

# HIV Prevention Strategies for Young People

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May 5, 2021

MEDICINE *of* THE HIGHEST ORDER



UNIVERSITY *of*  
**ROCHESTER**  
MEDICAL CENTER

# Learning Objectives

- Describe how adolescents represent a unique demographic in the context of STIs and HIV
- Understand adolescent epidemiologic trends for STIs and HIV
- List prevention strategies for HIV including PrEP and PEP

# Adolescence

- Developmental stage separating childhood and adulthood
- Occurs between ages 11-22
- Needs vary by development and personal circumstances
- Shaped by race, ethnicity, religion, socioeconomic status, family/peers



Slide adapted from *Adolescent Medicine: The HEADSSS Assessment* by Katherine Blumoff Greenberg, MD

# The Culture of Adolescence

- Peer dependent
- Egocentric
- Distinct language and dress
- Influenced by popular culture
- Ongoing search for identity

Slide adapted from *Adolescent Medicine: The HEADSSS Assessment* by Katherine Blumoff Greenberg, MD

# Major Causes of Morbidity in Teens

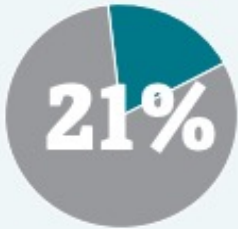
- Substance Use
- Teen Pregnancy
- Sexually Transmitted Infections
- Obesity
- Eating Disorders

# 15-24 year olds account for half of all new STD Infections



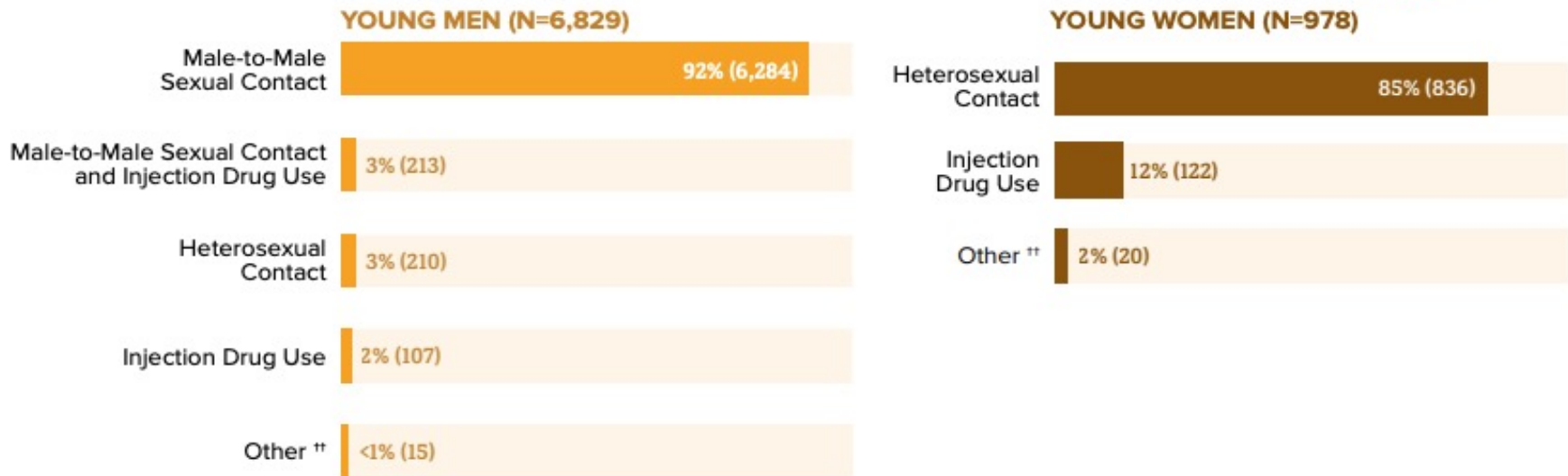
<https://www.cdc.gov/std/life-stages-populations/adolescents-youngadults.htm>

# HIV and Youth



Of the **37,832 NEW HIV DIAGNOSES** in the US and dependent areas\* in 2018, 21% were among youth. †

Most new HIV diagnoses among youth were among young gay and bisexual men. ‡ \*\*



Totals may not equal 100% due to rounding.

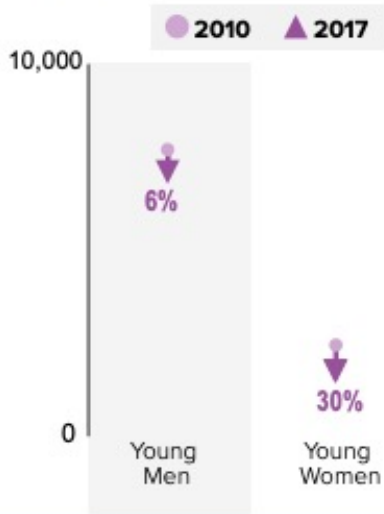
\* American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the US Virgin Islands.  
 † Persons aged 13 to 24 are referred to as *youth* or *young* in this fact sheet.  
 ‡ This fact sheet uses the term *gay and bisexual men* to represent gay, bisexual, and other men who have sex with men.  
 \*\* Includes infections attributed to male-to-male sexual contact and injection drug use (men who reported both risk factors).  
 †† Includes hemophilia, blood transfusion, perinatal exposure, and risk factors not reported or not identified.  
 ‡‡ In 50 states and the District of Columbia.  
 \*\*\* *Black* refers to people having origins in any of the black racial groups of Africa. *African American* is a term often used for Americans of African descent with ancestry in North America.  
 ††† Changes in subpopulations with fewer HIV diagnoses can lead to a large percentage increase or decrease.  
 †††† Hispanics/Latinos can be of any race.



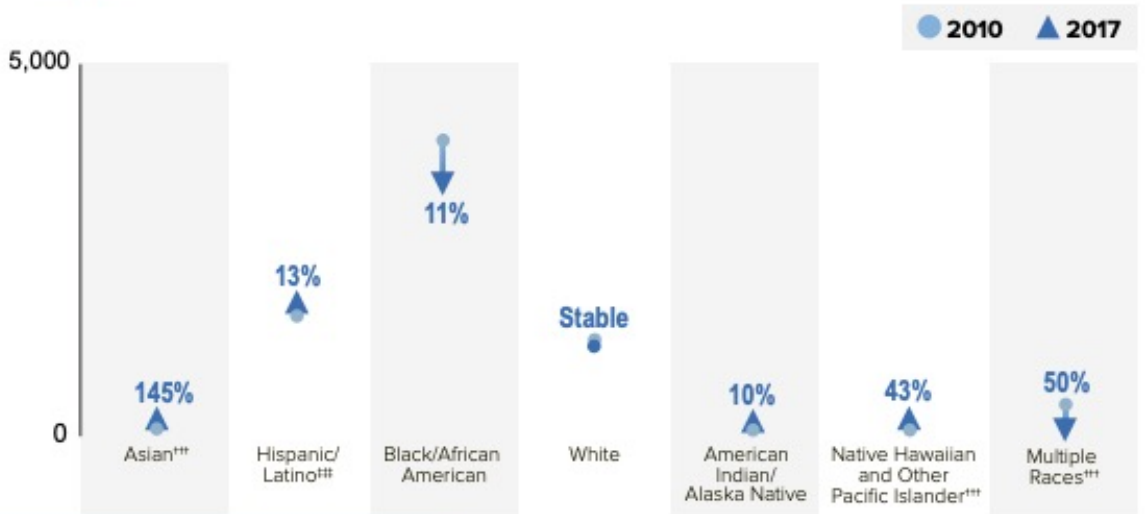
**HIV diagnoses declined 10% among youth overall from 2010 to 2017.<sup>†</sup> Although trends varied for different groups of youth, HIV diagnoses declined for groups most affected by HIV, including young black/African American gay and bisexual men.<sup>\*\*\*</sup>**



## Trends by Sex



## Trends for Young Gay and Bisexual Men by Race and Ethnicity



\* American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the US Virgin Islands.

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National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention  
Division of HIV/AIDS Prevention





# Youth who don't know they have HIV cannot get the care and treatment they need to stay healthy.



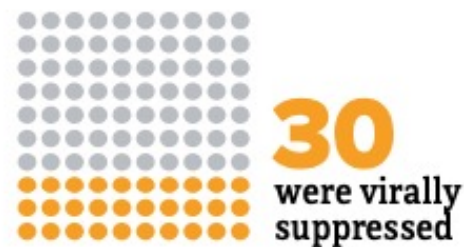
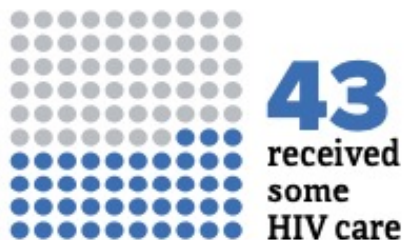
At the end of 2016, an estimated **1.1 MILLION PEOPLE** had HIV.# Of those, 50,900 were young people.

**Nearly 4 in 7**  
youth knew they had the virus.



Youth were the least likely to be aware of their infection compared to any other age group. It is important for youth to know their HIV status so they can take medicine to treat HIV if they have the virus. Taking HIV medicine every day can make the viral load undetectable. Youth who get and keep an undetectable viral load (or stay virally suppressed) have effectively no risk of transmitting HIV to HIV-negative sex partners.

Compared to all people with HIV, youth have the lowest rates of viral suppression. **For every 100 youth with HIV: #**



For comparison, for every **100 people overall** with HIV, **64 received some HIV care**, **49 were retained in care**, and **53 were virally suppressed**.

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## Several challenges make it difficult for youth to access the tools they need to reduce their risk or get treatment and care if they have HIV.

### Low Rates of HIV Testing



HIV testing rates among high school students are low. People who do not know they have HIV cannot take advantage of HIV care and treatment and may unknowingly transmit HIV to others.

### Low Rates of PrEP Use



Young people are less likely than adults to use medicine to prevent HIV. Barriers include cost, access, perceived stigma, and privacy concerns.

### Socioeconomic Challenges



Among people with HIV, young people are more likely than older people to be living in households with low income levels, to have been recently homeless, recently incarcerated, or uninsured. These factors pose barriers to achieving viral suppression.

### High Rates of Other STDs



Some of the highest STD rates are among youth aged 20 to 24. Having another STD can greatly increase the chance of getting or transmitting HIV.



