Making A Difference: HIV in Primary Care

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Objectives

At the end of this session, participants will be able to

- Describe the general history and current treatment of human immunodeficiency virus (HIV)
- Identify all elements of a sexual history using the 5 Ps and GOALS frameworks
- Recommend and interpret HIV testing based on Centers for Disease Control (CDC) and US Preventive Services Task Force (USPSTF) recommendations
- Prescribe HIV pre-exposure prophylaxis (PrEP) as part of primary care
Goal

- Empower you to make sexual histories, HIV testing, and HIV prevention part of your primary care practice
Roadmap

- HIV Primer
- Taking a Sexual History
- HIV Diagnostics
- HIV Prevention
- HIV in Primary Care
HIV Pathogenesis

- HIV infection disseminates quickly in the host and causes disease in almost all patients, if left untreated.

- Although thought of as an “immune deficiency” disease, other critical factors (e.g., immune activation, inflammation) contribute to health outcomes.

- Treatment of HIV prevents viremia, decreases inflammation, and improves immune function.
https://www.hiv.uw.edu/go/basic-primary-care/staging-initial-evaluation-monitoring/core-concept/all
HIV Key Virology

1. Binding and Attachment
2. Fusion
3. Reverse Transcription
4. Integration
5. Replication
6. Assembly
7. Budding
IS HIV REALLY A PROBLEM IN THE US TODAY?
Estimated HIV Incidence among Persons Aged ≥13 Years
2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Bars indicate the range of the lower and upper bounds of the 95% confidence intervals for the point estimate.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Estimated HIV Incidence among Persons Aged ≥13 Years, by Area of Residence 2019—United States and Puerto Rico

Total = 34,800†

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty.

†Total estimate for the United States does not include data for Puerto Rico.
Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence 2019—United States and Puerto Rico

Total = 1,189,700†

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates rounded to the nearest 100 for estimates >1,000 and to the nearest 10 for estimates ≤1,000 to reflect model uncertainty. Estimates for the year 2019 are preliminary and based on deaths reported to CDC through December 2020. Estimates should be interpreted with caution due to incomplete death ascertainment for Kansas, Massachusetts, Mississippi, Nevada, North Dakota, and Vermont.

†Total estimate for the United States does not include data for Puerto Rico.
Estimated HIV Incidence among Persons Aged ≥13 Years, by Sex at Birth
2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data.
* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Estimated HIV Incidence among Persons Aged ≥13 Years, by Transmission Category 2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Estimated HIV Incidence among Males Aged ≥13 Years by Transmission Category, 2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Estimated HIV Incidence among Females Aged ≥13 Years by Transmission Category, 2010–2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).
Diagnosed Infection among Persons Aged ≥13 Years Living with Diagnosed or Undiagnosed HIV Infection, by Age, 2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Estimates for the year 2019 are preliminary and based on deaths reported to CDC through December 2020.
Estimated HIV Incidence and Population among Persons Aged ≥13 Years by Race/Ethnicity, 2019—United States

Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Hispanic/Latino persons can be of any race.

† Estimate should be used with caution; relative standard error is 30%–50%.
‡ Incidence estimate is not provided for Native Hawaiians/other Pacific Islanders; relative standard error is >50%.
HOW HAS TREATMENT FOR HIV CHANGED?
HIV Treatment over the Decades

- **1980’s**: AIDS described, pneumocystis kills 90% of patients, clinicians develop skills in diagnosing, treating and preventing complications
- **1990’s**: First effective treatments, patients respond, death rates drop
- **2000’s**: New toxicities arise, resistance identified, adherence prioritized, limitations become apparent
- **2007**: Second round of effective antiretroviral agents (e.g., integrase inhibitors, CCR5 inhibitors)
- **2013**: First serious discussions of cure
- **2015-2016**: Preexposure prophylaxis and “treatment as prevention”
AIDS in 1985 – One Patient’s Experience

- 322 IV insertions
- 14 hospital admissions
- 11 months of hospital stay
- 60 phlebotomies
- 32 chest x-rays
- 5 CT scans of head
- 3 abdominal CT scans
- 6 bronchoscopies

- 8 intubations
- 4 lumbar punctures
- 3 bone marrows
- 5 cycles of chemotherapy
- 2 lymph node biopsies
Mortality and frequency of use of protease-inhibitor based antiretroviral therapy among patients with HIV and CD4 < 100

HIV Treatment Principles

- Most antiretroviral therapy (ART) regimens use three active agents, though some new regimens may only include two.

- Most ART regimens are one or two pills a day.

- Drug interactions are a significant concern (particularly with pharmacologic boosters like ritonavir and cobicistat).

