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

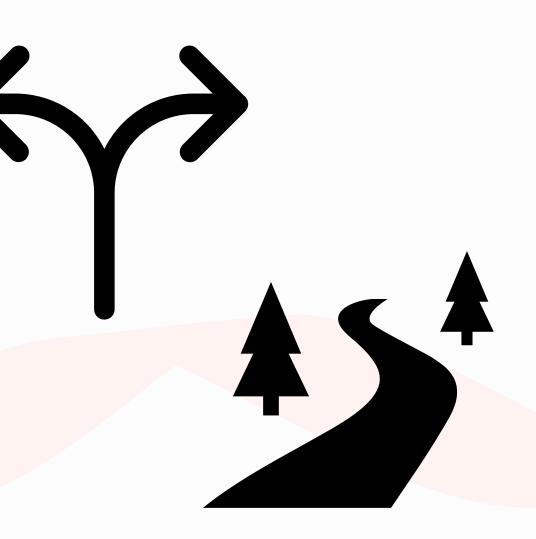
Empower you to make **sexual** histories, HIV testing, and HIV prevention part of your primary care practice





Roadmap

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

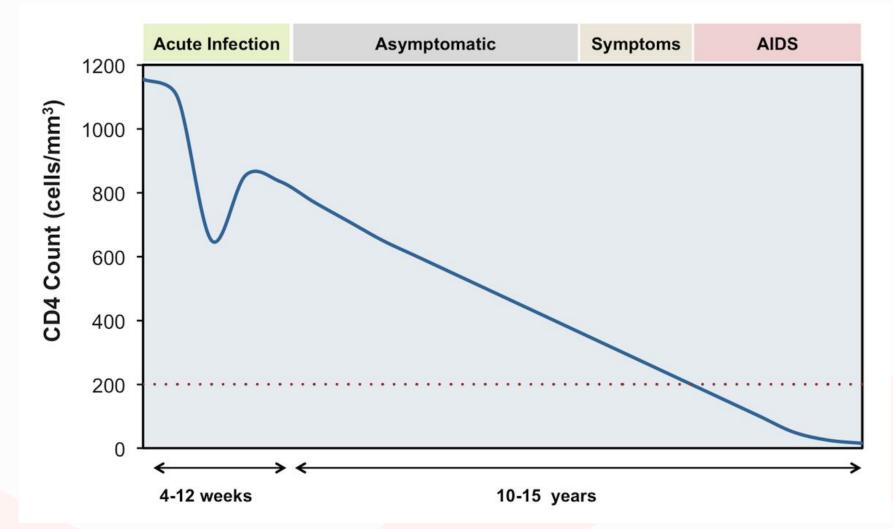




HIV Pathogenesis

- 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-evaluationmonitoring/core-concept/all



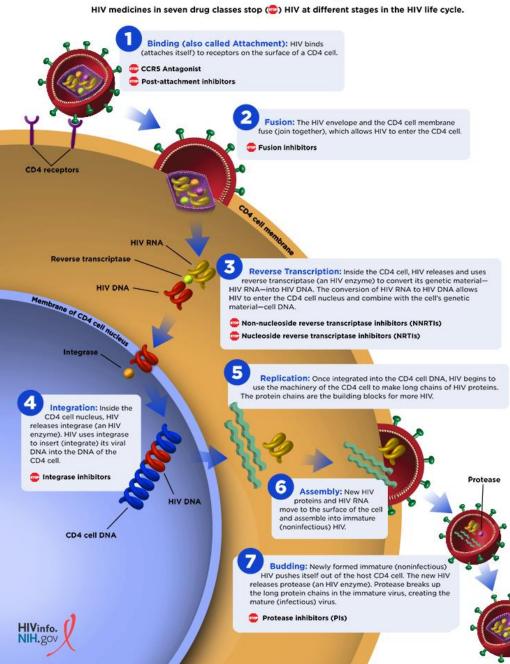
The HIV Life Cycle

HIV Key Virology

- 1. Binding and Attachment
- 2. Fusion
- 3. Reverse Transcription
- 4. Integration
- 5. Replication
- 6. Assembly
- 7. Budding

AETC AIDS Education & Training Center Program

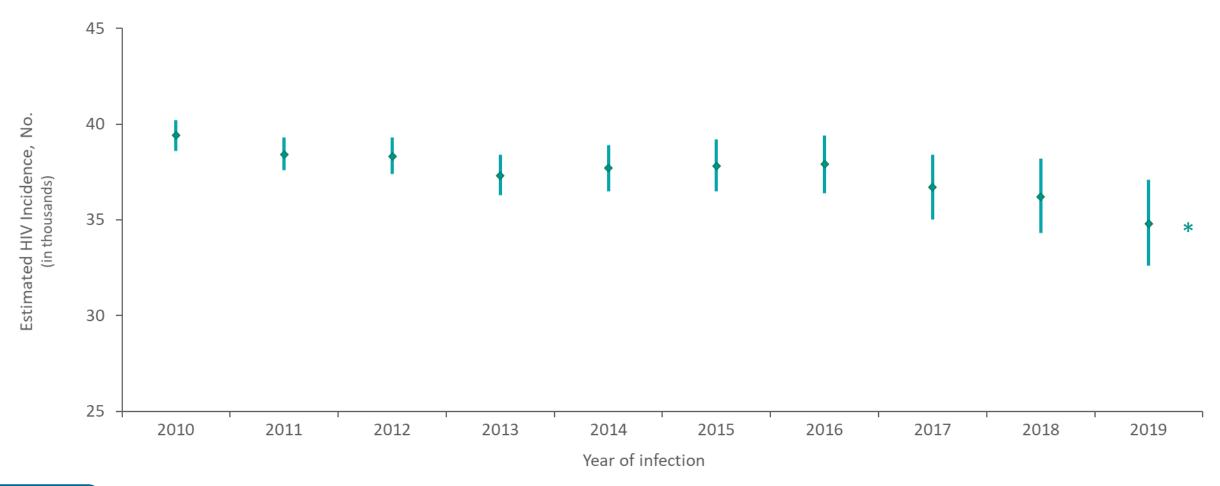
Southeast



IS HIV REALLY A PROBLEM IN THE US TODAY?



