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PrEP for HIV Prevention

Providing PrEP in the District of Columbia

May 2021

Collaborators





More resources available at:
<https://dchealth.dc.gov/dcrx>

Course Overview

- HIV and PrEP landscape in DC
- Stigma
- Prescribing Practices
- Payment Assistance Programs

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Conflicts of Interest

None of the speakers or advisors have a conflict of interests to declare.

Important Information



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PrEP for HIV Prevention

Adam Visconti MD MPH
Chief Medical Officer - DC Health
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Overview

- History and epidemiology of HIV nationwide
- HIV landscape in DC
- Ending the HIV Epidemic in DC
- PrEP Efficacy
- PrEP Indications and Prescribing

Objectives

By the end of this lecture you should be able to:

- Understand the distribution and demographics of HIV both in DC and nationwide
- Determine characteristics of who to screen for HIV infection
- Outline the indications for prescribing PrEP including the 2019 USPSTF recommendation
- Identify common side-effects with PrEP
- Explain how HIV stigma can affect prescribing and adherence

HIV after 40 years

Death

- Annually
 - Worldwide: 690,000 (1)
 - United States: 15,484 (2)
- Overall
 - Worldwide: 35.9 million
 - United States: 658,507

Persons Living with HIV (PLWH)

- Worldwide: 38 million
- United States: 1.1 million

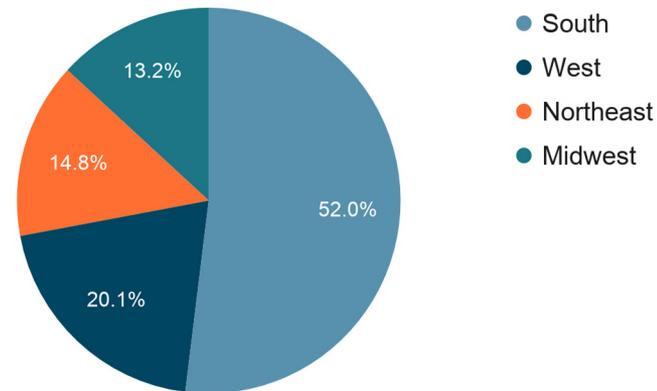
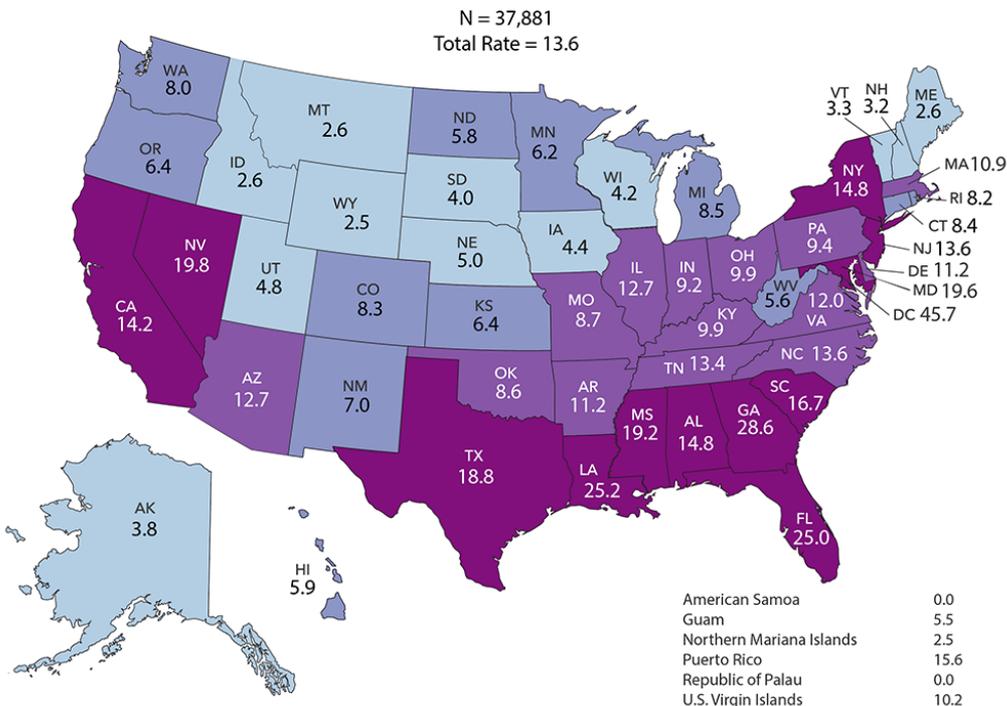
New Infections Per Year