# STI/HIV Risk Factors in Adolescents

## Unique factors place youth at risk



### Insufficient Screening

Many young women don't receive the chlamydia screening CDC recommends



### Confidentiality Concerns

Many are reluctant to disclose risk behaviors to doctors



### Biology

Young women's bodies are biologically more susceptible to STIs



### Lack of Access to Healthcare

Youth often lack insurance or transportation needed to access prevention services



### Multiple Sex Partners

Many young people have multiple partners, which increases STI risk

Early sexarche

MSM

Increased biologic susceptibility to infection (eg: cervical ectopy in females)

Incarceration/detention

Multiple partners, sequentially

Adolescents attending STD clinics

Poor condom use

Barriers to accessing healthcare

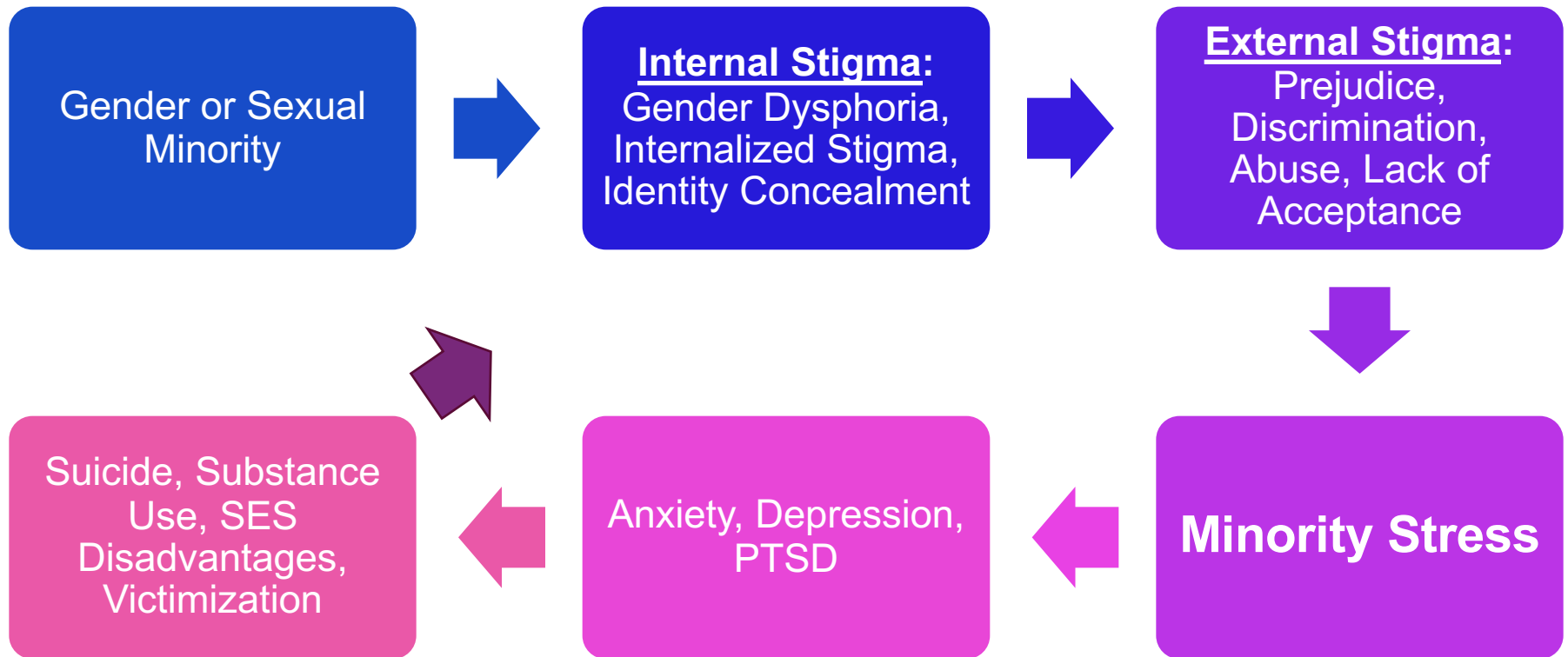
IVDU

<https://www.cdc.gov/std/products/youth-sti-infographic.pdf>

# Transgender Individuals:

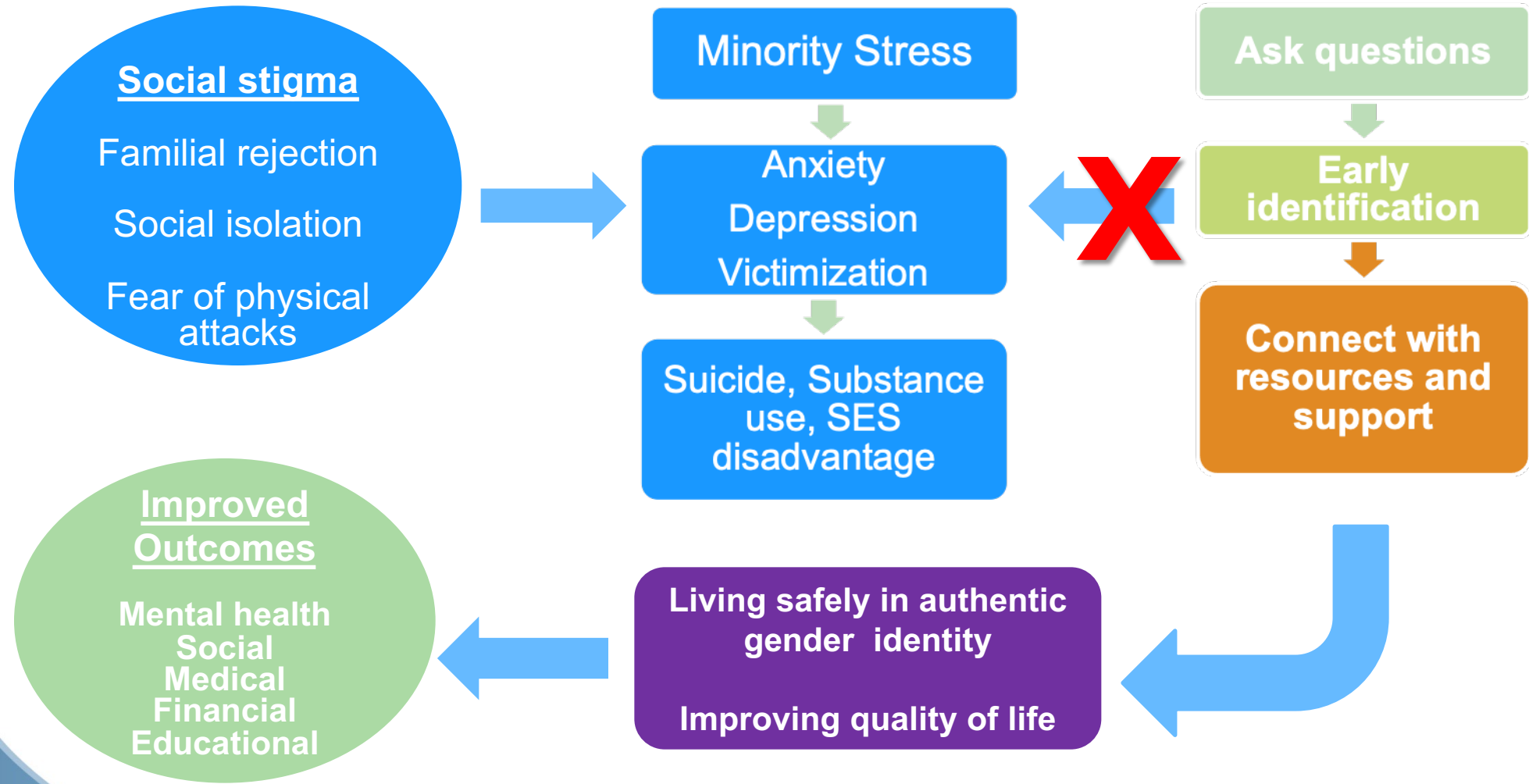
- Particularly at high risk for HIV, likely because also at risk for:
  - Lack of familial support
  - Violence
  - Stigma and discrimination
  - Limited health care access
  - Negative health care encounters
  - Substance use
  - Sex work/incarceration/homelessness/unemployment
  - Untreated MH needs

# Minority Stress Theory for LGBTQ People



Adapted from O'Hanlan, et al (1997). A review of the medical consequences of homophobia with suggestions for resolution. *JGLMA*;1:25-39.)  
Mai-Anh Tran Ngoc, DO

# Countering Minority Stress

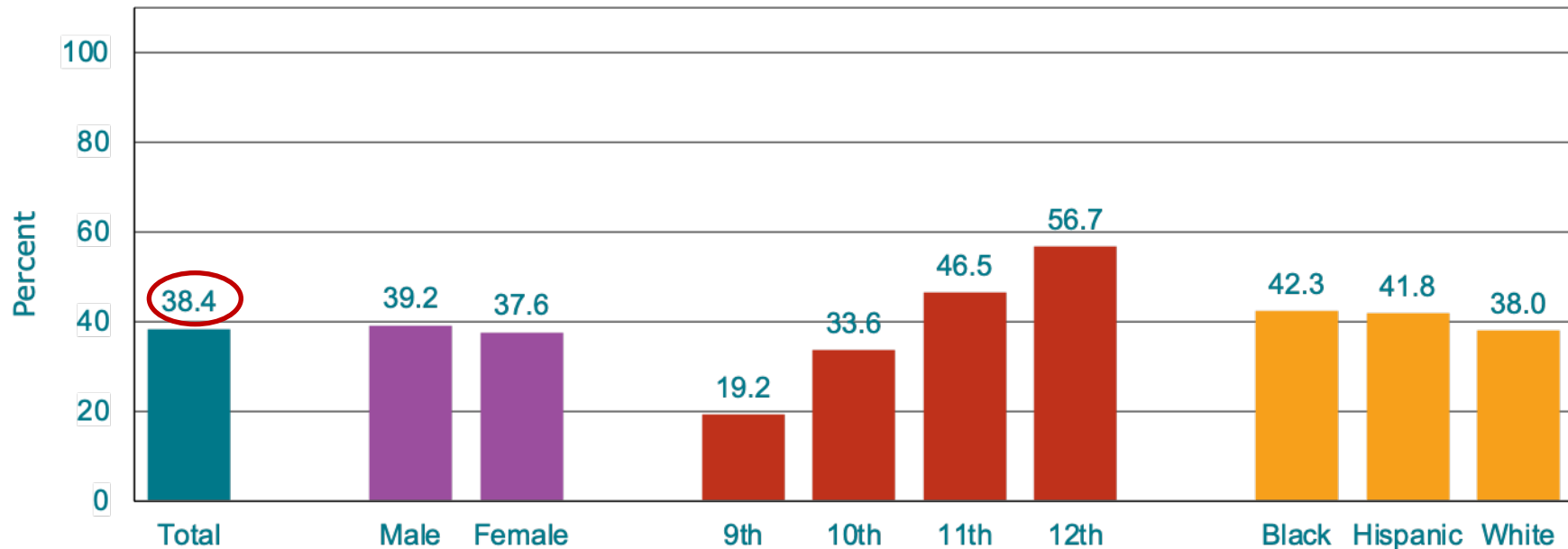


# 2019 YOUTH RISK BEHAVIOR SURVEY

Self-reported data from grade 9-12 high school students  
administered by CDC every 2 years

# Percentage of High School Students Who Ever Had Sexual Intercourse

by Sex, Grade,\* and Race/Ethnicity, 2019

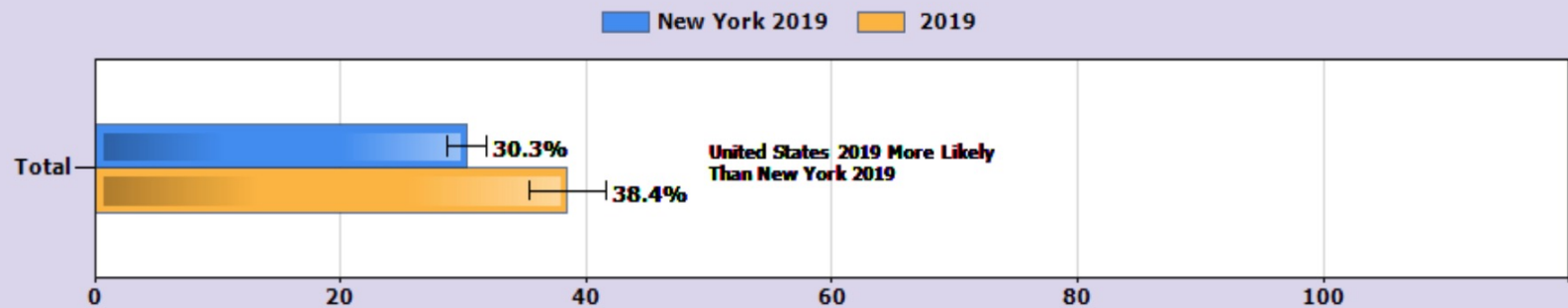


\*10th > 9th, 11th > 9th, 11th > 10th, 12th > 9th, 12th > 10th, 12th > 11th (Based on t-test analysis,  $p < 0.05$ .)  
All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.  
This graph contains weighted results.

