Pre-Exposure Prophylaxis (PrEP) for Adolescents and Young Adults (AYAs) in the Primary Care Setting
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Division of Adolescent & Young Adult Medicine
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

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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c) *Unprotected receptive anal sex*  
d) Any sex with substance use at time of intercourse  
e) B and D
HIV Risk Per-Act by Sexual Exposure Behavior

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>Risk per 10,000 Exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexual</td>
<td></td>
</tr>
<tr>
<td>Receptive Anal Intercourse</td>
<td>138</td>
</tr>
<tr>
<td>Insertive Anal Intercourse</td>
<td>11</td>
</tr>
<tr>
<td>Receptive Penile-Vaginal Intercourse</td>
<td>8</td>
</tr>
<tr>
<td>Insertive Penile-Vaginal Intercourse</td>
<td>4</td>
</tr>
<tr>
<td>Receptive Oral Intercourse</td>
<td>Low</td>
</tr>
<tr>
<td>Insertive Oral Intercourse</td>
<td>Low</td>
</tr>
<tr>
<td>Other*</td>
<td></td>
</tr>
<tr>
<td>Biting</td>
<td>Negligible</td>
</tr>
<tr>
<td>Spitting</td>
<td>Negligible</td>
</tr>
<tr>
<td>Throwing Body Fluids (Including Semen or Saliva)</td>
<td>Negligible</td>
</tr>
<tr>
<td>Sharing Sex Toys</td>
<td>Negligible</td>
</tr>
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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
e. A bank of study questions to help me pass my pediatric maintenance of certification (MOC) exam.
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Pre-Exposure Prophylaxis (PrEP) to Save the Day!
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™ vs. Truvada® 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

June 12, 2018
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
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

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

http://europepmc.org/articles/PMC5140725
https://jamanetwork.com/journals/jamapediatrics/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

http://www.theaidsreader.com/hiv-aids/prep-may-increase-sti-risk
## Eligibility Screening for PrEP

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

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<tr>
<th>Timeframe</th>
<th>Action</th>
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| 30 days after initiation:  
  Follow-up visit               | • Assess side effects and the patient’s interest in continuing  
                                    • Adherence counseling: reinforce importance of daily use and address any challenges patient has faced. |
| Every 3 months:  
  labs  
  visit  
  refills | • HIV test: 4th generation preferred  
                                    • If the patient has been off PrEP form more than a week, consider screening for acute HIV at time of PrEP re-initiation  
                                    • Creatinine: stop if CrCl < 60 ml/min  
                                    • STD screening  
                                    • 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.  
                                    • Renew prescription for 90 days only if HIV test negative  
                                    • At visit: adherence and risk reduction counseling |
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/](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 *LGBTQ 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)
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Thanks for your Attention!