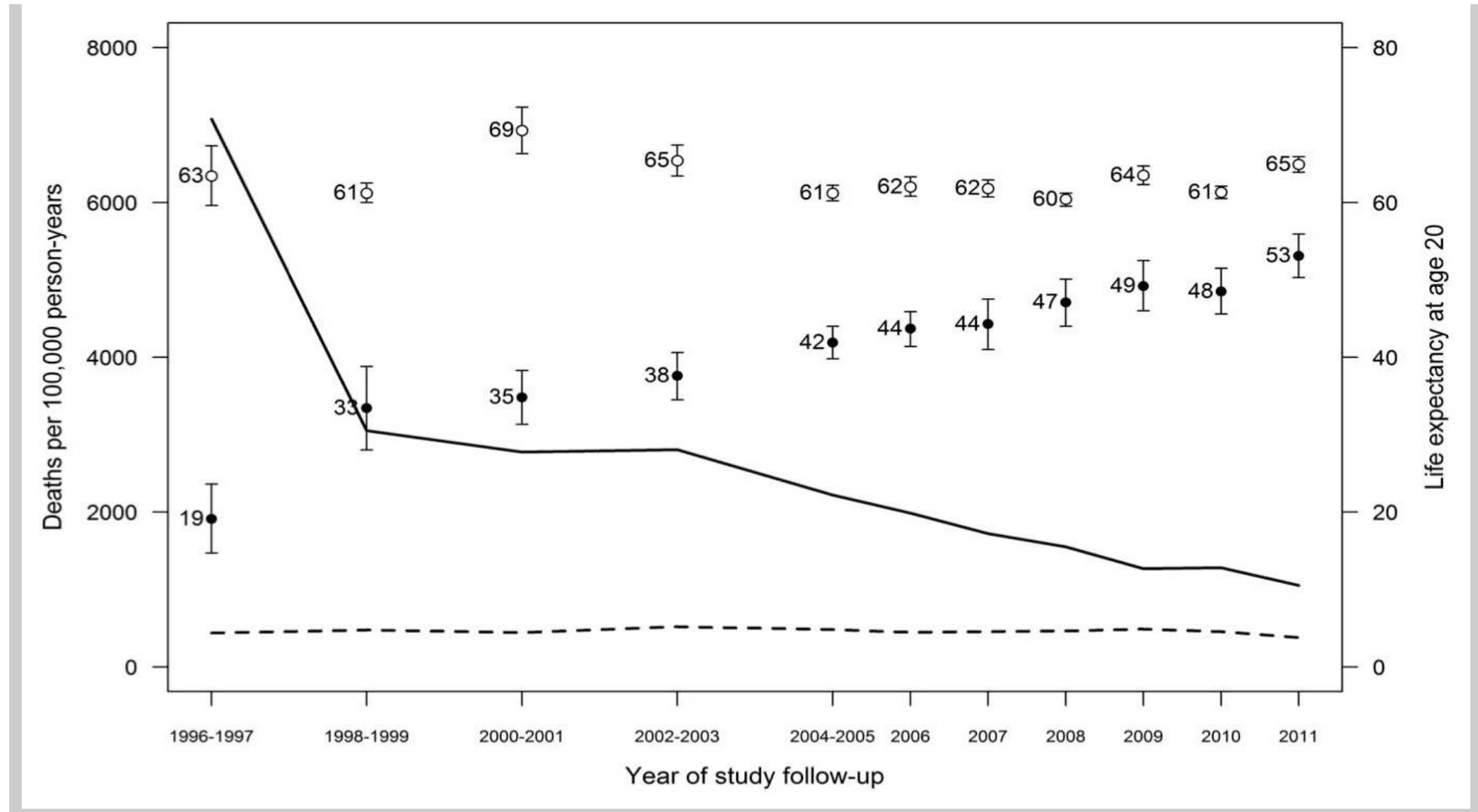


This means that people who take Antiretroviral Therapy (ART) daily as prescribed and achieve and maintain an undetectable viral load have effectively *no risk of sexually transmitting the virus to an HIV-negative partner.*

