



Children's National.

# **Pre-Exposure Prophylaxis (PrEP) for Adolescents and Young Adults (AYAs) in the Primary Care Setting**

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Financial Disclosures

**WE HAVE NO FINANCIAL DISCLOSURES.**

# Learning Objectives

- Identify AYAs at high risk for HIV acquisition
- Determine candidates for initiation of PrEP (Pre-Exposure Prophylaxis) based on updated 2017 CDC and USPHS clinical practice guidelines
- Apply clinical guidelines to counsel, initiate and manage AYAs on PrEP in the primary care setting, and if needed, in coordination with local Adolescent Medicine specialist(s)

# Why Should Pediatricians Be Concerned?

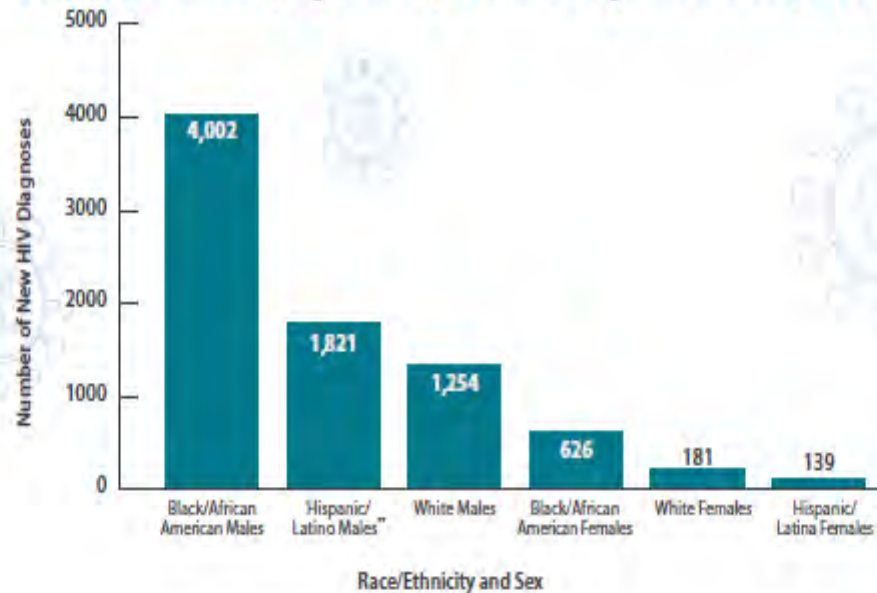
## HIV Diagnoses Among Youth in the US At a Glance

### According to the CDC:

- Only 60% of HIV infected youth are aware of their HIV status
- In 2015, AYAs ages 13-24, accounted for 22% of new HIV diagnoses
- Most new diagnoses among youth occurred in gay and bisexual men
- *As a consequence, youth with HIV are the least likely of any age group to be linked to care and have a suppressed viral load*

# New HIV Diagnoses Among Persons Aged 13-24 by Race and Gender

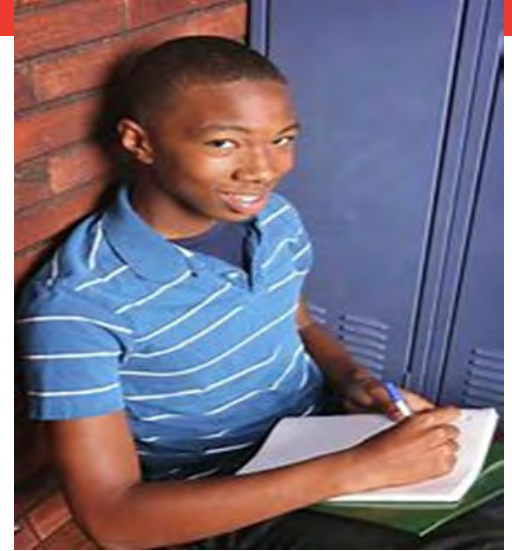
## HIV Diagnoses Among Youth in the United States, by Race/Ethnicity and Sex, 2016



Subpopulations representing 2% or less of all people who received an HIV diagnosis in 2016 are not represented in this chart.

