HIV/AIDS and PReP Update for the Primary Care OD

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DISCLOSURE STATEMENT

To participate in audience polling: www.Pollev.com/christopherw667

Learning Objectives

- Describe the Epidemic of HIV in the United States
- Discuss role of PReP in National HIV/AIDS Strategy
- Identify populations eligible for PReP
- Discuss PReP initiation and monitoring
- Discuss systems-based challenges and consideration in delivering PReP services

Early Reports

Diagnoses of HIV Infection among US Adults and Adolescents by Age at Diagnosis, 2015
Rates of Diagnoses of HIV Infection among US Adults and Adolescents by Age at Diagnosis, 2010–2014

<table>
<thead>
<tr>
<th>Year</th>
<th>13-24</th>
<th>25 - 34</th>
<th>35-44</th>
<th>45-54</th>
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<tr>
<td>2010</td>
<td>9%</td>
<td>13%</td>
<td>15%</td>
<td>15%</td>
<td>7%</td>
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<tr>
<td>2011</td>
<td>10%</td>
<td>14%</td>
<td>16%</td>
<td>16%</td>
<td>8%</td>
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<tr>
<td>2012</td>
<td>11%</td>
<td>15%</td>
<td>17%</td>
<td>17%</td>
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<td>2013</td>
<td>12%</td>
<td>16%</td>
<td>18%</td>
<td>18%</td>
<td>10%</td>
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<tr>
<td>2014</td>
<td>13%</td>
<td>17%</td>
<td>19%</td>
<td>19%</td>
<td>11%</td>
</tr>
</tbody>
</table>

Note: Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis.

Which of the following US populations has the greatest prevalence of HIV infection?
- White
- Pacific Islander
- Hispanic
- African American

Estimated HIV incidence among persons aged ≥13 years, by year of infection and selected characteristics, 2010–2016, Transmission Category

<table>
<thead>
<tr>
<th>Transmission Category</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
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<tbody>
<tr>
<td>M- to - M</td>
<td>0.5%</td>
<td>1.0%</td>
<td>59.0%</td>
<td>22.0%</td>
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<tr>
<td>IDU - Male</td>
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<td>1.0%</td>
<td>64.0%</td>
<td>19.0%</td>
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<tr>
<td>IDU - Female</td>
<td>0.5%</td>
<td>1.0%</td>
<td>63.0%</td>
<td>18.0%</td>
<td>49.0%</td>
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<tr>
<td>M- to - M + IDU</td>
<td>0.5%</td>
<td>1.0%</td>
<td>62.0%</td>
<td>17.0%</td>
<td>48.0%</td>
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<tr>
<td>Hetero - Male</td>
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<td>1.0%</td>
<td>61.0%</td>
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<td>47.0%</td>
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<tr>
<td>Hetero - Female</td>
<td>0.5%</td>
<td>1.0%</td>
<td>60.0%</td>
<td>15.0%</td>
<td>46.0%</td>
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</table>

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act (10,000 exposures)

<table>
<thead>
<tr>
<th>Exposure Act</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>Need-Share</td>
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<td>0.23</td>
<td>0.23</td>
<td>0.23</td>
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<tr>
<td>Need-Stick</td>
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<td>0.16</td>
<td>0.16</td>
<td>0.16</td>
<td>0.16</td>
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<tr>
<td>Anal-Rec</td>
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<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
<td>0.05</td>
</tr>
<tr>
<td>Anal-Ins</td>
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<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
<td>0.01</td>
</tr>
<tr>
<td>Vag-Rec</td>
<td>2.38</td>
<td>2.38</td>
<td>2.38</td>
<td>2.38</td>
<td>2.38</td>
</tr>
<tr>
<td>Vag-Ins</td>
<td>0.85</td>
<td>0.85</td>
<td>0.85</td>
<td>0.85</td>
<td>0.85</td>
</tr>
</tbody>
</table>
Rates of Diagnoses of HIV Infection among US, 2015

