

PREPARING FOR PrEP: SCIENCE, RESEARCH, AND ACCESS


September 29, 2016

1:00 PM EST

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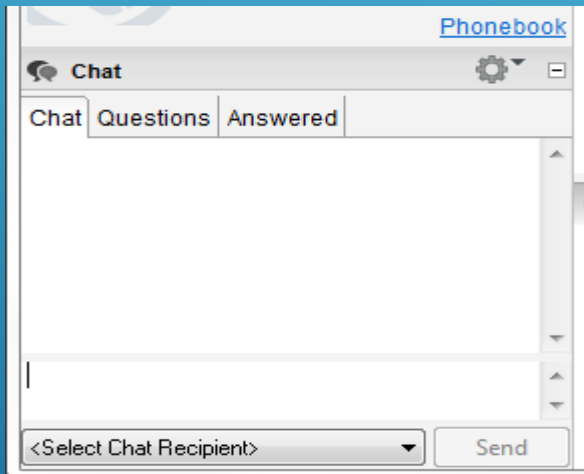
DISCLAIMER

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LOGISTICS

Please use the chat feature throughout the webinar to type any immediate questions or technical issues that come up. We will be sure to address all of them either ON the webinar, or through the chat feature.



MEET THE WEBINAR PLANNING GROUP



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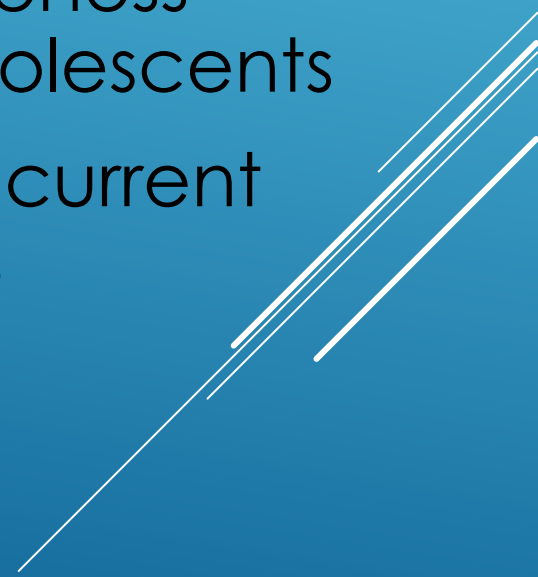


WELCOME
WE'RE GLAD YOU'RE HERE!

WHO'S HERE?

- Local Health Department
 - State Health Department
 - School District
 - School-based Health Center
 - State Education Agency
 - Community-Based Organization
 - Private Provider
 - Researcher
 - Other (please type in chat box!)
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OBJECTIVES


- ❑ Learn about PrEP and understand implications for use with adolescents
 - ❑ Explore examples of PrEP integration into sexual health education and preventive sexual health services
 - ❑ Identify strategies to raise awareness about PrEP omnibet among adolescents
 - ❑ Describe factors that influence current PrEP availability for adolescents
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KEEP IN MIND



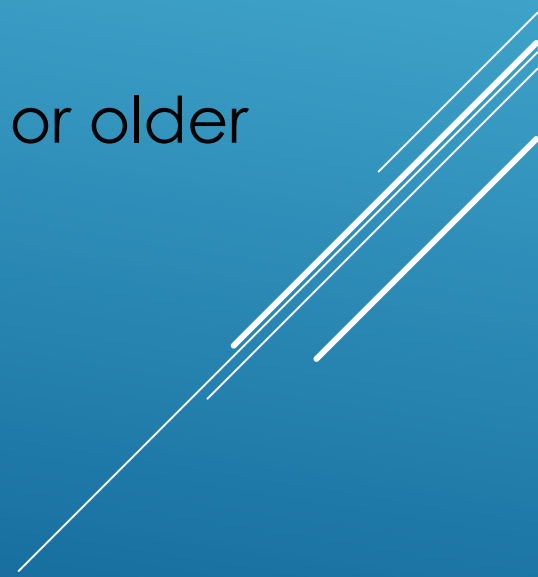
- ❑ The goals of this webinar are to increase your knowledge of PrEP and provide some examples of PrEP implementation from the field
- ❑ No safety studies have been published on the use of PrEP in individuals younger than 18
- ❑ Ideal PrEP delivery programs have not been defined for adolescents. It is reasonable to expect these programs may differ from those used by adults

DASH STRATEGIC IMPERATIVES

- ❑ Take sexual health education to scale nationally to assure teens have access to information and skills development
 - ❑ Address confidentiality protections for teens to increase their use of sexual health services
 - ❑ Expand the evidence base regarding sexual and gender minority (SGM) teen health to develop methods that decrease risk and increase protective factors
 - ❑ Integrate substance use prevention into HIV/STD prevention efforts for teens
- 


WHILE WAITING FOR ADOLESCENT-SPECIFIC PrEP RECOMMENDATIONS, YOU CAN:

- ❑ Include PrEP in ESHE curricula
- ❑ Answer students questions about PrEP
- ❑ Plan to add PrEP as a component of your referral systems
- ❑ Think through how to refer students 18 or older who are considering PrEP

