PrEP Overview
HIV Pre-Exposure Prophylaxis

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Women and PrEP Symposium
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Disclosures

- None

Objectives

- Describe the epidemiology of HIV incidence in the US and in Baltimore City with a focus on women
- Describe PrEP coverage, highlighting disparities
- Describe FDA-approved medications for PrEP and the clinical considerations for prescribing
- Describe resources to support PrEP access

United States

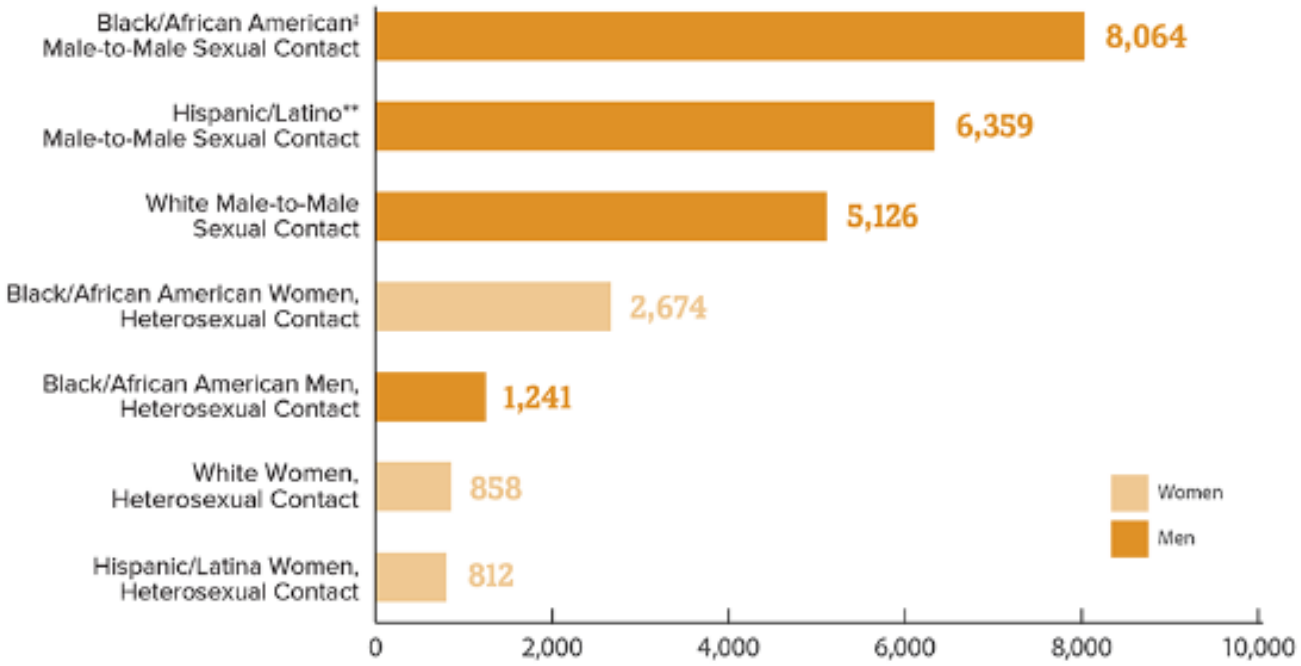
1.2 million people living with HIV

~35,000 new diagnoses per year

PREVENTABLE

https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics

New HIV Diagnoses in the US and Dependent Areas for the Most-Affected Subpopulations, 2019



Subpopulations representing 2% or less of all people who received an HIV diagnosis in 2020 are not represented in this chart.

* Among people aged 13 and older.

† Transmission category is classified based on a hierarchy of risk factors most likely responsible for HIV transmission. Classification is determined based on the person's sex assigned at birth. Data have been statistically adjusted to account for missing transmission category.

‡ *Black* refers to people having origins in any of the Black racial groups of Africa. *African American* is a term often used for people of African descent with ancestry in North America

** Hispanic/Latino people can be of any race.

Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2020. *HIV Surveillance Report* 2022;33.

https://www.cdc.gov/hiv/statistics/overview/ataglance.html, accessed 12/6/22

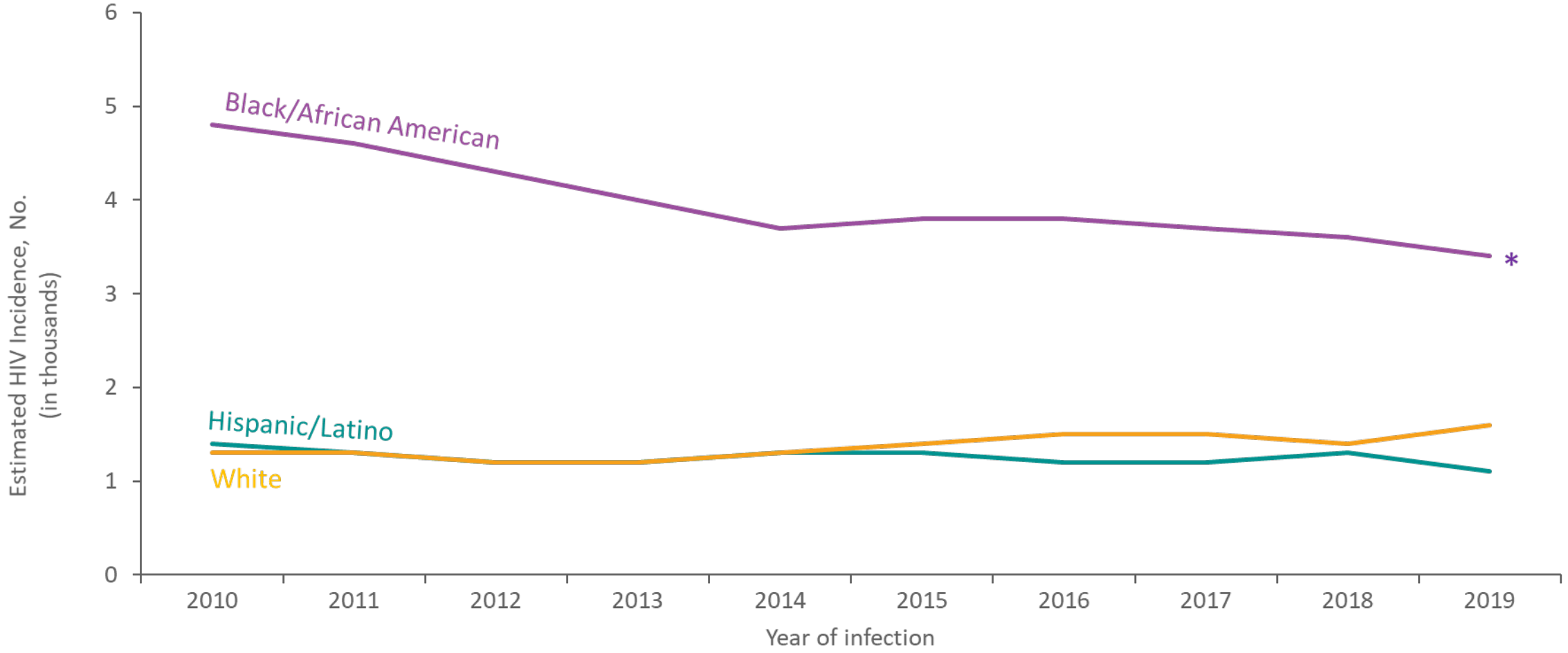
Of the 30,635 new HIV diagnoses in the US in 2020:

