Hakuna Truvada

IMPLEMENTING HIV PRE-EXPOSURE PROPHYLAXIS IN PRIMARY CARE OF ADOLESCENT AND YOUNG ADULTS

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Disclosures:

- I have no actual or potential conflict of interest in relation to this program/presentation
- I will be discussing “off-label” uses of medications
Los Angeles Public Service Announcement
Chemoprophylaxis...say what?

- Using medications to PREVENT illness
- Why???
  - Reduce incidence
- Is this new?? No!
  - Birth control
  - Vaccinations
  - Antibiotics in immunocompromised
Pre-exposure Prophylaxis for HIV - used by those without acute or established HIV infection

Truvada - 2 antiretroviral medications, 1 pill
- Tenofovir disoproxil fumarate (TDF) 300mg and emtricitabine (FTC) 200mg
- Reverse transcriptase inhibitors
  - Prevents virus from replicating
  - Virus unable to replicate = no infection
What research supports this use?

- **Men who have sex with men (iPrEX, N Engl J Med 2010)**
  - Results: Reduced HIV acquisition by 44%

  - Results: Reduced HIV acquisition by 67-75%

  - Results: Reduced HIV acquisition by 62%

- **PROUD (Lancet 2015)**
  - Results: Reduced HIV acquisition by 86%

- **TDF2 OLE (IAS 2015)**
  - Results: 0 HIV infections; 5-6 expected

- **Kaiser (Clin Infect Dis 2015)**
  - Results: 0 HIV infections; ~9% incidence expected
Research in Adolescent Population

- **15-to 17-year-olds in 6 U.S. cities (ATN 113)**
  - HIV incidence 6.4 per 100 person-years
  - 60% adherent at week 4; 28% at week 48

- **18-to 22-year-olds in 12 U.S. cities (ATN 110)**
  - HIV incidence 3.9 per 100 person-years
  - ~55% adherent at week 4; 34% at week 48
HIV and Youth

Of the 39,782 HIV diagnoses in 2016:

- 6,848 were among youth aged 13 - 24
- 8,451 were among young gay and bisexual men
- 4 out of 5 youth diagnosed with HIV were aged 20 – 24
- 21% of all new HIV diagnoses in the US were among youth
HIV Diagnoses Among Young Gay & Bisexual Men 2016

- Total HIV diagnoses among young people (13-24) in the US: 8,536
- 81% of all diagnoses in youth were among young gay and bisexual men.

Of all young gay and bisexual men who received an HIV diagnosis:

- 54% were black
- 25% were Hispanic/Latino
- 16% were white

* Data for the United States include the 50 states, the District of Columbia, and the dependent areas of American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, the Republic of Palau, and the US Virgin Islands.
** Does not include gay and bisexual men who inject drugs.
*** Hispanic/Latino can be of any race.
People who exchange sex for resources

- Estimated 10 times more at likely to acquire HIV compared with the general population (avert.org)
  - increased likelihood of being economically vulnerable, unable to negotiate consistent condom use, and experiencing violence, criminalization and marginalization
Cultural Safety

Caring for unique experience of the individual

Awareness of personal biases and assumptions
  • Gender, sexuality, etc.

Recognizing structural inequalities and power imbalance in health care

Patient centered individualized care
  • Ask patient about their needs & goals for care

(Ramsden, 1990 & Kelle & Fitton, 2016)
Vote with Your Feet
Sexual Health History

- CDC +2
  - Partners (who & how many)
  - Practices (how & with what)
  - Past History (STIs, pregnancies, trauma)
  - Protection (condoms, PrEP)
  - Pregnancy (prevention)
  - Pleasure
  - Conduct the interview in a sex positive way!
Safer Sex Guidelines

- In descending order, the HIV risk* for anal and vaginal sex
  - Receptive anal intercourse with ejaculation & no condom
  - Receptive vaginal intercourse with ejaculation & no condom
  - Insertive anal intercourse and no condom
  - Insertive vaginal intercourse and no condom
  - Receptive anal or vaginal intercourse with a condom
  - Insertive anal or vaginal intercourse with a condom

- Oral sex – same risk reduction pattern
  - Risk decreases as exposure to ejaculate and vaginal fluids decrease and barrier protection use increases

(HIV Counselor PRESEPECTIVES Vol 10 (2) March 2001)

*risk is a word we use as wellness professionals, do not use this term with clients
“The Talk” Game
Who should use PrEP?