Estimated HIV Incidence among Persons Aged ≥13 Years 2010–2019—United States



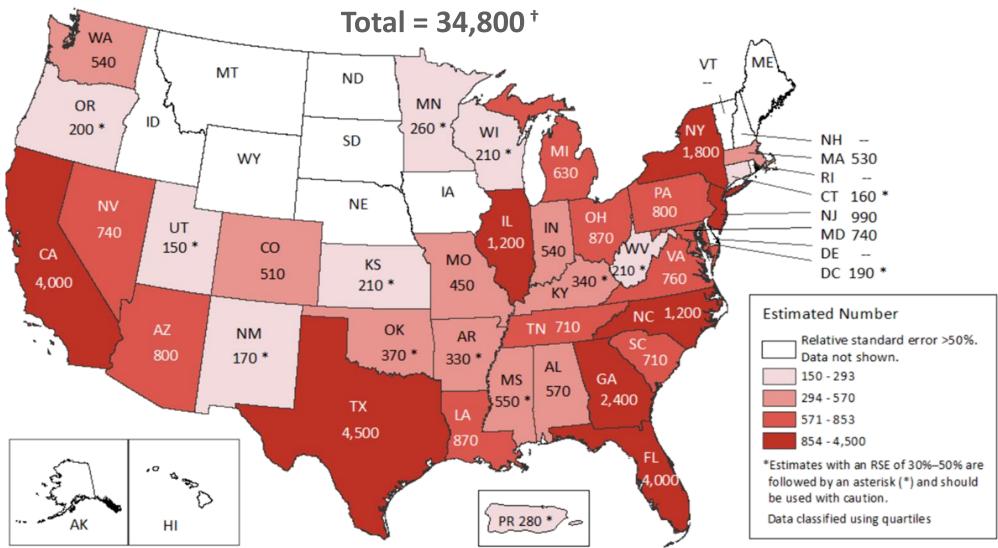


Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Bars indicate the range of the lower and upper bounds of the 95% confidence intervals for the point estimate.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).

Estimated HIV Incidence among Persons Aged ≥13 Years, by Area of Residence 2019—

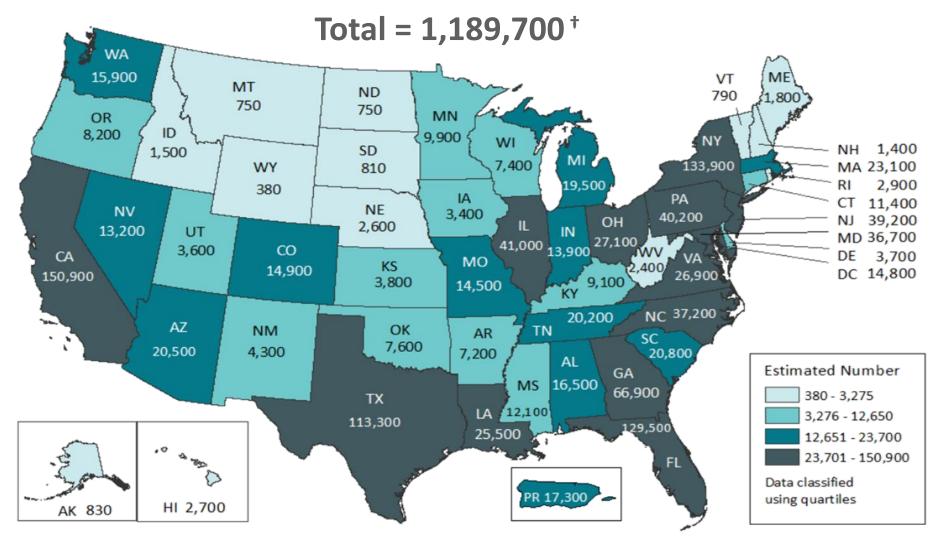
United States and Puerto Rico





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.

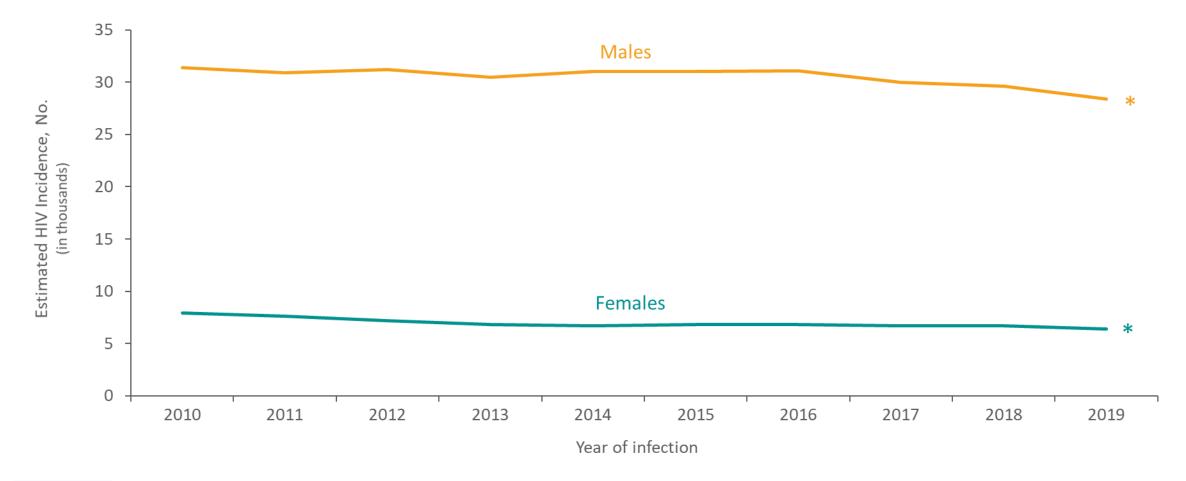
Estimated HIV Prevalence among Persons Aged ≥13 years, by Area of Residence 2019—United States and Puerto Rico