- Response to treatment is measured by drop in HIV RNA (viral load) and ultimately increase in CD4+ cell numbers.
Current Antiretroviral (ART) Classes

- Nucleoside/nucleotide reverse transcriptase inhibitors (NRTI’s)
- Non-nucleoside reverse transcriptase inhibitors (NNRTI’s)
- Protease inhibitors (PI’s)
- Fusion inhibitors
- CCR5 inhibitors
- Integrase strand transfer inhibitors (INSTI’s)
- Attachment inhibitors
- Capsid inhibitors
Current Available Medications

- **NRTI’s**: lamivudine, abacavir, emtricitabine, tenofovir
- **NNRTI’s**: efavirenz, nevirapine, etravirine, rilpivirine
- **PI’s**: ritonavir, lopinavir, atazanavir, darunavir
- **Fusion I’s**: enfuviritide
- **CCR5 I’s**: maraviroc
- **INS’s**: raltegravir, dolutegravir, elvitegravir, bictegravir, cabotegravir
- **Attachment I’s**: fostemsavir
- **Capsid I’s**: lencapgravir
Modern ART Treatment Options

▪ Most Single Tablet Regimens = 2 NRTIs + 1 “other”
  ▪ Biktarvy® = tenofovir alafenamide (TAF) + emtricitabine (FTC) + bictegravir (BIC)
  ▪ Genvoya® = tenofovir alafenamide (TAF) + emtricitabine (FTC) + elvitegravir* (EVG/c)
  ▪ Symtuza® = tenofovir alafenamide (TAF) + emtricitabine (FTC) + darunavir* (DRV/c)
  ▪ Odefsey® = tenofovir alafenamide (TAF) + emtricitabine (FTC) + rilpivirine (RPV)
  ▪ Triumeq® = abacavir (ABC) + lamivudine (3TC) + dolutegravir (DTG)

▪ Other Commonly Prescribed Medications
  ▪ Truvada® = tenofovir disoproxil fumarate (TDF) + emtricitabine (FTC)
  ▪ Descovy® = tenofovir alafenamide (TAF) + emtricitabine (FTC)
  ▪ Pifeltro® = doravirine
  ▪ Prezcobix® = darunavir* (DRV/c)
  ▪ Tivicay® = dolutegravir (DTG)

*also contains pharmacologic booster cobicistat (/c)
Benefits of HIV Treatment

- Improves survival
- Delays disease progression
- Preserves immune function
- Improves quality of life
- Reduces likelihood of transmission
Life Expectancy of People with HIV

For a person aged 21 who is diagnosed with HIV with a CD4 count ≥500 and initiated on antiretroviral therapy…

Number of expected years remaining of life found to be statistically the **SAME** as a person without HIV

Useful HIV Websites

www.seaetc.com
www.hiv.uw.edu
www.vanderbilthealth.com/vccc
www.aidsinfonet.org
www.aidsetc.org
www.hivaid.org (DHHS, USPHS/IDSA Guidelines)
www.cdc.gov/nchstp/hiv_aids.htm
www.hiv-web.lanl.gov (Resistance mutations)
www.niaid.nih.gov
www.AIDS.medscape.com
www.hopkins-aids.edu
www.ucsf.edu/medical
www.virology.net
Roadmap

- HIV Primer
- Taking a Sexual History
- HIV Diagnostics
- HIV Prevention
- HIV in Primary Care
The Sexual History

- Patients have sex in different ways.
- Patients may not anticipate discussing sex.
- Providers may not feel comfortable discussing sex.

Taking a sexual history is a potentially life-saving intervention.

- Recognize that it is a duty of responsible medical providers
- Recognize that it is a skill that improves with practice
Sexual History Misconceptions

- Married persons do not acquire STIs
- Persons who identify as “straight” only have sex with those of the opposite gender
- Persons who identify as “gay” or “lesbian” only have sex with those of the same gender
- Persons will an STI will have symptoms
Sexual History Goals

▪ To learn about the patient’s sexual health
  ▪ This is more than just assessing HIV/STI risk
    ▪ People tend to underestimate/not believe own risks

▪ To help the patient achieve the goals in their sexual health
  ▪ Emphasizes benefits over risk, which can be more effective in motivating patients toward prevention and positive care behavior
General Approach To Taking a Sexual History

- Be respectful, professional, and non-judgmental.
- Appropriate verbal and non-verbal communication.
- Use open-ended and specific questions.
- Use appropriate but specific language.
- Be aware and ask regarding gender identity and orientation.
Two Frameworks for the Sexual History