National Youth Risk Behavior Survey, 2019

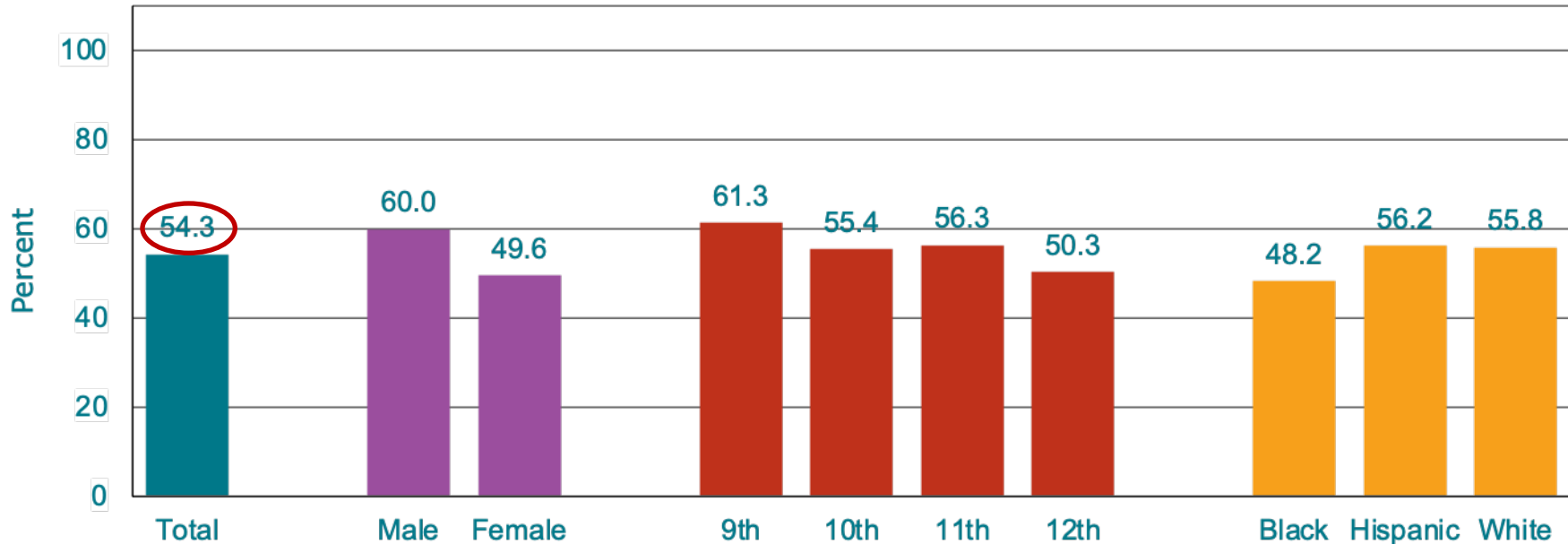


Ever had sexual intercourse  
High School Youth Risk Behavior Survey



# Percentage of High School Students Who Used a Condom During Last Sexual Intercourse\*

by Sex,† Grade,‡ and Race/Ethnicity,‡ 2019



\*Among students who were currently sexually active

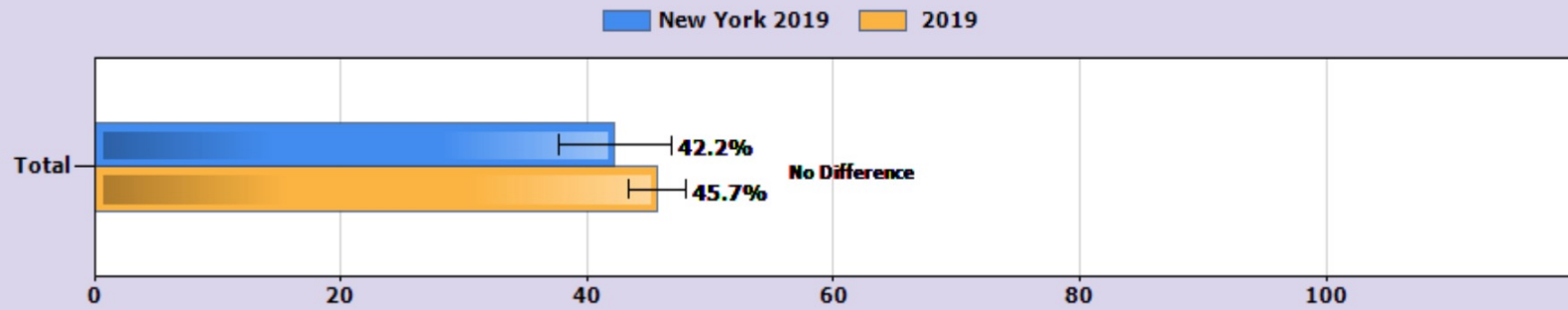
†M > F; 9th > 12th; H > B, W > B (Based on t-test analysis,  $p < 0.05$ .)

All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.

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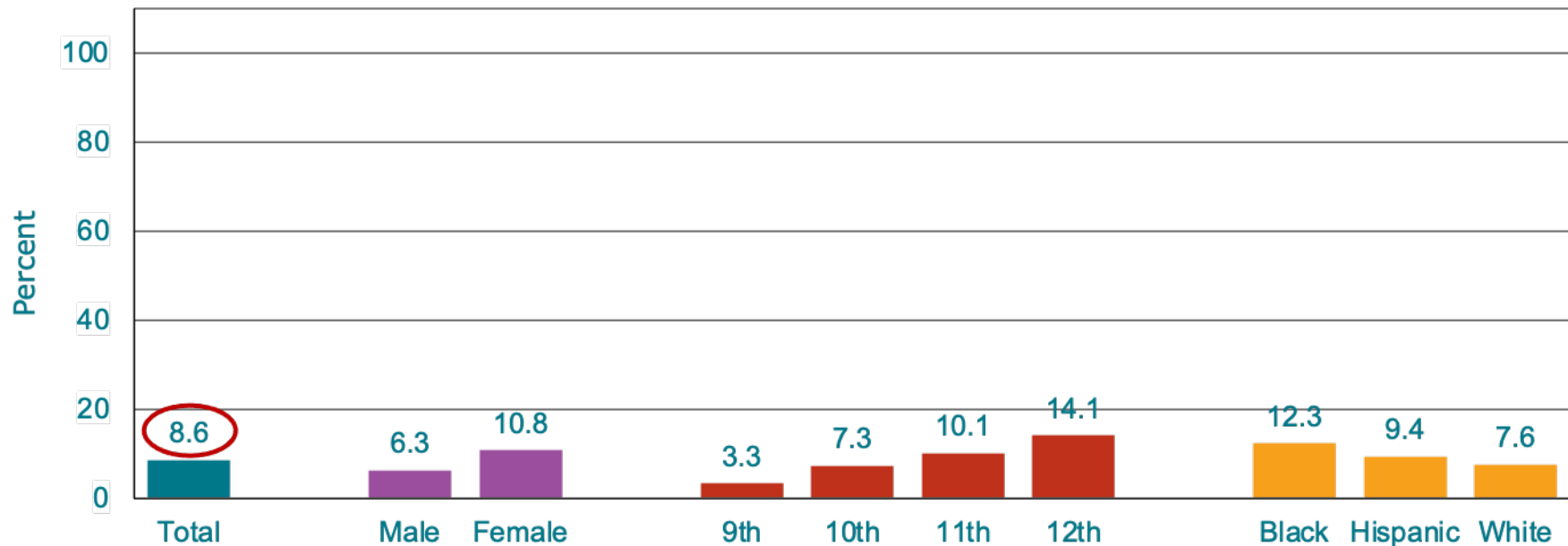
National Youth Risk Behavior Survey, 2019

Did not use a condom during last sexual intercourse  
High School Youth Risk Behavior Survey



# Percentage of High School Students Who Were Ever Tested for a Sexually Transmitted Disease (STD)\*

by Sex,† Grade,‡ and Race/Ethnicity,‡ 2019



\*Other than HIV, such as chlamydia or gonorrhea, during the 12 months before the survey

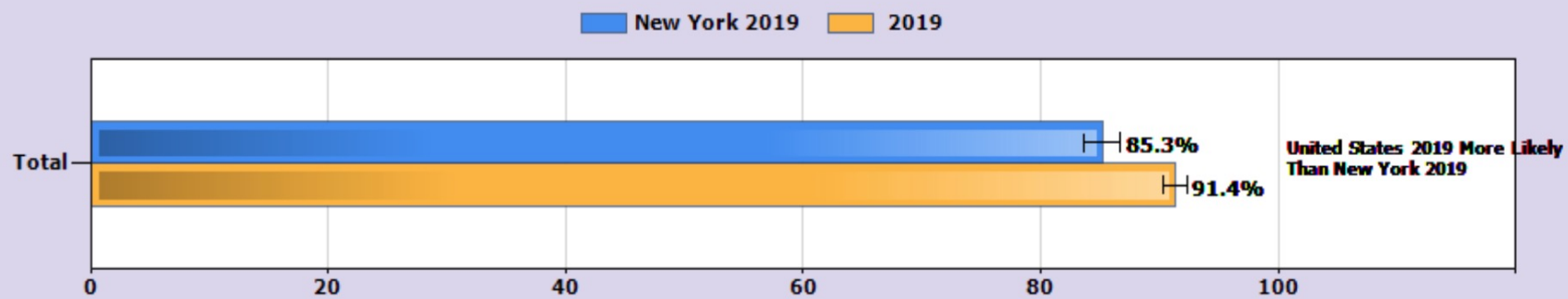
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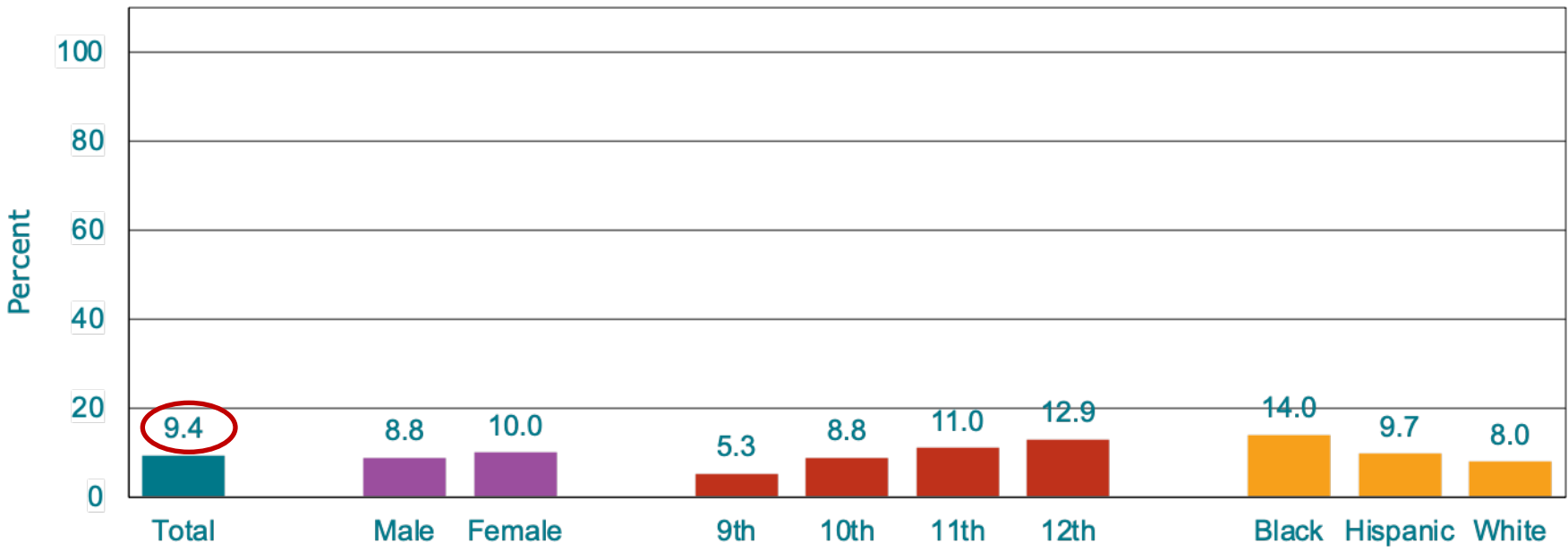
National Youth Risk Behavior Survey, 2019