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

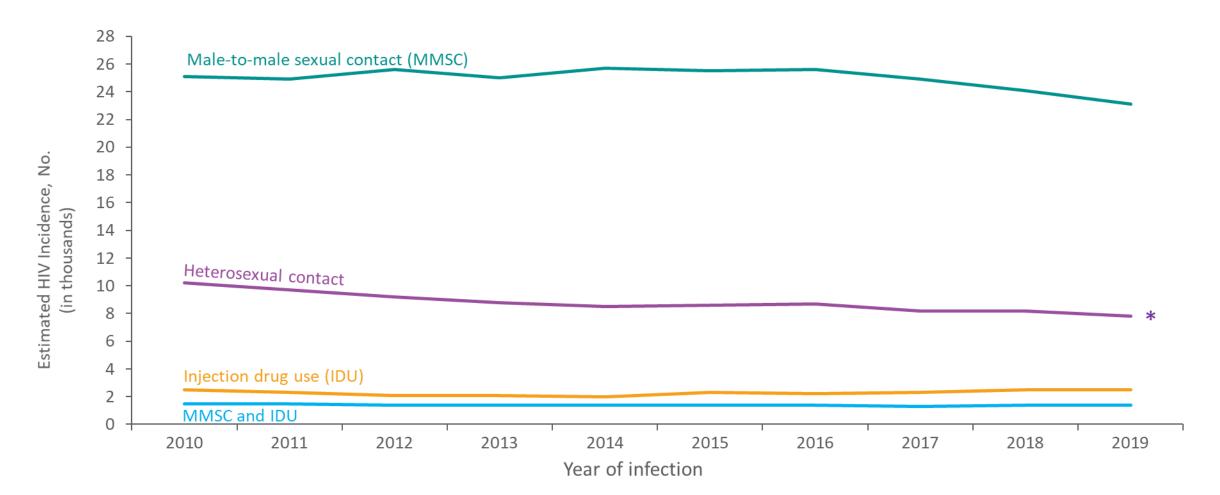




Note. Estimates were derived from a CD4 depletion model using HIV surveillance data.

* 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

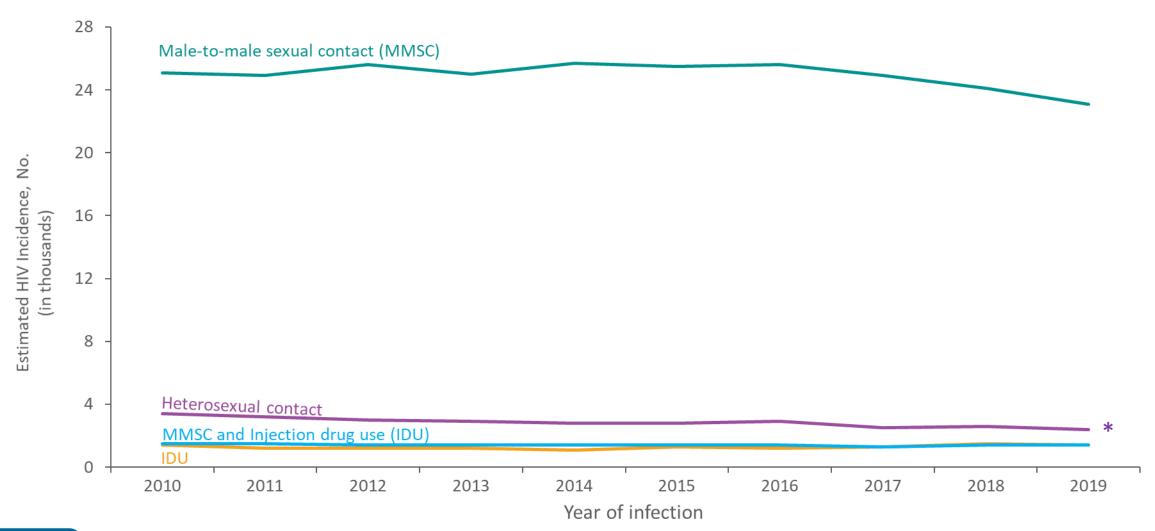




Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).

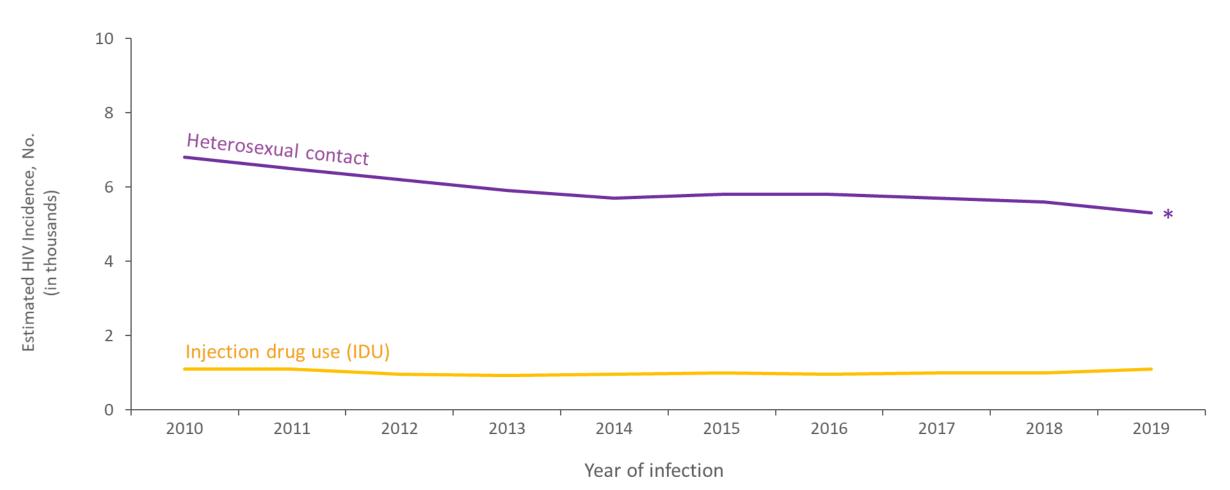
Estimated HIV Incidence among Males Aged ≥13 Years by Transmission Category, 2010–2019—United States





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

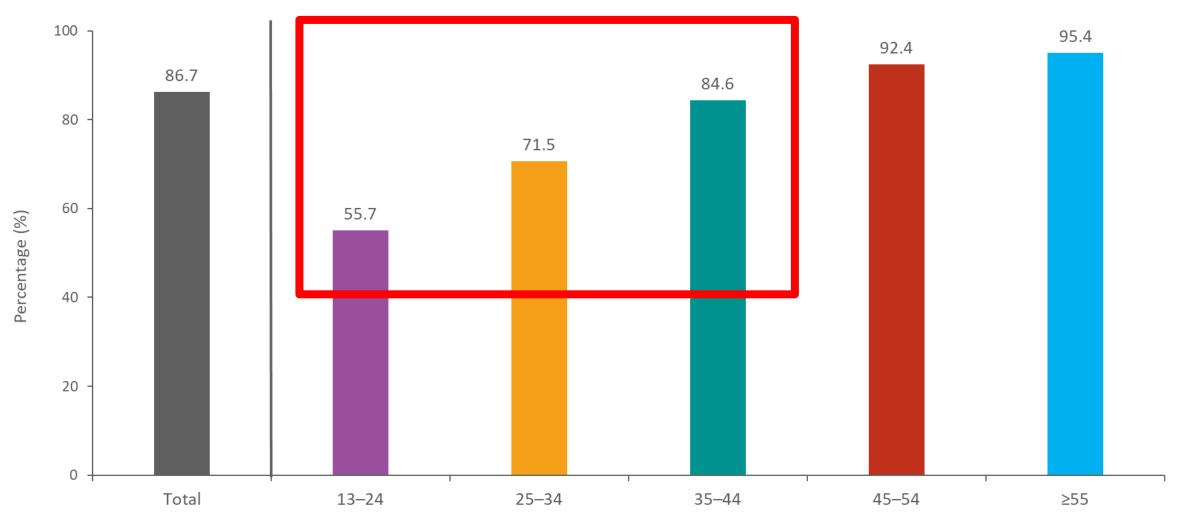




Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Data have been statistically adjusted to account for missing transmission category. Heterosexual contact is with a person known to have, or with a risk factor for, HIV infection.