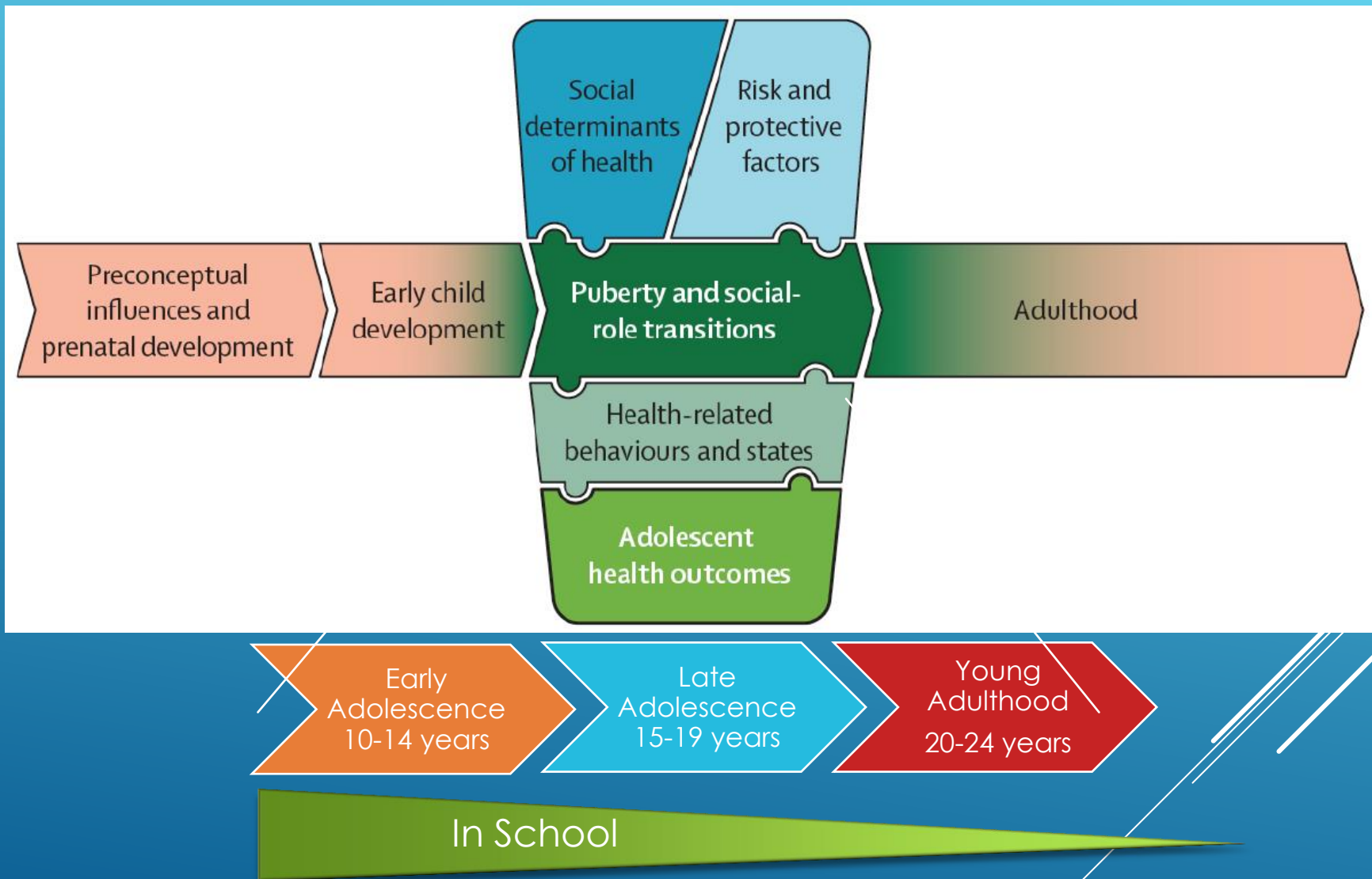


PrEP FOR HIV PREVENTION: IMPLICATIONS FOR ADOLESCENTS

Dawn K. Smith, MD, MS, MPH
Biomedical Intervention Activity Lead
Division of HIV/AIDS Prevention,
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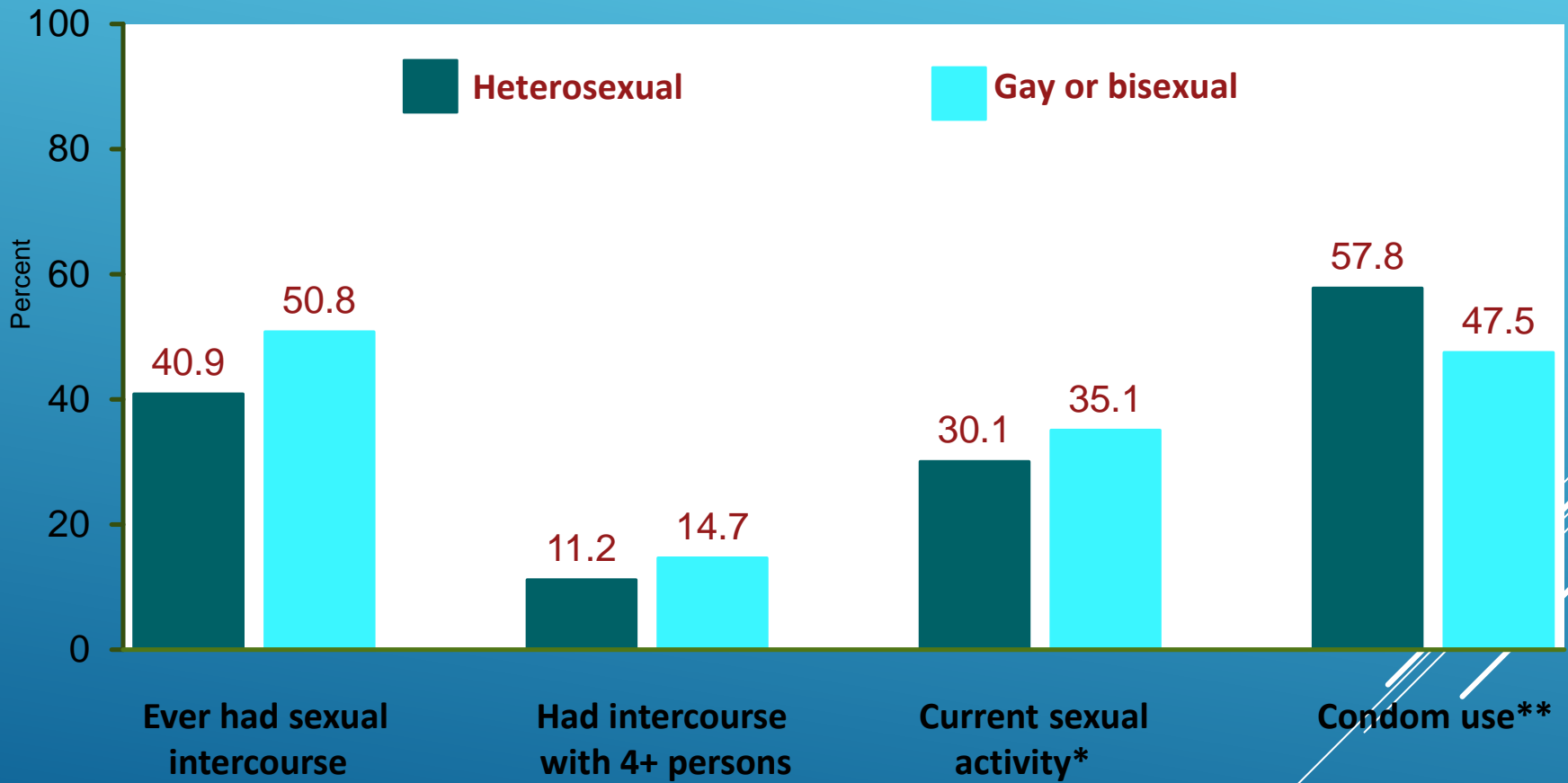
AGE DEVELOPMENTAL FRAMEWORK