- **5 Ps** (partners, practices, protection from STI, past history of STI, pregnancy intention)

  vs

- Give a preamble/preface
- Offer opt-out HIV and STI testing
- Ask open-ended questions
- Listen for relevant information, and ask more pointed questions to fill in the blanks
- Suggest a course of action, highlighting benefits
  - Such as HIV and STI testing, PrEP, contraception counseling
  - Benefits include exerting greater control of their sexual health, decreasing anxiety about potential STI/HIV transmission
The 5 “Ps” of Sexual Health

- Partners
- Practices
- Protection from STIs
- Past History of STIs
- Pregnancy Intention

http://www.cdc.gov/std/treatment/SexualHistory.pdf
Partners

- Number and gender of partner(s)
- Length of relationship
- Partner’s risk factors

- “Are you currently sexually active?”
- “How many partners have you had in the last 30 days, 3 months, past year?”
- “Do you have sex with men, women, or both?”
Practices

- Sexual practices will assist in determining the assessment of patient's risks and help identify:
  - Risk-reduction strategies
  - Immunizations
  - Appropriate anatomical sites for STI testing

- "I am going to be more specific about the kind of sex you've had over the last 12 months to better understand if you are at risk for sexually transmitted infections."

- "What kind of sexual contact do you have or have you had?"
  - "Have you had vaginal sex, meaning the penis in the vagina?"
  - "Have you had oral sex, meaning the mouth on the penis or vagina?"
  - "Have you had anal sex, meaning the penis in the anus?"

- "Are you a top, bottom, or vers?"
  - Top = anal insertive
  - Bottom = anal receptive
  - Vers/versatile = both insertive and receptive
Protection from STIs

- Based on prior discussion, explore options for protection from STIs, such as:
  - Need for STI testing
  - Patient’s perception of self-risk
  - Barrier protection (i.e., condoms)
  - Benefit of immunizations (i.e., hepatitis A, hepatitis B, and/or HPV)

- “Do you and your partner(s) use any protection against sexually transmitted infections?”
  - If not… “Why do you not use protection?”
  - If so… “What kind of protection do you use?”

- “How often do you use this protection?”
  - If sometimes… “In what situations or with whom do you use protection?”
Past History of STIs

- Discuss and document history of prior STIs
  - Prior STIs increase risk of future STIs

- “Have you ever been diagnosed with a sexually transmitted infection? When? How were you treated?”

- “Have you ever been tested for HIV or other sexually transmitted infections?”

- “Has your current partner or any former partners ever been diagnosed or treated for a sexually transmitted infection?”
  - If so… “Were you tested for the same infection?”
  - If yes and positive… “Were you treated?”
Pregnancy Intention

- Identify pregnancy intention
- Ask about contraceptive use and compliance
- Provide contraceptive education
- Identify unmet contraceptive use (including emergency contraception)
- Ask men about contraception and provide information (i.e., male methods of contraception)

- “Are you currently trying to conceive / father a child?”
- “Are you concerned about getting pregnant or getting your partner pregnant?”
- “Are you using contraception or practicing any form of birth control? Do you need any information on birth control?”
The 5 “Ps” of Sexual Health

- Partners
- Practices
- Protection from STIs
- Past History of STIs
- Pregnancy Intention
The GOALS Framework

• Reframes the sexual as an INTERVENTION that can:

  • Increase rates of routine HIV and STI screening
  • Increase rates of universal biomedical prevention and contraceptive education
  • Increase patients’ motivation for and commitment to sexual health behavior
  • Enhance the patient-care provider relationship, making it a lever for sexual health specifically and overall health and wellness in general

Sarit A. Golub, PhD, MPH, Hunter College and Graduate Center, City University of New York, in collaboration with the NYC Department of Health and Mental Hygiene, Bureau of HIV, July 2019.
GOALS

▪ Give a preamble/preface
▪ Offer opt-out HIV and STI testing
▪ Ask open-ended questions
▪ Listen for relevant information, and ask more pointed questions to fill in the blanks
▪ Suggest a course of action, highlighting benefits
  ▪ Such as HIV and STI testing, PrEP, contraception counseling
  ▪ Benefits include exerting greater control of their sexual health, decreasing anxiety about potential STI/HIV transmission
GOALS: Preamble/Preface Example

“I talk to all my patients about sexual health, because it’s such an important part of overall health. Some of my patients have questions or concerns about their sexual health, so I want to make sure I understand what your questions or concerns might be and provide whatever information or other help you might need.”

Sarit A. Golub, PhD, MPH, Hunter College and Graduate Center, City University of New York, in collaboration with the NYC Department of Health and Mental Hygiene, Bureau of HIV, July 2019.
Other Things to Think About When Taking a Sexual History

- Safety (e.g., domestic violence)
- Trading sex for money, drugs, or shelter
- Travel
Sexual History Scripting

- “Tell me about your sex life.”