* Difference from the 2010 estimate was deemed statistically significant (P < .05).

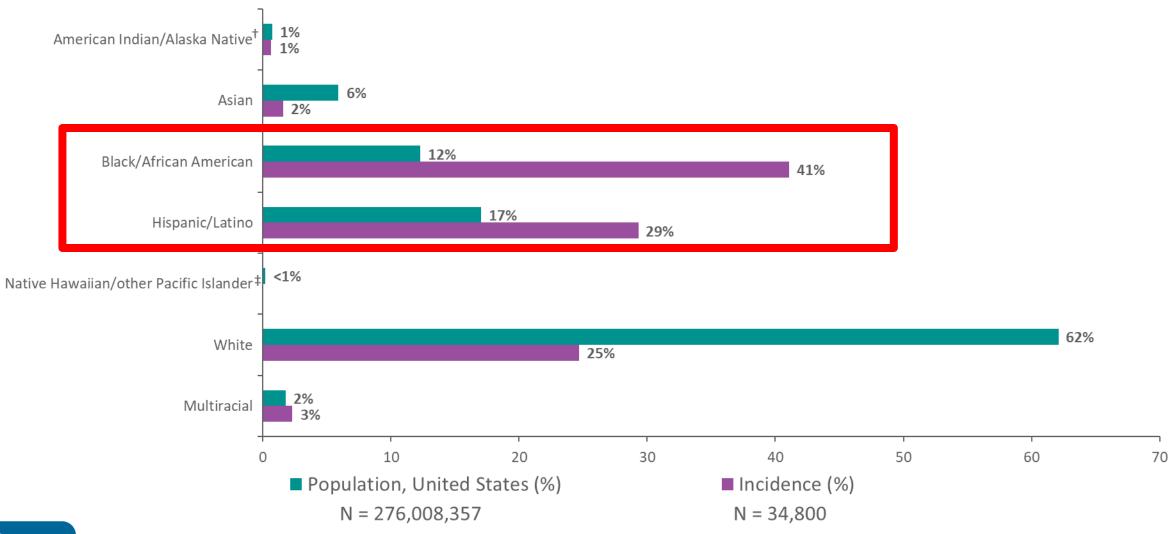
Diagnosed Infection among Persons Aged ≥13 Years Living with Diagnosed or Undiagnosed HIV Infection, by Age, 2019—United States





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

- <u>1980's</u>: AIDS described, pneumocystis kills 90% of patients, clinicians develop skills in diagnosing, treating and preventing complications
- <u>1990's</u>: First effective treatments, patients respond, death rates drop
- <u>2000's</u>: New toxicities arise, resistance identified, adherence prioritized, limitations become apparent
- <u>2007</u>: Second round of effective antiretroviral agents (e.g., integrase inhibitors, CCR5 inhibitors)
- <u>2013</u>: First serious discussions of cure
- <u>2015-2016</u>: 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

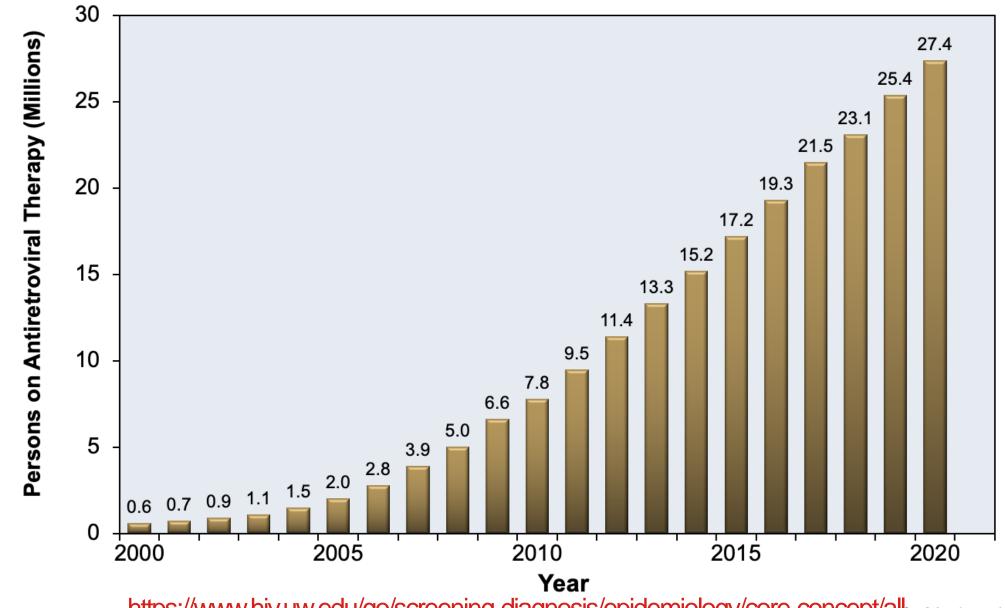


Mortality and frequency of use of protease-inhibitor based antiretroviral therapy among patients with HIV and CD4 < 100





Palella et al. New Engl J Med 1998;338:853-60



https://www.hiv.uw.edu/go/screening-diagnosis/epidemiology/core-concept/all-



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: lencapravir



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 <u>SAME</u> as a person without HIV





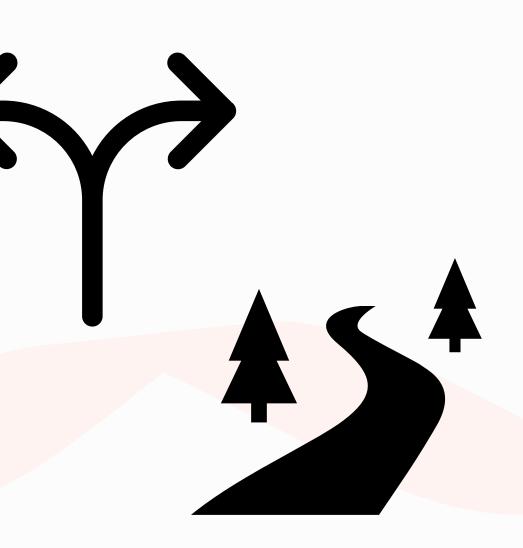
Useful HIV Websites

www.seaetc.com www.hiv.uw.edu www.vanderbilthealth.com/vccc www.aidsinfonet.org www.aidsetc.org www.hivaids.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

AEIC AIDS Education & Training Center Program Southeast

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. // https://www.cdc.gov/std/treatment/sexualhistory.pdf

The 5 "Ps" of Sexual Health

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



A GUIDE TO Taking a Sexual History



Centers for Disease Control and Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention



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 selfrisk
 - 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



A GUIDE TO Taking a Sexual History



Centers for Disease Control and Prevention National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention



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

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

AETC AIDS Education & Training Center Program

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

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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?

