Learning Objectives

At the end of this module, learners will be able to:

1. Describe HIV incidence, particularly among men who have sex with men and transgender women

2. Identify the current recommendations for HIV and STI screening and the importance of screening high risk populations for prevention of HIV

3. Describe how biomedical interventions including treatment as prevention, PEP, and PrEP are effective tools for reducing the incidence of new HIV cases among high risk populations
HIV in the United States

- 1,218,400 persons are living with HIV in the United States
  - 13% are unaware of their infection status
- HIV incidence has remained stable
  - ~50,000 new cases per year
- 13,712 people died in the U.S. in 2012 from AIDS
  - 658,507 have died with an AIDS diagnosis since the beginning of the AIDS epidemic
HIV in the United States

HIV Incidence by Transmission Route, 2013

Male-to-Male Sexual Contact (MSM) 65%
Injection Drug Use (IDU) 7%
Heterosexual Contact 25%
MSM/IDU 3%
Other <1%

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CDC 2015.
Men Who Have Sex with Men (MSM) are Most Affected by HIV

Estimated New HIV Infections in the United States, 2013, for the Most Affected Subpopulations

- Black MSM
- White MSM
- Hispanic/Latino MSM
- Black Heterosexual Women
- Black Heterosexual Men
- White Heterosexual Women
- Hispanic/Latino Black Heterosexual Women
- Male IDU

CDC 2015

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Gay and Bisexual Men are at High Risk

Gay and bisexual men make up only 2% of the population but are the group most affected by HIV

- 2 out of every 3 people who get HIV each year
- More than half of all people living with HIV
- About 50% of people who have died from AIDS
Black People Experience a High Burden of HIV

Diagnoses of HIV Infection in United States, 2013, by Race/Ethnicity

- Black: 46%
- Hispanic/Latino: 21%
- White: 28%
- Other: 5%

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CDC 2015
Black Males Have Highest Rates of HIV

Rate of Diagnoses of HIV Infection per 100,000 in United States, 2013

- **Male**
  - African American/Black: 105.7
  - Hispanic/Latino: 41.8
  - White: 13.8

- **Female**
  - African American/Black: 34.8
  - Hispanic/Latino: 7.0
  - White: 1.8
Young Black MSM have Very High Rates of HIV Infection

Estimated Number of New Diagnoses of HIV Infection Among Men Who Have Sex with Men, by Race/Ethnicity and Age at Infection, 2010, United States
HIV Incidence Among Young Black MSM is Rising

Estimated Number of New Diagnoses of HIV Infection Among Men Who Have Sex with Men Aged 13-24, 2007-2010, United States

CDC 2012.

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Why is HIV Incidence Highest Among Black MSM?

- Sexual risk behaviors and substance use do not explain the differences in HIV infection between black and white MSM.
- The most likely causes of disproportionate HIV infection rates are:
  - Barriers to access health care
  - Low frequency of recent HIV testing
  - Delayed treatment of STIs which facilitate HIV transmission
  - High HIV prevalence in black MSM networks, especially among those who identify as gay.

Transgender Women Have a High Prevalence of HIV

- Estimated HIV prevalence in transgender women
  - 28% in US
  - 56% in black transgender women
  - 18-22% worldwide

- Transgender women have a 49 fold increased odds of having HIV infection than other adults of reproductive age

Herbst JH et. al. AIDS Behav., 2008.
CDC 2012.
Injection Drug Use is a High-Risk Factor for HIV

- IDU accounted for 7% of new HIV infections in the U.S., 2013
- MSM and black people represent a majority of those infected with HIV through IDU
  - MSM/IDU accounts for 3% of all new HIV infections in U.S., 2013
Hispanic/Latinos are Disproportionately Affected by HIV

- Hispanic/Latino people accounted for 21.4% of new HIV infections in 2013
  - Represented only 16% of population
- HIV infection rates were 3 times that of white people in 2013
- 86% of HIV infections among Hispanic/Latinos were in men, the majority of whom identified as MSM
Basic Steps to Improve HIV Prevention in Clinical Settings

Universal HIV Screening

HIV Positive
- HIV Care / Antiretroviral Therapy / Counseling / Adherence

HIV Negative
- Safer Sex
- Address STIs
- PEP or PrEP
- Counseling / Adherence

Reduce HIV Incidence
Focus on Screening
Screening is Essential to Preventing HIV Transmission

1 in 8 people with HIV don’t know they have it.
HIV Screening Recommendations

- **USPSTF** recommends screening all adults, ages 15-65, at least once.