Were not tested for a sexually transmitted disease (STD) other than HIV  
High School Youth Risk Behavior Survey



# Percentage of High School Students Who Were Ever Tested for Human Immunodeficiency Virus (HIV)\*

by Sex,† Grade,† and Race/Ethnicity,† 2019



\*Not counting tests done if they donated blood

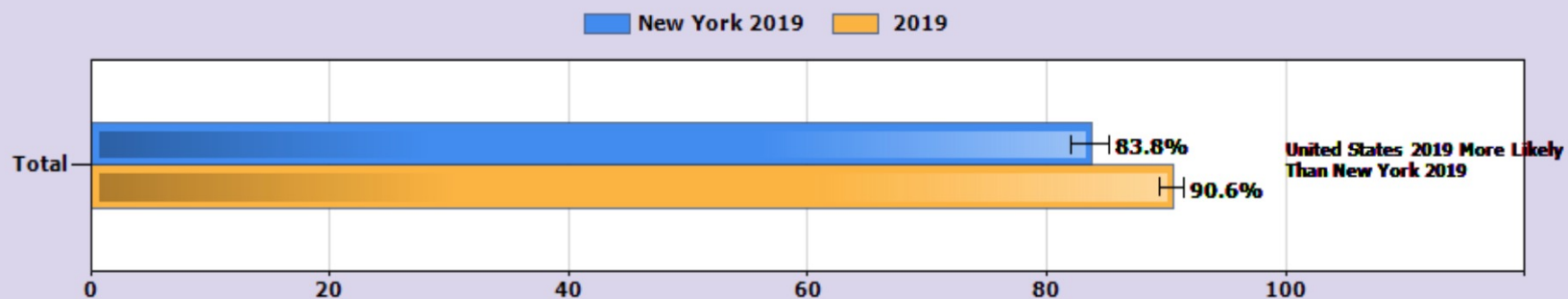
†F > M; 10th > 9th, 11th > 9th, 11th > 10th, 12th > 9th, 12th > 10th; B > H, B > W (Based on t-test analysis, p < 0.05.)

All Hispanic students are included in the Hispanic category. All other races are non-Hispanic.

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National Youth Risk Behavior Survey, 2019

Were never tested for human immunodeficiency virus (HIV)  
High School Youth Risk Behavior Survey



# HOW CAN WE HELP?

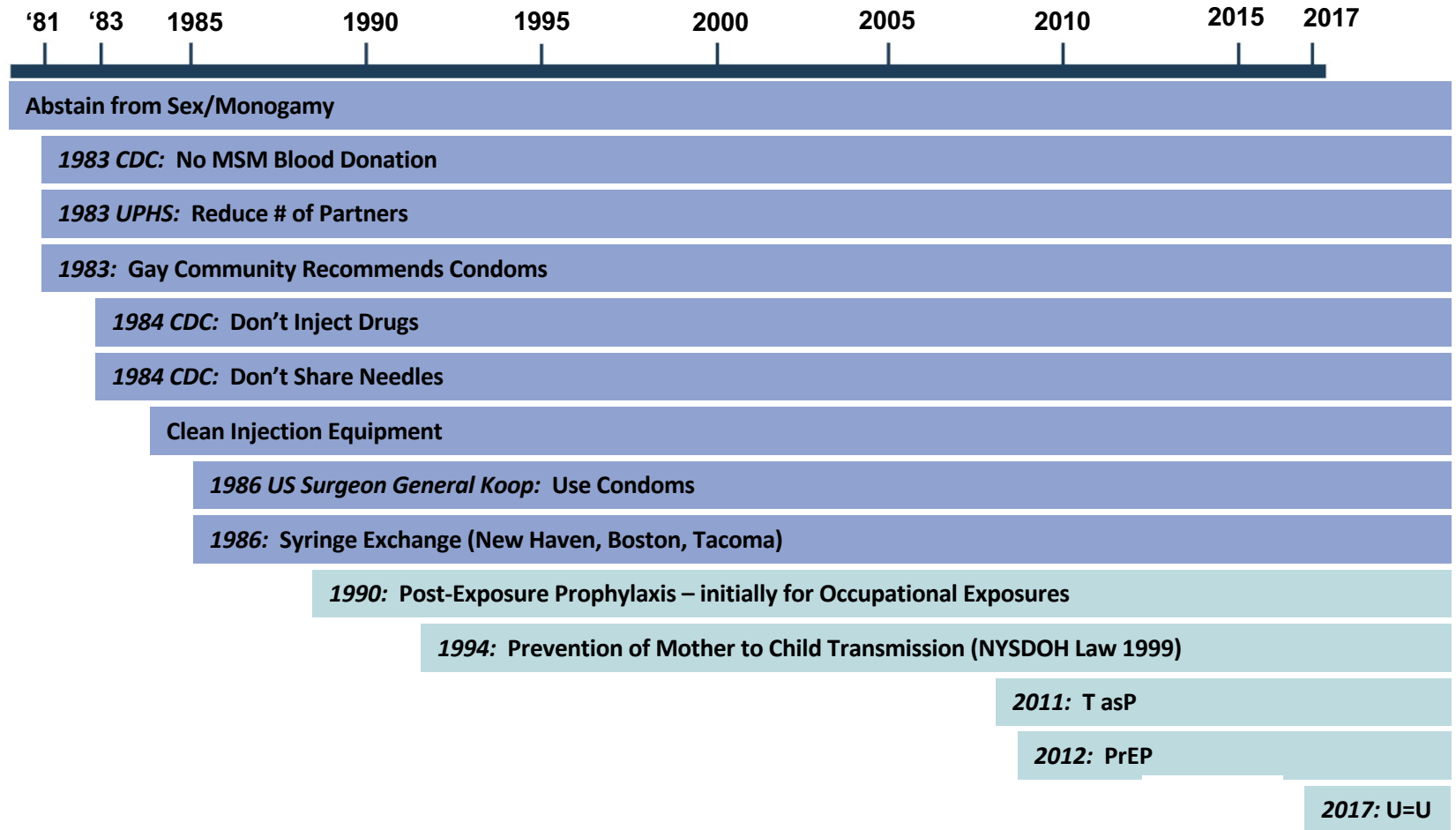


# A Trip Down HIV Prevention Memory Lane

- HIV Prevention Recommendations since 1981



# HIV Prevention Timeline



# HIV Prevention Strategies

- Abstinence
- Vaccination: Hepatitis B and HPV
- Mutual Monogamy
- Reducing the number of sex partners
- Avoid drugs and alcohol
- Condoms
- Dental dams
- Use a water-based lubricant
- Avoid sex with anyone who has symptoms of an STD
- Avoid sex with anyone who uses IV drugs
- Regular STD screening for all partners
- Pre-Exposure Prophylaxis (PrEP)
- Post-Exposure Prophylaxis (PEP)



# Ending the AIDS Epidemic in NY State

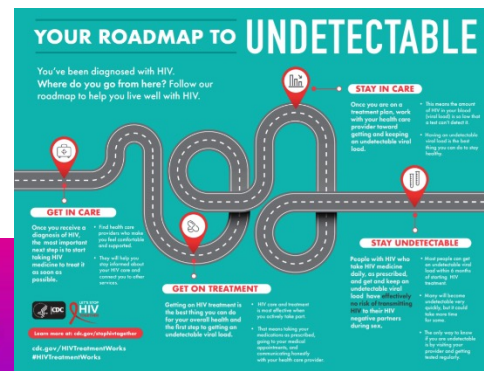
- June 29, 2014, Governor Cuomo detailed a plan to the **end of the AIDS epidemic in New York State.**
- Goal: ↓ the # of new HIV infections to just 750 by 2020 → **decrease in HIV prevalence in New York State (for the first time).**

# Ending the AIDS Epidemic in NY State

## The 3-point plan:

- **Identifies** persons with HIV who remain undiagnosed and **link** them to health care.
- Links and **retains** persons diagnosed with HIV in health care to maximize virus suppression so they remain healthy and **prevent further transmission.**
- **Facilitates** access to Pre-Exposure Prophylaxis (PrEP) for high-risk persons to keep them HIV negative.

<https://www.cdc.gov/hiv/risk/art/index.html>  
[https://www.health.ny.gov/diseases/aids/ending\\_the\\_epidemic/](https://www.health.ny.gov/diseases/aids/ending_the_epidemic/)