DISTRIBUTION OF SEXUAL IDENTITY AND SEX OF SEXUAL CONTACT SUBGROUPS AMONG MALE HIGH SCHOOL STUDENTS IN THE US, 2015

Sexual Identity				Sex of Sexual Contacts			
Heterosexual	Gay	Bisexual	Unsure	Females Only	Males Only	Both Males and Females	Never Had Sexual Contact
93.1%	2.0%	2.4%	2.6%	53.3%	1.3%	1.9%	43.6%
7,479,188	160,670	192,804	208,871	4,281,856	104,436	152,636	3,502,606

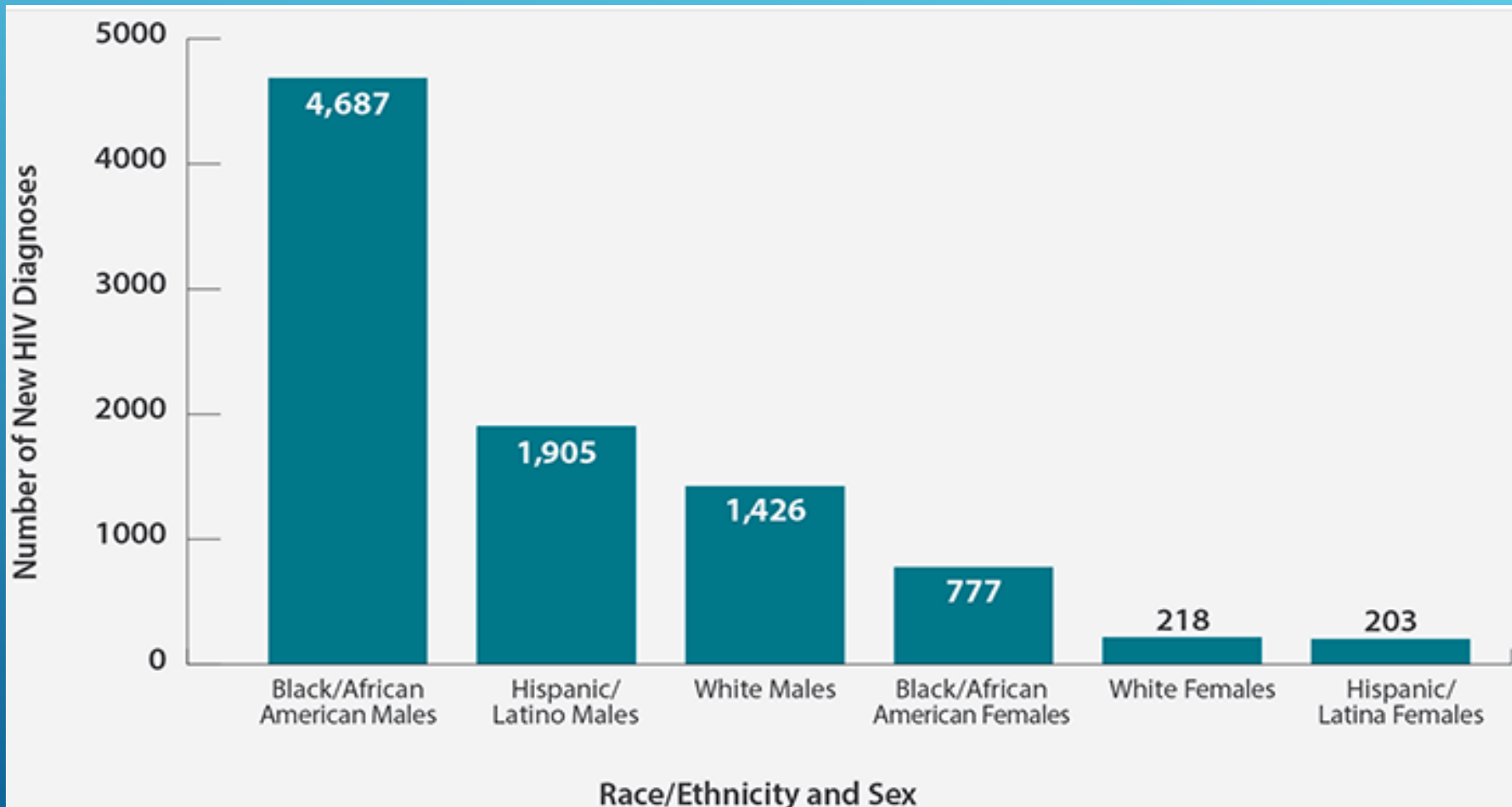
STUDENTS WHO REPORTED HIV-RELATED SEXUAL BEHAVIORS, BY SEXUAL IDENTITY, 2015



*Had sexual intercourse during the 3 months before the survey.

**Among students who were currently sexually active.

ESTIMATED NEW HIV DIAGNOSES AMONG YOUTH AGED 12-24 IN THE US, BY RACE/ETHNICITY AND SEX, 2014



*Subpopulations representing 2% or less of the overall US epidemic are not represented in this chart.

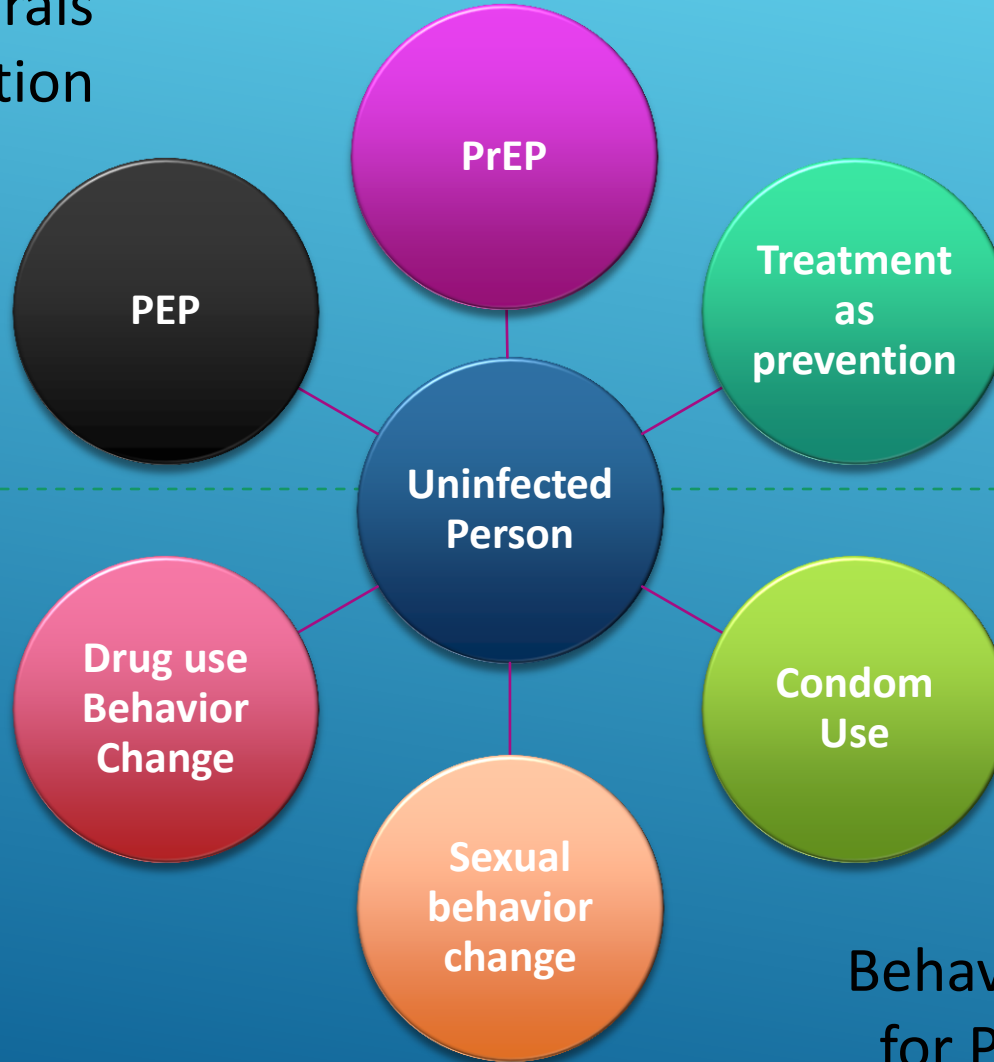
LIFETIME RISK OF AN HIV DIAGNOSIS BY STATE

