

Delivering PrEP: A Strategy for Ending the HIV Epidemic in America

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ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA

GOAL:

75%

reduction in new
HIV infections
in 5 years

and at least

90%

reduction
in 10 years.

PHASE 1: Focused effort to reduce new infections by 75% in 5 years

PHASE 2: Widely disseminated effort to reduce new infections by 90% in the following 5 years

PHASE 3: Intense case management to maintain the number of new infections at < 3,000 per year

Key actions to help end the HIV epidemic

TEST FOR HIV

HIV tests determine the next prevention step, PrEP or HIV treatment.

86% of people with HIV know they have it.

TARGET: 95%



PREVENT

People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.



TREAT

People who know they have HIV should take medicine daily to control the virus.

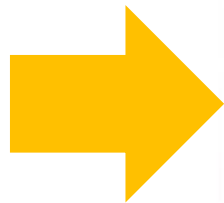


HAVE PREP PRESCRIPTION 18%

TARGET 50%

HAVE HIV UNDER CONTROL 63%

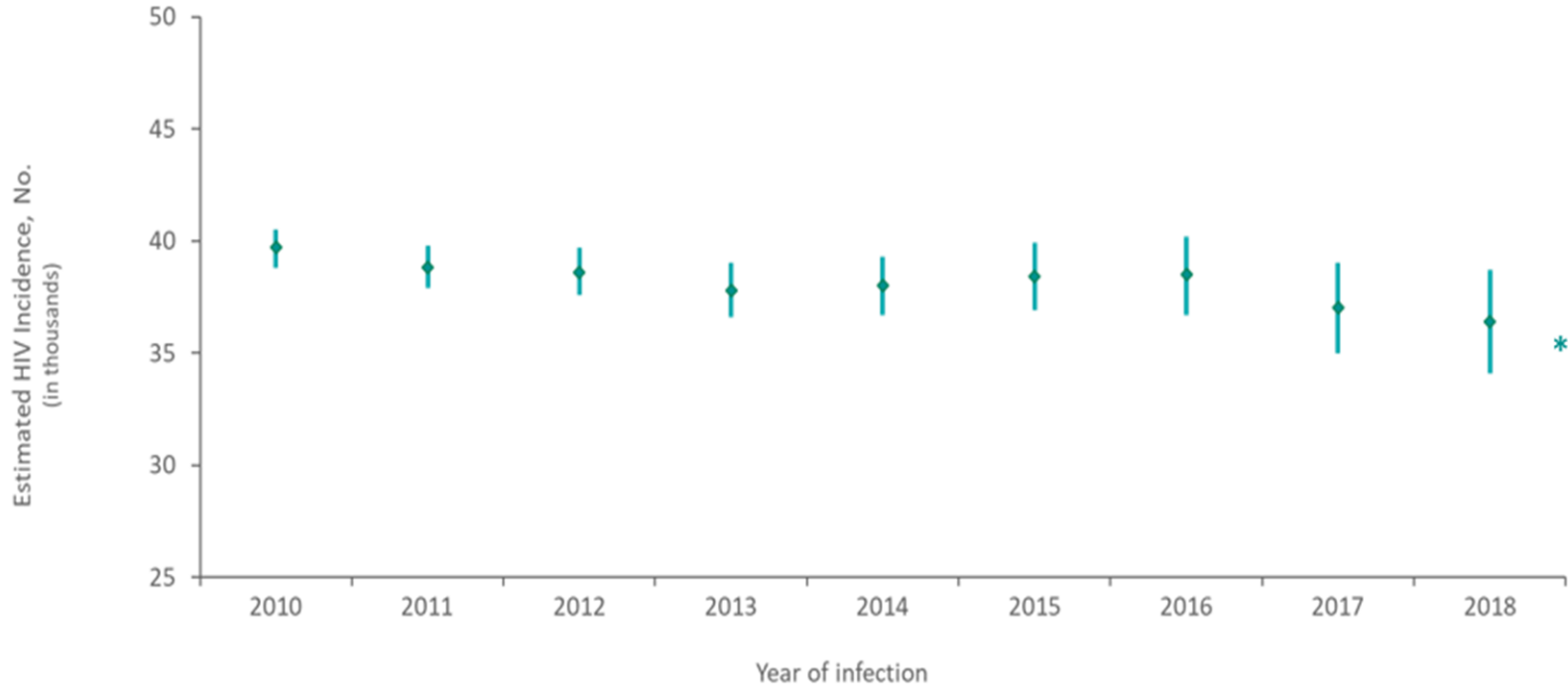
TARGET 95%





The Current State: Limited PrEP Provision

Estimated HIV Incidence among Persons Aged ≥ 13 Years 2010–2018—United States



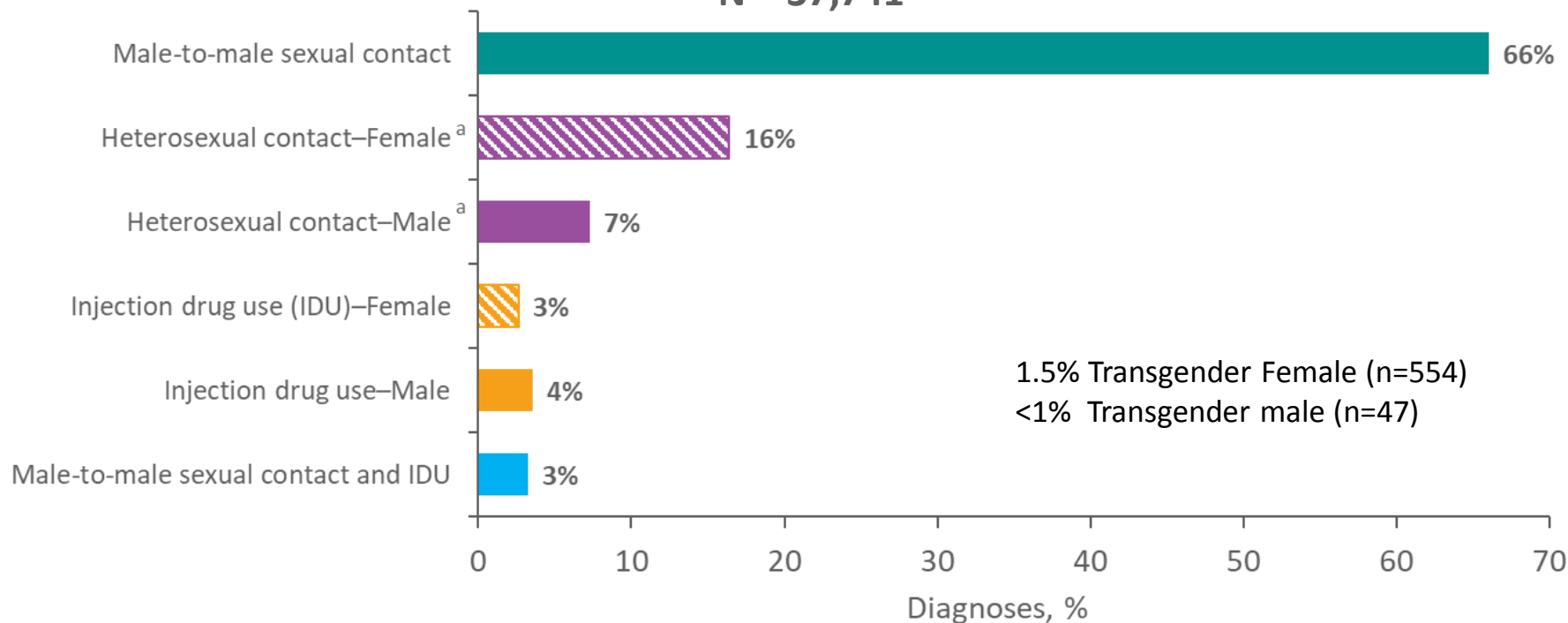
Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Bars indicate the range of the lower and upper bounds of the 95% confidence intervals for the point estimate.

* Difference from the 2010 estimate was deemed statistically significant ($P < .05$).