- “About how many partners have you had in the past 6 months?”

- “Tell me about your sexual partners.”

- “What gender are your partners?”

- “Are you a top, bottom, or vers?”
  - Top = anal insertive
  - Bottom = anal receptive
  - Vers/versatile = both insertive and receptive
Sexual History Scripting Part 2

- “What do you do to prevent STDs?”

- “How do you prevent pregnancy?”

- “Do you use condoms? What percentage of the time would you say you use condoms?”
Sexual History Scripting Part 3

- “Are any of your partners HIV-positive?”
  - If so, “do you know if they’re undetectable?”

- “Have any of your partners recently had an STD?”

- “Have you ever had an STD?”

- “Have you ever had HIV or STD testing?”
Sexual History Scripting Part 4

- “Do you ever use drugs, like poppers or meth, when you have sex?”

- “Do any of your partners make you scared or feel unsafe?”

- “Do you ever have to use sex to get things you need, like money to get food or to pay bills?”
Sexual History Debriefing

- What observations do you have about the video?
- What comments, questions, and/or concerns to you have about taking a sexual history?
Sexual History Summary

- The sexual history is a crucial part of delivering comprehensive primary care.

- Frame the sexual history in terms of benefits for the patient over risk factors.

- Include opportunities for opt-out HIV and STI screening in the sexual history.

- The 5 Ps and GOALS frameworks can provide useful guides.
Roadmap

- HIV Primer
- Taking a Sexual History
- HIV Diagnostics
- HIV Prevention
- HIV in Primary Care
Goals of HIV Testing

- Improve Survival & Quality of Life
- Prevent New HIV Infections

HIV Testing → HIV Diagnosis → Link to Care

Spach, D. Figure 1. HIV Screening Recommendations. National HIV Curriculum. hiv.uw.edu
Who Should We Screen?

- **Per CDC, screen all patients aged 13-64** for HIV infection after notifying them that testing will be performed unless declined (i.e., opt-out screening)

- **Per USPSTF, screen all patients aged 15-65**

- Counseling is **not** required with HIV diagnostic testing or as part of HIV screening programs in healthcare settings

- **More frequent screening (e.g., repeat testing as indicated)** in:
  - People with multiple partners, or whose partner has multiple partners
  - People who inject drugs, and their partners
  - Partners of people with HIV
  - People with an STI, viral hepatitis, or TB
  - People who exchange sex for money, commodities, drugs

Opt-out HIV screening

- Patients should be informed that HIV screening will be included as part of their standard evaluations

- Patients may decline (i.e., opt-out)

- Risk-based screening (vs. opt-out screening) miss HIV diagnoses among those who have a perceived low HIV risk

- Routine testing allows
  - Early linkage to care and treatment
  - Stigma reduction
  - Transmission reduction

https://www.cdc.gov/hiv/clinicians/screening/opt-out.html
Benefits of Knowing HIV Status

▪ For HIV-negative
  ▪ Safer sex and injection practices
  ▪ Access to pre-exposure prophylaxis (PrEP)

▪ For HIV-positive
  ▪ Safer sex and injection practices
  ▪ Antiretroviral use for individual patient health
  ▪ Treatment as prevention (i.e., U=U)
  ▪ Prophylaxis to prevent opportunistic infections, if indicated
Undetectable = Untransmittable

- Those who have an undetectable viral load have effectively no risk of transmitting the virus.

- Consensus opinion HIV experts and organizations including CDC, NIH, and IDSA/HIVMA.

- Combined data from 4 studies (HPTN 052, OPPOSITES ATTRACT, PARTNER and PARTNER2)
  - Among serodiscordant couples where the partner living with HIV had a durably undetectable viral load:
    - ZERO transmission among over a hundred thousand condomless sex acts
    - Results similar in both male-female and male-male partnerships
Sequence of Appearance of Lab Markers of HIV-1 Infection

Evolution of HIV Assays

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<thead>
<tr>
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<th>IgG-Sensitive</th>
<th>IgM-Sensitive</th>
<th>Antigen-Antibody</th>
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<tbody>
<tr>
<td><strong>First Generation</strong></td>
<td>Uses crude viral lysate</td>
<td>Uses recombinant HIV</td>
<td>Detects HIV IgG and IgM</td>
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<td>Detects IgG antibodies</td>
<td>antigens or peptides</td>
<td>antibodies and p24 antigen</td>
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<td><strong>Second Generation</strong></td>
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<td>Detects IgM and IgG</td>
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<td><strong>Third Generation</strong></td>
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Options for HIV Testing

- **HIV Antigen/Antibody Test (4th generation testing)**
  - Can detect acute HIV infection

- **HIV Antibody Test (3rd generation)**

- **Rapid HIV Test**
  - Blood or saliva
  - Requires confirmation

- **HIV viral load**
  - Can detect acute HIV infection
What happens if a test is positive?

