HIV Prevention Breakthroughs for Men Who Have Sex with Men and Transgender Individuals

Kevin Ard, MD, MPH
Brigham and Women’s Hospital and the Fenway Institute
Boston, MA

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Program Faculty: Kevin Ard, MD, MPH

Current Position: Chief Medical Resident, Brigham and Women’s Hospital, Instructor in Medicine, Harvard Medical School

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Learning Objectives

- Review the epidemiology of HIV transmission in the United States.

- Describe new HIV prevention tools.

- Discuss how to implement HIV prevention programs in patient-centered medical homes (PCMHs).
HIV Prevention Pathway

Universal HIV screening

HIV Positive
- HIV care / antiretroviral therapy

HIV Negative
- Safer sex
- Address STIs
- PEP or PrEP

Reduced HIV incidence
HIV in the United States
HIV in the United States

- Approximately 1.2 million people are living with HIV.
- There are ~50,000 new cases of HIV diagnosed every year.

CDC, 2012
HIV Incidence by Transmission Category

- MSM, 61%
- Heterosexual, 27%
- IDU, 9%
- MSM/IDU, 3%

CDC, 2011
HIV Incidence by Race and Ethnicity

- Black, 44%
- White, 32%
- Hispanic, 20%
- Asian, 2%
- Other, 2%

CDC, 2011
In which of the following is HIV incidence increasing?

A. Black heterosexual women
B. Black heterosexual men
C. Black MSM
D. White MSM
E. Injection drug users
Black MSM are disproportionately affected by HIV

CDC, 2011
HIV Incidence Among MSM and MSM/IDU

= Incidence among young, black MSM

Prejean, 2011
Why is HIV incidence highest among black MSM?

- Poor health care access
- Lower rates of HIV testing
- Higher HIV prevalence in black MSM networks
- Higher STI prevalence

CDC, 2011
Transgender women are at high risk

- Overall HIV prevalence: ~22%
- Prevalence among black transgender women: ~50%

Baral, 2013; Herbst, 2008; Schulden, 2008
Evidence-Based Approaches to Prevention

- “High-impact” prevention
- “Combination prevention”
- “PrEP Package”
Evidence-Based Interventions

ILI: Individual-level behavior change intervention; NLI: Network-level behavior change intervention; GLI: Group level Behavior change intervention. Size of bubble is proportional to strength of evidence. Blue: Behavior change; Green: Biomedical; Orange: Structural

Courtesy of Patrick Sullivan, www.nyas.org
HIV Prevention Pathway

Universal HIV screening

HIV Positive
  - HIV care / antiretroviral therapy

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  - PEP or PrEP

Reduced HIV incidence
HIV Testing

- Testing positive leads to decreased risk behavior.

- Testing is a pre-requisite for:
  - Treatment as prevention
  - Pre-exposure prophylaxis

- USPSTF grade A recommendation (draft)

Weinhardt, 1999
CDC Strategy for HIV Testing

- **Routinely** screen all adults, ages 13-64, for HIV in health-care settings.

- Testing should be **voluntary** and on an **opt-out** basis.

- Repeat screening is recommended **annually** for those at high risk.

Branson, 2006
What’s new in HIV testing?

- Newer testing algorithms which use successive immunoassays to eliminate the Western blot have been proposed.

- “Fourth generation” antibody/antigen tests shorten the window period by ~7 days.

- Home HIV tests may increase testing but raise concerns about cost, appropriate use, and follow-up.

Branson, 2010
More testing is needed

- **20%** of those with HIV do not know they are infected.

- **32%** received an AIDS diagnosis **within one year** of HIV diagnosis.
Barriers to HIV Testing

- **50%** of EDs are aware of CDC’s guidelines, and only **56%** offer HIV testing.

- Only **61%** of general internists offer HIV testing regardless of risk.

Haukoos, 2011; Korthuis, 2011
HIV testing is cost-effective

- Routine HIV testing is as cost-effective as mammography for women ages 50-69.

- Cost-effectiveness improves with better linkage of HIV-infected individuals to care.