- Worldwide: 1.7 million
- United States: 37,986

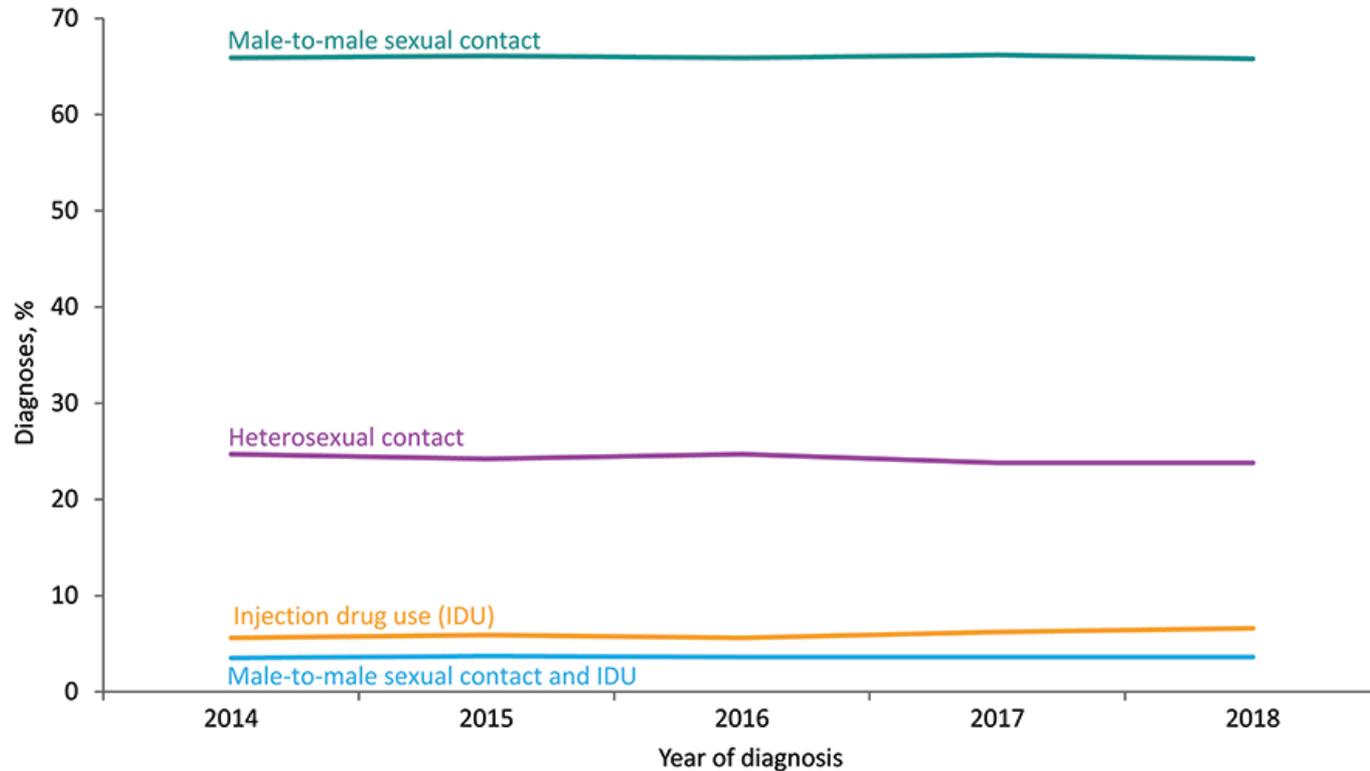


Rates of New HIV Diagnoses Among Adults/Adolescents 2018

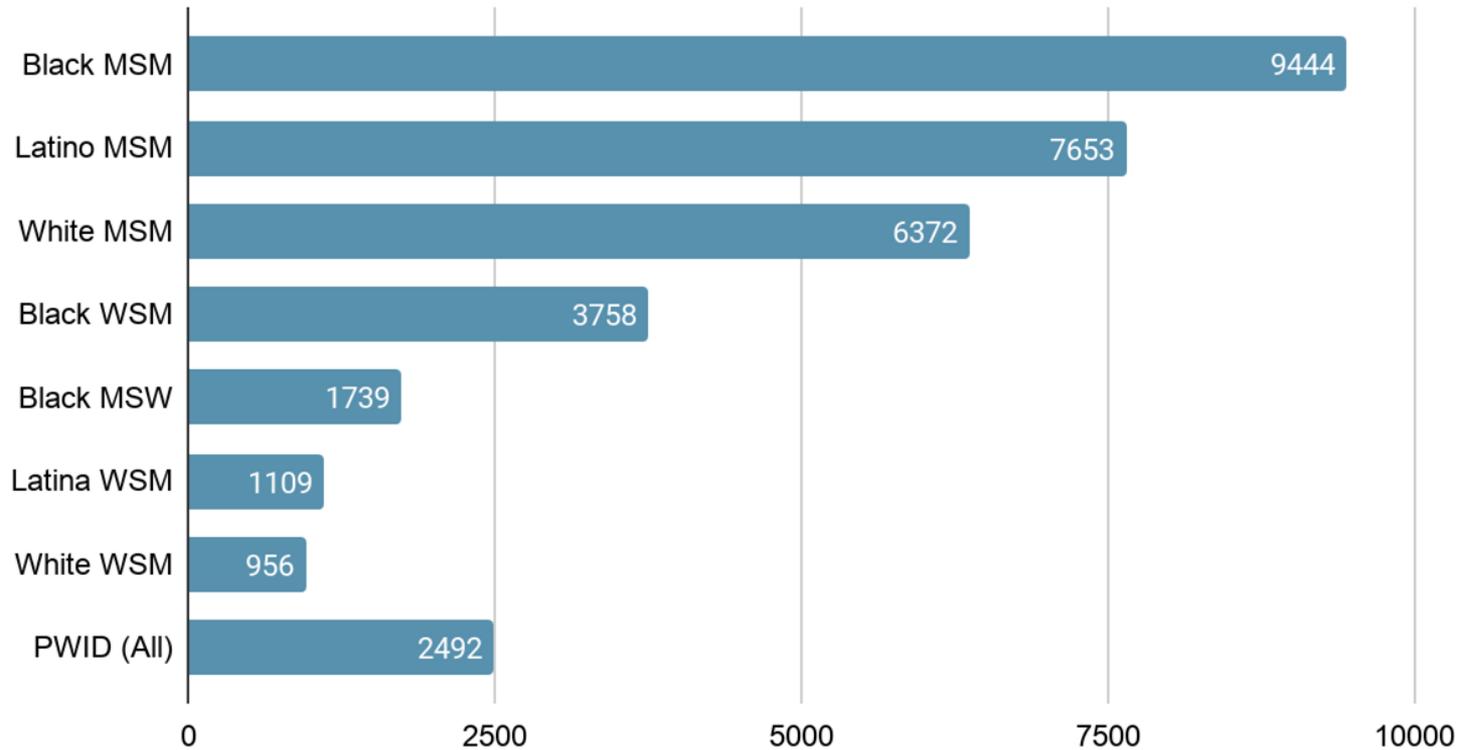
New HIV Diagnoses by Region- 2018



Percentages of Diagnoses of HIV Infection among Adults and Adolescents in US, by Transmission Category, 2014–2018



New HIV Diagnoses by Transmission and Race - US - 2018



Question 1

In the District of Columbia from 2015 to 2019, what is the correct order of those newly diagnosed with HIV, from most to least?

- A) White MSM, Black MSM, Black heterosexual women
- B) Black MSM, Black heterosexual women, White MSM
- C) Black heterosexual women, White MSM, Black MSM