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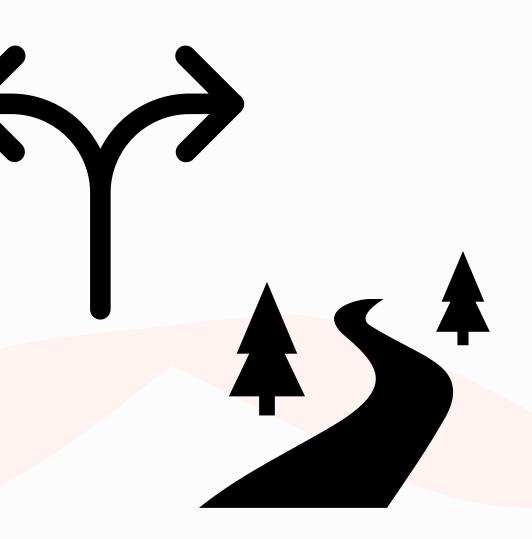
Sexual History Summary

- 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.



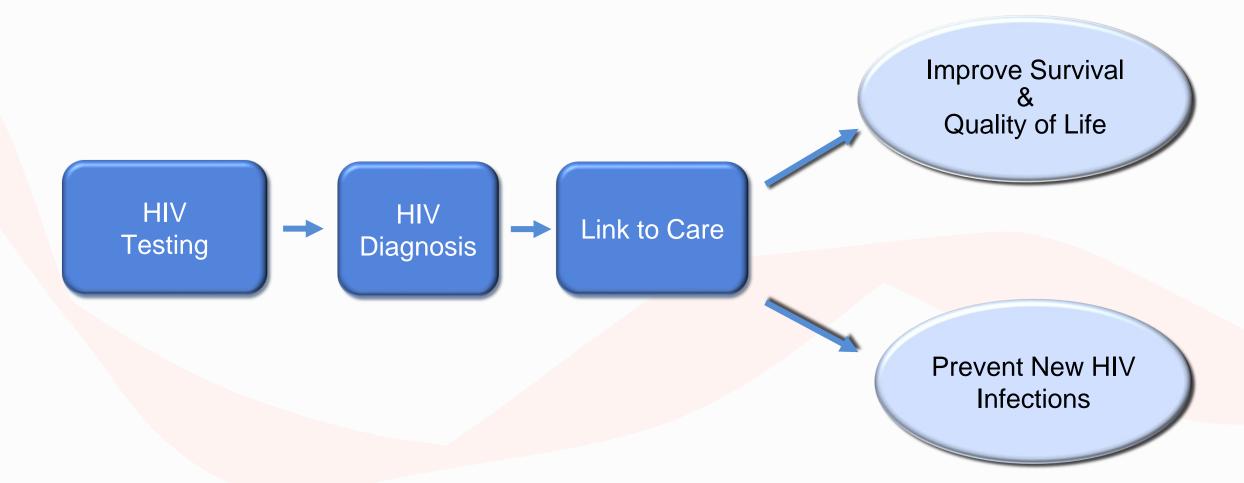
Roadmap

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Goals of HIV Testing





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., optout 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 <u>as part of</u> their standard evaluations
- Patients may decline (i.e., opt-out)
- Risk-based screening (vs. opt-our 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

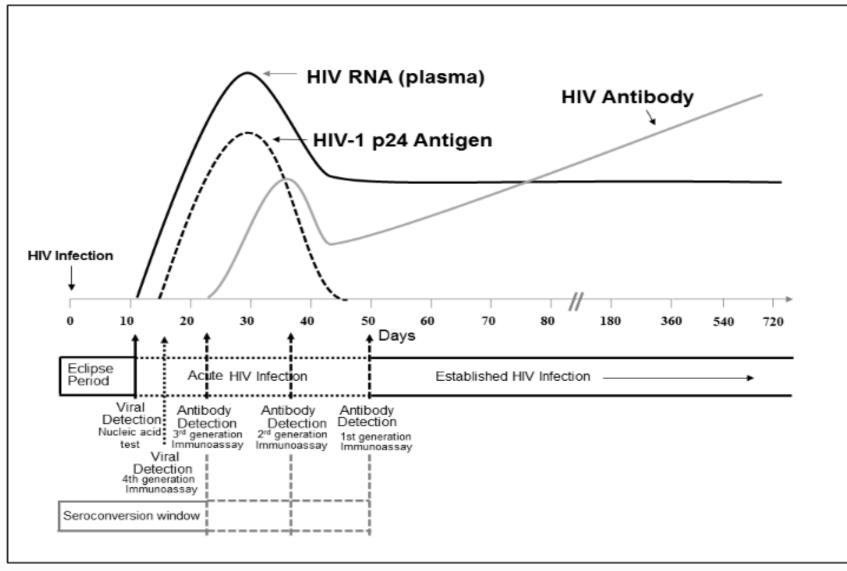
Undetectable = Untransmittable



- 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



Branson BM, et al. Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations. CDC.gov. June 27, 2014. Available at http://stacks.cdc.gov/view/cdc/23446.