Diagnoses of HIV Infection among Adults and Adolescents, by Transmission Category, 2018—United States and 6 Dependent Areas

N = 37,741

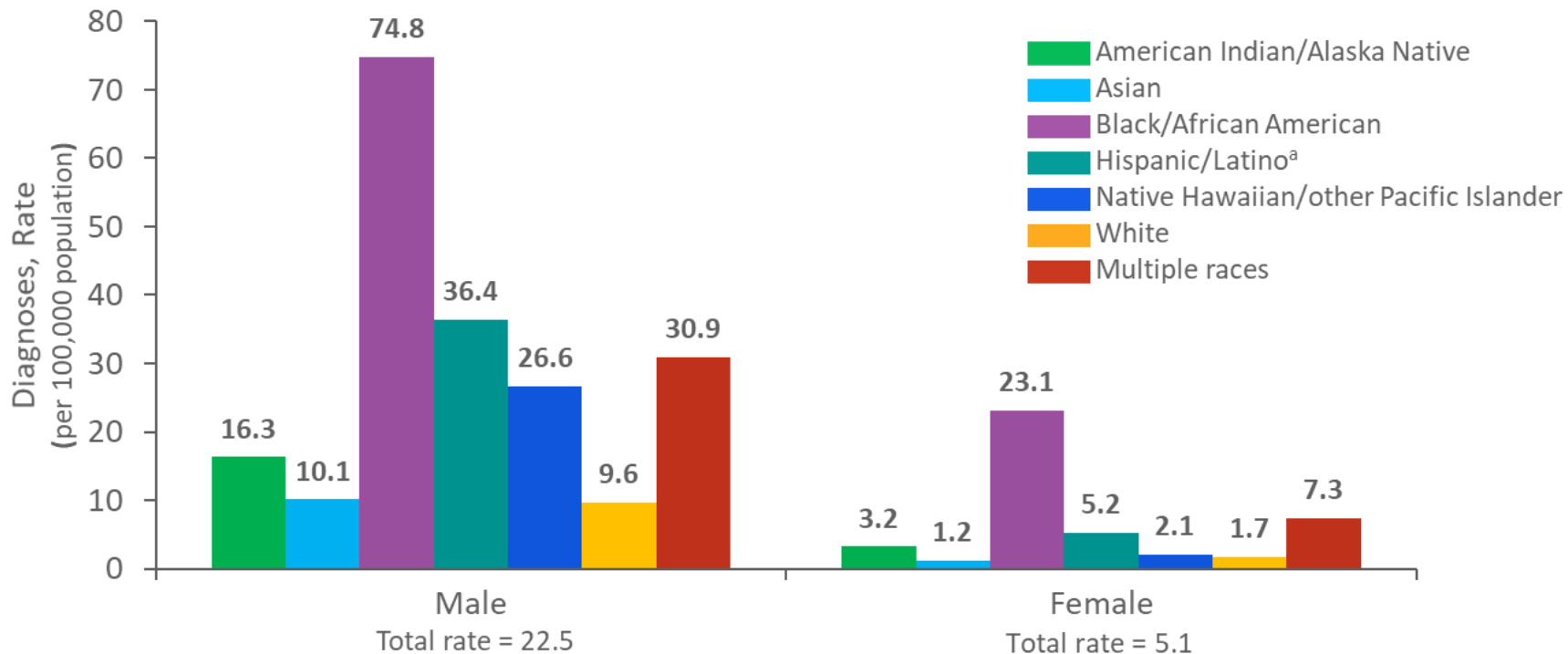


Note. Data for the year 2018 are considered preliminary and based on 6 months reporting delay. Data have been statistically adjusted to account for missing transmission category. “Other” transmission category not displayed as it comprises less than 1% of cases.

^a Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.



Rates of Diagnoses of HIV Infection among Adults and Adolescents by Sex and Race/Ethnicity, 2018—United States

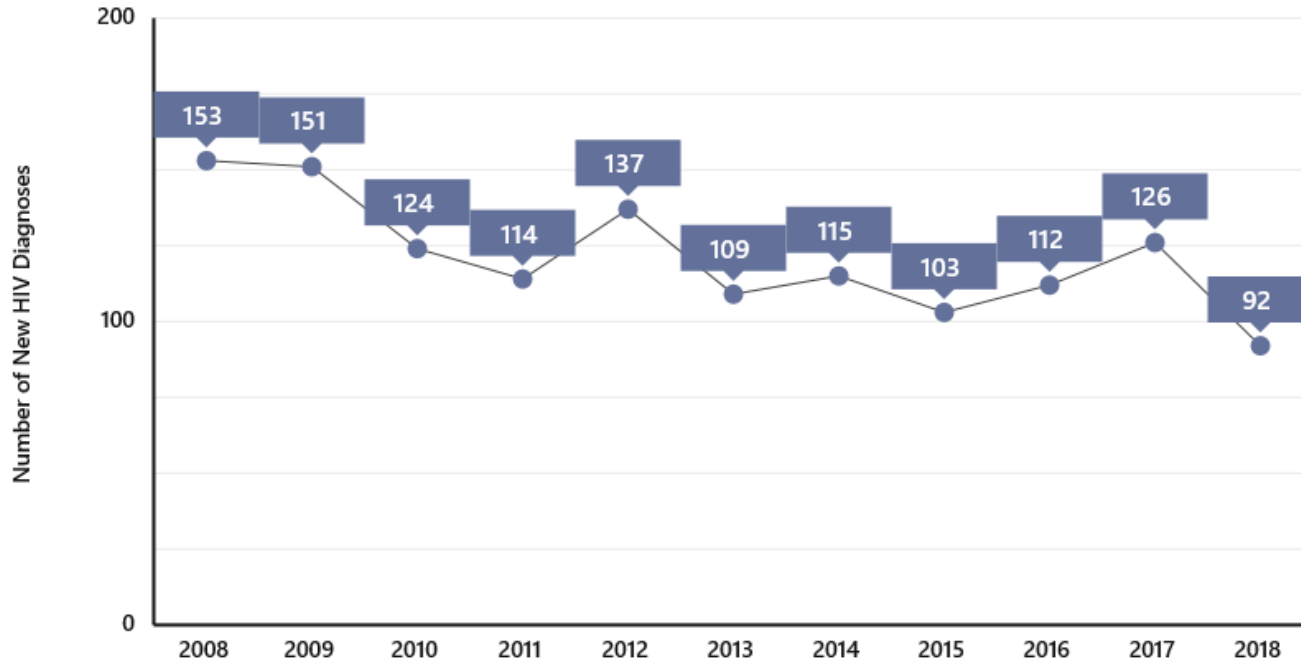


Note. Data for the year 2018 are considered preliminary and based on 6 months reporting delay.

^a Hispanics/Latinos can be of any race.