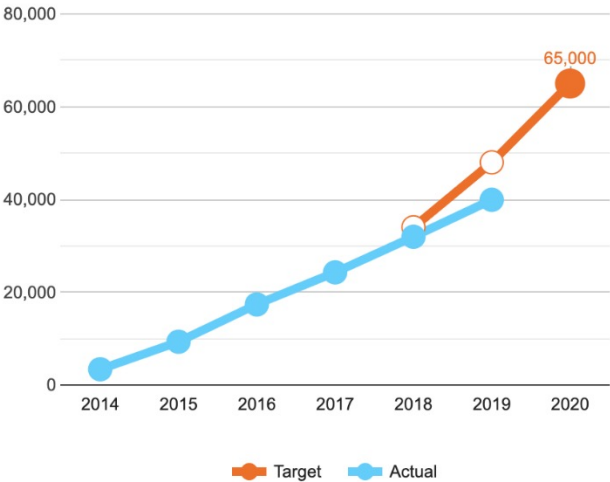
# ETE Metrics

-Ending the AIDS Epidemic in New York State by the end of 2020-

## INCREASE

the number of **individuals filling prescriptions for PrEP** to

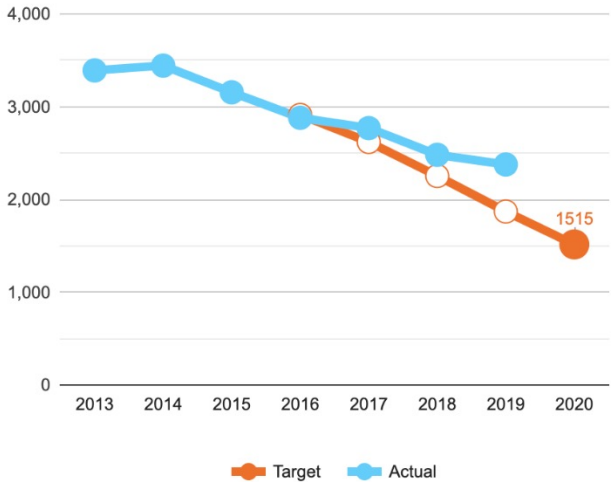
**65,000**



## REDUCE

the number of **new HIV diagnoses** by 55% to

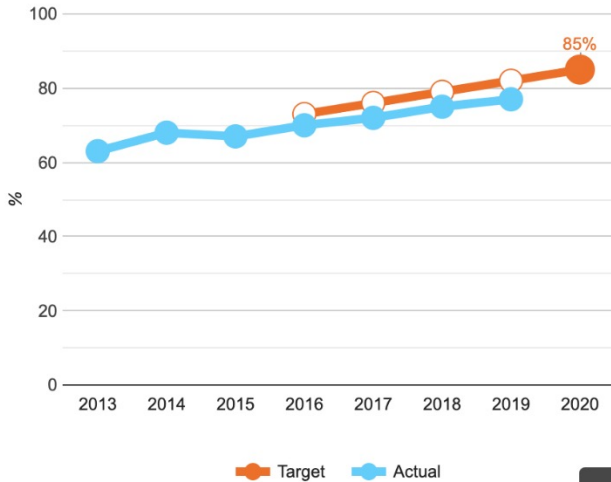
**1,515**



## INCREASE

**Viral load suppression** of all HIV-diagnosed persons to

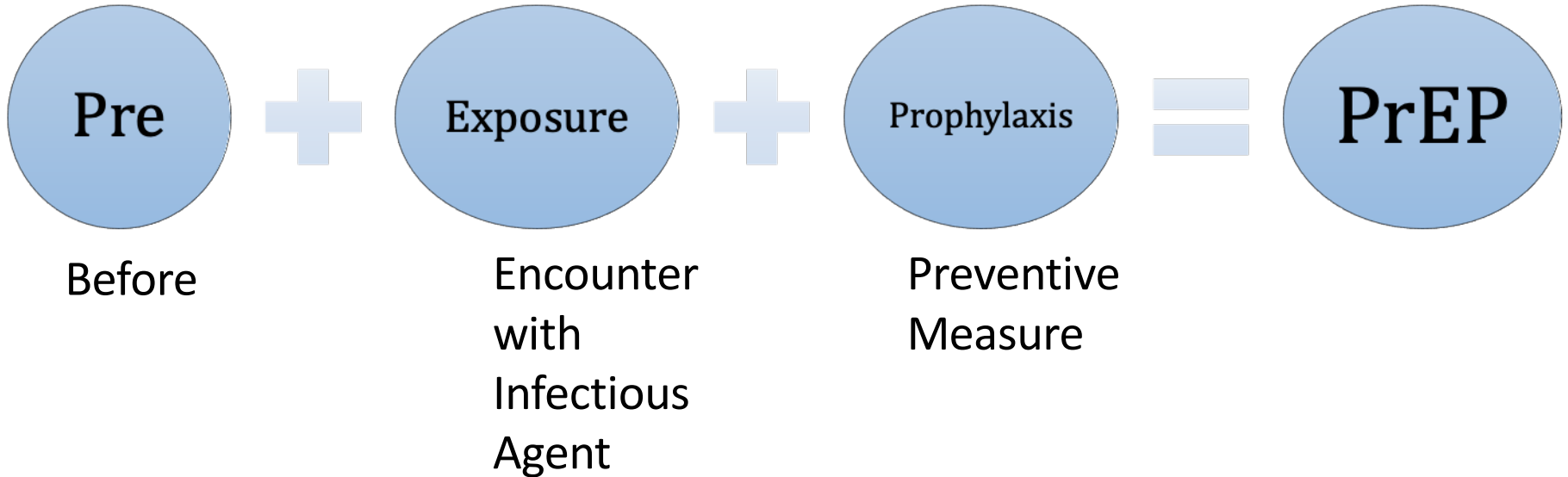
**85%**



# WHAT IS PrEP?

Let's break it down...

## Pre-Exposure Prophylaxis





# What Is PrEP?

- Once-a-day pill, Truvada<sup>R</sup> (emtricitabine/tenofovir disoproxil fumarate), that stops HIV from establishing an infection in the body
- FDA approved for adults in 2012
- Data suggests therapeutic concentration at ~20 days for blood and cervicovaginal tissue; ~7 days in rectal tissue; requiring an average of 4 pills per week
- Safe in pregnancy

<https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf>

# PrEP Approved by FDA for Adolescents

JAMA Pediatrics | Original Investigation

## Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States

Sybil G. Hosek, PhD; Raphael J. Landovitz, MD; Bill Kapogiannis, MD; George K. Siberry, MD; Bret Rudy, MD; Brandy Rutledge, PhD; Nancy Liu, MPH; D. Robert Harris, PhD; Kathleen Mulligan, PhD; Gregory Zimet, PhD; Kenneth H. Mayer, MD; Peter Anderson, PharmD; Jennifer J. Kiser, PharmD; Michelle Lally, MD; Jennifer Brothers, MPH; Kelly Bojan, DNP; Jim Rooney, MD; Craig M. Wilson, MD

- **May 2018: Truvada®** received **FDA approval** for PrEP in **adolescents** (October 2019: Descovy® received FDA approval for PrEP in adolescents as previously discussed)
- Based on data from **ATN 113**, a study of **HIV-negative adolescent males 15-17 yo** (n=78) who identified as “**males who have sex with males**” who received PrEP daily
- The study found that when the combination was taken appropriately, it can be **effective in reducing the chances for new HIV infections**. Researchers found **no evidence of harmful effects on the kidneys or bones** in this group.

# As of October 3, 2019...

FDA NEWS RELEASE

## FDA approves second drug to prevent HIV infection as part of ongoing efforts to end the HIV epidemic



For Immediate Release: October 03, 2019

*U.S. Food and Drug Administration today approved **Descovy® (emtricitabine 200 mg and tenofovir alafenamide 25 mg)** in at-risk **adults and adolescents** weighing at least 35kg for HIV-1 pre-exposure prophylaxis (**PrEP**) to reduce the risk of HIV-1 infection from sex, **excluding those who have receptive vaginal sex.***

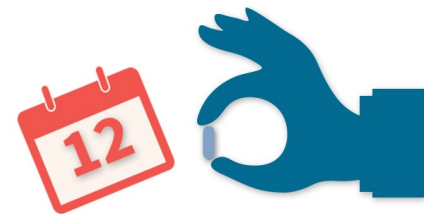
# WHO USES PrEP?

# Patient selection for PrEP

- PrEP is an option for anyone who is HIV negative
- Highest risk groups include people who:
  - have multiple or anonymous sex partners
  - do not use condoms or use condoms irregularly
  - people who have anal receptive sex; particularly gay men and trans females
  - drug use; esp. IV or mood-altering
  - survival sex
  - serodiscordant partners



PrEP is a prevention method in which **people who do not have HIV** infection **take a pill daily to reduce their risk** of becoming infected.



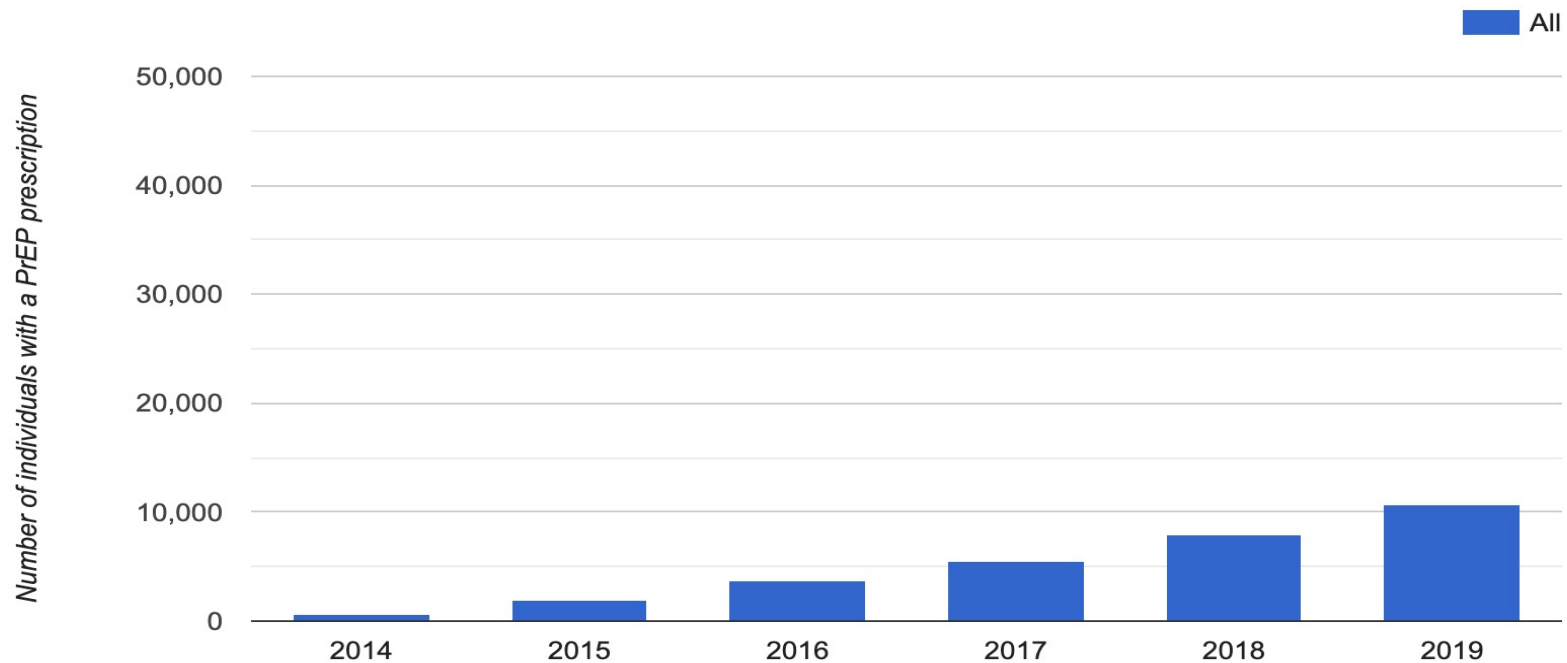
People who use PrEP must **commit to taking the drug every day** and seeing their health care provider **every 3 months for follow-up.**