- The **CDC** recommends routinely screening all adults, ages 13-64, for HIV in healthcare settings regardless of risk.

- HIV screening is recommended for all persons who seek evaluation or treatment for STIs. This testing should be performed at the time of STI diagnosis.

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

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

Workowski KA, and Bolan GA. MMWR, 2015.


High Risk Populations Should be Screened at Least Annually

- IDUs and their sex partners
- People who exchange sex for money or drugs
- Sex partners of HIV-infected persons
- People who have had more than one sex partner since their last HIV test
- MSM
  - If sexually active and not in a long-term monogamous relationship

15% of gay and bisexual men living with HIV are unaware of their infection

Those at especially high risk should be tested every 3-6 months

Current State of HIV Testing

- 4th generation immunoassay preferred over 3rd generation immunoassay
  - Detection of p24 antigen
- The western blot has been replaced by successive immunoassays in the CDC recommended testing algorithm
- Rapid home HIV testing approved by the FDA
  - Concerns about cost, appropriate use, and follow-up

CDC, 2014.  
FDA, 2012.
3\textsuperscript{rd} Generation vs. 4\textsuperscript{th} Generation Timeline

HIV RNA (plasma)

HIV-1 p24 Antigen

HIV Antibody

HIV Infection

Eclipse Period

Viral Detection
Nucleic acid test

Antibody Detection
3\textsuperscript{rd} generation Immunoassay

Seroconversion window

Antibody Detection
2\textsuperscript{nd} generation Immunoassay

Antibody Detection
1\textsuperscript{st} generation Immunoassay

Acute HIV Infection

Established HIV Infection

Days

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CDC, 2014.
CDC Recommendations on HIV Testing

HIV-1/2 antigen/antibody combination immunoassay

(+)

(-)

Negative for HIV-1 and HIV-2 antibodies and p24 Ag

HIV-1/HIV-2 antibody differentiation immunoassay

HIV-1 (+)  
HIV-2 (-)  
HIV-1 antibodies detected

HIV-1 (-)  
HIV-2 (+)  
HIV-2 antibodies detected

HIV-1 (+)  
HIV-2 (+)  
HIV antibodies detected

HIV-1 (-) or indeterminate

HIV-2 (-)

HIV-1 NAT

HIV-1 NAT (+)  
Acute HIV-1 infection

HIV-1 NAT (-)  
Negative for HIV-1

(+): indicates reactive test result
(-): indicates nonreactive test result
NAT: nucleic acid test
Cost-effectiveness of Screening

- Routine HIV testing is a cost-effective intervention
  - Diagnosis of HIV infection can lead to life-sustaining interventions (e.g., antiretroviral therapy) and reduce HIV transmission.
- Cost-effectiveness improves with better linkage of HIV-infected individuals to care.
Future Directions of HIV Testing

- Rapid testing and detection of acute HIV infection
  - Currently tests for HIV antibodies only
  - Accurate, fast, and affordable
  - Less sensitive than 4th/3rd generation immunoassays
- Self-testing
  - Feasible, convenient, and increase testing
  - Potentially poor linkage to care
- Partner Notification
  - Passive, contact, and provider referral

STI Screening and HIV Prevention

- Some STIs facilitate HIV transmission.
- Sexually active MSM should be tested for STIs annually.
- Testing should be performed every 3-6 months for those who
  - Have multiple or anonymous sexual partners.
  - Use illicit drugs (especially methamphetamine) in conjunction with sex.
  - Have sex partners who engage in any of the above.

Workowski, KA etl al. MMWR, 2015.
CDC MMWR, 2006.
MSM are at High-risk for Certain STIs

- CDC recommends that annual STI screening for MSM includes:

<table>
<thead>
<tr>
<th>Test</th>
<th>STI</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syphilis Serology</td>
<td>Syphilis</td>
<td>All MSM</td>
</tr>
<tr>
<td>Urine NAAT</td>
<td>Urinary infection with N. gonorrhoeae and C. trachomatis</td>
<td>Men who have had insertive intercourse during preceding year</td>
</tr>
<tr>
<td>Rectal NAAT</td>
<td>Rectal infection with N. gonorrhoeae and C. trachomatis</td>
<td>Men who have had receptive anal intercourse during preceding year</td>
</tr>
<tr>
<td>Pharyngeal NAAT</td>
<td>Pharyngeal infection with N. gonorrhoeae</td>
<td>Men who have had receptive oral intercourse during preceding year</td>
</tr>
</tbody>
</table>

