



HIV Update

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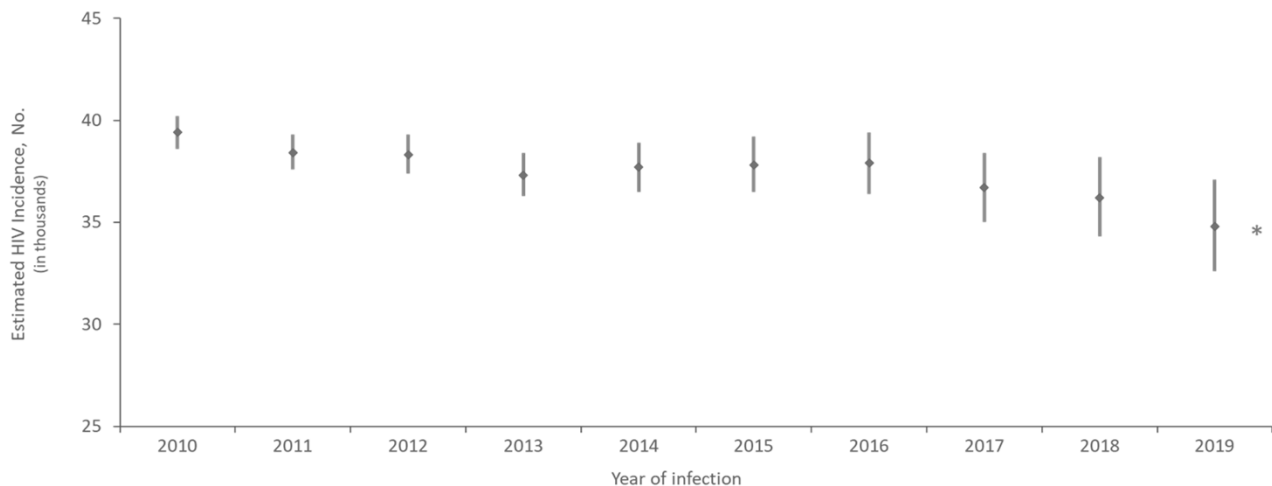
MedNet21

Center for Continuing Medical Education



THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

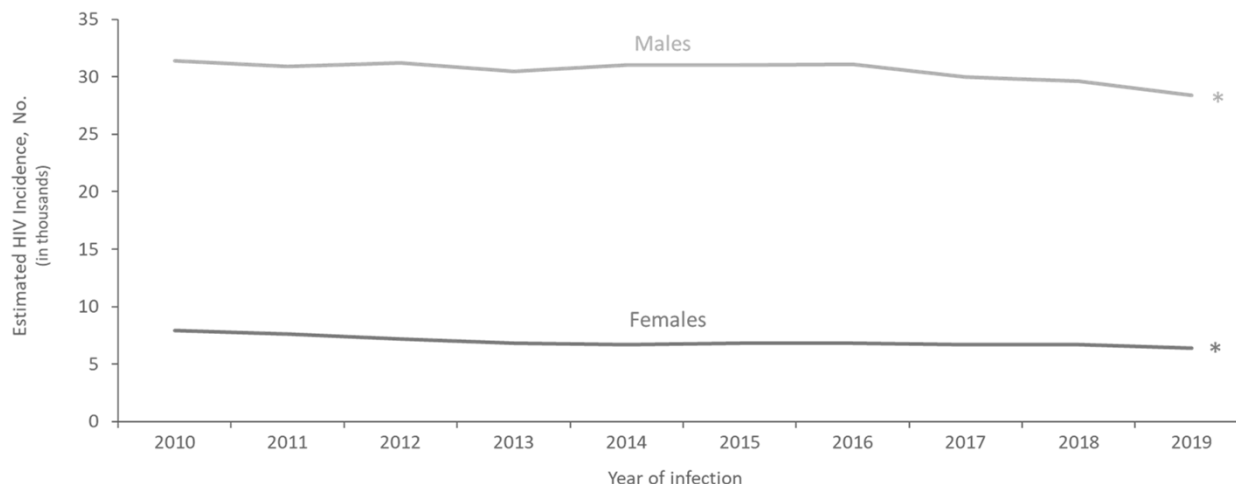
Estimated HIV Incidence among Persons Aged ≥13 Years 2010–2019—United States



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 ($P < .05$).

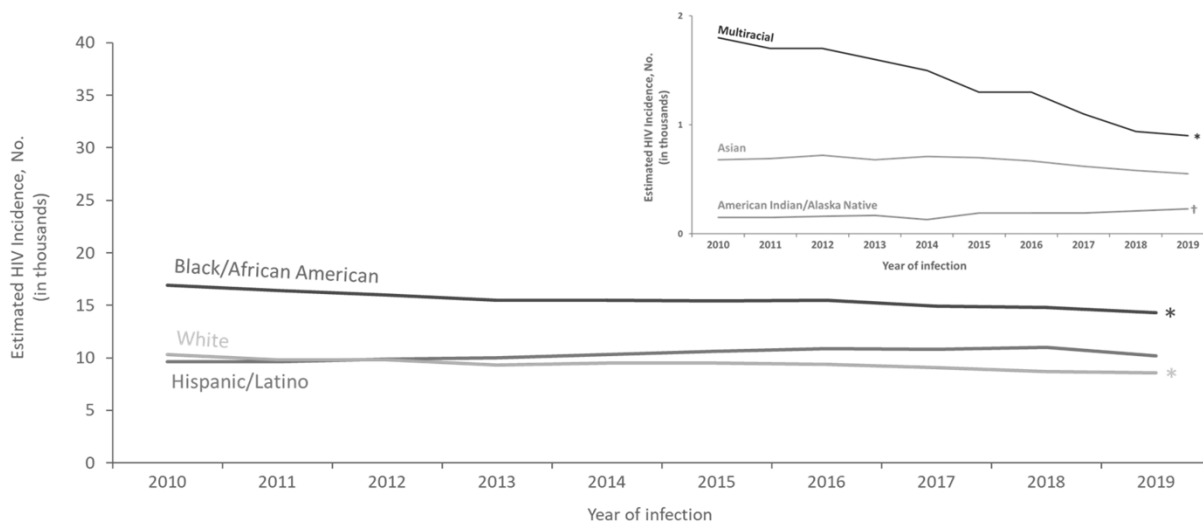
Estimated HIV Incidence among Persons Aged ≥13 Years, by Sex at Birth 2010–2019—United States



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 Race/Ethnicity 2010–2019—United States

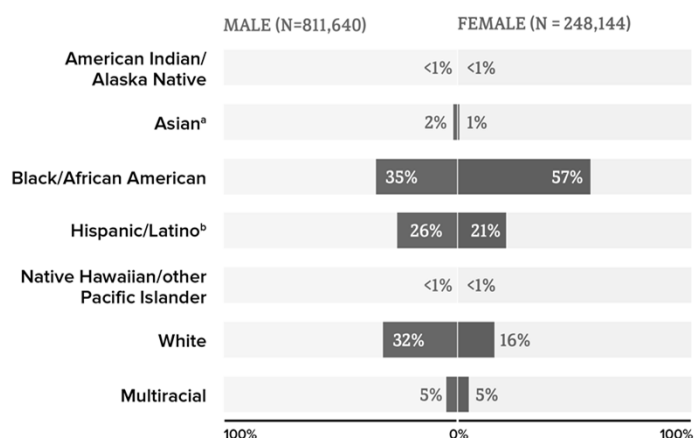


Note. Estimates were derived from a CD4 depletion model using HIV surveillance data. Hispanic/Latino persons can be of any race.

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

† Estimates should be used with caution; relative standard errors are 30%–50%.

Figure 10. Percentages of Adults and Adolescents Living with Diagnosed HIV Infection, by Sex at Birth and Race/Ethnicity, Year-end 2019—United States and 6 Dependent Areas



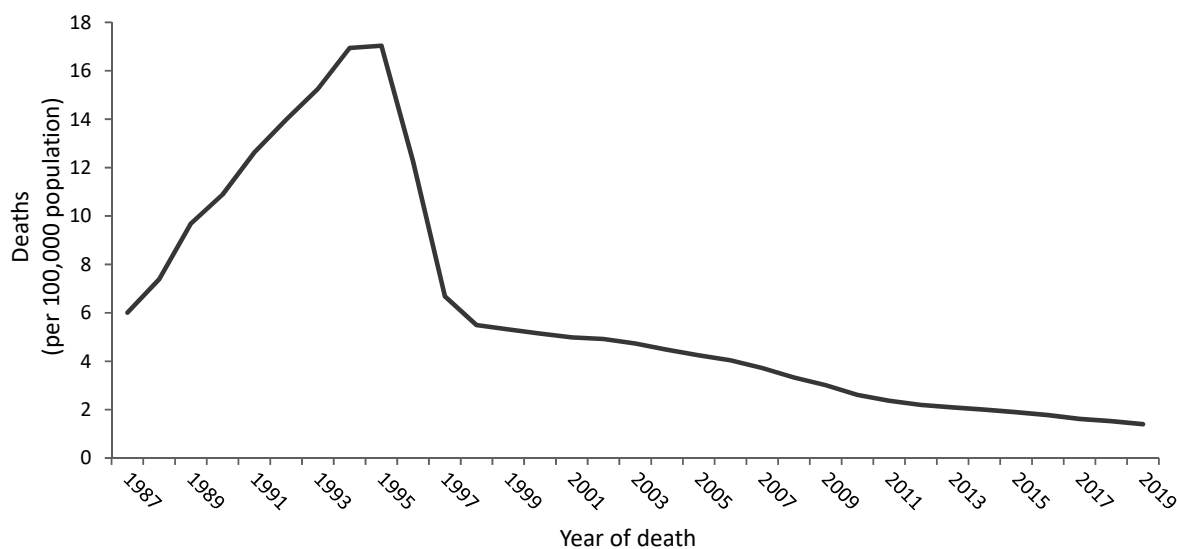
Note: Data have been statistically adjusted to account for missing transmission category. See section D4 in the Technical Notes for more information on transmission categories.

