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HIV Pre-Exposure Prophylaxis (PrEP)

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Maryland Department of Health

Anne Arundel County HIV Commission
February 7, 2018



Discussion Outline

- Review latest Local, State and National HIV Statistics
- Define Pre-Exposure Prophylaxis; discuss the science, efficacy and basics of prescribing PrEP
- Discuss available resources in Maryland to assist in development of PrEP clinics and case management programs
- Answer any questions



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Sexual Health - WHO Definition

“Sexual health is a state of physical, emotional, mental, and social well-being related to sexuality; it is not merely the absence of disease, dysfunction, or infirmity. Sexual health requires a positive and respectful approach to sexuality and sexual relationships, as well as the possibility of having pleasurable and safe sexual experiences, free of coercion, discrimination, and violence. For sexual health to be attained and maintained, the sexual rights of all persons must be respected, protected, and fulfilled.”



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Sexual Health Principles

Healthy sex is:

- Consensual
- Non-exploitive
- Mutually pleasurable
- Safe (from violence, STIs/HIV, unintended pregnancy, theft, etc.)
- Honest
- Supportive of recovery





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Principles Defined

- Consensual: everyone involved voluntarily agrees to have sex
- Non-exploitive: not taking advantage of another person; not using another person or situation in an unfair or selfish way in order to have sex with them
- Safe: everyone involved is safe from STIs/HIV, unintended pregnancy, violence, theft/robbery



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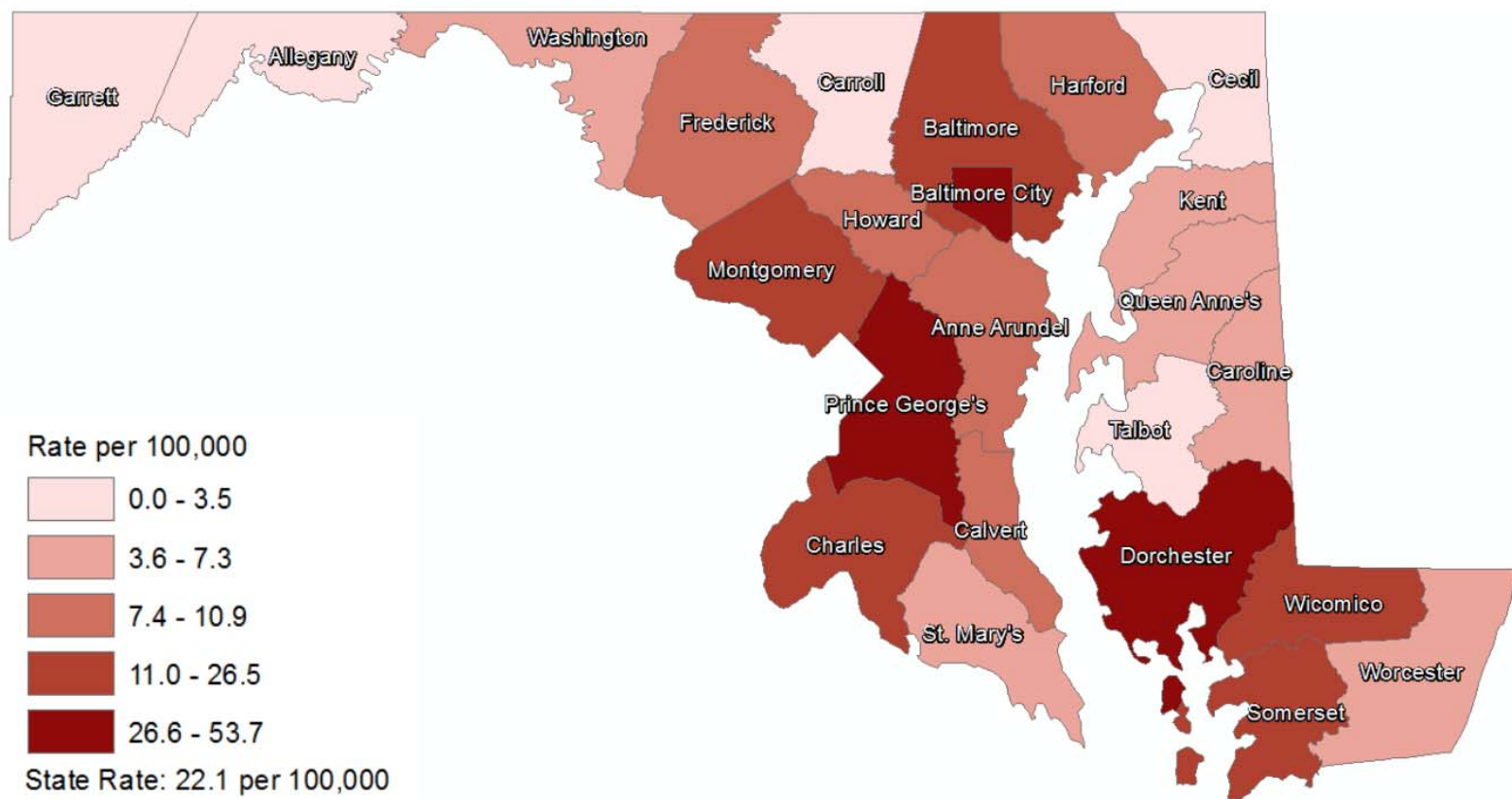
Principles Defined

- Mutually pleasurable: everyone involved is interested in his/her partner's pleasure; in both giving and receiving pleasure
- Honest: everyone involved is truthful about their sexual health, including behavior and relationship status
- Supportive of recovery: no one is pressured to use substances in conjunction with sex



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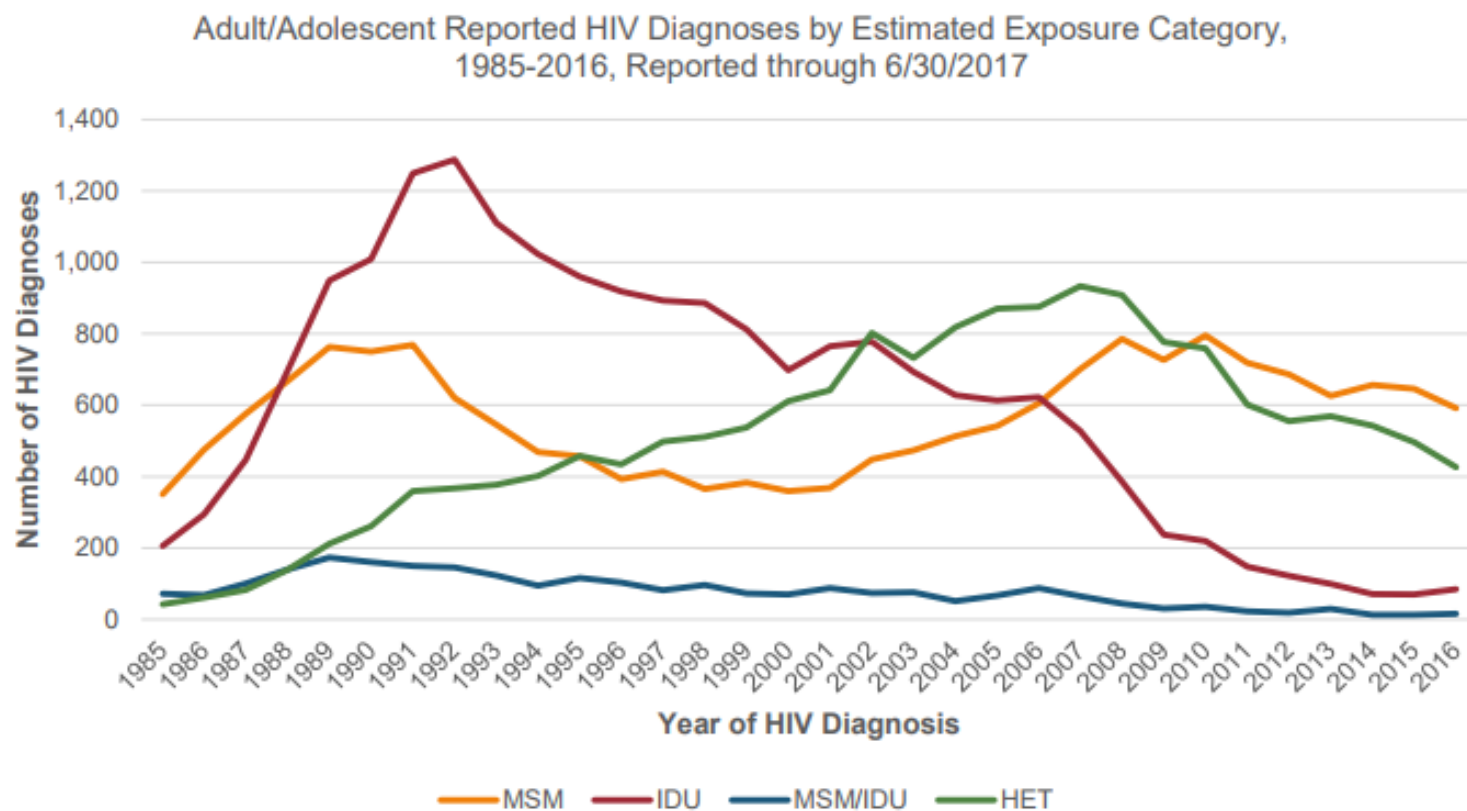
2016 HIV Diagnosis Rates by Jurisdiction





