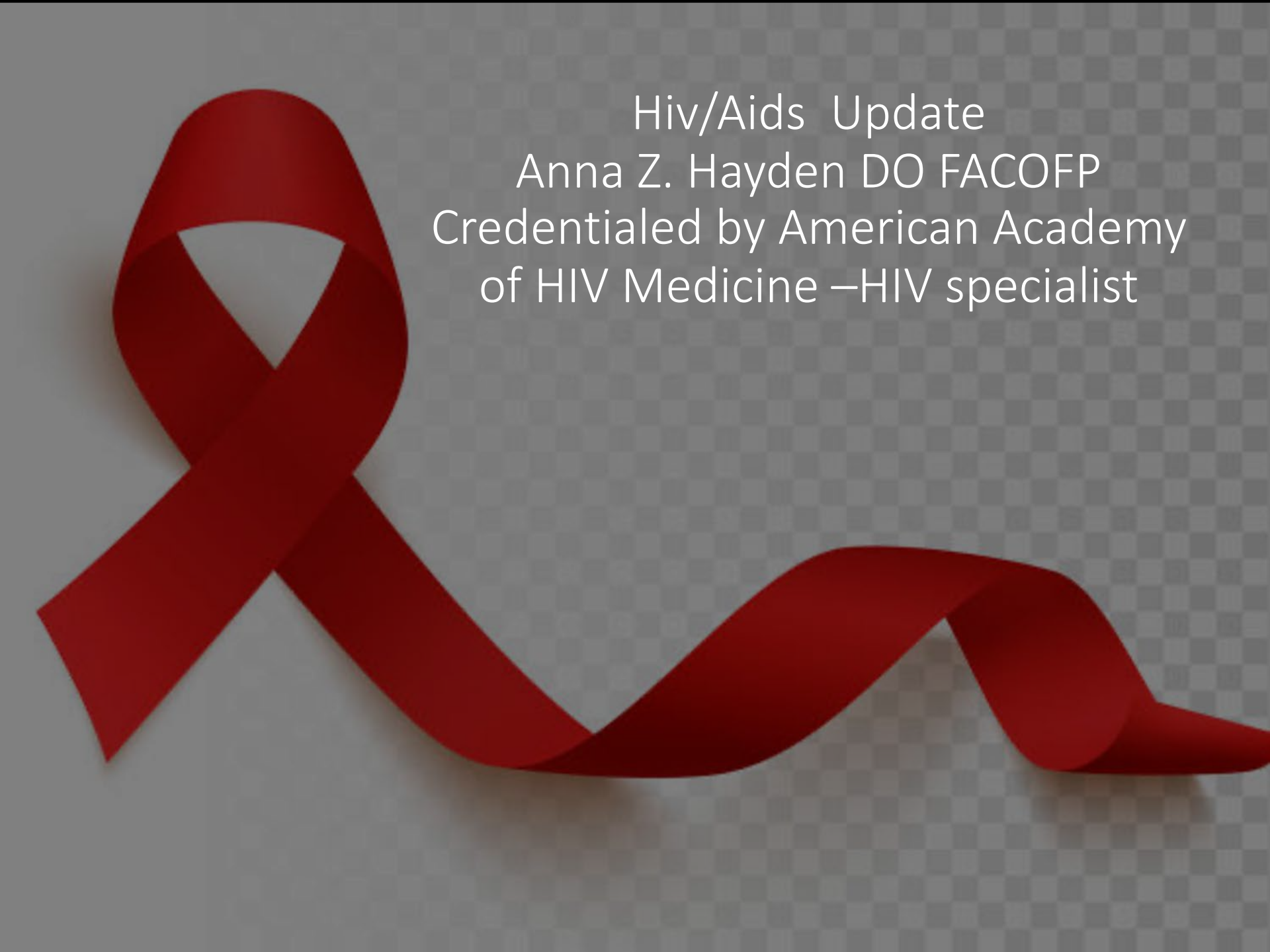


# Hiv/Aids Update

Anna Z. Hayden DO FACOFP
Credentialed by American Academy of HIV Medicine –HIV specialist

# Disclosures:

None

# 456.033 HIV

- Modes of transmission
- Screening procedures to diagnosis hiv
- Infection control

  behavioral-reducing condom less sex, dec # of partners, dec sex trade, dec IVDU frequency-treating SUD

  biomedical- TasP, PrEP, PEP, Tx STD & T&T

  structural- universal precautions to safe blood supply, clean syringe programs, funding HIV test
- Clinical management – identify a regime for a patient newly dx
- Prevention
- Florida Law

# Who should be routinely screened for HIV according to CDC guidelines?

- 1. All individuals regardless of risk
- 2. All individuals if written consent & post test counseling is done
- 3. Only those who request
- 4. High risk individuals (mandatory) & voluntary screening for ` everyone else
- 5. MSM: AA males > 13yo

# Which test is recommended for initial HIV testing?

- 1. Western Blot
- 2. 2nd Generation HIV antibody test
- 3. 4th Generation HIV antibody/p24 antigen test
- 4. HIV 1 nucleic acid test (RNA)

# What is the most accurate regarding the timing of ART initiation in person newly dx with acute hiv

1. ART should be initiated 4 weeks after dx
2. ART should begin on the same day of treatment initiation for most opportunistic infections
3. ART initiation should be delayed in the setting of new dx of cancer
4. ART should be initiated at the time of diagnosis

# What information is needed prior to treating + Hiv rapid test (Test & Treat) ?

- 1. CD4 count
- 2. HIV1 RNA
- 3. HIV genotype
- 4. HLAB 5701 status
- 5. all the above
- 6. none of the above

# What 3 drug regimen is recommended for initial tx of adults who are ART naïve?

1. Chemokine receptor 5 antagonist, integrase strand transfer inhibitor & protease inhibitor
2. Integrase strand transfer inhibitor, nucleoside & nucleotide reverse transcriptase inhibitor, & fusion inhibitor
3. Integrase strand transfer inhibitor & two nucleotide reverse transcriptase inhibitors
4. Fusion inhibitor & nonnucleoside reverse transcriptase inhibitor

# Which HIV viral load value is considered a virologic failure for individuals receiving ART without prior ART exposure?

1. >20 to < 50 copies/ml
2. >50 copies/ml but < 100 copies/ml
3. >50 copies/ml but < 150 copies/ml
4. > 200 copies/ml

# Which of the following individual is an appropriate candidate for PrEP?

- 1. HIV (-) male who has unprotected sex with multiple male sex partners in past yr.
- 2. HIV (-) female in a monogamous relation who has recently treated for HSV2 and uses cocaine
- 3. HIV (+) male who admits to sex with multiple partners
- 4. HIV (-) female who admits to unprotected sex with one male of uncertain HIV status.

The use of emtricitabine/tenofovir FTC/TAF (descovy) for HIV pre-exposure prophylaxis is not FDA approved for?

1. at risk MSM
2. person at risk for acquiring hiv infection from receptive vaginal sex
3. at risk heterosexual men

# Modes of transmission

- Body fluids are:
  - Blood
  - Semen (*cum*) and pre-seminal fluid *(pre-cum)*
  - Rectal fluids
  - Vaginal fluids
  - Breast milk

- One can only get HIV by coming into direct contact with certain body fluids from a person with HIV who has a detectable viral load.

# Modes of Transmission

- Homosexual and heterosexual intercourse (anal, vaginal, oral)
- Injection drug use
- Vertical transmission (pregnancy, delivery, breastmilk)
- Contaminated blood products/ transfusion
- Occupational transmission involving health-care workers exposed to HIV-infected specimens

# CDC HIV RISK

**Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act***

| Type of Exposure | Risk per 10,000 Exposures |
|---|---|
| **Parenteral** | |
| Blood Transfusion | 9,250 |
| Needle-Sharing During Injection Drug Use | 63 |
| Percutaneous (Needle-Stick) | 23 |
| **Sexual** | |
| Receptive Anal Intercourse | 138 |
| Insertive Anal Intercourse | 11 |
| Receptive Penile-Vaginal Intercourse | 8 |
| Insertive Penile-Vaginal Intercourse | 4 |
| Receptive Oral Intercourse | Low |
| Insertive Oral Intercourse | Low |
| **Other^** | |
| Biting | Negligible |
| Spitting | Negligible |
| Throwing Body Fluids (Including Semen or Saliva) | Negligible |
| Sharing Sex Toys | Negligible |

* 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 pre-exposure 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.

Source:


- Patel P, Borkowf CB, Brooks JT. Et al. Estimating per-act HIV transmission risk: a systematic review. AIDS. 2014. doi: 10.1097/QAD.0000000000000298.
- Pretty LA, Anderson GS, Sweet DJ. Human bites and the risk of human immunodeficiency virus transmission. Am J Forensic Med Pathol 1999;20(3):232-239.

# Universal HIV screening aka “opt-out” testing

- In all health-care settings, screening for HIV infection should be performed routinely for all
  - 15-65 yo USPSTF
  - 13-64 yo CDC
- Health-care providers should initiate screening unless prevalence of undiagnosed HIV infection in their patients has been documented to be <0.1%. In the absence of existing data for HIV prevalence, health-care providers should initiate voluntary HIV screening until they establish that the diagnostic yield is <1 per 1,000 patients screened, at which point such screening is no longer warranted.
- Screen those women who present in labor or at delivery whose hiv status is unknown
- All patients initiating treatment for TB should be screened routinely for HIV infection.
- All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection.

# Benefits of universal screening

- Earlier dx HIV
- Reduces stigma associated with testing that requires assessment risks & behaviors
- Improves survival
- Cost effective QOL not just tx OI
- Earlier linkage to care
- Decrease transmission via reducing community viral load
- Reduce risk HIV thru mother to child transmission

# Universal screening

All pregnant women in the United States should be screened for HIV infection

A second HIV test during the third trimester for women in settings with elevated HIV incidence (>17 cases per 100,000 person-years) is cost-effective and might result in substantial reductions in mother-to-child HIV transmission .

Prevention counseling is no longer required before HIV testing in health care settings. There is no written separate form for hiv testing.  Patients are notified that HIV testing is planned and can opt-out of testing.

If HIV testing is declined, then document in the medical record patient denial

# Repeat HIV screening annually

Persons likely to be at high risk include injection-drug users and their sex partners, persons who exchange sex for money or drugs, sex partners of HIV-infected persons, and MSM or heterosexual persons who themselves or whose sex partners have had more than one sex partner since their most recent HIV test.

Health-care providers should encourage patients and their prospective sex partners to be tested before initiating a new sexual relationship.

Repeat screening of persons not likely to be at high risk for HIV should be performed based on clinical judgment. Unless recent HIV test results are immediately available, any person whose blood or body fluid is the source of an occupational exposure for a health-care provider should be informed of the incident and tested for HIV infection at the time the exposure occurs.

# FS 381.004 opt out HIV testing

- No written consent in healthcare settings
- Inform the patient that you recommend the testing as per CDC guidelines – frame it as part of their yearly screening labs
- Inform if HIV (+) report DOH
- Encourage voluntary disclosure to all current & past partners and HCW
- Only 5 states in USA do not have “opt out” testing: Nebraska, New York, Massachusetts, Pennsylvania & Rhode Island

# FS 381.004 HIV required by state law

- 1. Persons convicted of prostitution or of procuring another to commit prostitution
- 2. Pregnant females
- 3. Test by medical examiners autopsy
- 4. Occupational exposure
- 5. Inmates before release from prison
- 6. Court ordered as in sexual battery cases

# The 2024 Florida Statutes (including 2025 Special Session C)



**945.355 HIV testing of inmates prior to release.**—

(1) As used in this section, the term "HIV test" means a test ordered to determine the presen of the antibody or antigen to human immunodeficiency virus or the presence of human immunodeficiency virus infection.

(2) If an inmate's HIV status is unknown to the department, the department shall, pursuant to s. 381.004(2), perform an HIV test on the inmate not less than 60 days prior to the inmate's presumptive release date from prison by reason of parole, accumulation of gain-time credits, or expiration of sentence. An inmate who is known to the department to be HIV positive or who has been tested within the previous year and does not request retesting need not be tested under this section but is subject to subsections (4) and (5). However, an inmate who is released due to an emergency is exempt from the provisions of this section.

(3) The department shall record the results of the HIV test in the inmate's medical record.

(4) Pursuant to ss. 381.004(2) and 945.10, the department shall notify the Department of Health and the county health department where the inmate plans to reside regarding an inmate who is known to be HIV positive or has received an HIV positive test result under this section prior to the release of that inmate.

(5) Prior to the release of an inmate who is known to be HIV positive or who has received a positive HIV test result under this section, the department shall provide special transitional assistance to the inmate, which must include:

(a) Education on preventing the transmission of HIV to others and on the importance of receiving followup care and treatment.

(b) A written, individualized discharge plan that includes referrals to and contacts with the county health department and local HIV primary care services in the area where the inmate plans to reside.

(c) A 30-day supply of all HIV/AIDS-related medications that the inmate is taking prior to release under the protocols of the Department of Corrections and the treatment guidelines of the United States Department of Health and Human Services.

(6) Notwithstanding any provision of the Florida Statutes providing for a waiver of sovereign

# 3rd degree felony 381.0041(11)(b) & 384.24

Hiv criminalization : Florida criminalizes nondisclosure of hiv status to sexual partners, which is a third-degree felony, and criminalizes donating blood or tissue while knowing one is hiv positive.

# Federal & State Laws

As of 2009 all states now have confidential name-based HIV infection reporting

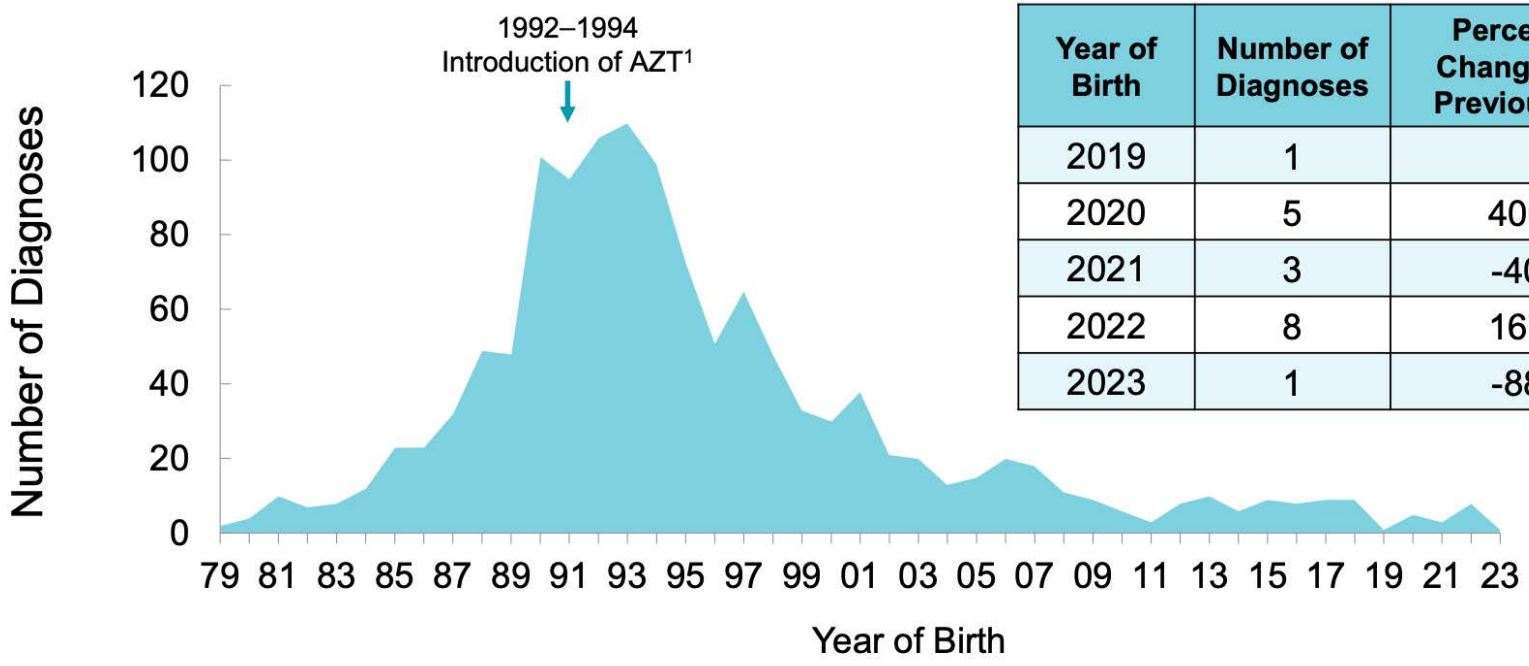
Florida partner notification service is available where name of HIV (+) is not disclosed

Federal law doesn't mandate hiv reporting

# EVIDENCE OF UNIVERSAL TESTING BENEFITS

- PRENATAL AND PERINATAL HIV TESTING HAS BEEN HUGE SUCCESS
- 1988-1993 USA  1000-2000 CHILDREN ANNUALLY BECAME INFECTED WITH HIV FROM MOTHER TO CHILD
- SINCE 2006 MOTHER TO CHILD ROUTE HAS DECREASED

# Perinatally Acquired HIV Diagnoses, 1979-2023, Babies Born in Florida




| Year of Birth | Number of Diagnoses | Percentage Change From Previous Year |
|---|---|---|
| 2019 | 1 | |
| 2020 | 5 | 400% |
| 2021 | 3 | -40% |
| 2022 | 8 | 167% |
| 2023 | 1 | -88% |

[1]AZT, short for azidothymidine, is an antiretroviral medication used during childbirth.

| Level of Transmission Risk During Breastfeeding by Maternal HIV RNA Levels | Description | Infant ARV Management During Breastfeeding[a] |
|---|---|---|
| **Sustained Viral Suppression (HIV RNA <50 copies/mL)** | When sustained maternal virologic suppression during pregnancy (at a minimum during the third trimester has been achieved, documented by at least two HIV RNA measurements below the limits of detection at least 1 month apart) and breastfeeding and there are no concerns about adherence | • After completion of 2-week ZDV prophylaxis in infants at low risk of *in utero* or intrapartum transmission, some Panel members recommend no additional ARV prophylaxis, but others recommend extended prophylaxis with NVP or 3TC during breastfeeding. The Panels did not reach consensus about the use of extended ARV prophylaxis during breastfeeding (see Table 12.1).<br>• Most Panel members recommend that, if used, extended ARV prophylaxis should be continued until 6 weeks after last exposure to breast milk. However, it may be reasonable to discontinue prophylaxis earlier when concern for maternal viremia is low. |

https://clinicalinfo.hiv.gov/en/guidelines/perinatal/management-infants-utero-intrapartum-breastfeeding-hiv-exposure#table-exposure-breastfeeding 8/17/2025 accessed

December 19, 2024

## *Preventing HIV Transmission During Infant Feeding*

- Bulleted recommendations now include information from the text on counseling about the infant feeding options of formula feeding, use of banked donor milk, or breastfeeding. Recommendations also address clinical management if viremia is identified.
    - In the case of a detectable viral load during breastfeeding, the Panels recommend breastfeeding be stopped temporarily or discontinued and replacement feeding initiated while the viral load is rechecked; causes for the viremia are assessed, and, when applicable, adherence counseling is reinforced **(AII).** Most experts recommend permanent discontinuation of breastfeeding when HIV RNA is ≥200 copies/mL **(CIII).**
    - Depending on the level and persistence of viremia during breastfeeding, next steps may include initiating or modifying infant antiretroviral (ARV) prophylaxis, permanently stopping breastfeeding, and considering the need for additional infant HIV testing.
    - If the repeat viral load is undetectable, a joint decision should be made by the parent and providers about whether breastfeeding may resume **(AIII).**

# Rating Scheme for Recommendations

- Strength of recommendation:
  - A: Strong
  - B: Moderate
  - C: Optional
- Quality of evidence:
  - I: ≥1 randomized controlled trials
  - II: ≥1 well-designed nonrandomized trials or observational cohort studies with long-term clinical outcomes
  - III: Expert opinion

# Origin and spread of HIV

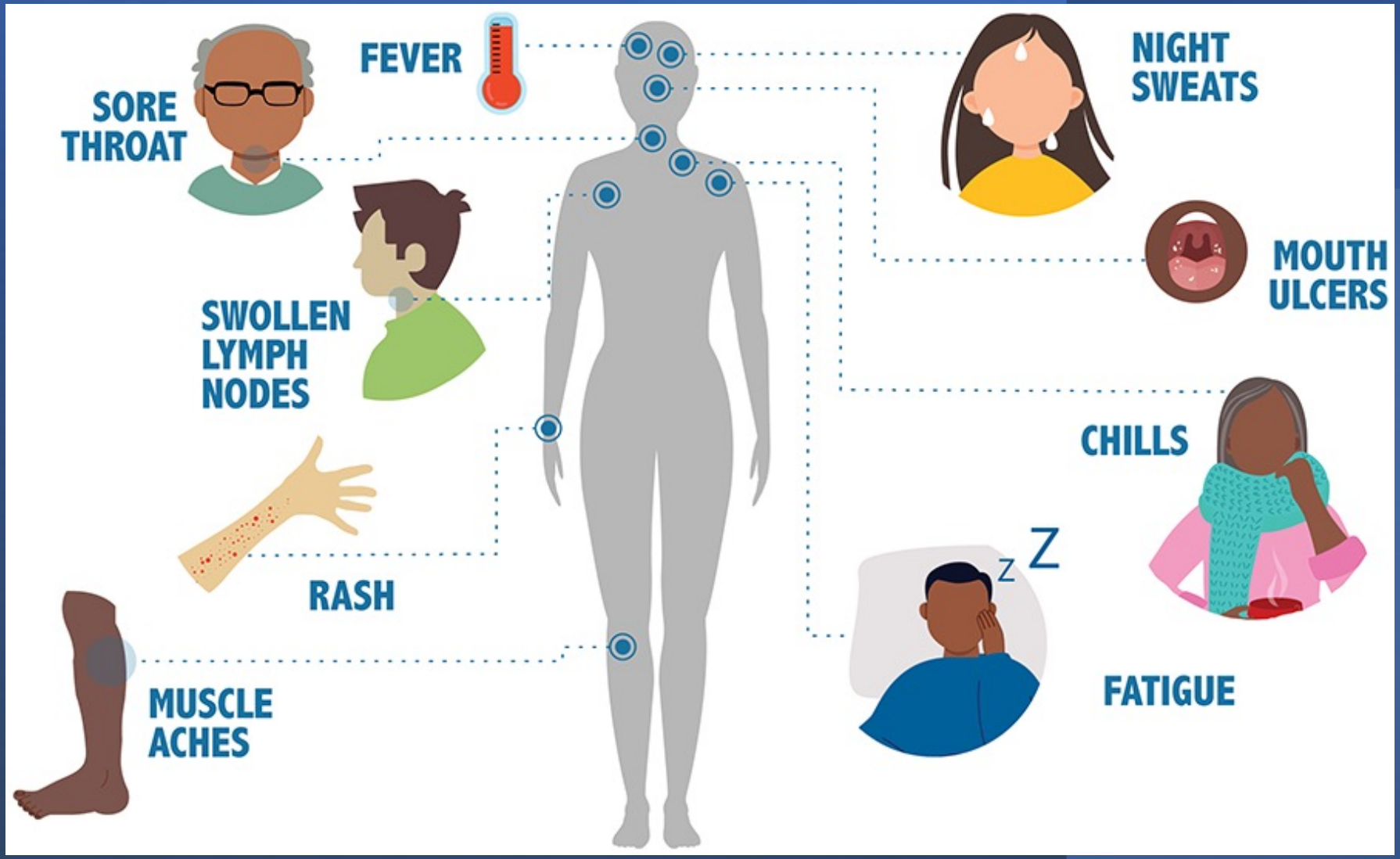
- AIDS outbreak becomes pandemic
  - Initially seen in Europe, United States
  - Spread to Asia and the Americas
  - HIV discovered in 1981 (family Retroviridae genus Lentivirus)
  - Clinical syndrome defined by CDC in 1982
  - Epidemiology  transmission via blood, semen, vaginal secretions, and breast milk from a person with detectable HIV viral load
  - HIV found in human blood sample from 1959

# Origin and spread of HIV

- HIV variants emerge
  - HIV-1
    - Isolated in 1983
    - Origin chimpanzee
    - Most prevalent strain worldwide
  - HIV-2
    - Isolated in 1985
    - Origin in the sooty mangabey
    - Dominant in West Africa