^aIncludes Asian/Pacific Islander legacy cases.

^bHispanic/Latino persons can be of any race.

HIV Surveillance Report: CDC

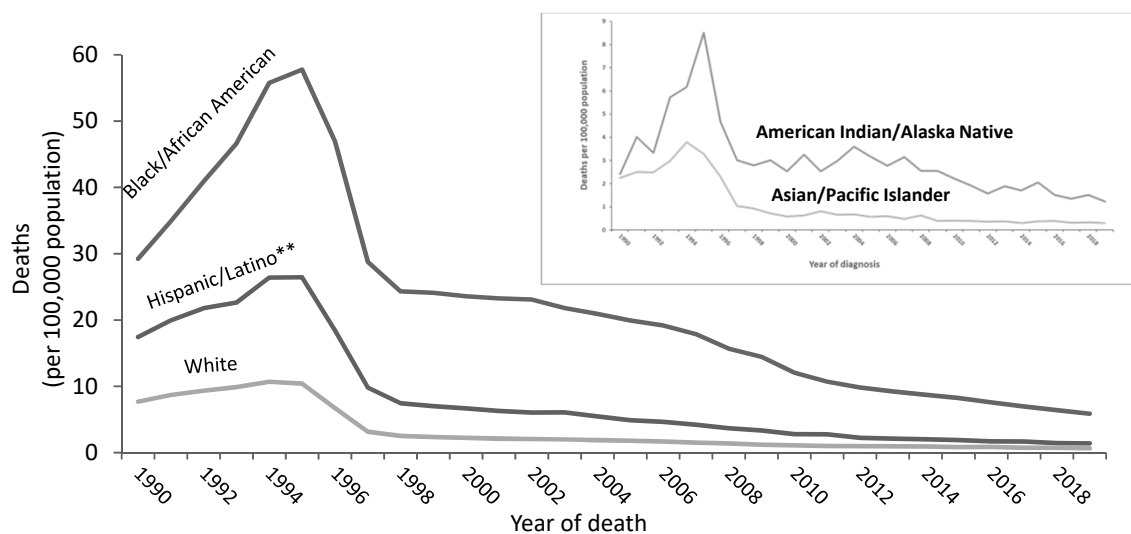
Trends in Annual Age-Adjusted* Rates of Death with HIV Disease as the Underlying Cause, 1987–2019—United States



Note. For comparison with data for 1999 and later years, data for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.

*Standard: age distribution of 2000 US population.

Trends in Age-Adjusted* Annual Rates of Death with HIV Disease as the Underlying Cause, by Race/Ethnicity, 1990–2019—United States

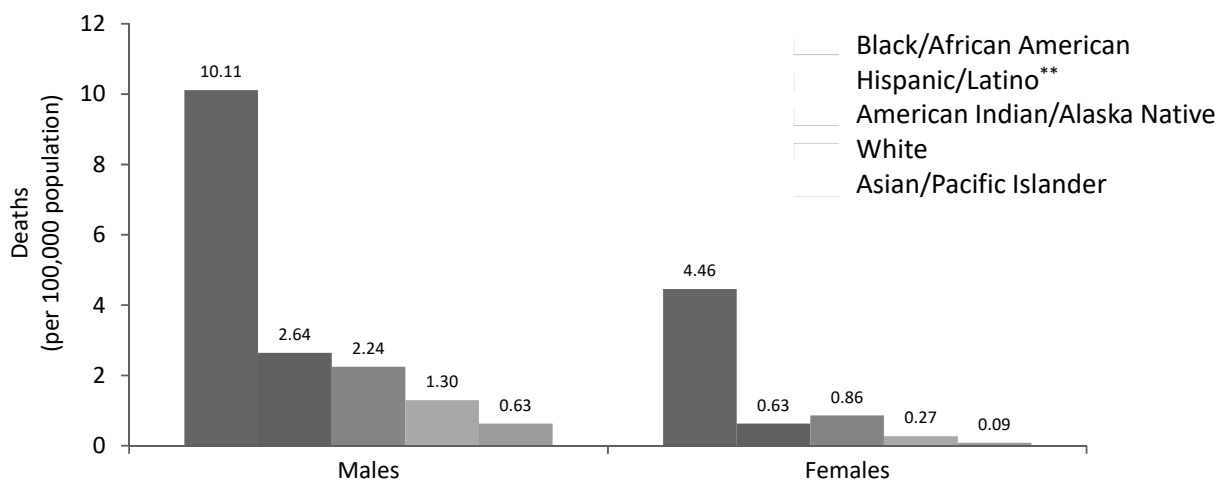


Note. For comparison with data for 1999 and later years, data for 1987–1998 were modified to account for ICD-10 rules instead of ICD-9 rules.

*Standard age distribution of 2000 US population.

**Hispanic/Latino persons can be of any race.

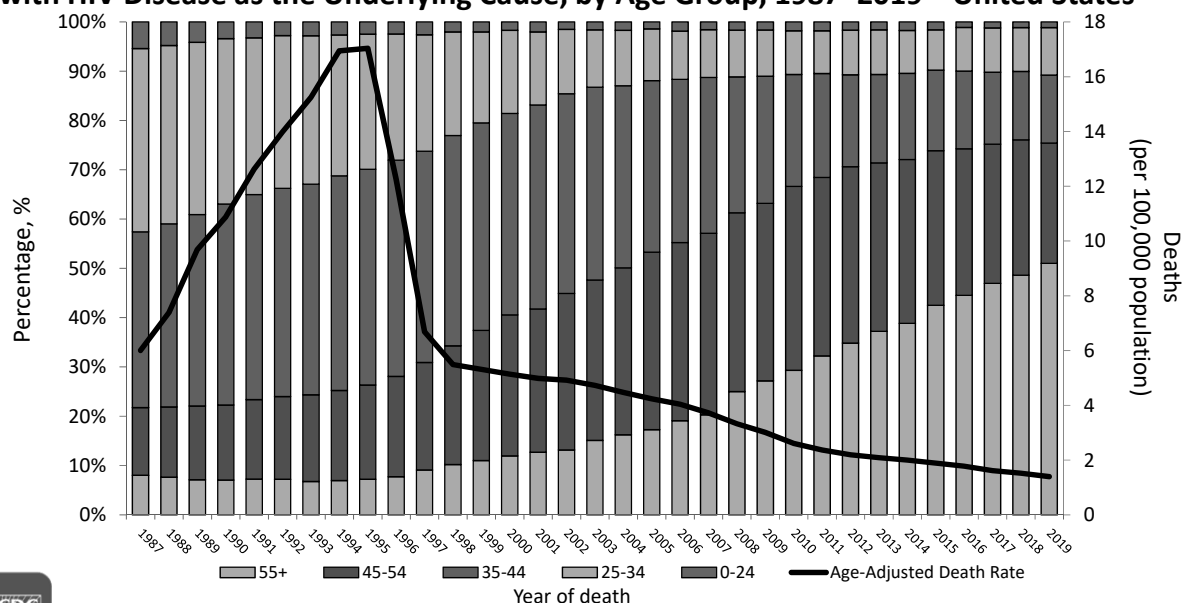
Age-Adjusted* Average Annual Rate of Death with HIV Disease as the Underlying Cause by Sex and Race/Ethnicity, 2015–2019 — United States



*Standard age distribution of 2000 US population

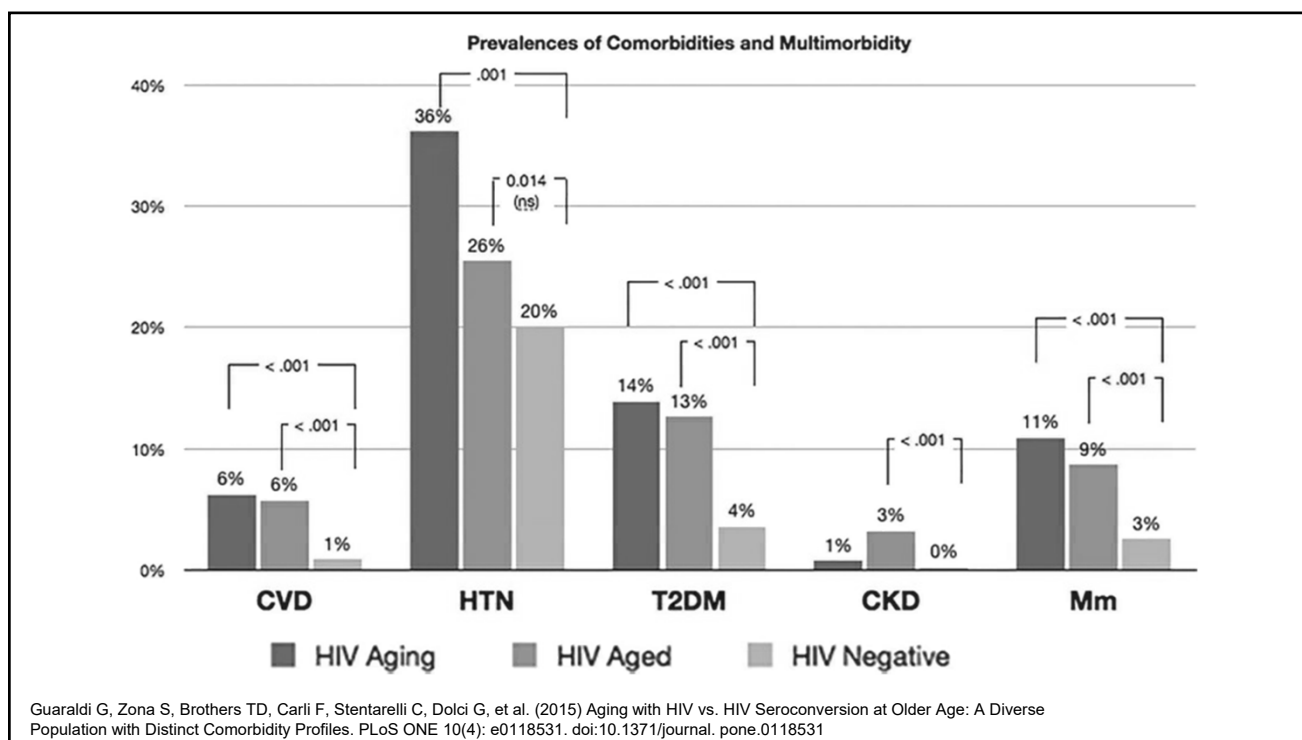
**Hispanic/Latino persons can be of any race.