Evolution of HIV Assays

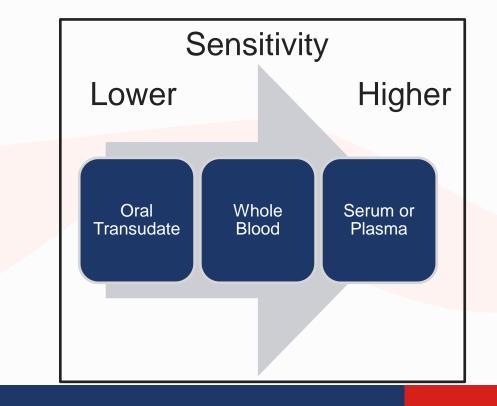
lgG-S	ensitive	IgM-Sensitive	Antigen-Antibody
First Generation	Second Generation	Third Generation	Fourth Generation
Uses crude viral lysate Detects IgG antibodies	Uses recombinant HIV antigens or peptides Detects IgG antibodies	Uses "Sandwich" EIA Detects IgM and IgG antibodies	Detects HIV IgG and IgM antibodies and p24 antigen

Spach, D. Figure 4. HIV Diagnostic Testing. National HIV Curriculum. hiv.uw.edu

Options for HIV Testing

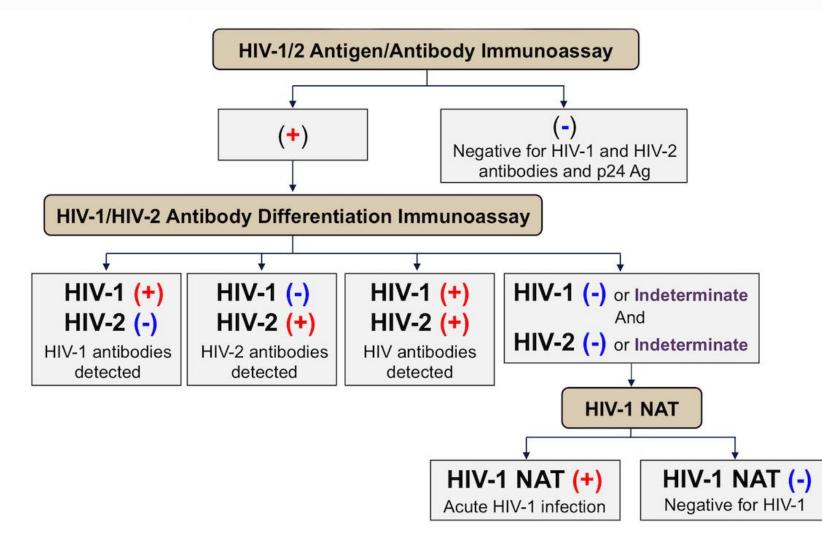
HIV Antigen/Antibody Test (4th generation testing)

- 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





CDC HIV Diagnostic Algorithm



AETC AIDS Education & Training Center Program

Southeast

Spach, D. Figure 10. HIV Diagnostic Testing. National HIV Curriculum. hiv.uw.edu

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

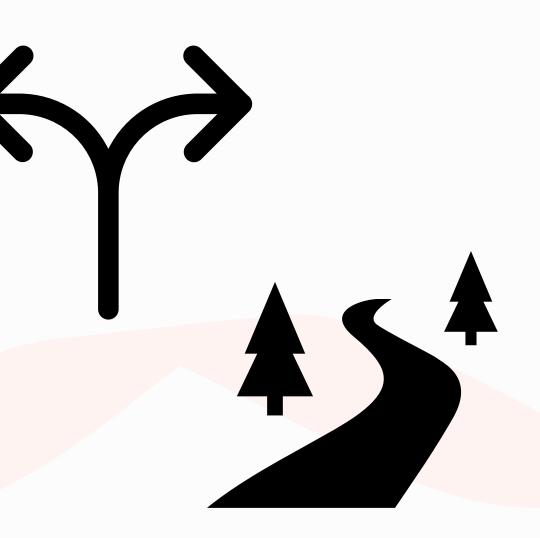
Be aware of symptoms and signs that suggest acute HIV infection

Remember type and indications of HIV testing methods



Roadmap

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Pre-exposure Prophylaxis (PrEP) Is <u>Primary</u> 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)

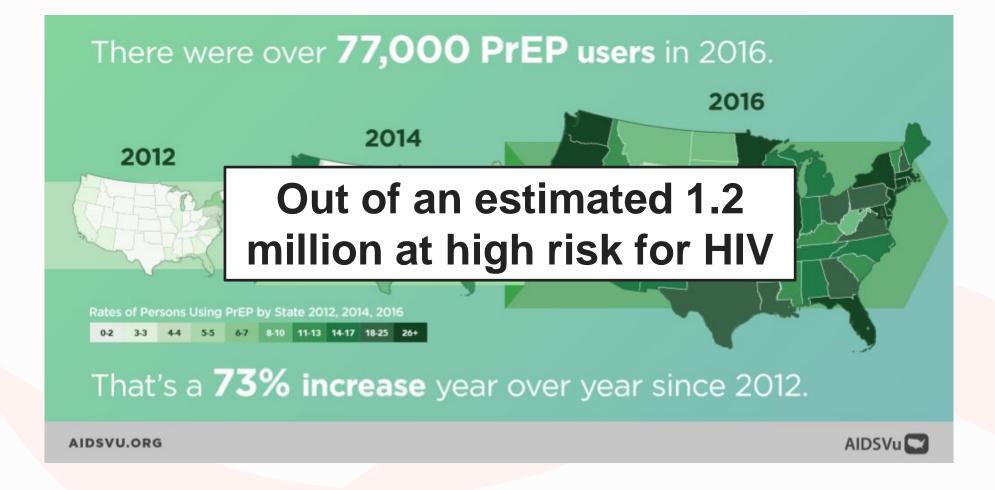


What Is PrEP?



- 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











MYTH: Delivering PrEP Is Too Difficult in Primary Care

	HIV Prevention	Heart Disease Prevention	
Assess risk	Take a sexual history	Take a past medical, family, social history Check cholesterol and screen for diabetes Calculate 10-year ASCVD risk by 2013 ACC/AHA guideline	
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	Lifestyle and diet modification counseling Treat comorbid conditions (e.g., hypertension, diabetes) Smoking cessation	
Medication options	Emtricitabine/tenofovir (FTC/TDF or FTC/TAF) Cabotegravir injection	AtorvastatinAspirinRosuvastatinPravastatinPitavastatinSimvastatinFluvastatinFluvastatin	