# Clinical features of acute HIV infection-AHI

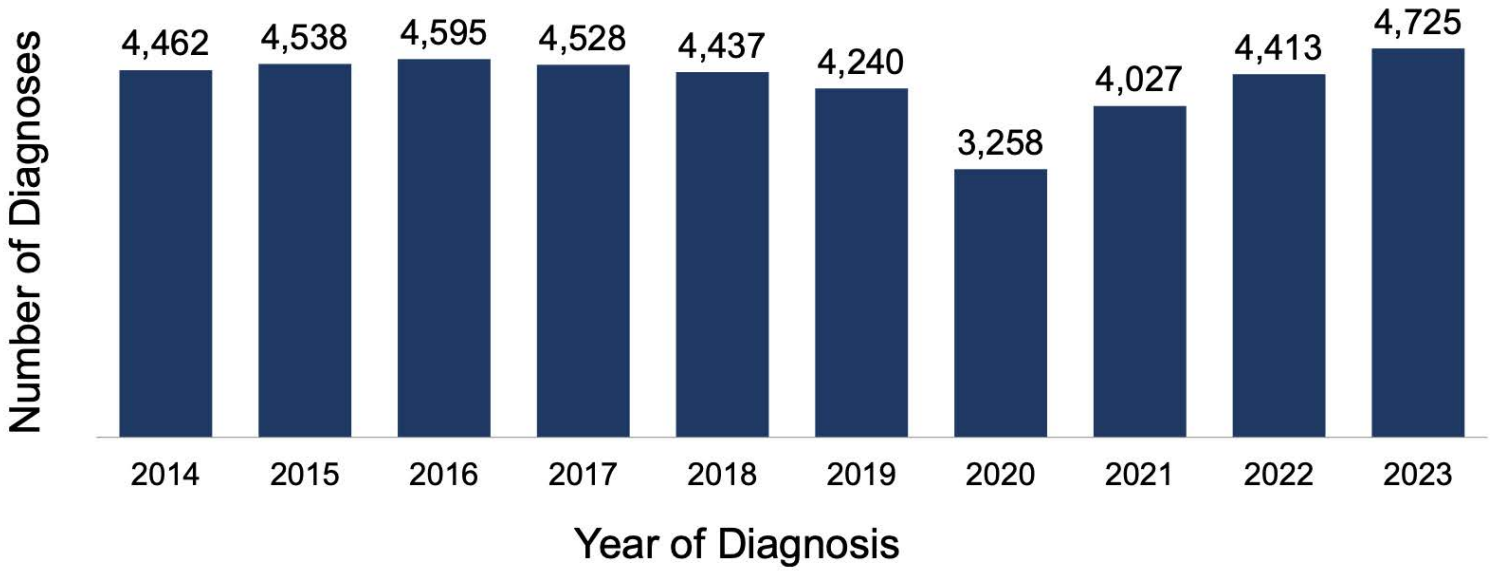
| Feature | Frequency |
| --- | --- |
| Fever | 70-80% |
| Fatigue | 66-70% |
| Rash | 50% |
| Myalgia | 50% |
| Sore throat | 40-80% |
| Headache | 45% |
| Lymphadenopathy | 40% |
| GI symptoms (n/v, diarrhea) | 30% |

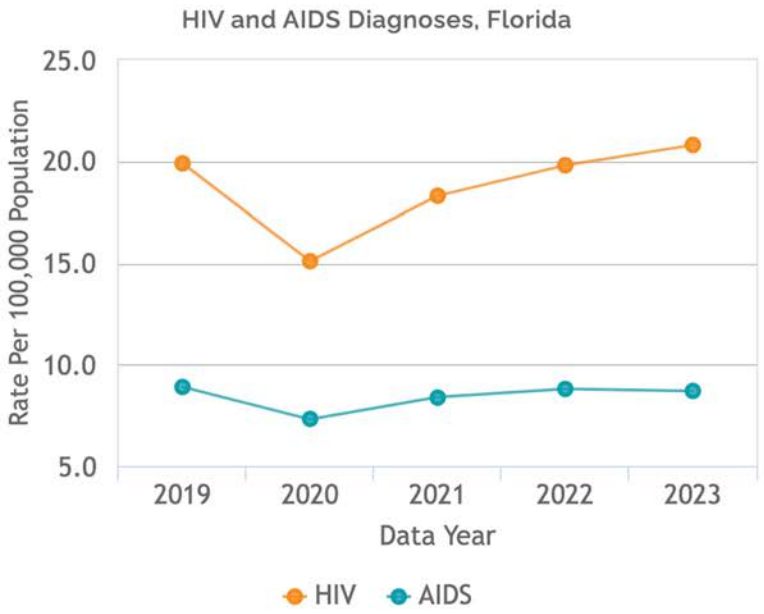

SORE THROAT
FEVER
NIGHT SWEATS
SWOLLEN LYMPH NODES
MOUTH ULCERS
CHILLS
RASH
MUSCLE ACHES
FATIGUE

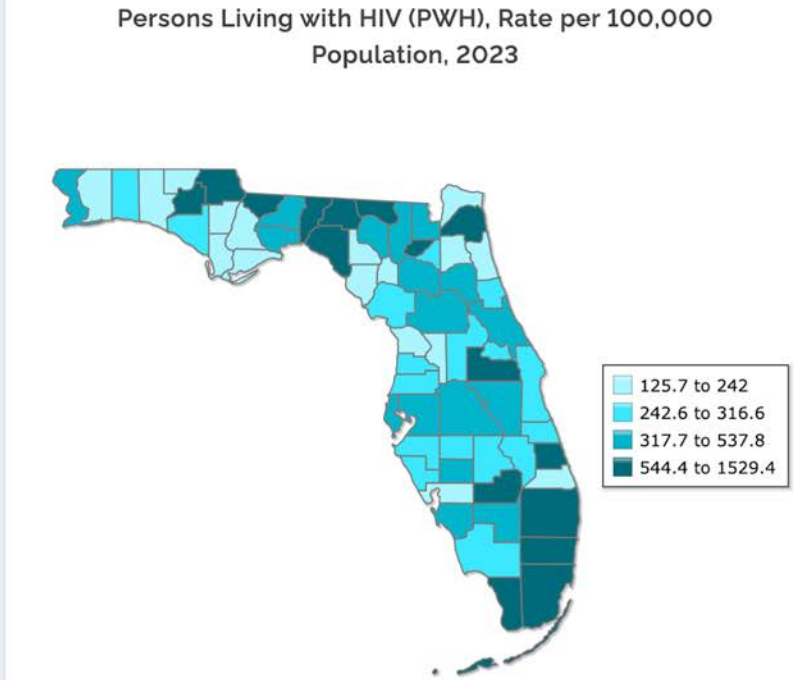
# HIV testing

- 4th generation HIV antibody/p24 antigen test
- HIV antibodies test for both HIV1 & HIV2
- Window period 10-33 days
- Detects 95% of infections at 4wks after exposure
- HIV  VL (PCR) is more sensitive than p24 Ag
- HIV VL turns (+) 3 days – 4 weeks post exposure which is 5 days prior to 4th generation HIV antibody test (use if suspect AHI)

# Diagnoses of HIV, 2014-2023, Florida




HIV and AIDS Diagnoses, Florida
25.0
20.0
15.0
10.0
5.0
Rate Per 100,000 Population
2019
2020
2021
2022
2023
Data Year
HIV
AIDS


Persons Living with HIV (PWH), Rate per 100,000 Population, 2023
125.7 to 242
242.6 to 316.6
317.7 to 537.8
544.4 to 1529.4

# Top Florida Counties

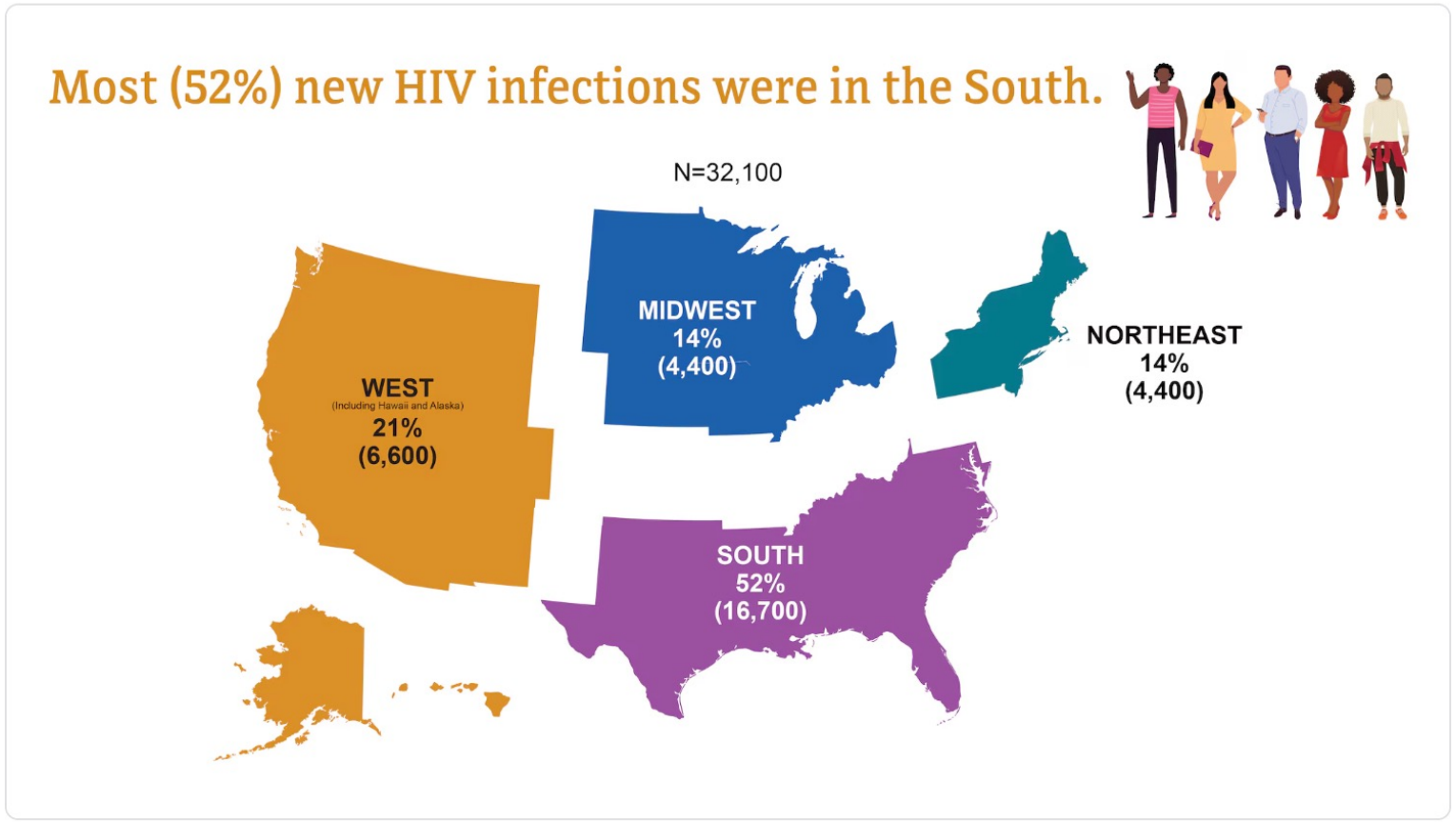
MIAMI DADE

BROWARD

ORANGE

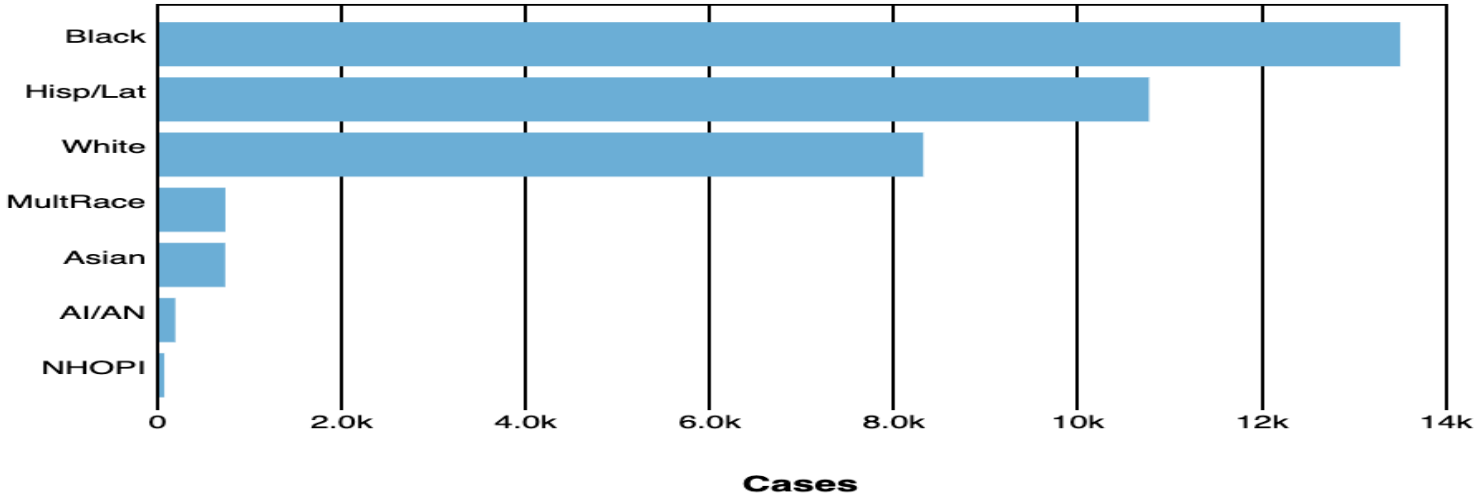
HILLSBOROUGH

PALM BEACH


Most (52%) new HIV infections were in the South.
N=32,100
MIDWEST
14%
(4,400)
NORTHEAST
14%
(4,400)
WEST
(Including Hawaii and Alaska)
21%
(6,600)
SOUTH
52%
(16,700)

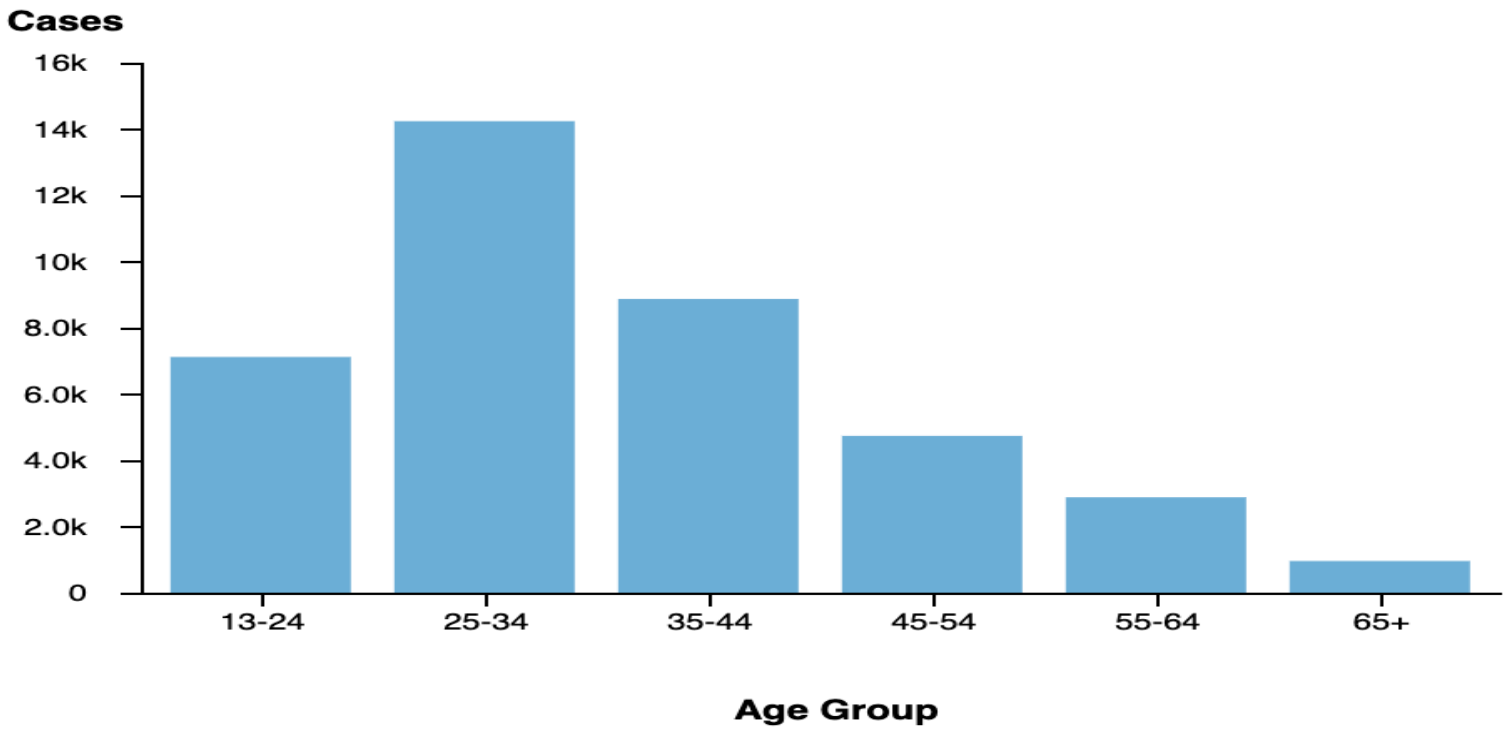
CDC -USA

## HIV diagnoses | 2023 | Ages 13 years and older | All races/ethnicities | Both sexes | All transmission categories | United States




**Footnotes:** Data for 2023 are considered preliminary (subject to a 12-month reporting delay). Inclusion of preliminary data in trend assessments is discouraged. Numbers less than 12, and rates and percentages based on these numbers, should be interpreted with caution. HIV diagnoses and PrEP data for the year 2020, which coincided with the onset of the COVID-19 pandemic, should be interpreted with caution due to the impact of the pandemic on access to HIV testing, PrEP prescriptions, and care-related services. Data by transmission category presented based on sex assigned at birth and are adjusted for missing transmission category. See Technical notes for more details on data availability and stratifications.
NA - Not Applicable.

## HIV diagnoses | 2023 | Ages 13 years and older | All races/ethnicities | Both sexes | All transmission categories | United States

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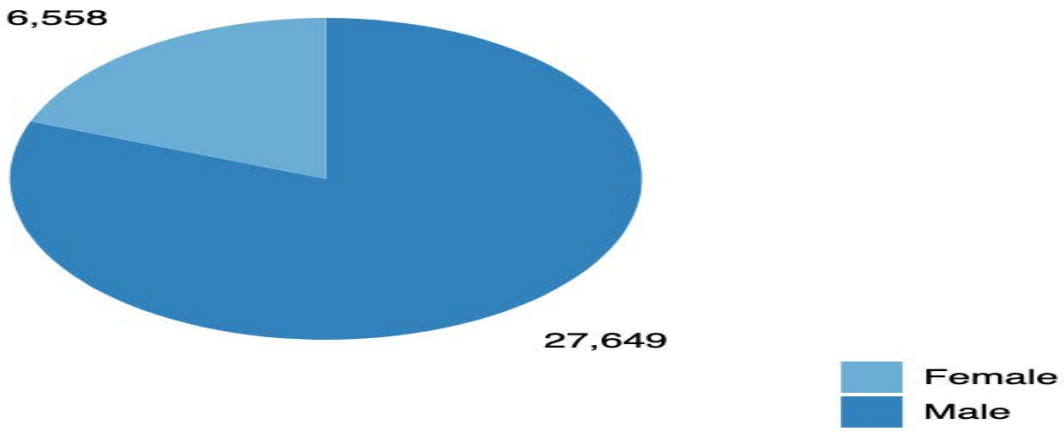
# CDC

**HIV diagnoses | 2023 | Ages 13 years and older | All races/ethnicities | Both sexes | All transmission categories | United States**

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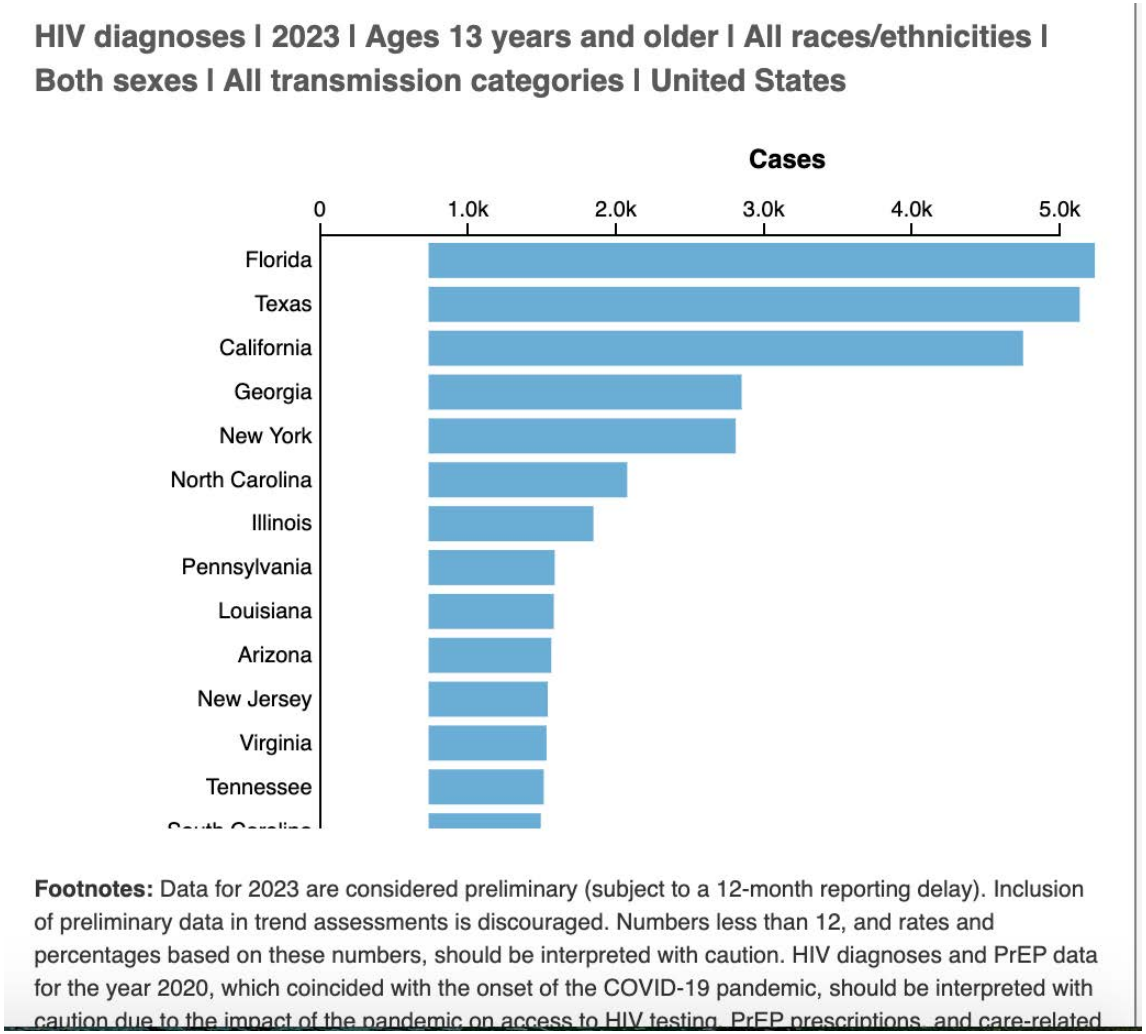
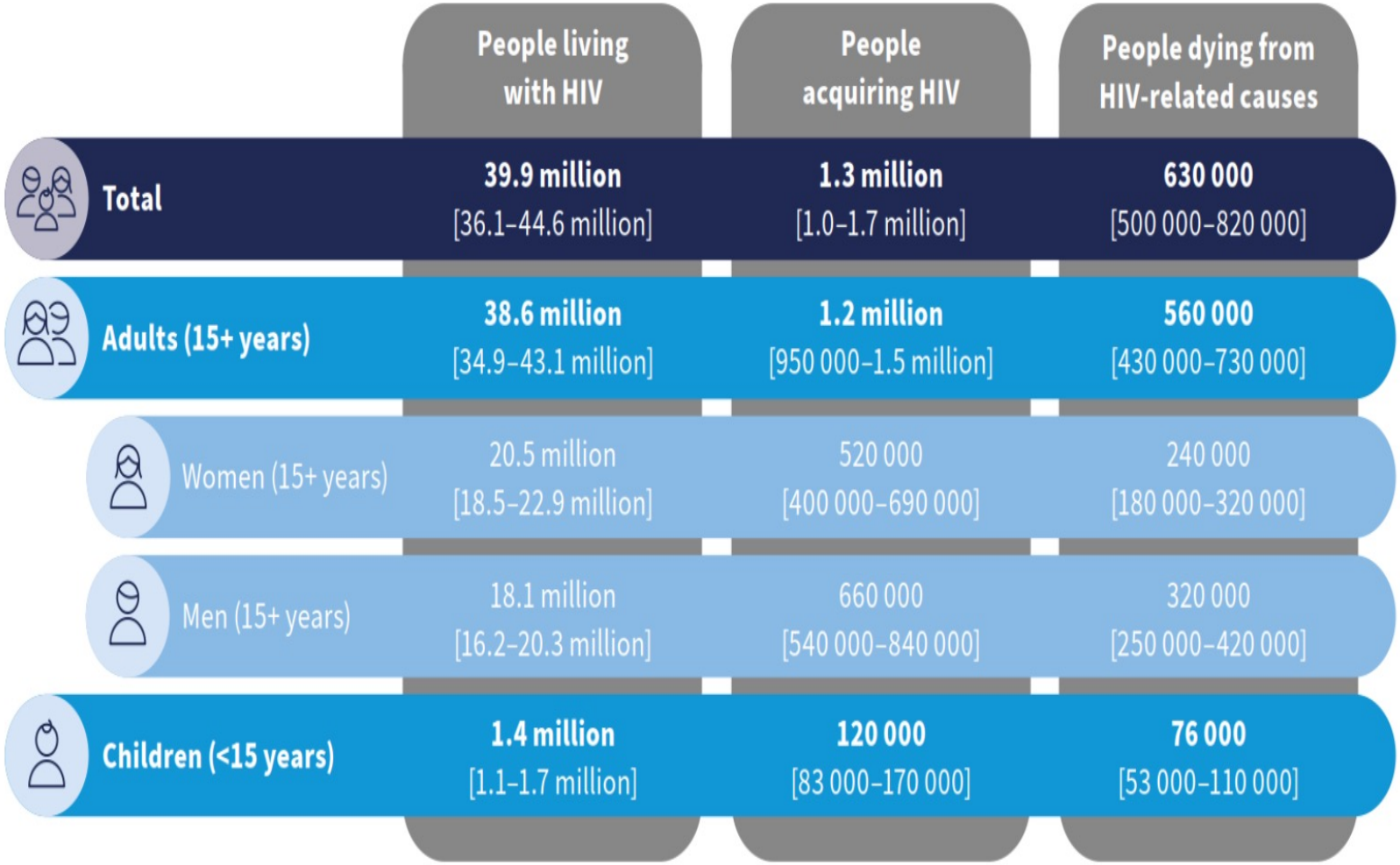
NA - Not Applicable.