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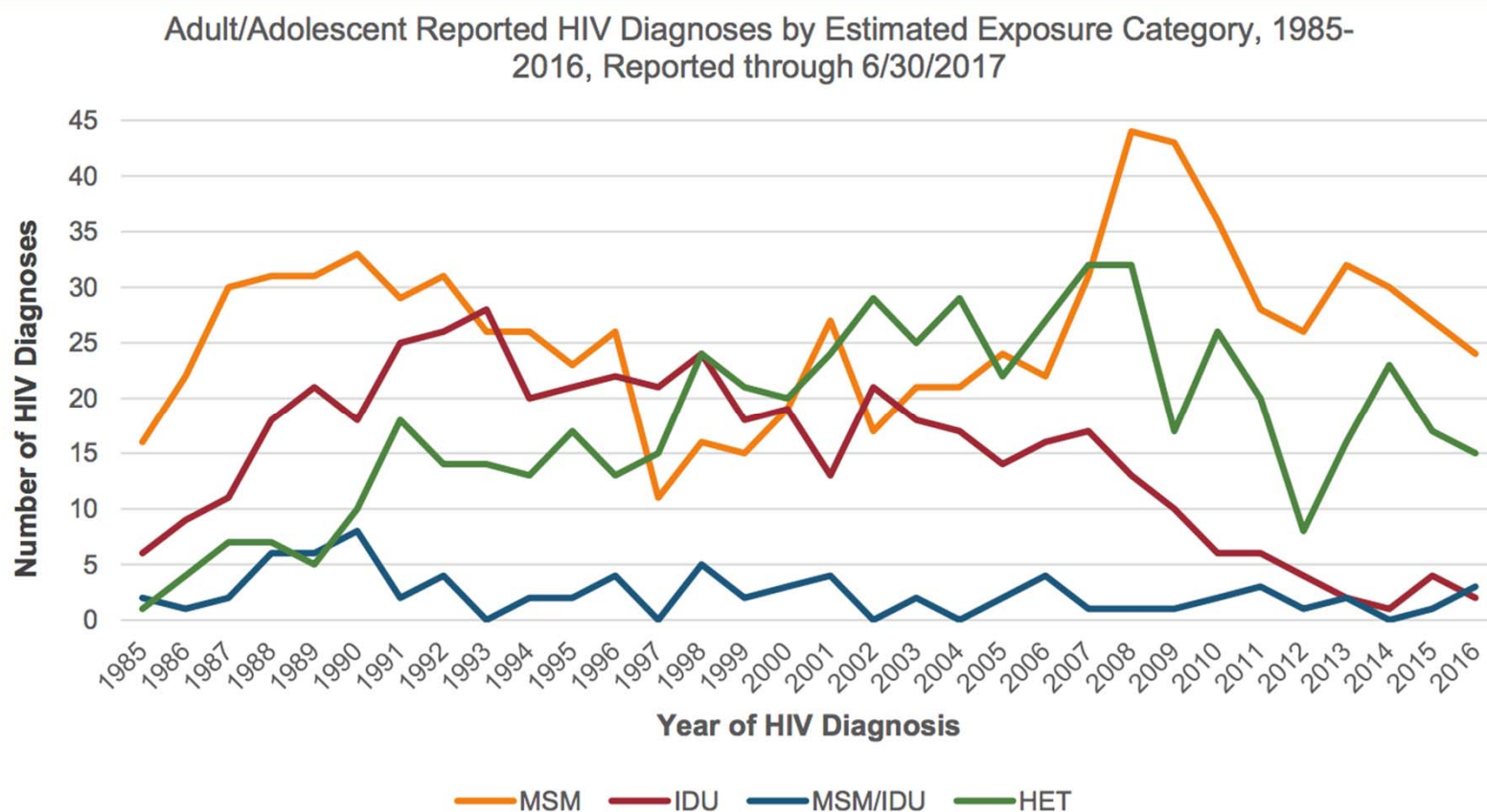
Maryland HIV Diagnoses by Exposure Category





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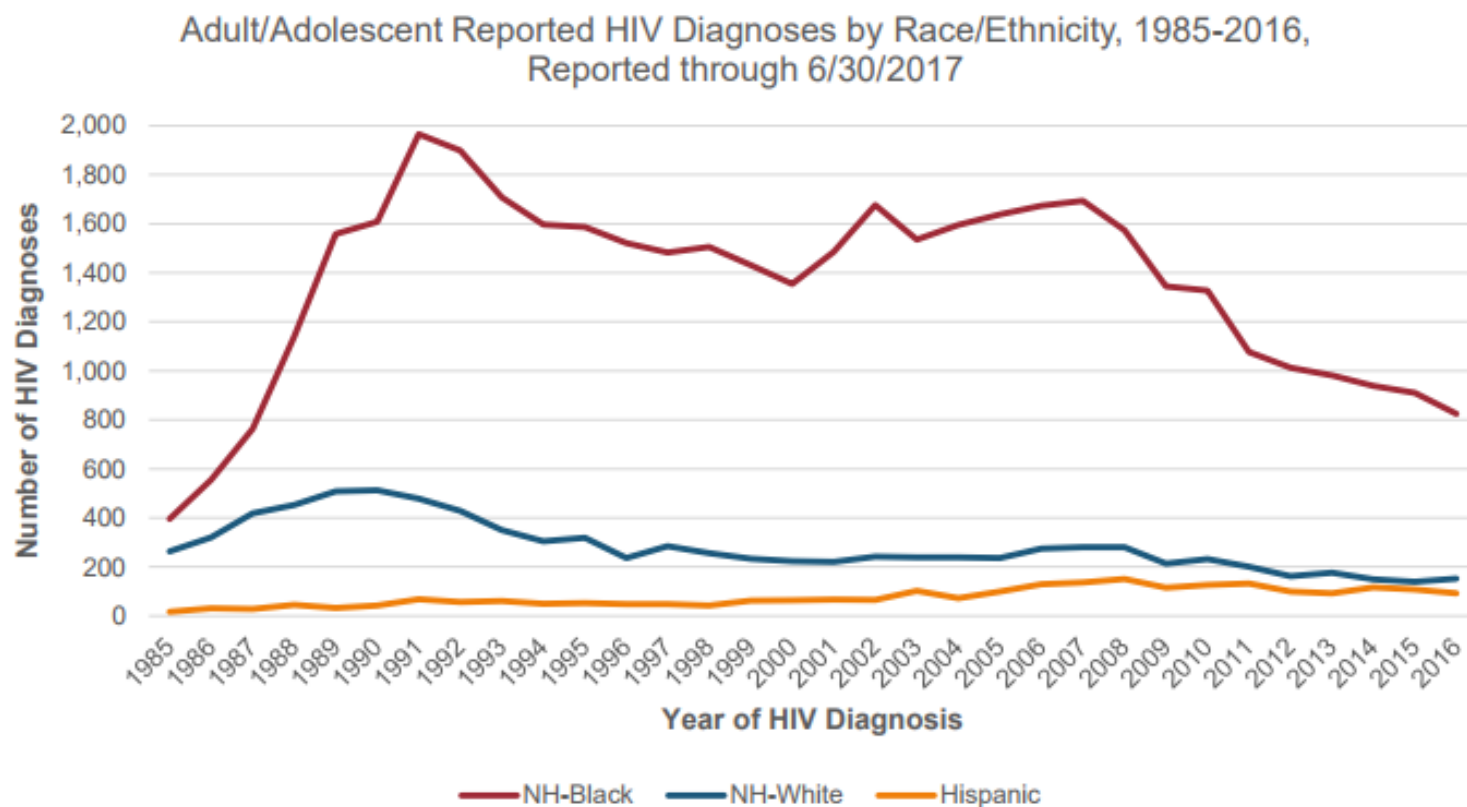
Anne Arundel Diagnoses by Exposure Category





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Maryland HIV Diagnoses by Race/Ethnicity