HIV Prevention Challenges
- Inadequate sex education
- Low rates of testing
- Low rates of condom use
- Substance use
- High rates of STIs
- Stigma around HIV
- Feelings of isolation
- Homophobia/transphobia
- Minority Stress

HIV Preventative Measures
- Abstinence
- Decrease number of sexual partners
- Regular condom use
- Avoid sex with partners symptomatic for STIs
- Regular STI screening
- Partners screened regularly for STIs
- Avoid alcohol or drug use
- Syringe exchange and other harm reduction
- PrEP (Pre-Exposure Prophylaxis)

National HIV/AIDS Strategy Vision
- The United States will become a place where new HIV infections are rare and when they do occur, every person regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination

National HIV/AIDS Strategy Goals
- Reducing new HIV infections
- Increasing access to care and improving health outcomes for people living with HIV
- Reducing HIV-related disparities and health inequities
- Achieving a more coordinated national response to the HIV epidemic

National HIV/AIDS Strategy Prevention Related Outcomes by 2020
- Reduce the number of new diagnoses by at least 25%
- Reduce the percentage of young gay and bisexual men who have engaged in HIV-risk behaviors by at least 15%
- Reduce disparities in the rate of new diagnoses by at least 15% among:
  - Gay and bisexual men
  - Young Black gay and bisexual men
  - Black females
  - Transgender women, especially Black transgender women
  - Persons living in the Southern United States
  - Latinos/Latinas
National HIV/AIDS Strategy Key Areas of Focus

- Widespread testing and linkage to care with early access to treatment
- Broad support for people living with HIV to remain engaged in comprehensive care
- Universal viral suppression
- Full access to comprehensive PrEP services
  - Increase provider training
  - Reduce barriers to PrEP
  - Increase uptake of PrEP

What is HIV Pre-Exposure Prophylaxis (PrEP)?

An HIV-negative person who engages in high-risk behavior for HIV takes one pill TDF/FTC (Truvada) once a day to prevent from becoming infected with HIV

What is the PrEP Pill?

- TDF+FTC
  - Tenofovir disoproxil fumarate (300mg)
  - Emtricitabine (200mg)
- 1 pill taken once daily
- FDA Approved to treat HIV in adolescents living with HIV if weight ≥ 35 kg and SMR 4 or 5 in 2004
- FDA Approved for HIV PrEP >18yo in 2012

How Does PrEP Work?

TDF+FTC interferes with reverse transcriptase and prevents viral replication

Potential PrEP Target Populations:

- Men who have sex with men (MSM)
- Heterosexual women and men
- Injection Drug Users (IDU)
- HIV+ sex partner
- HIV+ injecting partners
- Recent sexual STI (6 months)
- Recent drug treatment (6 months)
- Recent drug treatment but currently injecting
- Inconsistent condom use (with MSM, IDU, high risk partners)
- Commercial sex worker

Additional high-risk individuals:
- Individuals receiving PEP (especially if >1 course)
- Transgender individuals
- Individuals using stimulant drugs

During the iPrEx trial how much was the risk of contracting HIV reduced when there were detectable medication levels in the blood?
What’s the Evidence for PrEP? The iPrEX Trial

- 2500 MSM and transgender women in Peru, Ecuador, Thailand, Brazil, South Africa and United States
- Age ≥18 years old
- Randomized to daily Truvada or placebo
- Evaluated every 4 weeks
  - HIV test
  - Risk reduction and adherence counseling
  - Given new Rx and condoms

Results of the iPrEX Trial

- Overall 44% reduced risk of acquiring HIV
- Efficacy depends on compliance
  - 55% reduction if ≥55% compliance
  - 73% reduction if ≥65% compliance
- 92-99% reduction in acquiring HIV if drug level detectable in blood
- Behavior changes in BOTH groups
  - Fewer receptive anal intercourse partners
  - Increased condom use
- Differences seen in transgender women and adolescents/young adult’s 20 years

Participants received HIV testing, risk reduction counseling and condoms every 3 months

Note. Data include persons with a diagnosis of HIV infection regardless of stage of disease at diagnosis. Data have been statistically adjusted to account for missing transmission category. “Other” transmission category not displayed as it comprises less than 1% of cases.