OVERALL: 1 IN 99 (1.01%)



REDUCING HIV INFECTIONS

Antiretrovirals
for Prevention



Behavior Change
for Prevention

WHAT IS PrEP?

- ❑ Daily use of an antiretroviral pill for Pre-exposure prophylaxis (PrEP) is a highly effective method to reduce the risk of HIV infection
- ❑ FDA approved a once-daily pill containing a fixed-dose combination of two antiretrovirals:
 - Tenofovir disoproxil fumarate (TDF) 300 mg
 - Emtricitabine (FTC) 200 mg
- ❑ Brand name is Truvada



HOW PrEP WORKS

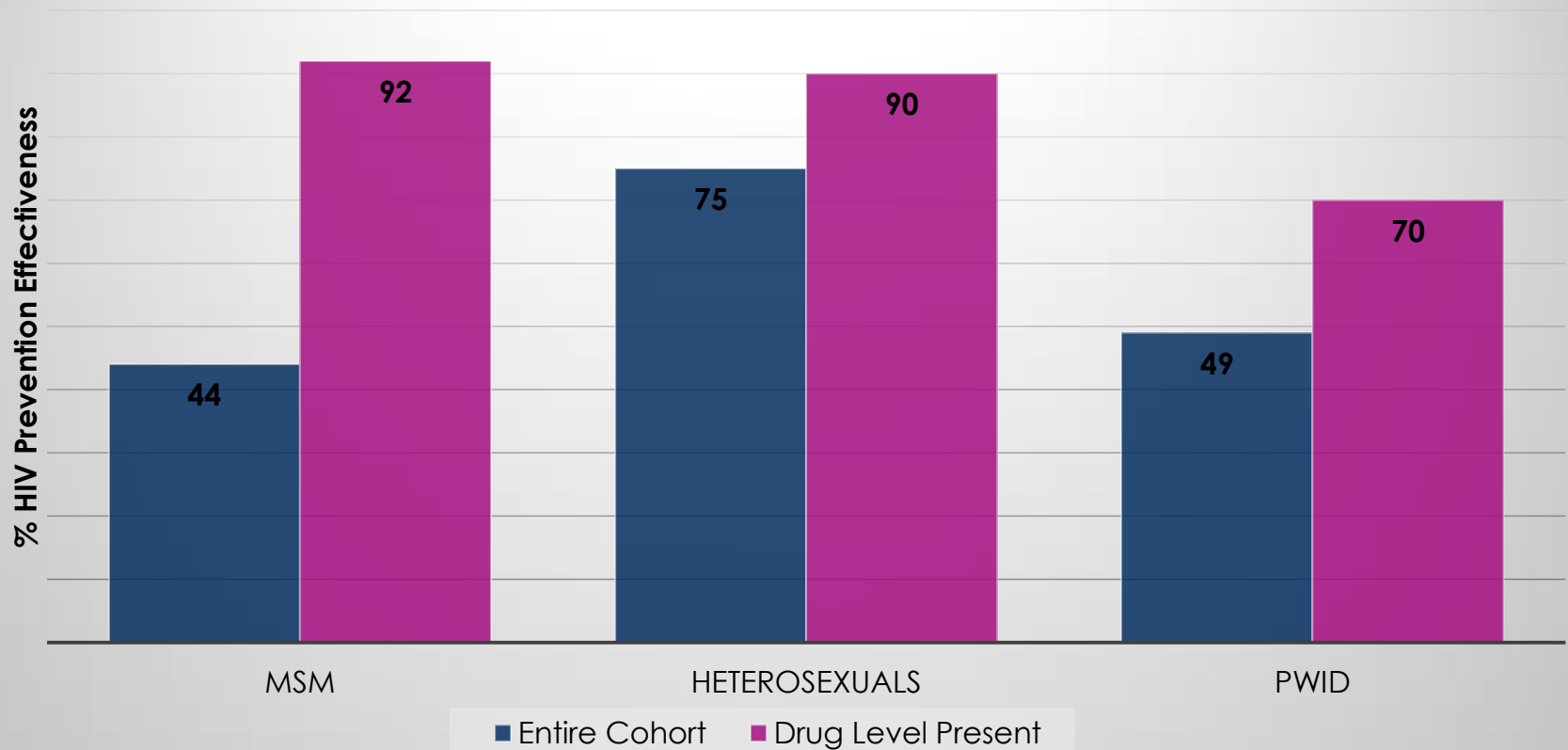
- Without PrEP, if a person is exposed to HIV, the virus will grow new copies of itself in the genital area and over 3-4 days will spread throughout the body.



- With PrEP inside a person's cells, if they are exposed to HIV, the virus cannot grow. So HIV does not spread in the body and become an established HIV infection.