HIV Now - DC

12,332 Persons Living with HIV in DC

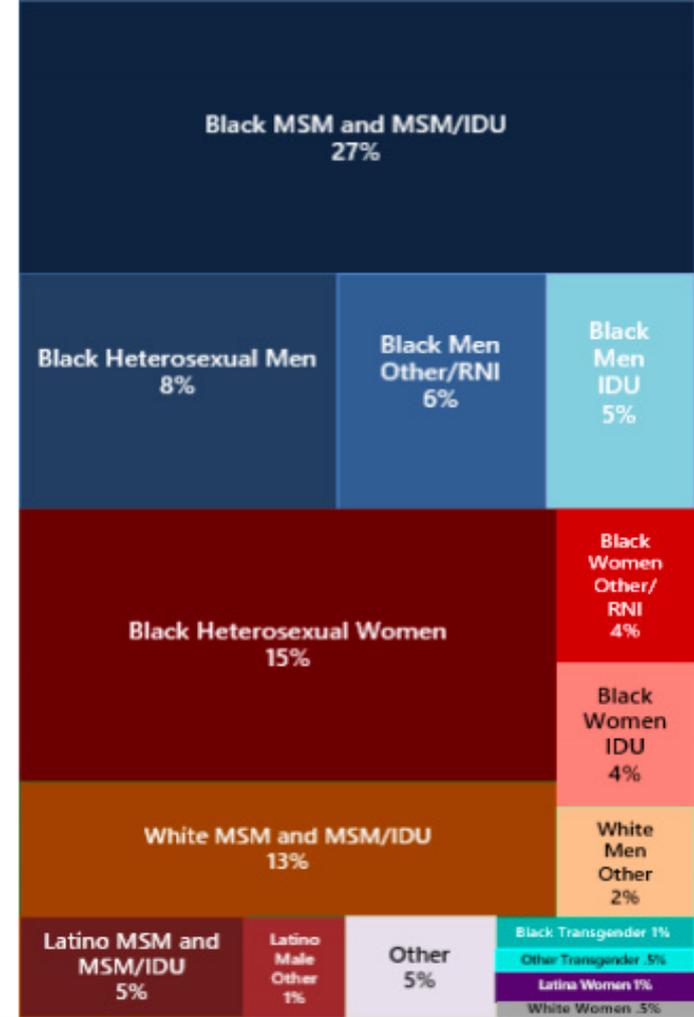
- 1.8% of District population

Race

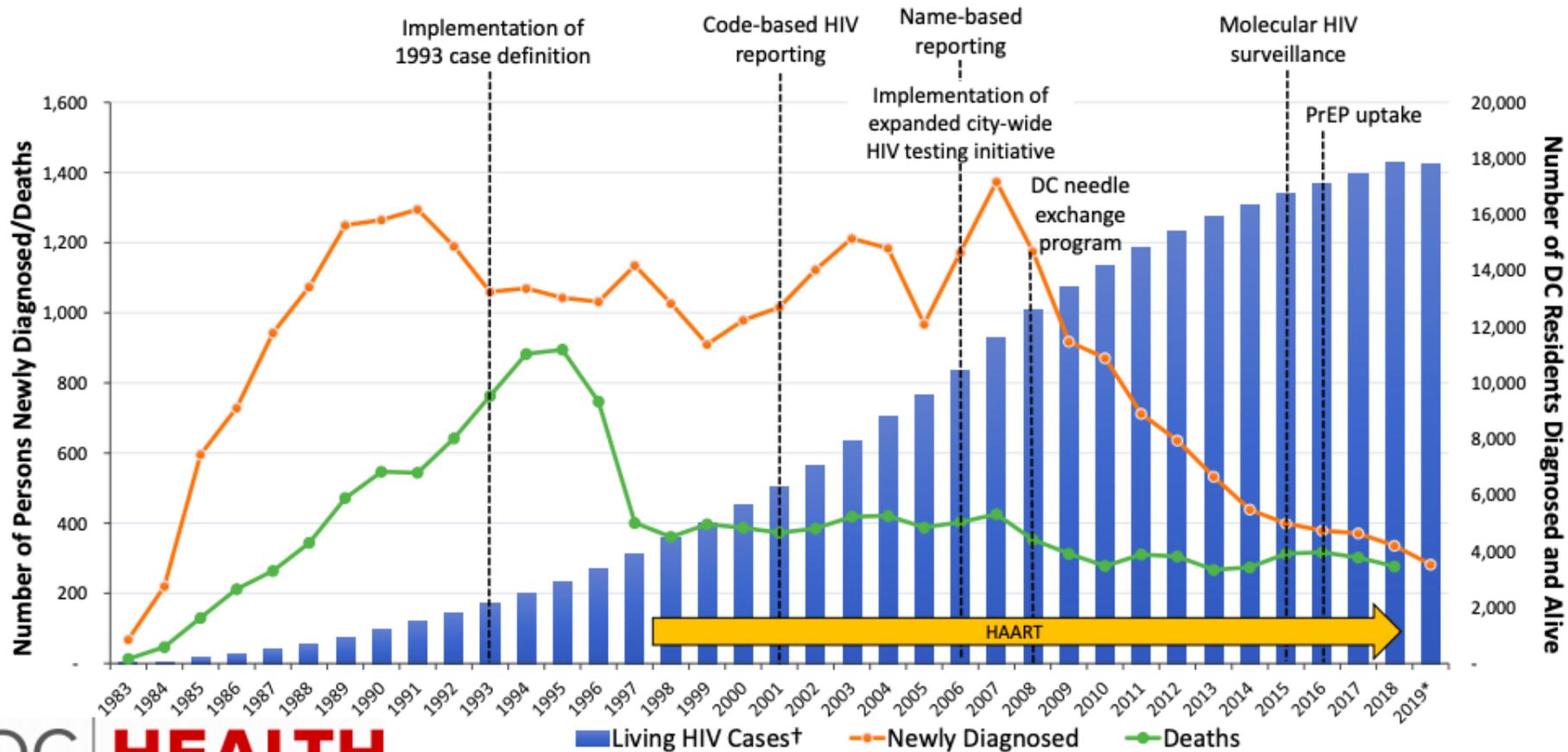
- 71.7% Black; 15.6% White, 7.6% Latinx
 - 27% Black MSM, 15% Black Heterosexual Women, 13% White MSM