# CDC


HIV diagnoses | 2023 | Ages 13 years and older | All races/ethnicities | Both sexes | All transmission categories | United States
Cases
0
1.0k
2.0k
3.0k
4.0k
5.0k
Florida
Texas
California
Georgia
New York
North Carolina
Illinois
Pennsylvania
Louisiana
Arizona
New Jersey
Virginia
Tennessee
Footnotes: Data for 2023 are considered preliminary (subject to a 12-month reporting delay). Inclusion of preliminary data in trend assessments is discouraged. Numbers less than 12, and rates and percentages based on these numbers, should be interpreted with caution. HIV diagnoses and PrEP data for the year 2020, which coincided with the onset of the COVID-19 pandemic, should be interpreted with caution due to the impact of the pandemic on access to HIV testing, PrEP prescriptions, and care-related

## Summary of the global HIV epidemic, 2023



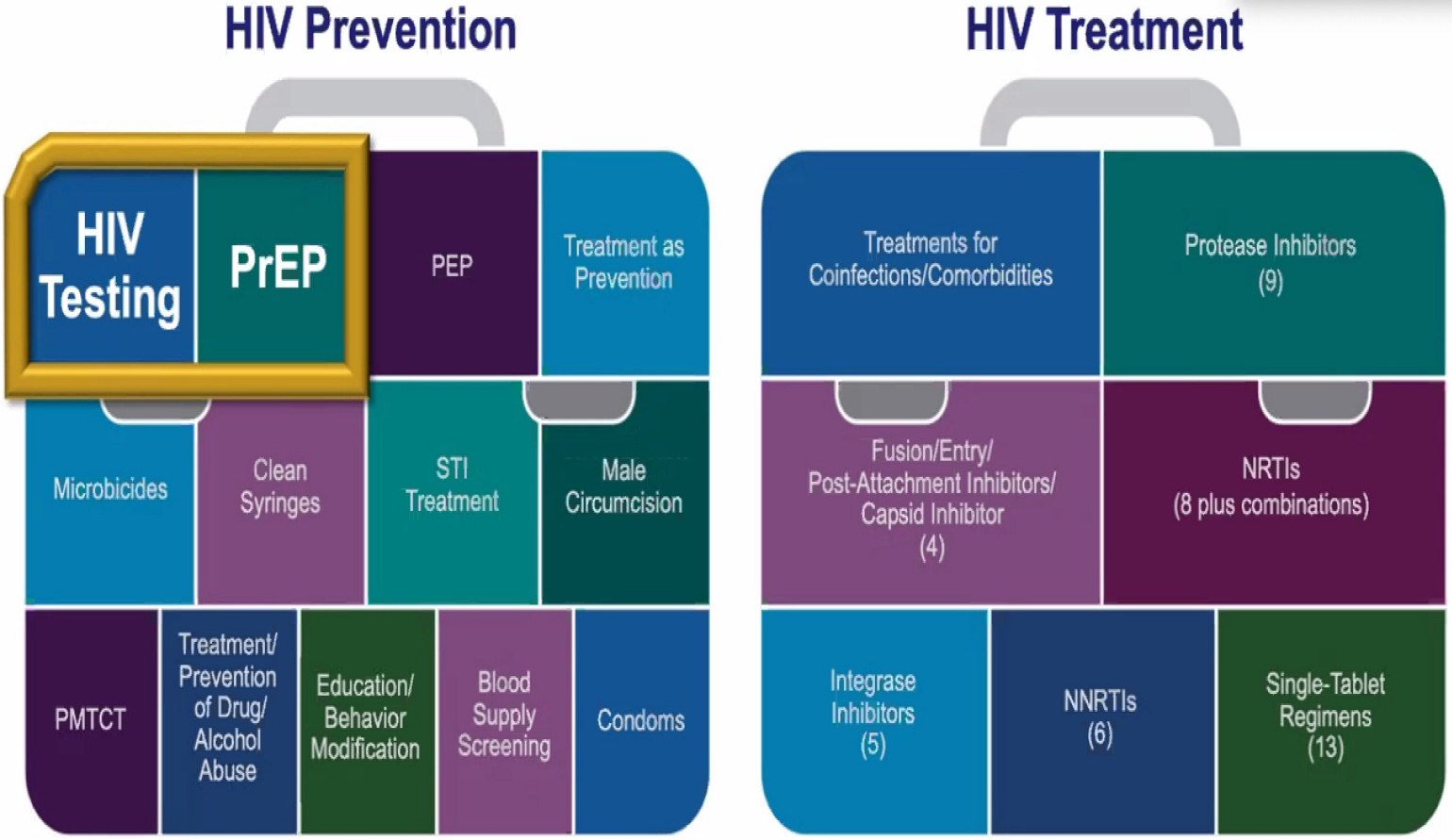

*Source:* UNAIDS/WHO estimates, 2024.

# Underlying Factors Affecting HIV/AIDS Disparities

- Amount of HIV already in the community
- Late diagnosis of HIV or AIDS*
- Access to/acceptance of care*
- Stigma, denial*
- Discrimination, homophobia*
- HIV/AIDS complacency*
- Poverty and unemployment

***Factors that HIV/AIDS initiatives can impact.**

# Some of the Tools for Achieving Status Neutral HIV Prevention and Care




"Simplifying HIV From Screening to ART Initiation" –Clinical Care Options accessed 12/30/2023

# Primary Mode Prevention-Condoms

- 1997 meta-analyses of condom effectiveness suggest that condoms are 60 to 70% effective when used for HIV prophylaxis, these studies do not isolate consistent condom use and therefore provide only a lower bound on the true effectiveness of correct and consistent condom use.
- Reexamination of HIV seroconversion studies suggests that condoms are 90 to 95% effective when used consistently, i.e., consistent condom users are 10 to 20 times less likely to become infected when exposed to the virus than are inconsistent or non-users.

https://pubmed.ncbi.nlm.nih.gov/9141163/#:~:text=A%20reexamination%20of%20HIV%20seroconversion,are%20inconsistent%20or%20non%2Dusers.

# BEHAVIORAL-PREVENTION-CONDOMS

- Condom fatigue
- Strategies to reinforce condom use
- Check out their HIV status and check the status of their partner as their sense of responsibility
- Proper usage can decrease dx 70%- 95%
- Consistent usage of latex condoms continue to be advocated for primary prevention

# Biomedical-Prevention

- Vaccines
- Microbicides
- Screening
- Treatment of sexually transmitted infections (STIs)
- Post-exposure prophylaxis (PEP)
- PrEP
- Test & treat
- Treatment as prevention (TasP)

# Biomedical prevention

- Vaccines- **No. There is currently no vaccine available that will prevent HIV infection or treat those who have it.**

# Vaginal microbicide

**long-acting vaginal rings** that continuously release one or more antiretroviral drugs over time.

- The ring at the most advanced stage of research is the monthly dapivirine ring, which was tested in two large clinical trials, including the NIH-funded ASPIRE study.
- This study and another trial called The Ring StudyExit Disclaimer found that the dapivirine ring reduced the risk of HIV acquisition by roughly 30% overall in women ages 18 to 45 years and was well-tolerated.
- WHO endorsed –not available in USA

*The dapivirine ring, pictured here, is made of flexible silicone and continuously releases the anti-HIV drug dapivirine in the vagina.*
*Credit: International Partnership for Microbicides*

# Occupational PEP
# Non occupation PEP

- HIV status source should be determined
- Should be started as soon as possible after occupation exposure <72 hours
- Test HIV  repeat 6 weeks & may be concluded 4 months post exposure if 4$^{th}$ generation (p24 antigen & HIV AB) testing is used
- Three drug therapy for 28 days
- Raltegravir  RAL (400 mg twice daily) + emtricitabine /tenofovir disoproxil fumarate 300/200  FTC/TDF

# The 5 P's for Sexual Behavior History Taking

Partners- preference men, women or both, how many partners

Practices – vaginal, oral, or rectal

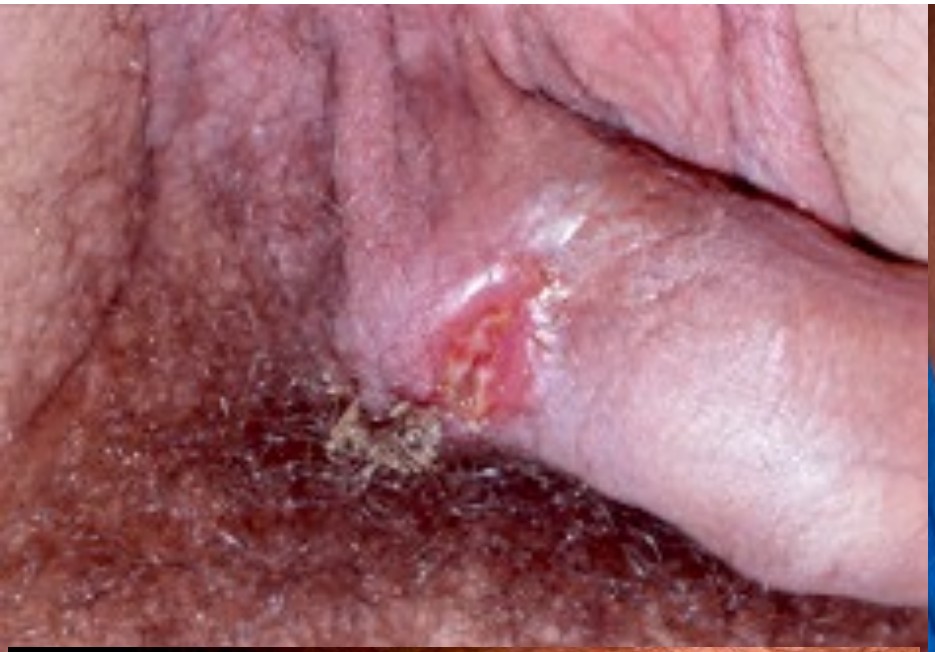
Prevention of Pregnancy

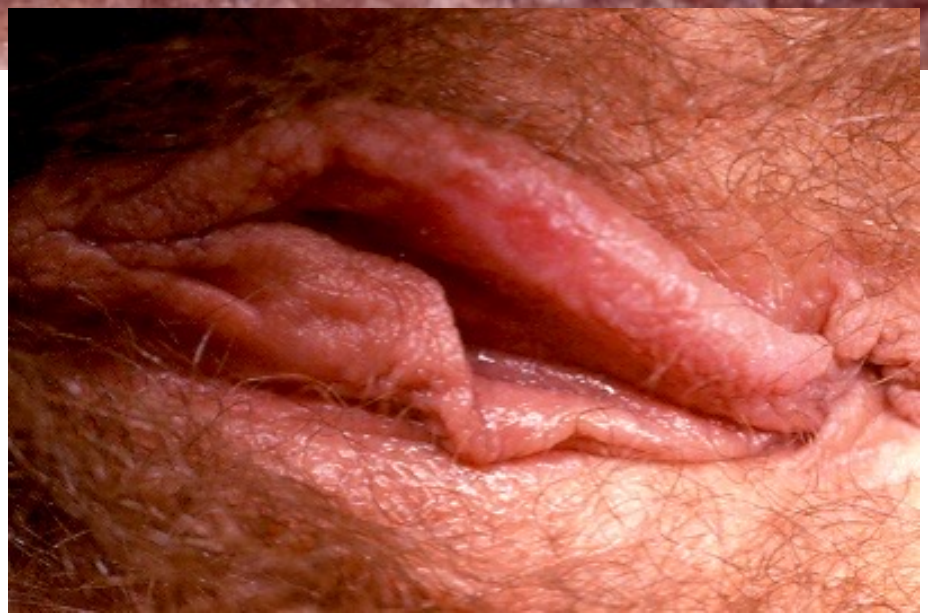
Protection from STD

Past Hx of STD

Screen when std, sti testing

Healing Chancres, Darkfield negative





# Who Is at Substantial Risk of Acquiring HIV Infection

- Sexually active adults and adolescents who had anal or vaginal sex in the past 6 months **AND** any of the following
  - Sexually active partner with HIV (especially if partner has an unknown or detectable viral load)
  - Bacterial STI in past 6 months
  - History of inconsistent or no condom use with sexual partner(s)
- PWID
  - Partner with HIV **OR** sharing injection equipment

**Previous Guidance**

- MSM
  - Sexual partner with HIV
  - Recent bacterial STI
  - High number of sexual partners
  - History of inconsistent or no condom use
  - Commercial sex work
- Heterosexual women and men
  - Same as MSM plus in a high HIV prevalence area/network
- PWID
  - Injecting partner with HIV
  - Sharing injection equipment

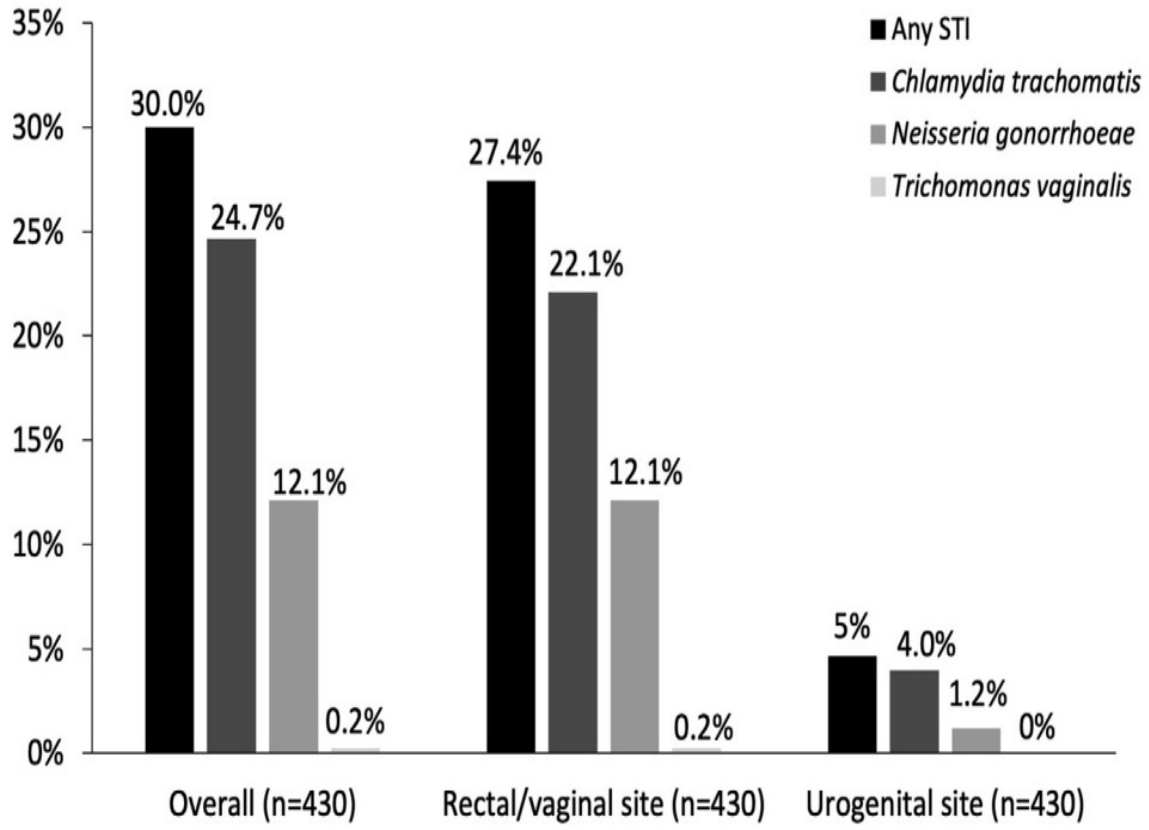



**Figure 1** The rates of chlamydia, gonorrhea, and/or trichomoniasis in HIV-positive participants.

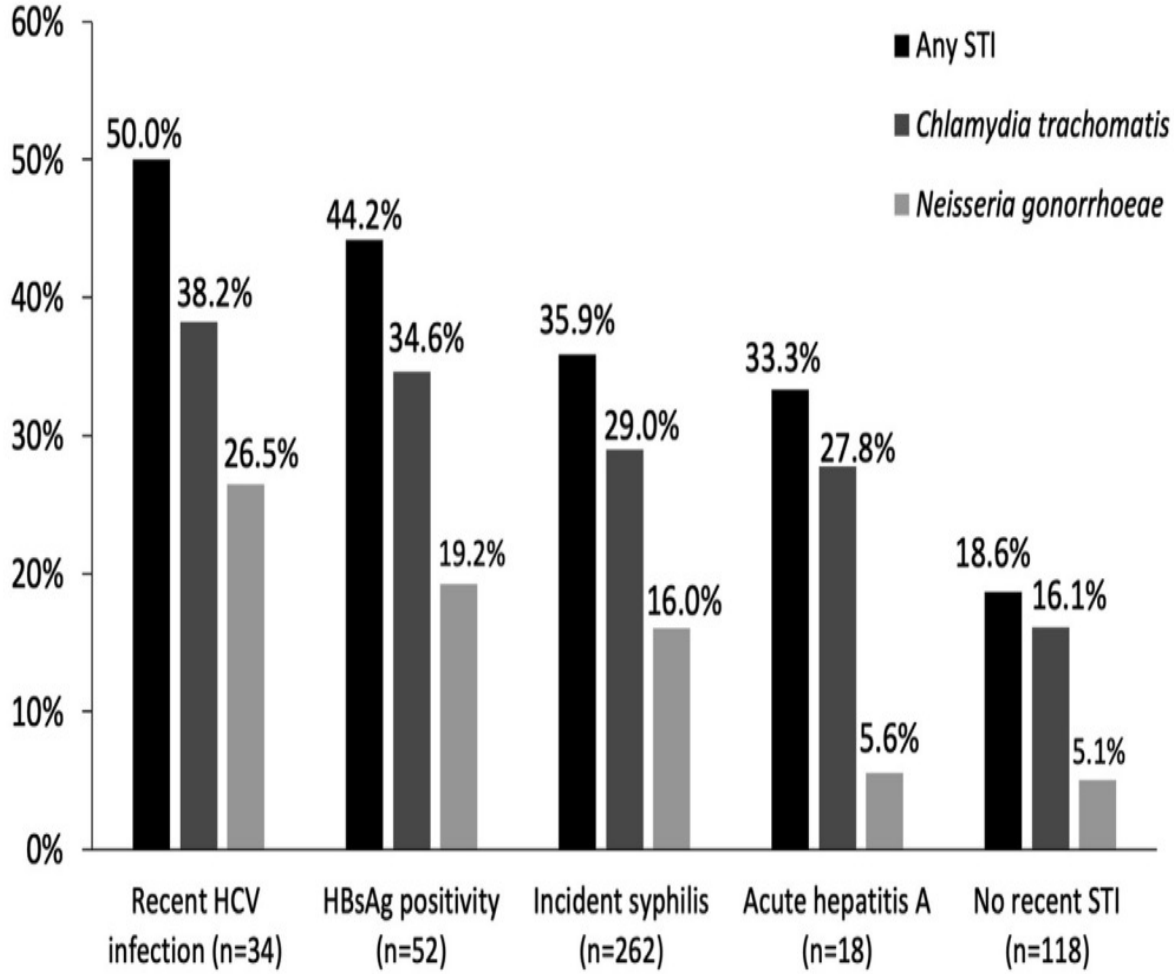



**Figure 2** Comparisons of the rates of HIV-positive participants diagnosed with chlamydia, gonorrhea, and/or trichomoniasis according to recent STI acquisition.