Heterosexual cis-gender women accounted for 15% of new diagnoses

Women who inject drugs accounted for 7% of new diagnoses

Transgender women accounted for 2% of new diagnoses

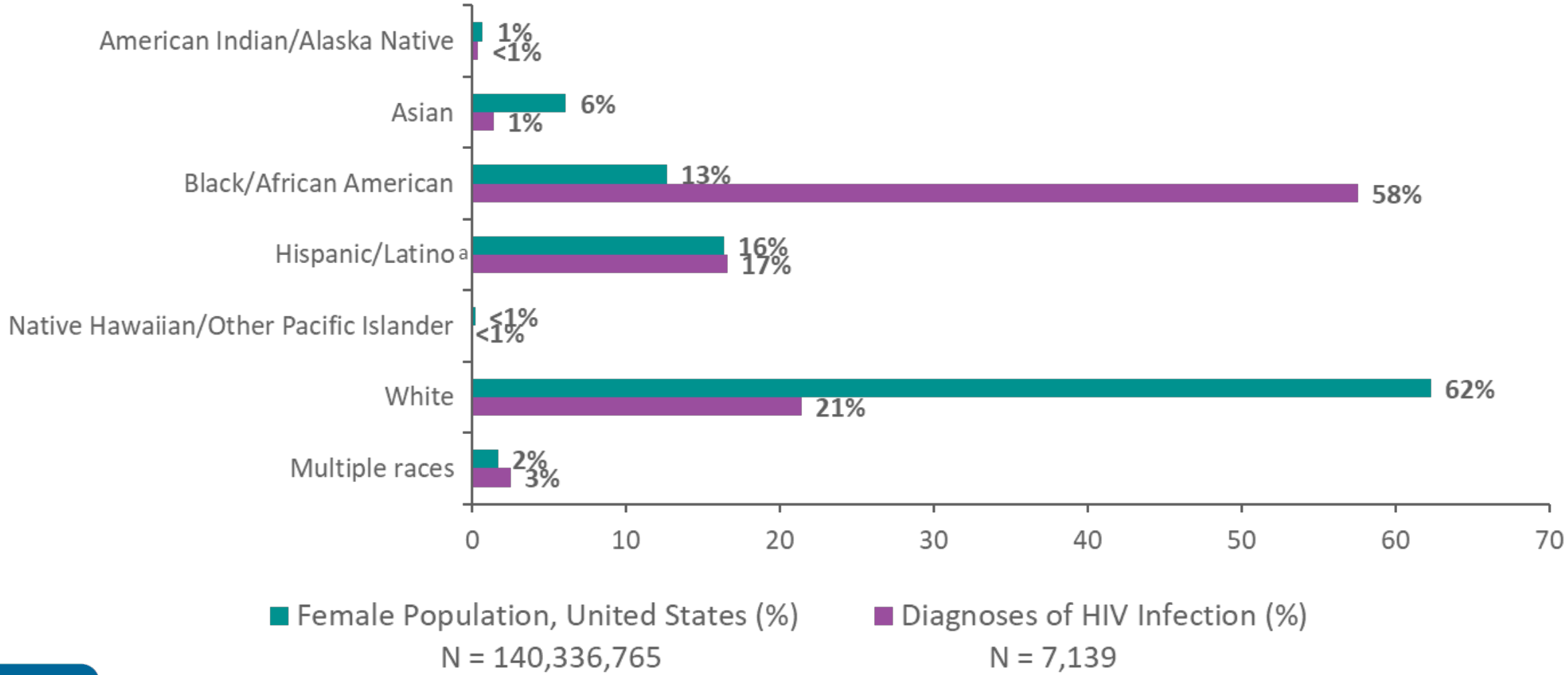
Estimated HIV Incidence among Females Aged ≥13 Years by Race/Ethnicity, 2010–2019—United States



Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Hispanic/Latino females can be of any race.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).

https://www.cdc.gov/hiv/library/slidesets/index.html, accessed 12/6/22

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

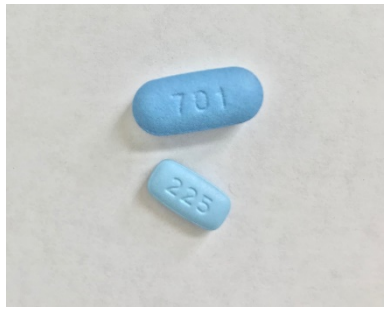


Note. Data for the year 2018 are considered preliminary and based on 6 months reporting delay.
[a] Hispanics/Latinos can be of any race.

https://www.cdc.gov/hiv/library/slidesets/index.html, accessed 12/6/21

HIV PREVENTION TOOLS

- Condoms
- Syringe exchange
- Safe blood supply
- STI diagnosis and treatment
- pMTCT
- HIV testing, linkage to care, and U=U
- **PrEP**
- PEP



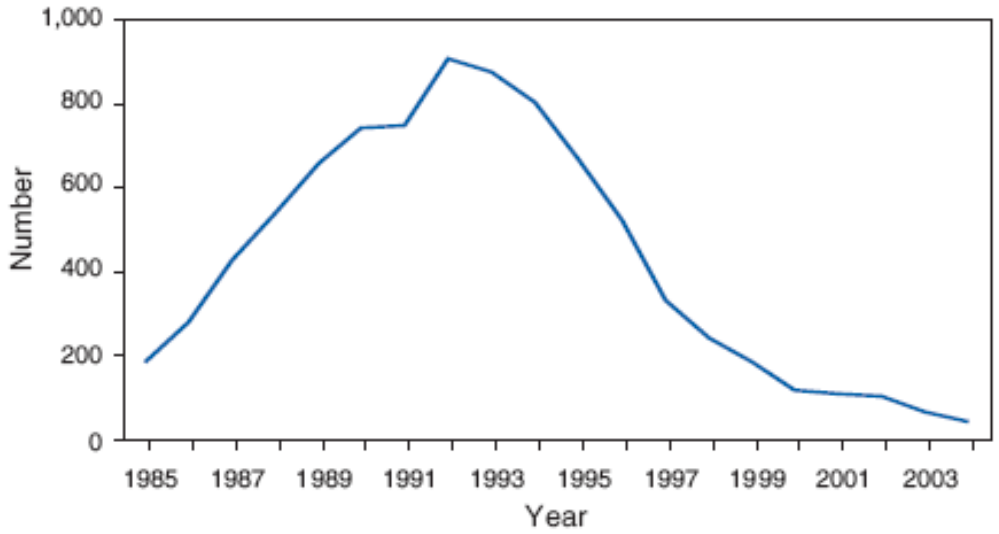
HIV Pre-Exposure Prophylaxis

Prophylaxis is a common medical intervention

- Migraines
- Malaria
- Aspirin
- Statins
- Birth control pills
- Etc…

And prophylaxis for HIV infection is not new

FIGURE. Estimated number of cases of perinatally acquired AIDS,* by year of diagnosis — United States, 1985–2004†



Achievements in Public Health: Reduction in Perinatal Transmission of HIV Infection – United States, 1985-2005. MMWR, June 2, 2006 55(21); 592-597.

History of HIV PrEP in the US

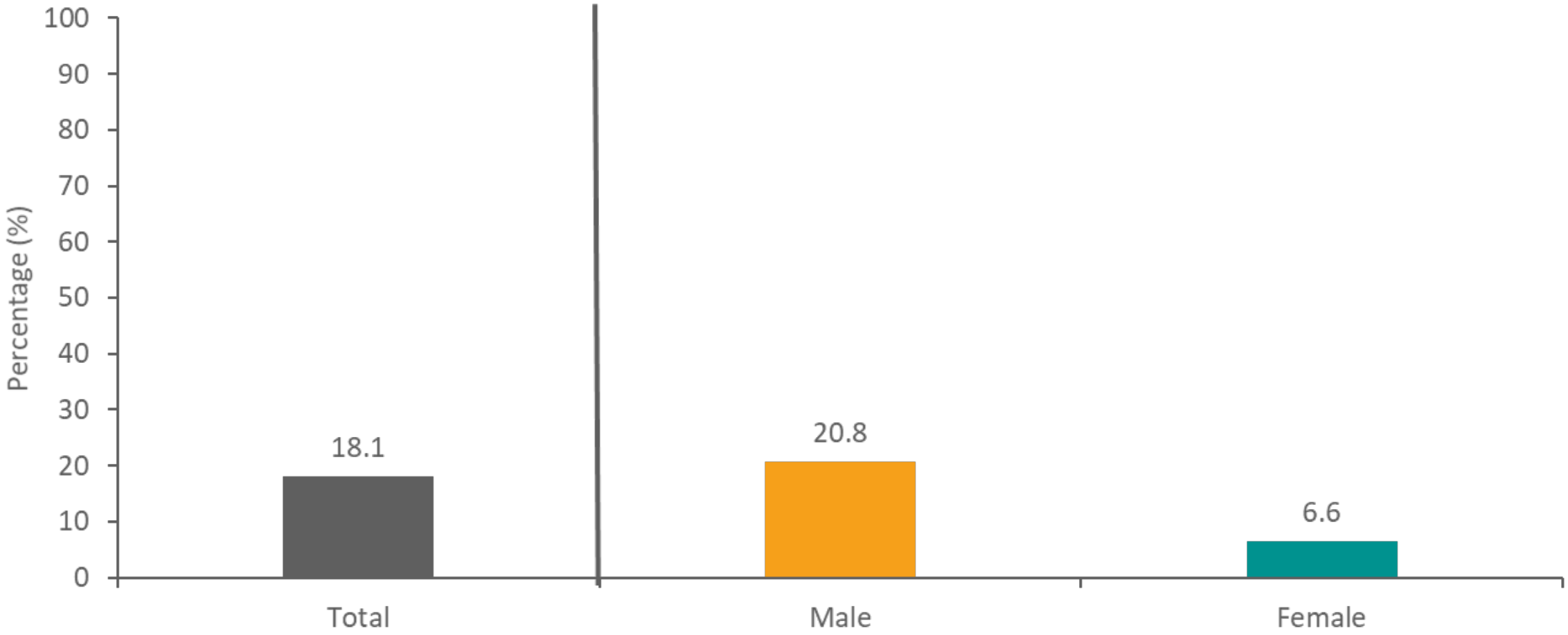
- TDF/FTC *tenofovir disoproxil fumarate* + *emtricitabine* (Truvada) approved by the FDA for PrEP in **2012**
- TAF/FTC *tenofovir alafenamide* + *emtricitabine* (Descovy) approved by the FDA for PrEP in **2019** (excluding those whose risk involves receptive vaginal sex)
- USPSTF grade A recommendation in **2019**
- Federal Government issues FAQ requiring insurers to cover PrEP without cost-sharing in July **2021**
- Injectable CAB-LA cabotegravir (Apretude) approved by the FDA for PrEP in **2021**

Recommendation Summary

Population	Recommendation	Grade (What's This?)
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.	A

https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis
https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf

PrEP Coverage among Persons Aged ≥16 Years, by Sex at Birth 2018—United States



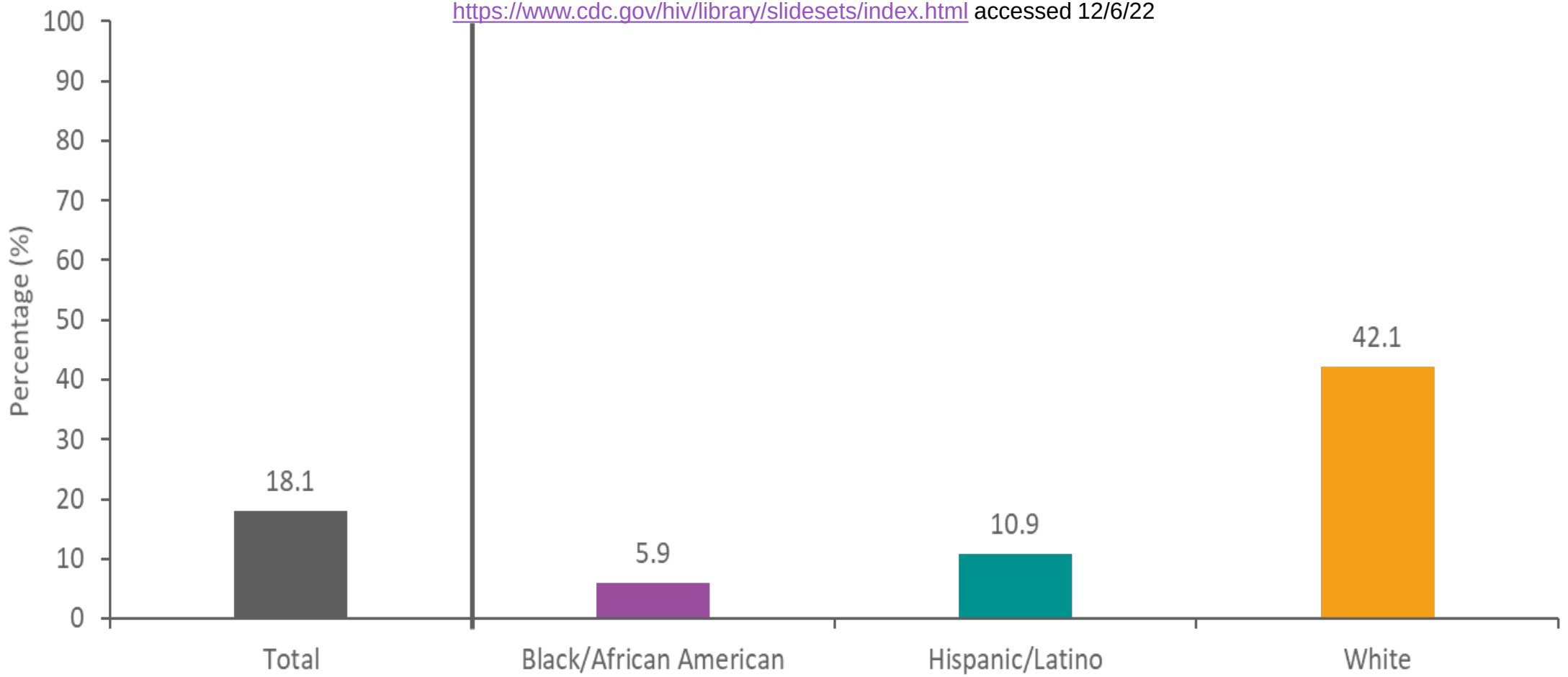
https://www.cdc.gov/hiv/library/slidesets/index.html accessed 12/6/22

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.

PrEP Coverage among Persons Aged ≥16 Years, by Race/ethnicity 2018—United States

https://www.cdc.gov/hiv/library/slidesets/index.html accessed 12/6/22



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. Race/ethnicity data were only available for 35% of persons prescribed PrEP in 2018. Number prescribed PrEP and PrEP coverage for race/ethnicity reported in the table were adjusted applying the distribution of records with known race/ethnicity to records with missing race/ethnicity. Different data sources were used in the numerator and denominator to calculate PrEP coverage.

PrEP users in Baltimore City

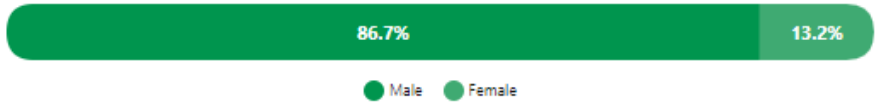
Number of PrEP users, 2021

933

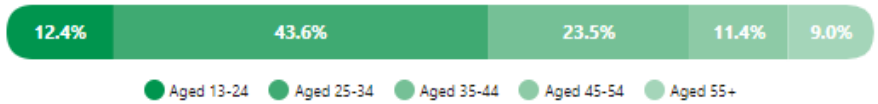
Rate of PrEP users per 100,000 population, 2021

183

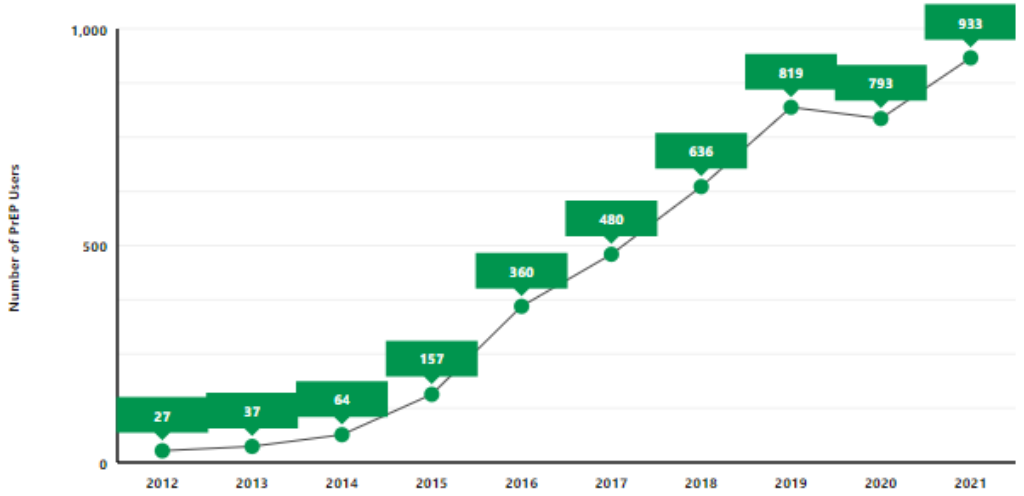
Percent of PrEP users, by Sex, 2021



Percent of PrEP users, by Age, 2021



Number of PrEP Users, 2012-2021



https://aidsvu.org/local-data/united-states/south/maryland/baltimore-city/ accessed 12/6/22

Baltimore City PrEP-to-Need Ratio

The 2021 PrEP-to-Need Ratio (PNR) is the ratio of the number of PrEP users in 2021 to the number of people newly diagnosed with HIV in 2020. PNR serves as a measurement for whether PrEP use appropriately reflects the need for HIV prevention. A lower PNR indicates more unmet need.