*Testing for C. trachomatis pharyngeal infection is not recommended.*

- MSM with particularly high risk behaviors should be screened every 3-6 months

Workowski, KA et al. MMWR, 2015.
CDC MMWR, 2006.
Hepatitis C and HIV

- 2.7 million infected with chronic HCV
- HIV significantly increases risk of sexual transmission of HCV
- Increasing incidence of acute HCV infection among HIV-infected MSM
  - Risk elevated by group sex and nonintravenous drug use such as cocaine
- There are now highly effective and tolerable treatments for Hepatitis C
  - Condom use is necessary to prevent sexual transmission of HCV

Lack of Awareness and Practice of HIV Screening Guidelines

- Only 50% of Emergency Departments (ED) are aware of CDC’s HIV screening guidelines, and only 56% offer HIV testing
  - Of the 3.4 million ED visits made by persons with increased risk for HIV, only 2.3% were tested for HIV.
- Only 61% of general internists offer HIV testing regardless of risk

Stigma Creates Barriers to HIV Screening

- Non-supportive relationships with health care providers
- Fear of stigma from community
- High perceived cost and low perceived benefits

Case Study: Michael

- 20 year old college student
- Self-identifies as black and gay
- Multiple male sex partners in past year
  - Behavior includes receptive anal and oral intercourse
  - Inconsistent condom use
Case Study: Michael

- Following the CDC recommendations for HIV and STI screening, how would you proceed? (more than one answer may be chosen)
  a) Avoid the topic of HIV screening altogether
  b) Tell Michael that you will be performing a lab-based HIV immunoassay and tell him that he can “opt-out”
  c) Perform STI screening including Rectal NAAT for N. gonorrhoeae and C. trachomatis, Pharyngeal NAAT for N. gonorrhoeae, and syphilis
  d) Screen every 3-6 months if risk behavior is unchanged
Focus on Treatment
**Recommendation: Treat HIV Immediately After Diagnosis**

- Antiretroviral therapy (ART) is recommended for all HIV-infected individuals
  - Reduction of disease progression
  - Prevention of HIV transmission
- Decision to start must consider:
  - Comorbid conditions
  - Patient’s willingness and readiness to initiate
  - Available resources

ART Guidelines, DHHS, 2015.
ART Reduces HIV Transmission among Heterosexual Serodiscordant Couples

- HPTN 052 Treatment as Prevention (TasP) Trial
  - 1,763 serodiscordant heterosexual couples
  - Early ART vs. delayed ART
  - Significant reduction in HIV transmission by 96%

![Graph showing cumulative probability of HIV transmission over years since randomization for early and delayed ART groups.](image-url)
ART Reduces HIV Transmission among MSM Serodiscordant Couples

- **Opposites Attract Study**
  - 0 HIV transmissions among all heterosexual and MSM couples after two years
  - 0 HIV transmissions in 150 MSM couples despite ~6,000 episodes of condomless anal sex

START Study Supports the Use of Early ART Regardless of CD4 Count

- 4,685 HIV-infected men and women at 215 sites in 35 countries
- ART-naïve, CD4 count >500 cells/mm³
- Early ART vs. deferred ART until CD4=350 cells/mm³
- Risk of serious AIDS illness, non-AIDS illness, or death decreased by 53% in early ART group

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DSMB, 2015.
Recommended ART Regimens

- There are currently 5 recommended regimens
  - 4 Integrase Strand Transfer Inhibitor-Based Regimens (INSTI)
    - Dolutegravir/abacavir/lamivudine
    - Dolutegravir plus tenofovir disoproxil fumarate/emtricitabine
    - Elvitegravir/cobicistat/tenofovir disoproxil fumarate/emtricitabine
    - Raltegravir plus tenofovir disoproxil fumarate/emtricitabine
  - 1 Protease Inhibitor/ritonavir-Based Regimen (PI/r)
    - Darunavir/ritonavir plus tenofovir disoproxil fumarate/emtricitabine
  - Atripla (tenofovir-emtricitabine-efavirenz) is now listed as an alternative regimen due to concerns about adverse side effects
Follow-up of Patients on ART

- Monitor HIV viral load every 6 months in stable patients
- Measure CD4 count every 6-12 months in stable patients
70% of HIV-infected persons have an unsuppressed viral load

HIV Care Continuum 2013

- 87% HIV Diagnosed
- 81% Linked to Care
- 39% Engaged in Care
- 36% Prescribed ART
- 30% ≤200 copies/ml

70% with Detectable Viral Load
93% of HIV-infected youth have an unsuppressed viral load