# Randomized controlled trials DOXY-PEP

Randomized controlled trials on the use of doxycycline as PEP to reduce bacterial STIs

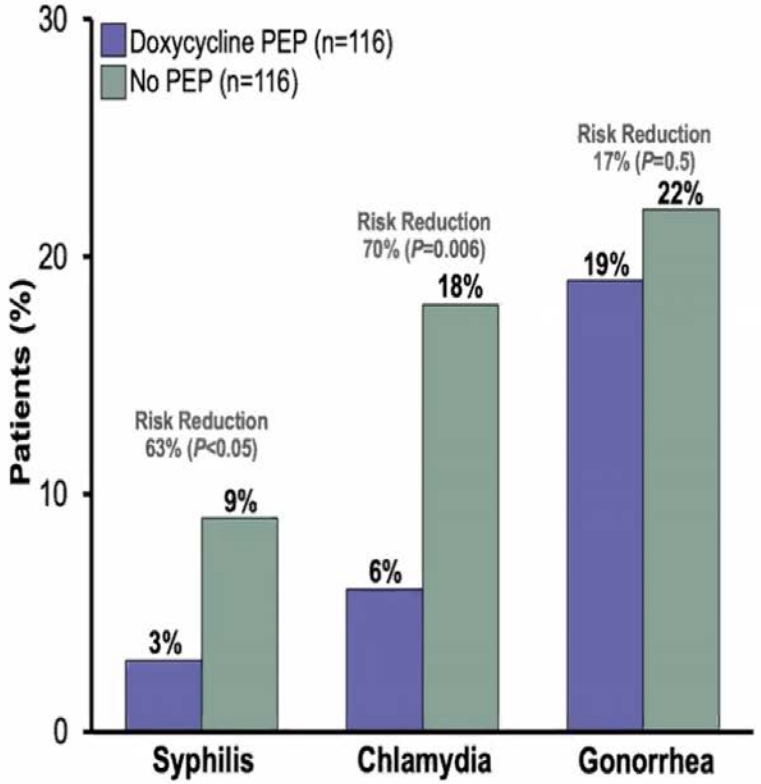
| | Design | Participants | Intervention | Primary Endpoint | Findings | Limitations | Quality of Evidence |
|---|---|---|---|---|---|---|---|
| iPrEx Trial France 2018(1) | RCT | N=232 MSM and TGW on TDF/FTC as PrEP (HIV-) | Doxycycline hyclate 200mg orally once within 24-72 hours after having condomless anal or oral sex versus no prophylaxis | First STI infection (gonorrhea, chlamydia or syphilis) during a 10-month follow-up period | Reduced risk of acquiring chlamydia and syphilis by 70% (HR 0.30 (95% CI 0.13-0.70) and 73% (HR 0.27 (95% CI 0.07-0.98), respectively.<br>No significant difference in gonorrhea | Open-label<br>Short follow-up | High |
| DoxyPeP USA 2023(2) | RCT | N=554 MSM and TGW (N=360 on PrEP; N=194 HIV+) | Doxycycline hyclate 200mg orally once within 72 hours after having condomless sex versus no prophylaxis | Relative risk of an STI infection per quarter. | PrEP: 65 STI endpoints (29.5%) occurred in controls and 47 (9.6%) in doxyPEP participants (RR 0.33; 95%CI 0.23-0.47; p<0.0001).<br>HIV: 30 STI endpoints (27.8%) in controls and 31 (11.7%) in doxyPEP participants (RR 0.42; 95% CI 0.25-0.75; p=0.0014). | Open-label<br>Short follow-up | High |
| DOXYVAC France CROI 2023(3) | RCT | N=502 MSM on HIV PrEP (HIV-) | Doxycycline monohydrate 200mg orally within 24-72 hours after sex versus no PEP versus 4CMenB vaccine versus no vaccine | Impact of doxycycline as PEP on time to first episode of syphilis or chlamydia and impact of 4CMenB vaccine on first episode of gonorrhea | Doxycycline as PEP reduced gonorrhea, chlamydia and syphilis infections (aHR of 0.49 (95% CI 0.32-0.76), 0.11 (95% CI 0.04-0.30) and 0.21 (95% CI 0.09-0.47), respectively). Receipt of 4CMenB was associated with a reduction in gonococcal infection (incidence 9.8/100 person years vs 19.7/100 person years in the study arm that did not receive vaccine; aHR 0.49 (95% CI 0.27-0.88) | Open-label<br>Short follow-up | High |
| dPEP Kenya CROI 2023 (4) | RCT | N= 449 Cisgender women | Doxycycline hyclate 200mg orally within 72 hours after sex versus no doxycycline PEP | Any incident C. trachomatis, N. gonorrhoeae or T. pallidum | All bacterial STIs (RR 0.88; 95%CI 0.60-1.29), C. trachomatis (RR 0.73; 95% CI 0.47-1.13); N. gonorrhoeae (RR 1.64; 95% CI 0.78-3.47). There were only two syphilis infections during the study. | Open label, short follow-up | High |

https://www.cdc.gov/std/treatment/doxycycline-as-pep-toe.htm accessed 1/17/2024

# Doxycycline PEP in High-Risk MSM on PrEP

- Open-label substudy of IPERGAY study (2015-2016)
  - High-risk MSMs without HIV (n=232)
    - Condomless anal sex with ≥2 partners within 6 months and eGFR >60 mL/min
  - Randomized groups: PEP (doxycycline)* or no PEP
- Primary endpoint
  - Occurrence of first STI (GC, CT, or syphilis)
- Doxycycline PEP versus no PEP reduced occurrence of first STI by 47% (*P*=0.008)
  - Significant reduction in syphilis and CT
  - Similar change in GC

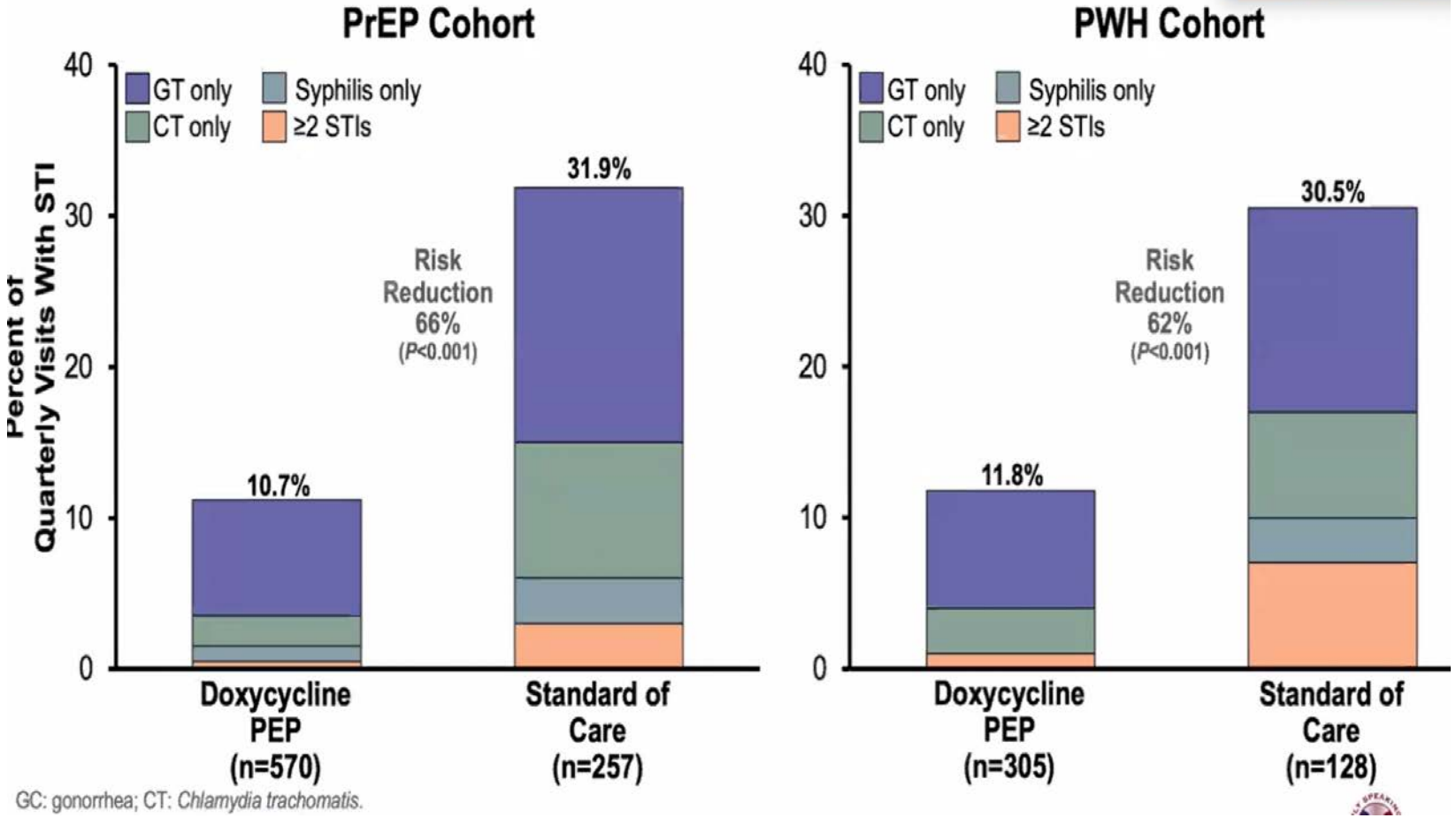
**Occurrence of First STI**




*200 mg within 24 hours and no later than 72 hours after condomless sexual contact.
GC: gonorrhea; CT: *Chlamydia trachomatis*.

Molina JM, et al. *Lancet Infect Dis*. 2018;18:308-317.

# DoxyPEP Study: STI Incidence per Quarter




GC: gonorrhea; CT: *Chlamydia trachomatis*.

# DoxyPEP

- DoxyPEP is a post-exposure preventative treatment for syphilis, chlamydia, and gonorrhea.
- **Think of it as a morning-after pill but for bacterial STIs instead of pregnancy**:
- Take one dose after a condomless sexual encounter to greatly reduce your risk of contracting bacterial STIs

# PrEP

| | | | |
|---|---|---|---|
| Prevention of Acquisition of HIV: Preexposure Prophylaxis: adolescents and adults at increased risk of hiv | The USPSTF recommends that clinicians prescribe preexposure prophylaxis using effective antiretroviral therapy to persons who are at increased risk of HIV acquisition to decrease the risk of acquiring HIV. See the Practice Considerations section for more information about identification of persons at increased risk and about effective antiretroviral therapy. | A | August 2023 * |

**465.1861 Ordering and dispensing HIV infection prevention drugs.**—

(1) As used in this section, the term:

(a) "HIV" means the human immunodeficiency virus.

(b) "HIV infection prevention drug" means preexposure prophylaxis, postexposure prophylaxis, and any other drug approved by the United States Food and Drug Administration for the prevention of HIV infection.

(c) "Postexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment following potential exposure to HIV.

(d) "Preexposure prophylaxis" means a drug or drug combination that meets the clinical eligibility recommendations of the United States Centers for Disease Control and Prevention guidelines for antiretroviral treatment for the prevention of HIV transmission.

(2) A pharmacist may screen an adult for HIV exposure and provide the results to the adult, with the advice that the patient should seek further medical consultation or treatment from a physician.

(3) A pharmacist may dispense HIV preexposure prophylaxis drugs pursuant to a valid prescription issued by a licensed health care practitioner authorized by law to prescribe such drugs.

(4) A pharmacist who is certified under subsection (6) may order and dispense HIV postexposure prophylaxis drugs pursuant to a written collaborative practice agreement between the pharmacist and a physician licensed under chapter 458 or chapter 459.

(a) A written collaborative practice agreement between a pharmacist and a physician under this section must include, at a minimum, all of the following:

1. Terms and conditions relating to the screening for HIV and the ordering and dispensing of HIV postexposure prophylaxis drugs by the pharmacist. Such terms and conditions must be appropriate for the pharmacist's training.

2. Specific categories of patients the pharmacist is authorized to screen for HIV and for whom the pharmacist may order and dispense HIV postexposure prophylaxis drugs.

# PrEP

- Truvada (emtricitabine /tenofovir disoproxil fumarate FTC/TDF) approved July 2012 for Pre exposure prophylaxis
- Descovy (emtricitabine / tenofovir alafenamide FTC/ TAF) approved in Oct 2019 in at risk adult & adolescent HIV (-) men and transgender women >35kg
- Descovy for PrEP does not include use in individuals at risk of HIV-1 from receptive vaginal sex (not studied)
- Studies show PrEP decreased risk of HIV from sex 99% daily use
- IVDU PrEP reduces risk of getting HIV at 74% when taken daily.

# Pre-exposure prophylaxis

- **Truvada FTC/TDF 200/300** must be taken daily if CrCl>60ml/min
  - Sero-discordant heterosexual couples at time of conception/pregnancy
  - MSM
  - Adult heterosexual active men & women at risk

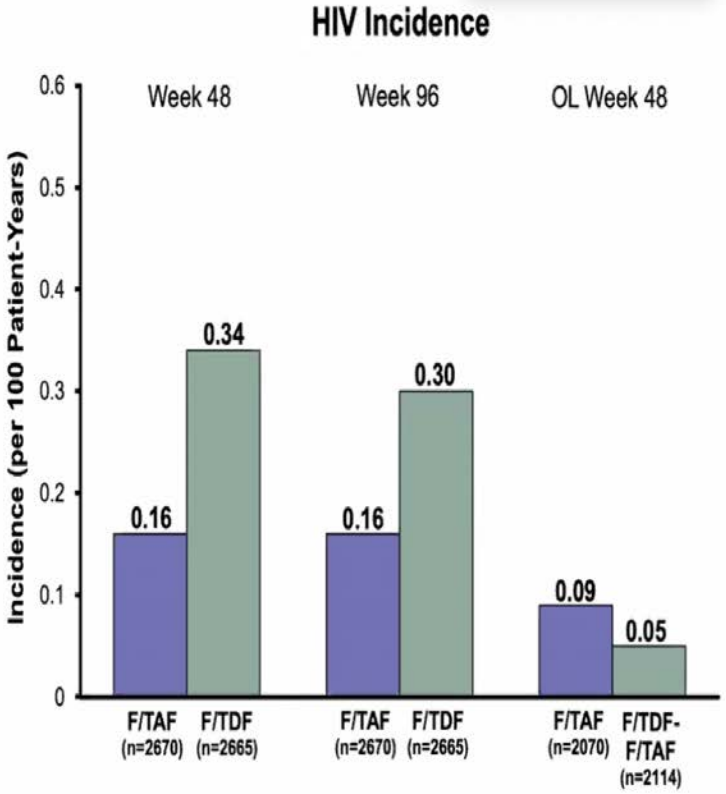
- **Descovy FTC/TAF 200/25** CrCl>30
  - At risk patients to reduce risk of HIV-1 infection from sex, excluding those at risk from receptive vaginal sex

# PrEP oral

- 7 days of daily use- gives one maximum protection from HIV for receptive (bottoming)anal sex
- 21 days of daily use- receptive vaginal sex and injection drug use
- There is full prevention potential  PrEP
- Renal dose adjustment precautions & osteoporosis
- Patients seen every 3 months for follow up and including HIV testing and Rx refills
- Test for hepatitis Hep A, HepBsAg, HepBcAB,  HepBsAB, RPR, HIV, GC/Chlamydia & renal status
- Best choice of regimen for any given patient is the one to which they can best adhere to.
- Risk reduction counseling, adr, sti

# DISCOVER Trial: Daily Oral F/TDF Versus F/TAF for PrEP

- Double-blind, phase 3, non-inferiority study with open-label extension after week 96
  - HIV-negative MSM and transgender women at risk for HIV
  - eGFR: ≥60 mL/min
- F/TAF was non-inferior to F/TDF for HIV prevention at both week 48 and 96
  - F/TAF had significantly better bone and renal safety outcomes ($P$<0.001) and greater weight gain
- Switching from F/TDF to F/TAF
  - Low HIV incidence rate
  - Improvements in eGFR and BMD indices
  - Increases in LDL-C, HDL-C, and body weight





Mayer KH, et al. *Lancet*. 2020;396:239-254.
Ogbuagu O, et al. *Lancet HIV*. 2021;8:e397-e407.
Spinner C, et al. *J Int AIDS Soc*. 2021;24(suppl 4):29. Abstract OALC0501.

# Oral PrEP: Clinical Eligibility

**Oral PrEP**

**F/TDF** 


**F/TAF** 


**Oral PrEP Eligible**
**(all conditions must be met)**

- Adults and adolescents (≥35 kg)
- Documented negative HIV Ag/Ab test result within 1 week before initially prescribing PrEP
- No signs/symptoms of acute HIV infection
- Estimated creatinine clearance ≥30 mL/min
- No contraindicated medications

CDC. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf. Published December 2021.
Gandhi RT, et al. *JAMA*. 2023;329:63-84.

# PrEP inject drugs

- 8 % risk of acquiring risk to HIV via IVDU
- included transfusion of infected blood, sharing equipment during IVDU and percutaneous needle sticks
- Strategies include needle & syringe programs – federal & state funding is low
- Opioid substitution therapy- buprenorphine based regimens/methadone
- Drug resistance data on Truvada – limited to those who had unrecognized acute HIV infection

# SCHEDULE ORAL PrEP

**Table 5 Timing of Oral PrEP-associated Laboratory Tests**

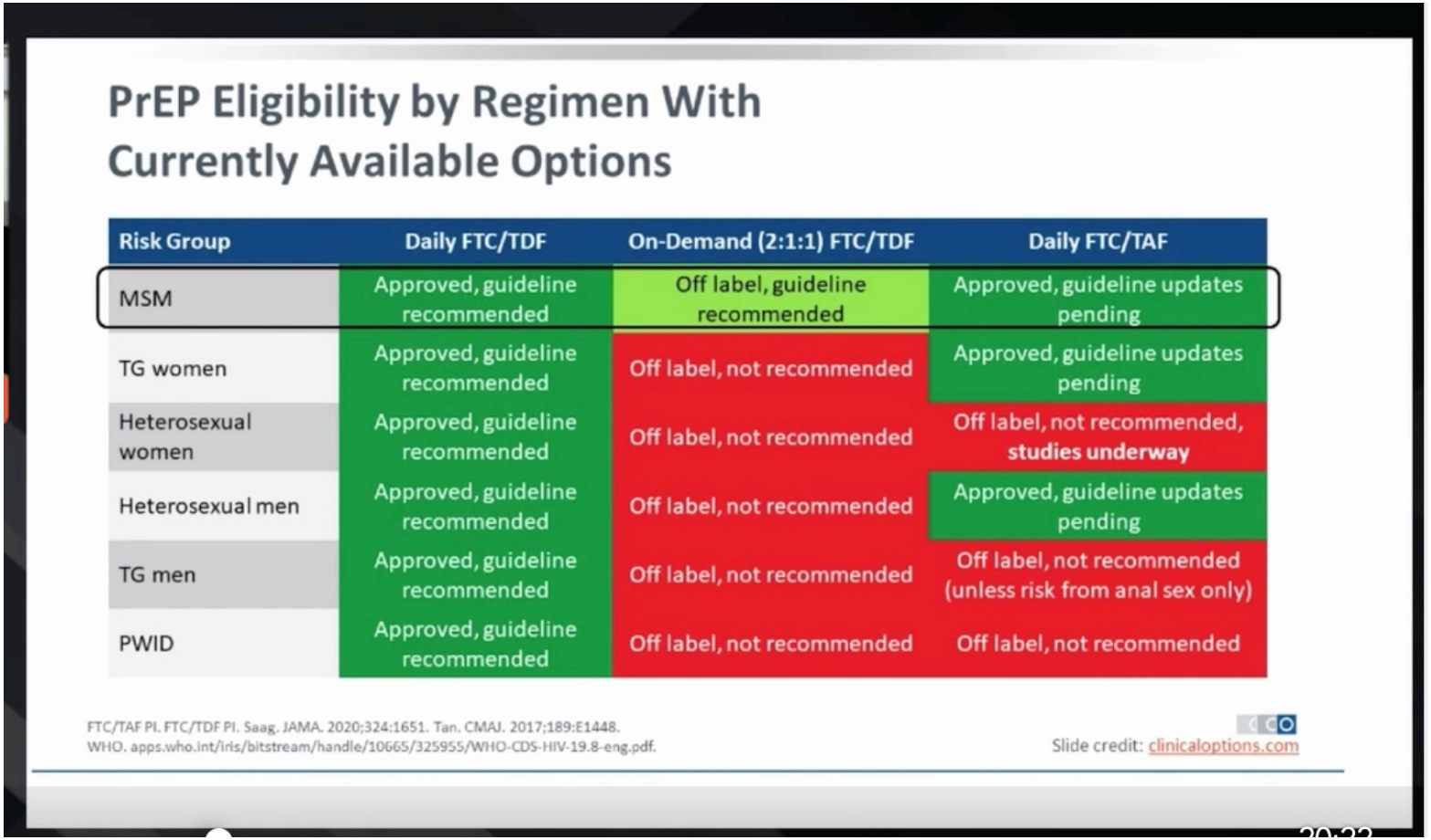
| Test | Screening/Baseline Visit | Q 3 months | Q 6 months | Q 12 months | When stopping PrEP |
|---|---|---|---|---|---|
| **HIV Test** | X* | X | | | X* |
| **eCrCl** | X | | If age ≥50 or eCrCL <90 ml/min at PrEP initiation | If age <50 and eCrCl ≥90 ml/min at PrEP initiation | X |
| **Syphilis** | X | MSM /TGW | X | | MSM/TGW |
| **Gonorrhea** | X | MSM /TGW | X | | MSM /TGW |
| **Chlamydia** | X | MSM /TGW | X | | MSM /TGW |
| **Lipid panel (F/TAF)** | X | | | X | |
| **Hep B serology** | X | | | | |
| **Hep C serology** | MSM, TGW, and PWID only | | | MSM,TGW, and PWID only | |

* Assess for acute HIV infection (see Figure 4)

# PrEP ON DEMAND

- 2:1:1
- 2 tabs 2-24 hours prior to sex, 1 tab 24 hours after the first 2 tabs, and another 1 tab 24 hours after that
- Ibergay study in gay and bisexual men The IPERGAY trial found that taking PrEP on a **2-1-1 schedule reduced risk of HIV infection by 86% in men** who have sex with men.
- A sub-study confirmed high efficacy among men with less-active sex lives who took doses of PrEP on demand fewer than three times per week on average.
- Endorsed by WHO, British HIV Association, European Aids Clinical Society and International Aids Society-USA

# PrEP on demand



## PrEP Eligibility by Regimen With Currently Available Options

| Risk Group | Daily FTC/TDF | On-Demand (2:1:1) FTC/TDF | Daily FTC/TAF |
|---|---|---|---|
| MSM | Approved, guideline recommended | Off label, guideline recommended | Approved, guideline updates pending |
| TG women | Approved, guideline recommended | Off label, not recommended | Approved, guideline updates pending |
| Heterosexual women | Approved, guideline recommended | Off label, not recommended | Off label, not recommended, **studies underway** |
| Heterosexual men | Approved, guideline recommended | Off label, not recommended | Approved, guideline updates pending |
| TG men | Approved, guideline recommended | Off label, not recommended | Off label, not recommended (unless risk from anal sex only) |
| PWID | Approved, guideline recommended | Off label, not recommended | Off label, not recommended |

FTC/TAF PI. FTC/TDF PI. Saag. JAMA. 2020;324:1651. Tan. CMAJ. 2017;189:E1448.
WHO. apps.who.int/iris/bitstream/handle/10665/325955/WHO-CDS-HIV-19.8-eng.pdf.