Heterosexual contact with a person known to have, or to be at high risk for, HIV infection.

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act (10,000 exposures)

Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act (10,000 exposures) With PReP

Estimated HIV Incidence IN MSM (>18 yo)

Clinical Studies of PrEP for HIV Prevention Among Youth in the U.S.

- HIV Pre-Exposure Prophylaxis Demonstration Project and Safety Study for Young MSM
  - ATN 110: ages 18-22
  - ATN 113: ages 15-17
- Key Objectives:
  - TDF/FTC safety data
  - Examine acceptability, adherence, and measured levels of drug exposure when YMSM are provided open-label TDF/FTC
  - Examine patterns of sexual behavior
ATN 100/113: Baseline Demographics

<table>
<thead>
<tr>
<th>Age Range</th>
<th>ATN 116</th>
<th>ATN 113</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td>18-22</td>
<td>15-17</td>
</tr>
<tr>
<td>Premastrcely discontinued</td>
<td>260 enrolled, 56</td>
<td>79 enrolled, 32</td>
</tr>
</tbody>
</table>

- Racial demographics: 35% Black, 31% White, 8% Latino, 7% Other/Mixed, 2% Asian
- STI Incidence: 66.4 per 100 person-years (95% CI 0.07 - 0.9)
- HIV Incidence: 3.29 per 100 person-years (95% CI 0.07 - 0.92)

- At baseline, high rates of condomless anal sex, history of STIs, exchange sex, and being kicked out of home.
- Lower TFV-DP levels across all time points in African-American MSM.
- Reasons for discontinuing use: nausea, headache, reasons for discontinuing use was nausea, headache.

In a real world population, what impact does Truvada use have on the incidence of chlamydia, gonorrhea, and syphilis?

- Increased risk for chlamydia only
- Reduced risk for gonorrhea only
- Increased risk for syphilis only
- Reduced risk for chlamydia, gonorrhea and syphilis

Kaiser Permanente study of PrEP Users

- 657 PrEP users (majority MSM)
- 84% had multiple partners
- Behaviors changes after 6 months of PrEP:
  - 74% unchanged number of partners
  - 56% unchanged condom use
  - 41% decreased condom use

PrEP users:

- 25x more likely to contract gonorrhea
- 11x more likely to contract chlamydia
- 45x more likely to contract syphilis

Kaiser Permanente Study STI and HIV Findings

- STI Diagnoses:
  - 35% diagnosed with an STI at 6 months
  - 50% diagnosed with an STI at 12 months

BUT NO NEW HIV INFECTIONS

Many individuals on PrEP engage in high risk activities:

- Undergo more frequent screening
- Asymptomatic infections are diagnosed and treated quickly

• CHAMPS: Choices for Adolescent Prevention Methods for South Africa
  • 148 healthy sexually active HIV-uninfected South African 15-19 year olds
  • 92 females and 56 males
  • Open label study of TDF/FTC
  • 1 HIV diagnosis (discontinued use 3 months prior)
  • Followed for up to 1 year
  - Detectable blood levels in 35% of participants
  - Reasons for discontinuing use was nausea, headache

Based on data from placebo arm of CHAMPS trial with similar high rates of anal STIs

- 199 females and 49 males
- Followed for up to 1 year
- Open label study of TDF/FTC
- Detectable blood levels in 38% of participants

99 females and 49 males

- 1 HIV diagnosis (discontinued use 3 months prior)

- 148 healthy sexually active HIV-uninfected South African 15-19 year olds
- 92 females and 56 males
- Followed for up to 1 year
- Open label study of TDF/FTC
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Followed for up to 1 year

Open label study of TDF/FTC

Detectable blood levels in 38% of participants

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Followed for up to 1 year

Open label study of TDF/FTC

Detectable blood levels in 38% of participants

99 females and 49 males

1 HIV diagnosis (discontinued use 3 months prior)
HIV PrEP: More Than a Daily Medication

1. Once daily pill
2. Periodic HIV tests
3. Periodic STI screens
4. Multidisciplinary team provide risk reduction (Psychiatrist, SW, Navigators)
1. Counseling about condom use
2. Education about harm reduction
3. Counseling to promote adherence to PrEP

Great Opportunity to Provide Screening and Counseling to Healthy high risk individuals Every 3 Months!