Source: CDC. Diagnosis of HIV infection in the United States and dependent areas, 2016

## Case 1: Michael



- “Mike” is a 17 year old healthy male presenting to your clinic for his annual physical exam
- He has had insertive and receptive anal sex with 2 male partners in the last 6 months and both vaginal and insertive anal sex with 1 steady female partner in the last year
- He identifies as heterosexual and reports condom use “always”
- He has not had STI screening in 2 years because he “feels fine”
- His physical exam is normal

# Which of the following sexual behaviors pose the **MOST** risk of HIV acquisition in AYAs?

- a) Unprotected vaginal sex
- b) Unprotected insertive anal sex
- c) Unprotected receptive anal sex
- d) Any sex with substance use at time of intercourse
- e) B and D

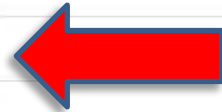
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# HIV Risk Per-Act by Sexual Exposure Behavior

| Type of Exposure                                 | Risk per 10,000 Exposures |
|--|---------------------------|
| <b>Sexual</b>                                    |                           |
| Receptive Anal Intercourse                       | 138                       |
| Insertive Anal Intercourse                       | 11                        |
| Receptive Penile-Vaginal Intercourse             | 8                         |
| Insertive Penile-Vaginal Intercourse             | 4                         |
| Receptive Oral Intercourse                       | Low                       |
| Insertive Oral Intercourse                       | Low                       |
| <b>Other^</b>                                    |                           |
| Biting   | Negligible                |
| Spitting   | Negligible                |
| Throwing Body Fluids (Including Semen or Saliva) | Negligible                |
| Sharing Sex Toys                                 | Negligible                |



<https://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html>

## Fill in the Blank:

PrEP is \_\_\_\_\_?

- a. A vaccine approved by the FDA in 2012 to prevent HIV infection when given every 2-3 months
- b. A one pill regimen that includes two HIV medications that prevent HIV infection when taken daily
- c. A one pill regimen that includes three HIV medications that prevent HIV infection when taken daily
- d. A microbicidal topical gel FDA approved for use in female patients for the prevention of HIV infection
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# Pre-Exposure Prophylaxis (PrEP) to Save the Day!



PrEP

**ONE PILL.  
ONCE A DAY.**

Protect against HIV.

## Are We PrEPared?

- >90% reduction of HIV transmission risk among *high* risk HIV uninfected patients who are committed to medication adherence
- FDA approved in 2012 for adults that are HIV uninfected
- FDA expanded indication in May 2018 to include adolescents at risk for HIV acquisition who are at least 35 kg (78 lbs)
- Once daily tablet containing 2 drugs:  
emtricitabine/tenofovir disoproxil fumerate (*TDF-FTC*)
- Marketed as *TRUVADA for PrEP*<sup>™</sup> vs. Truvada<sup>®</sup> for treatment

## Risk Behaviors that SHOULD Facilitate Provider Discussion with AYAs about PrEP Use

- Having unprotected vaginal, anal or oral sex with someone who is infected with HIV or persons with unknown HIV status
- Having multiple sexual partners
- Having prior bacterial sexually transmitted infections (STI) i.e. chlamydia or gonorrhea
- Having sex after drinking alcohol or taking drugs

# Recommended Indications for PrEP Use

- Adolescents and Adults weighing > 35kg (78 lbs)
- Without acute or established HIV infection
- Not in a monogamous relationship with a recently tested HIV negative partner
- Sex partners in the last 6 months

AND one of the following:

## **Heterosexually Active Youth**

- Behaviorally bisexual male (see →)
- Infrequent condom use with partners:
  - unknown HIV status, AND
  - bisexual or injects drugs
- Bacterial STI (syphilis or gonorrhea; not chlamydia) diagnosed or reported in the previous 6 months
- In an ongoing sexual relationship with an HIV positive person

## **MSM Youth**

- Any anal sex without condoms (receptive or insertive) in the previous 6 months
- Bacterial STI (syphilis, gonorrhea, or chlamydia) diagnosed or reported in the previous 6 months
- In an ongoing sexual relationship with an HIV positive person



# Who is the best candidate for Pre-Exposure Prophylaxis?

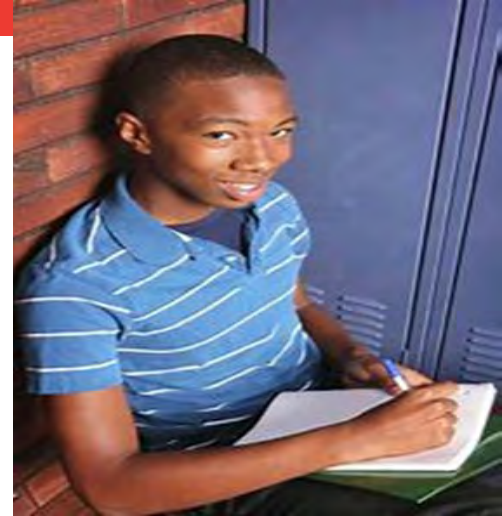
- a) 13 yo adolescent male with no sexual history onset but is interested in preventing HIV
- b) 16 yo sexually active female with recent chlamydial infection who reports female partners only and denies penetrative intercourse
- c) 17 yo MSM with SLE, lupus nephritis and subsequent stage III CKD reporting polysubstance use and multiple sexual partners in the last 6 months
- d) 15 yo female with 1 male partner with unknown HIV status reporting inconsistent condom use who is concerned that her partner has other male and female sexual partners