DAILY ORAL PrEP EFFECTIVENESS BY ADHERENCE IN INITIAL RANDOMIZED TRIALS



Sources: Grant RM, et al. *N Engl J Med.* 2010;363:2587-99; Baeten JM, et al. *N Engl J Med.* 2012;367:399-410; Choopanya K, et al. *Lancet.* 2013;381: 2083-90

PrEP EFFECTIVENESS AND ADHERENCE IN OPEN-LABEL AND OBSERVATIONAL STUDIES

□ MSM

- No HIV infections among men with protective drug levels

□ HIV discordant couples

- No infections among consistent PrEP users whose partners were not on ARVs for treatment

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

PrEP SIDE EFFECTS AND SAFETY

❑ **Start-up syndrome**

- <10% with nausea, vomiting, cramps
- Lasts a couple of weeks in most patients
- Can be managed with over the counter medication

❑ **Renal safety**

- Small decrease in creatinine clearance
- Not clinically important
- Returns to normal after PrEP use discontinued

❑ **Bone safety**

- Small decrease in bone mineral density
- Not associated with increased fractures
- Returns to normal after PrEP use discontinued

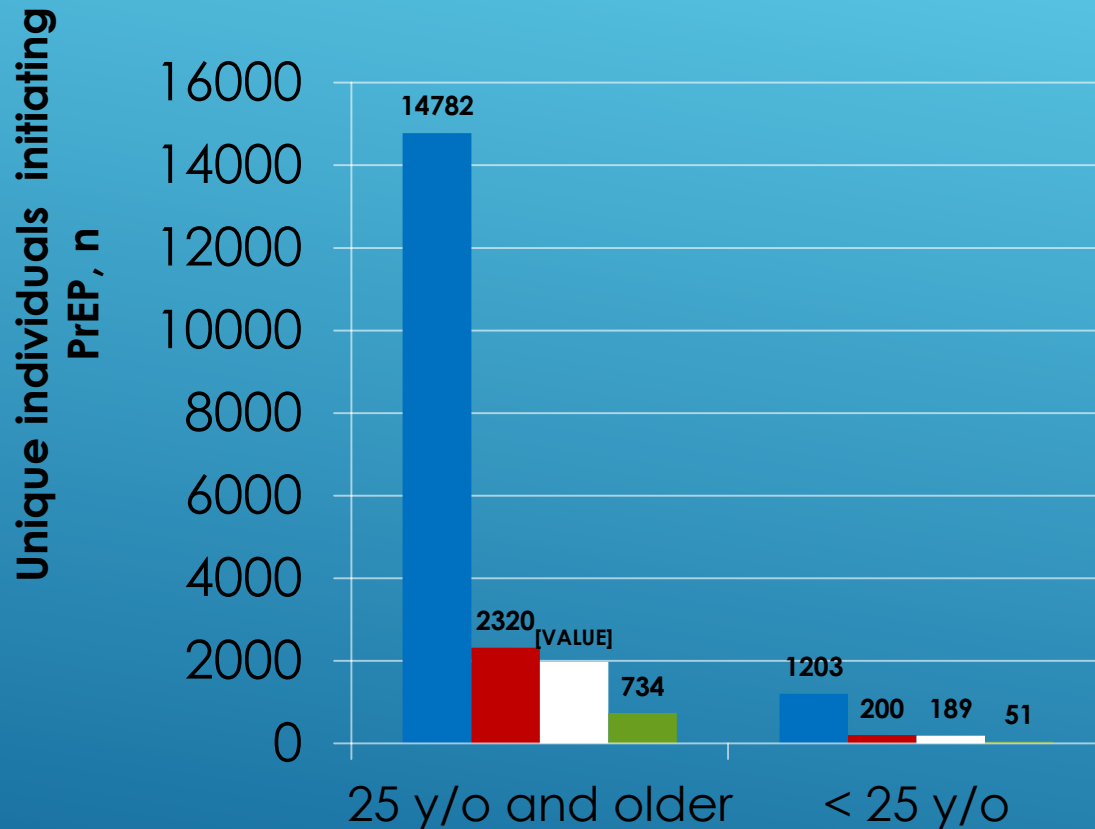
CDC PrEP GUIDELINES SUMMARY

Component	Recommendation
Risk assessment	<ul style="list-style-type: none">• PrEP is indicated for adult MSM, heterosexually-active women and men, and PWID who are at substantial risk for HIV infection through ongoing exposures
Lab screen before prescribing	<ul style="list-style-type: none">• HIV test, test for acute HIV infection if symptomatic• Adequate renal function (eCrCl \geq 60 mL/min)
Prescribing	<ul style="list-style-type: none">• 1 daily TDF/FTC tablet (Truvada)• Prescribe no more than 90 day supply
Follow-up	<ul style="list-style-type: none">• Test for HIV and pregnancy every 3 months• Test for sexually transmitted infections (STIs) every 6 months, even if asymptomatic• Counsel on risk reduction and medication adherence• Test creatinine clearance at 3 months and then every 6 months
Discontinuation	<ul style="list-style-type: none">• At least every 12 months, assess risk behavior, medication adherence, and need for continuing PrEP use

PEOPLE AT SUBSTANTIAL RISK OF HIV INFECTION (MEET INDICATIONS FOR PrEP)

MSM	Heterosexual Men and Women	PWID
<p>In the past 6 months:</p> <ul style="list-style-type: none">• HIV-positive sexual partner• Bacterial STI (esp. GC or syphilis)• More than one sex partner not known to have HIV infection• Inconsistent or no condom use• Commercial sex work		<p>In the past six months</p> <ul style="list-style-type: none">• HIV-positive injecting partner• Sharing injection equipment
	<p>In high-prevalence area</p>	

NEW FTC/TDF FOR PrEP STARTS BY RACE/ETHNICITY AND AGE*



1 in 5 new HIV diagnosis occurs in those < 25 y/o:
 56% (n=5,464) were AA,
 22% (n=2,108) Hispanic,
 17% white (n= 1,644).

	25 y/o and older	< 25 y/o
Asian	3.7%	3.1%
AA	10.0%	11.5%
Hispanic	11.7%	12.2%
White	74.6%	73.2%

7.6% of those who initiated FTC/TDF for PrEP were under 25 y/o.
 Racial demographics were similar, both below and above the age of 25 y/o.

* These data represent 43.7% (n=21,463) of unique individuals who have started FTC/TDF for PrEP from 2012-3Q2015.