CDC recommendations:

<table>
<thead>
<tr>
<th>Table 1: Summary of Guidance for PrEP Use</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Men Who Have Sex with Men</strong></td>
</tr>
<tr>
<td>Detecting substantial risk of acquiring HIV infection</td>
</tr>
<tr>
<td>HIV-positive sexual partner</td>
</tr>
<tr>
<td>Recent bacterial STI</td>
</tr>
<tr>
<td>High number of sex partners</td>
</tr>
<tr>
<td>History of inconsistent or no condom use</td>
</tr>
<tr>
<td>Commercial sex work</td>
</tr>
<tr>
<td>Commercial sex work</td>
</tr>
<tr>
<td>HIV-positive injecting partner</td>
</tr>
<tr>
<td>Sharing injection equipment</td>
</tr>
<tr>
<td>Recent drug treatment (but currently injecting)</td>
</tr>
<tr>
<td>In high-prevalence area or network</td>
</tr>
<tr>
<td>Clinically eligible</td>
</tr>
<tr>
<td>Documented negative HIV test result before prescribing PrEP</td>
</tr>
<tr>
<td>No signs/symptoms of acute HIV infection</td>
</tr>
<tr>
<td>Normal renal function: no contraindicated medications</td>
</tr>
<tr>
<td>Documented hepatitis B virus infection and vaccination status</td>
</tr>
<tr>
<td>Prescription</td>
</tr>
<tr>
<td>Daily, continuing, oral doses of TDF/FTC (Truvada), ≤90-day supply</td>
</tr>
<tr>
<td>Other services</td>
</tr>
<tr>
<td>Follow-up visits at least every 3 months to provide the following:</td>
</tr>
<tr>
<td>HIV test, medication adherence counseling, behavioral risk reduction support, side effect assessment, STI symptom assessment</td>
</tr>
<tr>
<td>At 3 months and every 6 months thereafter, assess renal function</td>
</tr>
<tr>
<td>Every 6 months, test for bacterial STIs</td>
</tr>
<tr>
<td>Do oral/rectal STI testing</td>
</tr>
<tr>
<td>Assess pregnancy intent</td>
</tr>
<tr>
<td>Pregnancy test every 3 months</td>
</tr>
<tr>
<td>Access to clean needles/syringes and drug treatment services</td>
</tr>
</tbody>
</table>

STI: sexually transmitted infection
How do you use PrEP?

- FDA approved for Adolescents at least 35kg and up
- Taken by mouth once a day
  - Max. blood concentrations reached after 20 days
    - Max. rectal tissue concentration 7 days
    - Max. cervico-vaginal tissue concentration 20 days
- Taken at least 5/7 days remains effective
- Most common side effects
  - Headache & GI symptoms
  - Anecdotal – vivid dreams
- Monitor renal function
- See a medical provider to restart
What about the young folks?

- CDC: “Adolescents weighing at least 35kg”
- Michigan: Minor consent Laws – STI screening and treatment
- Parental consent
  - MDHHS direction - + STI √, Title X clinic √, all others need parental consent
- Risk and benefits
  - Kidney changes – mild
  - Bone density

https://www.theodysseyonline.com/keeping-the-yuletide-gay
Starting PrEP

- It’s important to evaluate before starting
  - HIV 4th generation if last exposure >2wks ago or <2wks ago with no s/s of acute viral infection (follow up testing 2-4 weeks after start)
  - Creatinine clearance
  - Hep B & C

* Tests that are sent to facility labs may send home statements or bills
STI Testing

- STI testing
  - RPR – syphilis screening
  - Gonorrhea & Chlamydia
    - Inquire about all three sites
      - Urine
      - Throat
      - Rectum
- Make condoms available – if possible

* Tests that are sent to facility labs may send home statements or bills
What is the key to success?