- Positive rapid tests require confirmation with 4th generation testing algorithm
- Results should be confidentially and directly, ideally through personal contact
- **Provide counseling**
  - HIV is a manageable condition that can be effectively treated
  - Patient should inform current and prior partners
  - Discuss HIV risk reduction practices
  - Discuss ways and resources to process diagnosis
  - Link patient to care
What if a test is negative?

- Reinforce safer sex and needle sharing practices, when appropriate

- Recommend additional and/or repeat testing as indicated

- Consider HIV pre-exposure prophylaxis (PrEP)
HIV Testing Summary

- HIV testing should be done on all patients aged 13-64 regardless of risk

- Some patients require more frequent screening based on risks or concomitant diagnoses

- Be aware of symptoms and signs that suggest acute HIV infection

- Remember type and indications of HIV testing methods
Roadmap

- HIV Primer
- Taking a Sexual History
- HIV Diagnostics
- HIV Prevention
- HIV in Primary Care
Pre-exposure Prophylaxis (PrEP) Is Primary Prevention

It is intended to PREVENT the onset of a disease in those who are AT RISK.

It is an underutilized tool that can greatly reduce the risk of HIV transmission.
PrEP Can Also Be Part Of A Program

- Comprehensive sexual healthcare includes:
  - HIV screening and prevention
  - Screening, treatment, and prevention for other sexually transmitted infections (STIs)
  - Vaccination (e.g., Hepatitis A, Hepatitis B, and HPV)
What Is PrEP?

- Medication to reduce risk of HIV infection after exposure

- Multiple FDA-Approved Options
  - Tenofovir disoproxil fumarate / emtricitabine (brand or generic)
  - Tenofovir alafenamide / emtricitabine by mouth (brand only)
  - Cabotegravir by injection (brand only)

- High efficacy rate (often >90%) for HIV prevention across a variety of patient populations and contexts
Out of an estimated 1.2 million at high risk for HIV
The South accounted for more than half of all new HIV diagnoses in the U.S. in 2016, yet only 30% of all PrEP users.
## MYTH: Delivering PrEP Is Too Difficult in Primary Care

<table>
<thead>
<tr>
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<th>HIV Prevention</th>
<th>Heart Disease Prevention</th>
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<tbody>
<tr>
<td><strong>Assess risk</strong></td>
<td>Take a sexual history</td>
<td>Take a past medical, family, social history</td>
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<tr>
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<td>Check cholesterol and screen for diabetes</td>
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<td>Calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines</td>
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</table>
| **Laboratory evaluation** | Serum creatinine  
HIV screen  
Hepatitis B virus (HBV) screen | Comprehensive metabolic panel  
Cholesterol profile  
Hemoglobin A1C |
| **Further risk reduction** | Condom use  
Sexual health and substance use counseling  
STI screening | Life style and diet modification counseling  
Treat comorbid conditions (e.g., hypertension, diabetes)  
Smoking cessation |
| **Medication options** | Emtricitabine/tenofovir (FTC/TDF or FTC/TAF)  
Cabotegravir injection | Atorvastatin  
Rosuvastatin  
Pravastatin  
Pitavastatin  
Simvastatin  
Fluvastatin  
Aspirin |
### HIV Prevention

**Assess risk**
- Take a sexual history

**Laboratory evaluation**
- Serum creatinine
- HIV screen
- Hepatitis B virus (HBV) screen

**Further risk reduction**
- Condom use
- Sexual health and substance use counseling
- STI screening

**Medication options**
- Emtricitabine/tenofovir (FTC/TDF or FTC/TAF)
- Cabotegravir injection

### Heart Disease Prevention

**Assess risk**
- Take a medical, family, social history
- Control and screen for diabetes
- Calculate 10-year ASCVD risk by 2013 ACC/AHA guidelines

**Laboratory evaluation**
- Comprehensive metabolic panel
- Cholesterol profile
- Hemoglobin A1C

**Further risk reduction**
- Lifestyle and diet modification counseling
- Treat comorbid conditions (e.g., hypertension, diabetes)
- Smoking cessation

**Medication options**
- Atorvastatin
- Rosuvastatin
- Pravastatin
- Pitavastatin
- Simvastatin
- Fluvastatin
- Aspirin

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**MYTH:** Delivering PrEP is too difficult in primary care

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**PrEP IS EASY**
PrEP Number needed to treat

*MSM-10+ = PrEP prioritization scenario targeting all MSM with HIRI-MSM score of ≥10

While the rate of PrEP use has increased consistently across all races/ethnicities, equity in PrEP use by race/ethnicity has decreased over time.