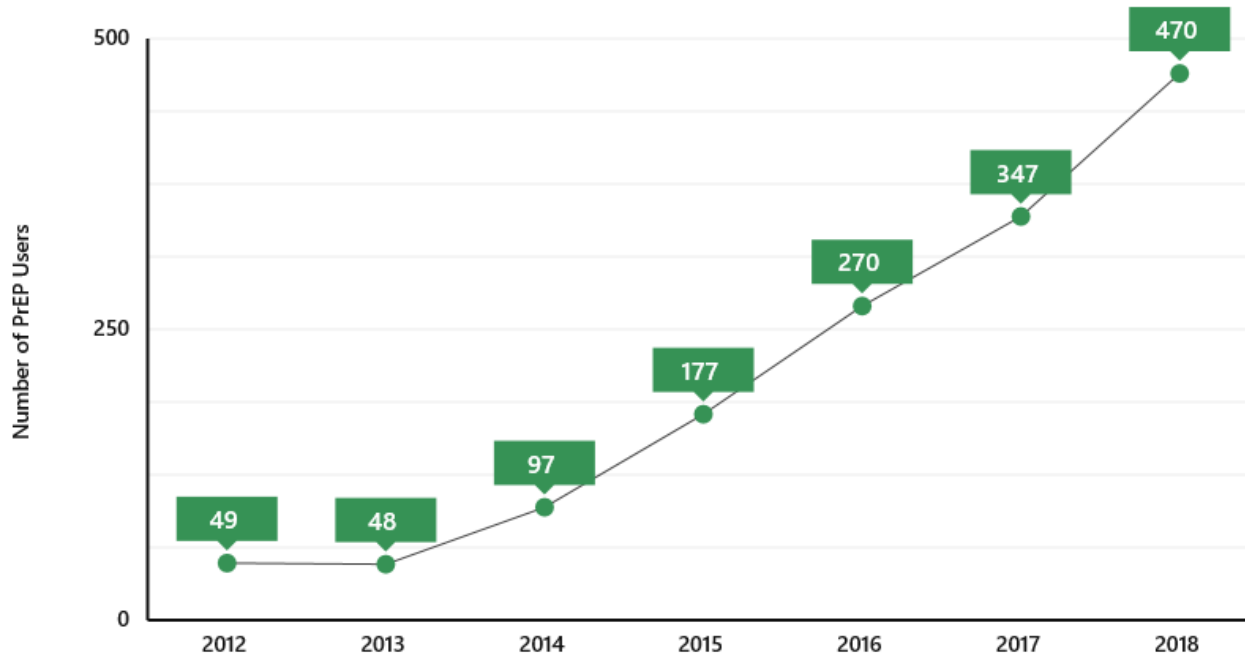


Number of New HIV Diagnoses in Delaware, 2008-



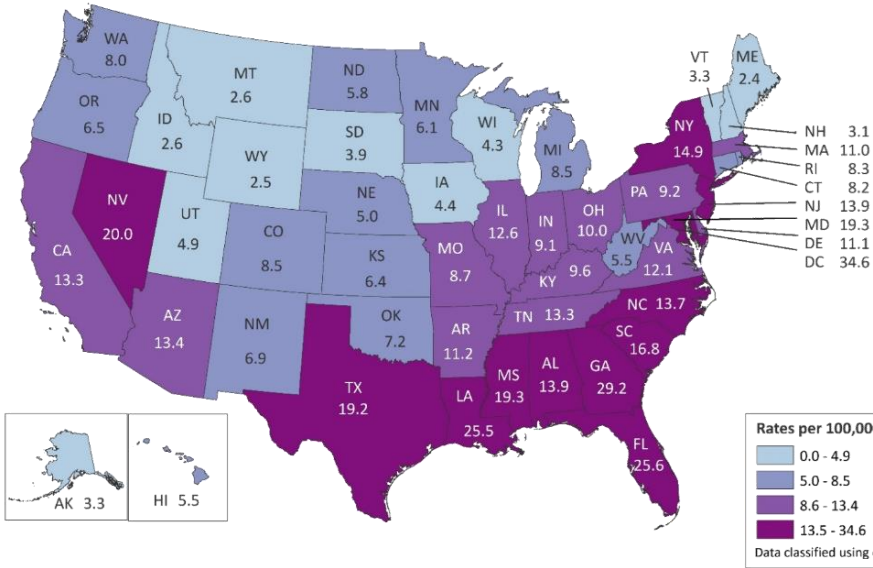
- 75% male
- 25% female
- 65% Black
- 13% Hispanic
- 20% White

Number of PrEP Users in Delaware, 2012-2018

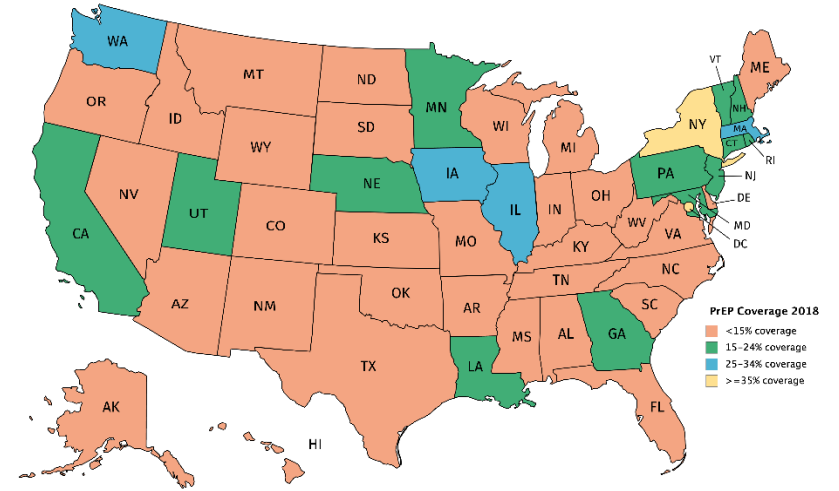


- 93% male
- 7% female
- 4600 with indications
- 8.7% coverage

Rates of HIV Diagnoses in the US, 2018

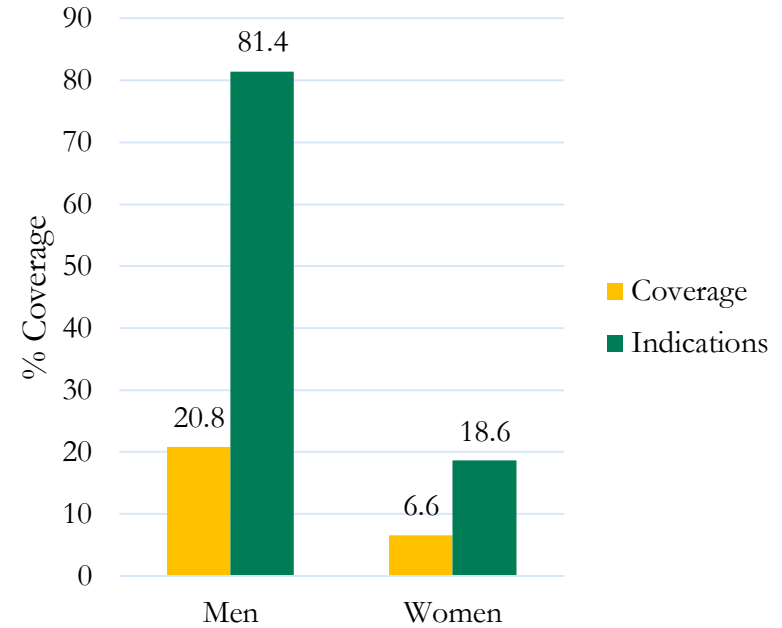
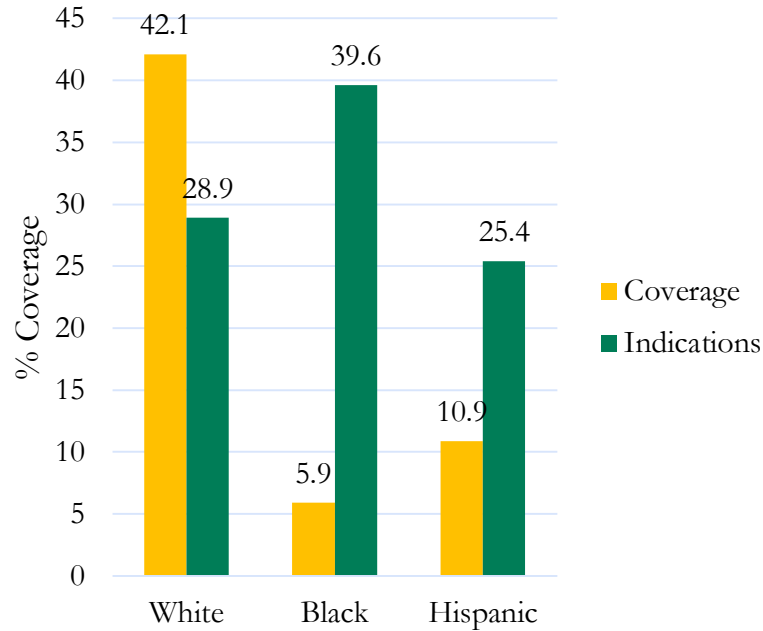