SPECIAL ISSUES FOR PrEP IN SCHOOL-AGE YOUTH

❑ **Individualizing care**

- Younger vs older adolescents
- Safe disclosure vs support for adherent use

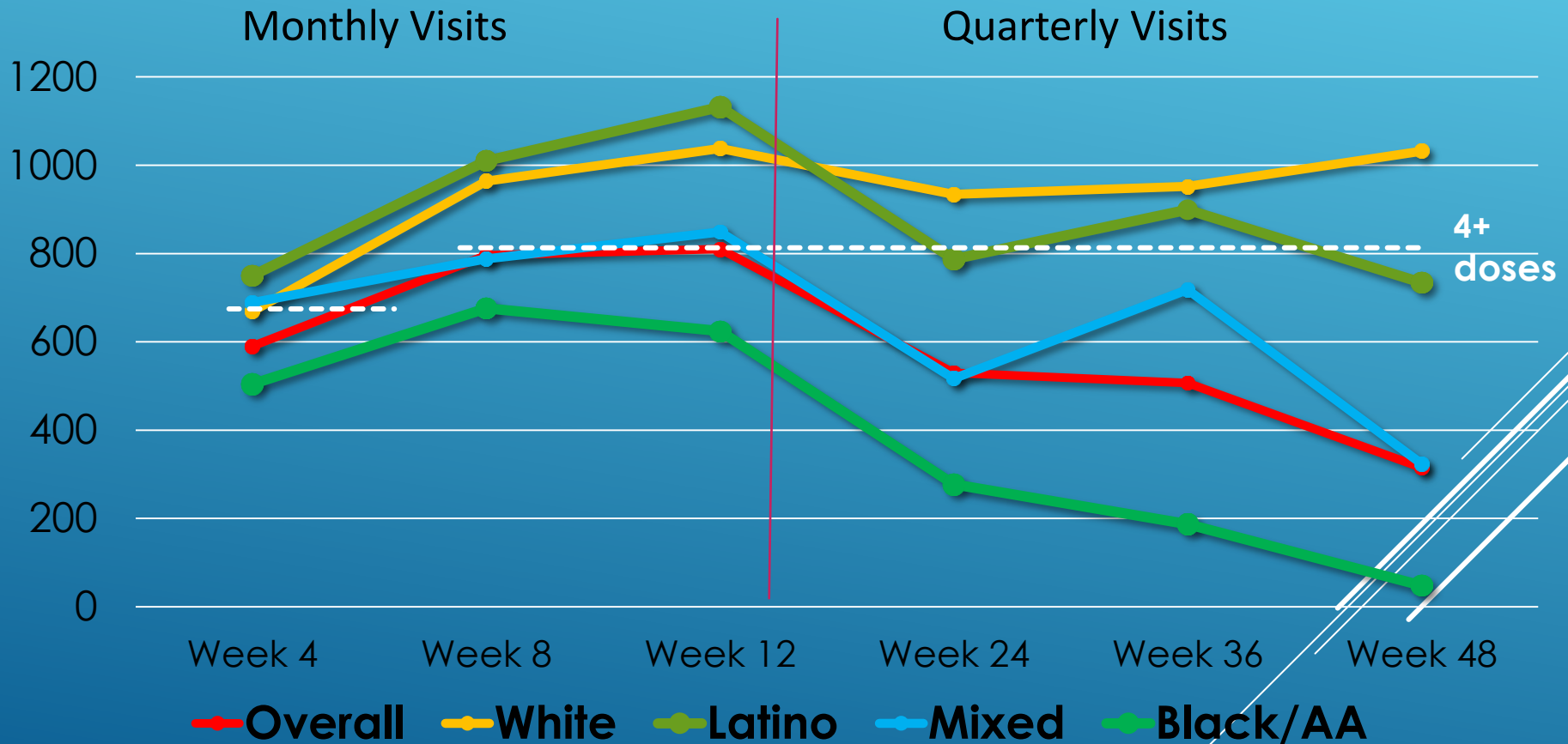
❑ **Access to age/socially-appropriate health care**

- School health services
- Autonomous consent
- Insurance and Explanation of Benefits
- Confidentiality and reporting issues

❑ **Access to social services**

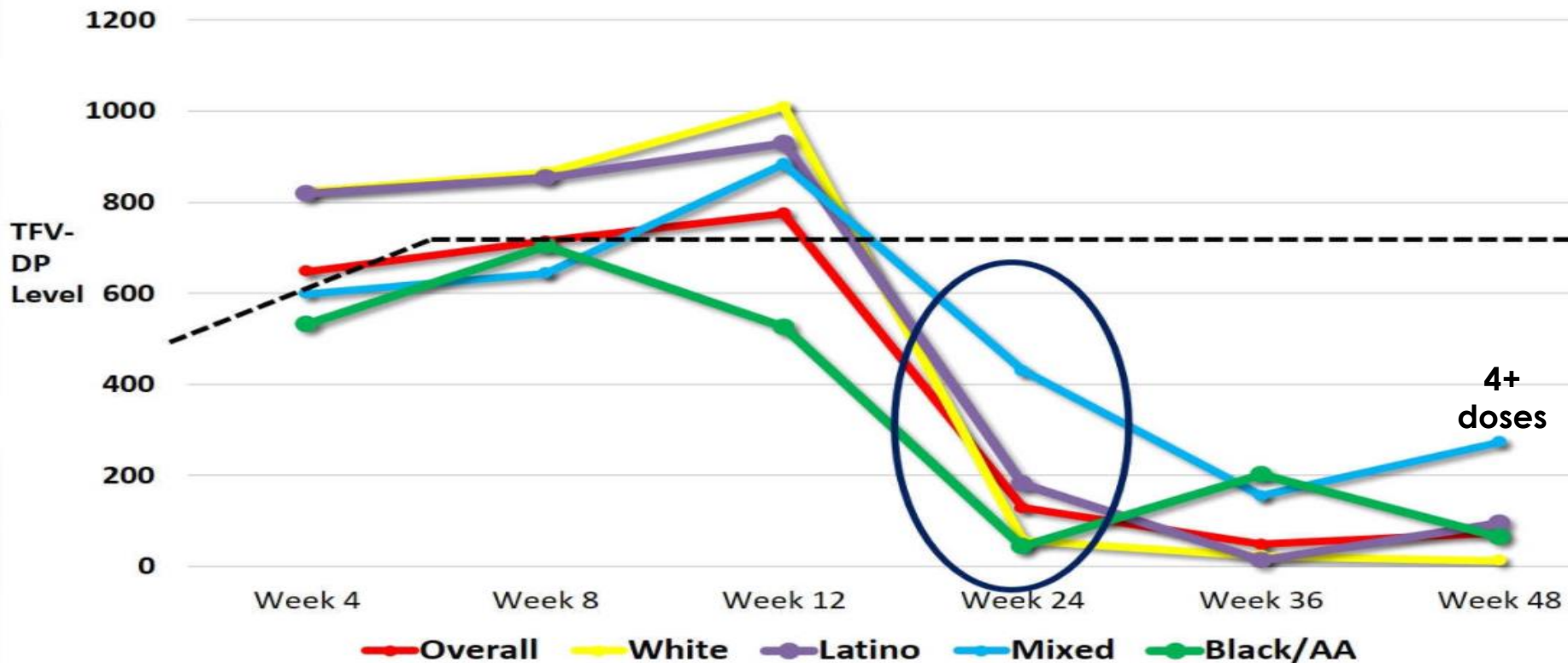
- Counseling and mental health services
- Housing
- Out of school safety