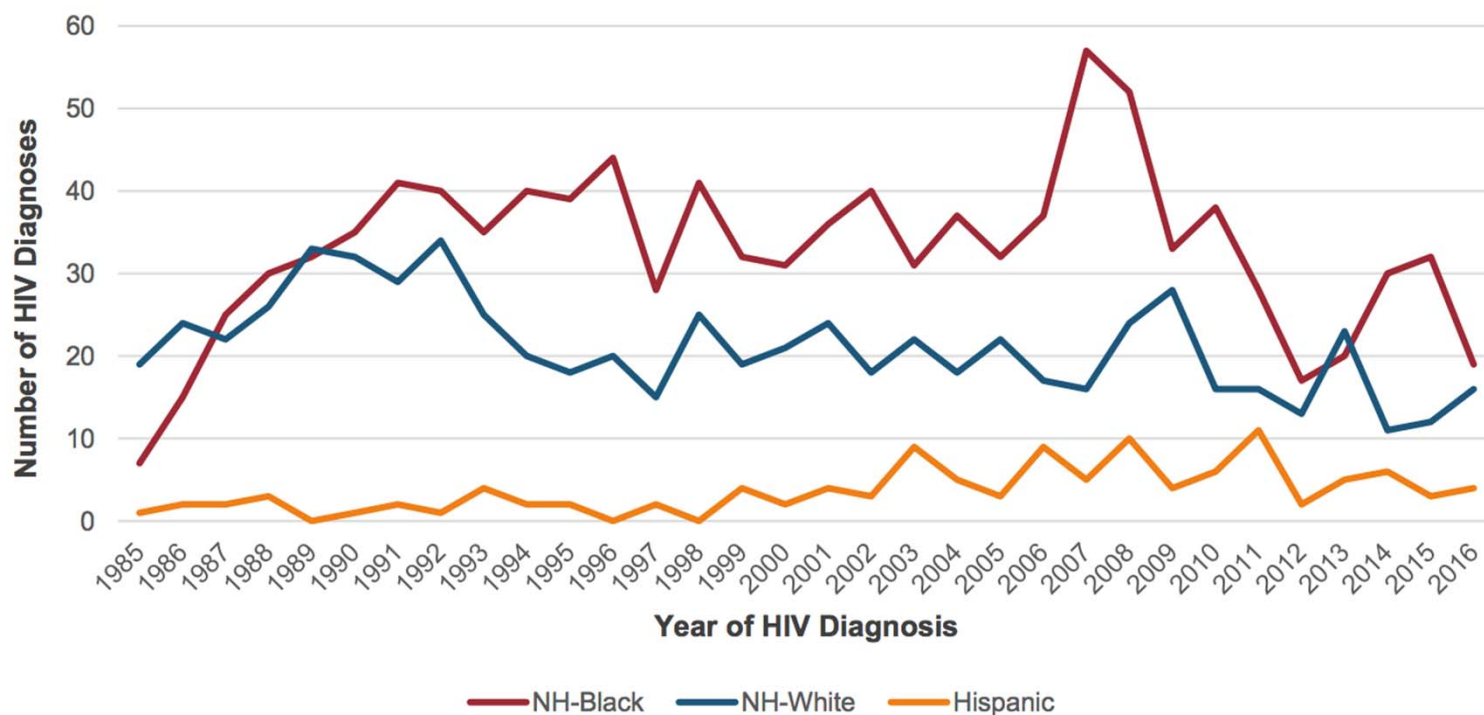




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Anne Arundel HIV Diagnoses by Race/Ethnicity

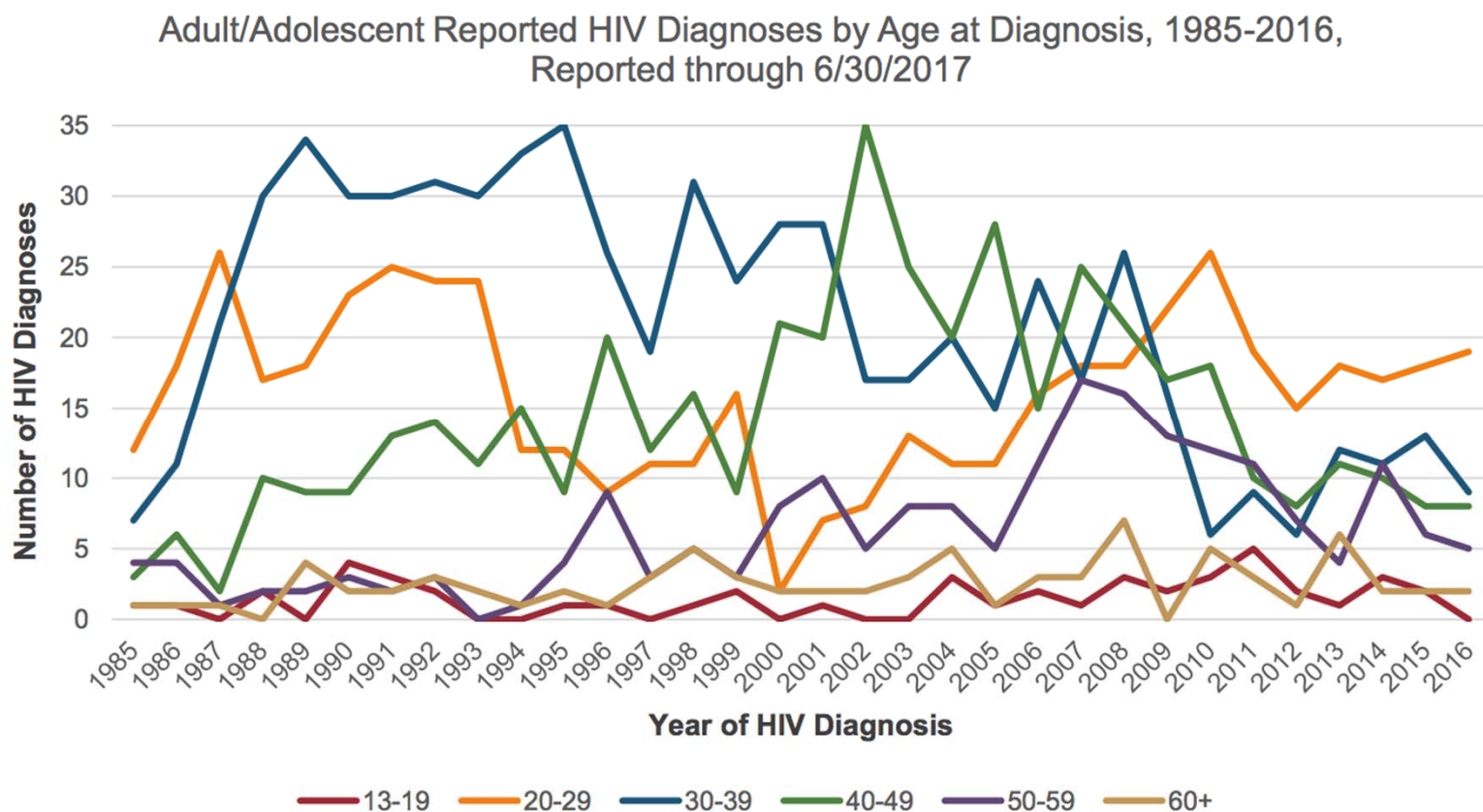
Adult/Adolescent Reported HIV Diagnoses by Race/Ethnicity, 1985-2016,
Reported through 6/30/2017





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Anne Arundel HIV Diagnoses by Age at Diagnosis