# HIV pipeline 2021: targets in the HIV lifecycle



# With Effective ART, Survival of People With HIV Continues to Improve





# Barriers to HIV/AIDS Care in Rural Communities

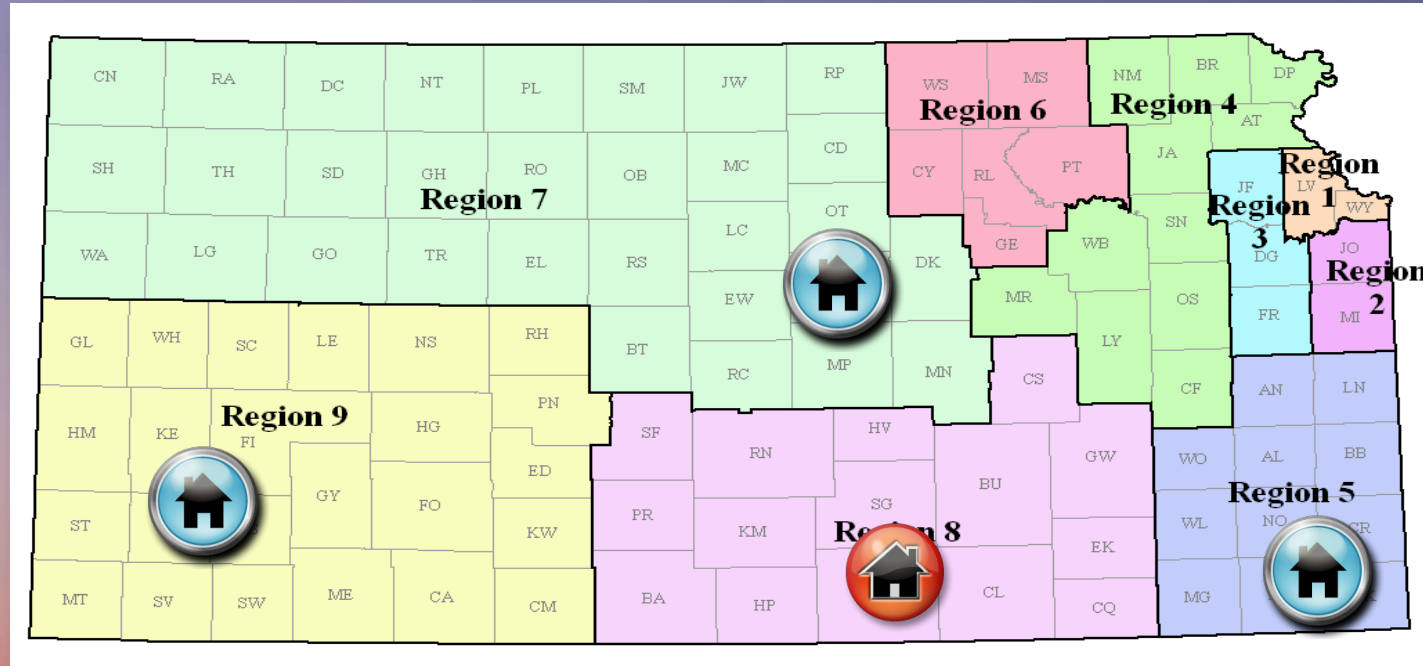
## Physical Isolation, Low Population Density, and Persistent Poverty

### Unique Social Aspects of Rural Communities

- Stigma
- Privacy and lack of anonymity
- Lack of awareness

- Lack of services
- Lack of health insurance
- Lack of specialized service providers
- Lack of Ryan White providers
- Low population density and HIV prevalence
- Cost of treatment
- Insufficient internet access

# Satellite Clinic Sites





# Kansas Satellite Clinics

- Charter aircraft
- Team:
  - Physician, APRN's and/or PA – all AAHIVM Certified
  - MA, Lab tech, Outreach Case Manager
- Local FQHC Clinic or Health Departments provide space and local CM support
- Supplies: computers, support materials and vaccines are taken to each visit.





# Kansas Prison Telehealth

- Tele video connection for consultation
- Medical records are sent in advance
- Video connection is in the exam room with nurse and into the physician's office



# COVID-19 and HIV

- Recent ramp up of telemedicine due to COVID-19 has led some rural populations to recently experience telemedicine visits for linkage to their care provider
- Has led to a greater need for virtual healthcare services and advancements in telehealth and telemedicine services being provided
- Increasing primary and secondary prevention activities to rural at-risk populations
- HHS allocated \$20 million for expansion of telehealth services
- Potential paradigm shift in the delivery of care for rural and underserved populations in the near future



# People With HIV

PWHIV face a unique lifetime continuum of risks that compound and accumulate, with potential adverse effects on health and quality of life





With the right treatment and care, people with HIV can live a normal lifespan.

People who have a good response to HIV treatment have excellent long-term prospects.

You can increase your life expectancy by not smoking and having a healthy lifestyle.

# HIV Life Expectancy



# HIV Life Expectancy

Once again, a life expectancy study has shown that HIV-positive people who start antiretroviral therapy (ART) promptly and have good access to medical care live as long as their HIV-negative peers.

But the researchers found that HIV-positive people were living with additional health problems for many of those years – on average, they had major co-morbidities 16 years earlier than HIV-negative people.

If the person with HIV started ART with a CD4 count above 500, they would be expected to live to the age of 87 – a little longer than those without HIV.

# ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA



**Diagnose** HIV as early as possible



**Treat** HIV quickly and effectively



**Protect** people at risk



**Respond** quickly to clusters of new cases

# MATEC Resources

- Clinical Consultation Center  
<http://nccc.ucsf.edu/>
  - HIV Management
  - Perinatal HIV
  - HIV PrEP
  - HIV PEP line
  - HCV Management
  - Substance Use Management
- Present case on ECHO  
<http://echo.unm.edu>  
[hivecho@salud.unm.edu](mailto:hivecho@salud.unm.edu)
- Additional trainings  
[scaetcecho@salud.unm.edu](mailto:scaetcecho@salud.unm.edu)
- AETC National HIV Curriculum  
<https://aidsetc.org/nhc>
- AETC National HIV-HCV Curriculum  
<https://aidsetc.org/hivhcv>
- Hepatitis C Online  
<https://www.hepatitisc.uw.edu/>
- AETC National Coordinating Resource Center  
<https://targethiv.org/library/aetc-national-coordinating-resource-center-0>



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