Transmission

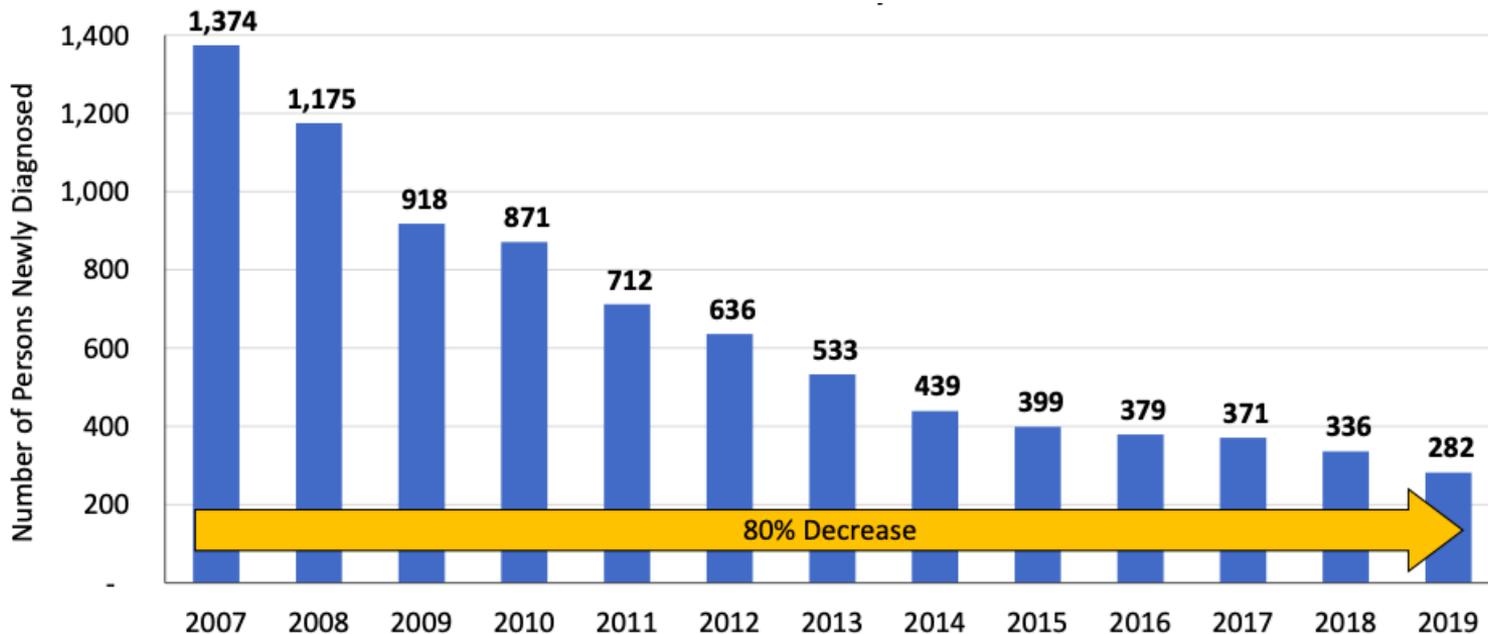
- 73.0% sexual transmission; 9.7% injection drug associated



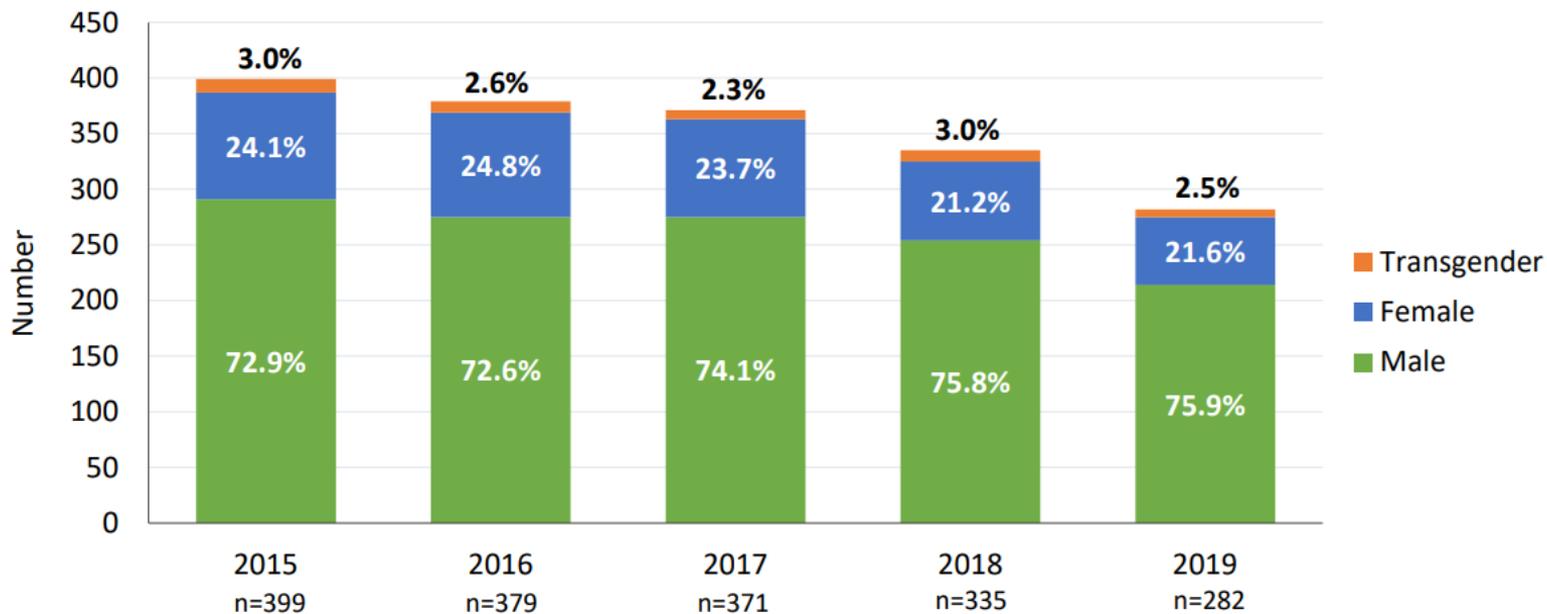
Newly Diagnosed HIV Cases, Deaths, and Living HIV Cases by Year in DC, 1983-2019



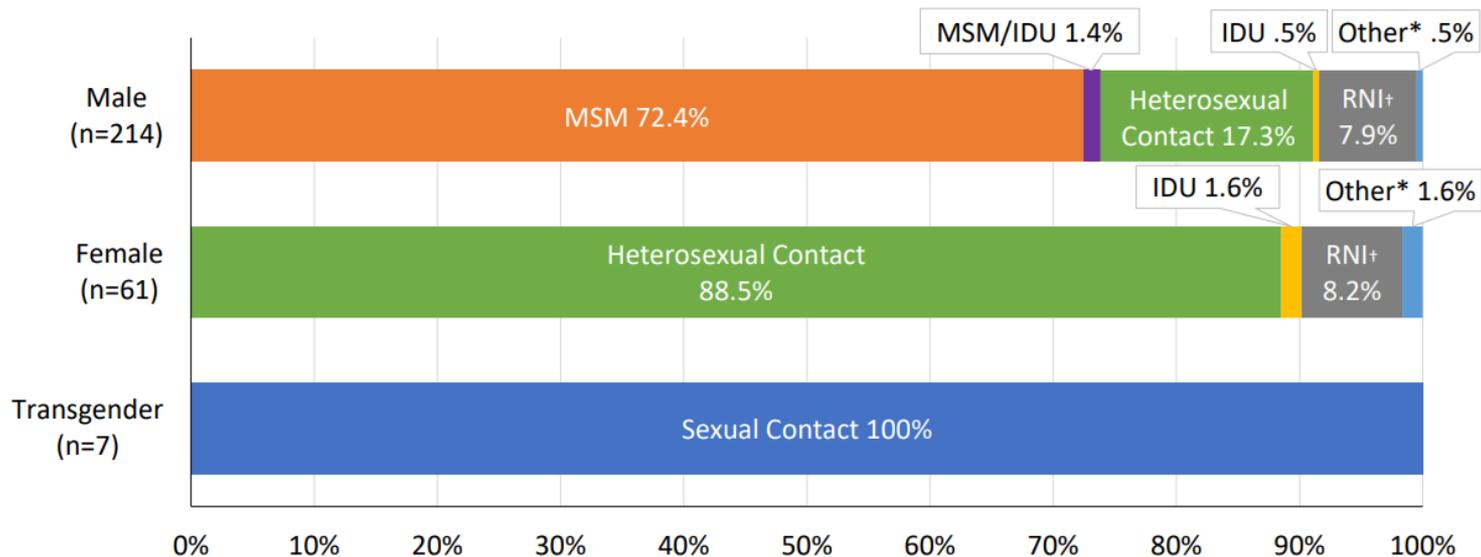
New HIV Diagnoses by Year of Diagnosis – DC, 2007-2019