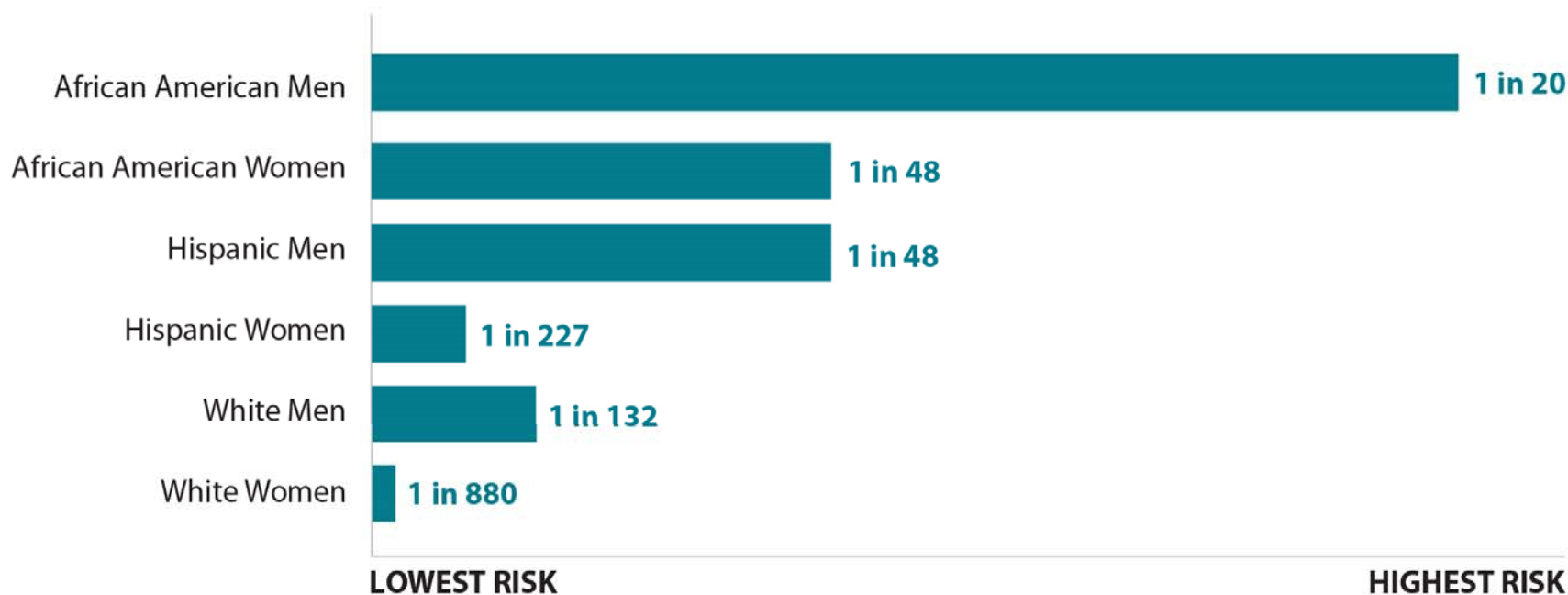




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HIV Inequities: Lifetime Risk of HIV by Race/Ethnicity

Lifetime Risk of HIV Diagnosis by Race/Ethnicity



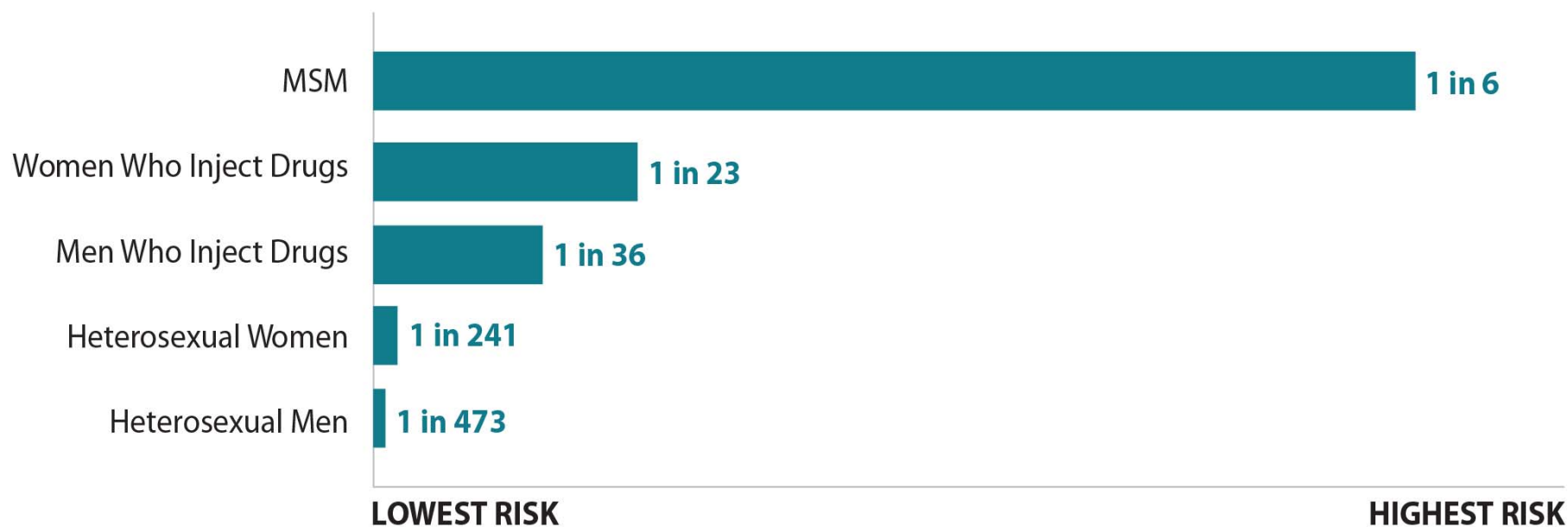
Source: Centers for Disease Control and Prevention



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HIV Inequities: Lifetime HIV Risk by Transmission Group

Lifetime Risk of HIV Diagnosis by Transmission Group



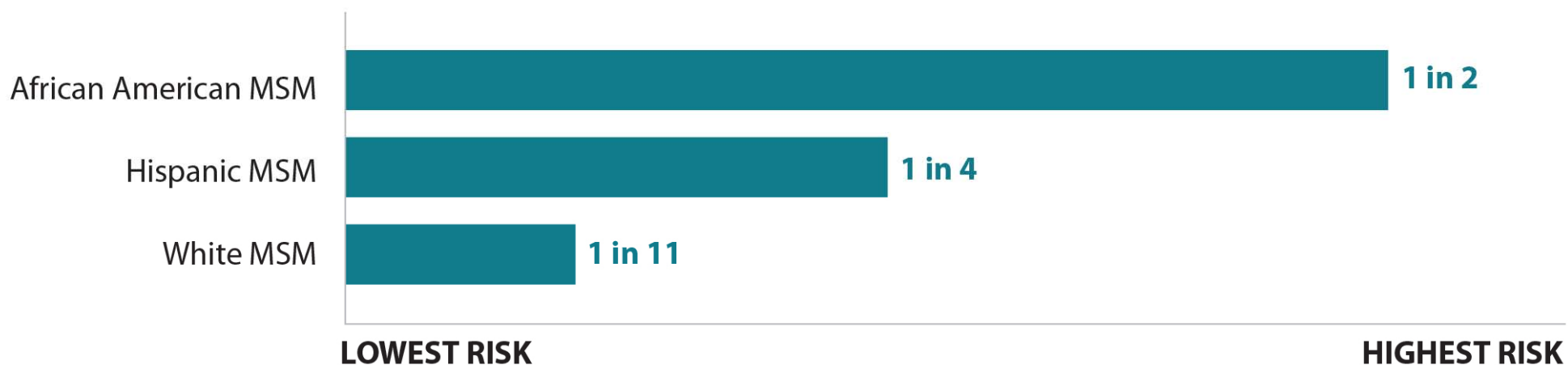
Source: Centers for Disease Control and Prevention



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HIV Inequities: Lifetime Risk for MSM by Race/Ethnicity

Lifetime Risk of HIV Diagnosis among MSM by Race/Ethnicity



Source: Centers for Disease Control and Prevention



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HIV Prevention Strategies

- Routine HIV Testing / knowing your status
- Routine STI Testing / Treatment
- HIV Treatment as Prevention (TasP)
- Latex condoms with water or silicone-based lubricant
- Serosorting
- Pursuing recovery
- Post-Exposure Prophylaxis
- Pre-Exposure Prophylaxis



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Truvada as PrEP

- Tenofovir (TDF) + Emtricitabine (FTC) = Truvada



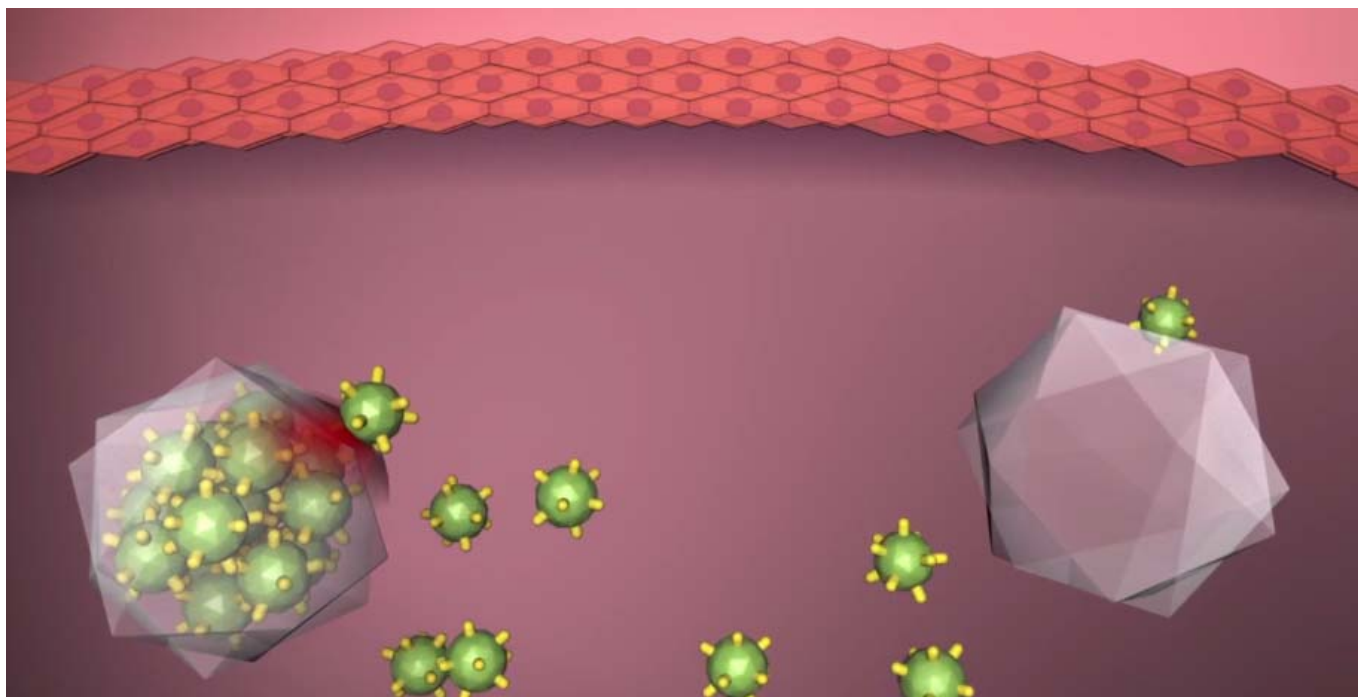
- Truvada is the only medication currently FDA approved for PrEP