The PrEP-to-Need Ratio (PnR) is the number of PrEP users divided by the number of new diagnoses in a given year. PnR serves as a measurement of how PrEP use compares to the need for PrEP in a population.
PrEP Inequity

- Black persons make up 14% PrEP users but **42%** of new HIV diagnoses.

- Hispanic/Latinx persons make up 17% of PrEP users but **27%** of new HIV diagnoses.

- Caucasian/White persons make up 65% of PrEP users but **26%** of new HIV diagnoses.

- Black persons in the South make up 21% of PrEP users but **52%** of new HIV diagnoses.
PrEP Eligibility

Sex with men, women, or both?

Yes

Anal or vaginal sex in past 6 months?

Yes

HIV+ partner?

Yes

Unknown or detectable viral load?

Yes

Prescribe PrEP

No

Discuss PrEP

Prescribe if requested

No

Discuss PrEP

Prescribe if requested

No

Discuss PrEP

Prescribe if requested

No

MSM: GC, chlamydia, or syphilis

Yes

Prescribe PrEP

No

Discuss PrEP

Prescribe if requested

No

Discuss PrEP

Prescribe if requested

No

MSW and WSM: GC or syphilis

Yes

Prescribe PrEP

No

Discuss PrEP

Prescribe if requested

No

Discuss PrEP

Prescribe if requested

No

Always used condoms?

Yes

Prescribe PrEP

No

Discuss PrEP

Prescribe if requested

No

Discuss PrEP

Prescribe if requested

No

1 or more sex partners of unknown HIV status?

Yes

Had bacterial STI in past 6 months?

Yes

Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update Clinical Practice Guideline

Clinical Assessment of Person At Risk for HIV

- **History**
  - HIV risk factor assessment
  - Medical history
  - Medications & allergies
  - Sexual history
  - Substance use history
  - Social history

- **Physical Exam**

- **Laboratory Assessment**
  - HIV screening test
  - Renal function
  - Hepatitis B serology
  - Routine sexually transmitted infection (STI) testing:
    - Chlamydia
    - Gonorrhea
    - Hepatitis A, B, and/or C
    - Syphilis
TDF/FTC

- Fixed dose combination of tenofovir disoproxil fumarate (TDF) 300 mg and emtricitabine (FTC) 200 mg
- FDA-approved for use as PrEP for adults on June 6, 2012
- FDA-approved for use as PrEP for adolescents on May 15, 2018
- Generic TDF/FTC approved June 2017 and became available September 2020
TAF/FTC

- Similar to TDF/FTC but includes tenofovir alafenamide (TAF) 25 mg in combination with emtricitabine (FTC)
- Non-inferior to TDF/FTC
- Approved for PrEP October 2, 2019 for non-vaginal sex
- TAF achieves high intracellular concentrations, but lower (>10-fold) plasma and tissue concentrations than TDF
  - Lower risk of BMD loss and reduced creatinine clearance
  - Can be used in people with chronic kidney disease (CrCl >30 mL/min)
LA Cabotegravir

- Long-active injectable
  - Optional oral lead-in
  - 2 doses 1 month apart, then every 2 months
    - Consecutive doses can be given 7 days before or after target date
- Approved December 2021
- Demonstrated superiority to TDF/FTC
- Not commonly used due to cost and implementation barriers to date
<table>
<thead>
<tr>
<th>Pros</th>
<th>Cons</th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>TDF/FTC</td>
<td></td>
<td>TAF/FTC</td>
<td></td>
</tr>
<tr>
<td>More data on efficacy, PK, dosing…</td>
<td>Low risk of renal dysfunction</td>
<td>Lower risk of renal dysfunction</td>
<td>Fewer data, less experience</td>
</tr>
<tr>
<td>More experience</td>
<td>Reversible bone mineral density loss</td>
<td>Lower risk of bone mineral density loss</td>
<td>Shouldn’t be used for HIV prevention for receptive vaginal sex or IDU</td>
</tr>
<tr>
<td>Covered by most insurance</td>
<td>Larger pill size</td>
<td>Smaller pill size</td>
<td>Less insurance coverage</td>
</tr>
<tr>
<td>Can be used for prevention with vaginal sex, anal sex, and IDU</td>
<td>Shouldn’t be used if eGFR &lt;60</td>
<td>Faster time to therapeutic level</td>
<td>No data on 2-1-1 dosing</td>
</tr>
<tr>
<td>More brand recognition</td>
<td>Can be used if eGFR &gt;30</td>
<td>Weight gain?</td>
<td>Not cost effective</td>
</tr>
<tr>
<td>Generic available</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PrEP Medication Counseling