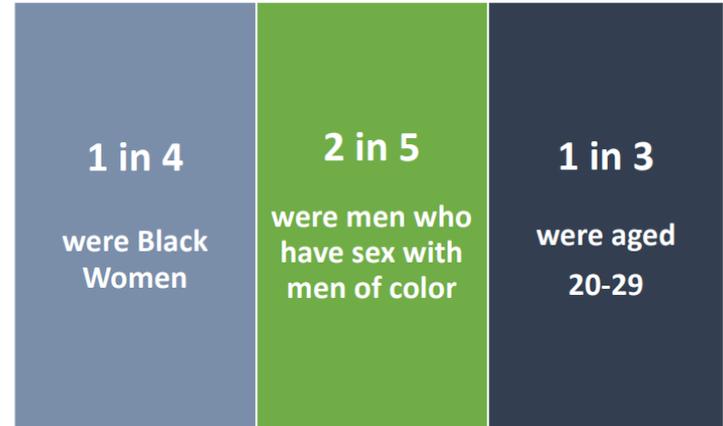
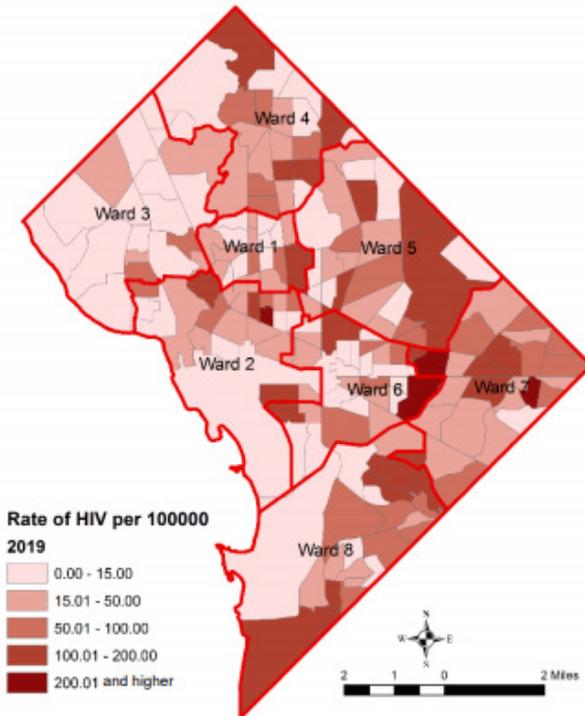
New HIV Diagnoses by Year and Gender Identity - DC, 2015-2019



New HIV Diagnoses by Gender Identity and Mode of Transmission - DC, 2019



New HIV Diagnoses 2019



Ending HIV in DC

- **Diagnose**
 - HIV screening and testing
 - *95% know HIV status*
- **Treat**
 - Rapid HIV treatment and sustained suppression
 - Undetectable = Untransmittable (U=U)
 - *95% in treatment*
 - *95% reach viral suppression*
- **Respond**
- **Prevent**
 - STI treatment/prevention, condom distribution, behavioral health, syringe service programs, harm reduction, non-occupational post-exposure prophylaxis
 - **PrEP**

Mayor Muriel Bowser

DC ENDS HIV

Ending the HIV Epidemic in the District of Columbia for All Communities by 2030

WASHINGTON AIDS CENTER DC AHAUSD DC HEALTH DISTRICT OF COLUMBIA MURIEL BOWSER, MAYOR

Mayor Muriel Bowser

90/90/90/50 Plan

Ending the HIV Epidemic in the District of Columbia by 2020

The poster features a grid of diverse people's faces in various colors, with a circular inset showing a woman and a man. Logos for the Washington AIDS Center, DC AHAUSD, DC Health, and the District of Columbia Government are visible.

Question 2

Per the CDC HIV screening guidelines, which of the following individuals would not be indicated for annual HIV screening?

- A) A 29 year-old female with two male partners over the last year with no history of a bacterial STI
- B) A 45 year-old gay male with one monogamous HIV negative partner
- C) A 55 year-old male with opiate use disorder on methadone replacement therapy but occasional heroin injection.
- D) A 18 year-old male who has exchanged sex for housing with a female partner in the last year

Ending HIV: Diagnose - Screening

Screening:

- Improve survival / quality of life; prevent new infections
 - Persons aware of status 68% lower prevalence of unprotected intercourse (1)
 - Persons unaware of HIV status 3.5 times more likely to transmit
 - Estimate of 54% of attributable HIV infections (2)
- **CDC Recommendation: Routine** screening for people aged 13 to 64 in all healthcare settings (3)
 - Repeat at least once per year for PWID, exchange sex for money or drugs, serodiscordant couples, >1 partner since most recent HIV test
- **USPSTF: Grade A:** Screening for those 15 to 65, or at high risk
 - Repeat screening if engaged in elevated risk activities, prevalence >1% (4)
 - DC prevalence: 1.8%

Ending HIV: Prevent - Pre-Exposure Prophylaxis for HIV (PrEP)

Daily medication to reduce risk of HIV acquisition

- Tenofovir disoproxil fumarate (TDF) and Emtricitabine (FTC) (Truvada®)
- Tenofovir alafenamide (TAF) and Emtricitabine (FTC) (Descovy®)
 - Descovy *only* approved for those *without* vaginal sex as a risk for HIV acquisition

CDC recommended HIV prevention option for:

- Sexually-active MSM at substantial risk of HIV
- Heterosexually-active men and women at substantial risk of HIV
- PWID at substantial risk of HIV



PrEP: Effectiveness

Study: Meta-analysis of 8 RCT trials of TDF/FTC vs. placebo (n=10,626) for men and women with high risk sexual contact, MSM, transgender women.