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HIV Pre-Exposure Prophylaxis

- www.whatisprep.org





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HIV Pre-Exposure Prophylaxis

- PrEP is *biobehavioral* HIV prevention – combining **biomedical** science (medication) with client **behavior** (adherence to medication and medical care)
- PrEP is not just a pill; the same social determinants of health that impact HIV risk impact adherence



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Classes of HIV Treatment

HIV treatment inhibits the progress of HIV's assault on the immune cells.

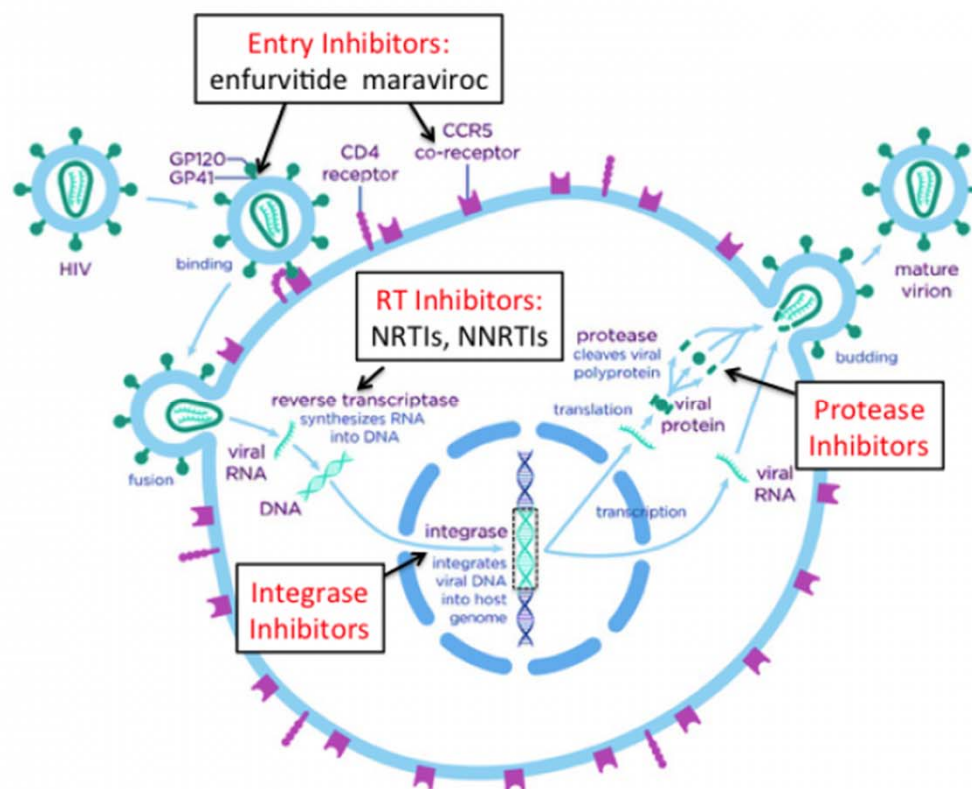
Classes of HIV medications include:

- Entry/Fusion Inhibitors
- Reverse Transcriptase Inhibitors
- Integration Inhibitors
- Protease Inhibitors



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Truvada = Reverse Transcriptase Inhibitor





- When people are adherent, PrEP reduces their risk of acquiring HIV by 90% -100%
- Recommended for persons
 - In ongoing relationships w/ persons living with HIV*
*who have not achieved viral suppression
 - Sharing injection drug use equipment
 - With a recent STI
 - Having unprotected sex with persons of unknown status



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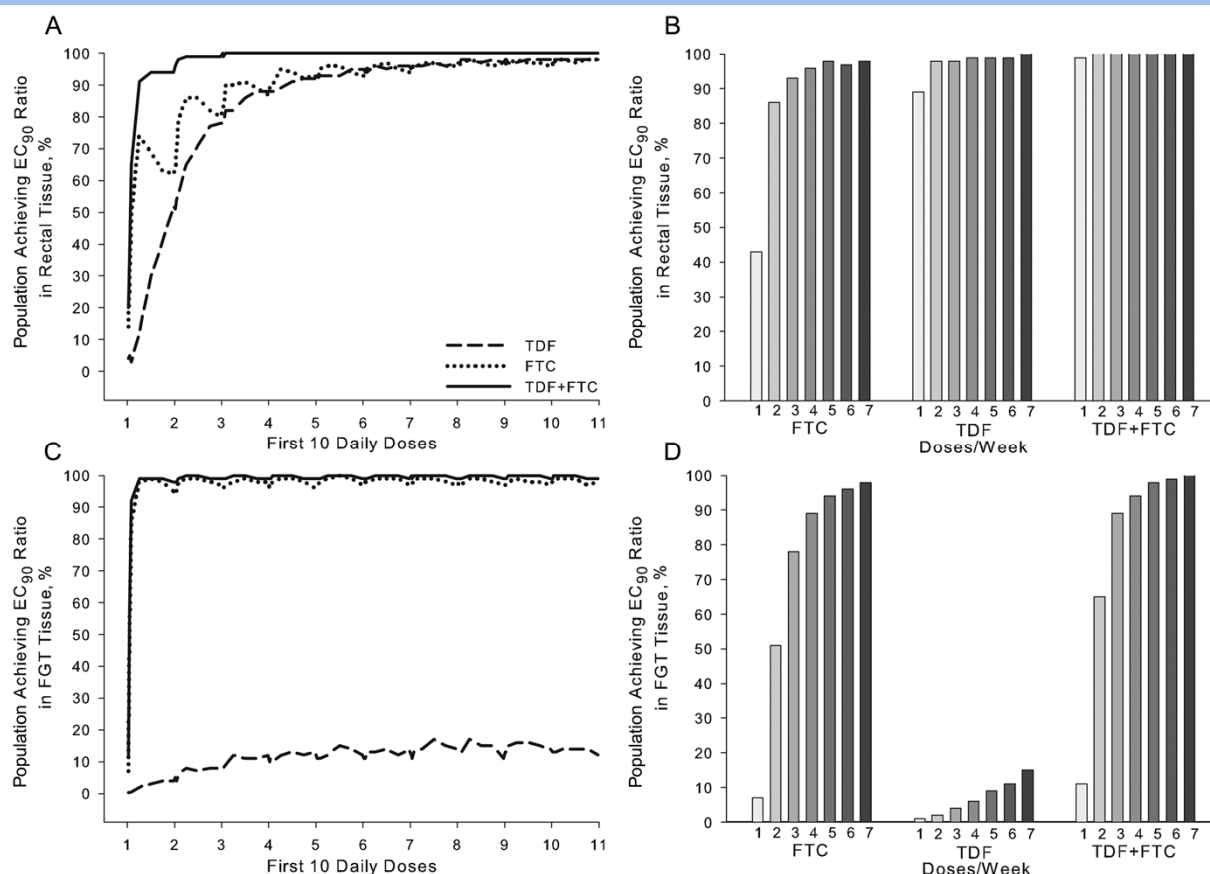
Differences in Protection

- It takes about 20 days of daily adherence to PrEP to achieve optimal protection in the vagina or in the blood
- It takes about 7 days of daily adherence to PrEP to achieve optimal protection in the rectum



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Differences in Protection - Modeling Study



SOURCE:

Mackenzie L. Cottrell, et al;
*A Translational
Pharmacology Approach to
Predicting Outcomes of
PrEP Against HIV in Men
and Women Using
Tenofovir Disoproxil
Fumarate With or Without
Emtricitabine.*