Slide adapted from Fernando Mueller,  
Ashley Zuppelli and Mai-Anh Tran Ngoc

# PrEP in NYS (excluding NYC)

Total individuals in NYS with PrEP Rx (Jan '14-Dec '19) → **17,598**

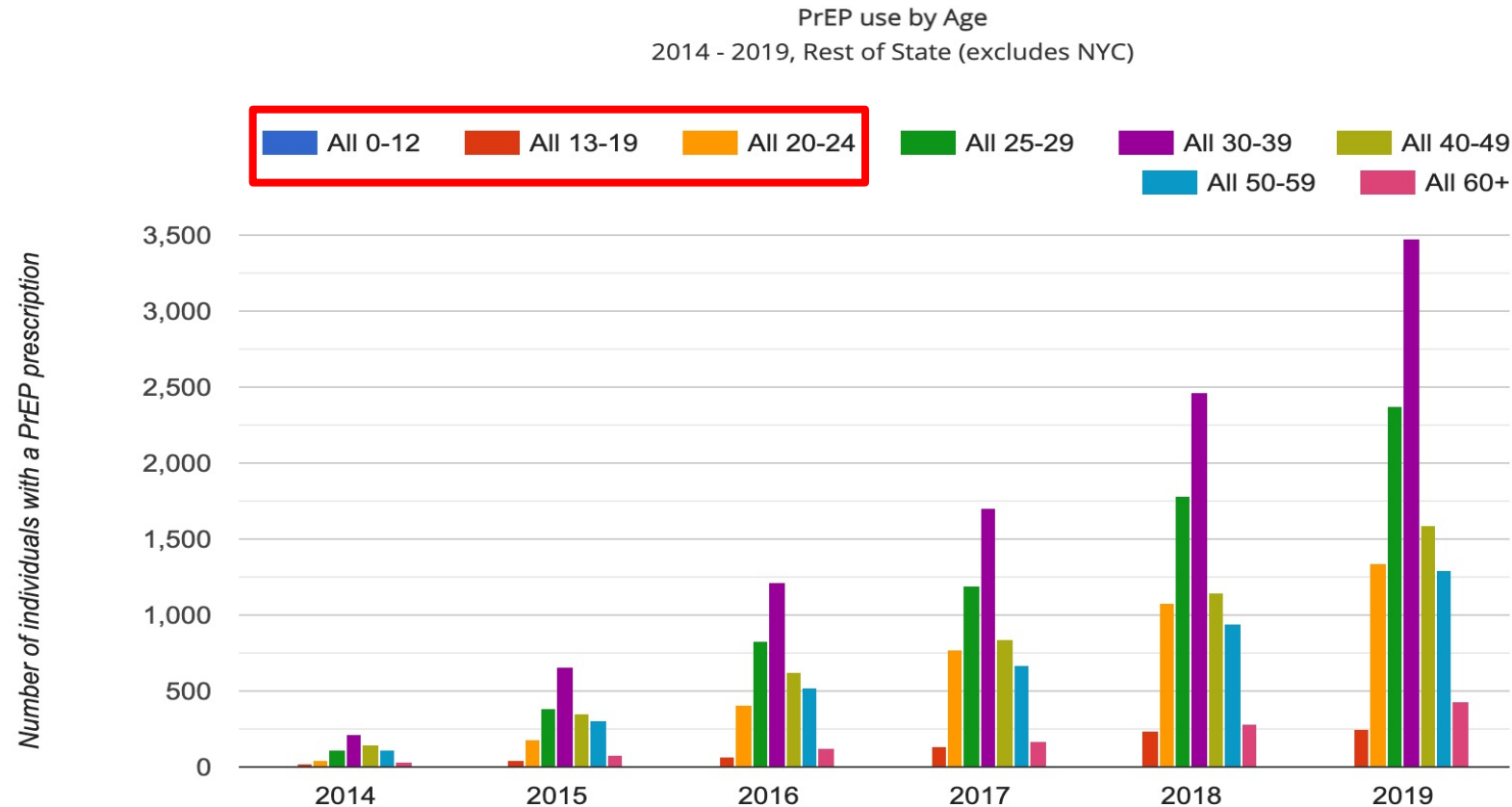
*Total PrEP use defined as persons who filled at least one PrEP prescription during a 6 month time period*



<http://etedashboardny.org/data/prevention/prep-nys/>

# PrEP use by age in NYS (excluding NYC)

Majority of PrEP use in 30-39 year olds, but a significant amount of users are adolescents

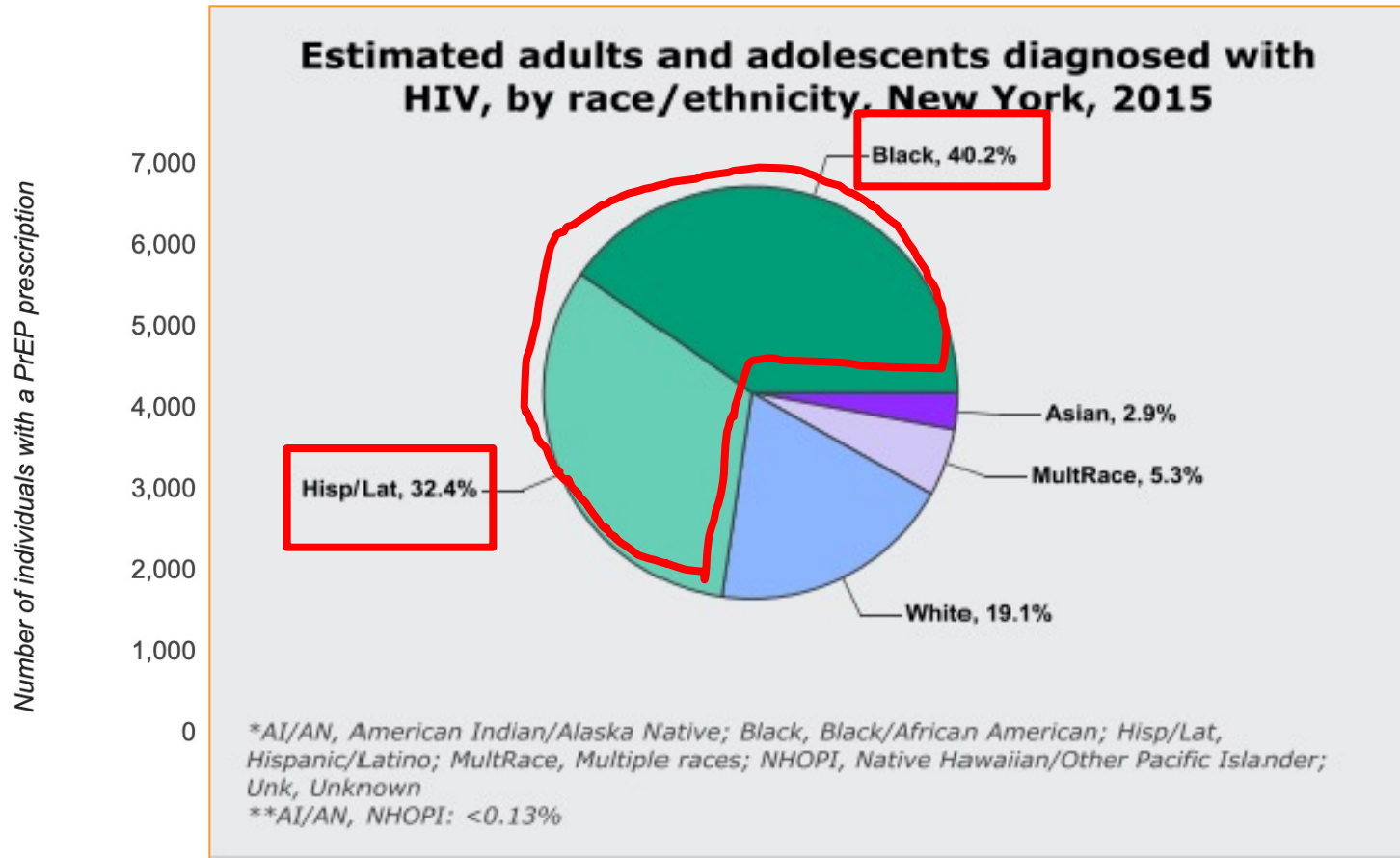


<http://etedashboardny.org/data/prevention/prep-nys/>

# PrEP use by race/ethnicity in NYS (excluding NYC)

Overwhelming majority of PrEP users are White/Caucasian; when the majority of those diagnosed with HIV are Black and Hispanic

PrEP use by Race  
2014 - 2019, Rest of State (excludes NYC)



<http://etedashboardny.org/data/prevention/prep-nys/>



# WHAT ABOUT ADOLESCENTS?

# Unique Concerns for Adolescents

## Bone Density:

- Slight decrease in BMD z scores, most in 1st 6 mons, not to abnormal ranges
- Slight decrease over the course of the study, stabilized after a year, and was reversible once discontinued (data from ATN 110, MSM age 18-22 yo)

## Adherence:

- 3 participants acquired HIV (all had sub-therapeutic levels, mean of 2 doses per week of pill) → adolescents may benefit from more frequent follow-up

## Sexual Risk Behavior:

- # of sexual partners and condom-less acts did not change significantly over time
- STI incidence declined over the course of the study (vs ATN 110, it remained stable)

Mulligan K (Wilson C presenting). *Changes in bone mass after discontinuation of PrEP with tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in young men who have sex with men (YMSM): extension phase results of Adolescent Trials Network (ATN)110*. 21st International AIDS Conference, Durban, abstract WEAC0305LB, 2016.

# Adolescent Confidentiality & Consent

- **Confidentiality:** privacy, **NOT** about keeping secrets
- **Consent:**
  - **Minors** have a right to **consent** to care for **sexual/reproductive** health concerns, **mental health** concerns, **drug or alcohol treatment**
  - **As of 2018, minors now can consent to HIV treatment and preventative services such as PrEP and PEP without a parent/guardian (10 NYCRR Part 23)**
  - *Authoritative*, NOT authoritarian approach
  - Determine what is essential; negotiate what is optional

## MINORS' RIGHTS TO CONFIDENTIAL REPRODUCTIVE & SEXUAL HEALTH CARE IN NEW YORK

When a young person seeks health care, a parent or guardian is usually involved. However, in some cases communication with parents or guardians about reproductive and sexual health care is difficult, and involving a parent can even be dangerous. In extreme cases, young people have been abused or forced to leave their homes when a parent discovers that a child is sexually active. In fact, fear of the consequences that result from disclosure prevents some young people from seeking necessary treatment or preventive care, leading to serious health consequences. This card outlines the provisions in federal and New York State law that allow minors to consent on their own to confidential health care.



[www.nyclu.org](http://www.nyclu.org)

Slide adapted from *Adolescent Medicine: The HEADSSS Assessment*  
by Katherine Blumoff Greenberg, MD

# Privacy continued...

New York State Department of Health AIDS Institute - June 2018

***FAQ 15: If a young person does not want their parent(s) or guardian(s) to be informed that they are taking PrEP or PEP, what can be done to stop the explanation of benefits form (EOB) from being sent to the parent's address?***

Minors may contact the health care plan and request that an alternative address be used when issuing an EOB for services provided to the adolescent patient. The minor, with assistance from a health or support services provider when possible, should contact the health plan to determine what procedures or forms are required to request an address change. Furthermore, minors should make this request before seeking billable health care services in order to allow enough time for the health plan to make the necessary changes to their information system. In some situations, the minor may list the health care provider's address as the alternative address for EOB notifications. Minors should be advised that Insurance Law §3234(c) allows the primary policyholder to demand an EOB even if one is not required. Adult children who are covered by their parents' insurance plan as well as other adults who are concerned about, or at risk of, retaliation from their partner or spouse may also wish to redirect EOBs. Insurance Law §2612(h)(2)(A) and 11 NYCRR 244.3 provide protections for the redirection of communications from health plans for victims of domestic violence.

[https://www.health.ny.gov/diseases/aids/providers/testing/docs/testing\\_fact\\_sheet.pdf](https://www.health.ny.gov/diseases/aids/providers/testing/docs/testing_fact_sheet.pdf)

# "THE TALK"

“Hey Doc, I’ve been thinking about it, and I think I should get on PrEP. Can you prescribe it for me?”

Next Steps:

1. Determine risk for HIV infection
2. Determine clinical eligibility
3. Initiate
4. Maintain



Slide from “Implementing PrEP in Primary Care” by Kachina M Kudroff, MPH, CHES

# “The Talk”

- Because PrEP is an option for promoting **sexual** health, we will need to talk about **sex**.
- But 25% of MSM respondents in a survey indicated that one barrier to PrEP was feeling uncomfortable talking about sexual health with their providers

Golub, S. A., Gamarel, K. E., Rendina, H. J., Surace, A., & Lelutiu-Weinberger, C. L. (2013). From efficacy to effectiveness: facilitators and barriers to PrEP acceptability and motivations for adherence among MSM and transgender women in New York City. *AIDS patient care and STDs*, 27(4), 248-254.

Slide from “Implementing PrEP in Primary Care” by Kachina M Kudroff, MPH, CHES

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ALABAMA AT BIRMINGHAM  
Knowledge that will change your world

# Asking About Sexual Behaviors

BE SPECIFIC, AND NORMALIZE THE CONVERSATION:

- Have you ever had: oral sex, vaginal sex, anal sex (may need to describe what these mean)?
- What does “safe sex” or “using protection” mean to you?
- Have you ever had sex for drugs, money or shelter?
- Has anyone touched you in a way that you did not consent to or agree with?
- Do you have any concerns about sex?
- Looking forward, do you see yourself becoming a parent in the next few years?