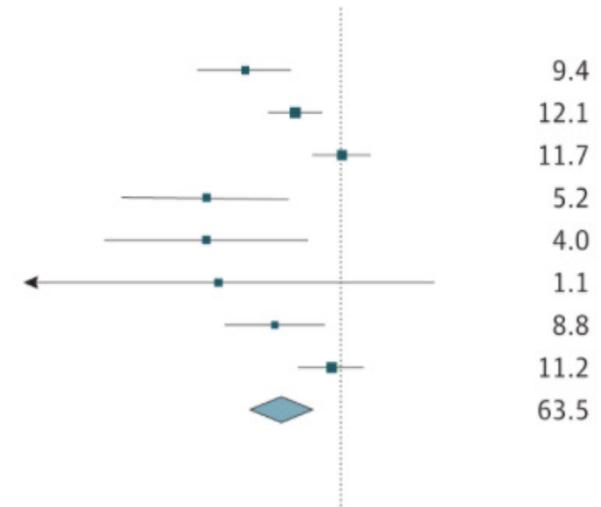
Results: Over 4 months to 4 years of follow-up, TDF/FTC significantly associated with reduced risk of HIV infection vs. placebo, **RR: 0.44** (0.27-0.72).

Tenofovir disoproxil fumarate/emtricitabine

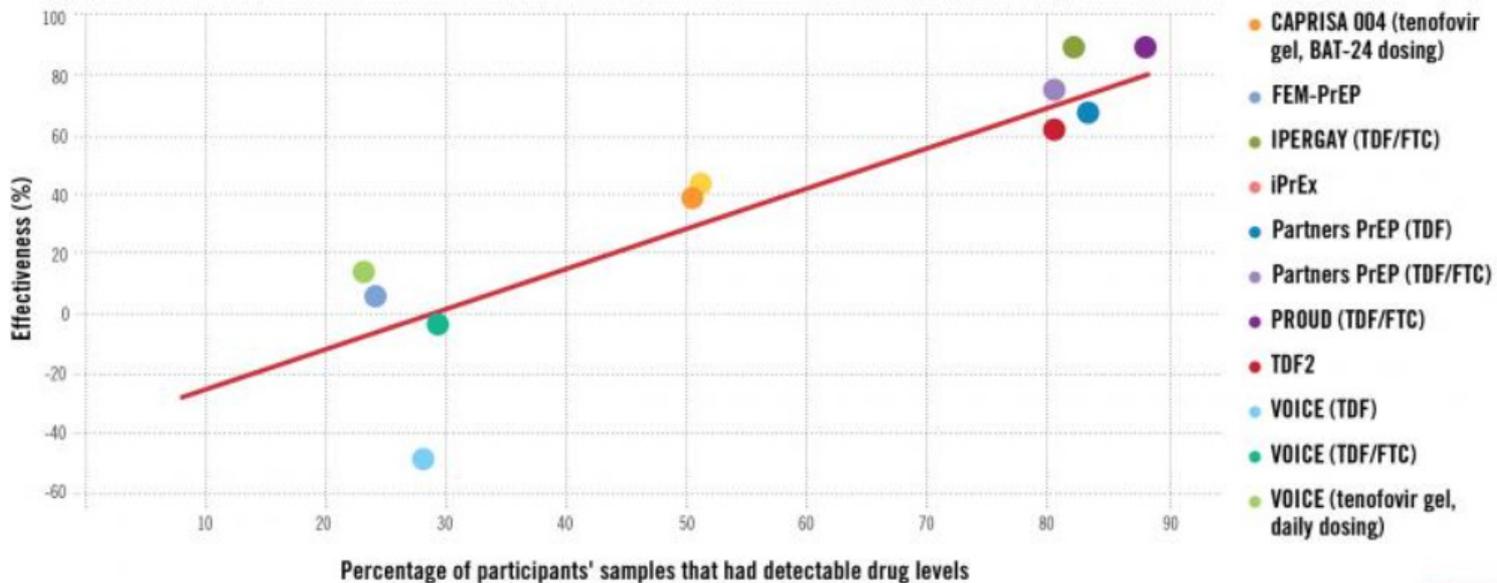
Baeten et al, ¹² 2012 ^c	13/1568	26/793	0.25 (0.13-0.49)
Grant et al, ¹⁷ 2010	38/1251	72/1248	0.53 (0.36-0.77)
Marrazzo et al, ²⁷ 2015 ^c	61/1003	30/505	1.02 (0.67-1.56)
McCormack et al, ³¹ 2016 ^b	3/268	20/255	0.14 (0.04-0.47)
Molina et al, ³³ 2015 ^b	2/199	14/201	0.14 (0.03-0.63)
Mutua et al, ³⁹ 2012	0/48	1/24	0.17 (0.01-4.03)
Thigpen et al, ⁴² 2012	10/601	26/606	0.39 (0.19-0.80)
Van Damme et al, ⁴³ 2012	31/1024	35/1032	0.89 (0.55-1.44)
Subtotal	158/5962	224/4664	0.44 (0.27-0.72)

$I^2 = 74\%$; $\chi^2 = 27.08$ for heterogeneity, $P < .001$; $\tau^2 = 0.30$

Overall effect: $z = 3.31$, $P < .001$



Adherence and Efficacy



PrEP: Safety

Renal: No significant difference in 12 RCTs in TDF/FTC v. placebo in serious (Grade 3/4) adverse events RD, 0.00 [-0.01-0.02]

- Increase risk of Grade 1-2 renal adverse events (RR:1.43 [1.18-1.75]) but most **Grade 1** (1.1-1.3 ULN) (2), RD 0.02 (0.01-0.03).
 - ❖ TDF/FTC: 336/7843 (4.3%), Control: 178/7835 (2.3%)
 - DISCOVER: TDF/FTC mean of eGFR decrease of 2.3 mL/min/1.73m²
- Resolved following cessation of medication

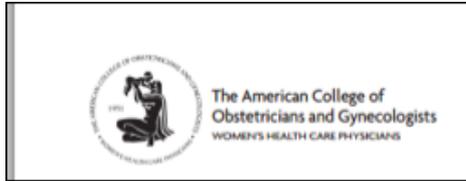
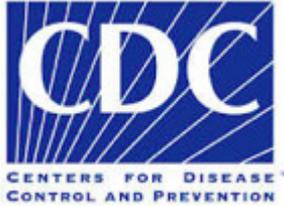
Bone: No significant difference between TDF/FTC vs placebo in risk of fracture RD:0.00 (-0.00-0.01, p=.50)

- PrEP (TDF/FTC) (217/5789), Control (189/5795)

GI: Significantly increased gastrointestinal (primarily nausea) adverse events (12 trials [n = 18,300]; RR, 1.63 [1.26-2.11])

- No grade 3/4, mostly nausea and diarrhea (4-6%)

PrEP: Recommendations



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.	A

PrEP: Risk Compensation?