The Journal of Infectious
Diseases, Vol. 214, Iss. 1,
1 July 2016, Pgs 55-64,
Acc. 8/23/17

<https://doi.org/10.1093/infdis/jiw077>



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Overview of Major PrEP Clinical Trials

Clinical Trial	Participants	Medication(s)	mITT Efficacy % (CI)	Adjusted for Adherence % (CI)
Bangkok TDF	Persons who inject drugs	TDF	49 (18-90)	74 (17-94)
Partners PrEP	Heterosexual discordant couples	TDF	67 (44-81)	86 (67-94)
		TDF/FTC	75 (55-87)	90 (58-98)
TDF2	Heterosexual men/women	TDF/FTC	63 (21-83)	85 (NS)
iPrEx	Men who have sex with men	TDF/FTC	44 (15-63)	92 (40-99)
Fem-PrEP	Heterosexual women	TDF/FTC	NS	
VOICE	Heterosexual women	TDF	NS	
		TDF/FTC	NS	

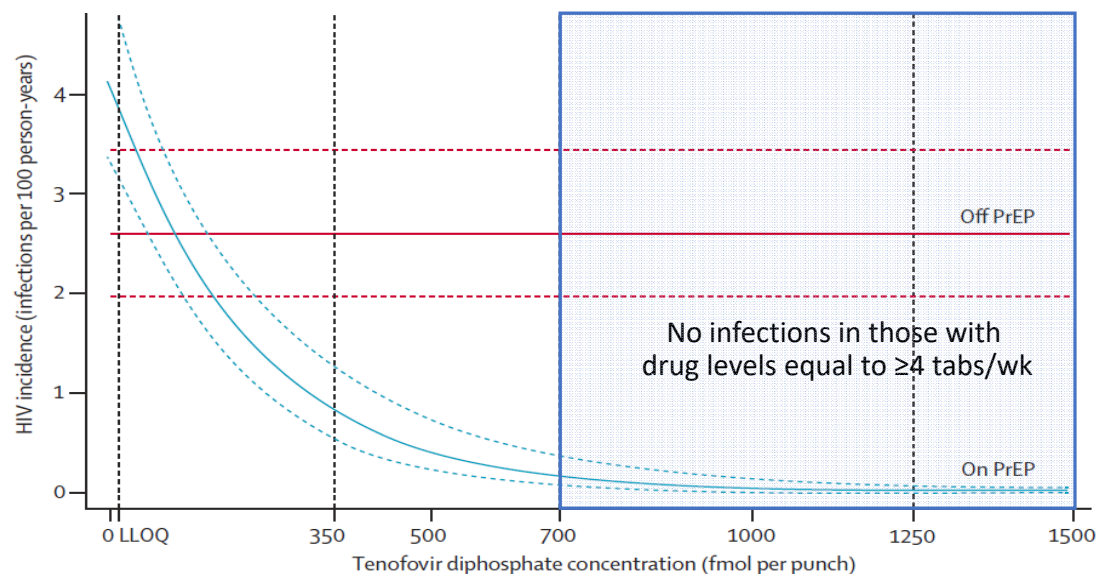
*Adapted from Centers for Disease Control and Prevention (CDC). Preexposure prophylaxis for the prevention of HIV infection in the United States - 2014. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2014.



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iPrEx Open-Label Extension (iPrEx OLE) HIV Incidence and Drug Concentration

Participants in randomized placebo-controlled iPrEx, ATN 089, or US PrEP Safety trials were enrolled in the 72-week open label extension (iPrEx OLE)



In iPrEx OLE,

PEOPLE WHO TOOK TRUVADA
4 TIMES A WEEK HAD
NO NEW INFECTIONS—
100% EFFICACY.

PEOPLE WHO TOOK TRUVADA
2 OR 3 TIMES A WEEK HAD AN
84% LOWER RISK
OF INFECTION.

BUT THOSE WHO TOOK
FEWER THAN 2 DOSES SAW
NO SIGNIFICANT
PROTECTION.

Drug Concentration	none	<2 pills/week	2-3 pills/week	≥ 4 pills/week	7 pills/week
HIV Incidence per 100 PY (95%CI)	4.7 (2.99-7.76)	2.25 (1.19-4.79)	0.56 (0.00-2.50)	0	0
Risk Reduction (95%CI)		44% (-31-77)	84% (21-99)	100% (86-100)	

Grant R, et al. IAC 2014. Melbourne, Australia. #TUAC0105LB

Grant R, et al. Lancet published on line 22 July 2014 [http://dx.doi.org/10.1016/S1473-3099\(14\)70847-3](http://dx.doi.org/10.1016/S1473-3099(14)70847-3)

Truvada® (FTC/TDF). US Prescribing Information. Gilead Sciences Inc. December 2013



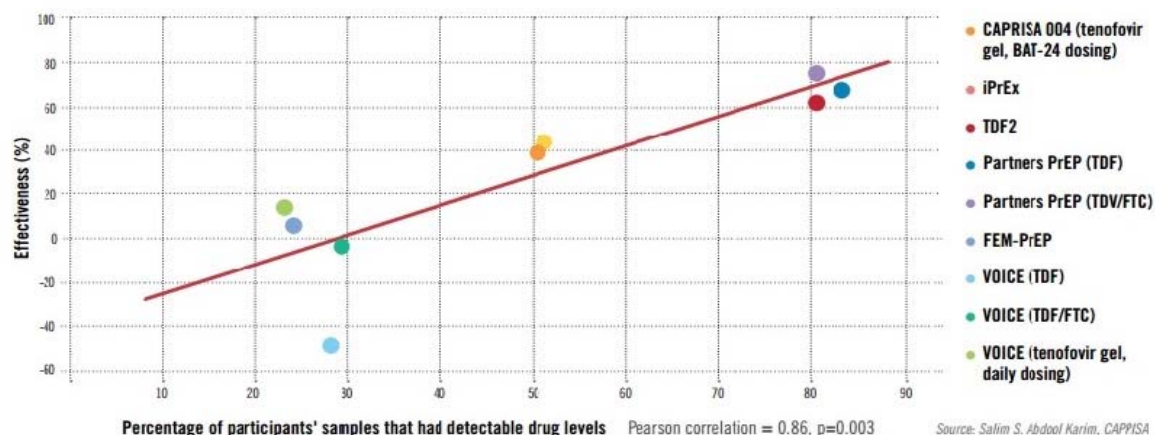
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PrEP Efficacy = Adherence!

PrEP Works if You Take It — Effectiveness and Adherence in Trials of Oral and Topical Tenofovir-Based Prevention

Trials of oral and topical tenofovir-based PrEP show that these strategies reduce risk of HIV infection if they are used correctly and consistently. Higher adherence is directly linked to greater levels of protection.

Calculations based on analyses involving a subset of total trial participants.



The findings of the PrEP trials in all populations have been strikingly consistent: in individuals who took the drug as prescribed (as determined by levels of drug detectable in the blood), there was high levels of protection. Adherence and protection are closely linked in all participants and subgroup analyses across all of the trials to date. The overall efficacy findings reported by various trials reflect analyses of all participants; most trials have also provided subgroup analyses focusing on protection in those who had detectable drug in the blood. The two sets of findings – overall and adherence-related – have sometimes been used interchangeably and may cause confusion, as two trials of daily oral tenofovir-based PrEP in young women found no efficacy, but also found very low adherence. This is consistent with the findings of other trials—eg that PrEP works when taken, but has led to confusion as to whether PrEP works for women.

Source: PrEP Watch, www.prepwatch.org



PrEP Steps

- Client is at risk for HIV and learns about PrEP
- HIV test is done & provider discusses the window period
 - Based on type of HIV test and recent behavior, client re-tests to verify HIV negative status
- Provider educates that PrEP doesn't protect against other STIs or pregnancy; efficacy is dependent on adherence; PrEP may have side effects or adverse events like gas, stomach upset, impairment of renal function or loss of bone mineral density
 - Side effects are more common but tend to go away after some weeks of PrEP use; adverse events are very rare and usually reversible when PrEP is stopped



PrEP Steps - Continued

Prior to initiating PrEP, provider tests for:

- HIV infection
- Kidney function (creatinine clearance)
- Pregnancy
- Other STIs including Hepatitis B

Provider offers:

- Hepatitis A & B vaccinations (if negative)
- HPV vaccination if eligible
- Condoms



PrEP Steps - Continued

Considerations when prescribing PrEP:

- Truvada is generally considered safe during pregnancy/ breastfeeding, but most providers discuss possible risks and benefits with pregnant patients and allow patient to choose whether to continue or stop
 - If continuing PrEP, providers encourage registration on the ARV Pregnancy Registry – www.apregistry.com
- Truvada is a treatment for Hepatitis B, so if Hep B +, rigorous adherence counseling is provided and patient is informed of risks re: poor or non-adherence