Walensky, 2007
HIV Prevention Pathway

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Reduced HIV incidence
Early antiretroviral therapy decreases HIV transmission

1763 stable, healthy, serodiscordant couples, sexually active
CD4 count: 350 to 550 cells/mm$^3$

Randomization

Early antiretroviral therapy
CD4 350-550

Delayed antiretroviral therapy
CD4 ≤250

Cohen, 2011

Courtesy of Doug Krakower, Ken Mayer
Early antiretroviral therapy decreases HIV transmission

- Randomization

1763 stable, healthy, serodiscordant couples, sexually active
CD4 count: 350 to 550 cells/mm$^3$

Early antiretroviral therapy
CD4 350-550
- 4 infections
  - 1 linked, 3 unlinked

Delayed antiretroviral therapy
CD4 ≤250
- 35 infections
  - 27 linked, 8 unlinked

96% relative risk reduction in linked transmissions
Lapses in care limit the impact of “treatment as prevention”
HIV Prevention Pathway

Universal HIV screening

HIV Positive

HIV care / antiretroviral therapy

HIV Negative

Safer sex
Address STIs
PEP or PrEP

Reduced HIV incidence
Pre-Exposure Prophylaxis (PrEP)
## PrEP is generally effective

<table>
<thead>
<tr>
<th>Trial</th>
<th>Agent</th>
<th>Population</th>
<th>Risk Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>iPrEx</td>
<td>TDF-FTC†</td>
<td>MSM, transgender women</td>
<td>44%</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>TDF-FTC</td>
<td>Women</td>
<td>---</td>
</tr>
<tr>
<td>TDF2-CDC</td>
<td>TDF-FTC</td>
<td>Heterosexual men and women</td>
<td>62.2%</td>
</tr>
<tr>
<td>Partners PrEP</td>
<td>TDF, TDF-FTC</td>
<td>Heterosexual couples</td>
<td>75% TDF-FTC, 67% TDF</td>
</tr>
<tr>
<td>VOICE</td>
<td>TDF-FTC</td>
<td>Women</td>
<td>---</td>
</tr>
</tbody>
</table>

(†TDF-FTC = tenofovir-emtricitabine)

Adapted from van der Straten, 2012
Better adherence = better efficacy

- FTC/TDF:
  - <90% Pill Use: 20.6 (95% CI: -31.0–51.8)
  - ≥90% Pill Use: 72.8 (95% CI: 40.7–87.5)

- Placebo:
  - <90% Pill Use: (below graph)
  - ≥90% Pill Use: (above graph)

$P = 0.02$
Is PrEP Safe?

- No major safety concerns in PrEP trials
- Nausea more common with TDF-FTC than placebo
- No difference in creatinine elevations or bone fractures (potential TDF toxicities)
- No “risk compensation”
“The PrEP Package”

INTRODUCING THE “PrEP PACKAGE” FOR ENHANCED HIV PREVENTION:
A Practical Guide for Clinicians
October, 2012

PROTECTING YOURSELF FROM HIV THROUGH PRE-EXPOSURE PROPHYLAXIS (PrEP):
What You Need to Know
October, 2012

THE FENWAY INSTITUTE

THE FENWAY INSTITUTE
Determine eligibility:
- Document a negative HIV test
- Confirm high risk of infection
- Check that the creatinine clearance is ≥ 60 mL/minute

Other steps:
- Check a pregnancy test
- Check for chronic hepatitis B infection
Prescribe: TDF-FTC, 1 tablet by mouth daily

While on PrEP:
- Check an HIV test, pregnancy test, and creatinine every 2-3 months
- Assess for STIs at least every 6 months
- Counsel regarding risk reduction and adherence; provide condoms
Key Points about PrEP

- Does not replace condoms, safer sex counseling, and STI treatment.

- Must be available to highest-risk individuals.
  - Offered where these individuals access health care.
  - Affordable.

- On the horizon: Rectal microbicides, vaginal rings, injections, incorporation of PrEP with contraception.
Questions and Controversies

- What is the “lower limit” of adherence?
- What level of risk warrants PrEP?
- Who should prescribe it?
What concerns do you have about prescribing PrEP to high-risk patients?

A. Medication Adherence
B. Increased risk behavior
C. Cost
D. Something else
E. I don’t have concerns
HIV Prevention in Patient-Centered Medical Homes

- Comprehensive Care
- Patient-Centered
- Coordinated Care
- Accessible Services
- Quality and Safety
HIV Prevention in Patient-Centered Medical Homes

- **Comprehensive Care**
  - Testing, counseling, linkage to care, treatment, and PrEP at the same health center
  - Linking behavioral and biomedical care

- **Patient-Centered**
  - Addressing stigma and homophobia in healthcare
  - Understanding the social determinants of health

- **Coordinated Care**
  - Case management to ensure linkage to/retention in care for those with HIV
  - Linkage of high-risk individuals to the PrEP package

- **Quality and Safety**
  - Collecting information on SO/GI in the EMR
  - Electronic decision support for HIV testing
Summary

- HIV disproportionately affects MSM and transgender individuals.
- HIV testing is the cornerstone of most prevention interventions.
- Treatment-as-prevention and PrEP are powerful bio-behavioral tools to decrease HIV incidence.
- PCMHs offer opportunities to create and improve HIV prevention programs.
Questions?