PrEP Coverage, US States, 2018



Source: Harris et al, MMWR, 2019

PrEP Coverage by Race Ethnicity and Sex, 2018

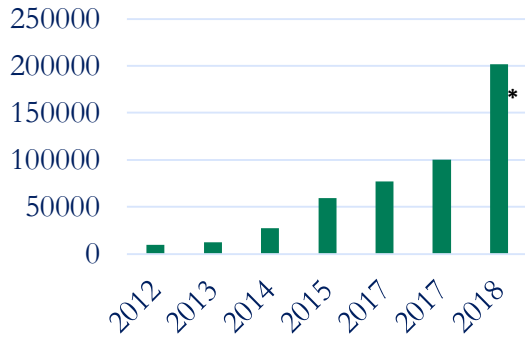




**Models of PrEP coverage impact
on HIV incidence**

Key factors in effective PrEP use

Annual number of US persons prescribed Truvada for PrEP



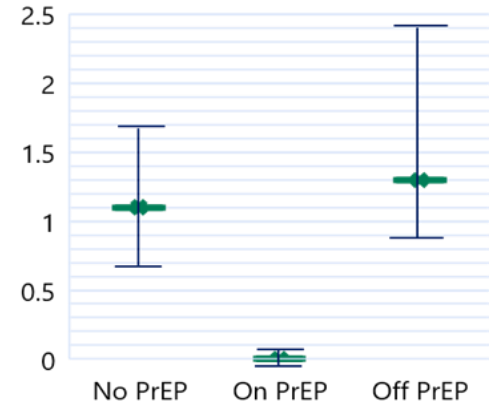
- Higher uptake among those at substantial risk (“coverage”)

MSM

Adherence by Drug Concentration	HIV Incidence per 100 PY
0 pills/week	4.7
<2 pills/week	2.3
2-3 pills/week	0.6
≥4 pills/week	0.0

- High medication adherence

HIV Incidence



- Persistent use of PrEP throughout periods of risk of HIV exposure

Rapid PrEP Scale-up = Measurable Impact

■ IAS 2018 Abstract 1037

- Sexual health clinic serving MSM
- From 2011-2016
 - HIV incidence dropped 56%
 - PrEP use increased “exponentially” from 3 to 729
 - % with VL suppression increased slightly from 92-95%

Year	HIV diagnoses (N=703)	New HIV infections per 100 persons tested	Annual Percent change in HIV rates	PrEP Consults (N=1318)	% of HIV patients with undetectable viral load
2011	126	2.31		3	92
2012	120	2.02	-12.6	5	91
2013	145	2.45	21.2	27	93
2014	118	1.85	-24.3	94	94
2015	112	1.60	-13.5	460	94
2016	82	1.03	-36.0	729	95

Effect of Rapid Scale-up of PrEP among MSM, Australia

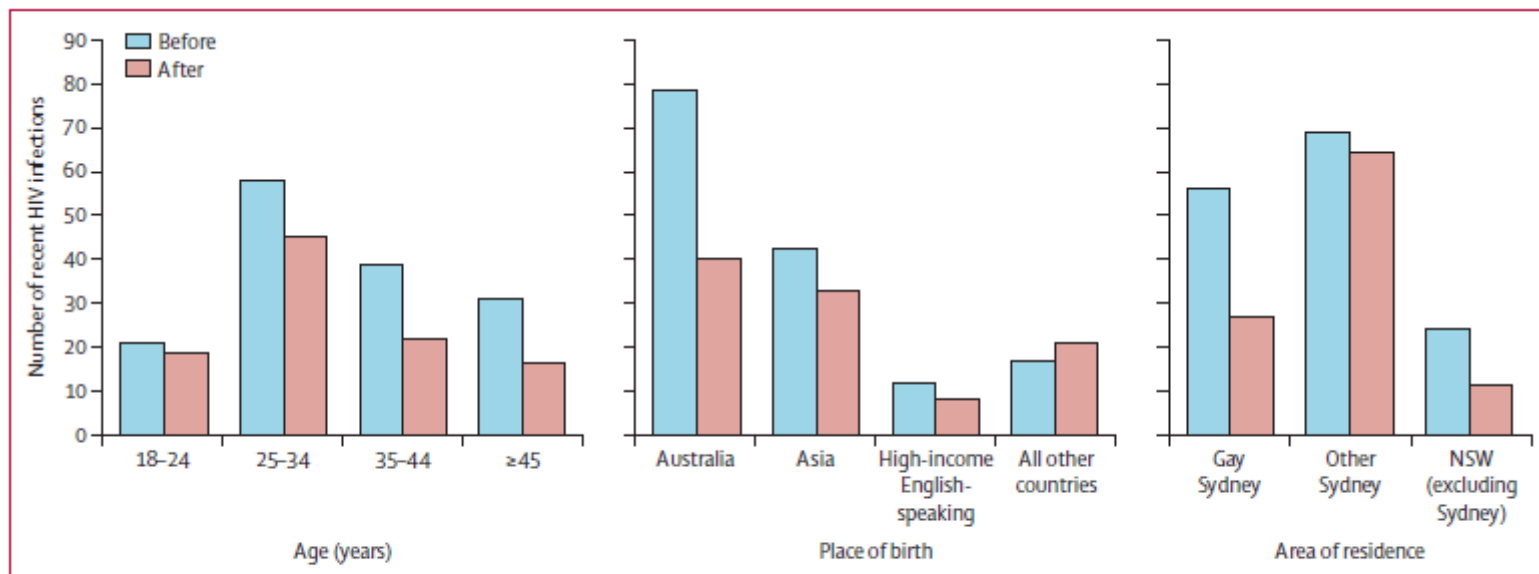
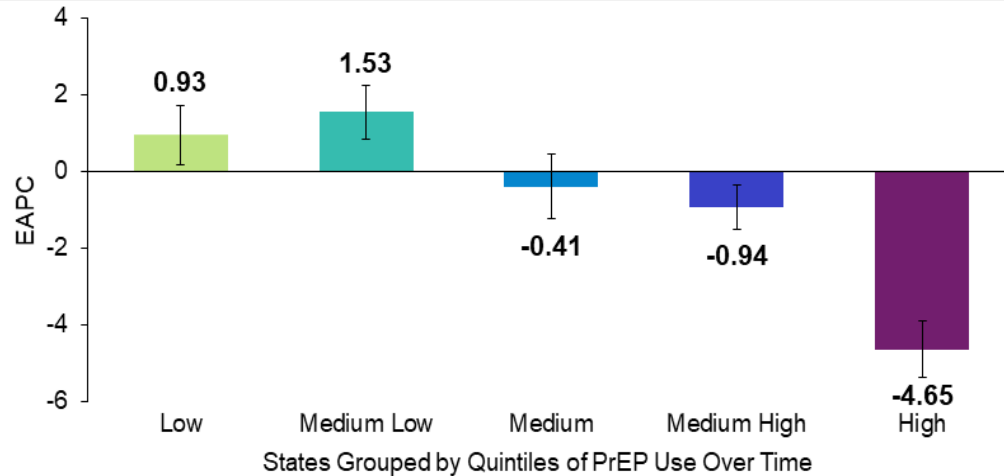


Figure 2: Number of recent HIV infections in New South Wales

Figure shows data for the 12 months before commencement of recruitment to EPIC-NSW (n=149, "before") and the 12 months after the 3700th EPIC-NSW participant was recruited (n=102, "after") by age, country or region of birth, and area of residence. NSW=New South Wales.

More PrEP = Fewer HIV Infections

EAPC in HIV Diagnoses of Persons Age ≥ 13 in US States
Grouped Into PrEP Use Quintiles
USA 2012–2016