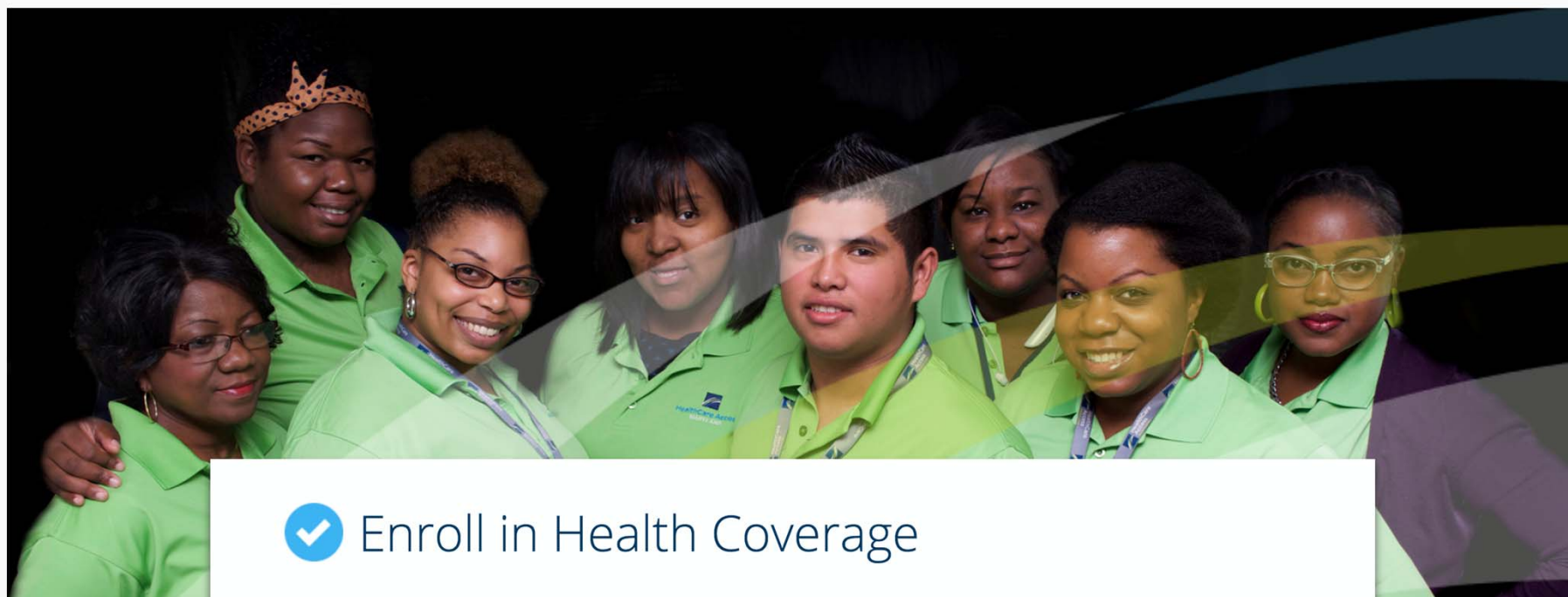


- Many providers are utilizing PrEP Navigators to assess client insurance coverage, as well as to address barriers to care and adherence
- If clients are uninsured, they can receive assistance from an Assister or Navigator to enroll in a private plan or Medicaid on Maryland Health Connection



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Health Insurance Enrollment

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Enroll in Health Coverage



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Paying for Truvada as PrEP

- Insured
 - Gilead Co-Pay Program for Truvada (no income requirement)
\$4,800/year www.GileadCoPay.com
Co-Pays, Co-Insurance, Deductibles; **P** Private Insurance only
 - Patient Advocate Foundation Co-Pay Relief
<https://www.copays.org/diseases/hiv-aids-and-prevention>
Co-Pays, Co-Insurance, Deductibles; **P** + Medicare/Medicaid
 - Patient Access Network (PAN) Foundation
<http://www.panfoundation.org/application-instructions>
Co-Pays, Co-Insurance, Deductibles; Medicare, not Medicaid



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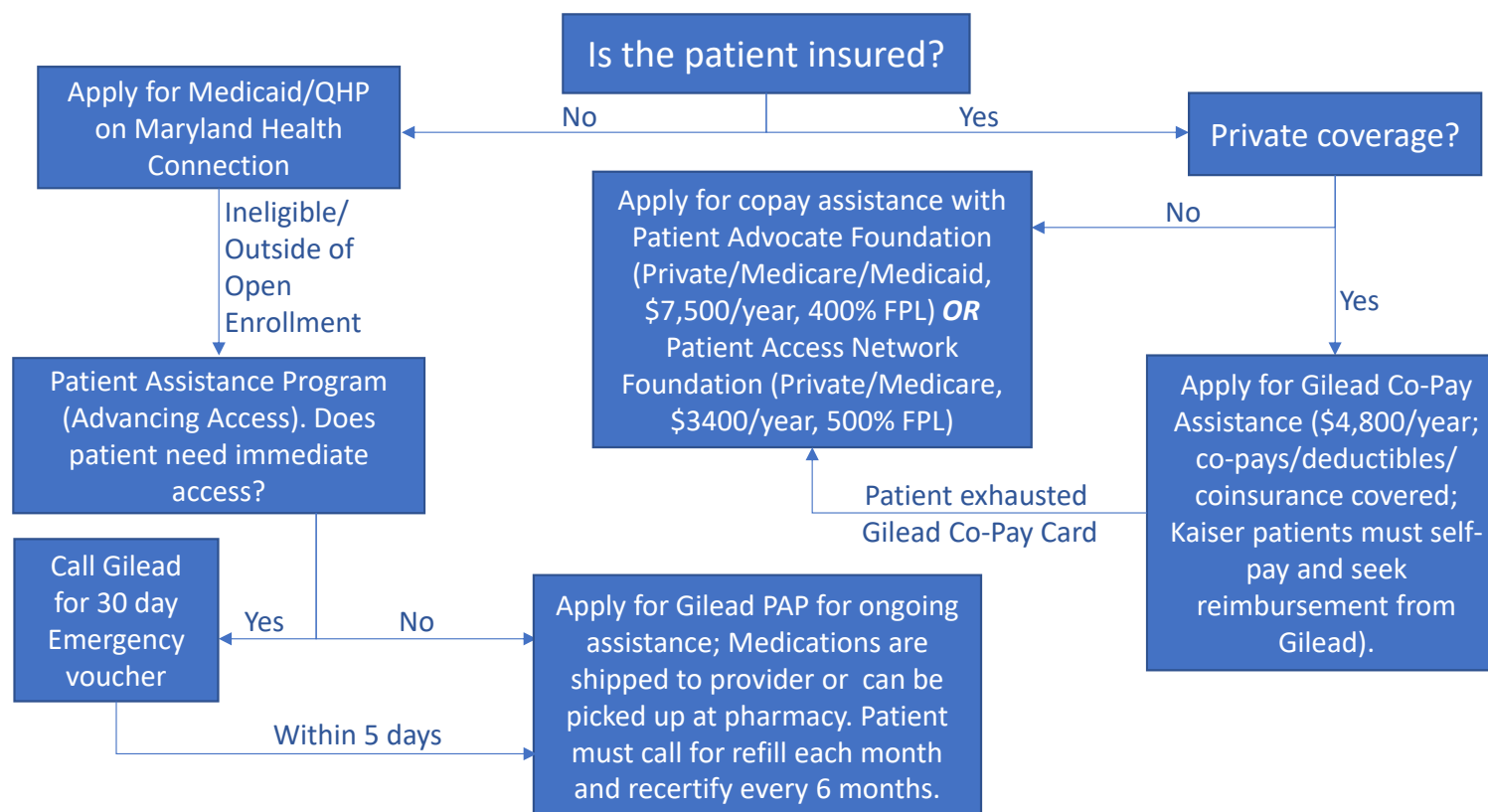
Paying for Truvada as PrEP, continued

- Uninsured
 - Gilead Medication Assistance Program (up to 500% FPL) medications sent to prescriber or pharmacy
<http://www.gilead.com/responsibility/uss-patient-access/truvada%20for%20prep%20medication%20assistance%20program>



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PrEP Assistance Program Flowchart





- Client goes to the pharmacy and initiates PrEP
- 1 month later, client returns to discuss side effects and adherence
- 3 months after initiating PrEP, client returns to be screened for STIs (and if appropriate, tested, and if needed, treated)



- Also at 3-month visit, PrEP Navigator does
 - Risk reduction counseling
 - Adherence counseling
 - Pregnancy testing (when appropriate)
 - Condom distribution
- At 6-month visit, provider does all of the above *and* a metabolic panel to check creatinine clearance
- Visits recur every 3 months



Discontinuing PrEP

- Regular risk screening by PrEP Navigator will inform whether or not it's appropriate for client to remain on PrEP (life changes)
- Provider may recommend discontinuing PrEP based on clinical evidence (e.g., stress on kidney)
- Client may become pregnant and choose to stop, or may acquire HIV and need treatment



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www.prepmaryland.org

HOME

PrEP & PEP Facts

GET PrEP & PEP

RESOURCES

FOR PROVIDERS

PrEP Maryland

You may be able
to protect yourself
with a once a day pill



If you are HIV-negative

At risk for HIV

Recently been exposed to HIV or another STD



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PrEP Locator – Anne Arundel

Where to get PrEP and PEP

* Also offers Post Exposure Prophylaxis (PEP)

*** Only Post Exposure Prophylaxis (PEP) is available (no PrEP)

To start, this list is ordered alphabetically. To order from a specific address enter the street address and city.