Slide credit: clinicaloptions.com

# APRETUDE FOR PrEP FDA APPROVED 12/20/2021

- Cabotegravir (CAB)-IM extended-release formulation of integrase strand transfer inhibitor for use. Intramuscular injections of CAB q 2 months for sexually active men, women, and transgender persons with indications for PrEP use.
- Vocabria = oral formulation approved optional use for short term lead in or when an injection must be missed (travels)
- 600 mg cabotegravir administered as one 3 ml intramuscular injection in the gluteal muscle 0,1 mos., then q 2mos.
- 7- day leniency. Doses can be administered up to 7 days early or late, if a dose must be missed, then oral cabotegravir can be substituted
- For BMI >30 a longer needle is needed to insure IM not SQ administration (2in.) otherwise 1.5 in needle
- Great choice for patients with oral regimen adherence issues or with severe renal impairment
- More effective than oral FTC/TDF in preventing HIV

# PrEP injectable

**Table 7 Timing of CAB PrEP-associated Laboratory Tests**

| Test | Initiation Visit | 1 month visit | Q2 months | Q4 months | Q6 months | Q12 months | When Stopping CAB |
|---|---|---|---|---|---|---|---|
| **HIV*** | X | X | X | X | X | X | X |
| **Syphilis** | X | | | MSM^/TGW~ only | Heterosexually active women and men only | X | MSM/TGW only |
| **Gonorrhea** | X | | | MSM/TGW only | Heterosexually active women and men only | X | MSM/TGW only |
| **Chlamydia** | X | | | MSM/TGW only | MSM/TGW only | Heterosexually active women and men only | MSM/TGW only |

* HIV-1 RNA assay

X all PrEP patients

^ men who have sex with men

~ persons assigned male sex at birth whose gender identification is female

# Lenacapavir (Yeztugo) for Hiv Pre-exposure prophylaxis

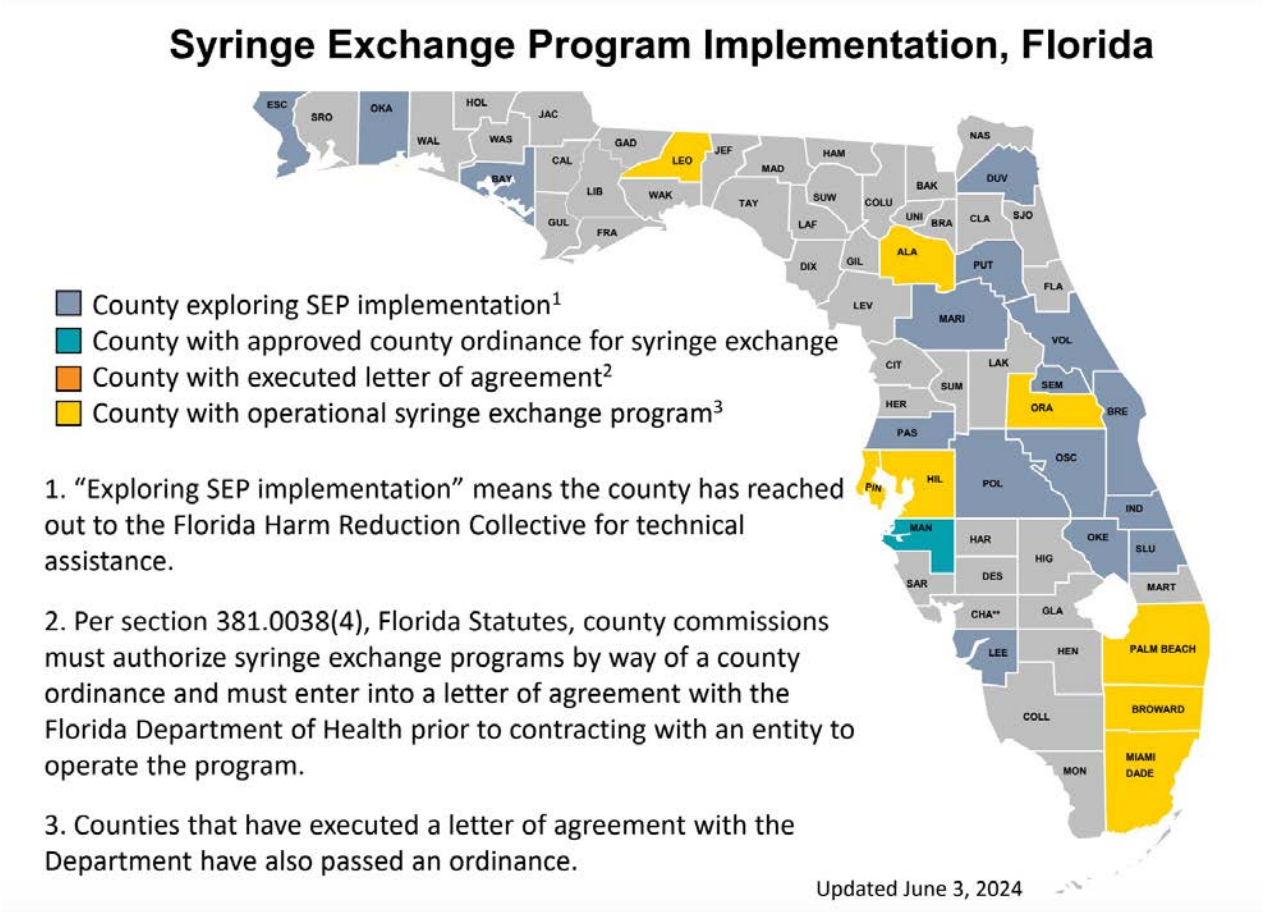
- Hiv -1 capsid inhibitor indicated for PrEP to reduce the risk for sexually acquired hiv-1 in at risk adolescents & adults.
- Given twice yearly
- Previously approved in 2022 as Sunlenca for use with other ART to treat MDR-HIV

**Table 1. Dosing Schedule for LEN Initiation and Continuation in Adults and Adolescents weighing ≥35 kg**

| Time | Dosage |
|---|---|
| | **Dosage of LEN: Initiation[a]** |
| Day 1 | 927 mg by SUBQ injection (2 x 1.5 mL injections)<br>and<br>600 mg orally (2 x 300 mg tablets) |
| Day 2 | 600 mg orally (2 x 300 mg tablets) |
| | **Dosage of LEN: Continuation** |
| Every 6-months (26 weeks)[b] +/- 2 weeks | 927 mg SUBQ injection (2 x 1.5 mL injections) |

[a] The complete initiation dosing schedule, consisting of SUBQ injections and oral tablets, is required; the efficacy of LEN has only been established with this dosing schedule.
[b] From the date of the last injection.

# Structural prevention- Infectious Disease Elimination Act- 2019



# Syringe Services Program

1. Nearly 30 years of research shows that comprehensive SSPs are safe, effective, and cost-saving;
2. Do not increase illegal drug use or crime;
3. Play an important role in reducing the transmission of viral hepatitis, HIV, and other infections.
4. People who use syringe services programs are five times more likely to enter drug treatment and three times more likely to stop injecting drugs.

https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs

# Prevention –structural blood donation- FDA

- The May 2023 FDA guidelines recommend asking every potential blood donor the same screening questions. These questions ask about behavior that raises risk for HIV, which can be spread through a transfusion.
- For male donors who would have been deferred for having sex with another man: the agency is changing the recommended deferral period from 12 months to 3 months.
- For female donors who would have been deferred for having sex with a man who had sex with another man: the agency is changing the recommended deferral period from 12 months to 3 months.
- For those with recent tattoos and piercings: the agency is changing the recommended deferral period from 12 months to 3 months.
- Good health at time of donation
- >16 years old and weight >110lbs
- Screened for abo blood groups and Rh type, Hepatitis b&c, hiv, rpr, htlv I&II, & west nile virus

# Prevention-Role of voluntary Male Circumcision

- African study of 3274 men/ 1674 underwent circumcision
- Study stopped early after interim analysis 60% reduction in HIV transmission heterosexually acquired in the circumcised group
- Three randomized controlled trials have shown that male circumcision provided by well trained health professionals in properly equipped settings is safe.
- WHO/UNAIDS recommendations emphasize that male circumcision should be considered an efficacious intervention for HIV prevention in countries and regions with heterosexual epidemics, high HIV and low male circumcision prevalence.

    - Penile foreskin contains large numbers of Langerhans' cells with HIV receptors-primary point of viral entry into the penis

# Study: Brothers Y Hermanos

- Brothers y Hermanos Study 2,235 Black and Latino MSMs in New York, Philadelphia and Los Angeles May 2005 to April 2006 “Is your penis circumcised or cut?
- Black participants were more than twice as likely to be circumcised as the Latinos: 74% versus 33%
- Summary: Circumcision conferred neither risk nor protection among Black men or Latino men who have sex with men.

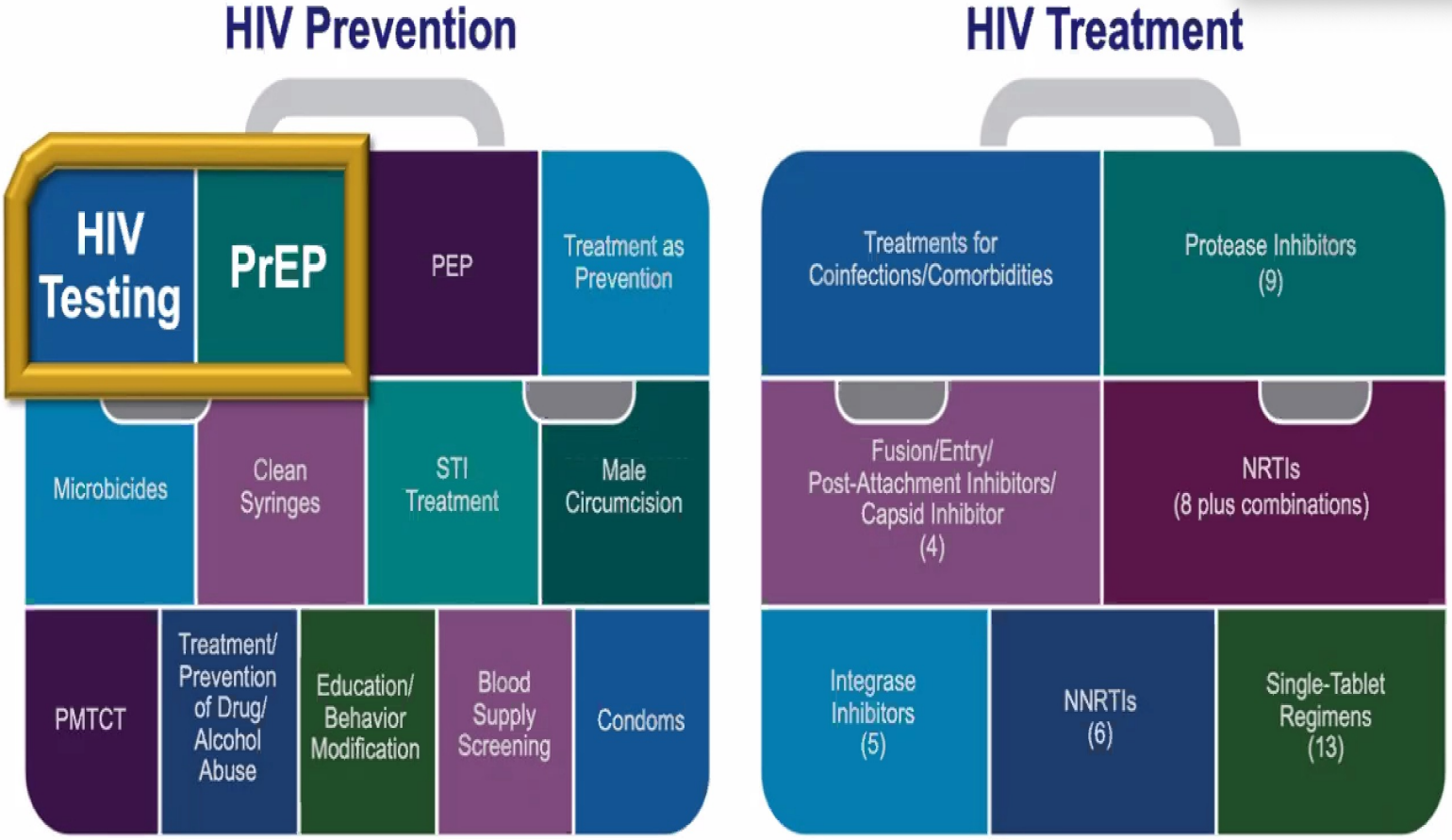
*Journal of Acquired Immune Deficiency Syndromes, December 15, 2007*

# Circumcision

- Male circumcision provides only partial protection, & therefore should be only one element of a comprehensive HIV prevention package which includes:

1. the provision of HIV testing and counseling services;
2. treatment for sexually transmitted infections;
3. the promotion of safer sex practices; PrEP & PEP
4. the provision of male and female condoms &
5. promotion of their correct and consistent use.

# Some of the Tools for Achieving Status Neutral HIV Prevention and Care




"Simplifying HIV From Screening to ART Initiation" –Clinical Care Options accessed 12/30/2023

# Prevention-biomedical

- Treatment as Prevention

# ART

Easier, less toxic, and more potent therapy

# Potential Benefits of Early Therapy

- Potential decrease in risk of many complications, including:
  - HIV-associated nephropathy
  - Liver disease progression from hepatitis B or C
  - Cardiovascular disease
  - Malignancies (AIDS defining and non-AIDS defining)
  - Neurocognitive decline
  - Blunted immunological response owing to ART initiation at older age
  - Persistent T-cell activation and inflammation

TOXICITY

PRESERVATION TX OPTIONS

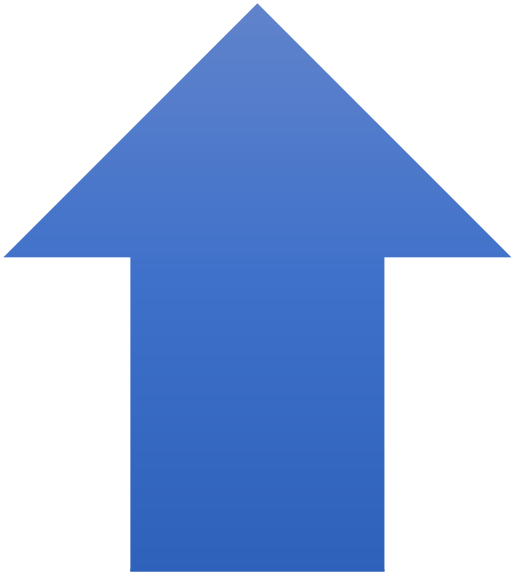
RISK OF RESISTANCE

DECREASED TRANSMISSION

INCREASED POTENCY

DURABILITY

SIMPLICITY SAFETY OF CURRENT TX



# Goals of Antiretroviral Therapy

- Maintain or restore the health of people with HIV-1 (PWH) through suppression of HIV-1 replication
- Minimize or eliminate short and long-term adverse effects of the therapy
- Have therapies that are accessible to all PWH
- Prevent transmission of HIV-1 to others via any route of exposure



Joseph Enron's Lecture slide accessed 6/30/2023

# Recommendations for Initiating ART: Considerations

1. "Patients starting ART should be willing and able to commit to treatment & should understand the benefits & risks of therapy & the importance of adherence."
2. Patients may choose to postpone ART
3. Providers may elect to defer ART, based on an individual patient's clinical or psychosocial factors, but ART should be started as soon as it is feasible so
4. **US DHHS guidelines currently recommend universal ART for all people living with HIV (regardless of CD4 count) as soon as possible. Increasing data show a medical benefit to the client when immediate ART is initiated, particularly during acute/early HIV infection.**

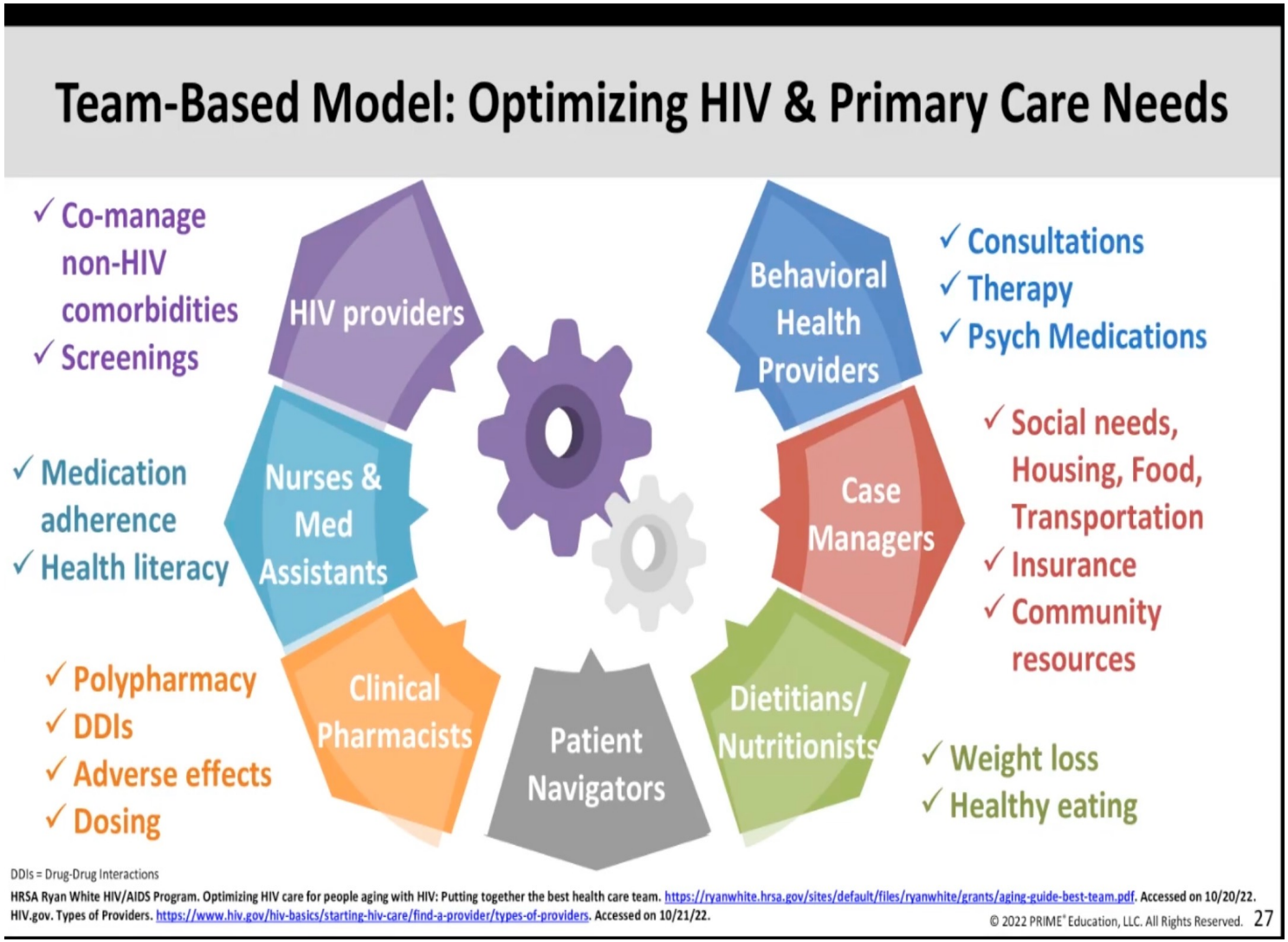
# Initiation of therapy

- Begin therapy at diagnosis or as soon as possible
- Integrase inhibitors are backbone of therapy
- A single pill once daily combination
- Stress adherence importance regimen's barrier to resistance
- Potential adverse effects and drug toxicities, including risk for development of comorbid diseases.
- Known or potential drug interactions with other medications
- Convenience (e.g., pill burden, dosing frequency, availability of a fixed-dose combination or STR formulations, food requirements)
- Cost and access

# Adherence

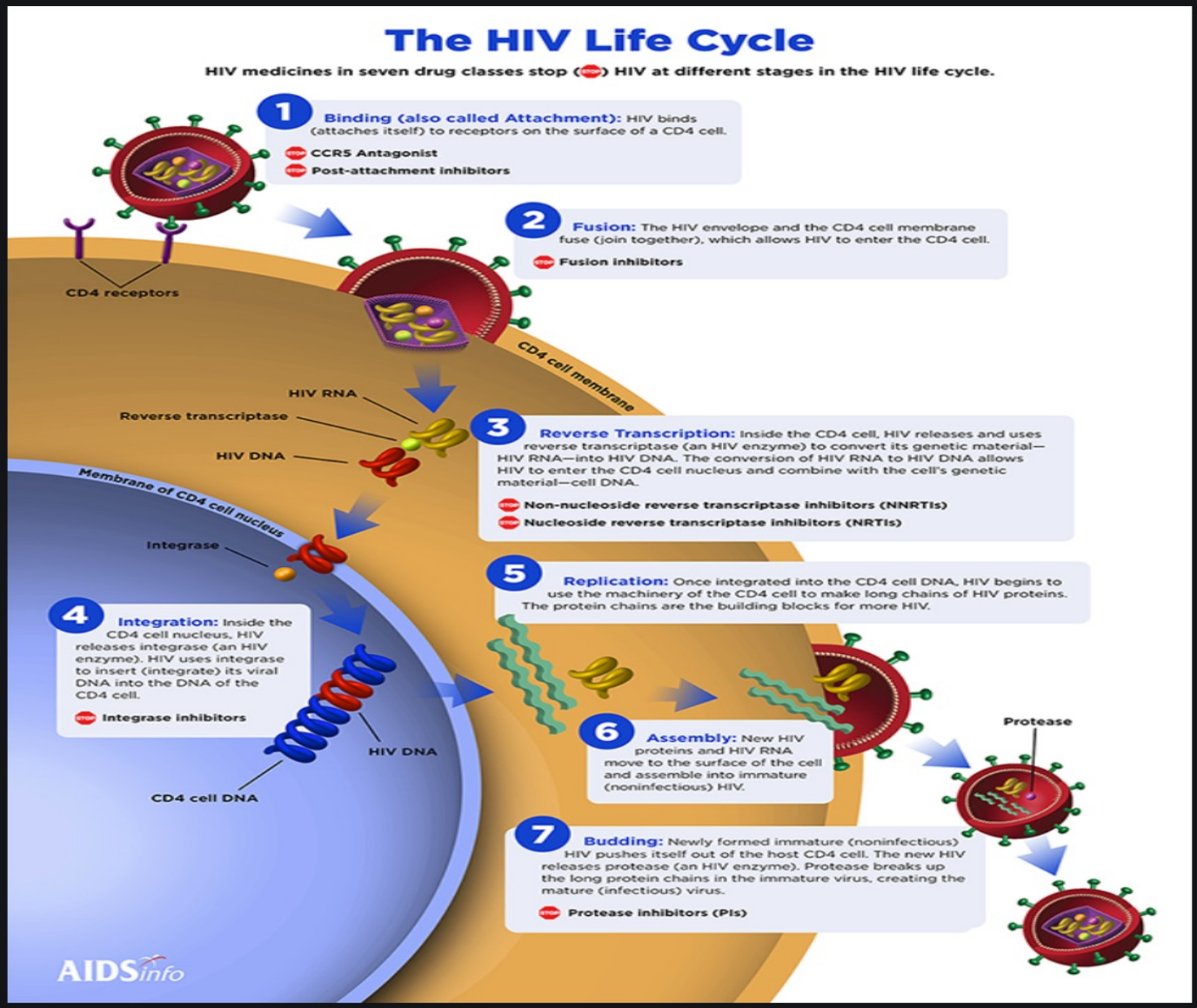
- Support and reinforcement
- Simplified dosing strategies
- Reminders, alarms, timers,  blister-pak, pillboxes
- Home delivery  90 days med supply
- Ongoing patient education
- Trust in primary care provider

# Team based care



# Drug - drug interactions

- Antacids -cobi /integrase inhibitors
- H2blockers
- Proton pump inhibitors
- Alpha adrenergic antagonist
- Rifampin/rifabutin
- Warfarin
- Clopidogrel -all PI
- Beta blockers
- Simvastatin & lovastatin contraindicated PWH on EFV/ritonavir/cobicistat
- Beta Agonist long acting-salmeterol


The HIV Life Cycle
HIV medicines in seven drug classes stop (STOP) HIV at different stages in the HIV life cycle.
1 Binding (also called Attachment): HIV binds (attaches itself) to receptors on the surface of a CD4 cell.
CCR5 Antagonist
Post-attachment inhibitors
CD4 receptors
2 Fusion: The HIV envelope and the CD4 cell membrane fuse (join together), which allows HIV to enter the CD4 cell.
Fusion inhibitors
CD4 cell membrane
HIV RNA
Reverse transcriptase
HIV DNA
3 Reverse Transcription: Inside the CD4 cell, HIV releases and uses reverse transcriptase (an HIV enzyme) to convert its genetic material—HIV RNA—into HIV DNA. The conversion of HIV RNA to HIV DNA allows HIV to enter the CD4 cell nucleus and combine with the cell's genetic material—cell DNA.
Non-nucleoside reverse transcriptase inhibitors (NNRTIs)
Nucleoside reverse transcriptase inhibitors (NRTIs)
Membrane of CD4 cell nucleus
Integrase
4 Integration: Inside the CD4 cell nucleus, HIV releases integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of the CD4 cell.
Integrase inhibitors
HIV DNA
CD4 cell DNA
5 Replication: Once integrated into the CD4 cell DNA, HIV begins to use the machinery of the CD4 cell to make long chains of HIV proteins. The protein chains are the building blocks for more HIV.
6 Assembly: New HIV proteins and HIV RNA move to the surface of the cell and assemble into immature (noninfectious) HIV.
Protease
7 Budding: Newly formed immature (noninfectious) HIV pushes itself out of the host CD4 cell. The new HIV releases protease (an HIV enzyme). Protease breaks up the long protein chains in the immature virus, creating the mature (infectious) virus.
Protease inhibitors (PIs)
AIDSinfo

# Approved ART: 2024*

## nucleoside/tide RTIs (NRTIs)

- zidovudine (ZDV, AZT)
- lamivudine (3TC)
- abacavir (ABC)
- emtricitabine (FTC)
- tenofovir (TAF, TDF)

## NNRTIs

- nevirapine (NVP)
- efavirenz (EFV)
- etravirine (ETR)
- rilpivirine (RPV)
- doravirine (DOR)

## protease inhibitors (PIs)

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

## integrase inhibitors (IIs)

- raltegravir (RAL)
- elvitegravir (EVG)
- dolutegravir (DTG)
- bictegravir (BIC)
- cabotegravir (CAB)

## entry inhibitors (EIs)

- enfuvirtide (T-20, fusion inhibitor)
- maraviroc (MVC, CCR5 antagonist)
- ibalizumab (IBA, CD4 post-attachment inhibitor)
- fostemsavir (FTR, CD4 attachment inhibitor)

## capsid inhibitors (CIs)

- lenacapavir (LEN)

# Approved ART: 2024*

## nucleoside/tide RTIs (NRTIs)

- ~~zidovudine (ZDV, AZT)~~
- lamivudine (3TC)
- ~~abacavir (ABC)~~
- emtricitabine (FTC)
- tenofovir (TAF, TDF)

## NNRTIs

- ~~nevirapine (NVP)~~
- efavirenz (EFV)
- etravirine (ETR)
- rilpivirine (RPV)
- doravirine (DOR)

## protease inhibitors (PIs)

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

## integrase inhibitors (IIs)

- ~~raltegravir (RAL)~~
- ~~elvitegravir (EVG)~~
- dolutegravir (DTG)
- bictegravir (BIC)
- cabotegravir (CAB)

## entry inhibitors (EIs)

- ~~enfuvirtide (T-20, fusion~~ inhibitor)
- ~~maraviroc (MVC, CCR5~~ antagonist)
- ibalizumab (IBA, CD4 post-attachment inhibitor)
- fostemsavir (FTR, CD4 attachment inhibitor)

## capsid inhibitors (CIs)

- lenacapavir (LEN)

*ddI, ddC, d4T, DLV, APV, and FPV discontinued from market

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# Recommended First-Line ART for Most Patients With HIV

BIC = bictegravir DTG = dolutegravir TXF = tenofovir XTC = 3TC or FTC

| Class | DHHS[1] | IAS-USA[2] | EACS[3] |
|---|---|---|---|
| INSTI | ▪ BIC/TAF/FTC*<br>▪ ~~DTG/ABC/3TC*~~<br>▪ DTG + TXF/XTC<br>▪ [ | ▪ BIC/TAF/FTC*<br>▪ DTG + TXF/XTC | ▪ BIC/TAF/FTC*<br>▪ DTG/ABC/3TC*<br>▪ DTG + FTC/TAF or TDF/XTC<br>C or TDF/XTC<br>3TC/DTG |
| NNRTI | | | C*<br>TC or TDF/XTC |

**The following have been removed from DHHS "other regimens"**

- Elvitegravir/cobicistat and raltegravir-based regimens
- Boosted atazanavir-based regimens
- Efavirenz-based regimens
- Rilpivirine (RPV)/tenofovir disoproxil fumarate/emtricitabine (FTC) regimens

- DTG plus TAF/FT … V switch to oral
- The durability of DTG/3TC has been established[1]
- HIV infection if recently received CAB LA PrEP: resistance testing prior to start or boosted DRV-based therapy[1,2]
- Is there a reason to use abacavir an initial regimen even as an alternative regimen?