Trends in Annual Age-Adjusted* Rates of Death and the Percentage Distribution of Deaths with HIV Disease as the Underlying Cause, by Age Group, 1987–2019—United States



Reported Persons Living with HIV in Ohio, 2020 (n=25,096)

Characteristic	Living With Diagnosed HIV Infection in 2020		
	Rate ^a	No.	%
Sex at birth			
Males	346.4	19,856	79%
Females	87.9	5,240	21%
Age at end of year			
<13	2.7	49	<1%
13-14	7.1	21	<1%
15-19	15.3	114	<1%
20-24	97.1	726	3%
25-29	243.0	1,927	8%
30-34	350.2	2,693	11%
35-39	322.4	2,339	9%
40-44	346.9	2,377	9%
45-49	380.4	2,634	10%
50-54	474.5	3,452	14%
55-64	400.9	6,362	25%
65+	114.5	2,402	10%
Race/Ethnicity^b			
American Indian/Alaska Native	66.3	15	<1%
Asian/Pacific Islander	56.7	173	1%
Black/African American	745.4	11,095	44%
Hispanic/Latino	373.7	1,824	7%
White	118.7	10,828	43%



Trends in MI Risk in 2 United States Healthcare Systems

- Cohort study (2005-2010)
 - Kaiser Permanente Northern California (n=4.5 million)
 - Partners cohort (Massachusetts General Brigham) (n=1.5 million)
- Similar CVD risk profiles at baseline
- Outcomes during calendar era 2005-2009 and 2010-2017
 - New MI diagnosis by HIV status
- MI risk (HIV versus no HIV)
 - 2005-2009: no difference (aHR 1.1 95% CI 0.8, 1.5)
 - 2010-2017: higher in HIV (aHR 1.6 95% CI 1.1, 2.4; $P=0.007$)
 - HIV-specific factors, such as longer HIV duration and newer ART, may have prevented PWH from realizing the same improvements in MI risk as person without HIV

Cumulative Incidence of MI

	With HIV	No HIV
2005-2009 (%)	1.1	1.1
2010-2017 (%)	1.2	0.9

* $P<0.03$ versus no HIV.

Silverberg MJ, et al. CROI 2022. Abstract 53.

2014 CDC Revised Classification System: Stage 3-Defining Opportunistic Illnesses in HIV Infection

- | | |
|---|---|
| <ul style="list-style-type: none"> • Bacterial infections, multiple or recurrent* • Candidiasis of bronchia, trachea, or lungs • Candidiasis of esophagus • Cervical cancer, invasive* • Coccidioidomycosis, disseminated or extrapulmonary • Cryptococcosis, extrapulmonary • Cryptosporidiosis, chronic intestinal (>1 month) • Cytomegalovirus disease (other than liver, spleen, or nodes), onset age > 1 month • Cytomegalovirus retinitis (with loss of vision) • Encephalopathy attributed to HIV[^] • Herpes simplex: chronic ulcers (present for >1 month) or bronchitis, pneumonitis, or esophagitis (onset at age > 1 month) • Histoplasmosis, disseminated or extrapulmonary • Isosporiasis, chronic intestinal (> 1 month's duration) • Kaposi's sarcoma | <ul style="list-style-type: none"> • Lymphoma, Burkitt's (or equivalent term) • Lymphoma, immunoblastic (or equivalent term) • Lymphoma, primary of brain • <i>Mycobacterium avium</i> complex or <i>Mycobacterium kansasii</i>, disseminated or extrapulmonary • <i>Mycobacterium tuberculosis</i> of any site, pulmonary*, disseminated, or extrapulmonary • <i>Mycobacterium</i>, other species or unidentified species, disseminated or extrapulmonary • <i>Pneumocystis jirovecii</i> (previously known as "<i>Pneumocystis carinii</i>") pneumonia • Pneumonia, recurrent* • Progressive multifocal leukoencephalopathy • Salmonella septicemia, recurrent • Toxoplasmosis of brain, onset at age > 1 month • Wasting syndrome attributed to HIV |
|---|---|

*Only among children aged < 6 years

*Only among adults, adolescents, and children aged ≥ 6 years

[^]Suggested diagnostic criteria for these illnesses are defined in prior surveillance case definitions

CDC.gov. Revised surveillance case definition for HIV Infection – United States, 2015. MMWR Recomm Rep. 2014;63(RR-03):1-10.

Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV



Recommendations from the Centers for Disease Control and Prevention, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America

<https://aidsinfo.nih.gov/guidelines>

Last update: February 17, 2022

Primary Prophylaxis

OI	Indication	Preferred
Pneumocystis Pneumonia (PCP)	CD4 < 200 CD4 < 14% If ART initiation has to be delayed, CD4 ≥ 200, but < 250 and can't monitor every 3 mos	1. TMP-SMX 1 DS tab PO daily 2. TMP-SMX 1 SS tablet daily
<i>Toxoplasma gondii</i> Encephalitis	Toxoplasma IgG positive with CD4 < 100	TMP-SMX 1 DS PO daily
<i>Mycobacterium avium</i> Complex (MAC)	CD4 < 50 • Not recommended for those who immediately start ART • Rule out active disease before starting	1. Azithromycin 1200 mg PO once weekly 2. Clarithromycin 500 mg PO BID 3. Azithromycin 600 mg PO twice weekly

Excerpted from Table 1

Why do we still see OIs?

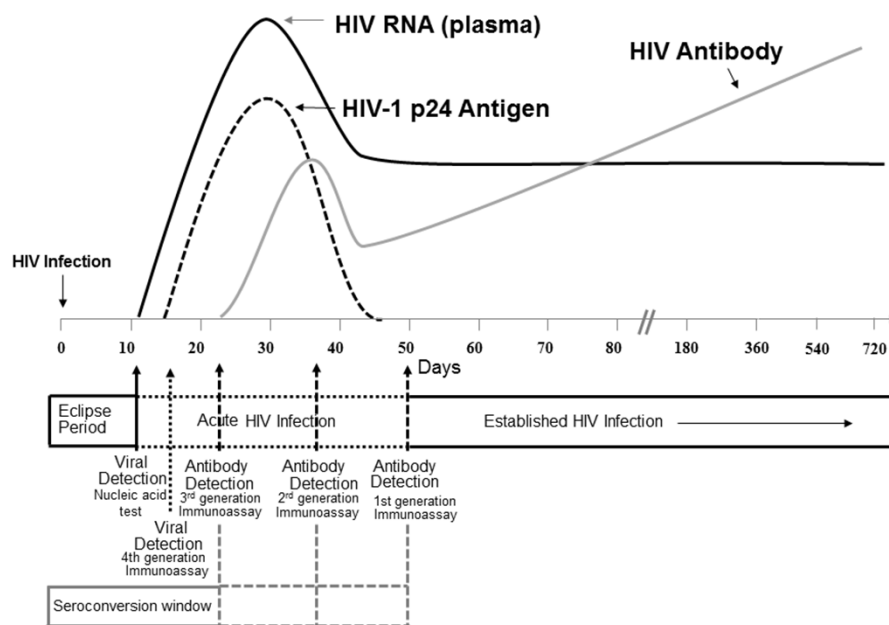
- Undiagnosed or late diagnosis of HIV
- Known HIV infection with poor retention in care
- Not on stable antiretroviral therapy (ART)

HIV testing in the US

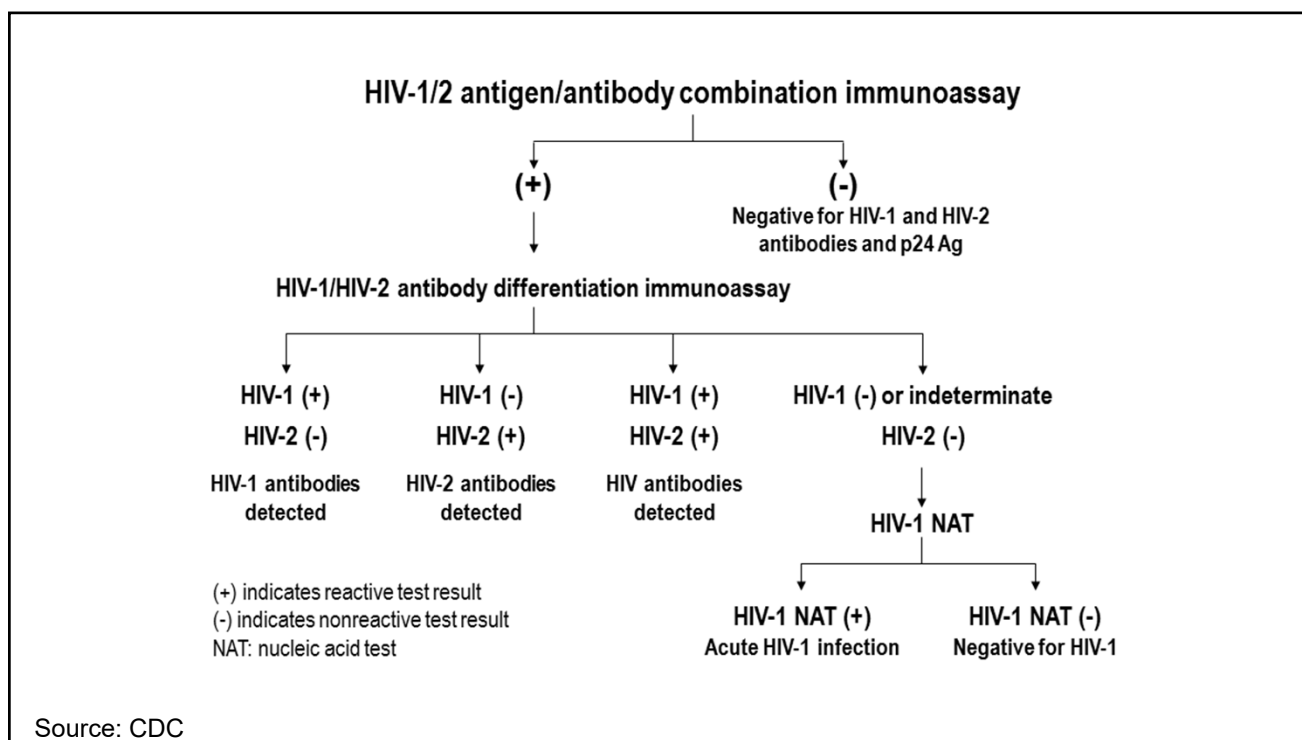
4 generations of assays to test for HIV:

- 1st: detects IgG (examples: Western Blot, IFA)
- 2nd: detects IgG (examples: HIV-1 EIA, rapid HIV Ab tests)
- 3rd: detects IgM & IgG (examples: HIV-1/2 immunoassay and HIV1/2 chemiluminescent immunoassays)
- 4th: detects IgM & IgG and p24 Antigen (example: combination test - 3rd gen plus one rapid test that uses separate indicators for HIV-1/2 antigen and antibodies)

CDC: Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations June 27, 2014

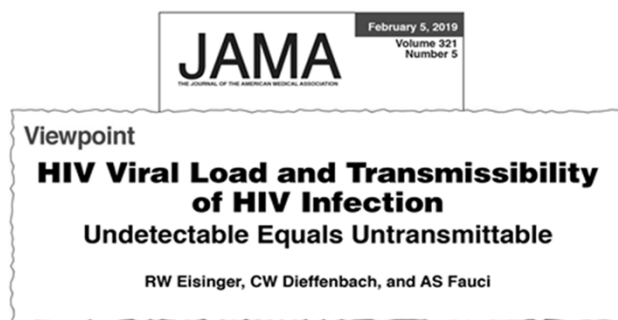


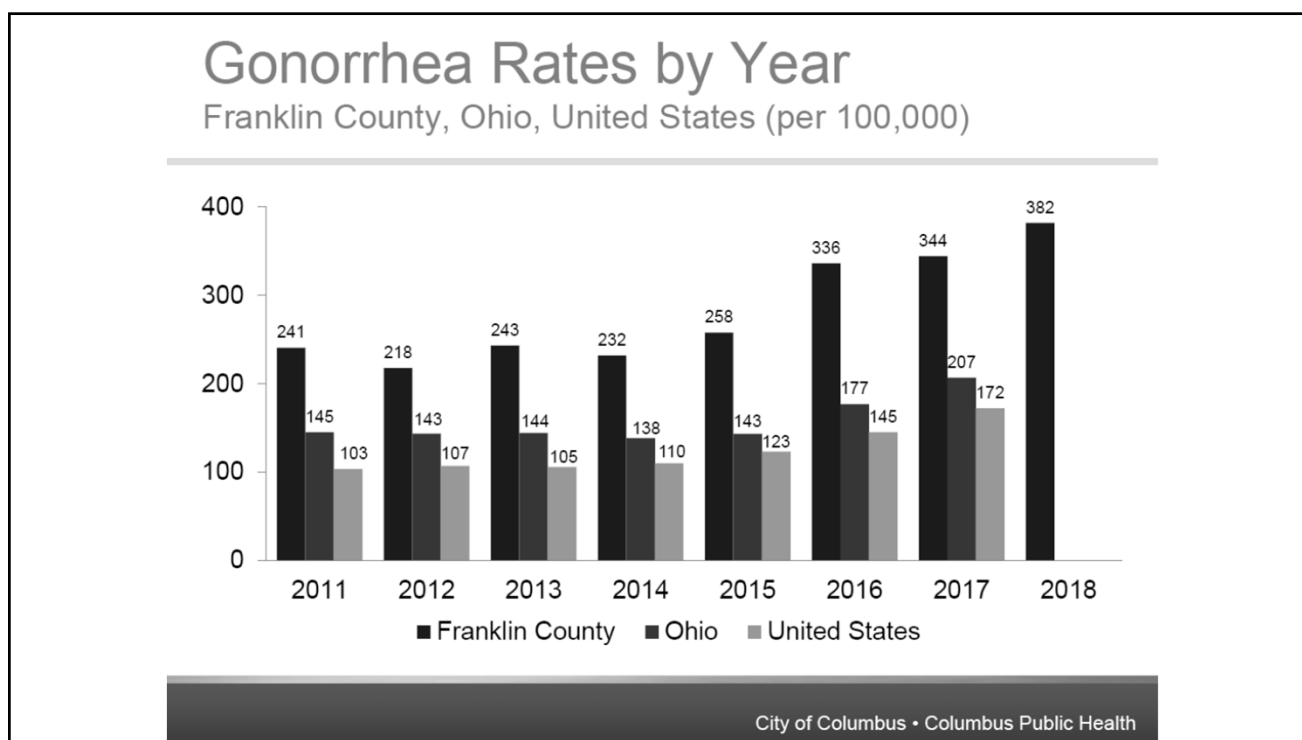
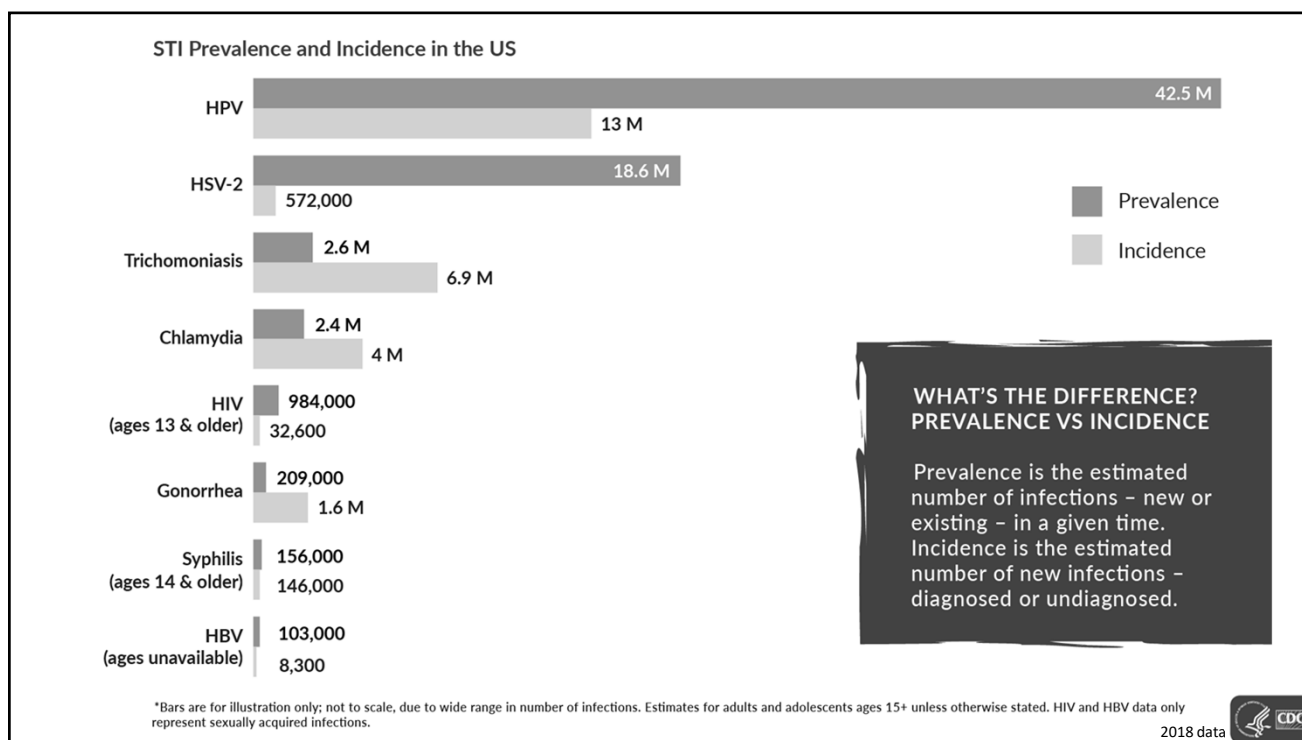
Source: CDC