HIV Care Continuum, Aged 13-24, SMILE Study

- HIV Infected: 100%
- Linked to Care: 68%
- Engaged in Care: 54%
- Retained in Care: 30%
- ART Initiated: 31%
- Virus Suppressed: 7%

93% with Detectable Viral Load

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Optimizing the Continuum of HIV Care Requires Eliminating Barriers

Screening Testing  Linkage  Retention Engagement  Adherence  Outcomes
Ryan White HIV/AIDS Program

- Designed to respond to populations with the highest burden of HIV:
  - Poor
  - Lack health insurance
  - Disenfranchised from the health care system
  - Communities of color

- Reaches an estimated 536,000 people each year
  - 67% live below the federal poverty line
  - 70% identify as racial/ethnic minority
Ryan White HIV/AIDS Program

- **Part A**: Grants to Eligible Metropolitan Areas
- **Part B**: Grants to States and Territories and AIDS Drug Assistance Program
- **Part C**: Capacity Development Grant Program and Early Intervention Services
- **Part D**: Services for Women, Infants, Youth, and their Families
- **Part F**: Grants for Special Programs
HIV and the Affordable Care Act

- Most people with HIV that had insurance did not experience major changes in their coverage
- For people who were uninsured, many gained new access to stable and affordable coverage
- Ryan White HIV/AIDS Program still needed
  - Especially for those in states that did not expand Medicaid
Case Study

- Michael
  - Now 24 years old
  - Currently in a 2-year monogamous relationship with Brian, an HIV-positive male
    - Reports consistent condom use with anal intercourse
  - His partner is on the INSTI-based regimen dolutegravir/abacavir/lamivudine with a suppressed undetectable viral load
Case Study

- Based on Michael’s current relationship and sexual activity, what is his risk for HIV infection and why?
  a) His partner's use of antiretroviral therapy reduces his risk of HIV infection.
  b) Anal sex confers a higher risk of HIV infection than oral sex.
  c) Consistent condom use reduces his risk of HIV infection from anal sex by approximately 70%.
  d) Integrase-inhibitor based antiretroviral regimens are not recommended by the DHHS, and Michael's risk of HIV infection is higher because his partner is using a non-recommended regimen.
Focus on Prevention
Risk Reduction Education and Counseling

- Approaches include:
  - Monogamy with an uninfected partner
  - Reduction in the number of sexual partners
  - Engaging in lower-risk sexual practices
  - Consistent and correct use of barrier methods
  - Avoiding excessive substance use

www.lgbthealtheducation.org
Condoms are effective in preventing HIV transmission

- When used consistently and correctly, condoms are effective in preventing transmission of HIV
  - Transmission rate is significantly lower among serodiscordant couples that report consistent condom use
  - 80% effective in heterosexual and 70% effective in MSM

- Statewide availability of free condoms in Louisiana led to increased condom usage, especially in high-risk groups

Post-Exposure Prophylaxis (PEP)

- Antiretrovirals initiated within 72 hours (and best if < 36 hours) after exposure
- Indicated for exposures of “substantial risk”
- Consists of 28 days of antiretroviral therapy
- Perform HIV antibody testing at 1, 3, and 6 months post-exposure
CDC algorithm for evaluation and treatment of possible non-occupational HIV exposures

**Substantial exposure risk**

- ≤72 Hours since exposure
  - Source patient known to be HIV positive
    - nPEP recommended
  - Source patient of unknown HIV status
    - Case-by-case determination

**Negligible exposure risk**

- >72 Hours since exposure
  - nPEP not recommended

**Substantial Risk for HIV Exposure**

- Exposure of vagina, rectum, eye, mouth, or other mucous membrane, nonintact skin, or percutaneous contact
  - With blood, semen, vaginal secretions, rectal secretions, breast milk, or any body fluid that is visibly contaminated with blood
  - When the source is known to be HIV-infected

**Negligible Risk for HIV Exposure**

- Exposure of vagina, rectum, eye, mouth, or other mucous membrane, intact or nonintact skin, or percutaneous contact
  - With urine, nasal secretions, saliva, sweat, or tears if not visibly contaminated with blood
  - Regardless of the known or suspected HIV status of the source

DHHS, MMWR, 2005.
The window period for PEP efficacy is narrow.
Pre-Exposure Prophylaxis (PrEP)

- A once-daily, oral medication containing 2 antiretrovirals (tenofovir-emtricitabine)
- The only medication approved for PrEP by the FDA
- Recommended for high-risk individuals by CDC and WHO
PrEP protects against HIV with continuous level of available medication