EAPC – estimated annual percent change in HIV diagnoses

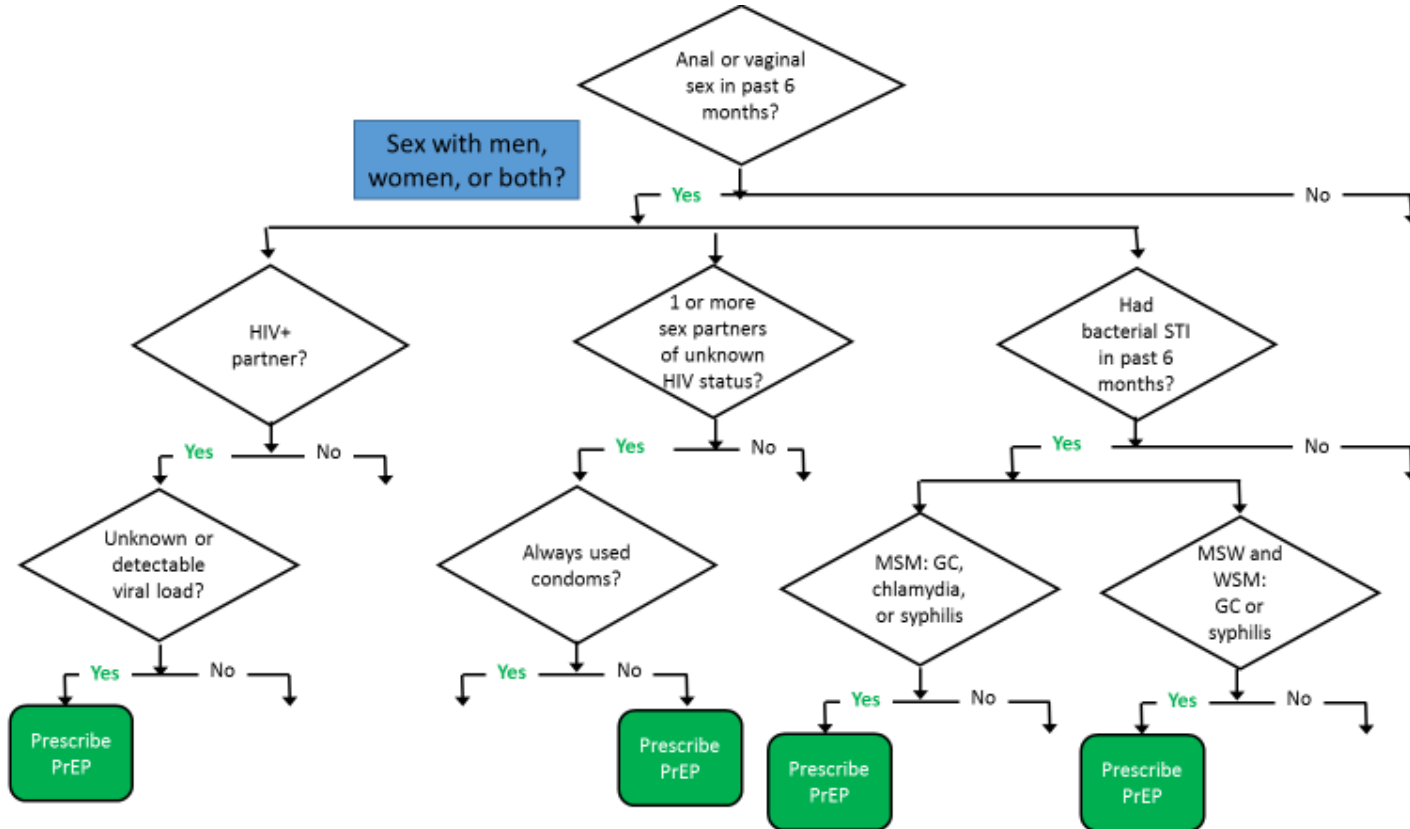


Indications for PrEP Education and Provision

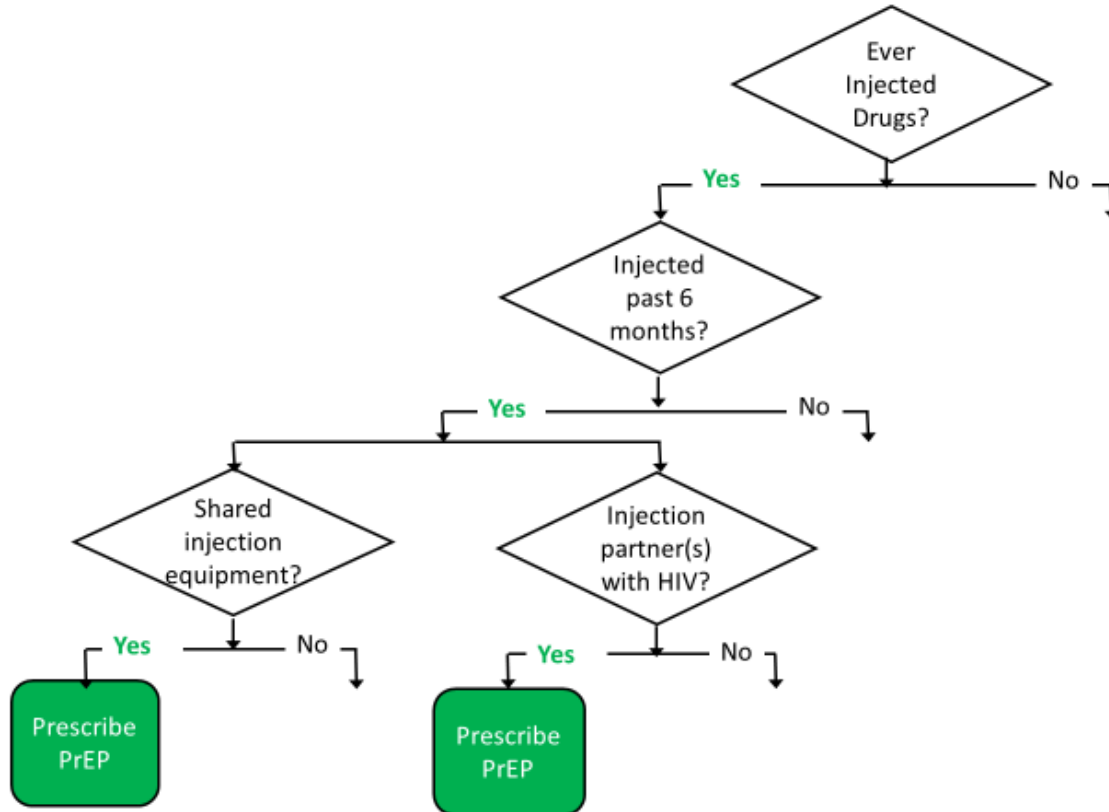
Informing Patients about PrEP

- **PrEP should be as well known as other preventive health care**
- **Not all patients will need or use PrEP but all should be aware of it**
 - Can inform family and friends who may benefit from it
 - Normalizes PrEP use and reduces stigmatizing assumptions
 - Motivates acknowledging behaviors or requesting PrEP
- **Inform**
 - All sexually active adults and adolescents
 - All HIV-positive patients
 - Pre-sexual adolescents when discussing onset of sexual activity
 - Persons with recent substance use problems, including injection drug use