Benefits of Testing/Knowing HIV Status

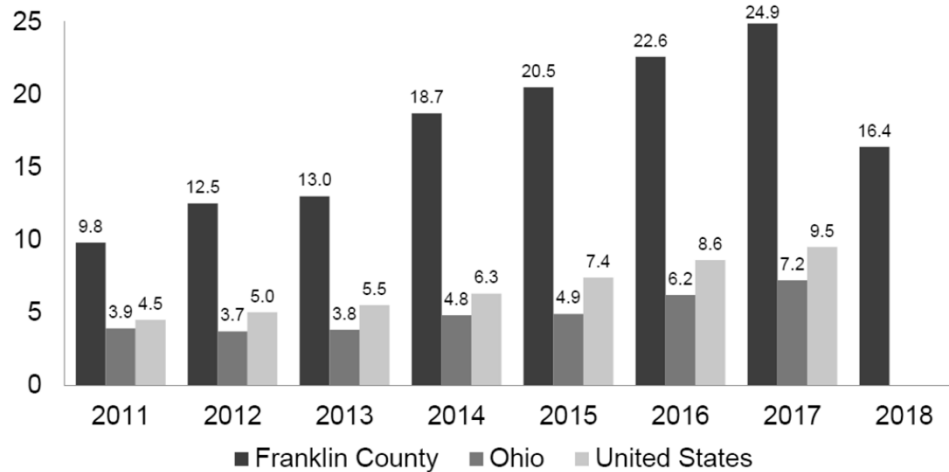
- Individual health
- Public Health



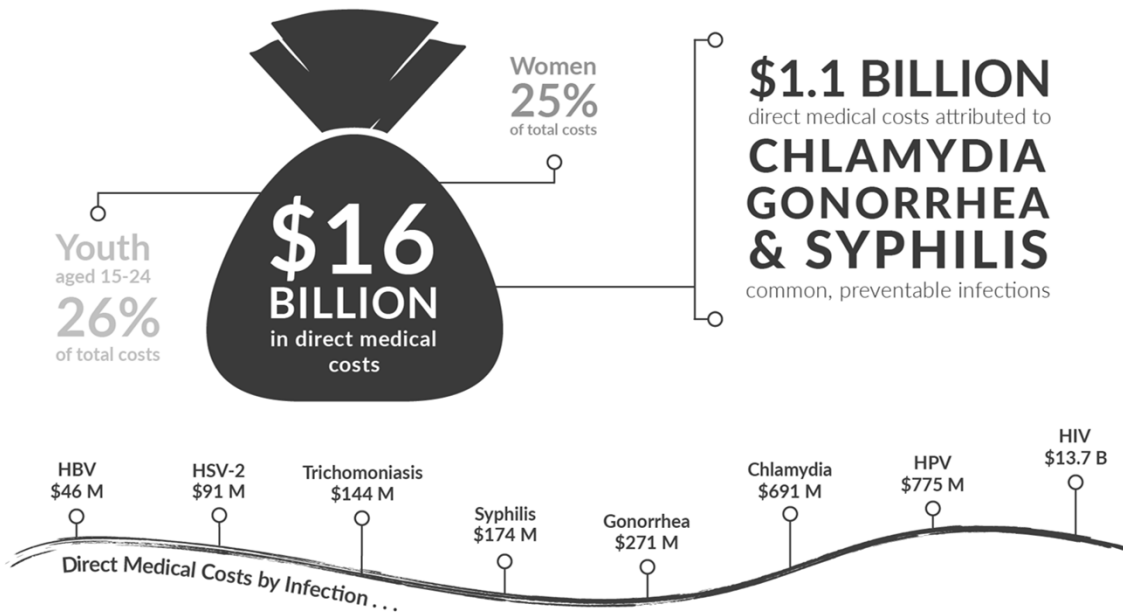


Syphilis Rates by Year

Primary & Secondary; Franklin County, Ohio, U.S. (per 100,000)



City of Columbus • Columbus Public Health



2018 data

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2022

Vaccine	Pregnancy	Immu- compromised (excluding HIV infection)	HIV Infection CD4 percentage and count <15% or <200 mm ³ ≥15% and ≥200 mm ³	Asplenia, complement deficiencies	End-stage renal disease, or on hemodialysis	Heart or lung disease; alcoholism ¹	Chronic liver disease	Diabetes	Health care personnel ²	Men who have sex with men
IIIV4 or RIV4 or LAIV4										
Tdap or Td	1 dose Tdap each pregnancy									
MMR	Contraindicated ³	Contraindicated								
VAR	Contraindicated ³	Contraindicated								
RZV			2 doses at age ≥19 years							
HPV	Not Recommended ⁴	3 doses through age 26 years								
Pneumococcal (PCV15, PCV20, PPSV23)										
HepA										
HepB	3 doses (see notes)									
MenACWY			1 or 2 doses depending on indication							
MenB	Precaution		2 or 3 doses depending on vaccine and indication, see notes for booster recommendations							
Hib		3 doses HSCT ⁵ recipients only								



Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of past infection
 Recommended vaccination for adults with an additional risk factor or another indication
 Recommended vaccination based on shared clinical decision-making
 Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction
 Contraindicated or not recommended—vaccine should not be administered.
 *Vaccinate after pregnancy.
 No recommendation/Not applicable



HIV Update

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PrEP

Pre-Exposure Prophylaxis

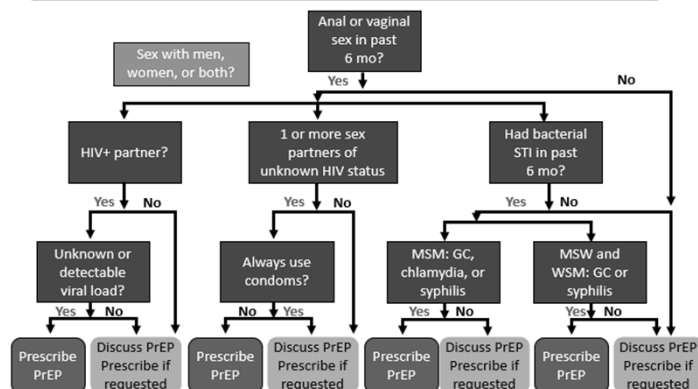
Pre-exposure Prophylaxis: A pharmacologic HIV prevention intervention for persons at high risk of acquiring HIV.

A person without HIV takes antiretroviral medication(s) **before** potential HIV exposure

First option was daily oral TDF/FTC (FDA approved in 2012)

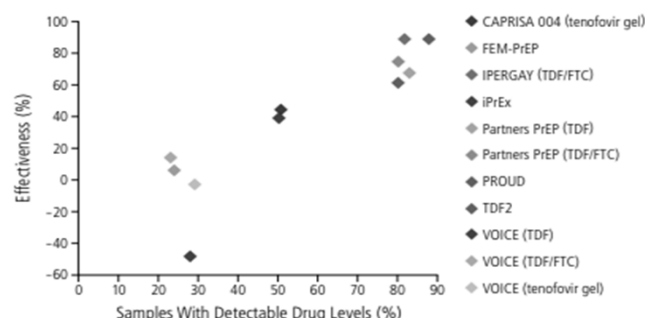
TAF/FTC is an alternative oral option (not evaluated in cis-gender women)

“All sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition”

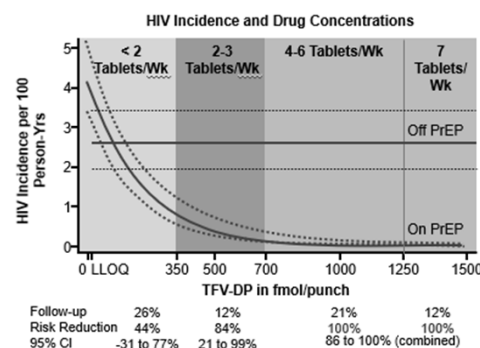


CDC. PrEP Guidelines. 2021.

Adherence is Important for Oral PrEP



Buchbinder. *Top Antivir Med.* 2018;25(4):138-142



- In Men Who have Sex With Men 100% adherence was not required to attain full benefit from PrEP
- Benefit of 4-6 tablets/wk similar to 7 tablets/wk

1. Grant R, et al. IAC 2014. Abstract TUAC0105LB.

Oral PrEP Safety

TDF/FTC is well tolerated

Start-up syndrome

- 1-18.5% with nausea, vomiting \pm dizziness

Renal safety

- 0.2% Grade 2-4 elevations in creatinine among 5469 participants randomized to TDF/FTC

Bone safety

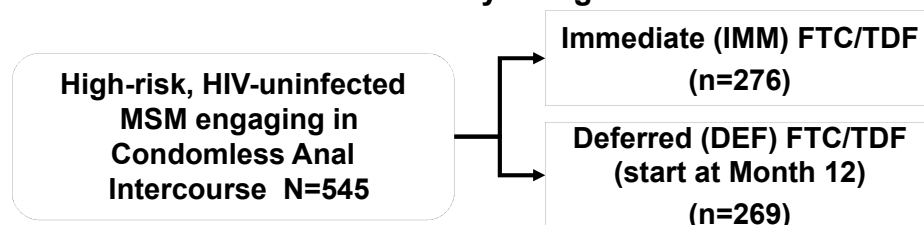
- 0.4 to 1.5% loss of BMD across total hip, spine
- Return to baseline after discontinuation
- Not associated with increased fracture risk

1. Grant RM, et al. *N Engl J Med.* 2010;363:2587-2599.
2. Van Damme. *N Engl J Med* 2012; 367:411-422
3. Thigpen MC, et al. *N Engl J Med* 2012; 367:423-434
4. Grant, et al. Abstract 48 LB. CROI 2016. Boston, MA
5. Baeten JM, et al. *N Engl J Med.* 2012;367:399-410.