- **Dosing**
  - One tab daily, with or without food
  - 2-1-1 dosing alternative for TDF/FTC in some settings

- **Adherence, and its relationship to efficacy**

- **Time to effectiveness**
  - 7-10 days for men, 21 days for women
  - Barrier protection particularly necessary during this window due to lower drug levels

- **Adverse effects**
  - Nausea, vomiting, diarrhea, loss of appetite, weight loss
  - Fatigue, headache

- **Requirements for monitoring**
## Testing While on Oral PrEP

<table>
<thead>
<tr>
<th>Encounter</th>
<th>Action Steps</th>
</tr>
</thead>
</table>
| Month 0    | • Screen for HIV  
  • Confirm HBV and HCV status  
  • Check serum creatinine  
  • Screen for STIs  
  • Counseling  
  • Prescribe |
| Month 3    | • Screen for HIV  
  • Counseling  
  • Prescribe |
| Month 6    | • Screen for HIV  
  • Screen for STIs  
  • Counseling  
  • Prescribe |
| Month 9    | • Screen for HIV  
  • Counseling  
  • Prescribe |
| Month 12   | • Screen for HIV  
  • Screen for STIs  
  • Check serum creatinine  
  • Counseling  
  • Prescribe |

### Labs Over One Year:
- HIV screen: 5
- Lipid panel: 1*  
- Serum creatinine: 2**  
- STI screen: 3***

* Lipid panel Q12 months if taking TAF/FTC  
** Serum creatinine should be done Q6 months if age ≥50 years or who have an CrCl <90 mL/min at initiation  
*** Tri-compartment GC/chlamydia, syphilis, HCV depending on risk

### Prescriptions/Refill authorizations: 5

### Discussions: 5+

HIV screening

- At baseline, 4th generation HIV Ag/Ab combination assay

- During PrEP maintenance, HIV Ag/Ab AND HIV RNA PCR currently recommended
  - Incident HIV infections during PrEP use may exhibit lower viral replication and longer time to antibody production (seroconversion)

- Routine HIV RNA PCR may not be readily available or affordable in some contexts
  - When this is the case, providers should use tests that are available to them to continue PrEP

When to Stop PrEP

▪ If the patient doesn’t want it

▪ If behavior or life situations have changed that lower risk for HIV infection

▪ If intolerable adverse events/toxicities occur

▪ If HIV infection is detected
Post-Exposure Prophylaxis (PEP)

- Intended to prevent the establishment of HIV infection AFTER exposure has occurred
- Occupational and non-occupational
- Can reduce risk of HIV infection by >80% after exposure

Table 1. Estimated per-act risk for acquiring human immunodeficiency virus (HIV) from an infected source, by exposure act

<table>
<thead>
<tr>
<th>Exposure type</th>
<th>Rate for HIV acquisition per 10,000 exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenteral</td>
<td></td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>9,250</td>
</tr>
<tr>
<td>Needle sharing during injection drug use</td>
<td>63</td>
</tr>
<tr>
<td>Percutaneous (needlestick)</td>
<td>23</td>
</tr>
<tr>
<td>Sexual</td>
<td></td>
</tr>
<tr>
<td>Receptive anal intercourse</td>
<td>138</td>
</tr>
<tr>
<td>Receptive penile-vaginal intercourse</td>
<td>8</td>
</tr>
<tr>
<td>Insertive anal intercourse</td>
<td>11</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>
</tbody>
</table>

Source: http://www.cdc.gov/hiv/policies/faw/risk.html

* Factors that may increase the risk of HIV transmission include sexually transmitted diseases, acute and late-stage HIV infection, and high viral load. Factors that may decrease the risk include condom use, male circumcision, antiretroviral treatment, and preexposure prophylaxis. None of these factors are accounted for in the estimates presented in the table.