PNR, 2021

5.33

PNR, by Sex, 2021

Male: 6.08

Female: 2.93

PNR, by Age, 2021

Aged 13-24: 3.05

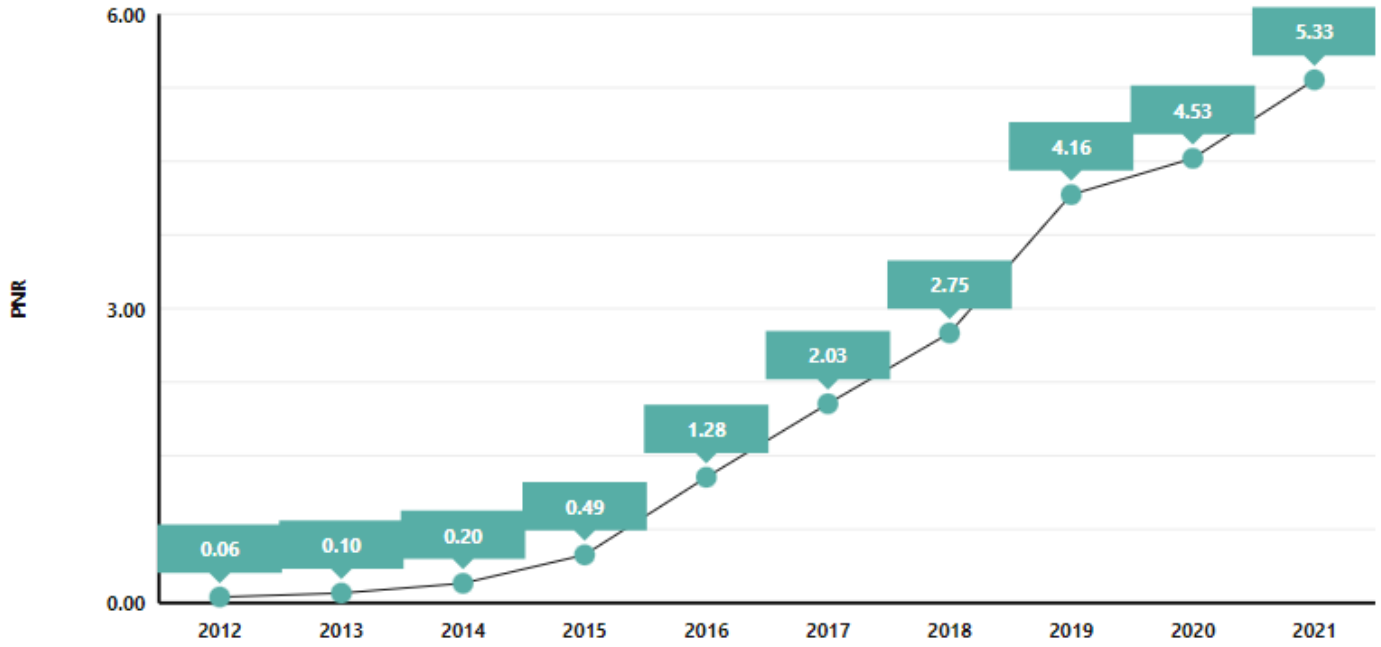
Aged 25-34: 6.90

Aged 35-44: 6.08

Aged 45-54: 6.24

Aged 55+: 3.36

PNR, 2012-2021

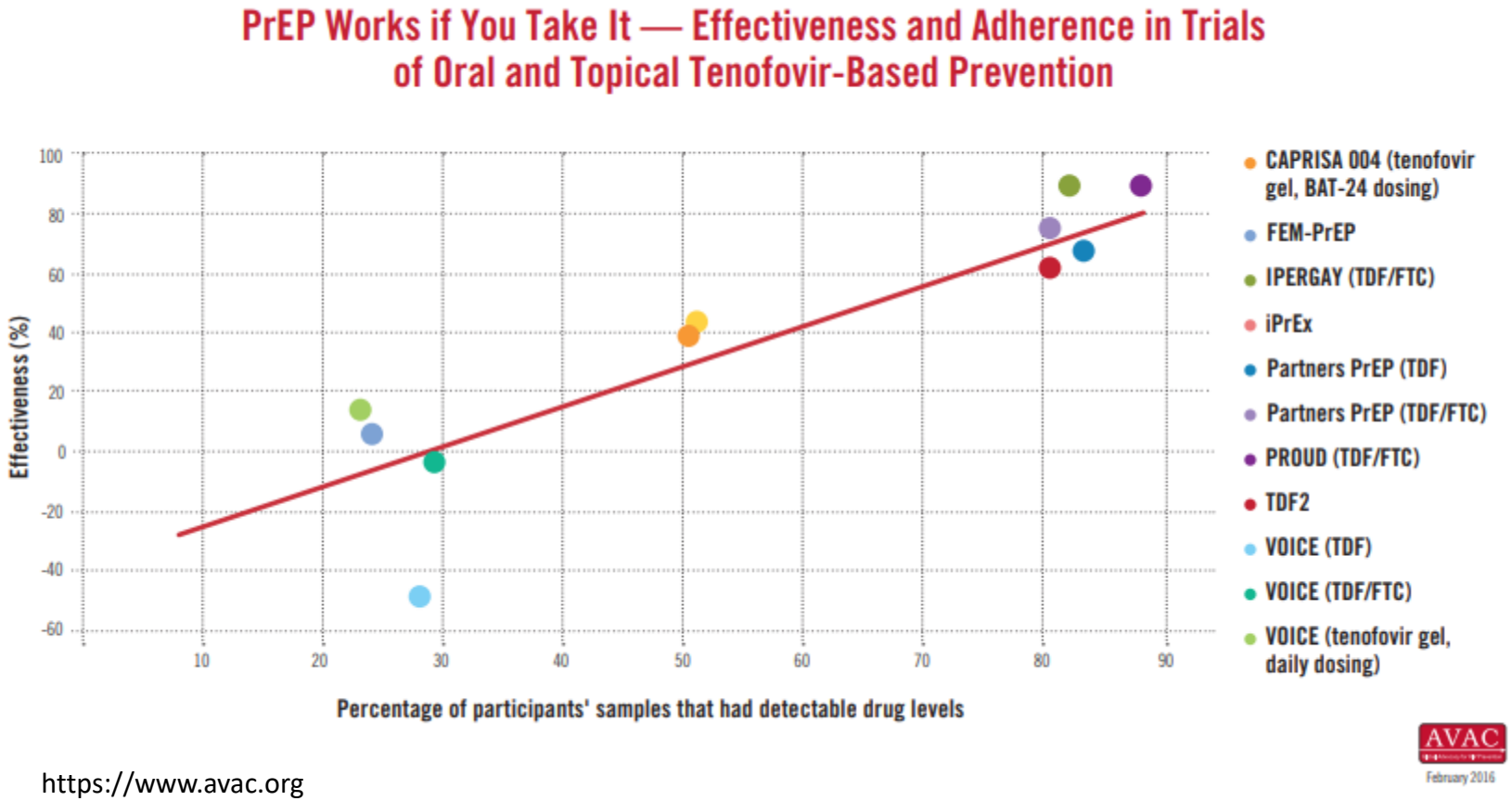


In Baltimore, 24% of new HIV diagnoses in 2020 were female. However, 13% of PrEP users are female

https://aidsvu.org/local-data/united-states/south/maryland/baltimore-city/ accessed 12/6/22
https://health.maryland.gov/phpa/OIDEOR/CHSE/SiteAssets/Pages/statistics/Baltimore-City-Annual-HIV-Epidemiological-Profile-2020.pdf

PrEP is HIGHLY effective for HIV prevention…

PrEP works if you take it



https://www.avac.org

How well does PrEP work for women?

- Meta-analysis of 5 RCTs of oral PrEP among women [1]
  - 3 reported evidence of effectiveness and 2 did not
  - Estimates by adherence (based on plasma drug levels)
    - 25% adherence: *no protection* (RR 1.19 95% CI: 0.89 – 1.61)
    - 50% adherence: *32% protective* (RR 0.68 95% CI: 0.53 – 0.88)
    - 75% adherence: *61% protective* (RR 0.39 95% CI: 0.25 – 0.60)

- Partners PrEP study
  - Clinical trial of HIV-negative men and women in serodiscordant heterosexual relationships in Uganda and Kenya [2]
  - Substudy measured plasma TDF levels among participants receiving TDF/FTC. Detectable drug level was associated with a **90% reduction** in the risk of HIV acquisition

1. *Hanscom et al. JAIDS 2016; 73(5):606-608*
2. *Baeten et al. NEJM 2012; 367(5): 399-410*

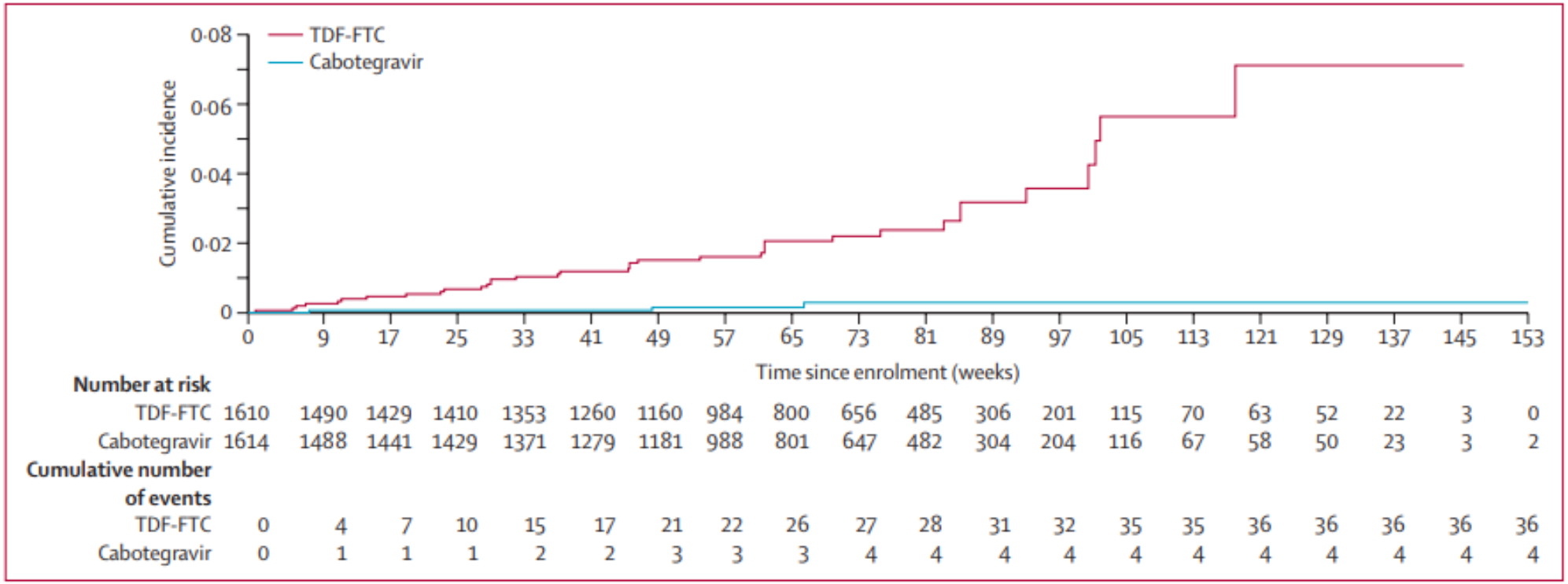
HPTN 084: injectable cabotegravir in women