HIV
HIV
HIV
Effective Levels of ART
# CDC Guidance for PrEP Use

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

- Determine eligibility
- Prescribe tenofovir-emtricitabine 1 tablet by mouth daily
- Provide condoms and risk-reduction counseling
- Monitor closely (at every 3 months: HIV testing, follow BUN/Cr, repeated risk assessment and counseling)
- Also see NYS DOH guidelines (hivguidelines.org)
Trial Data: Support for Efficacy of PrEP

iPRES (N Engl J Med 2011)
- **Population:** 2,499 MSM and transgender women in 6 countries
- **Intervention:** Oral tenofovir-emtricitabine
- **Results:** Reduced HIV acquisition by 44%

- **Population:** 4,747 sero-discordant couples in Kenya and Uganda
- **Intervention:** Oral tenofovir-emtricitabine or tenofovir alone
- **Results:** Reduced HIV acquisition by 67-75%

- **Population:** 1,219 heterosexual men and women in Botswana
- **Intervention:** Oral tenofovir-emtricitabine
- **Results:** Reduced HIV acquisition by 62%
Trial Data: Failure to support efficacy of PrEP

- **Population:** 2,120 women in sub-Saharan Africa
- **Intervention:** Oral tenofovir-emtricitabine
- **Results:** No HIV risk reduction with PrEP

- **Population:** 5,029 women in sub-Saharan Africa
- **Intervention:** Oral tenofovir-emtricitabine, oral/vaginal tenofovir
- **Results:** No HIV risk reduction with PrEP

Adherence is the Achilles Heel of PrEP

<table>
<thead>
<tr>
<th>Pre-exposure prophylaxis trial</th>
<th>Adherence by drug-level analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partners PrEP</td>
<td>&gt; 80%</td>
</tr>
<tr>
<td>FEM-PrEP</td>
<td>&lt; 40%</td>
</tr>
<tr>
<td>VOICE</td>
<td>&lt; 40%</td>
</tr>
</tbody>
</table>

Imperfect adherence to PrEP may be less forgiving for heterosexual women.

With daily use, maximal tenofovir levels are achieved in:
- Rectal tissue after 7 days
- Cervicovaginal tissue after 20 days
Daily PrEP for women results in high adherence and drug levels

- **HPTN 067/ADAPT Study**
  - Investigate if non-daily dosing would improve adherence and coverage of sex events with pre-and post-sex PrEP dosing compared to a daily PrEP dosing regimen.
  - **Population:** 179 women who have sex with men, Cape Town, South Africa
  - **Intervention:** PrEP dosing regimens for 24 weeks: a) daily, b) time-driven: twice weekly with a post-sex dose, or c) event-driven: before and after sex.
  - **Results:** Daily dosing resulted in better coverage of sex acts and adherence, and higher drug levels.

Dispelling Concerns about PrEP

- Risk Compensation: not seen in trials
- Renal insufficiency: rare, usually reversible
- Bone demineralization: statistically significant, not clinically significant at 18 months, needs follow-up
- Development of resistance
  - Rare, almost all in patients with acute HIV
  - Tenofovir resistance is very rare
- Ongoing monitoring is needed
PrEP does not reach the people that need it most

- A minority of patients who would benefit from PrEP are taking it
  - Pharmacy data suggest that ~3200 individuals started PrEP from 2012-2014
  - HIV incidence data indicates that ~100,000 could have benefitted from PrEP
  - Or, ~44,000 HIV infections could have been prevented with aggressive scale-up of PrEP
PrEP Prescription is Initiated Mainly by Primary Care Providers

- 68% of PrEP prescriptions were written by five major specialities

- 19% Internal Medicine
- 18% Family Practice
- 11% Infectious Disease Specialists
- 10% Nurse Practitioners
- 10% Physician Assistants
- Other 32%

Case Study

- Michael
  - 26 years old
  - Still in relationship with Brian but it is now an open relationship with outside male sexual partners
  - Reports usually using condoms
  - Tested negative for HIV
Case Study

Which of the following statements are true (more than one answer may be chosen):

a) Michael is a good candidate for daily oral emtricitabine/tenofovir (PrEP)

b) Michael is at risk for developing higher risk sexual behavior through risk compensation if prescribed PrEP

c) If Michael is prescribed PrEP, he is at high risk of developing resistance to HIV should he later become infected

d) Increased adherence to PrEP medication is associated with better protection against HIV
Getting to Zero: Overcoming Barriers
Getting to Zero: Removing the Barriers

Screening Testing  Linkage  Retention Engagement  Adherence  Outcomes