Psychosocial Assessment

Comprehensive assessment used to assess and understand a patient’s immediate and secondary needs
- Housing
- Insurance
- Mental health
- Substance use
Assess readiness to start PrEP
Identify barriers, risk perception and other conflicting needs

Mental Health Assessment

- Anxiety
- Depression
- Substance Use
- Post-Traumatic Stress Disorder
- Nightmares, flashbacks, difficulty functioning, avoiding specific situations
- Intimate partner violence
Refer to Social Work or Psychiatrist if Appropriate

Adverse Effects of PrEP

- Mild GI affects (Nausea, Diarrhea, Gas) in ~9% of individuals
- Occasional Headache or dizziness

Symptoms usually improve within 1+ month
- Renal toxicity (<4%) * 
  - Reversible if medication stopped
- Slight decreased bone mineral density* 
  - Most self-reversed
- Pregnancy Category B
- * Noted in HIV+ individuals on TDF-FTC

Psychosocial Assessment

Follow-up appointments 1 month and 3 months after PrEP start, then at least every 3 months
- Only 90-day supply of medication prescribed

At each appointment
- Screen for difficulties with daily adherence
- Screen for adverse effects
- Screen for STI symptoms
- Discuss risk reduction and provide condoms

Recommended testing every 3 months
- HIV test
- Pregnancy test

Recommended testing every 6 months
- Serum creatinine and Creatinine (starting 3 months after PrEP start)
- STI tests (Triple Screen)
- Hepatitis C serology – annually
- Adolescents on PrEP frequently benefit from more frequent appointments

Post-exposure prophylaxis (PEP)

- Taking medications after possible exposure to HIV
- Must be started within 72 hours of exposure
- Eligibility for PEP:
  - Sexual assault
  - Unprotected anal or vaginal sex
  - Needle sharing (drug use, hormones)
- 28-day regimens
  - Preferred: Tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) with emtricitabine (200 mg) once daily plus raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily.
  - Alternative: Tenofovir DF (300 mg) with emtricitabine (FTC) (200 mg) once daily plus raltegravir (RAL) (400 mg) twice daily or ritonavir (RTV) (100 mg) once daily
- NY State Dept of Health AIDS Institute

Minimum Recommended PrEP Follow Up

- Follow-up appointments 1 month and 3 months after PrEP start, then at least every 3 months
- Only 90-day supply of medication prescribed

- At each appointment
  - Screen for difficulties with daily adherence
  - Screen for adverse effects
  - Screen for STI symptoms
  - Discuss risk reduction and provide condoms

- Recommended testing every 3 months
  - HIV test
  - Pregnancy test

- Recommended testing every 6 months
  - Serum creatinine and Creatinine (starting 3 months after PrEP start)
  - STI tests (Triple Screen)
  - Hepatitis C serology – annually
  - Adolescents on PrEP frequently benefit from more frequent appointments
PrEP Use

• CDC estimates 1.2 million possible PrEP users in U.S. in 2014 (Based on NHANES data)
  • 55% of sexually active MSM
  • 59% of IVDU
  • 0.9% of heterosexual adults

• BUT there are only 40,000 PrEP users currently

PrEP Use


PrEP Use


• Personal reasons to stop use:
  • Personal choice
  • Life change (not sexually active)
  • Fear of disclosure
  • Stigma associated with PrEP
  • Too busy
  • Unable to take pills daily
  • Unable to maintain every 3 month appointments for laboratory tests
  • Cost

• Truvada costs $1,540 per month.