HIV transmission through these exposure routes is technically possible but unlikely and not well documented.
PEP

- Must be started within 72 hours of exposure and continued for 28 days

- Recommended Regimens:
  - Tenofovir/emtricitabine + raltegravir
  - Tenofovir/emtricitabine + dolutegravir

- HIV Screening Intervals
  - Baseline
  - 28 days
  - 3 months
  - 6 months
Roadmap

- HIV Primer
- Taking a Sexual History
- HIV Diagnostics
- HIV Prevention
- HIV in Primary Care
Addressing HIV in Primary Care

- **Taking a Sexual History**
- **HIV Screening and Diagnosis**
- **Prevention (e.g., Pre-exposure Prophylaxis)**
- **Primary Care for People with HIV**
Clinical Assessment of Person With HIV

- Laboratory Assessment
  - HIV-Specific
    - Laboratory confirmation of HIV
    - CD4 cell count with percentage
    - Quantitative HIV RNA level
    - HIV drug-resistance testing
  - Routine Laboratory Testing
    - Complete blood count with differential
    - Basic chemistry panel with creatinine clearance
    - Hepatic aminotransferase levels
    - Urinalysis
    - Fasting lipid panel
    - Fasting glucose
    - *Serum testosterone (in men who are symptomatic)*
  - Coinfection and Comorbidity Screening
    - Hepatitis A serology
    - Hepatitis B serology
    - Hepatitis C serology
    - *Toxoplasma gondii* serology
    - Syphilis testing
    - Routine STI testing

- History
  - HIV-related history
  - Medical history
  - Surgical history
  - Psychiatric history
  - Medications & allergies
  - Sexual history
  - Substance use history
  - Social history
  - Family history

- Comprehensive physical exam
# Myth: Delivering HIV Care is Too Difficult for Primary Care

## HIV Care in Primary Care

- **Assess risk**
  - Take a past medical, family, social, sexual history
  - Perform pertinent physical examination

- **Laboratory evaluation**
  - Complete blood count,
  - Comprehensive metabolic profile
  - Immune function assessment
  - HIV assays and associated infection screening

- **Further risk reduction**
  - Condom use
  - Sexual health and substance use counseling
  - STI screening

- **Medication options**
  - Several first-line single-tablet treatment options

## Heart Disease Prevention in Primary Care

- **Assess risk**
  - Take a past medical, family, social history
  - Check cholesterol and screen for diabetes
  - Calculate 10-year ASCVD risk by ACC/AHA guidelines

- **Laboratory evaluation**
  - Comprehensive metabolic panel
  - Cholesterol profile
  - Hemoglobin A1C

- **Further risk reduction**
  - Lifestyle and diet modification counseling
  - Treat comorbid conditions (e.g., hypertension, diabetes)
  - Smoking cessation

- **Medication options**
  - Several first-line single-tablet treatment options
  - Atorvastatin
  - Rosuvastatin
  - Pravastatin
  - Pitavastatin
  - Simvastatin
  - Fluvastatin
  - Aspirin
<table>
<thead>
<tr>
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<th>Healthcare in Primary Care</th>
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<td>STI screening</td>
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<tr>
<td><strong>Medication options</strong></td>
<td></td>
</tr>
<tr>
<td>Several first-line single-tablet treatment options</td>
<td>Aspirin</td>
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<tr>
<td>Atorvastatin</td>
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<td>Fluvastatin</td>
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**HIV CARE IS POSSIBLE IN PRIMARY CARE**
Primary Care for PWH

Increased Risk
- Cardiovascular disease
- Diabetes mellitus
- Chronic kidney disease
- Osteoporosis
- Testosterone deficiency
- Tobacco use
- Obstructive lung disease
- Cancer

Approach
- Evidence-based screening
- Guideline-based interventions
- Awareness of HIV adverse effects and drug-drug interactions
- “Primary care in the fast lane”
Objectives Achieved!

At the end of this session, you are now able to:

- Describe the general history and current treatment of human immunodeficiency virus (HIV)
- Identify all elements of a sexual history using the 5 Ps and GOALS frameworks
- Recommend and interpret HIV testing based on Centers for Disease Control (CDC) and US Preventive Services Task Force (USPSTF) recommendations
- Prescribe HIV pre-exposure prophylaxis (PrEP) as part of primary care
Mission Accomplished

- You **CAN** now make sexual histories, HIV testing, and HIV prevention part of your primary care practice
Thank You! Questions? Cody.A.Chastain@VUMC.org
AETC Program National Centers and National HIV Curriculum

• National Coordinating Resource Center serves as the central web-based repository for AETC Program training and capacity building resources; its website includes a free virtual library with training and technical assistance materials, a program directory, and a calendar of trainings and other events. Learn more: https://aidsetc.org

• National Clinician Consultation Center provides free, peer to peer, expert advice for health professionals on HIV prevention, care, and treatment and related topics. Learn more: https://nccc.ucsf.edu

• National HIV Curriculum provides ongoing, up to date HIV training and information for health professionals through a free, web-based curriculum; also provides free CME credits, CNE contact hours, CE contact hours, and maintenance of certification credits. Learn more: www.hiv.uw.edu