*Single-tablet regimens. †HIV RNA <500,000 c/mL, no active HBV, and no genotype resistance testing available. ‡Not for rapid start and only if HIV RNA <500,000 c/mL, no active HBV.
Abbreviations: 3TC, lamivudine; ABC, abacavir; ART, antiretroviral therapy; BIC, bictegravir; CAB-LA, long-acting cabotegravir; DHHS, US Department of Health and Human Services; DRV, darunavir; DTG, dolutegravir; EACS, European AIDS Clinical Society; FTC, emtricitabine; HBV, hepatitis B virus; HIV, human immunodeficiency virus; IAS, International Antiviral Society; INSTI, integrase strand transfer inhibitor; NNRTI, non-nucleoside reverse transcriptase inhibitor; PrEP, pre-exposure prophylaxis; RAL, raltegravir; RNA, ribonucleic acid; TAF, tenofovir alafenamide; TDF, tenofovir disoproxil fumarate; XTC, lamivudine or emtricitabine.
1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services,Update 9/12/24: https://clinicalinfo.hiv.gov/en/guidelines/adult-and-adolescent-arv. 2. Gandhi RT, et al. *JAMA*. 2025 Feb 18;333(7):609-628. 3. European AIDS Clinical Society. Guidelines Version 11.1. October 2022. Accessed 5/15/23 at: https://www.eacsociety.org/media/guidelines-11.1_final_09-10.pdf.

**Table 6a. Recommended Initial Regimens for Most People With HIV**

Recommended regimens are those with demonstrated durable virologic efficacy, favorable tolerability and toxicity profiles, and ease of use. Choice of ART during pregnancy should be guided by recommendations from the **Perinatal Guidelines.**

**For people who do not have a history of using CAB-LA as PrEP, one of the following regimens is recommended[a]:**

- BIC/TAF/FTC **(AI)**
- DTG plus (TAF or TDF)[b] plus (FTC or 3TC) **(AI)**
- DTG/3TC **(AI),** except for individuals with HIV RNA >500,000 copies/mL, HBV coinfection, or in whom ART is to be started before the results of HIV genotypic resistance testing for reverse transcriptase or HBV testing are available.

**For people who have a history of CAB-LA use as PrEP, INSTI genotype resistance testing should be performed before starting ART. If ART is to be started before results of genotypic testing results, the following regimen is recommended:**

- DRV/c[c] or DRV/r with (TAF or TDF)[b] plus (FTC or 3TC)—pending the results of the genotype test **(AIII)**

# Alternative Regimes

| | | | |
|---|---|---|---|
| **NNRTI Plus Two NRTIs** | DOR/TDF/3TC[b] **(BI)** or DOR plus TAF/FTC[b] **(BIII)** | To avoid an INSTI-based regimen (e.g., with suspected or documented INSTI resistance), *and*<br><br>To avoid a PI-based regimen (e.g., with significant DDIs with concomitant medications) | |
| | RPV/TAF/FTC **(BII)**<br><br>Only if HIV RNA <100,000 copies/mL **and** CD4 count >200 cells/mm$^3$ | To avoid an INSTI-based regimen (e.g., with suspected or documented INSTI resistance), *and*<br><br>To avoid a PI-based regimen (e.g., with significant DDIs with concomitant medications), *and*<br><br>When a single-tablet regimen containing an NNRTI and TAF is desired | Cannot take with PPI; space apart from H2 antagonist.<br><br>Needs to be taken with a meal. |

| Type of Regimen | ARV Regimen | For Certain Clinical Scenarios | Other Considerations |
|---|---|---|---|
| **INSTI Plus Two NRTIs** | DTG/ABC/3TC **(BI)** (if HLA-B*5701-negative) | When concern about renal- or bone-associated AEs precludes the use of TDF or TAF | Test for HLA-B*5701 before prescribing ABC; do not prescribe if HLA-B*5701-positive.<br><br>Consider avoiding ABC for people with multiple CV risk factors or known CV disease.<br><br>Do not use in people with HBV coinfection unless an HBV-active drug, such as entecavir, TAF, or TDF is also used.<br><br>Do not use following exposure to CAB-LA unless INSTI genotype shows sensitivity. |

# Alternative regimes

| | | | |
|---|---|---|---|
| **Boosted PI Plus Two NRTIs** | (DRV/c[a] or DRV/r) plus (TAF or TDF[b]) plus (FTC or 3TC) **(BI)** | To avoid an INSTI-based regimen (e.g., documented INSTI resistance). | Assess for potential RTV- or COBI-related DDIs. |
| | (DRV/c[a] or DRV/r) plus ABC/3TC **(BII)**<br><br>(if HLA-B*5701-negative) | To avoid an INSTI-based regimen (e.g., with suspected or documented INSTI resistance), *and*<br><br>When concern about renal or bone-associated AEs precludes the use of TDF or TAF | Test for HLA-B*5701 before prescribing ABC; do not prescribe if HLA-B*5701-positive.<br><br>Consider avoiding ABC for people with multiple CV risk factors or known CV disease.<br><br>Do not use in people with HBV coinfection unless used with an HBV-active drug other than 3TC.<br><br>Assess for potential RTV- or COBI-related DDIs. |

## Single-Tablet Regimens

### Bictegravir-Tenofovir alafenamide-Emtricitabine

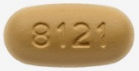
*Biktarvy*

Clinical Trials »
References »
Slide Deck »


### Darunavir-Cobicistat-Tenofovir alafenamide-Emtricitabine

*Symtuza*

Clinical Trials »
References »
Slide Deck »




### Dolutegravir-Abacavir-Lamivudine

*Triumeq*

Clinical Trials »
References »
Slide Deck »


### Dolutegravir-Lamivudine

*Dovato*

Clinical Trials »
References »
Slide Deck »


### Dolutegravir-Rilpivirine

*Juluca*

Clinical Trials »
References »
Slide Deck »


### Doravirine-Tenofovir DF-Lamivudine

*Delstrigo*

Clinical Trials »
References »
Slide Deck »


### Efavirenz-Tenofovir DF-Emtricitabine

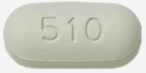
*Atripla*

Clinical Trials »
References »
Slide Deck »


### Elvitegravir-Cobicistat-Tenofovir alafenamide-Emtricitabine

*Genvoya*

Clinical Trials »
References »
Slide Deck »




### Elvitegravir-Cobicistat-Tenofovir DF-Emtricitabine

*Stribild*

Clinical Trials »
References »
Slide Deck »


### Rilpivirine-Tenofovir alafenamide-Emtricitabine

*Odefsey*

Clinical Trials »
References »
Slide Deck »


### Rilpivirine-Tenofovir DF-Emtricitabine

*Complera*

Clinical Trials »
References »
Slide Deck »

# Single tablet - complete regimes - once daily

- Atripla- efavirenz tenofovir emtricitabine EVF/FTC/TDF
- Triumeq -abacavir dolutegravir lamivudine ABC/DTG/3TC
- Complera- rilpivirine FTC/RPV/TDF
- Odefsy- rilpivirine FTC/RPV/TAF
- Stribild- elvitegravir EVG/COBI/FTC/TDF
- Genvoya - elvitegravir EVG/COBI/FTC/TAF
- Symtuza darunavir DRV/COBI/FTC/TAF
- Juluca dolutegravir rilpivirine DTG/RPV
- Dovato - dolutegravir lamivudine DTG/3TC
- Biktarvey - bictegravir BIC/FTC/TAF
- Delstrigo - doravirine DOR/3TC/TDF

# Injectable Cabotegravir/rilpivirine (cabenuva)

- First 2 drug complete regimen approved in virologically suppressed hiv + patients
- Oral lead in with rilpivirine 25mg and cabotegravir 30mg once daily for at least 4 weeks in required. On the last day of the oral lead in a 600mg injection of cabo and 900 mg injection of rilpivirine both given IM at different gluteal sites at least 2 cm apart. Subsequent injections (400 mg of cabo and 600 mg of rilpivirine should be given once monthly for 2 months, then beginning 2 months after last initiation injection cabo 600 and rilpivirine 900 once every 2 months, 7 -day leniency
- Non inferior to treatment with daily standard oral antiretroviral regimens in maintaining hiv –1 suppression
- ADR- injection site discomfort

# Treatments for Highly Treatment Experienced Patients
## with resistance

| Drug | Mechanism | Administration | Development stage |
|---|---|---|---|
| **Fostemsavir** | Gp120-directed attachment inhibitor | Oral<br>*Twice daily* | FDA-approved 2020 |
| **Ibalizumab** | CD4-directed post-attachment inhibitor | Intravenous<br>*Every 2 weeks* | FDA-approved 2018 |
| **Lenacapavir** | Capsid inhibitor | Subcutaneous<br>*Every 6 months* | FDA approved 2022 |

**Combination therapy – 2 or more active agents**
**2nd Gen INSTI may have activity at increased dose**
**NRTI (XTC) may also have residual activity**

# Lenacapavir FDA approved 12/22/2022

- **Sunlenca® (lenacapavir) Receives FDA Approval as a First-in-Class, Twice-Yearly Treatment Option for People Living With Multi-Drug-Resistant HIV**
- ***Sunlenca is the First and Only Approved Capsid Inhibitor-Based HIV Treatment Option***
- ***New Drug Application Approval Based on High Rates of Sustained Virologic Suppression in the CAPELLA Trial –***

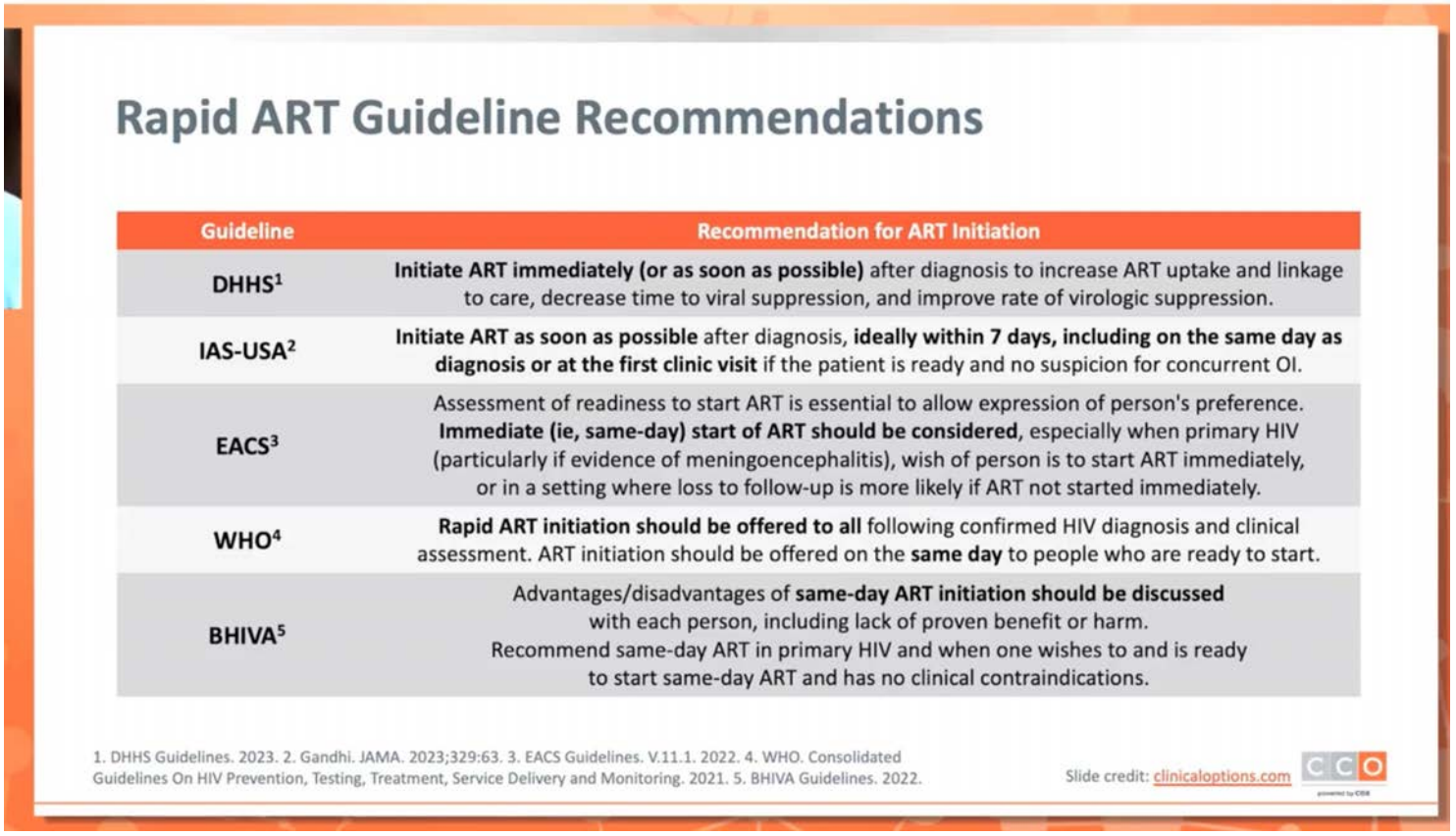
# Test & Treat

- T&T is a clinical program providing immediate linkage to HIV primary care and initiation of Antiretroviral Therapy (ART) at the time of HIV diagnosis or a return to care after a gap in services.

- Rapid test +, confirmation 4th generation hiv antibody testing, & baseline labs drawn. Preferably 1st tab given in office post lab draw.

- The program benefits the client's health and the community by providing initial ART while working through the issues of eligibility and linkage to ongoing HIV primary care.

# Rapid start


Rapid ART Guideline Recommendations
Guideline
Recommendation for ART Initiation
DHHS[1]
Initiate ART immediately (or as soon as possible) after diagnosis to increase ART uptake and linkage to care, decrease time to viral suppression, and improve rate of virologic suppression.
IAS-USA[2]
Initiate ART as soon as possible after diagnosis, ideally within 7 days, including on the same day as diagnosis or at the first clinic visit if the patient is ready and no suspicion for concurrent OI.
EACS[3]
Assessment of readiness to start ART is essential to allow expression of person's preference. Immediate (ie, same-day) start of ART should be considered, especially when primary HIV (particularly if evidence of meningoencephalitis), wish of person is to start ART immediately, or in a setting where loss to follow-up is more likely if ART not started immediately.
WHO[4]
Rapid ART initiation should be offered to all following confirmed HIV diagnosis and clinical assessment. ART initiation should be offered on the same day to people who are ready to start.
BHIVA[5]
Advantages/disadvantages of same-day ART initiation should be discussed with each person, including lack of proven benefit or harm. Recommend same-day ART in primary HIV and when one wishes to and is ready to start same-day ART and has no clinical contraindications.
1. DHHS Guidelines. 2023. 2. Gandhi. JAMA. 2023;329:63. 3. EACS Guidelines. V.11.1. 2022. 4. WHO. Consolidated Guidelines On HIV Prevention, Testing, Treatment, Service Delivery and Monitoring. 2021. 5. BHIVA Guidelines. 2022.
Slide credit: clinicaloptions.com
CCO

**TEST AND TREAT MEDICATIONS (revised September 2021)**

| Brand Name | Generic Name | Therapeutic Class | Pharmacologic Class | Samples and Vouchers |
|---|---|---|---|---|
| BIKTARVY | bictegravir/emtricitabine/ tenofovir alafenamide | antiretroviral | INSTI/NRTI combo | Samples |
| DESCOVY | emtricitabine/tenofovir alafenamide | antiretroviral | NRTI combo | Samples |
| SYMTUZA | darunavir/cobicistat/ emtricitabine/tenofovir alafenamide | antiretroviral | PI/NRTI combo | Samples and vouchers, can get both |
| TIVICAY | dolutegravir | antiretroviral | INSTI | No samples or vouchers |
| TRUVADA | emtricitabine/tenofovir disoproxil fumarate | antiretroviral | NRTI combo | No samples or vouchers |
| DOVATO | dolutegravir/lamivudine | antiretroviral | INSTI/NRTI combo | Samples and vouchers, but practitioner can access only one or the other, not both |

NOTE: Clinical trial data indicate that Dovato (dolutegravir/lamivudine) is an option for Test and Treat use for newly diagnosed persons with HIV. Department of Health and Human Services guidelines only recommend Dovato if HIV RNA is <500,000 copies/mL, patient does not have coinfection with hepatitis B virus, and resistance testing results show no resistance to lamivudine. Dovato is available through samples or via the manufacturer's patient assistance program.

# Switching Regimens

Rationale for switching in setting of virologic suppression

- To simplify therapy (reduce pill burden, dosing frequency, improve adherence)
- To enhance tolerability, decrease or prevent short- and long-term toxicity
- To change food or fluid requirements
- To minimize or address current or future drug interactions
- To allow for optimal use of ART during or in event of pregnancy
- To reduce cost to the patient
- Improve quality of life (reduce stigma, anxiety, isolation)

# The Bottom Line…

"Drugs don't work
if people don't take them."

*- C. Everett Koop, Former US Surgeon General*

# Baseline labs

- HIV antibody testing (if prior documentation is not available or if HIV RNA is below the assay's limit of detection) **(AI)**;
- CD4 T-cell count (CD4 count) **(AI)**;
- Plasma HIV RNA (viral load) **(AI)**;
- Complete blood count, chemistry profile, transaminase levels, blood urea nitrogen (BUN), and creatinine, urinalysis, and serology for hepatitis A, B, and C viruses **(AIII)**;
- Fasting blood glucose and serum lipids **(AIII)**; and
- Genotypic resistance testing at entry into care, regardless of whether ART will be initiated immediately **(AII)**. For patients who have HIV RNA levels <500 to 1,000 copies/mL, viral amplification for resistance testing may not always be successful **(BII)**.
- Tropism and HLA- B5701

# Baseline

- Pap smear
- Pregnancy test lactating female
- RPR and std testing
- QuanitiFeron gold

# TX plan

- Immunizations in HIV/AIDS avoid live vaccines
- Pneumococcal,  Tdap, Hep A& B if nonimmune, meningococcal, HPV
- Recommended the recombinant herpes zoster vaccine (RZV) for all individuals with HIV who are 18 years and older rather than 50 years and older.
- CD4 count guides your prophylaxis for OI:

CD4 < 200  PCP  Bactrim DS, dapsone, mepron

CD4 <100  TOXO  “

CD4 < 50  MAC  azithromycin 1200mg once weekly

Discussion on safe sex, nutrition, transmission, adherence, review herbals /otc meds looking for DDI

# Live Vaccines Contraindicated in HIV-Infected

- **Contraindicated only if CD4 <200 cells/mm$^3$**
  - Measles/Mumps/Rubella (MMR) Vaccine
  - Varicella/Chickenpox Vaccine (*Varivax*)
  - Yellow Fever Vaccine
- **Contraindicated in All People with HIV**
  - Live Attenuated Influenza Vaccine (*Flumist*)
  - Vaccinia/Smallpox Vaccine (ACAM 2000)
  - Live Oral Polio Vaccine
  - Live attenuated oral Typhoid/Ty21a (*Vivotif*)

Source: OI Guidelines. Immunizations for Preventable Diseases in Adults and Adolescents with HIV. December 16, 2024.

# General Immunization Principles for People with HIV

**Vaccine efficacy** is generally better when a person has a CD4 count > 200 cells/$mm^3$

**May experience a blip in HIV viral load** but vaccinations should not be withheld

**Live vaccines should not be used** in people with **low CD4 counts** due to risk for disseminated infection

**Vaccines contraindicated in people with HIV**

- **Live, attenuated influenza** (all persons with HIV)
- **Measles, mumps, rubella** (when CD4 count <200 $mm^3$ or <15%)
- **Varicella** (when CD4 count <200 $mm^3$ or <15%)

Centers for Disease Control and Prevention. Adult Immunization Schedule by Medical Condition and Other Indication. Available at https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html#table-conditions. Accessed on 10/25/2022. National Institutes of Health. Vaccines and People with HIV. Available at https://www.hiv.gov/hiv-basics/staying-in-hiv-care/other-related-health-issues/immunizations-recommended-for-people-living-with-hiv. Accessed on 10/25/2022.