Baseline STI incidence for MSM on PrEP is elevated

- Syphilis: 9.1/100PY; Gonorrhea: 48.5/100PY; Chlamydia: 41.8/100PY; Hepatitis C: 1.3/100PY (1)
- Within first year on PrEP, significant increase in rectal chlamydia (OR: 1.5, CI: 1.2-2.1)
 - Trend, but not significant increase in any STI diagnosis (OR: 1.2; CI: 0.99-1.5)

13 studies showed a trend, but no significant increase in proportion of MSM reporting condomless sex

- Variance among individuals within PrEP cohort (2)

PrEP: Indications (1)

Males with Male Partners

- Adult man
- Without HIV infection (acute or established)
- Any male sex partners in past 6 months
- Not in a monogamous partnership with a recently tested, HIV-negative man

AND at least one of the following:

- Any anal sex without condoms (receptive or insertive) in past 6 months
- Any bacterial STI diagnosed or reported in past 6 months
- Is in an ongoing sexual relationship with an HIV-positive male partner

PrEP: Indications (2)

Heterosexual Males and Females

- HIV negative
- Sexually active within the last six months
- NOT in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men
- Inconsistent condom use with 1 or more partners with unknown HIV status
- Ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

PrEP: Indications (3)

Persons Who Inject Drugs (PWID)

- HIV negative
- Injection of any drug not prescribed by a clinician in past 6 months

AND at least one of the following:

- Sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition

Question 3

Per the 2017 CDC / USPHS PrEP Clinical Practice Guidelines, which of the following labs **is not indicated** for all patients starting on PrEP?

- A) HIV Antibody or HIV Antigen/Antibody test
- B) Serum creatinine with a calculation of renal function
- C) Hepatitis B Surface Antigen
- D) Hepatitis B Surface Antibody
- E) Tuberculosis Interferon Gamma Release Assay test

PrEP: Starting Medication

- Negative HIV test within one week of initiating
 - Serum or rapid fingerstick
- Negative screen for acute HIV symptoms in last four weeks
 - Fatigue, malaise, fever, rash, lymphadenopathy
- Baseline renal function
 - Caution in patients with creatinine clearance <60
- Hepatitis B status (HbSAg) / immunity (HbSAb)
 - Consider hepatitis C, though not mandatory
- At-risk site gonorrhea and chlamydia testing
- No risk event within last 72 hours
 - If event, then non-occupational post-exposure prophylaxis (nPEP)

Protection Timeline

20 days for max serum concentration, 7 days until detectable in rectal tissue, 20 days for cervical tissue

PrEP: Initiation Counseling

Side Effects

- Nausea, flatulence may occur
 - First few weeks of treatment, quickly subside
 - PrEP after meal with fat / carbs, daytime dosing if sleep disturbances
- TDF/FTC: kidney injury occurs rarely, avoid nephrotoxic medications
 - Resolve with drug discontinuation
 - Small decrease in bone mineral density, no increased risk of fractures
- TAF/FTC: minor increases in total cholesterol/LDL, weight (0.5 BMI, 1.0 kg)

Adherence

- Daily use shown to have highest efficacy
 - Efficacy in women highest with daily dosing; less forgiving for missed doses than with men/rectal coverage

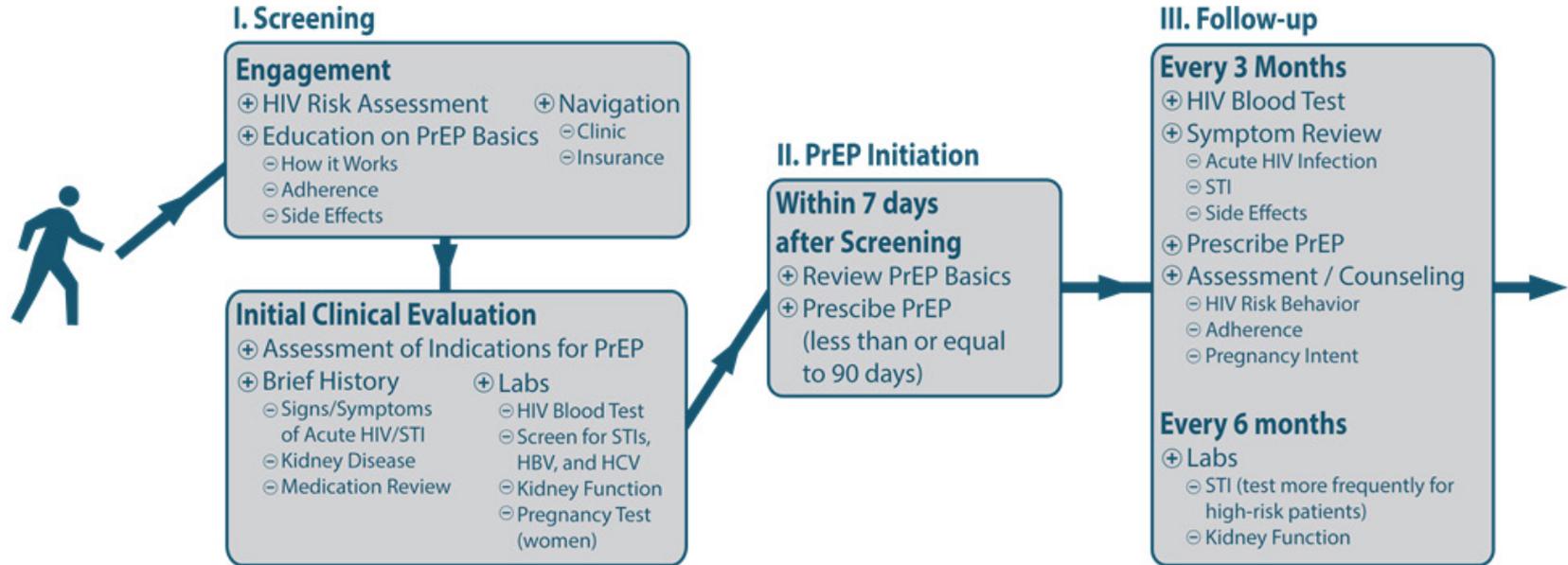
Discontinuation

- Continue for 28 days after last condomless sexual encounter
 - If stop and wants to restart PrEP- repeat HIV test needed prior to restart