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## Case 1: Michael



- Based on the information provided by Michael during this visit, is he a candidate for PrEP?
  - Recall that:
    - Sexually active with both males (2 in the last 6 months) and females (1 in the last year)
    - Reported consistent condom use
    - Unknown HIV status of partners or self
- Counseling should include:
  - Discussion of increased risk for HIV based on his sexual practices
  - Education about risk reduction with condoms and medical intervention with a once a day pill
  - Initiation of PrEP or Referral to Adolescent Medicine for further management

**YES!**

# Adolescent Focused HIV Prevention Studies in the US

## ATN 110

- *18-to 22-year-old MSM*
- 200 participants
- >90% adherent at week 12;  
34% at week 48

**Relevance:** Suggested decline in adherence associated with decrease in follow up frequency

<http://europepmc.org/articles/pmc5140725>

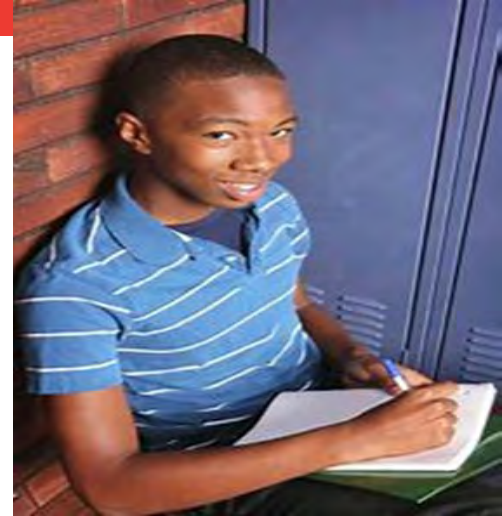
## ATN 113

- *15-to 17-year-olds MSM*
- 78 participants
- 60% adherent at week 12;  
28% at week 48

**Relevance:** Tested acceptability, safety and adherence to PrEP in adolescents

<https://jamanetwork.com/journals/jama-pediatrics/fullarticle/2652312>

## Case 1: Michael



- Michael decides that PrEP is right for him and asks you if the medication would prevent HIV as soon as he started taking it.
- How should you advise him?

# Importance of Promoting PrEP with Safer Sex Practices

- Pharmacokinetic data suggests the following protection from HIV:
  - **7 days** after PrEP initiation for persons engaging in receptive anal sex
  - **21 days** after PrEP initiation for persons participating in receptive vaginal sex
- Providers should emphasize importance of condom use during medication initiation **AND** throughout management for STI prevention



# No Proof that PrEP directly Increases STI Rates



TREATMENT NEWS

## STI Diagnoses Rise Among PrEP Users in a Northern California Health System

### PrEP May Increase STI Risk

By Veronica Hackethal, MD

Mar 19, 2018

[HIV AIDS](#),

What effect does PrEP have on sexual behavior? This meta-analysis offers sobering insights.

<http://www.theaidsreader.com/hiv-aids/prep-may-increase-sti-risk>

<https://www.poz.com/article/sti-diagnoses-rise-among-prep-users-northern-california-health-system>

# Eligibility Screening for PrEP

| Labs before initiating PrEP   | PrEP considerations   |
|---|---|
| <b>HIV testing:</b><br>HIV-1/2 Ag & Abs 4 <sup>th</sup> Generation<br>or HIV RNA PCR  | Need to confirm HIV negative status   |
| <b>Renal Function:</b><br>Creatinine  | CrCL must be $\geq 60$ mL/min   |
| <b>Hepatitis B serology:</b><br>HBsAg, HBcAb (IgM), HBsAb (IgG)                       | -If HBV infection, refer patients to provider experienced in HBV treatment<br>-If no evidence of prior immunity to Hep B, vaccinate |
| <b>Pregnancy testing (females):</b><br>Urine HCG                                      | Positive pregnancy test result does not preclude women from PrEP, but potential risks and should be discussed (category B)          |
| <b>STI testing:</b><br>RPR, gonorrhea, chlamydia<br>(at all sites of sexual activity) | No impact on use of PrEP  |