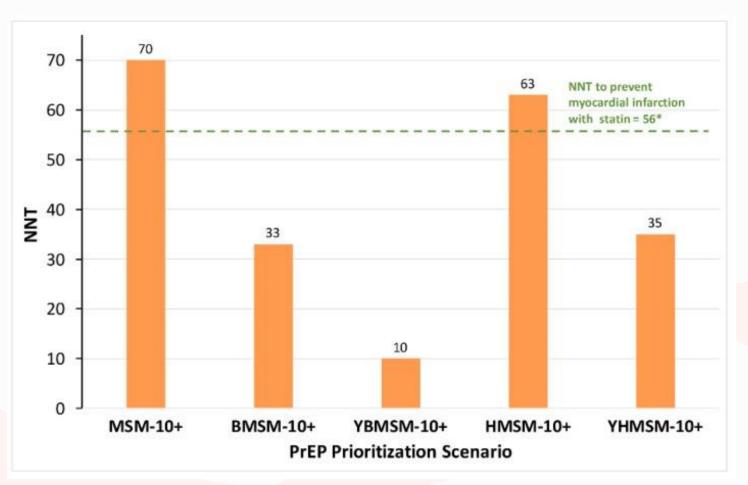


MYTH: Delivering PrEP Is Too Difficult in Primary Care

	HIV Prevention		Heart Disease Prevention	on
Assess risk	Take a sexual history	Tar	pedical, family, social history rol and screen for diabetes ear ASCVD risk by 2013 ACC/AF	HA guidelines
Laboratory evaluation	Serum creatinine HIV screen Hepatitis B virus (HBV) scree		nensive metabolic panel erol profile obin A1C	
Further risk reduction	Condom use Sexual health an STI screenin	unseling Treat cor	and diet modification counseling morbid conditions (e.g., hypertension, o cessation	diabetes)
Medication options	Emtric Caboteg	FTC/TAF) Atorvasta Rosuvas Pravasta Pitavasta Simvasta Fluvasta	tatin Itin Atin Atin	



PrEP Number needed to treat



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



Elion RA, Kabiri M, Mayer KH, Wohl DA, Cohen J, Beaubrun AC, Altice FL. Estimated Impact of Targeted Pre-Exposure Prophylaxis: Strategies for Men Who Have Sex with Men in the United States. Int J Environ Res Public Health. 2019 May 7;16(9):1592.

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

PrEP Use Rate by Race/Ethnicity Over Time, 2012-2021 150 120 90 60 30 0 2012 2014 2015 2016 2017 2018 2019 2020 2021 2013

White



PrEP-to-Need Ratio by Race/Ethnicity Over Time, 2012-2021

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.

AIDSVu.ORG

Black

Hispanic

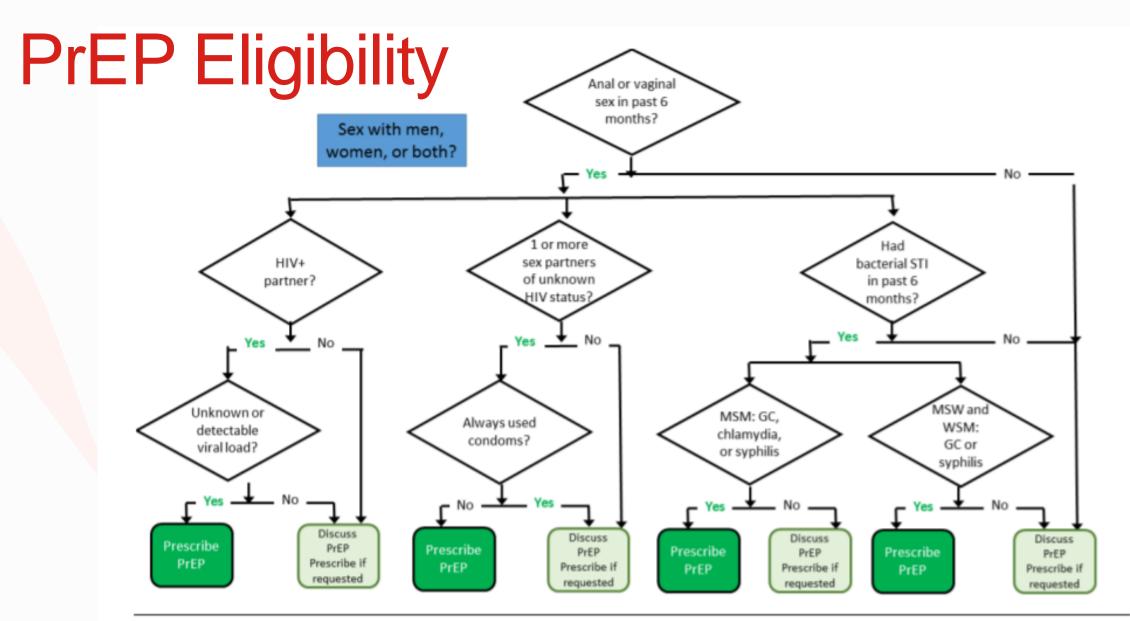
SOURCE: AIDSVu



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.





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



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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







- 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





- 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



TDF/FTC		TAF/FTC		
Pros	Cons	Pros	Cons	
More data on efficacy, PK, dosing	Low risk of renal dysfunction	Lower risk of renal dysfunction	Fewer data, less experience	
More experience	Reversible bone mineral density loss	Lower risk of bone mineral density loss	Shouldn't be used for HIV prevention for receptive vaginal sex or IDU	
Covered by most insurance	Larger pill size	Smaller pill size	Less insurance coverage	
Can be used for prevention with vaginal sex, anal sex, and IDU	Shouldn't be used if eGFR <60	Faster time to therapeutic level	No data on 2-1-1 dosing	
More brand recognition		Can be used if eGFR >30	Weight gain?	
Generic available			Not cost effective	
AETC AIDS Education & Training Center Program Southeast				

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

Encounter Action Steps

Month 0	 Screen for HIV Confirm HBV and HCV status Check serum creatinine Screen for STIs Counseling Prescribe
Month 3	Screen for HIVCounselingPrescribe
Month 6	 Screen for HIV Screen for STIs Counseling Prescribe
Month 9	Screen for HIVCounselingPrescribe
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+



https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf

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 nonoccupational
- 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^a

Exposure type	Rate for HIV acquisition per 10,000 exposures
Parenteral	
Blood transfusion	9,250
Needle sharing during injection drug use	63
Percutaneous (needlestick)	23
Sexual	
Receptive anal intercourse	138
Receptive penile-vaginal intercourse	8
Insertive anal intercourse	11
Insertive penile-vaginal intercourse	4
Receptive oral intercourse	Low
Insertive oral intercourse	Low
Other ^b	
Biting	Negligible
Spitting	Negligible
Throwing body fluids (including semen or saliva)	Negligible
Sharing sex toys	Negligible

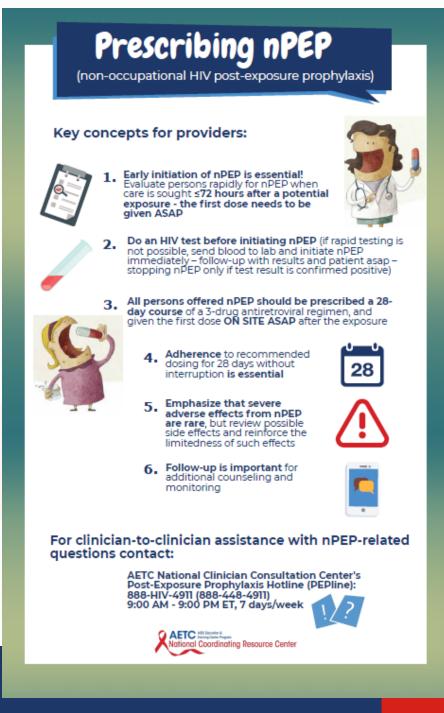
Source: http://www.cdc.gov/hiv/policies/law/risk.html

^a 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.