# Harm Reduction

## **Access to Sexual and Reproductive Health services:**

- Condoms
- STI screening (normalize as part of all visits)
- Comprehensive contraception counseling and provision (reproductive justice framework, facilitate referral if need be)
- HIV prevention services → PrEP, PEP
- Plan for close follow-up to continue the conversation (may need a few visits to build rapport)

## **Psychosocial Support:**

- Case management, vocational assistance
- Mental health services, substance abuse resources
- Housing/food/shelter resources

**OK, YOU HAVE IDENTIFIED  
AN APPROPRIATE  
PATIENT, WHAT'S NEXT?**

# Warnings and Precautions for PrEP

- **Boxed Warning:** Risk of drug resistance in undiagnosed early HIV-1 infection and post-treatment acute exacerbation of Hepatitis B
- **Contraindication:** Positive or unknown HIV status (emtricitabine/tenofovir alone is NOT a complete regimen for treating HIV-1)
- **Adverse Reactions:**
  - **Minor:** Headaches, GI upset, abnormal dreams, weight loss → usually self-resolve in a few weeks to 1 month
  - **Severe:** renal impairment (avoid in CrCl<60), possible BMD changes, lactic acidosis, severe hepatomegaly w/steatosis, drug interactions

# PrEP Follow-up

- **Baseline:** 4th gen HIV test, CMP, UA, Hep panel, site-specific STI screen, Upreg
- **1 month after initiation:** confirm HIV negative status (evaluate for acute HIV), assess tolerance, adherence
- **Q3-6 months:** CrCl, 4th gen HIV test (q3), site-specific STI screen, Upreg, assess tolerance, adherence
- **At 12 months** recheck UA, HCV, assess tolerance, adherence and indication to continue PrEP

# Patient Barriers and Facilitators to PrEP

## Barriers:

- Low perceived risk
- Not wanting to take a daily pill/adherence issues

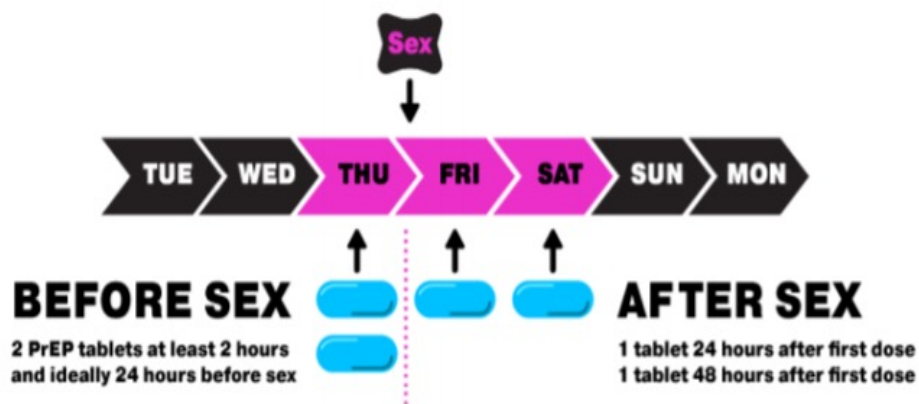
## Facilitators:

- One study showed those who reported being single, depressed, hx of arrest, knowledge of PrEP, belief in “HIV conspiracies” were more likely to use PrEP
- Recent engagement in unprotected anal intercourse
- Wanting “extra protection against HIV”

Ojikutu BO, Bogart LM, Higgins-Biddle M, et al. *Facilitators and Barriers to Pre-Exposure Prophylaxis (PrEP) Use Among Black Individuals in the United States: Results from the National Survey on HIV in the Black Community (NSHBC)*. *AIDS and Behavior*. 2018 Nov;22(11):3576-3587.

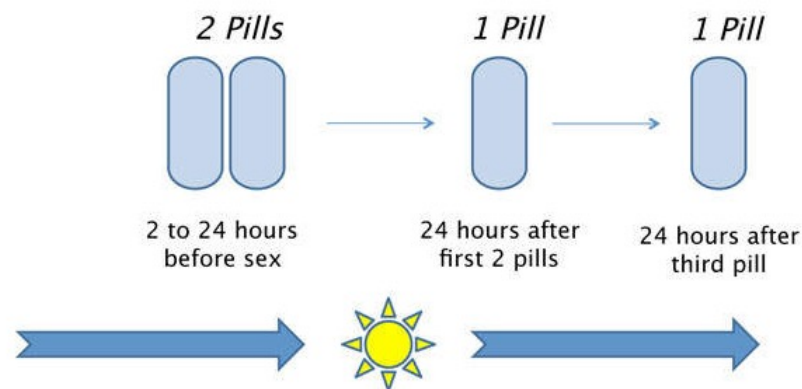
Rolle CP, Rosenberg ES, Luisi N, Grey J, et al. *Willingness to use pre-exposure prophylaxis among Black and White men who have sex with men in Atlanta, Georgia*. *Int J STD AIDS*. 2017 Aug;28(9):849-857.

# Daily PrEP Is What Is FDA Approved And Recommended, But Alternative Dosing May Be Appropriate For Certain Patient Populations.



If sexual activity continues, take 1 PrEP tablet every 24 hours until 48 hours after last sex. (Adapted from i-Base.info.)

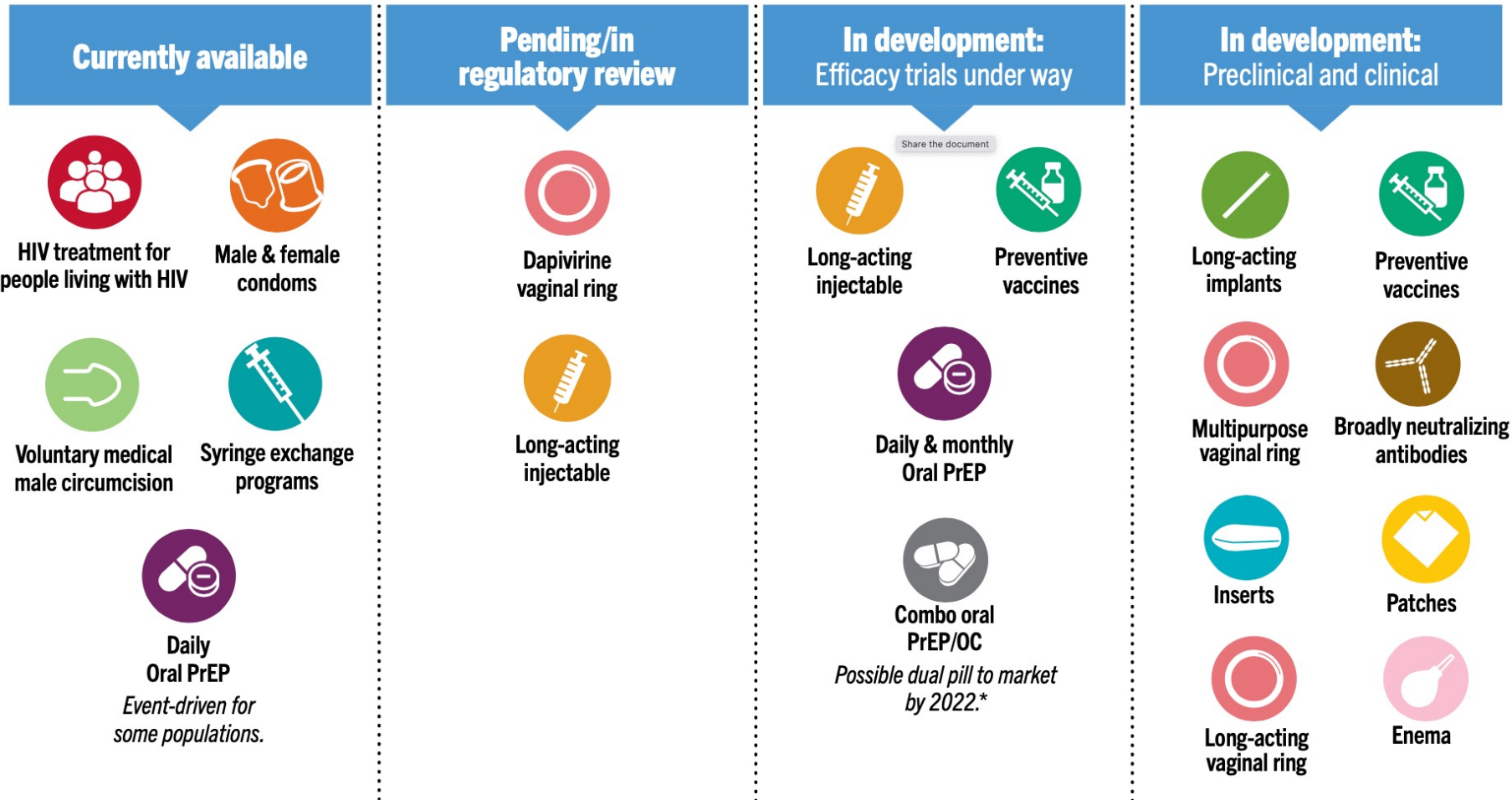
“2-1-1”  
“On-demand” PrEP



Timing of PrEP Before and After Sex Participants in a pre-exposure prophylaxis (PrEP) trial comparing TDF/FTC (Truvada) with a look-alike dummy pill aimed to take two pills 2 to 24 hours before sex, one pill 24 hours after the first two pills, and one pill 24 hours after the third pill.

The Center for AIDS Information & Advocacy

# HIV Prevention Research, Development and Implementation Pipeline in 2021—and Beyond

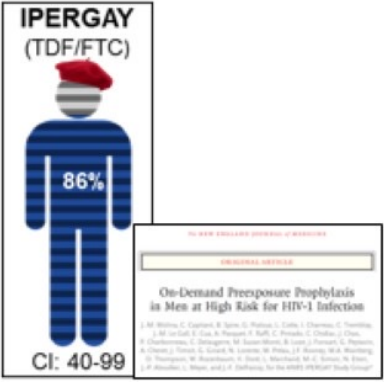
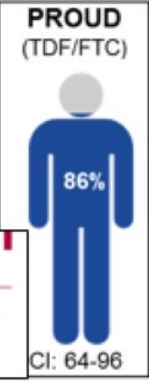
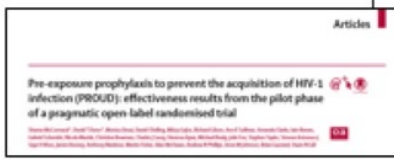
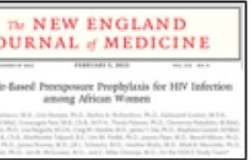
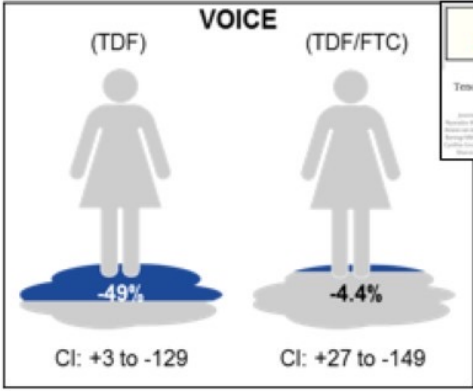
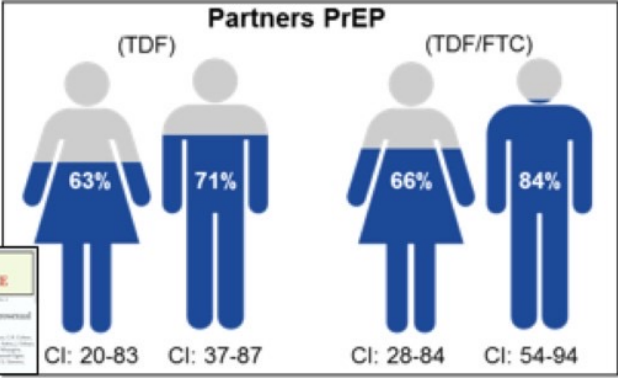
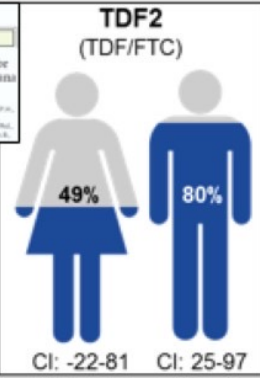
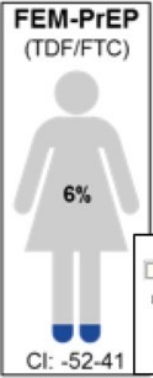
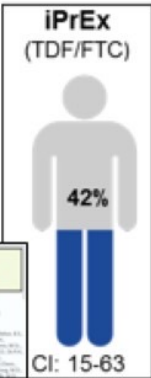


\* Efficacy trials not required; bioequivalency of the two approved products when dosed together may be all that is required.