PrEP ADHERENCE IN YOUNG ADULTS (ATN 082): MEDIAN TFV-DP BY RACE/ETHNICITY, 18-24 YO



PrEP IN ADOLESCENTS (ATN 113), 15-17 YO

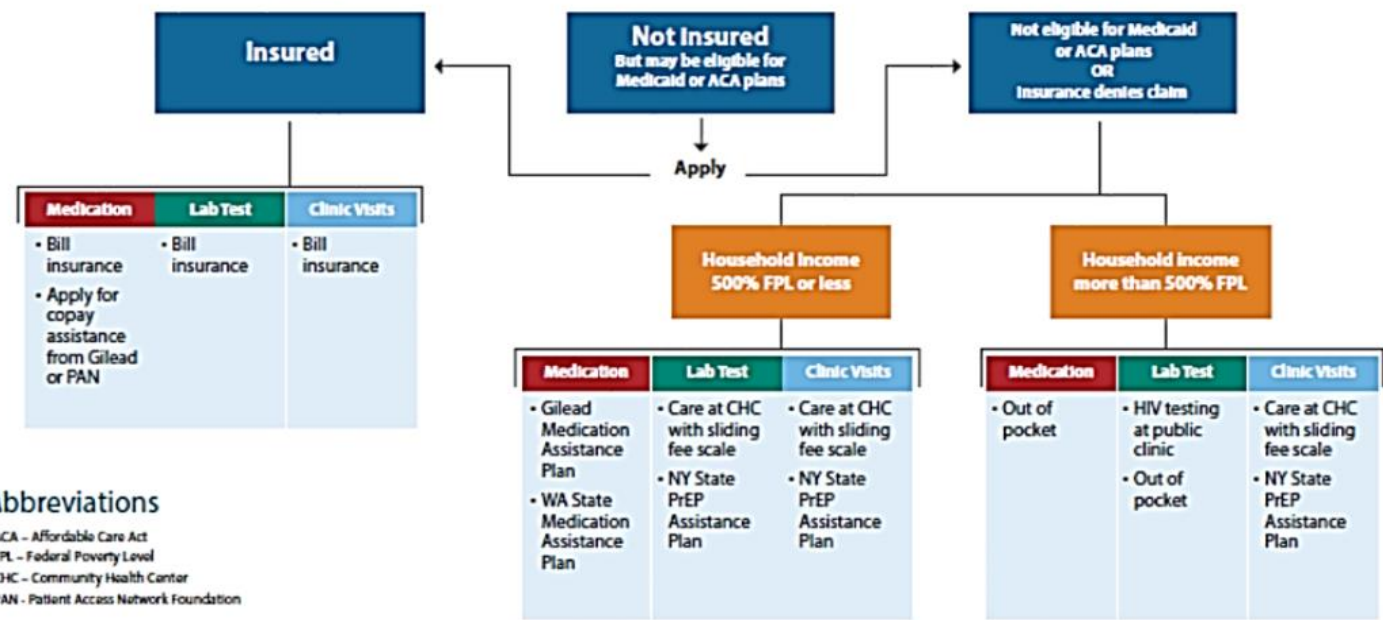
Adherence: Median TFV-DP by Race/Ethnicity



PAYING FOR PrEP CARE



Covering the Cost of PrEP Care



Abbreviations

ACA - Affordable Care Act
 FPL - Federal Poverty Level
 CHC - Community Health Center
 PAN - Patient Access Network Foundation

Definitions

PrEP Daily pill to prevent HIV infection (pre-exposure prophylaxis)

Co-pay fixed amount to be paid by insured person per prescription

Co-insurance fixed percentage of prescription cost to be paid by insured person

Deductible amount of health care cost (including prescriptions) that must be paid by the insured person before insurance begins to cover costs

PrEP Medication Assistance Program (Gilead Sciences)

- People eligible for this program must :
- Be 18 years of age or older
 - Be without insurance or have payment declined by their insurance carrier
 - Be resident in the US (social securing number not required)
 - Have family income ≤500% of the federal poverty level
- Once enrolled in this program:
- Medication will be sent to the provider, a pharmacy, or the patient's home
 - Patients can get their medication at no charge from their for as long as they are eligible
 - Eligibility must be confirmed every 6 months by the provider

PrEP Medication Assistance Program

Family Size	500% Federal Poverty Level* Household annual income must be less than:
1	\$58,850
2	\$79,650
3	\$100,450
4	\$121,250
5	\$142,050
6	\$162,850

*Source: <https://www.healthcare.gov/glossary/federal-poverty-level-fpl/>



PrEP LINE

(855) 448-7737 OR (855) HIV-PREP

Clinical advice available Monday-Friday

11:00 am to 6:00 pm EST

Voice mail available 24 hours a day. Typical response within 2 hours

Clinical consultation staff:

- ID Specialists
- Family Physicians
- Clinical Pharmacists
- Obstetricians
- General Internists
- Nurses

Advice on :

- Initial and follow-up laboratory evaluation
- Administering medications
- Addressing adherence issues
- Transitioning from PEP to PrEP
- Managing PrEP for conception and pregnancy

FROM THE FIELD:

Cassie Warren


Howard Brown Health Center



The Broadway Youth Center



PrEP AT BYC

- ❑ Integrated social & medical services
 - ❑ Medical- primarily FREE walk-in HIV/STI clinic
 - ❑ Added primary care to provide PrEP, hormones, and birth control services
 - ❑ Same day PrEP
 - ❑ Medication assistance
- 

BYC & CHICAGO PUBLIC SCHOOLS RELATIONSHIP

❑ Train the Trainer

- CPS → community health workers and teachers
- Community health workers → teachers
- Teachers and community health workers can give presentations

❑ Celebrations

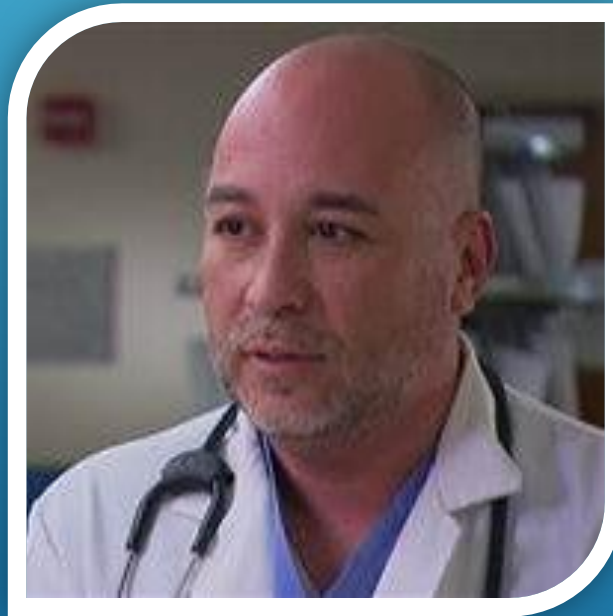
- Huge commitment and passion
- PrEP and PEP added
- Process for submitting own curriculum to review board

❑ Areas of Growth

- Defining HIV
- Treatment options with HIV
- Testing measures for Trainers

FROM THE FIELD:

Dr. Tomás Magaña, MD, MA,
FAAP




FUENTE WELLNESS CENTER – LA CLÍNICA DE LA RAZA, CALIFORNIA




Our school-based health center practice...