PrEP Use

FTC/TDF for PrEP by Age* and Race


• Patients unaware that PrEP exists
  • 8% of sample of YBMSM age 15-24 heard about PrEP
  • Awareness associated with having disclosed sexual orientation
  • Only 31% of high risk transgender women had heard of PrEP
  • After explanation, 69% were interested in taking PrEP

• Lack of perceived risk

• Concern about need for consistent adherence

• Concern about long term side-effects

• Concern about social disinhibition

• Race-based medical mistrust

Payment Options for PrEP

INSURED PATIENTS

Medicaid
• Covers all PrEP costs
• Prior approval may be required with renewal every 3 months

Private Insurance
• Many cover PrEP costs
• Copays and deductibles apply

Gilead: Co-Pay Coupon Card
• Patient must have insurance (NOT Medicaid or Medicare)
• Covers up to $300/month for prescription copays

Gilead: Medication Assistance Program
• Patient must be uninsured or have NO prescription coverage, under 500% FPL
• Covers prescription cost

Many PrEP Programs have AMPs (Assistance Programs) to help navigate these programs.
• Providers unaware that PrEP exists
  • 34% primary care docs and nurses haven’t heard of HIV PrEP
• Discomfort performing sexual history
• Discomfort caring for sexual and gender minority groups
• Discomfort prescribing HIV medication
• Concern that patients on PrEP may engage in riskier behaviors

Who Should Prescribe PrEP?
Primary Care Docs
Subspecialists

• Provider discomfort in asking “sensitive questions” and taking sexual histories
• Studies indicate that only about 10-33% of providers obtain routine sexual histories
• And, when they do…
  • Infrequently ask about key parameters such as sexual practices
  • Wimberly et al. Journal National Medical Association 2006

Primary Care Docs Already Prescribe Preventative Medications

• Prescribe malaria prophylaxis for individuals before traveling overseas
  • Still recommend mosquito nets and insect repellent
• Don’t withhold prophylaxis if an individual refuses to use insect repellent
• Prescribing statins for individuals at risk for having a heart attack
  • Even if patients continue to eat poorly and not exercise

Primary Care Providers and Sexual History Taking

• CDC recommends use of the 5 P’s
  • Partners (men, women or both; HIV+, IDU partner)
  • Practices (insertive, receptive intercourse (vaginal or anal; IDU; exchange sex)
  • Protection from STDs/HIV (without a condom)
  • Past history of STDs/HIV (last 6 months)
  • Prevention of pregnancy (without a condom)

Comprehensive Sex History (Modified for PrEP)

• Individuals on HIV PrEP do NOT also need to use condoms
  • Condoms should be used along with PrEP
    • Protect against other STIs (which PrEP does not)
    • Provide protection prevention
    • Provide back-up prevention for HIV

Myths About HIV PrEP

• PrEP is ineffective to treat HIV infection
  • TOP-FTC alone is insufficient treatment for HIV infection
  • Individuals infected with HIV should be linked to an HIV specialist for treatment

• TOP-FTC alone is insufficient treatment for HIV infection
  • TOP-FTC alone is insufficient treatment for HIV infection

NOT

• Episodic PrEP use taken only 1 day before an expected sexual encounter is effective
  • Effective protection against HIV
    • Receptive anal sex ~ 7 days
    • Insertive sex
    • Vaginal sex

• As long as PrEP is taken at least a few times each week it will be effective
  • Efficacy of PrEP improves with better adherence
    • As makes:
      • 95% decreased risk with 1 dose
      • 89% decreased risk with 4 doses
      • 79% decreased risk with 2 doses
PrEP Support

PrEP Summary Points

- Patients on PrEP require visits at least every 3 months
  - Monitor HIV status, adherence, and side effects
- Follow-up also includes prevention services:
  - Risk-reduction counseling with access to condoms
  - STI screening
  - Mental health and substance use screening
- Individuals who become HIV+ should stop using PrEP
  - Linkage to care to specialist to begin HAART

Resources


Questions?