3 Harry S. Truman Pkwy, Annapolis, MD

Click Apply to submit search address.

Apply

11.3 miles

Chase Brexton - Anne Arundel County Center *

200 Hospital Drive

Suite 300

Glen Burnie, MD 21061

[Map It](#)

Telephone: 410-837-2050

Hours: Monday through Friday: 8:30 am to 5:00 pm

15.6 miles

Heart to Hand, Inc

9701 Apollo Drive, Suite 400

Largo, MD 20774

[Map It](#)

Telephone: 301-772-0103

Hours: Monday - Friday 9AM - 5PM



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PrEP Resources – Continued

	Men Who Have Sex With Men	Heterosexual Women and Men	Injection Drug Users
Detecting substantial risk for HIV infection	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work	HIV-positive sexual partner Recent bacterial STI High number of sex partners History of inconsistent or no condom use Commercial sex work In high-prevalence area or network	HIV-positive injecting partner Sharing injection equipment Recent drug treatment (but currently injecting)
Clinically eligible	Documented negative HIV test result before prescribing PrEP No symptoms/signs of acute HIV infection Normal renal function; no contraindicated medications Documented hepatitis B virus infection and vaccination status		
Prescription	Daily, continuing oral doses of TDF–FTC (Truvada, Gilead Sciences), ≤90-day supply		
Other services	Follow-up visits at least every 3 months to provide the following: 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		
	Do oral/rectal STI testing	Assess pregnancy intent Pregnancy test every 3 months	Access to clean needles/syringes and drug treatment services

At baseline provider offers: Hepatitis A & B vaccinations (if negative) & HPV vaccination (if eligible)

At every visit, provider offers: Condoms and/or Lubricant (water or silicone-based)



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PrEP Resources – Continued

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE

US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES – 2017 UPDATE

A CLINICAL PRACTICE GUIDELINE



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PrEP Resources – Continued

- PrEP Program Drive (Google)

PrEP Program Drive ▾ 2 members + Add members		
Name ↑	Last modified	File size
Articles	Aug 22, 2017 me	–
Blank Quarterly Reports	Sep 15, 2017 me	–
Newsletters	Sep 15, 2017 me	–
Outreach Materials	Aug 22, 2017 me	–
PrEP Community Workshops	Sep 15, 2017 me	–
PrEP Financing and Billing	Sep 15, 2017 me	–
Program Implementation Documents	Aug 22, 2017 me	–



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PrEP Resources – Continued

Learn about PrEP.
Chat with a navigator.
Get an appointment.

Dig into the research &
take a survey find out if
PrEP is a good fit for you

Chat with a navigator
who can schedule you an
appointment

Or view a location-based
list of providers to schedule
your own appointment

For iOS and Android



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Johns Hopkins University Support

- The Johns Hopkins REACH Initiative at the School of Nursing offers a free online course at <https://www.coursera.org/learn/prep> as well as an in-person free training; the next Skills Building Workshop will be February 27
- The Johns Hopkins REACH Initiative and AETC also offer PrEP clinical advice



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MDH Support for PrEP

- Provider awareness and education
- Awards for PrEP Navigation
- Partnering with Johns Hopkins University AIDS Education and Training Center
- Social marketing campaigns will start this year now that programs are established



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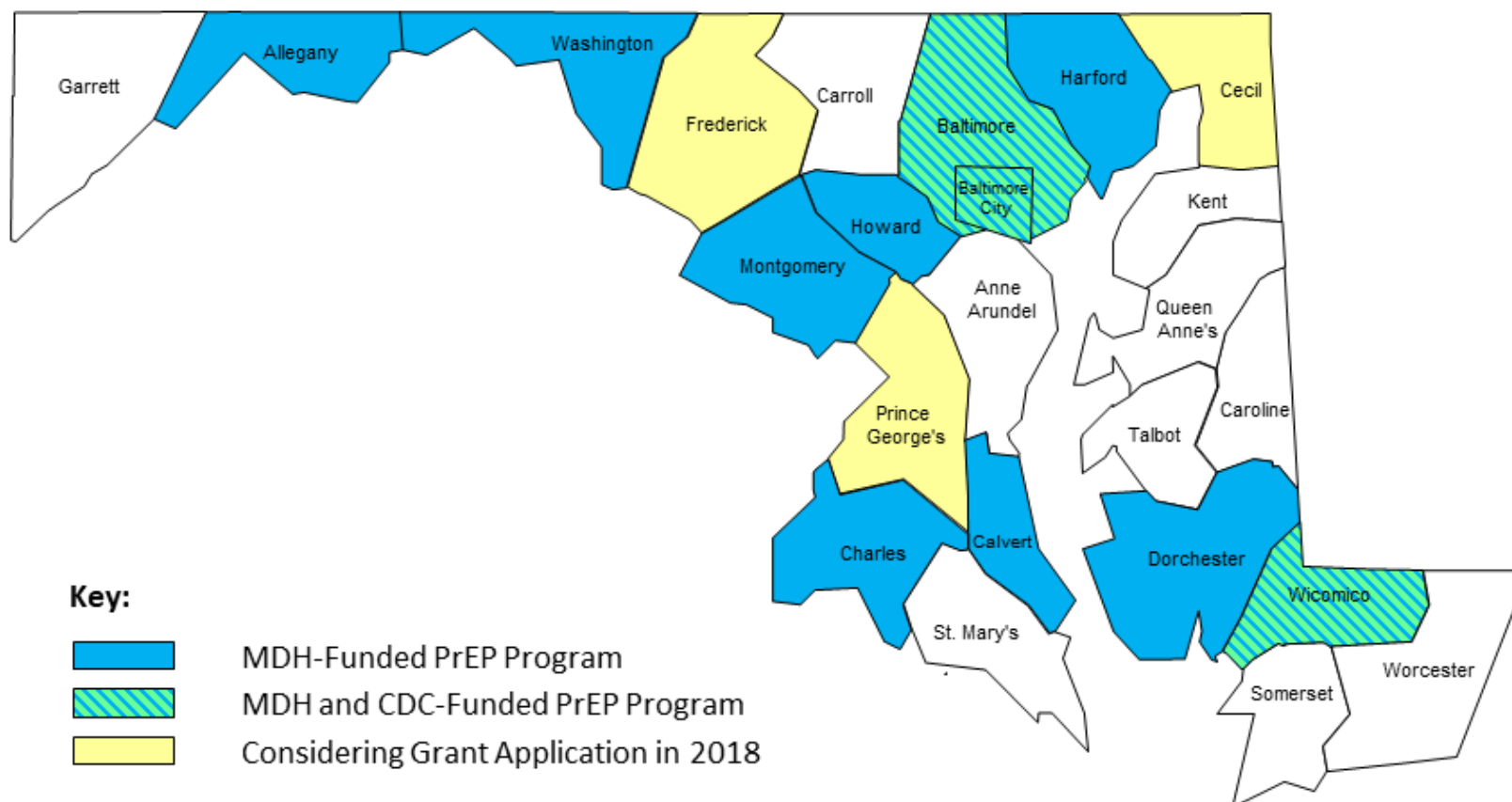
MDH PrEP Funding

- MDH began providing grants to Local Health Departments in FY16 for PrEP Navigation and/or Clinical Services
- Programs are funded with a combination of CDC and State Special Funds
- 11 Programs are currently funded by MDH
- 3 Programs are currently considering applying in 2018
- Programs are prioritized by HIV epidemiologic data as well as other factors (geographic, rising injection drug use, movement into county from higher incidence/prevalence regions, etc)



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MDH PrEP Program Reach





What You Can Do!

- Educate staff, clients and community stakeholders about PrEP
- Refer clients who are vulnerable to HIV to existing PrEP clinics
- Consider applying as a Health Department to conduct navigation and outreach, partnering with Planned Parenthood and Chase Brexton to support existing efforts
- Continue being incredible champions against HIV and PrEP stigma, as well as fierce advocates for evidence-based interventions to end the HIV epidemic and treat PLWHA!



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Questions?





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Contact Information

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Prevention and Health Promotion Administration

<http://phpa.health.maryland.gov>