- ❑ Department within large regional safety-net community health center
- ❑ Serves diverse adolescent population aged 11-24 years old
- ❑ Largely uninsured or underinsured
- ❑ Medical, reproductive and/or behavioral health home

OUR PATIENT POPULATION CONSIDERATIONS

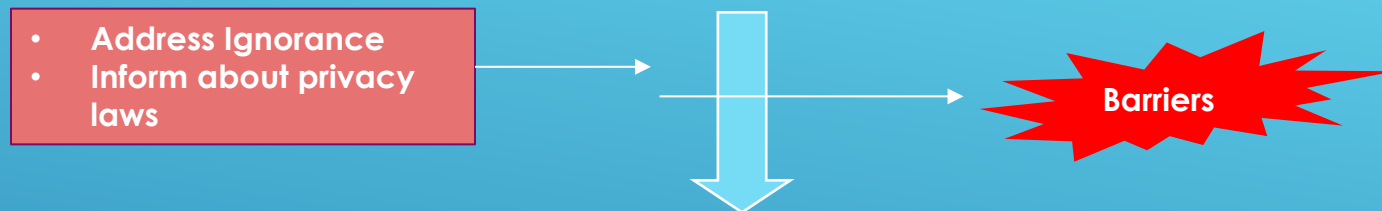
- ❑ At-risk population – profound disparities exist
 - ❑ Spectrum of cognitive developmental stages
 - ❑ Unique values – confidentiality & privacy
- 

PrEP SERVICES

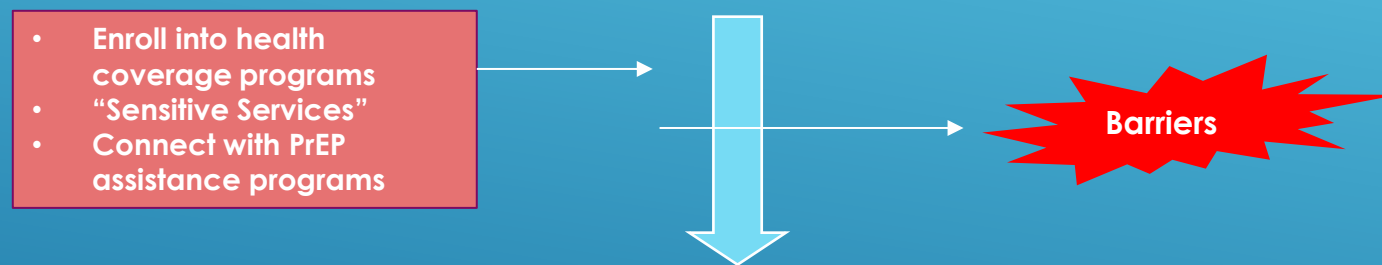
- ❑ Referrals to outside agencies & PCPs ineffective
 - ❑ Awareness of high-risk populations
 - ❑ Transition to provide PrEP services on site
- 

ADDRESSING OBSTACLES TO CARE

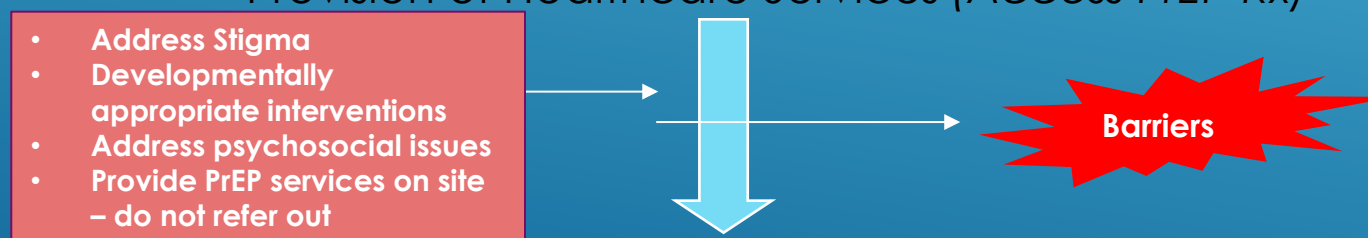
Patient Concern (*Unprotected sex*)



Entry into Health Care (*Make appointment*)




Provision of Healthcare Services (*Access PrEP Rx*)



Positive health outcomes (*Free from HIV infection*)

OPPORTUNITIES FOR COLLABORATION


Work with local healthcare partners to:

- ❑ Empower youth to become informed healthcare consumers
 - ❑ Inform students about local resources – where can they access confidential care?
 - ❑ Include PrEP in health education
 - ❑ Address stigma and biases
 - ❑ Advocate for on-site services
- 

MESSAGING AND AWARENESS

Sara Stahlberg, MPH

Senior Program Manager, Adolescent Sexual Health
National Coalition of STD Directors



PrEP AND DASH 1308

DASH partners can begin preparing for this change by:

- ❑ Being able to answer students' questions
- ❑ Including mention of PrEP in your sexual health education curricula
- ❑ Planning to add PrEP as a component of your referral systems in the future.
- ❑ There may be adolescents <18 years of age, who are candidates for PrEP based on careful evaluation by their healthcare provider

PrEP AND CONDOMS



- ❑ PrEP does not prevent the spread of bacterial STDs, but correct and consistent condom use can
- ❑ When taken every day, PrEP provides a high level of protection against HIV—especially when combined with condoms
- ❑ Messaging to adolescents should include a dual protection approach
- ❑ Condom availability programs can bring down barriers to access

KEY MESSAGES

Differences for adolescents:

- ❑ More structured support to successfully maintain a regimen
- ❑ Strategies to help ensure medication adherence
- ❑ More frequent follow-up intervals



Of note:

- ❑ No safety data currently available for HIV uninfected youth
- ❑ Collaboration with community efforts and educating parents and adolescents provide an infrastructure
- ❑ PrEP does not protect against STDs

QUESTIONS?



RESOURCES

PrEP Basics

<http://www.cdc.gov/hiv/basics/prep.html>

Are You Ready for PrEP? (Infographic Series)

<https://npin.cdc.gov/publication/are-you-ready-prep-prep-basics>

Are You Ready for PrEP? (Video)

<https://www.youtube.com/watch?v=TR8-3uAuZGo>



CONTACT INFORMATION

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