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

PEP

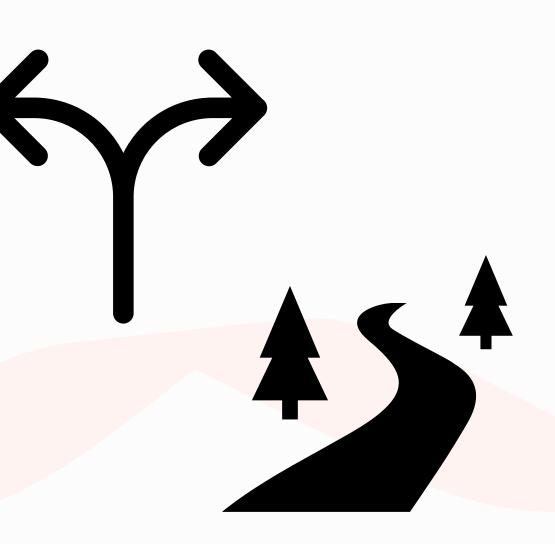
- Must be started within 72 hours of exposure and continued for 28 days
- Recommended Regimens:
 - Tenofovir/emtricitabine + raltegravir
 - Tenofovir/emtricitabine + dolutegravir
- HIV Screening Intervals
 - Baseline
 - 28 days
 - 3 months
 - 6 months





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





Comprehensive physical exam

HIV-related history

Psychiatric history

Medications & allergies

Substance use history

Medical history Surgical history

Sexual history

Social history

Family history

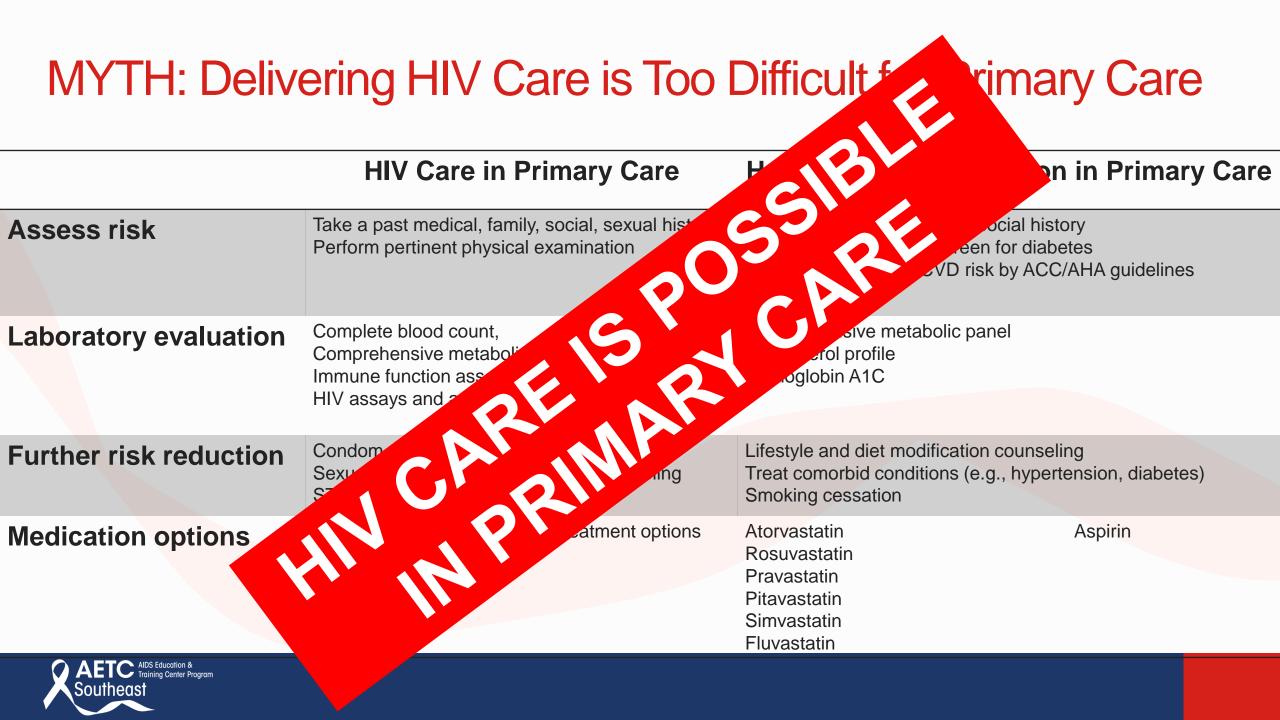


History

MYTH: Delivering HIV Care is Too Difficult for Primary Care

	HIV Care in Primary Care	Heart Disease Prevention in Pr	rimary Care
Assess risk	Take a past medical, family, social, sexual history Perform pertinent physical examination	Take a past medical, family, social history Check cholesterol and screen for diabetes Calculate 10-year ASCVD risk by ACC/AHA gu	idelines
Laboratory evaluation	Complete blood count, Comprehensive metabolic profile Immune function assessment HIV assays and associated infection screening	Comprehensive metabolic panel Cholesterol profile Hemoglobin A1C	
Further risk reduction	Condom use Sexual health and substance use counseling STI screening	Lifestyle and diet modification counseling Treat comorbid conditions (e.g., hypertension, Smoking cessation	diabetes)
Medication options	Several first-line single-tablet treatment options	AtorvastatinAspirinRosuvastatinPravastatinPravastatinSimvastatinSimvastatinFluvastatin	





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"



https://www.hiv.uw.edu/go/basic-primary-care/primary-care-medical-management/core-concept/all

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 <u>CAN</u> now make sexual histories, HIV testing, and HIV prevention part of your primary care practice









Questions?

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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