Identifying Sexual Indications



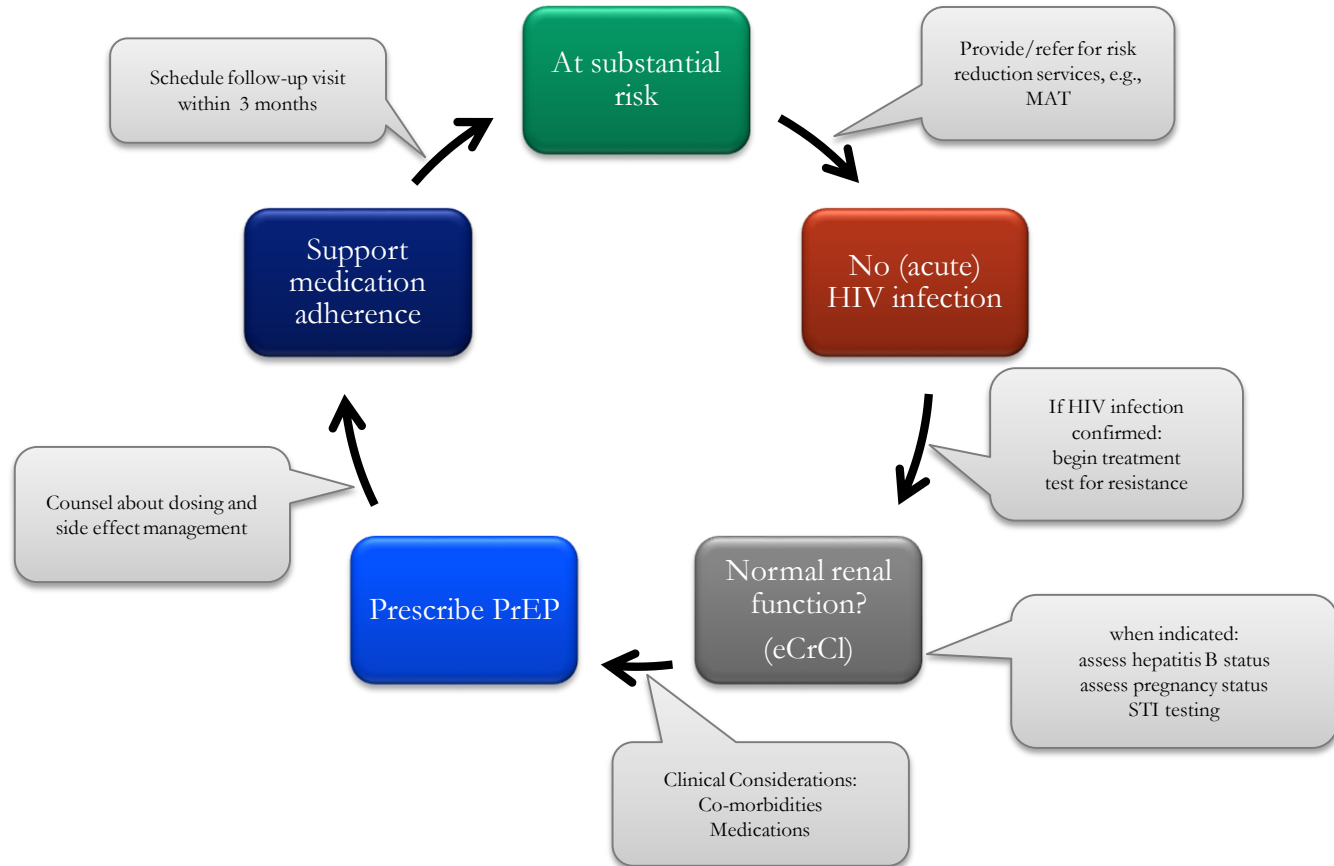
Identifying Injection Indications

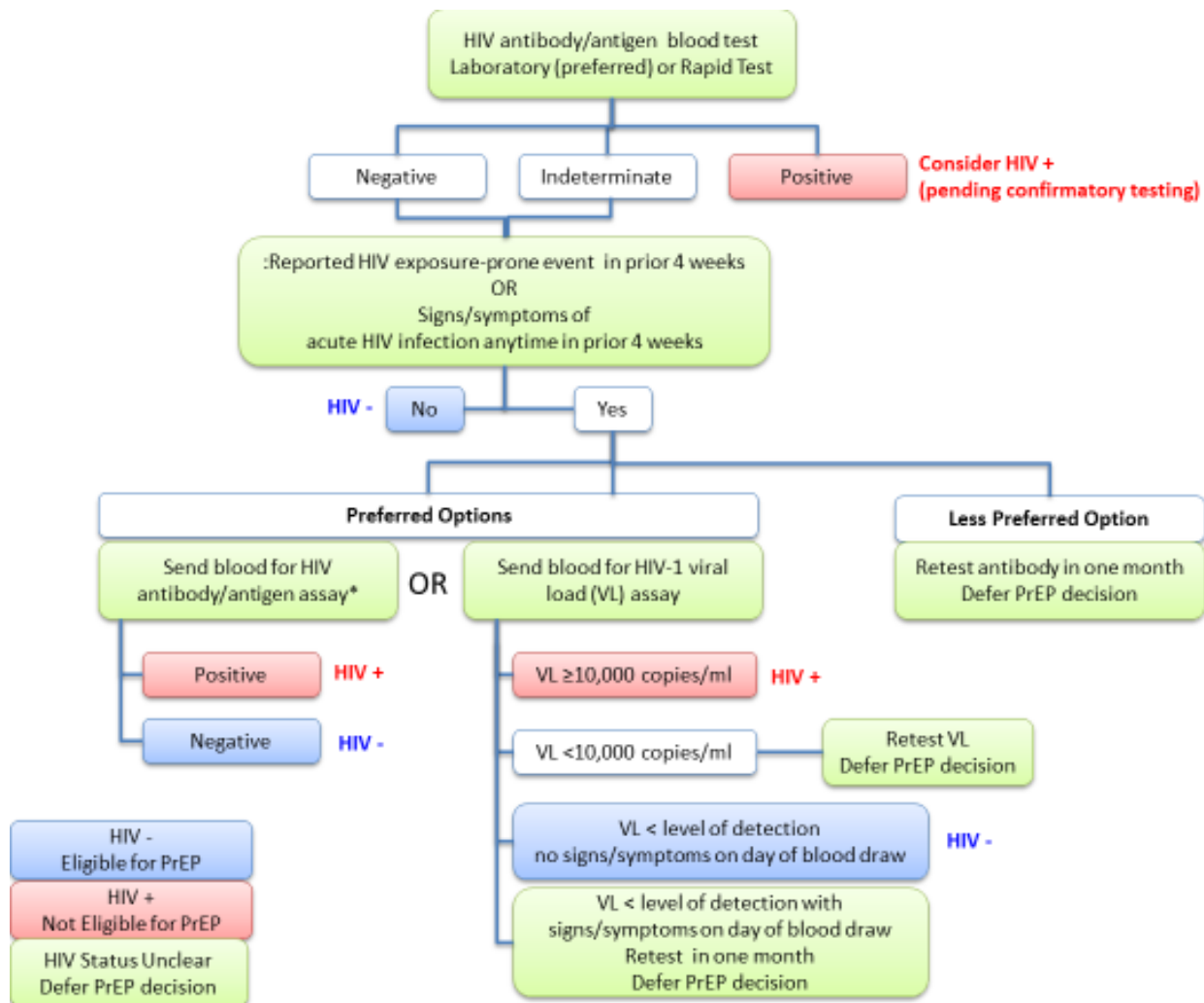




Standard PrEP Provision

Prescribing PrEP

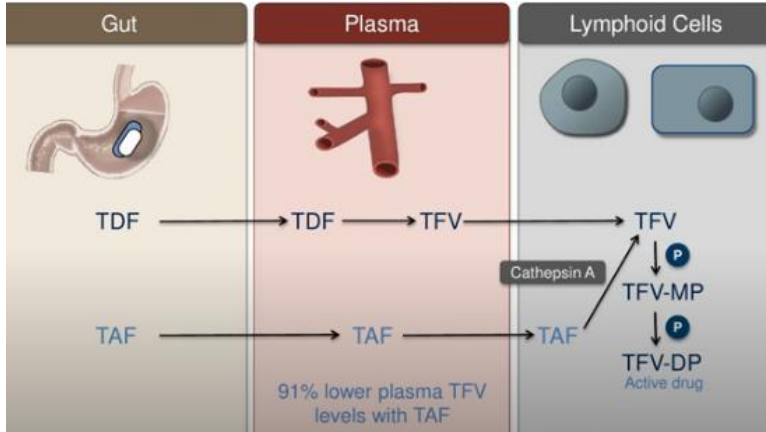




FDA-approved daily oral PrEP medications

- **Approved for adults and adolescents (weighing at least 35kg)**
 - F/TDF (Truvada, generic)
 - Emtricitabine+tenofovir disoproxil fumarate
 - Estimated creatinine clearance ≥ 60 ml/min
 - Effectiveness studied in all transmission risk groups and both sexes
 - F/TAF (Descovy)
 - Emtricitabine + tenofovir alafenamide
 - Estimated creatinine clearance ≥ 30 ml/min
 - Effectiveness only studied in MSM and TGW
 - Not approved for persons exposed to HIV through receptive vaginal sex

F/TDF or F/TAF?