- injectable CAB-LA vs. oral TDF/FTC
- HIV-uninfected women
  - Assigned female sex at birth
  - Ages 18-45
  - Sexually active and at risk for HIV acquisition
- 20 clinical research sites in 7 countries in sub-Saharan Africa
- 3,224 participants
- 40 incident HIV infections
  - **4** in the CAB-LA group
  - **36** in the TDF/FTC group
- In a random subset of the TDF/FTC group, 42% had drug levels consistent with daily use. Injection coverage was 93%
- Both products were safe, well-tolerated and effective, but ***cabotegravir was superior to TDF/FTC in preventing HIV infections in women***

Check out HPTN 083:
Injectable cabotegravir for cisgender men and transgender women.
Landovitz et al. NEJM 2021; 385: 595-608

Delany-Moretlwe et al. Lancet 2022; 399: 1779-89

HPTN 084



Number at risk																				
TDF-FTC	1610	1490	1429	1410	1353	1260	1160	984	800	656	485	306	201	115	70	63	52	22	3	0
Cabotegravir	1614	1488	1441	1429	1371	1279	1181	988	801	647	482	304	204	116	67	58	50	23	3	2
Cumulative number of events																				
TDF-FTC	0	4	7	10	15	17	21	22	26	27	28	31	32	35	35	36	36	36	36	36
Cabotegravir	0	1	1	1	2	2	3	3	3	4	4	4	4	4	4	4	4	4	4	4

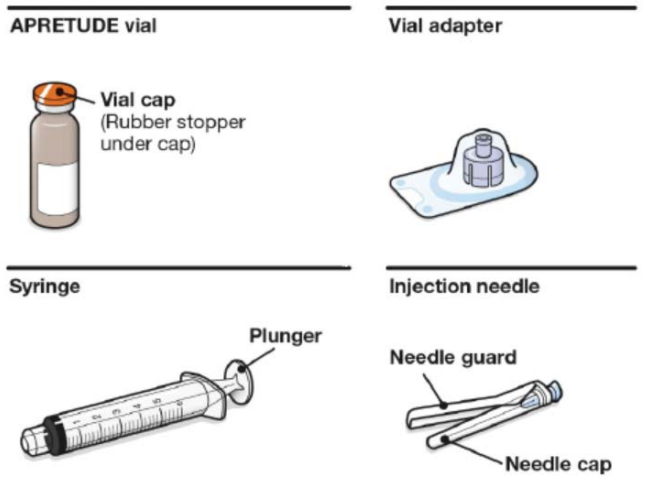
***Figure 3*: Cumulative HIV incidence by study group**

Kaplan-Meier estimates of HIV infection are shown. Four HIV infections were observed in the cabotegravir group (HIV incidence 0·20 per 100 person-years [95% CI 0·06–0·52]) and 36 in the TDF-FTC group (1·85 per 100 person-years [1·3–2·57]). Participants in the cabotegravir group had an 88% lower risk of HIV infection than those in the TDF-FTC group (hazard ratio 0·12 [0·05–0·31]; p<0·0001). TDF-FTC=tenofovir disoproxil fumarate plus emtricitabine.

Delany-Moretlwe et al. Lancet 2022; 399: 1779-89

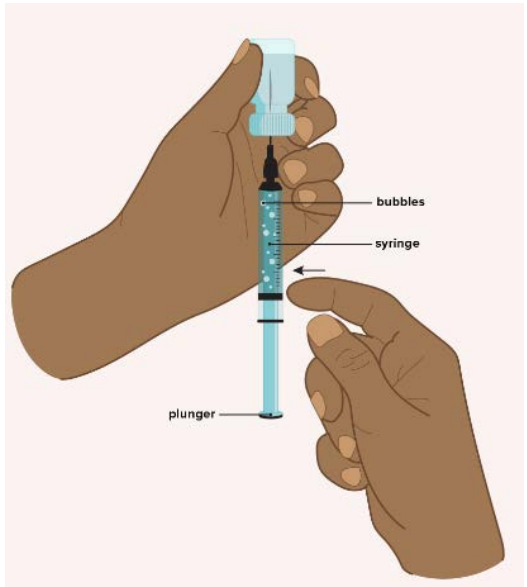
Apretude (cabotegravir extended-release injectable suspension)

- Approved by the FDA on 12/20/2021
- 600mg (3mL) gluteal IM injection
- Initiation injection, followed by a second injection in 1 month. Then every 2 month injections



https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/215499s000lbl.pdf

Providing PrEP



PrEP:
HIV PREVENTION
WITH JUST
1 PILL A DAY

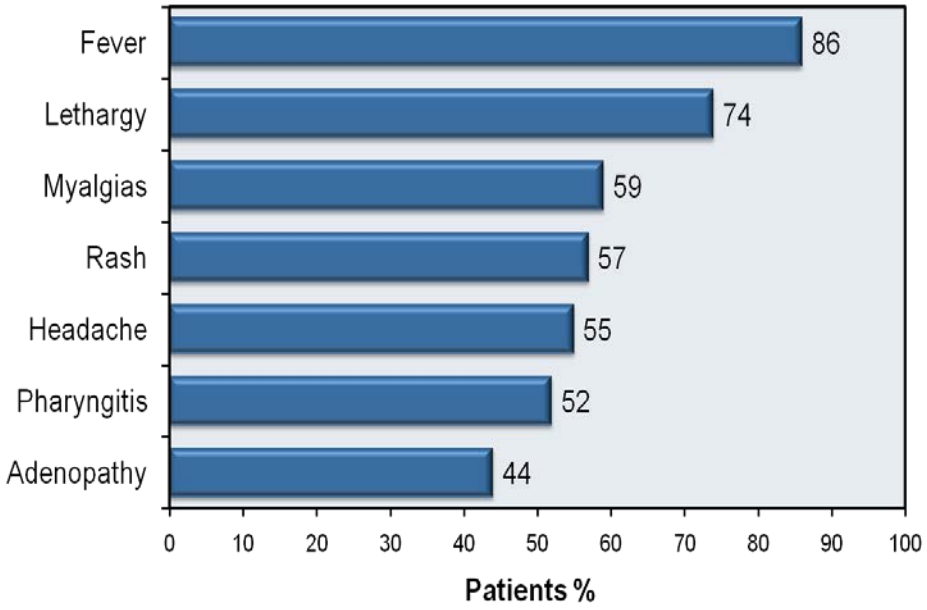
Or an injection every 2 months!

PrEP Checklist

- ❑ History
- ❑ Rule out HIV infection
- ❑ Baseline labs
- ❑ Patient counseling/education
- ❑ Rx

PrEP Checklist

- **History**
  - PrEP indication(s)
  - Consider nPEP eligibility
  - Current medications
  - Hepatitis B
  - Kidney disease
  - Symptoms of acute HIV in the last 4-6 weeks



Vanhems P, et al. AIDS. 2000;14:375-81.

Who should be offered PrEP

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

"All sexually active adult and adolescent patients should receive information about PrEP."

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

☑ **Candidates who should be offered PrEP include individuals who:**

- Engage in condomless sex with partners whose HIV status is unknown, or who have untreated HIV, or who have unsuppressed virus while on treatment for HIV. [Smith, et al. 2012; Grov, et al. 2013].
- Are attempting to conceive with a partner who has HIV.
- Are at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus [Heffron, et al. 2016].
- Have, or are involved with partners who may have, multiple or anonymous sex partners.
- Engage in sexual activity at parties and other high-risk venues, or have sex partners who do so.
- Are involved, or have partners who may be involved, in transactional sex (i.e., sex for money, drugs, food, or housing), including commercial sex workers and their clients.
- Have been diagnosed with at least 1 bacterial sexually transmitted infection (STI) in the previous 12 months [Zetola, et al. 2009; LaLota, et al. 2011].
- Report recreational use of mood-altering substances during sex, including but not limited to alcohol, methamphetamine [Buchacz, et al. 2005; Zule, et al. 2007; Koblin, et al. 2011; Smith, et al. 2012; Grov, et al. 2013], cocaine, ecstasy, and gamma hydroxybutyrate.
- Report injecting substances or having sex partners who inject substances, including illicit drugs, hormones, or silicone.
- Are receiving non-occupational post-exposure prophylaxis (nPEP) and anticipate ongoing risk or have used multiple courses of nPEP [Heuker, et al. 2012].
- Request the protection of PrEP even if their sex partners have an undetectable HIV viral load (see the discussion of U=U, below).
- Self-identify as being at risk without disclosing specific risk behaviors.
- Acknowledge the possibility of or anticipate engaging in risk behaviors in the near future.