- **Adherence** - Remembering to take the medication
- Strategies for increasing adherence with youth
  - Welcoming and affirming environment
  - Frequent follow-up
  - Make access to the medication & testing convenient
    - Observed daily dosing at school health center
  - Setting phone reminder with audio before leaving office
  - Providing pill boxes
- When taken as directed can decrease the uptake of HIV by more than 90%
### What should parents know

#### Safety & efficacy
- Used to treat children with HIV age 12 and up
- Prevent life threatening chronic condition

#### Risk reduction
- Parental and family support is #1 risk reduction method
- Support healthy choices
- Talk often, if not with parent, then another trusted adult
Post-Exposure Prophylaxis (nPEP)

- nPEP – post exposure prophylaxis
  - HIV seronegative person with possible exposure
  - Should be started within 72 hours of exposure
  - Available in Emergency Department & some Health Centers
  - 28 day treatment with Truvada & Raltegravir
- After completing 28-day PEP, start PrEP if good candidate & desired
- MDHHS nPEP Guideline
PrEP, PEP or Nah?

- 16yo AA cisgender gay young man with recent history of rectal gonorrhea who is estranged from his family: **PrEP**
- 21yo Caucasian cisgender woman reporting sexual assault 2 nights ago: **PEP**
- 18yo AA transgender woman who is unstably housed and is considering trading sex for money: **PrEP**
- 16yo Hispanic cisgender bisexual woman in mutually monogamous relationship with cisgender heterosexual male: **NAH**
- 20yo AA transgender woman who has multiple partners of unknown status who she meets on social media sites or at bars: **PrEP**
- 19yo Hispanic gay man reports condom breaking while having sex with a partner of unknown status last night: **PEP**
- 21yo Transgender man who trades sex for resources and a place to stay: **PrEP**
Michigan HIV Consultation Program

- Developed in partnership with MDHHS and HFHS
- Provider to provider advice from HIV experts at Henry Ford Hospital
  - PEP and PrEP
  - HIV disease management
  - Drug interactions
  - Perinatal treatment
- Non-urgent question submission
  - www.henryford.org/HIVconsult
Billing & Coverage

Bill as you would for sexual health visit – using z codes and billing for time
- Z70.9 – Sexual health counseling, Z71.7 – HIV Counseling
- Z11.3 – STI screening, Z11.4 – HIV screening
- Z20.2 Possible exposure to STI
- Z29.9 – Prophylactic measure

Insurance Coverage
- Medicaide coveres with $3 copay and can order 90day supply
- Private insurance coverage varies
  - High copays can apply for/activate copay card from Gilead
- Uninsured – Gilead has advancing access program that covers most

https://www.gileadadvancingaccess.com/ - can apply on line, paper or by phone
Billing for Time

- Statement at the end of the note that reads
  - Over 50% of this *** minute visit was spent on guidance and counseling regarding ***.

<table>
<thead>
<tr>
<th>E&amp;M Code</th>
<th>Description</th>
<th>Total Visit Time (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>99201</td>
<td>New Patient</td>
<td>10</td>
</tr>
<tr>
<td>99202</td>
<td>New Patient</td>
<td>20</td>
</tr>
<tr>
<td>99203</td>
<td>New Patient</td>
<td>30</td>
</tr>
<tr>
<td>99204</td>
<td>New Patient</td>
<td>45</td>
</tr>
<tr>
<td>99205</td>
<td>New Patient</td>
<td>60</td>
</tr>
<tr>
<td>99211</td>
<td>Established Patient</td>
<td>5</td>
</tr>
<tr>
<td>99212</td>
<td>Established Patient</td>
<td>10</td>
</tr>
<tr>
<td>99213</td>
<td>Established Patient</td>
<td>15</td>
</tr>
<tr>
<td>99214</td>
<td>Established Patient</td>
<td>25</td>
</tr>
<tr>
<td>99215</td>
<td>Established Patient</td>
<td>40</td>
</tr>
</tbody>
</table>
The future of PrEP

NIAID is funding research on 4 types of long-acting HIV prevention.

**INTRAVAGINAL RING (IVR)**
- Polymer ring inserted into the vagina releases antiretroviral drug over time.

**IMPLANT**
- Device implanted in the body releases antiretroviral drug over time.

**INJECTABLE**
- Long-acting antiretroviral drug is injected into the body.

**ANTIBODY**
- Antibody is infused or injected into the body.

Questions???
Resources


Contact Information

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