Helping Patients Afford PrEP Medication

- **Health plan marketplace PrEP coverage calculator (NASTAD)**
- **Gilead medication assistance and co-pay plan**
 - Uninsured or insurance declines to cover PrEP
 - Household income <500% of federal poverty level
 - US residence
- **HHS “Ready Set PrEP” program**
 - Uninsured or insurance declines to cover PrEP
 - US residence
- **Generic F/TDF soon available**
- **USPSTF A grade – no out of pocket cost for most insured (2021)**

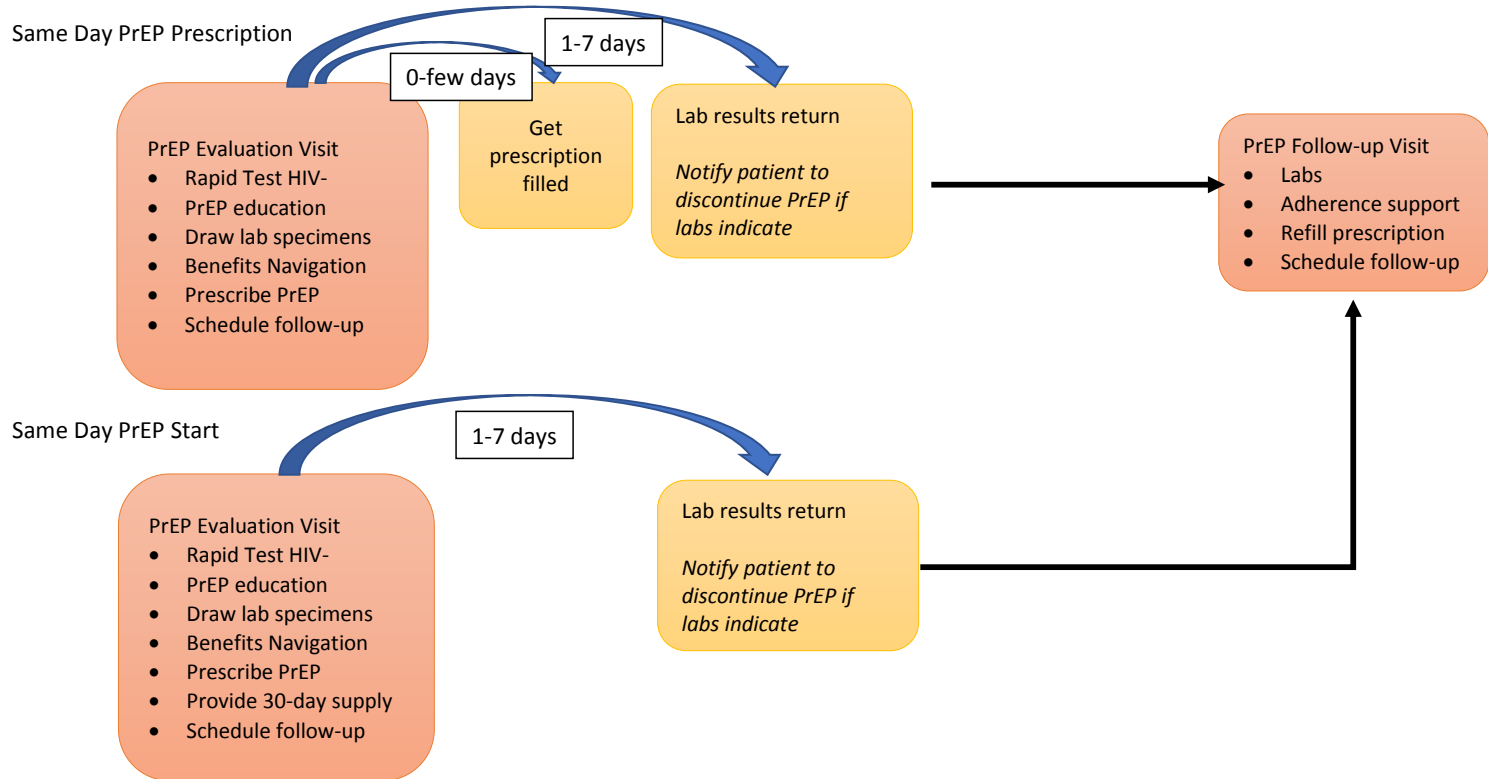


Practice Variations in PrEP Provision

Adaptations to PrEP Care in the COVID Era

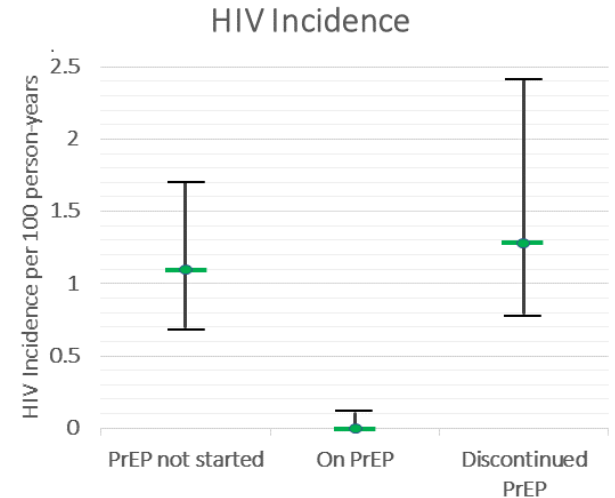
- **Telemedicine visits for initiation and follow-up visits**
 - ✓ Voice calls
 - ✓ Web/smartphone video visits
 - ✓ Web portal results
- **Laboratory testing**
 - ✓ HIV self-test (with phone image documentation)
 - ✓ Mailed kits for STD and creatinine self specimen collection (Molecular Testing Labs)
 - ✓ Lab-only visits
- ✓ **Medication**
 - ✓ Prescribe a 90-day supply to reduce pharmacy visits

Rapid Start PrEP



Stopping and Re-starting PrEP

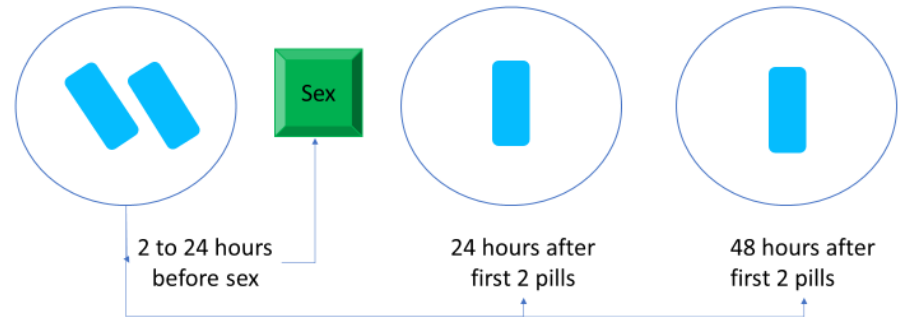
- **High rates of HIV acquisition before starting and after stopping daily PrEP**
- **Safely starting and stopping daily PrEP use**
 - ✓ Best option for those with long breaks between sexual exposure (e.g., > a week)
 - ✓ Need HIV test before restarting



A Less-preferred Adaptation

■ Event-driven PrEP (“2-1-1”)

- ✓ Not FDA-approved or CDC-recommended
- ✓ Difficult dosing schedule, easy to miss critical doses
- ✓ Provides less coverage of sexual exposures than daily PrEP
- ✓ Unclear how often HIV tests are needed for safety
- ✓ Only studied for MSM (risk of inadvertent disclosure)
- ✓ Only studied for F/TDF



PrEP medications approaching FDA review

■ Cabotegravir

- Noninferiority RCT in MSM and TGW stopped early for efficacy
 - Injection weeks 5 and 9 then every 2 months vs daily oral F/TDF
 - 66% reduction in risk of HIV infection among those given CAB compared to F/TDF
- Superiority RCT in cisgender women ongoing
 - Next scheduled DSMB review in November

■ Dapivirine vaginal ring

- 2 RCTs in southern Africa showed partial efficacy
 - 27-33% reduction in HIV acquisition;
 - Recent approval by European Medicines Agency
 - Planned submission for FDA review in mid-late 2021



Resources

PrEP Resources for Clinicians and Patients

- PrEP Clinical Practice Guideline and Provider's Supplement
<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>
<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>
- CDC HIV NEXUS
<https://www.cdc.gov/hiv/clinicians/index.html>
- Gilead Medication Assistance Plan
<https://www.gileadadvancingaccess.com/>
- HHS Ready, Set, PrEP Program
<https://www.getyourprep.com/>
- NASTAD PrEP Health Plan Calculator
<https://nastad.checkbookhealth.org/prepcost/2020/>

PrEP Care Guidance during COVID-19

- **Dear Colleague Letters**

- ✓ HIV DCL

- https://www.cdc.gov/nchhstp/dear_colleague/2020/dcl-042820-HIV-self-testing-guidance.html

- ✓ PrEP DCL

- https://www.cdc.gov/nchhstp/dear_colleague/2020/dcl-051520-PrEP-during-COVID-19.html

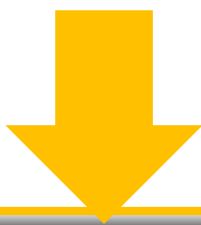
- ✓ STD DCL

- [https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf?deliveryName=USCDCNPIN_252-](https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf?deliveryName=USCDCNPIN_252-DM25769)

- [DM25769](https://www.cdc.gov/std/dstdp/DCL-STDTreatment-COVID19-04062020.pdf?deliveryName=USCDCNPIN_252-DM25769)

EHE is More than PrEP Delivery

- **EHE Framework includes 4 pillars**
 - Diagnose
 - Treat
 - Prevent
 - Including increased availability and use of comprehensive Syringe Services Programs (SSPs)
 - Respond
- **EHE activities include expanding the EHE workforce in jurisdictions**
- **EHE is collaboration with multiple federal agencies**
 - CDC, HRSA BPHC, HRSA HAB, IHS, SAMHSA, NIH
- **Monitoring progress toward goals critical to reduce HIV incidence**



TEST FOR HIV



HIV tests determine the next prevention step, PrEP or HIV treatment.