PrEP: Routine Follow-up

	MSM	Heterosexual Women and Men	PWID
Specific tests	Oral/rectal gonorrhea and chlamydia NAAT, and syphilis serology	Assess pregnancy intention (+/- test) every 3 months	Access to clean needles/ syringes and treatment services
Other services Every 3 months	HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment		
At 3 months and every 6 months thereafter	Assess renal function		
Every 6 months	Test for bacterial STIs at any site at risk (or more frequently if needed)		

PrEP: Providing Care Overview



Landscape of PrEP in DC

- **13,000** persons with estimated need for PrEP in DC
 - **2,296** estimated persons on PrEP in 2018
 - 2nd highest per capita rate (36.5%) (1)
 - Expansion of PrEP starts
 - DC Health Partners: Increase from 500 in 2016 to 2,000 in 2019
 - DCHWC: ~200 new PrEP starts annually
 - Significant disparities
 - Women
 - ~10% of PrEP starts, 1 in 5 new infections
 - Less likely to maintain on treatment (2)
 - Black MSM (3)
 - Stigma

Stigma and HIV / PrEP (1)

Stigma - an attitude of disapproval and discontent toward a person or group because of the presence of an attribute perceived as undesirable.(1)

- **External:** Discriminatory practices - unfair / unlawful actions against persons belonging to a stigmatized group
 - Structural: HIV criminalization laws, inequitable service provision, social isolation
 - Health: Denial of services, informing others without consent, dependent ART provision, forced testing or procedures (2)
- **Internal:** Individual takes in the negative ideas and stereotypes and starts to apply them to themselves.
 - Results in shame, fear of disclosure, isolation, and despair
- Compounded and intersectional with race / ethnicity, sexual orientation, sexual behavior, substance use, sex work, socioeconomic circumstance, homelessness
- Stigmatization by association

Stigma and HIV / PrEP (2)

Stigma and PrEP

- Medication-associated stigmatization
 - Provider and individual level
- PrEP as one option for HIV risk reduction
 - Seen as “less safe” option (1)
 - Unfounded concerns that PrEP causes people to have more high risk sexual behaviors (2,3)
- Stigmatizing sexual desire and expression

Result

- **Reduced prescribing, client interest, and adherence**
 - Persons who meet criteria don't see themselves as candidates (4)
 - Persons don't want others to see them as candidates for PrEP (5)

Stigma and HIV / PrEP (3)

Paths Forward

- **Community-level:** normalizing PrEP, sex positive approach, advocacy
- **Structural level:** Insurance coverage, EOB provision, expanded funding, reimbursement (1)
- **Provider level:**
 - Education:
 - Broad criteria for eligibility
 - Avoidance of “high risk” designation
 - Trap of “risk compensation”
 - Normalization in clinical settings
 - Education of all patients
 - Awareness of implicit biases
 - How do you feel about PrEP?
 - Condom use
 - Gender of patients and risk

HIV / PrEP Stigma Summary

- **HIV** continues to disproportionately affect racial and sexual minorities
- **Structural level:** Insurance coverage, EOB provision, expanded funding, reimbursement
- **Provider level:**
 - Education:
 - Broad criteria for eligibility
 - Avoidance of “high risk” designation
 - Trap of “risk compensation”
 - Normalization in clinical settings
 - Education of all patients
 - Awareness of implicit biases
 - How do you feel about PrEP?
 - Condom use
 - Gender of patients and risk

In Conclusion

Using PrEP is a choice

- May not be a lifelong commitment

PrEP is one of many HIV prevention strategies

- The more approaches used, the better the protection against HIV
- Talk to patients, see where they are at

PrEP is for **anyone** at risk for HIV

Individuals must test HIV negative to initiate and continue PrEP

Side effects are minimal, manageable, and reversible

Adherence is essential for effectiveness

- >99% effective when taken correctively
 - 0% effective in preventing STIs

You can start your patients on PrEP

- Resources available for DC Providers



Thank You

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Pharmacy Benefits Program

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DC PrEP Drug Assistance Program

Program Description

DC PrEP DAP- pays for medication for Pre-Exposure Prophylaxis therapy to reduce the spread of HIV-1 infection for high risk populations.



Population served

Negative District Metropolitan area residents that are **uninsured** or **underinsured**, and meet established program eligibility criteria.

DC PrEP DAP Program Requirements



- **Must be a DC metropolitan resident**
- **Applicant's personal income must be at or below 500% Federal Poverty Level**
 - **Varies based on household size.**
- **Risk Factors for contracting HIV**

DC PrEP Drug Assistance Program Eligibility Requirements

Who is Eligible?

- In order to be eligible for the PrEP DAP program, individuals must:
- be a DC Metropolitan Area resident which includes DC, MD and some parts of VA
- be HIV negative
- be at risk for contracting HIV

Having insurance is preferred, however, uninsured applicants can contact Gilead's Advancing Access Patient Assistance Program at 1-800-226-2056 or [GileadAdvancingAccess.com](https://www.gileadadvancingaccess.com) prior to applying.

Required Eligibility Documents

Valid state Driver's License or Identification Card

Proof of Residency (1 of the following)

- Rental/Mortgage Agreement
- Utility bill within last. 60 days
- DC voter registration
- Social Security Benefit Statement

Insurance Card

No access to any of the above? Provide statement by case manager on facility letterhead.

Online Enrollment Site



<https://dcenroll.ramsellcorp.com>

Please contact DC ADAP for registration code

Frequently asked questions

Is insurance required to apply?

How old must the applicant be to enroll?

- DC Health will follow all DC Minor Health Consent law's
- Truvada is FDA approved from ages 15 and older, and/or weight requirement of at least 35 kilograms/ 77 pounds.

Are there any income requirements?

- Yes 500% below FPL

How can I apply?

- Fax, mail, online

Frequently asked questions continued

What if applicant is homeless?

How long does application process take?

- Typically, processing takes 72 hours

How often does a patient have to re-apply?

- Every six months

Scenario

A young black MSM presents to the DC Health and Wellness Clinic and requests to initiate treatment of PrEP. He is 17 years old weighs, 117 pounds, and has a history of one STD. He is currently in a non-monogamous relationship and concerned about disclosing his PrEP treatment since he is currently on his parents' health insurance plan.

Question

What is the best option for medication coverage for this patient?

- A) Use their parent's private insurance plan
- B) Enroll the patient into DC Health's PrEP DAP program
- C) Enroll in the Gilead patient assistance program.
- D) Enroll the patient into DC Medicaid



Thank You

DC | HEALTH

GOVERNMENT OF THE DISTRICT OF COLUMBIA

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