# Counseling

- Provide risk reduction and adherence counseling
  - i.e. Suggesting a pill box to help patient with adherence or setting phone alarm
- Provide anticipatory guidance about common side effects
  - Most common are GI symptoms and headache
    - Referred to commonly as “start up syndrome”
      - i.e. flatulence, nausea, weight loss
    - Patients can be supported by:
      - Counseling to take medication with food
      - Prescribing PRN anti-emetics
      - Educate patients that studies show resolution within first 4 weeks
      - Offer close follow up
- **Decreased BMD risk**
  - Greatest during first 6 months
  - Studies suggest bone loss normalizes in most patients approximately six months after discontinuation





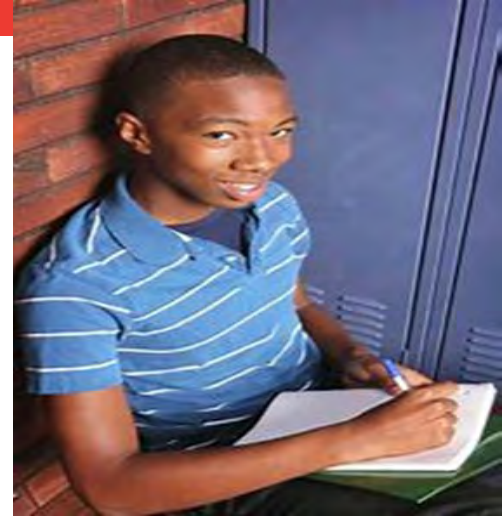
# Surveillance

| Timeframe                                    | Action  |
|--|---|
| 30 days after initiation:<br>Follow-up visit | <ul style="list-style-type: none"><li>● Assess side effects and the patient's interest in continuing</li><li>● Adherence counseling: reinforce importance of daily use and address any challenges patient has faced.</li></ul>  |
| Every 3 months:<br>labs<br>visit<br>refills  | <ul style="list-style-type: none"><li>● HIV test: 4<sup>th</sup> generation preferred</li><li>● If the patient has been off PrEP form more than a week, consider screening for acute HIV at time of PrEP re-initiation</li><li>● Creatinine: stop if CrCl &lt; 60 ml/min</li><li>● STD screening</li><li>● Pregnancy test for women; If pregnant, ensure that the patient has been informed about use during pregnancy and that she discusses PrEP use with her prenatal provider.</li><li>● Renew prescription for 90 days only if HIV test negative</li><li>● At visit: adherence and risk reduction counseling</li></ul> |

# Goals of PrEP Use for Prevention in Adolescents and Young Adults

- Ultimate goal:
  - Reduce acquisition of HIV infection, thereby reducing associated morbidity, mortality and healthcare costs
- Clinicians should:
  - Provide risk reduction counseling and offer prevention services to help minimize HIV exposure
  - Educate patients about their medication to maximize safe use
  - Prescribe medication regimens that are proven safe and effective for uninfected youth who meet criteria to reduce HIV transmission
  - Provide support for medication adherence to help patients achieve and maintain protective levels
  - Monitor closely for acute HIV infection, medication toxicities and risk behaviors

## Case 1: Micheal



- On the way out the door, Michael asks “How much will this PrEP pill cost me? I don't want to tell my mom about it.”

# What is the Cost?: Paying for PrEP

- Uninsured
  - \$1250/month for PrEP alone; without office visits and lab costs
- Medicaid
  - most plans cover (with co-pay), some require prior authorization
- Gilead PrEP patient assistance program
  - Will provide TDF-FTC at no cost for those who are uninsured and meet income guidelines <http://www.gileadcopay.com/>

# Local DC area PrEP Collaborators

## District of Columbia

### Children's National Adolescent Health Center

- Appointments for PrEP consultation
  - Medical appointments can be made with Ms. Angela Ellis, Sr. Admin Assistant, at 202-476-2178 or by calling AHC at 202-476-5464
- Appointments for **PRIDE clinic** consultations, focused on *LGTBQ youth*
  - For medical call 202-476-5464
  - For therapy call 202-476-4976

### Children's SIS/Infectious Disease Clinic

- For appts call 202-476-3508

# Other DC and Maryland PrEP Collaborators

## District of Columbia

- Andromeda Transcultural Health (Decatur Center)
- Whitman-Walker Health Headquarters
- Metro Health
- Whitman-Walker Health/Anacostia
- The Women's Collective

## Maryland

- Montgomery Infectious Disease Associates (Silver Spring, MD)
- Heart to Hand, Inc. (Largo MD)
- Chase Brexton - Columbia Center (Columbia, MD)

## Contact Us

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Thanks for your Attention!