86% of people with HIV know they have it.
TARGET: 95%

PREVENT

People without HIV, but at risk for it, can take PrEP as prescribed to prevent getting HIV.



TREAT

People who know they have HIV should take medicine daily to control the virus.



HAVE PREP PRESCRIPTION 18%

TARGET 50%

HAVE HIV UNDER CONTROL 63%

TARGET 95%

HIV Testing and Diagnosis

■ Increase

- Routine HIV screening in clinical settings
- HIV testing in non-clinical settings
- Access to HIV self-testing (“home testing”)
- Frequency of HIV testing among persons at high risk of acquiring HIV
- Early detection of HIV

TEST FOR HIV

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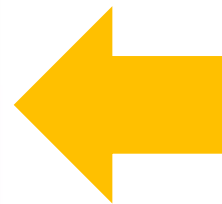


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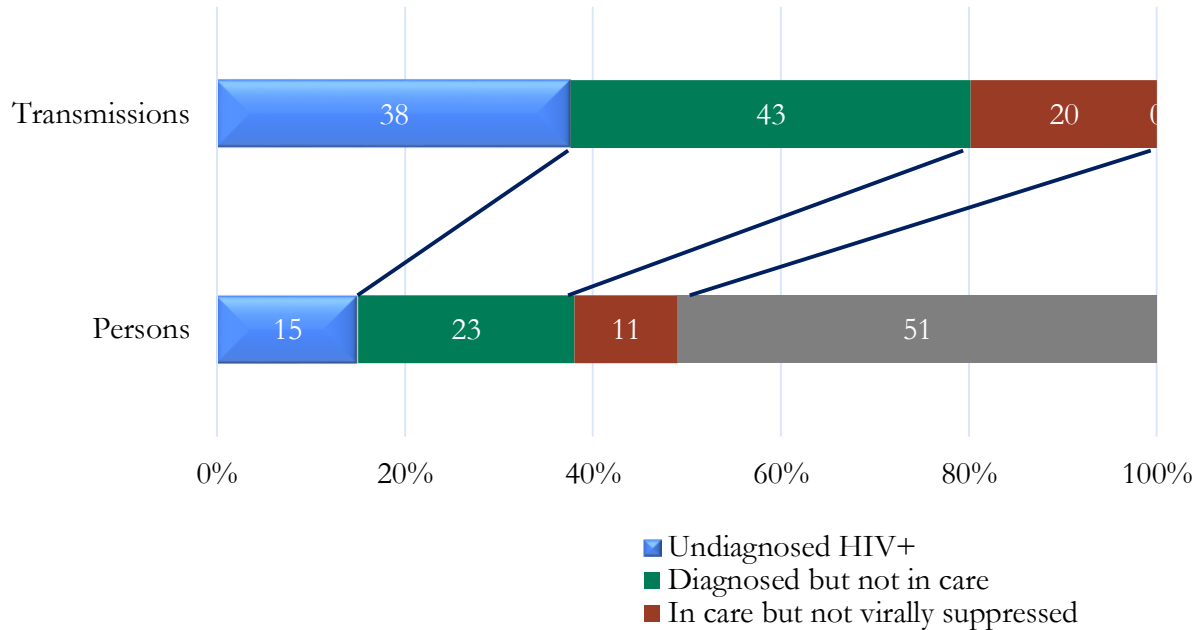


HIV Treatment and Viral Suppression

■ Increase

- Immediate linkage to HIV care at first positive HIV test
- Rapid initiation of antiretroviral treatment after diagnosis
- Use of interventions to support medication adherence
- Rapid re-engagement of persons who drop-out of care
- Durable viral suppression (“U=U”)

HIV-negative Partners Who Could Benefit from PrEP



Respond

- Develop partnerships, processes, data systems, and policies to facilitate robust, real-time cluster detection and response
- Investigate and intervene in networks with active transmission
- Identify and address gaps in programs and services revealed by cluster detection and response

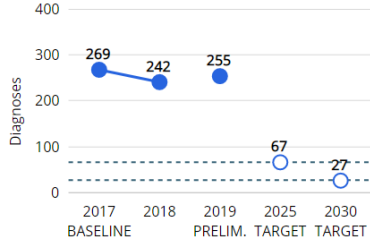
Monitoring Progress

- **AHEAD: America's HIV Epidemic Analysis Dashboard**
 - <https://ahead.hiv.gov/>
- **Leading indicators**
 - Diagnoses
 - Linkage to HIV medical care
 - Viral Suppression
 - PrEP coverage
- **Intermediate goal**
 - Knowledge of HIV status
- **Overarching goal**
 - HIV incidence

Diagnoses



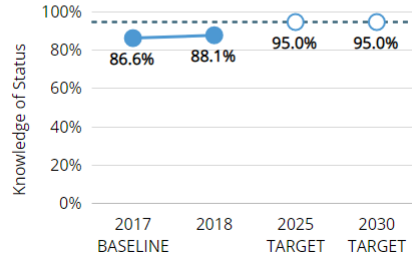
Diagnoses refer to the number of people diagnosed with HIV infection in a given year, regardless of when infection occurred.



Knowledge of Status



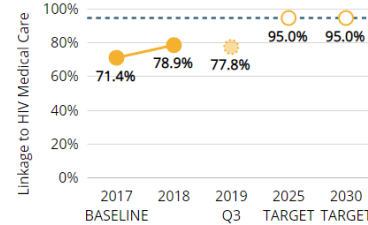
Knowledge of status is the estimated percentage of people with HIV who have received an HIV diagnosis.



Linkage to HIV Medical Care



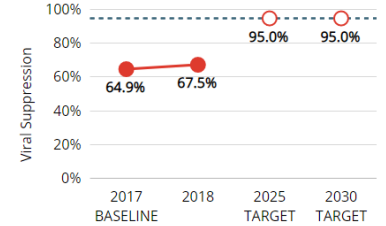
Linkage to HIV medical care is the percentage of people diagnosed with HIV in a given year who have received medical care for their HIV infection within one month of diagnosis.



Viral Suppression



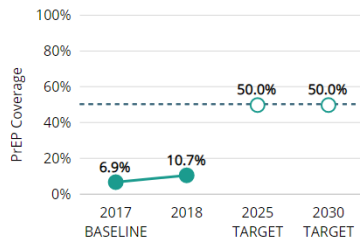
Viral suppression is the percentage of people living with diagnosed HIV infection who have an amount of HIV that is less than 200 copies per milliliter of blood, in a given year.



PrEP Coverage



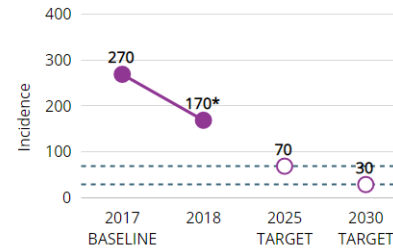
PrEP coverage is the estimated percentage of individuals prescribed PrEP among those who need it.



Incidence



Incidence is the estimated number of new HIV infections in a given year.





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**The United States will become a place where
new HIV infections are rare...**

National HIV/AIDS Strategy