PrEP Highly Effective in “Real World” Evaluation

PROUD Trial: Randomized, multi-center, open-label pilot study in London

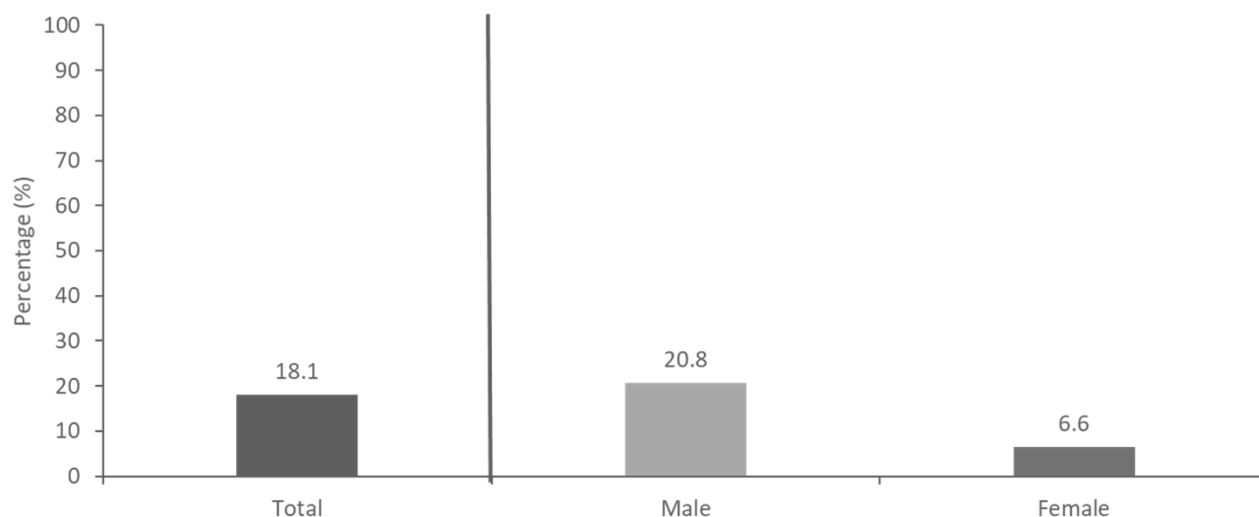
Study Design



- **DSMB stopped study early due and recommended that all participants be offered PrEP**
- **86%** reduction in risk seen over 60 wks with immediate PrEP (90% CI: 58% to 96%, $P = .0002$)
 - Rate difference: 7.6 (90% CI: 4.1-11.2)
 - Number needed to treat to prevent 1 infection: 13 (90% CI: 9-25)

McCormack S, et al. CROI 2015; Seattle, WA. #22LB

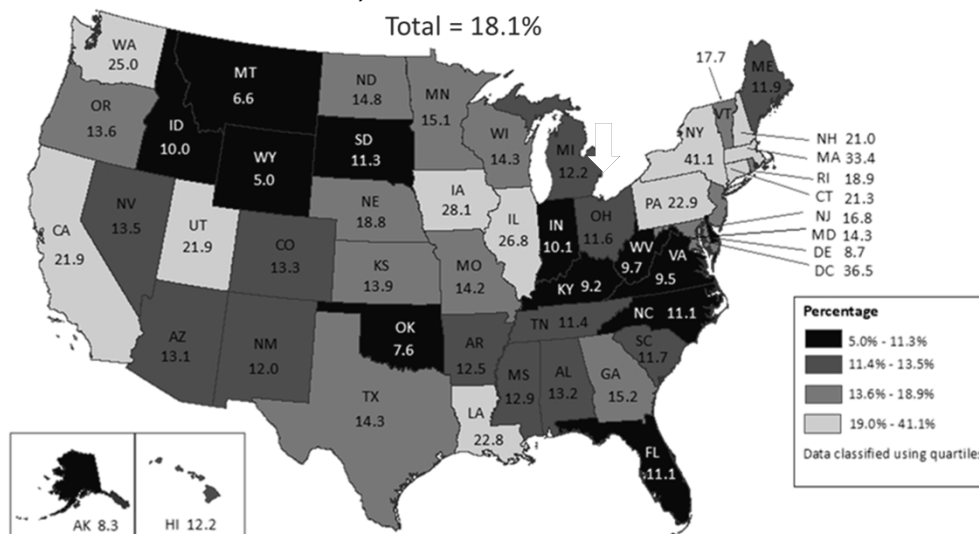
PrEP Coverage among Persons at Risk Remains Very Low



Abbreviation: PrEP, preexposure prophylaxis.

Note. PrEP coverage, reported as a percentage, was calculated as the number who have been prescribed PrEP divided by the estimated number of persons who had indications for PrEP. Different data sources were used in the numerator and denominator to calculate PrEP coverage.

PrEP Coverage among Persons Aged ≥16 Years, by Area of Residence, 2018—United States



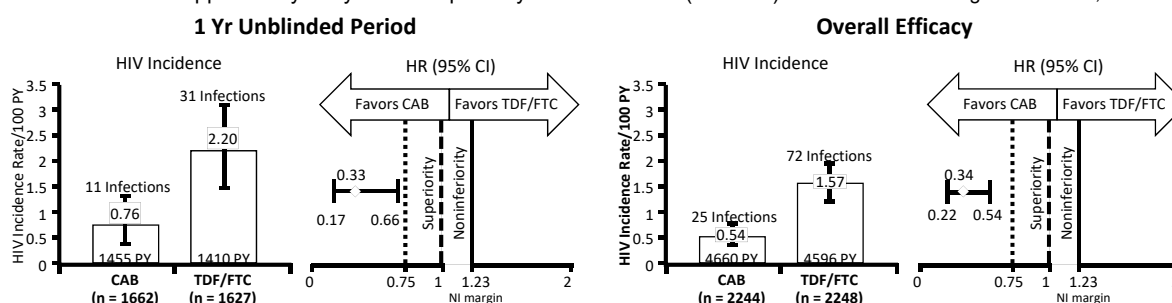
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Source: CDC

Long Acting Acting Cabotegravir Superior to TDF/FTC

HPTN 083: DSMB stopped study early due to superiority of LA-CAB arm (HR 0.75) Landovitz et al. N Engl J Med 2021; 385:595-608



Landovitz. CROI 2022. Abstr 96

Primary Efficacy Endpoint	HPTN 083 ^{1,2}		HPTN 084 ^{3,4}	
	CAB (n = 2244)	FTC/TDF (n = 2247)	CAB (n = 1614)	FTC/TDF (n = 1610)
HIV infections, n	13*	39	4*	36
HR for CAB vs FTC/TDF (95% CI)	0.34 (0.18-0.62)		0.11 (0.04-0.32)	

*Includes 1 case readjudicated post hoc as a baseline infection

1. Landovitz. NEJM 2021 Aug 12;385:595. 2. Landovitz. AIDS 2020. Abstr OAXLB0101.
3. Delany-Moretlwe. HIVR4P 2021. Abstr HY01.02. 4. Marzinke. IAS 2021. Abstr PECLB25.

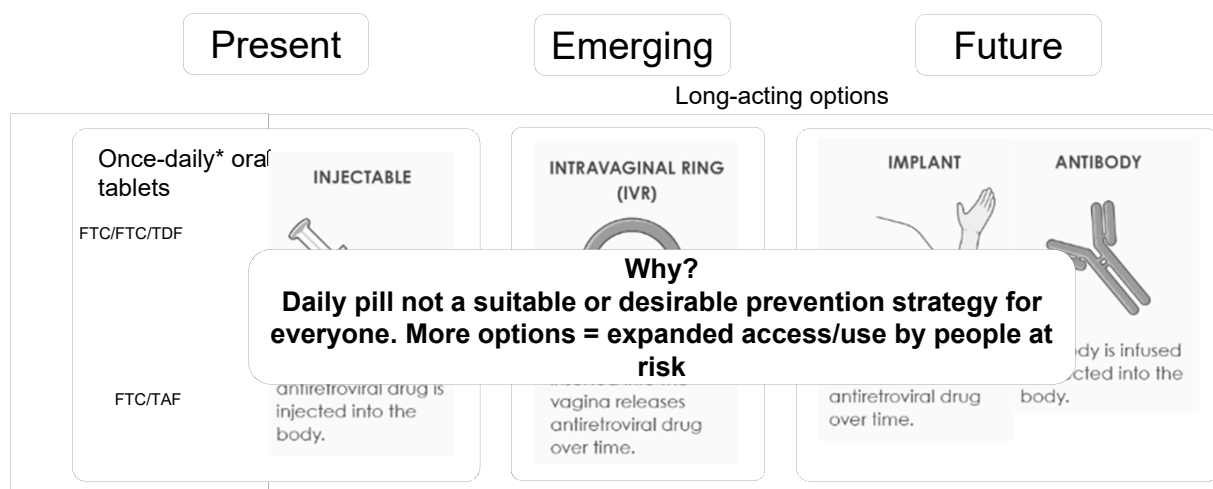
New Long-Acting Option for PrEP

Long-acting cabotegravir (IM injection every 2 months)

- For use as PrEP in at-risk adults and adolescents weighing ≥ 35 kg to reduce the risk of sexually acquired HIV
- Initiated as 2 injections administered 1 mo apart, and then every 2 mo thereafter
- Patients can either start with cabotegravir injections or take oral cabotegravir for 4 wk to assess how well they tolerate the drug

Cabotegravir extended-release injectable suspension PI.