# HOW WELL DOES PrEP WORK?



# Effectiveness of Daily TDF/FTC in Clinical Trials



Slide from "PrEP 2.0: TDF/FTC and Beyond" by Raphael Landovitz, MD, webinar, iasusa.org

# ATN 110 Results

- Well tolerated with minimal adverse events
- The number of STI diagnoses was high at onset of trial and remained high
- 4 seroconversions; higher than other PrEP studies, however those who seroconverted had undetectable drug levels, supporting non-adherence
- Adherence was lowest among black YMSM
- more nonadherence when clinic visits increased from 4 to 12 weeks.
  - Suggesting that youth need more frequent or longer visit with providers

**Executive summary** forum on adolescent prep: successes, challenges & opportunities . Meeting report/ February 2016

# The DISCOVER Study

- **Safety and efficacy** of TAF (tenofovir alafenamide) + FTC (emtricitabine) brand name Descovy® evaluated in DISCOVER Study
- **Randomized, double-blind, multinational trial** in 5,387 HIV-negative **cis men and transgender women** who have **sex with men**
- Compared daily TDF+FTC and TAF+FTC
- The primary endpoint: **rate of HIV-1 infection** in each group → TDF+FTC and TAF+FTC were **similarly efficacious** in reducing the risk of acquiring HIV-1 infection



## PrEP STUDY

**DISCOVER** is a new clinical study for men who have sex with men and trans women who have sex with men. This study is to evaluate if a once-daily investigational medicine can help reduce the risk of getting HIV infection from sex ("PrEP", or Pre-exposure Prophylaxis).

### TO BE ELIGIBLE:

- You must be at least 18 years of age
- You must be HIV negative

If you are accepted into the **DISCOVER** Study, you will receive study-related exams, lab tests, and study medicine at no cost.

For more information, please contact:  
**Linden Lalley-Charezcko** at 215-525-8695  
Or go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search NCT number 02842086



# The DISCOVER Study

- However, safety analysis showed differences between TDF+FTC and TAF+FTC
- **Both well tolerated**, mainly GI complaints
- **Bone density:** TAF+FTC did not show a decrease in BMD that has been seen with TDF+FTC
- **Renal function:** several markers examined, overall CrCl increased with TAF+FTC, compared to a decrease seen with TDF+FTC



## PrEP STUDY

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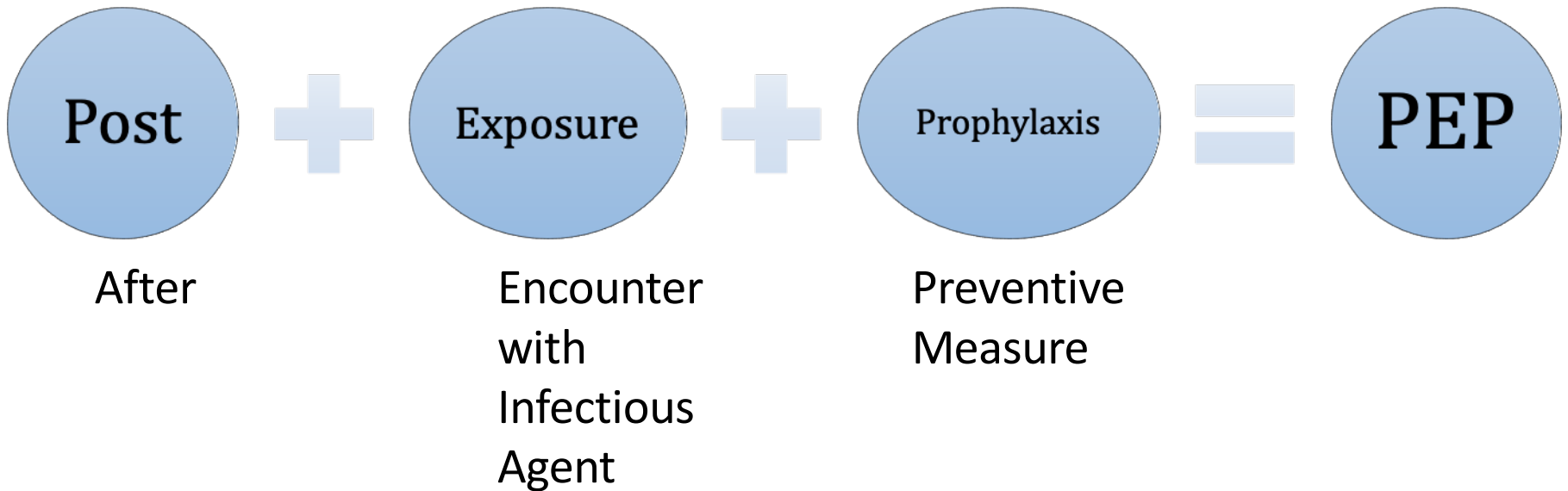
# In Summary: PrEP

- PrEP does not provide 100% protection.
- Clinical trials have demonstrated 92-99% efficacy when patients adhere to the medication
- Use of condoms during sex reduces the risk of infection even further.
- Given this exceptional efficacy, PrEP continues to be a key tool in the **HIV prevention toolkit** to end the epidemic of HIV in NYC and NYS.

# WHAT IS PEP?

Let's break it down...

## Post-Exposure Prophylaxis



# What is PEP (or nPEP)?

- PEP, **post-exposure prophylaxis**, is the use of antiretroviral medications to **prevent HIV infection in an HIV-negative person that had a recent high-risk exposure to HIV**
  - Sometimes referred to as **nPEP, non-occupational post-exposure prophylaxis**
- Because HIV can establish quickly, it is important to **start PEP quickly: within 24-36 hours and can be assessed up to 72 hours after exposure**
- **Requires an HIV negative test to start**



# Considerations for PEP

- **Adherence** support may be **essential** for some patients
  - Remembering to take the medication and manage side effects
- PEP is **unlikely to be effective** in individuals that had an exposure **over 72 hours prior**
- PEP should be used **infrequently**
  - Repeated need for PEP may indicate that a patient would be an appropriate candidate for PrEP

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# In Summary: PEP

- **FOR:** people exposed to HIV during a single event (e.g., during episodes of unprotected sex, needle-sharing injection drug use, or sexual assault)
- **TO:** try to reduce the chance of becoming HIV positive (NOT intended as primary means of HIV prevention, eg: PrEP)
- **BY:** taking anti-HIV medications as soon as possible after exposure to HIV
  - PEP must **begin within 72 hours** of exposure (req. neg HIV test)
  - PEP consists of 2-3 *antiretroviral* medications **prescribed for 28 days**
  - PEP is **safe** but may cause side effects like nausea in some people
  - These side effects can be treated and are not life threatening

<b>Post</b> = after
<b>Exposure</b> = a situation where HIV has a chance to get into someone's bloodstream
<b>Prophylaxis</b> = a treatment to stop an infection happening

90... <b>PEP</b> = a treatment to stop a person becoming infected with HIV after it's got into their body
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# RESOURCES

# PrEP and PEP Providers

- In an effort to increase access to HIV pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), the New York State Department of Health AIDS Institute (NYSDOH AI) has compiled a list of providers that prescribe PrEP/PEP:

<https://www.health.ny.gov/diseases/aids/general/prep/docs/directory.pdf>

# PrEP providers

## NYS voluntary directory

- <https://www.health.ny.gov/diseases/aids/general/prep/docs/directory.pdf>

## US Directory

- <https://prelocator.org/>

## Global directory

- <https://www.pleaseprepme.global/>

# Resources: HIV Screening and Treatment

- <http://gettested.cdc.gov/>
  - (free fast confidential testing)
- [health.ny.gov/diseases/communicable/std/clinics/clinics.htm](http://health.ny.gov/diseases/communicable/std/clinics/clinics.htm)
- National STD hotline (1-800-232-4636)



# Resource Guide

## NYS Confidentiality Hotline

- 1-800-962-5065

SMH ID Clinic Provider Hotline: 585-273-2793

## Websites

- NYS HIV Guidelines
  - <http://www.hivguidelines.org/>
  - The Statewide Forum on PrEP for adolescents
    - [http://www.hivguidelines.org/quality-of-care/prep-implementation/#tab\\_1](http://www.hivguidelines.org/quality-of-care/prep-implementation/#tab_1)





# Payment for PrEP



- Covered by Insurance
- NYSDOH PrEP patient assistance program
  - - PrEP-AP provides financial assistance to cover patient health care and lab costs (visits, HIV testing, STD and other lab tests)
  - - Facility needs to participate in the PrEP-AP program
  - - [http://www.health.ny.gov/diseases/aids/general/prep/prep-ap\\_consumer.htm](http://www.health.ny.gov/diseases/aids/general/prep/prep-ap_consumer.htm)
- Truvada for PrEP medication assistance program and Copay program
  - <http://www.gilead.com/responsibility/uspatientaccess/truvada%20for%200prep%20medication%20assistance%20program>
  - [www.GileadCoPay.com](http://www.GileadCoPay.com)

July 23, 2019

TO: All Insurers Authorized to Write Accident and Health Insurance in New York State, Article 43 Corporations, Health Maintenance Organizations, Student Health Plans Certified Pursuant to Insurance Law § 1124, and Municipal Cooperative Health Benefit Plans

RE: Health Insurance Coverage for Pre-exposure Prophylaxis ("PrEP") for the Prevention of Human Immunodeficiency Virus ("HIV") Infection and for HIV Screening

*Prior to the USPSTF recommendation on PrEP, grandfathered and non-grandfathered plans that cover prescription drugs should have been covering PrEP under their prescription drug benefit, but could impose cost-sharing. **However, now that offering PrEP with effective antiretroviral therapy to persons who are at high risk of HIV acquisition is an "A" rated recommendation, issuers, other than grandfathered health plans, must provide coverage for PrEP for the prevention of HIV infection at no cost-sharing pursuant to Insurance Law §§ 3216(i)(17)(E), 3221(l)(8)(E) and (F), and 4303(j)(3).** This will remove insurance barriers and ensure that New Yorkers have access to this important preventive medication. The Department of Financial Services ("Department") expects issuers, other than grandfathered plans, to **provide coverage for PrEP** with effective antiretroviral therapy at no cost-sharing to persons who are at high risk of HIV acquisition **as soon as possible, but no later than January 1, 2020**, for policies or contracts that are issued or renewed on or after that date.*



# Who pays for PEP?



- If prescribed PEP after sexual assault:
  - may qualify for partial or total reimbursement for medications and clinical care costs through the Office for Victims of Crime funded by the U.S. Department of Justice
- If prescribed PEP for another reason:
  - healthcare provider can help apply for free antiretroviral medications through the patient assistance programs of the drug manufacturers.

<https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/post-exposure-prophylaxis/>

# Thank you!

## Questions?

Many slides adapted from:

“HIV Basics for Health Educators” by Taylor Starr DO, MPH 10/3/16

“PrEP and PEP 101” by Mike Wilson, March 2021

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