☑ ***Do not withhold* PrEP from candidates who:**

- Are pregnant or planning a pregnancy.
- Use other risk-reduction practices inconsistently, including condoms.
- Report substance use.
- Have mental health disorders, including those with serious persistent mental illness.
- Report intimate partner violence.
- Have unstable housing or limited social support.
- Report a recent STI.
- Request PrEP even in they have a partner living with HIV with an undetectable viral load.

New York State Guidelines
https://www.hivguidelines.org/

PrEP Checklist

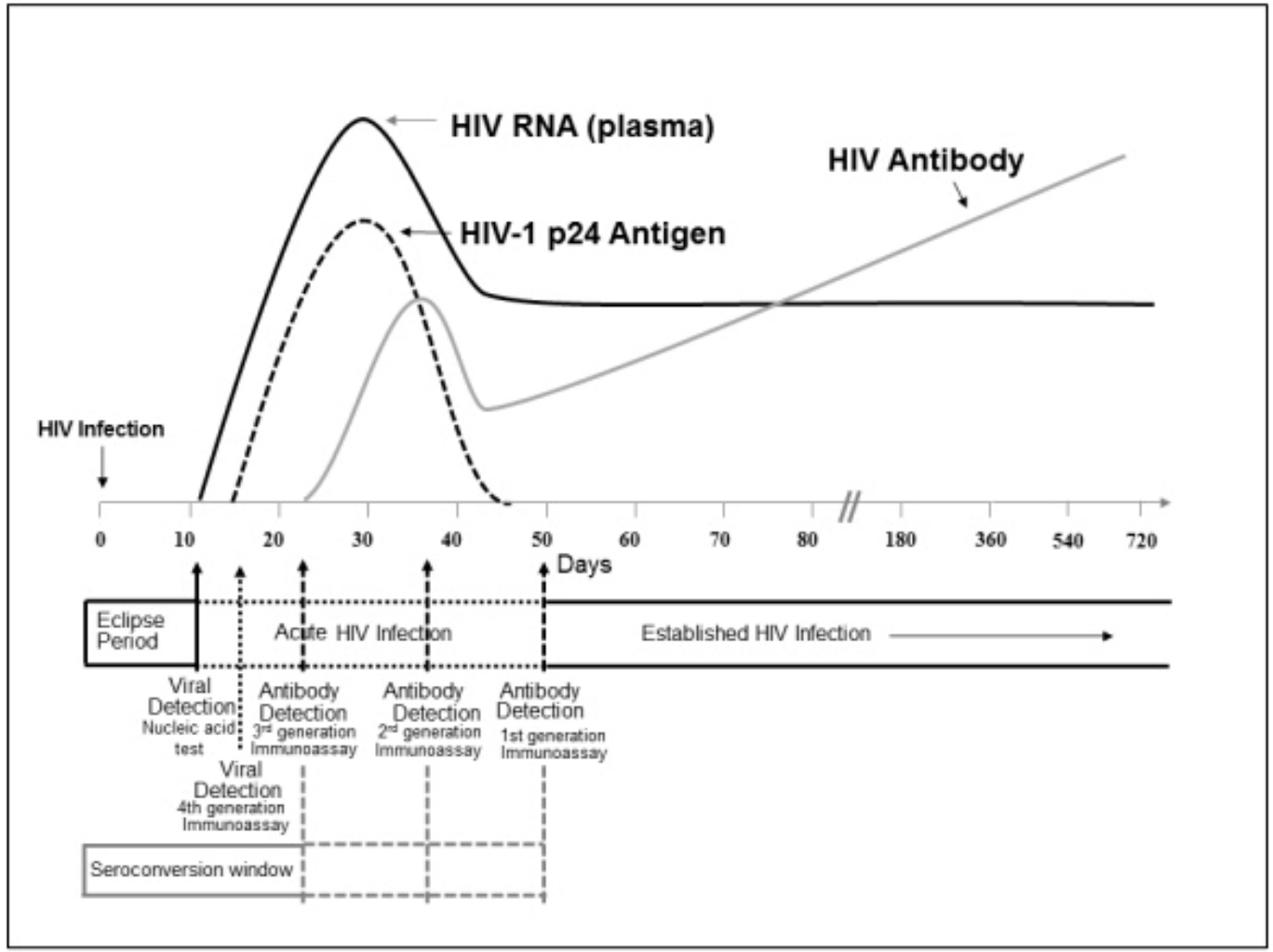
- History
- ❑ Rule out HIV infection
- ❑ Baseline labs
- ❑ Patient counseling/education
- ❑ Rx

PrEP Checklist

- **Rule out HIV infection**
  - Recommend ordering a lab-based HIV 4th generation test even if a rapid POC result is negative
  - In addition, order an HIV RNA if recent (within the last 4 weeks) high-risk exposure, or s/s of acute HIV infection “flu-like symptoms”
    - Fever
    - Lethargy
    - Myalgias
    - Rash
    - Headache
    - Pharyngitis
    - Lymphadenopathy
  - HIV RNA should be done prior to initiating CAB-LA regardless of acute HIV symptoms or recent exposure

https://www.hivguidelines.org/prep-for-prevention/prep/#tab_3

Figure 1. Sequence of appearance of laboratory markers for HIV-1 infection



Note. Units for vertical axis are not noted because their magnitude differs for RNA, p24 antigen, and antibody. Modified from MP Busch, GA Satten (1997)[50] with updated data from Fiebig (2003),[48] Owen (2008),[49] and Masciotra (2011, 2013).[46,66]

Laboratory Testing for the Diagnosis of HIV infection: Updated Recommendations https://stacks.cdc.gov/view/cdc/23447

Types of HIV tests

- **Antibody-only**
  - ELISA, Western Blot
  - Multiple point-of-care (POC) options available
  - 3-12 weeks post-infection
  - IgM response begins around day 20, IgG day 30
  - 2 IgG/IgM sensitive POC tests available
- **Antigen/antibody (4th generation)**
  - p24 antigen/antibody combined immunoassay
  - Recommended 1st step for HIV screening
  - 2-6 weeks post-infection
  - P24 antigen is detectable in plasma by day 15, rises through day 30. Often cleared by day 50
  - First and only POC Ag/Ab test was approved in 2013, at least 4 lab-based Ag/Ab tests available
- **HIV-1 RNA (NAT)**
  - "Viral load", qualitative or quantitative
  - 1-4 weeks post-infection
  - 50% have detectable plasma RNA within 12 days of infection, levels peak between 20-30 days

STD 2017; vol 44 no 12: 739-745

Recommended HIV testing algorithm

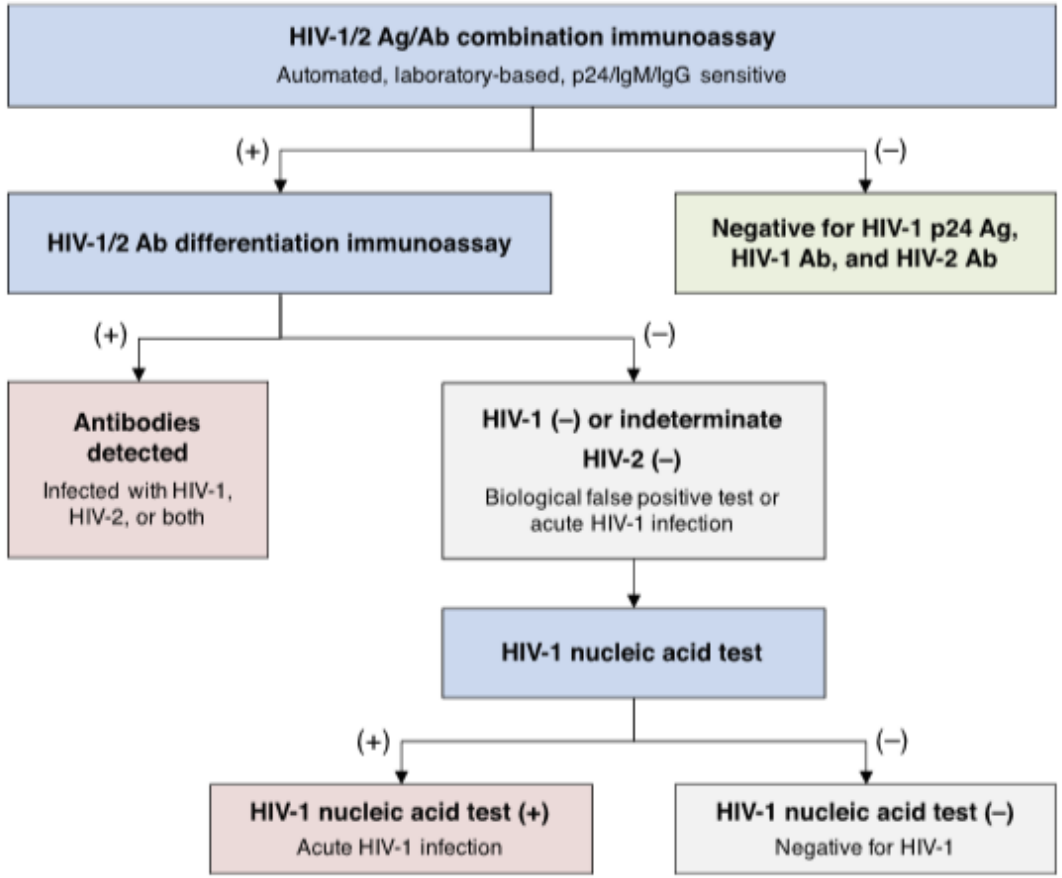


Figure 4. Recommended laboratory HIV testing algorithm. Any assay capable of reliably detecting p24 antigen (Ag) and both IgM and IgG antibodies (Ab) is the recommended starting point for HIV screening in the CDC algorithm, updated in 2014. Reactive specimens from the initial test are subjected to an IgG-sensitive supplemental immunoassay capable of differentiating HIV-1 from HIV-2; this step replaces the HIV-1 Western blot. Indeterminate or negative results from the differentiation test indicate either acute HIV infection (positive for p24 antigen or IgM antibody) or a biological false-positive test; the presence of detectable HIV RNA on a subsequent NAT is the arbitrator. Adapted from CDC.[8]

Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. Available at http://stacks.cdc.gov/view/cdc/23447 & STD December 2017: 44(12): 739-746

PrEP Checklist

- ❑ History
- ❑ Rule out HIV infection
- ❑ Baseline labs
- ❑ Patient counseling/education
- ❑ Rx

PrEP Checklist

❑ Baseline labs

- HIV Ag/Ab (plus HIV RNA prn)
- Metabolic panel (SCr) to calculate creatinine clearance
  - TDF/FTC should not be used if CrCl is <60mL/min
  - TAF/FTC should not be used if CrCl is <30mL/min
- HBsAg, anti-HBs, anti-HBc
- STI testing (GC/CT, Syphilis serology)
- Pregnancy test prn
- Take the opportunity to screen for HepC if never tested or ongoing risk factors

PrEP Checklist

- ☑ History
- ☑ Rule out HIV infection
- ☑ Baseline labs
- ❑ Patient counseling/education
- ❑ Rx

PrEP Checklist

❑ Patient counseling/education

- PrEP efficacy is highly dependent on adherence
- Time to protection:
  - Likely after 7 days of daily dosing for vaginal protection with maximum protection after 20 days[1]
- PrEP does not protect against other STIs. Encourage additional risk reduction and offer or refer to services
- Side effects are uncommon and usually resolve in the first month: headache and nausea can be managed by OTCs prn
- Discuss U=U for those in a discordant relationship
- Importance of routine follow up with HIV testing every 3 months
- Review how to navigate pharmacy refills and pay for PrEP

1. https://cdn.hivguidelines.org/wp-content/uploads/20221107095404/NYSDOH-AI-PrEP-to-Prevent-HIV-and-Promote-Sexual-Health_11-7-2022_HG.pdf (page 16: Time to protection)

PrEP Checklist

- ☐ History
- ☐ Rule out HIV infection
- ☐ Baseline labs
- ☐ Patient counseling/education
- ☐ Rx

HIV Lifecycle & major classes of HIV medications

NRTI

Nucleoside reverse transcriptase inhibitor

NNRTI

Non-nucleoside reverse transcriptase inhibitor

PI

Protease inhibitor

INSTI

Integrase inhibitor

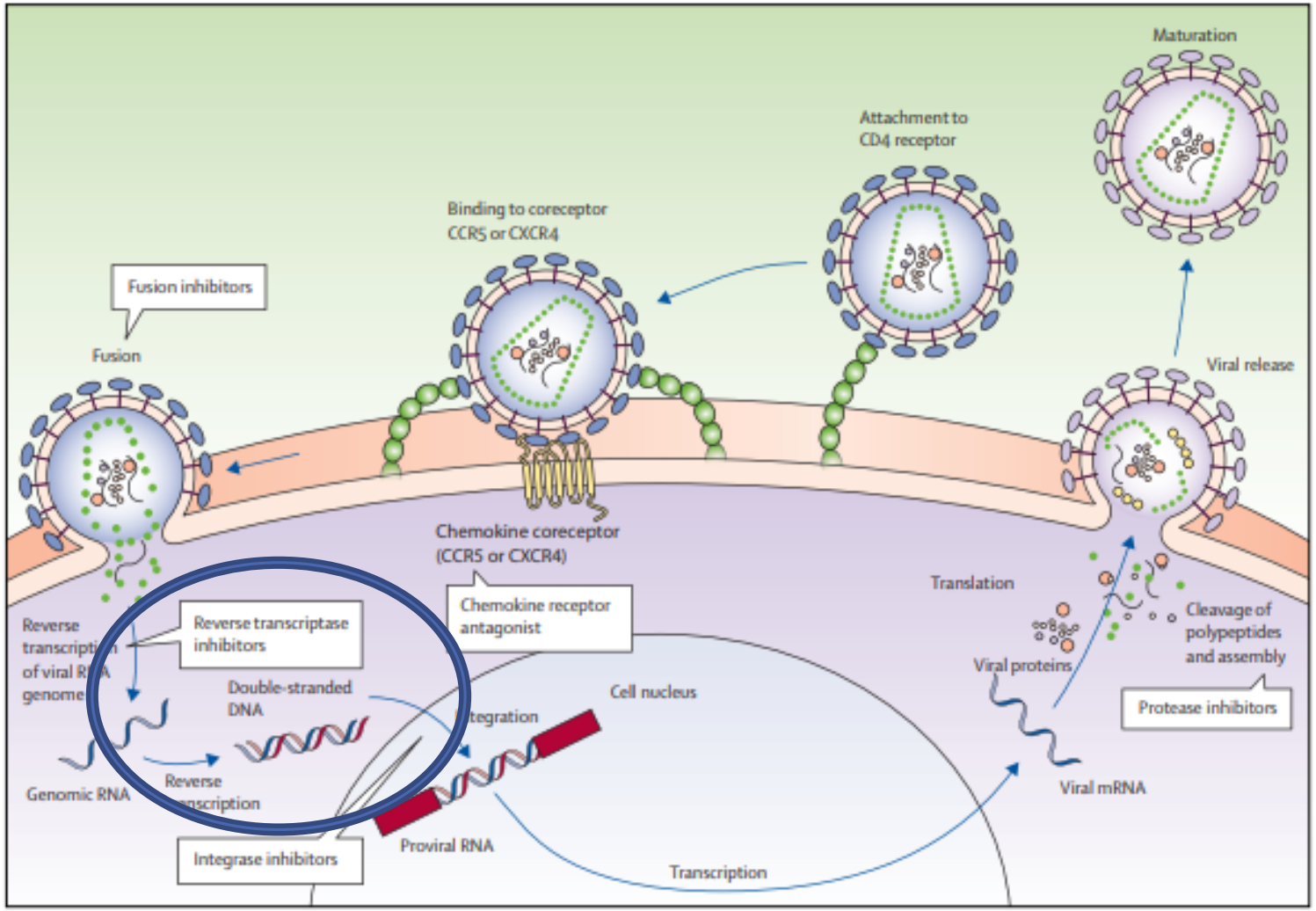


***Figure 2:* HIV life cycle showing the sites of action of different classes of antiretroviral drugs**
Adapted from Walker and colleagues,[36] by permission of Elsevier.

Medications currently used for PrEP

Drug name	Abbr.	HIV medication class	Brand Name
Tenofovir disoproxil fumarate	TDF	NRTI	TDF/FTC (***Truvada***) TAF/FTC (***Descovy***)
Tenofovir alafenamide	TAF	NRTI	
Emtricitabine	FTC	NRTI	
Cabotegravir extended-release injectable susp.	CAB-LA	INSTI	***Apretude***

TDF vs. TAF

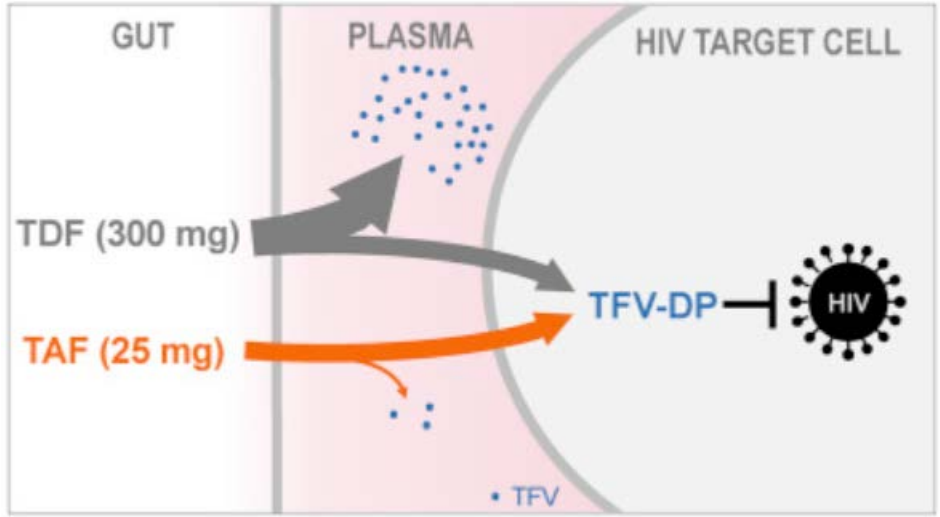


Fig. 3. Comparison of the efficiency of HIV-target cell delivery following oral administration of tenofovir prodrugs. Oral administration of TAF at 25 mg, 1/10th the molar equivalents of TFV present in 300 mg TDF, results in 90% lower systemic levels of TFV while maintaining intracellular levels of the pharmacologically active metabolite TFV-DP in HIV-target cells.