HIV PrEP: Present, Emerging, and Future



*Off-label on-demand use of FTC/TDF supported by international guidelines.

hiv.gov/hiv-basics/hiv-prevention/potential-future-options/long-acting-prep

Resources

Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents

<http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>

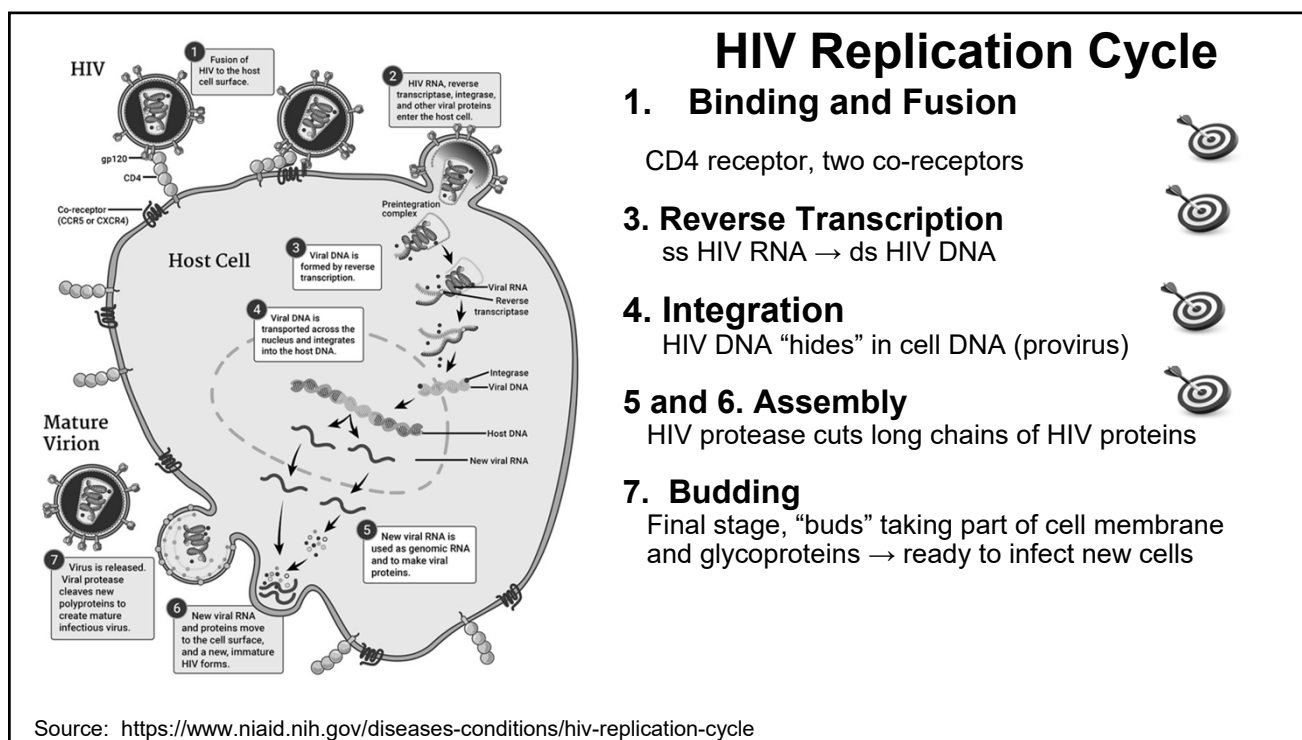
PrEP Guideline 2021 Update-CDC

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

Primary Care Guidelines for the Management of Persons Infected With HIV: 2020 Update by the HIV Medicine Association of the Infectious Diseases Society of America

<https://academic.oup.com/cid/article-lookup/doi/10.1093/cid/ciaa1391>

Antiretroviral Treatment (ART)



Current ARV Medications 2022

NRTIs (Nucleoside RTIs)

- abacavir (ABC)
- didanosine (ddI)
- emtricitabine (FTC)
- lamivudine (3TC)
- stavudine (d4T)
- tenofovir (TDF/TAF)
- zidovudine (AZT, ZDV)

Integrase Inhibitor

- raltegravir (RAL)
- elvitegravir (ELV)
- dolutegravir (DTG)
- Cabotegravir (CAB)*

Non-NRTIs

- delavirdine (DLV)
- efavirenz (EFV)
- etravirine (ETR)
- nevirapine (NVP)
- rilpivirine (RPV)
- Doravirine (DOR)

Entry Inhibitors

Fusion Inhibitor

- enfuvirtide (T-20)

CCR5 Antagonist

- maraviroc (MVC)

CD4 Blocker

- Ibalizumab

Protease Inhibitors

- atazanavir (ATV)
 - ATV/c
- darunavir (DRV)
 - DRV/c
- fosamprenavir (FPV)
- indinavir (IDV)
- lopinavir/r (LPV/r)
- nelfinavir (NFV)
- ritonavir (RTV)
- saquinavir (SQV)
- tipranavir (TPV)

Current Combination ARV Medications

NRTIs (Nucleoside RTIs)

- abacavir (ABC)/lamivudine (3TC) = **Epzicom**
- zidovudine (ABC)/lamivudine (3TC) = **Combivir**
- abacavir (ABC)/lamivudine (3TC)/zidovudine (AZT) = **Trizivir**
- emtricitabine (FTC)/tenofovir (TDF) = **Truvada** **TAF Version: Descovy**

Protease Inhibitors

- lopinavir (LPV) + ritonavir (r) = **Kaletra**
- atazanavir (ATV) + cobicistat* = **Evotaz**
- darunavir (DRV) + cobicistat = **Prezcobix**

Current Combination ARV Medications

“Complete” Single Tablet Regimens

- Descovy+BIC=**Biktarvy**
- Truvada + EFV (Sustiva) = **Atripla**
- Truvada + RPV (Edurant) = **Complera** **TAF Version: Odefsey**
- Truvada + EGV/cobi = **Stribild** **TAF Version: Genvoya**
- Epzicom + DTG (Tivicay) = **Triumeq**
- Rilpivirine+DTG (Tivicay)=**Juluca**
- Lamivudine+DTG (Tivicay)=**Dovato**

Principles of HIV Treatment

- 2-3 fully active drugs given together to maintain viral suppression
- Current ART regimens are potent and safe with minimal adverse effects
- ART should be fully suppressive
 - Target HIV RNA < limit of quantification
 - “Detectable HIV RNA on Rx = **Failure**”
- All or none principle (decreases risk of viral resistance)
- Compliance $\geq 95\%$ with daily oral regimen to achieve goal HIV RNA
- CD4 T cell reconstitution occurs after HIV RNA = undetectable
- We can maintain viral suppression indefinitely but we are not yet able to eradicate long-lived latently infected cells (“HIV reservoir”)

Undetectable HIV Viral Load Equals Untransmittable HIV Infection (U=U)

- In 2017, HIV Medical Association officially endorsed the U=U Consensus Statement
 - “When a person living with HIV has an undetectable viral load, they will **not** transmit HIV to their sexual partners.”
- Supported by data from several studies from 2008-2016 showing zero linked HIV transmissions after > 100,000 condomless sex acts within both female–male and male–male serodiscordant couples in which the partner living with HIV had a **durably undetectable viral load**

UNDETECTABLE = UNTRANSMITTABLE



HPTN 052

PARTNER

Opposites Attract

PARTNER 2

<https://www.hivma.org>

HIV START Trial

Early vs Delayed ART

CD4>500/mm³ and No Symptoms

Early therapy vs delay until CD4<350/mm³ or AIDS defining illness

Early therapy permits rapid achievement of viral suppression

Early ART prevents

AIDS events

AIDS related cancers

Major cardiovascular, renal and liver disease

Non-AIDS cancer

Death not attributable to AIDS

Serious AIDS events, serious non-AIDS events and death ↓ 57%

START Study Group, Lundgren JD, et al. NEJM. 2015 Aug 27;373(9):795-807

Future of HIV Treatment

- Recent ART options are potent, well tolerated and safe and permit simplification to single tablet regimens with minimal DDIs
- New drug classes soon to become available (capsid inhibitors, broadly neutralizing antibodies, etc)
- More long-acting options (oral, injectable, implants) dosed every 2-4 months and possibly every 6 months!
- Lots of research ongoing to achieve functional cure

Putting It All Together

PrEP+Treatment as Prevention

HIV Care Continuum

- *“The HIV care continuum is a public health model that outlines the steps or stages that people with HIV go through from diagnosis to achieving and maintaining viral suppression”*

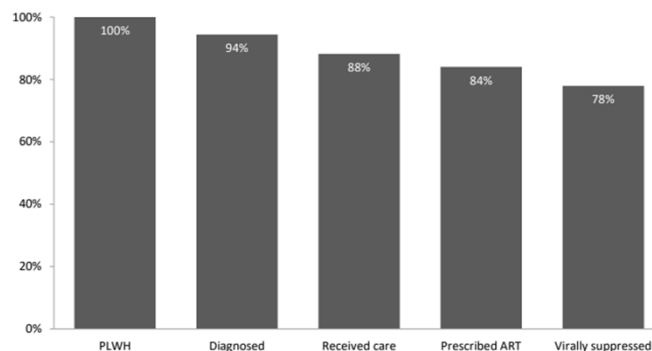


<https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum>

90-90-90 UNAIDS Targets

- By 2020
 - 90% of PLWH will know their HIV status
 - 90% of people with diagnosed HIV will receive ART
 - 90% of people receiving ART will be virally suppressed
- If 90-90-90 targets are achieved, 73% of PLWH would be virally suppressed and the HIV epidemic would end by 2030

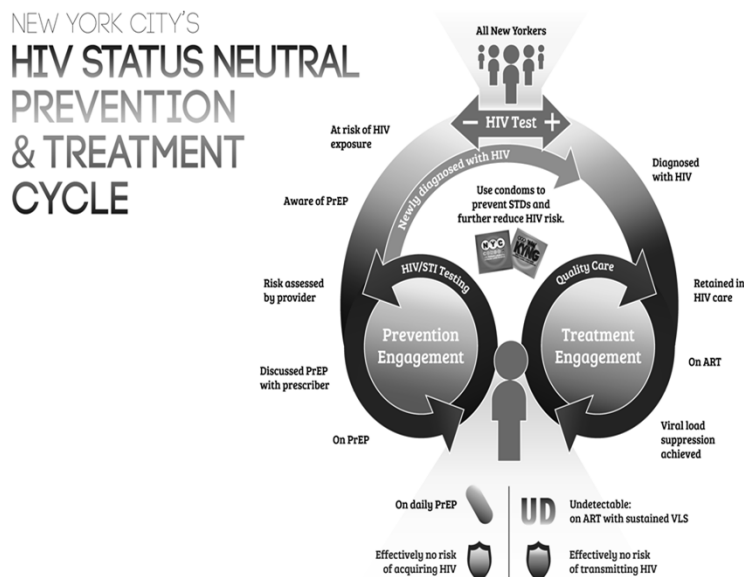
HIV Care Continuum (New York City 2020)



- NYC and other cities around the world have achieved 90-90-90 targets

HIV Epidemiology and Field Services Program. *HIV Surveillance Annual Report, 2020*. New York City Department of Health and Mental Hygiene: New York, NY. December 2021