# Updates to CDC Pneumococcal Vaccine Recommendations for People with HIV

**No history of pneumococcal vaccine or unknown history**

- PCV 15 → 8 weeks → PPSV 23
- -OR-
- PCV 20 → Vaccination complete after PCV20

**Received only PPSV23 previously**

1 year → PCV 15 -OR- PCV 20

**Received PCV13 previously**

8 weeks → PPSV 23 (at < 65 years) → 5 years → PPSV 23 (at < 65 years) → 5 years → PPSV 23 (at ≥ 65 years)

PCV13 = 13-Valent Pneumococcal Conjugate Vaccine; PCV15 = 15-Valent Pneumococcal Conjugate Vaccine; PCV20 = 20-Valent Pneumococcal Conjugate Vaccine; PPSV23 = 23-Valent Pneumococcal Polysaccharide Vaccine

**Centers for Disease Control and Prevention. Pneumococcal Vaccine Timing for Adults. Available at https://www.cdc.gov/vaccines/vpd/pneumo/downloads/pneumo-vaccine-timing.pdf. Accessed 10/21/2022.**

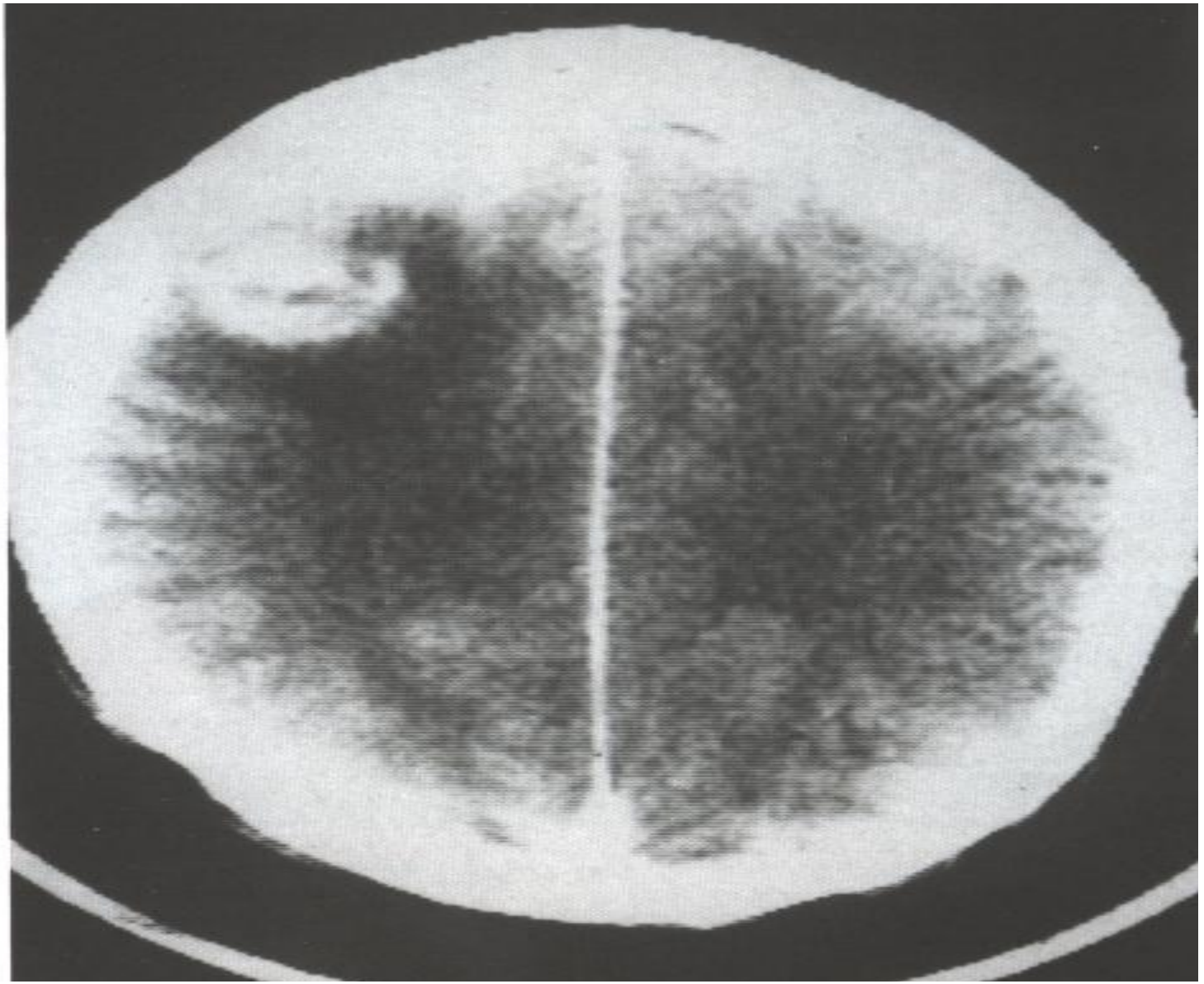
# HIV stages

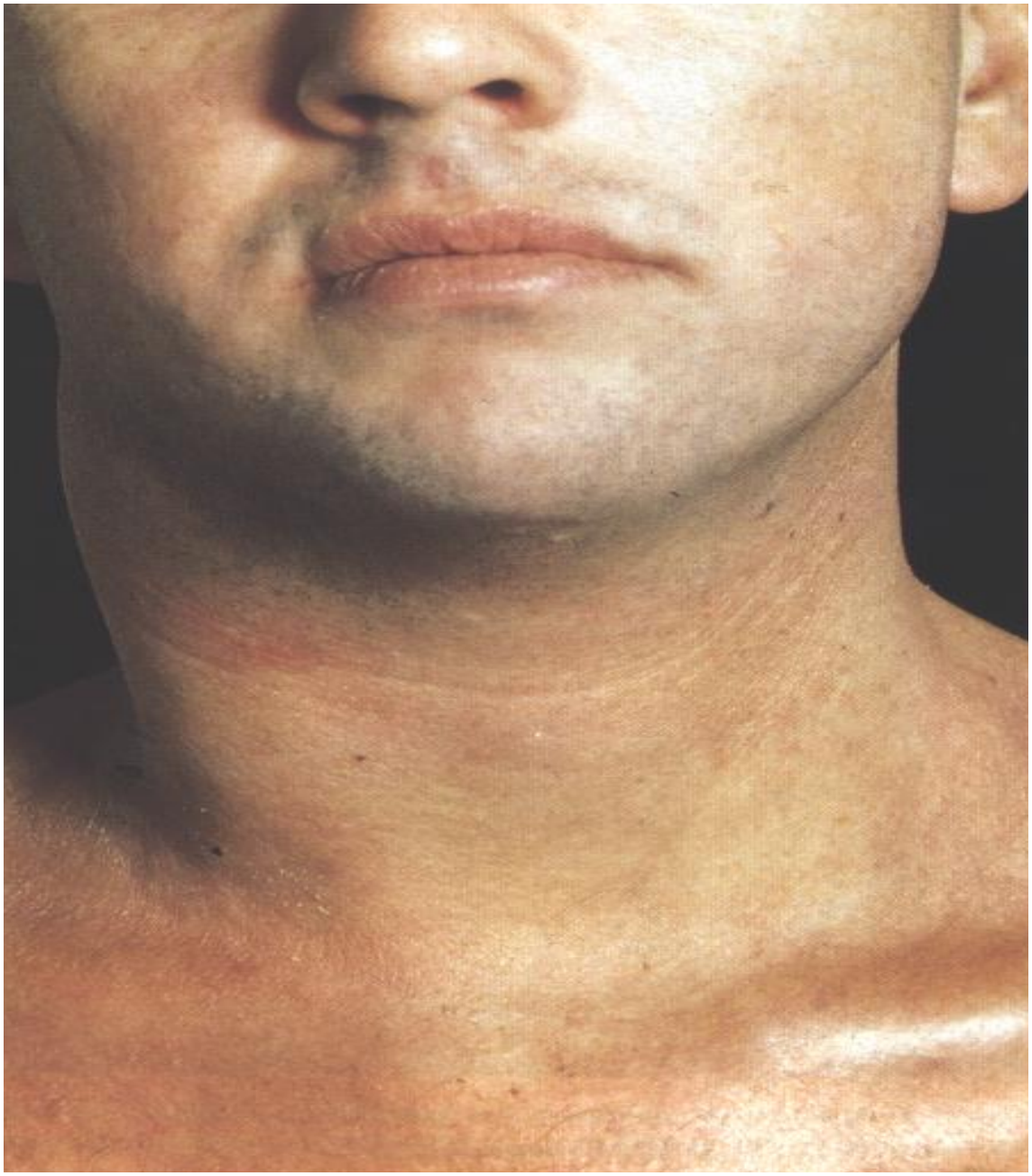
- Stage 1 Acute HIV untreated
- Stage 2 Chronic Hiv virologically suppressed
- Stage 3 Aids , CD4< 200 or hx of aids defining illness

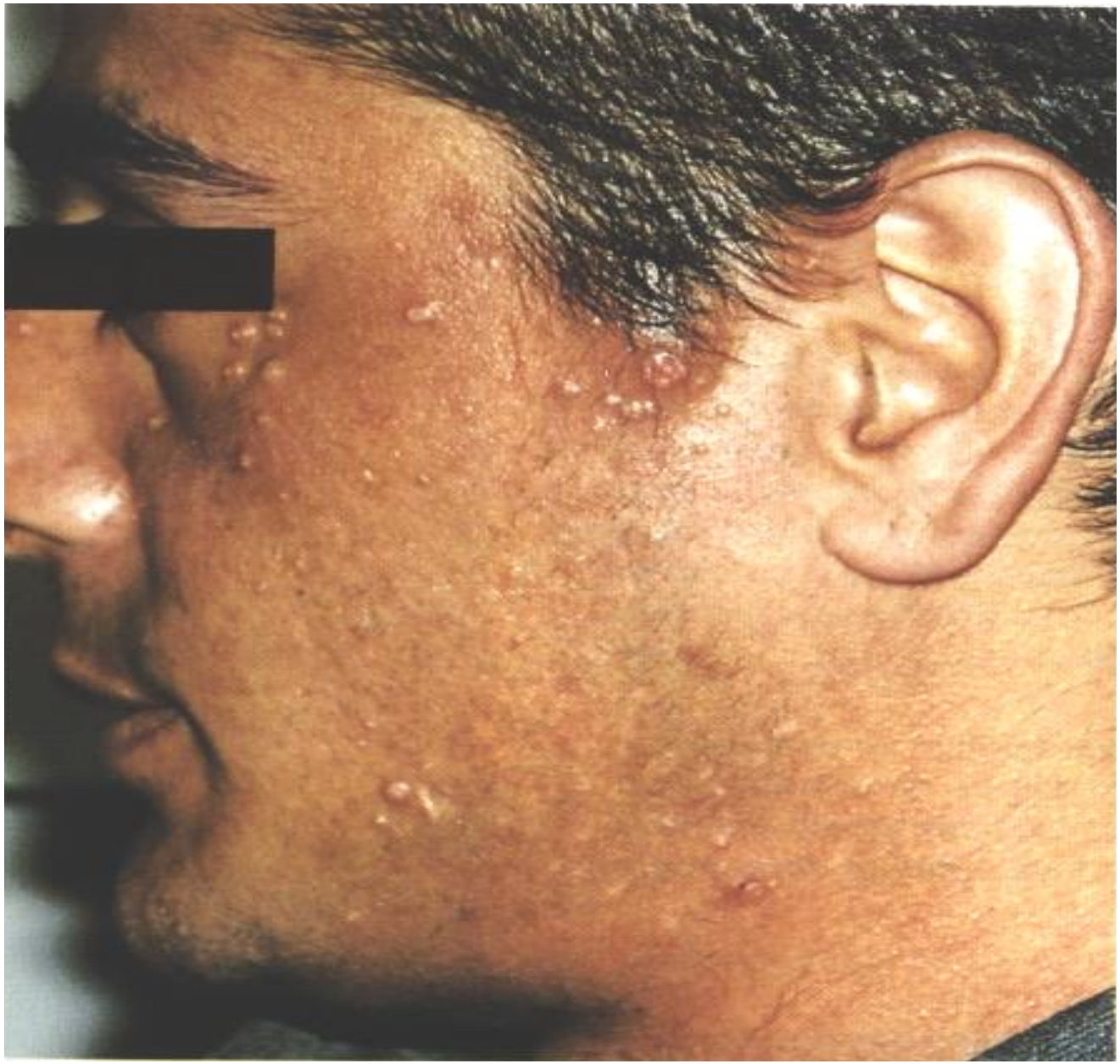

/hat is an opportunistic infection?

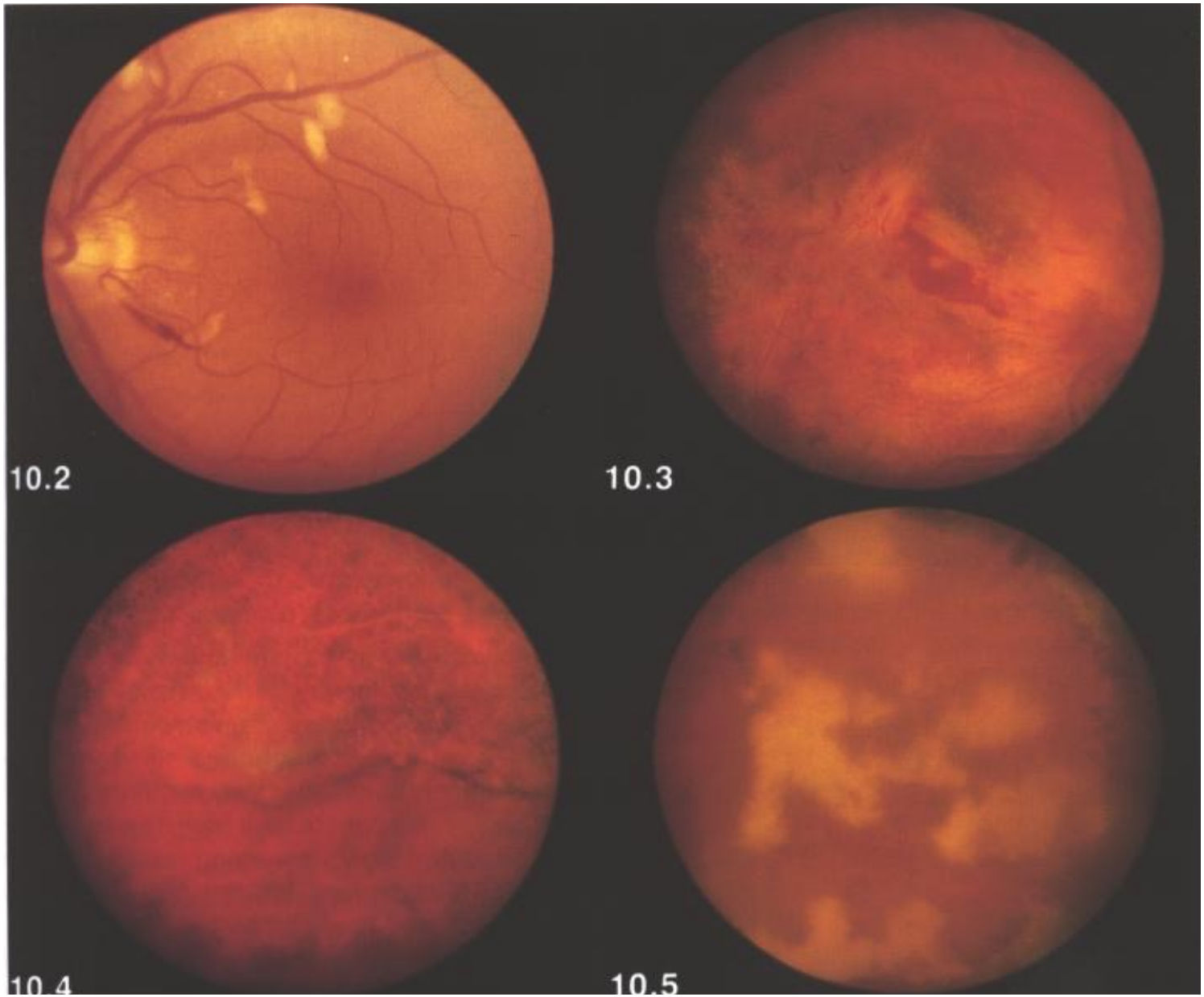
AIDS DEFINING

- CD4 <200
- *Candidiasis* of bronchi, trachea, esophagus, or lungs
- *Invasive cervical cancer*
- *Coccidioidomycosis*
- *Cryptococcosis*
- *Cryptosporidiosis*, chronic intestinal (greater than 1 month's duration)
- *Cytomegalovirus* disease (particularly CMV retinitis)
- *Encephalopathy*, HIV-related
- *Herpes simplex*: chronic ulcer(s) (greater than 1 month's duration); or bronchitis,
- pneumonitis, or esophagitis
- *Histoplasmosis*
- *Isosporiasis*, chronic intestinal (greater than 1 month's duration)
- *Kaposi's sarcoma*
- *Lymphoma*, multiple forms
- *Mycobacterium avium complex*
- *Tuberculosis*
- *Pneumocystis carinii pneumonia*
- *Pneumonia*, recurrent
- *Progressive multifocal leukoencephalopathy*
- *Salmonella septicemia*, recurrent
- *Toxoplasmosis* of brain
- *Wasting syndrome* due to HIV





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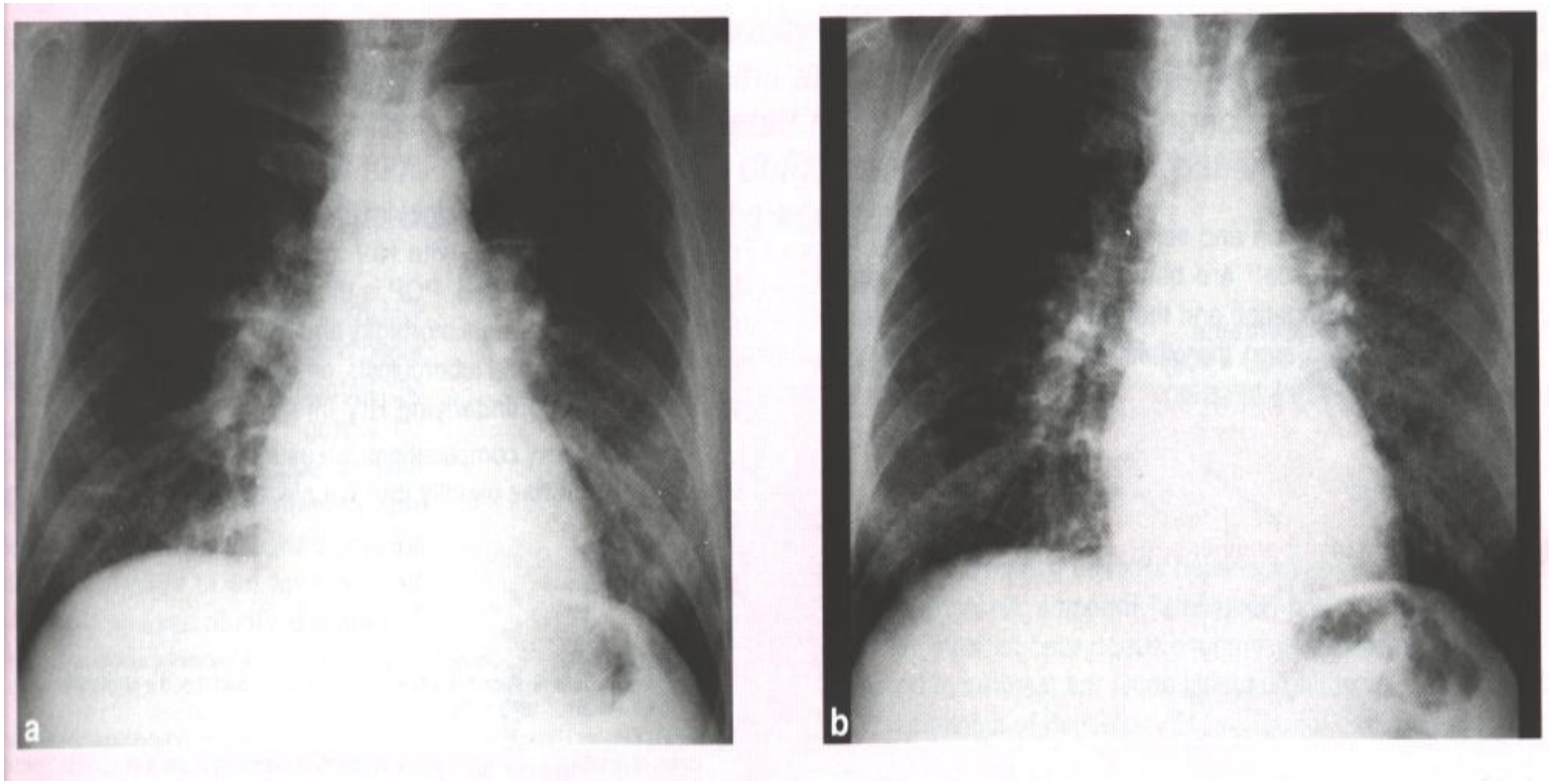
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b

# 456.061 practitioner disclosure of confidential information: immunity from civil or criminal liability

1. Shall not be civilly or criminally liable for disclosure of confidential information to a sexual partner or a needle sharing partner under the following circumstances

A. if your pt test (+) & pt discloses their needle sharing partner or sexual partner

B. The doctor recommends the pt notify the sexual partner or needle sharing partner of their positive status & the pt refuses & the doctor informs the pt of his or her intent to inform the partner

C. in good faith advises the partner shall be done in accordance with protocols developed by the DOH

# 456.061

- (2) The practitioner shall not be civilly or criminally liable for failure to disclose information relating to  a positive  HIV test result to a sexual partner or needle sharing partner

# Florida state statue 381.004 HIV test

- A general release without such prior written authorization is not sufficient to release HIV test results.
- “This information has been disclosed to you from records whose confidentiality is protected by state law. State law prohibits you from making any further disclosure of such information without the specific written consent of the person to whom such information pertains, or as otherwise permitted by state law.
- A general authorization for the release of medical or other information is NOT sufficient for this purpose.”

# FLORIDA STATUE SECTION 381.004 2016 UPDATE

- Informed consent is no longer required in health care settings in Florida prior to testing for HIV.
- Patients must be notified either orally or in writing that they will be tested for HIV unless they decline (opt-out of) testing.
- Notification must include information that a positive HIV test result, along with identifying information will be reported to the county health department and of the availability and location of sites at which anonymous testing is performed.
- If the patient opts out, it must be noted in their medical record.
- A patient need not be notified that their blood is being tested for HIV in the event of a significant exposure for health care personnel.
- A patient need not be notified that their blood is being tested for HIV in the event of a significant exposure for non-health care personnel during a medical emergency.

# statute 384.25 in Florida

- Diagnosis and/or treatment of STDs (including HIV and AIDS) – State law (Section 384.25, F.S.) requires that practitioners report evidence of sexually transmitted diseases, including HIV and AIDS, to the county health department.
- Not  to exceed 2 weeks

# Previous DHHS

- Panel **recommends against** the use of the long-acting ART regimen of intramuscular CAB and RPV in people who have detectable viral load due to suboptimal adherence to ART and who have ongoing challenges with retention in HIV care, except in a clinical trial **(AIII).**

# New

## LA CAB and RPV in Viremic Patients

IAS-USA Guidelines

- Unable to take oral ART consistently despite extensive efforts and clinical support
- High risk of HIV disease progression (CD4+ cell count <200/µL or history of AIDS-defining complications)
- A virus susceptible to both cabotegravir and rilpivirine
- If applicable, individuals should also be referred for treatment of SUD (or mental health disorders)

DHHS Guidelines

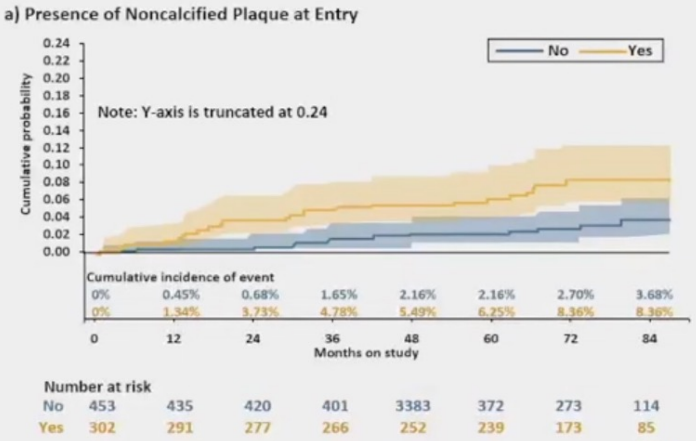
- Based on very limited data, the Panel recommends the use of LA CAB/RPV on a case-by-case basis in select individuals with persistent virologic failure despite intensive adherence support on oral ART, who have no evidence of resistance to CAB or RPV, and with shared decision-making between providers and people with HIV **(CIII).**

# New

## REPRIEVE: Plaque, Inflammation and Major Adverse Cardiac Events (MACE)

- Among >7700 participants with HIV, pitavastatin reduced MACE by 36%
- Among 803 participants in a sub-analysis:
  - Age 51 years, ASCVD 6.6%
  - Baseline non-calcified plaque associated with higher risk for MACE (HR, 2.5)
  - Elevated hsCRP, IL-6 and subclinical myocardial injury associated with higher risk of MACE