- TDF has been administered extensively (>9 million patient years) as a preferred backbone of HIV therapy
- Tenofovir diphosphate is the active drug, once in cells
- Renal and bone toxicity observed with TDF is associated with high circulating plasma levels of tenofovir
- Tenofovir alafenamide more efficiently delivers tenofovir to target cells resulting in 90% lower systemic exposure

Ray et al. 2016 Antiviral Research 125: 63-70

TAF/FTC for PrEP

- Studied only in HIV-negative MSM and transgender women who have sex with men at high risk for HIV (total n = 5,387) in one RCCT [1]
- Non-inferior to TDF-FTC
- Incremental improvements in renal and bone measures but clinical impact not demonstrated; no serious toxicities reported with TDF/FTC for PrEP
- FDA approved in 2019 for HIV prevention for sexual exposures EXCEPT vaginal receptive sex.
- Insufficient data for use among heterosexual cis-gender women, transgender men, people who inject drugs, people who use 2-1-1 (on-demand) PrEP

1. Mayer et al. 2020 Lancet 396(10246): 239-254

PrEP Checklist

- **Rx**
  - TDF/FTC (Truvada) 300/200mg 1 tablet by mouth once daily
  - TAF/FTC (Descovy) 25/200mg 1 tablet by mouth once daily
  - Take with or without food
  - On demand dosing 2-1-1 of TDF/FTC, off-label use, only studied in MSM
    - 2 tablets of TDF/FTC 2-24 hours before sex, then 1 tab 24 hours later, and another 1 tab 24 hours later
  - No more than 90 days at a time
    - For example: #30, 2 refills
  - CAB-LA (Apretude) 600mg (3mL) IM gluteal injection

PrEP Checklist

- ☐ History
- ☐ Rule out HIV infection
- ☐ Baseline labs
- ☐ Patient counseling/education
- ☐ Rx

Rapid/Same-day/Immediate PrEP

- Start PrEP while awaiting test results
  - IF:
    - Point-of-care HIV test is negative
    - No symptoms of acute HIV in the last 4 weeks
    - No hx of renal disease or HepB
    - No exposures in the last 72 hours warranting nPEP
- Engage patients more fully in care and reduce exposures to HIV while awaiting test results
- Some risk for starting a non-suppressive ART regimen on someone with HIV
- Consider strategies to ensure you will be able to stop PrEP if there are medical contraindications based on initial lab results

Table 1a: Summary of Clinician Guidance for Daily Oral PrEP Use

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

	Sexually-Active Adults and Adolescents[1]	Persons Who Inject Drug[2]
Identifying substantial risk of acquiring HIV infection	Anal or vaginal sex in past 6 months AND any of the following: • HIV-positive sexual partner (especially if partner has an unknown or detectable viral load) • Bacterial STI in past 6 months[3] • History of inconsistent or no condom use with sexual partner(s)	HIV-positive injecting partner OR Sharing injection equipment
Clinically eligible	**ALL OF THE FOLLOWING CONDITIONS ARE MET:** • Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP • No signs/symptoms of acute HIV infection • Estimated creatinine clearance ≥30 ml/min[4] • No contraindicated medications	
Dosage	• Daily, continuing, oral doses of F/TDF (Truvada®), ≤90-day supply OR • For men and transgender women at risk for sexual acquisition of HIV; daily, continuing, oral doses of F/TAF (Descovy®), ≤90-day supply	
Follow-up care	**Follow-up visits at least every 3 months to provide the following:** • HIV Ag/Ab test and HIV-1 RNA assay, medication adherence and behavioral risk reduction support • Bacterial STI screening for MSM and transgender women who have sex with men[3] – oral, rectal, urine, blood • Access to clean needles/syringes and drug treatment services for PWID **Follow-up visits every 6 months to provide the following:** • Assess renal function for patients aged ≥50 years or who have an eCrCl <90 ml/min at PrEP initiation • Bacterial STI screening for all sexually-active patients[3] – [vaginal, oral, rectal, urine- as indicated], blood **Follow-up visits every 12 months to provide the following:** • Assess renal function for all patients • Chlamydia screening for heterosexually active women and men – vaginal, urine • For patients on F/TAF, assess weight, triglyceride and cholesterol levels	

[1] adolescents weighing at least 35 kg (77 lb)

[2] Because most PWID are also sexually active, they should be assessed for sexual risk and provided the option of CAB for PrEP when indicated

[3] Sexually transmitted infection (STI): Gonorrhea, chlamydia, and syphilis for MSM and transgender women who have sex with men including those who inject drugs; Gonorrhea and syphilis for heterosexual women and men including persons who inject drugs

[4] estimated creatine clearance (eCrCl) by Cockcroft Gault formula ≥60 ml/min for F/TDF use, ≥30 ml/min for F/TAF use

PrEP during pregnancy

- HIV acquisition is higher during pregnancy
- Risk of perinatal transmission is significantly higher during acute seroconversion when a patient is pregnant or breastfeeding
- PrEP is indicated for those at ongoing risk of HIV acquisition during pregnancy through inconsistent condom use with sex partners who have unsuppressed virus
- Do not withhold PrEP from those who are pregnant or planning a pregnancy
- Tenofovir disoproxil fumarate (TDF) in combination with emtricitabine (FTC) is a preferred NRTI combination for use in treatment naïve pregnant women with HIV
  https://clinicalinfo.hiv.gov/en/guidelines/perinatal/overview-2

Future of PrEP delivery

- Lenacapavir
  - SQ every 6 months
- Dapivirine vaginal ring
  - 30% reduction in HIV infection
  - Endorsed by WHO, approved in 8 countries for PrEP in cis-women
  - Unlikely to be approved in the US
- PrEP/contraception combinations
- Patches and implants

- Mobile services
- At-home self-testing + telemed
- Pharmacy-delivered PrEP
- Apps and creative behavioral interventions

BCHD PrEP Patient Survey

- 2019
  - 40 respondants
  - 62% had pharmacy/insurance issues filling their first Rx
    - Copay was too high
    - No insurance coverage
    - Problems getting my Rx filled at the pharmacy
- 2021
  - 86 respondents
  - 1 in 5 have ever had a cost-related issue filling a PrEP prescription
    - Errors with the Patient assistance program codes
    - Insurance not covering TAF/FTC
    - No health insurance and unsure how to obtain it

Paying for PrEP

Gilead Advancing Access

https://www.gileadadvancingaccess.com/

- Co-pay Coupon Program
  - For those with copays through private insurance
  - up to $7,200/yr
  - Enroll online or over the phone, immediate co-pay card to print or save, then show to the pharmacy
- Patient Support Program
  - For uninsured individuals, regardless of immigration status
  - Income limit 500% FPL, need to submit proof of income
  - Must use a participating pharmacy
- No copay or payment assistance programs are available for generic TDF/FTC

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AFFORDING YOUR MEDICINE | UNDERSTANDING YOUR COVERAGE | UNINSURED 24/7 SUPPORT

Gilead's Advancing Access® Program Is Here to Help You

Gilead's Advancing Access program is committed to helping you afford your medication no matter your situation. Whether you have insurance or not, we can explore potential coverage options that might be right for you.

Our dedicated program specialists are here to help you. Talk to someone right away by calling **1-800-226-2056**.
Advancing Access phone lines are open M - F 9am - 8pm ET. If you reach us after hours, leave a message, and we will call you back during the next business day.

The Advancing Access CO-PAY COUPON PROGRAM

The Advancing Access PATIENT SUPPORT PROGRAM

https://www.gileadadvancingaccess.com/

Obtaining CAB-LA

- Must be administered by a medical provider
- Only available through a limited distribution system/specialty pharmacies
- Medication can be obtained by a health care provider by:
  - Buy-and-bill: Clinic purchases the medication from a specialty distributor and maintains an inventory. After administration to a patient the clinic submits for reimbursement from the patient's insurance
  - White bagging: Provider submits a prescription for the medication to a pharmacy within Viiv's specialty network. The pharmacy processes the claim and ships the medication to the clinic so it can be administered to that patient.
- ViiVConnect assistance program
  - https://www.viivconnect.com/

Guidelines

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2021 UPDATE

A CLINICAL PRACTICE GUIDELINE

https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

NEW YORK STATE DEPARTMENT OF HEALTH AIDS INSTITUTE

CLINICAL GUIDELINES PROGRAM

https://www.hivguidelines.org/

Resources

Current PrEP guidelines
https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

Current nPEP guidelines
https://stacks.cdc.gov/view/cdc/38856

New York State clinical guidelines, includes HIV, PEP and PrEP
https://www.hivguidelines.org/

Paying for PrEP
https://www.nastad.org/prep-access/prep-assistance-programs

I like this resource for webinars, one-day in person conferences, and guidelines.
https://www.iasusa.org/

My favorite ID blog, especially his "really rapid review" after big HIV/ID conferences
https://blogs.jwatch.org/hiv-id-observations/

Warm line consultation from UCSF, also great resources
https://nccc.ucsf.edu/

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