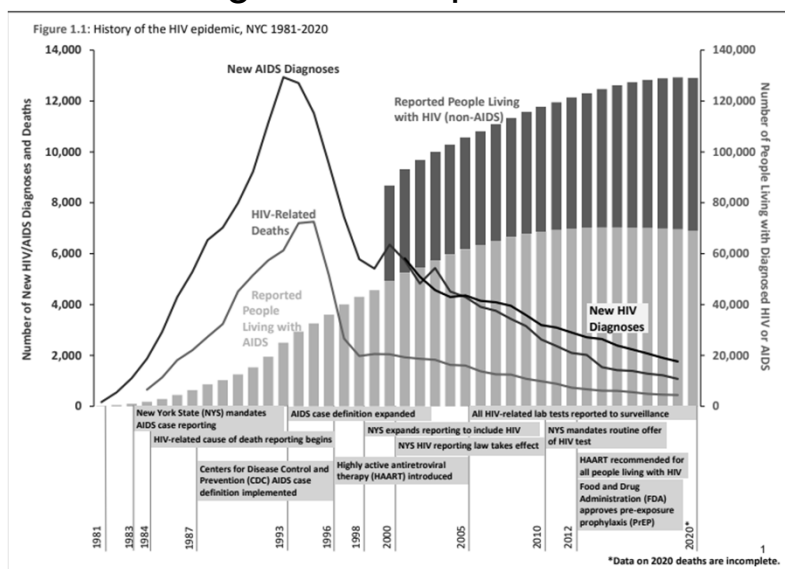
NEW YORK CITY'S HIV STATUS NEUTRAL PREVENTION & TREATMENT CYCLE



People at risk of HIV exposure taking daily PrEP and people with HIV with sustained viral load suppression do not acquire or transmit HIV.

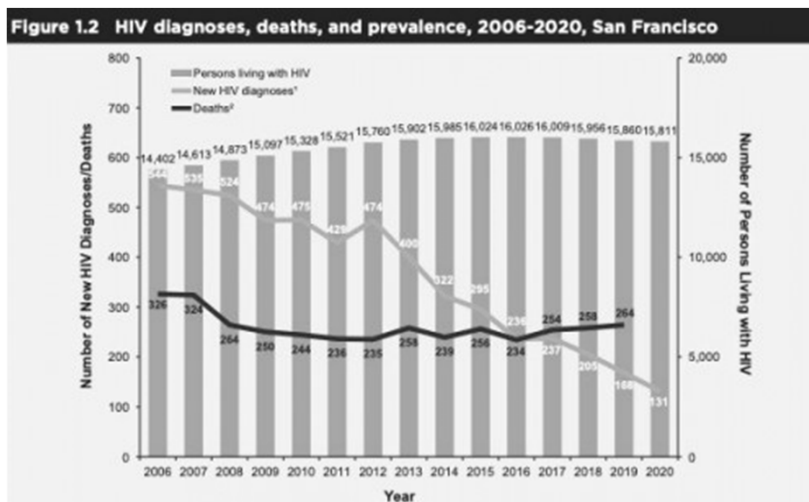
NYC Department of Health

Ending the HIV Epidemic in New York City



HIV Epidemiology and Field Services Program. *HIV Surveillance Annual Report, 2020*. New York City Department of Health and Mental Hygiene: New York, NY. December 2021

Declining HIV Incidence in San Francisco



San Francisco HIV Epidemiology Report 2020

Ending the HIV Epidemic: We have the tools to do it

Ending the HIV Epidemic: A Plan for America

February 2020

The U.S. Department of Health and Human Services (HHS) has launched Ending the HIV Epidemic: A Plan for America. The cross-agency initiative leverages critical scientific advances in HIV prevention, diagnosis, treatment, and outbreak response by coordinating the highly successful programs, resources, and infrastructure of many HHS agencies and offices.

GOAL:

reaching
75%
reduction
in new HIV
infections
by 2025
and at least
90%
reduction
by 2030.

HHS will work with each community to establish local teams on the ground to tailor and implement strategies to:



Diagnose all people with HIV as early as possible after infection.



Treat the infection rapidly and effectively to achieve sustained viral suppression.

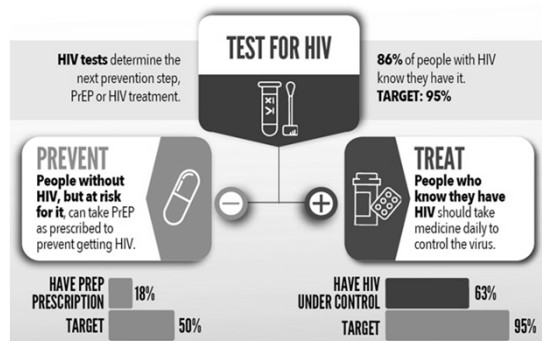


Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).



Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

<https://www.cdc.gov/endhiv/about.html>



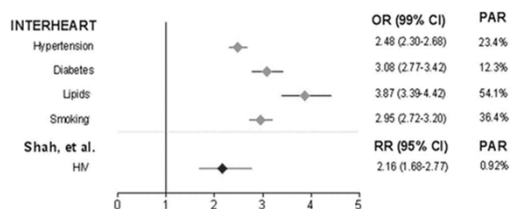
Comorbidities in HIV: Cardiovascular Disease

Cardiovascular Disease in HIV

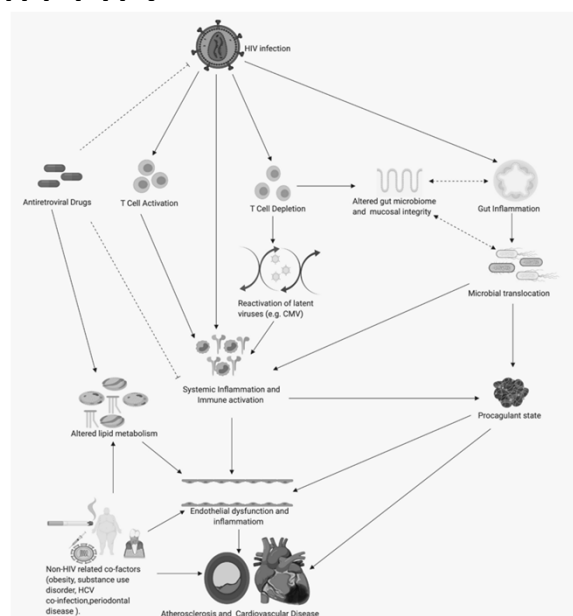
CVD is a leading cause of death for PWH

Associated in part to increased prevalence of traditional risk factors (smoking, HTN, diabetes)

But HIV itself is an independent risk factor for CVD (related to chronic inflammation and immune activation despite viral suppression)



Hsue PY, Waters DD. Time to Recognize HIV Infection as a Major Cardiovascular Risk Factor. Circulation. 2018 Sep 11;138(11):1113-1115

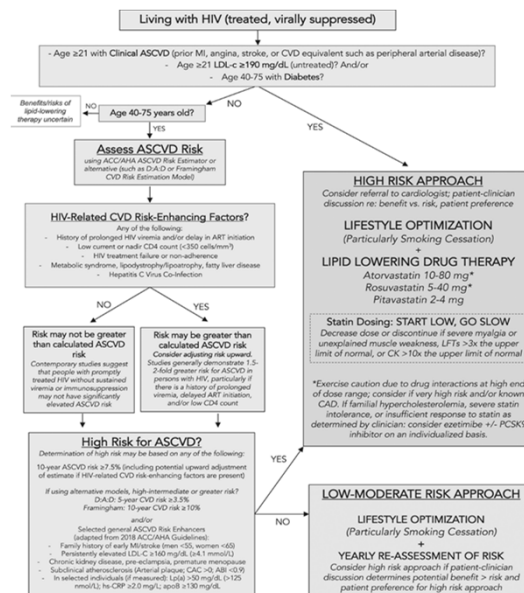


Titanji B, et al. J Am Heart Assoc. 2020 Feb 4;9(3):e014873

Management of CVD Risk in PWH

ACC/AHA and Framingham risk ASCVD risk calculators may underestimate risk in PWH

AHA Guidelines recommend taking into account HIV-related CVD Risk-Enhancing Factors



Triant VA, et al. *Circulation* 2018;137(19):2203-14

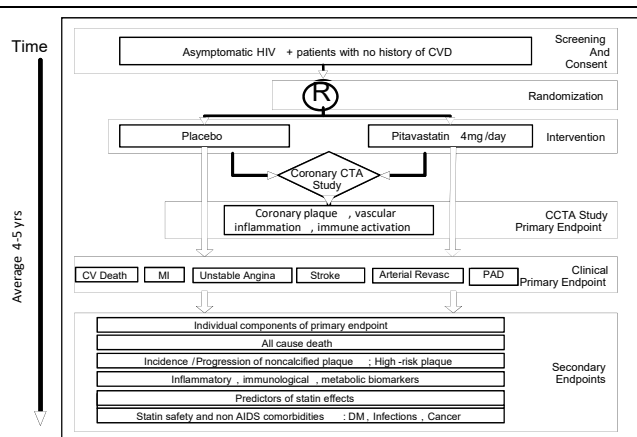
Feinstein MJ et al. Characteristics, prevention, and Management of CVD in People Living with HIV: A Scientific Statement from the American Heart Association. *Circulation* 2019;140(2):e98-e124.

Statins to Reduce Cardiovascular Events in PWH

The JUPITER trial showed impact of statins on inflammation and mortality in people without HIV (Ridker et al. NEJM 2008;359:2195-2207)

REPRIEVE Trial evaluating use of statin as primary prophylaxis in PWH on ART with mild to moderate ASCVD risk

REPRIEVE Trial Design
N=7700



Source: Steve Grinspoon MD