**Cumulative incidence of MACE over time, by baseline non-calcified plaque**




REPRIEVE

ACTG

Lu M, Grinspoon S, et al, CROI 2025, Abstract 178

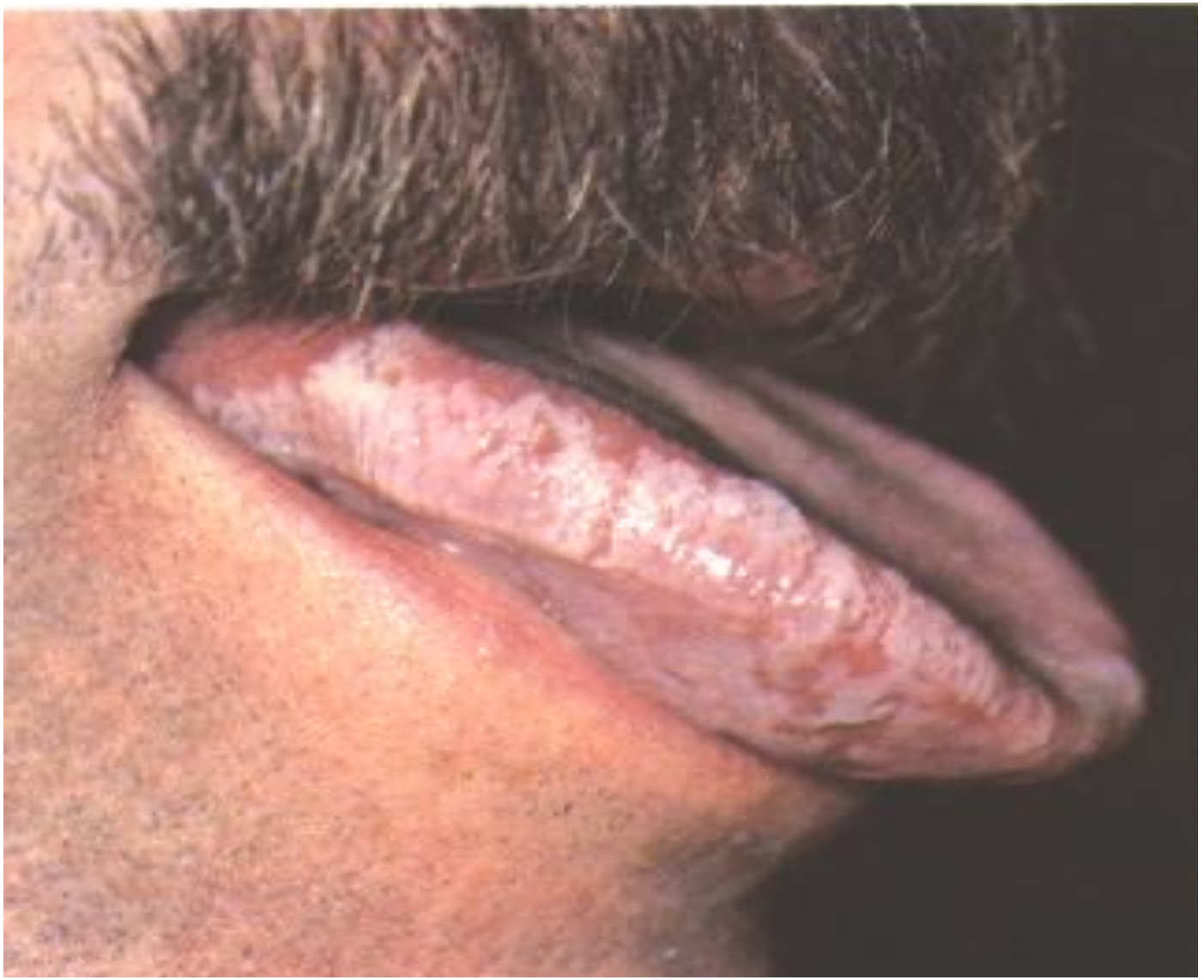
## Panel's Recommendations

### For People With HIV Who Have Low-to-Intermediate (<20%) 10-Year Atherosclerotic Cardiovascular Disease (ASCVD) Risk Estimates

- Age 40–75 Years
  - When 10-year ASCVD risk estimates are 5% to <20%, the Panel for the Use of Antiretroviral Agents in Adults and Adolescents with HIV (the Panel) recommends initiating at least moderate-intensity statin therapy **(AI).**
    - Recommended options for moderate-intensity statin therapy include the following:
      - Pitavastatin 4 mg once daily **(AI)**
      - Atorvastatin 20 mg once daily **(AII)**
      - Rosuvastatin 10 mg once daily **(AII)**

# Success=Adherence

- Adherence is a key determinant of clinical outcome in patients receiving HAART
- Adherence is a complex process influenced by patient-related variables, provider-related variables, and regimen-related variables
- The number of prescribed daily doses is inversely related to adherence
- Patients tend to prefer regimens with fewer daily doses, low pill burden, no food restrictions
- The expansion in HIV treatment options means that some patients can now start therapy using a once-a-day regimen with a low pill burden



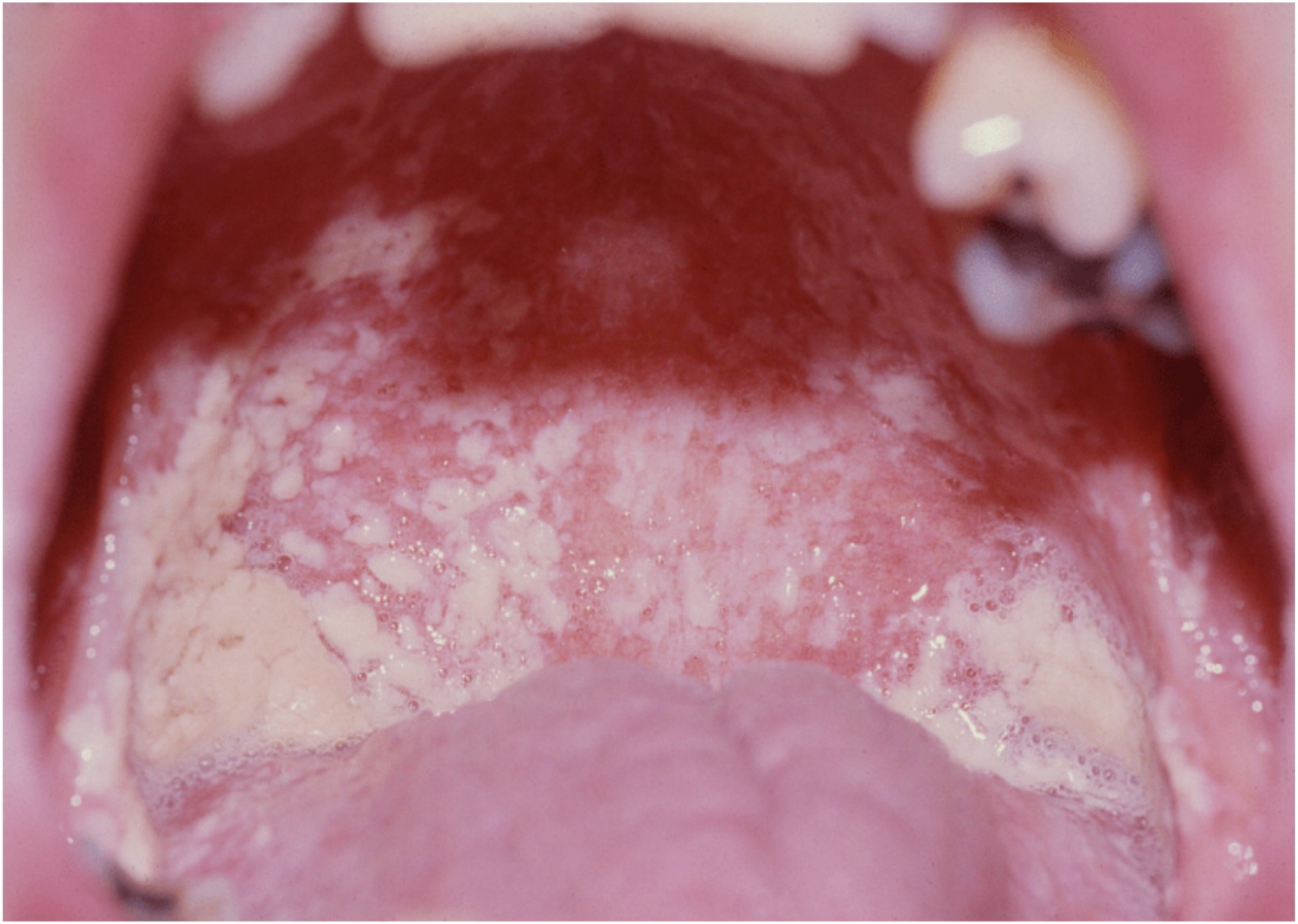


Figure 2A. Pseudomembranous Candidiasis on Palate
Photograph from David H. Spach, MD

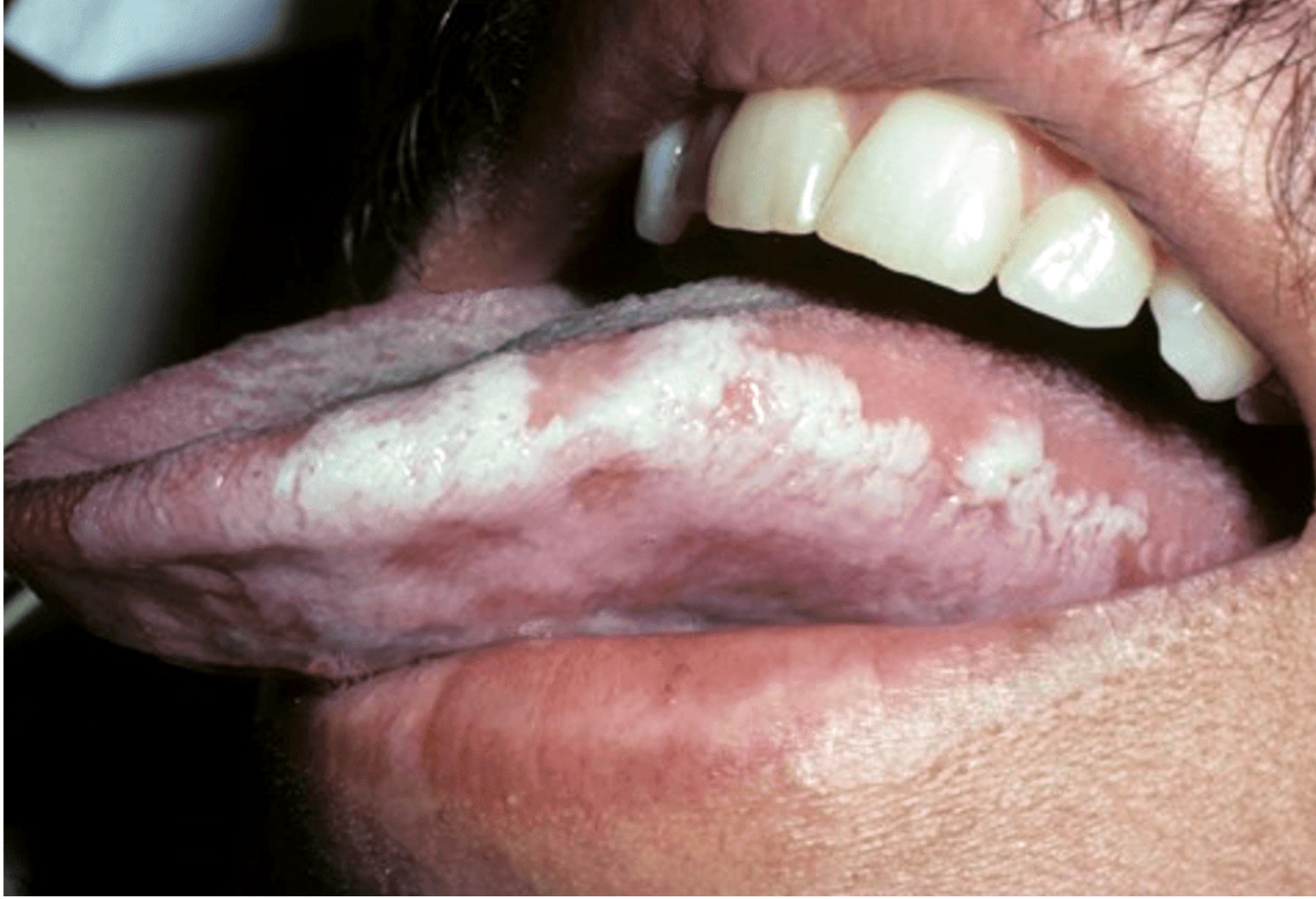


Figure 6A. Oral Hairy Leukoplakia with Diffuse Tongue Involvement (Lateral View)

Photograph from Mark Nichols, DDS, Dental Director, South Central AETC

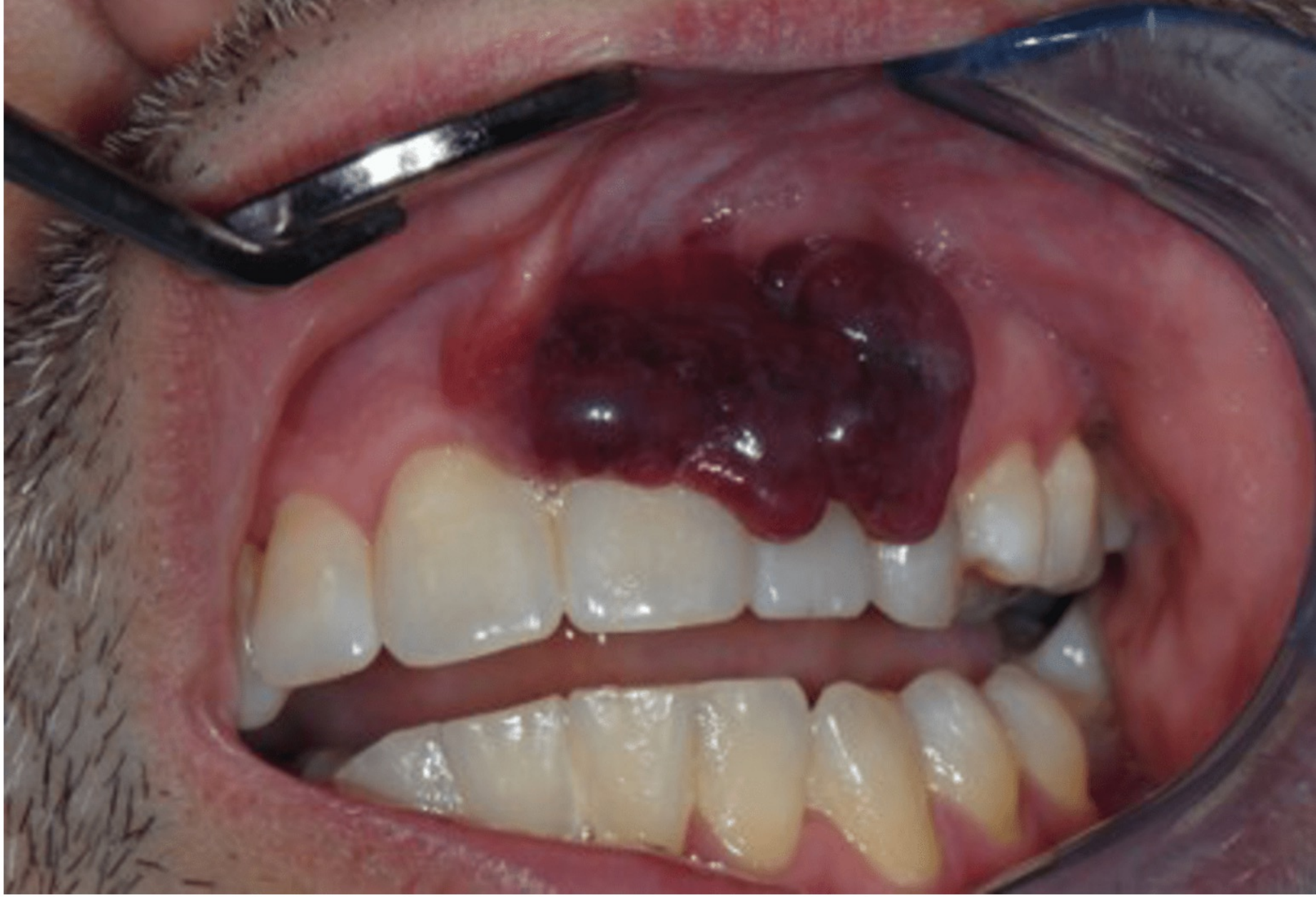


Figure 9A. Oral Kaposi's Sarcoma on Maxillary Gingiva

Photograph courtesy of Mark Nichols, DDS, Dental Director, South Central AETC

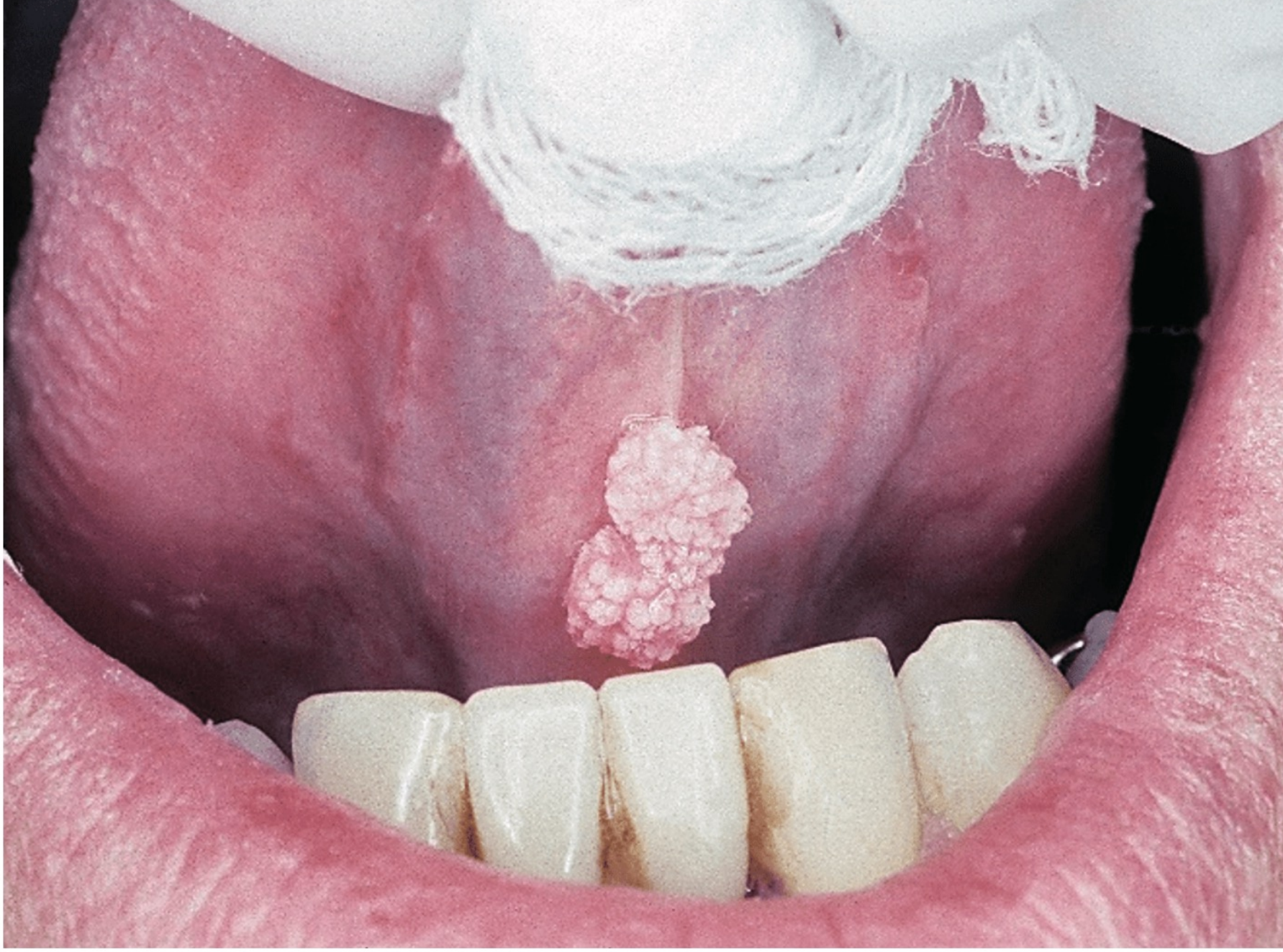


Figure 10A. HPV-Associated Oral Squamous Papilloma

Photograph courtesy of Fariba S. Younai, DDS, Dental Director, Pacific AETC

# Who should be routinely screened for HIV according to CDC guidelines?

- 1. All individuals regardless of risk
- 2. All individual if written consent & post test counseling is done
- 3. Only those who request
- 4. High risk individuals (mandatory) & voluntary screening for everyone else
- 5. MSM: AA males > 15yo

# Which test is recommended for initial HIV testing?

- 1. Western Blot
- 2. 2nd Generation HIV antibody test
- 3. 4th Generation HIV antibody/antigen test
- 4. HIV 1 nucleic acid test

# Which of the following individual is an appropriate candidate for PrEP?

- 1. HIV (-) Male who has unprotected sex with multiple male sex partners in past yr.
- 2. HIV (-) female in a monogamous relationship who has recently treated for HSV2 and uses cocaine
- 3. HIV (+) male who admits to sex with multiple partners
- 4. HIV (-) female who admits to unprotected sex with one male of uncertain HIV status.

The use of emtricitabine/tenofovir FTC/TAF (descovy) for HIV pre-exposure prophylaxis is not FDA approved for?

- 1, at risk MSM
- 2. person at risk for acquiring hiv infection from receptive vaginal sex
- 3. at risk heterosexual men

# What information is needed prior to treating + Hiv rapid test (Test & Treat) ?

- 1. CD4 count
- 2. HIV1 RNA
- 3. HIV genotype
- 4. HLAB 5701 status
- 5. all the above
- 6. none of the above

# Which HIV viral load value is considered a virologic failure for individuals receiving ART without prior ART exposure?

1. >20 to < 50 copies/ml
2. >50 copies/ml but < 100 copies/ml
3. >50 copies/ml but < 150 copies/ml
4. > 200 copies/ml

# What 3 drug regimen is recommended for initial tx of adults who are ART naïve?

1. Chemokine receptor 5 antagonist, integrase strand transfer inhibitor & protease inhibitor
2. Integrase strand transfer inhibitor, nucleoside & nucleotide reverse transcriptase inhibitor, & fusion inhibitor
3. Integrase strand transfer inhibitor & two nucleotide reverse transcriptase inhibitors
4. Fusion inhibitor & nonnucleoside reverse transcriptase inhibitor

# What is the most accurate regarding the timing of ART initiations in person newly dx with acute hiv

1. ART should be initiated 4 weeks after dx
2. ART should begin on the same day of tx initiation for most opportunistic infections
3. ART initiation should be delayed in the setting of new dx of cancer
4. ART should be initiated at the time of diagnosis

# 456.033 HIV

- Modes of transmission
- Screening procedures to diagnosis hiv
- Infection control

  behavioral-reducing condom less sex, dec # of partners, dec sex trade, dec IVDU frequency-treating OUD,

  biomedical- TasP, PrEP, PEP, Tx STD & T&T

  structural- universal precautions to safe blood supply, clean syringe programs, funding HIV test
- Clinical management – identify a regime for a patient newly dx
- Prevention
- Florida Law

# Team-Based Model: Optimizing HIV & Primary Care Needs


DDIs = Drug-Drug Interactions

HRSA Ryan White HIV/AIDS Program. Optimizing HIV care for people aging with HIV: Putting together the best health care team. https://ryanwhite.hrsa.gov/sites/default/files/ryanwhite/grants/aging-guide-best-team.pdf. Accessed on 10/20/22.
HIV.gov. Types of Providers. https://www.hiv.gov/hiv-basics/starting-hiv-care/find-a-provider/types-of-providers. Accessed on 10/21/22.


- Screen all pregnant women and individuals ages 15-65 y.o.
- If Hiv+ and you do not feel comfortable treating them link them to a local colleague
- Prescribe oral FTC/TAF, FTC/TDF or long-acting injectable Cabotegravir, or lenacapavir for PrEP for patients at high risk of acquiring HIV
- Harm reduction-Offer needle & syringe exchange programs. Refer when appropriate for SUD therapy to individuals who inject/use drugs

Thank you all for your attendance

# Websites to Access the Guidelines

- http://www.aidsetc.org
- https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new-guidelines accessed 12/31/2022
- http://aidsinfo.nih.gov
- http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/37/whats-new-in-the-guidelines-
- http://ahca.myflorida.com/medicaid/Prescribed_Drug/pharm_thera/paforms/Diagnosis_Verification.pdf
- WWW.CDC.GOV/HIV/RISK/PREP/INDEX.HTML
- http://www.truvada.com/truvada-patient-assistance
- https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6195215/
- www.clinicalinfo.hiv.gov/en/guidelines
- OpMan 3/25/2025

# Harm reduction training & resources

- http://www.ihra.net/north-america-harm-reduction-programmes
- http://www.samhsa.gov/medication-assisted-treatment
- http://pcssmat.org/
- http://www.floridahealth.gov/diseases-and-conditions/aids/prevention/testing-counseling.html
- https://www.floridahealth.gov/diseases-and-conditions/aids/surveillance/index.htmlhttps://www.cdc.gov/hiv/statistics/overview/ataglance.html accessed 12.31.2022
- https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/drug-resistance-testingaccessed 6/24/2023
- OpMan of Hiv Disease & Hepatitis Clinical Conference XXXI