MIDWEST AIDS TRAINING + EDUCATION CENTER

Multidisciplinary Core Seminar:
Current Approaches to HIV Care

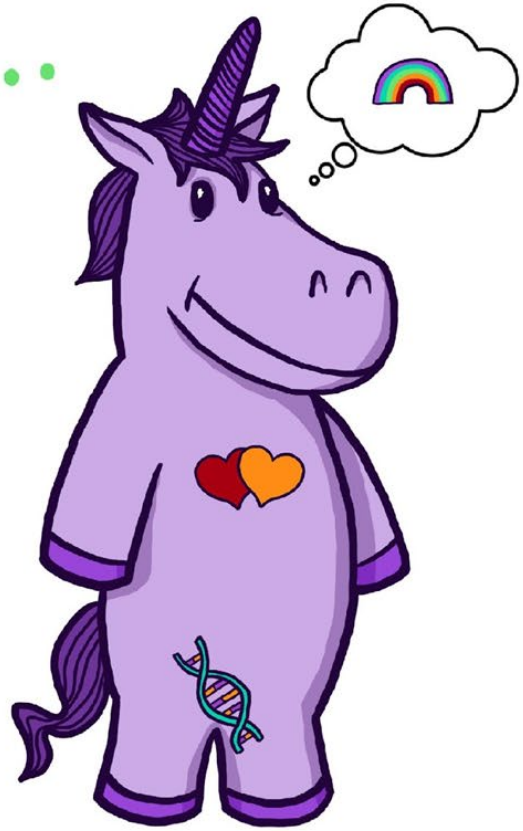
Disclosure of Interest

The presenters for this program have the following financial interest/relationship with manufacturers of commercial products.

- John Parisot MSN, RN, PhD
  - speakers bureau: no relationship
  - research support: no relationship
- Sarah Williams MSN, APRN
  - speakers bureau: no relationship
  - research support: no relationship

The Gender Unicorn

Graphic by:
TSER
Trans Student Educational Resources



Gender Identity

- Female / Woman / Girl
- Male / Man / Boy
- Other Gender(s)

Gender Expression

- Feminine
- Masculine
- Other

Sex Assigned at Birth

Female | Male | Other/Intersex

Physically Attracted to

- Women
- Men
- Other Gender(s)

Emotionally Attracted to

- Women
- Men
- Other Gender(s)

To learn more, go to:
www.transstudent.org/gender

Design by Landyn Pan and Anna Moore

Introductions

- Name
- Preferred gender pronouns, if any
- Workplace/Agency
- Your goals for today's program

Objectives

- Identify current trends in the HIV epidemic and implications for patient care
- Describe the clinical course of HIV disease and common manifestations
- Describe laboratory tests used to diagnose, assess and monitor response to HIV treatment
- Explain current recommendations for managing the primary care of Persons Living With HIV (PLWH)

Objectives

- Explain current HIV treatment guidelines for the use and management of antiretroviral therapy (ART)
- Describe common legal, emotional, and psychosocial issues that impact PLWH
- Identify systems of power and stigma that affect the primary care of PLWH

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Epidemiology

study of the distribution and determinants of health-related states and events in specified populations

HIV/AIDS: The New Paradigm

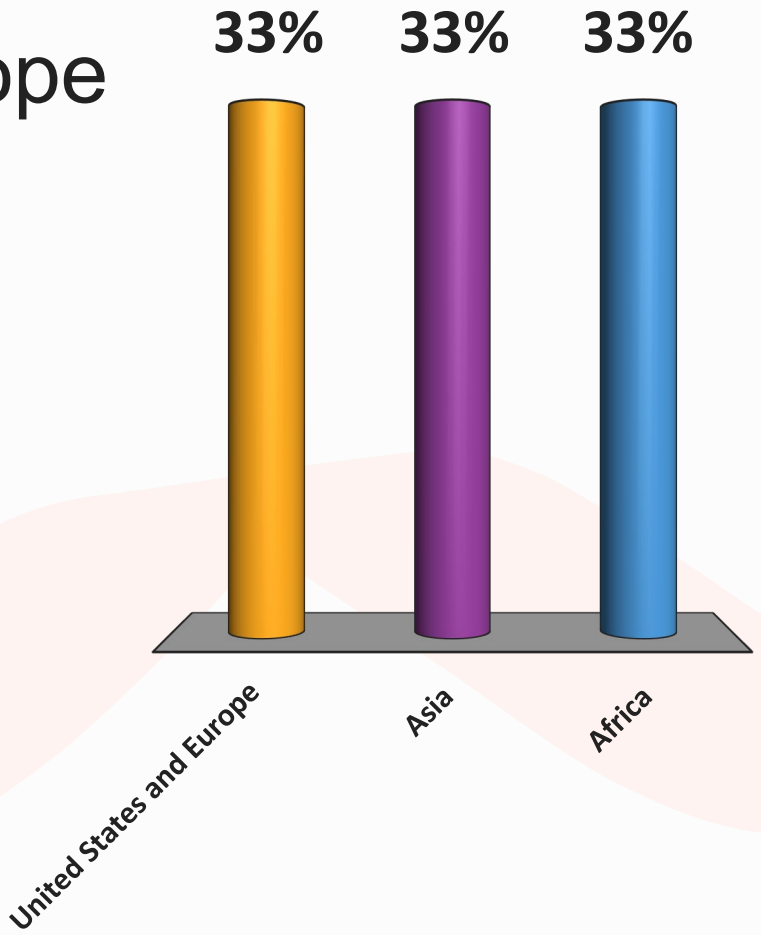
- Once a universally terminal illness
  - now a chronic, manageable disease
- Similar to other chronic, manageable diseases
- Today, Persons Living With HIV (PLWH) are more likely to die from non-HIV related causes
  - World-wide: tuberculosis
  - U.S.: cardiac, non-HIV related cancers, COPD, liver-related
- There is optimism and a strategic plan to get to zero new infections in Illinois by the year 2030

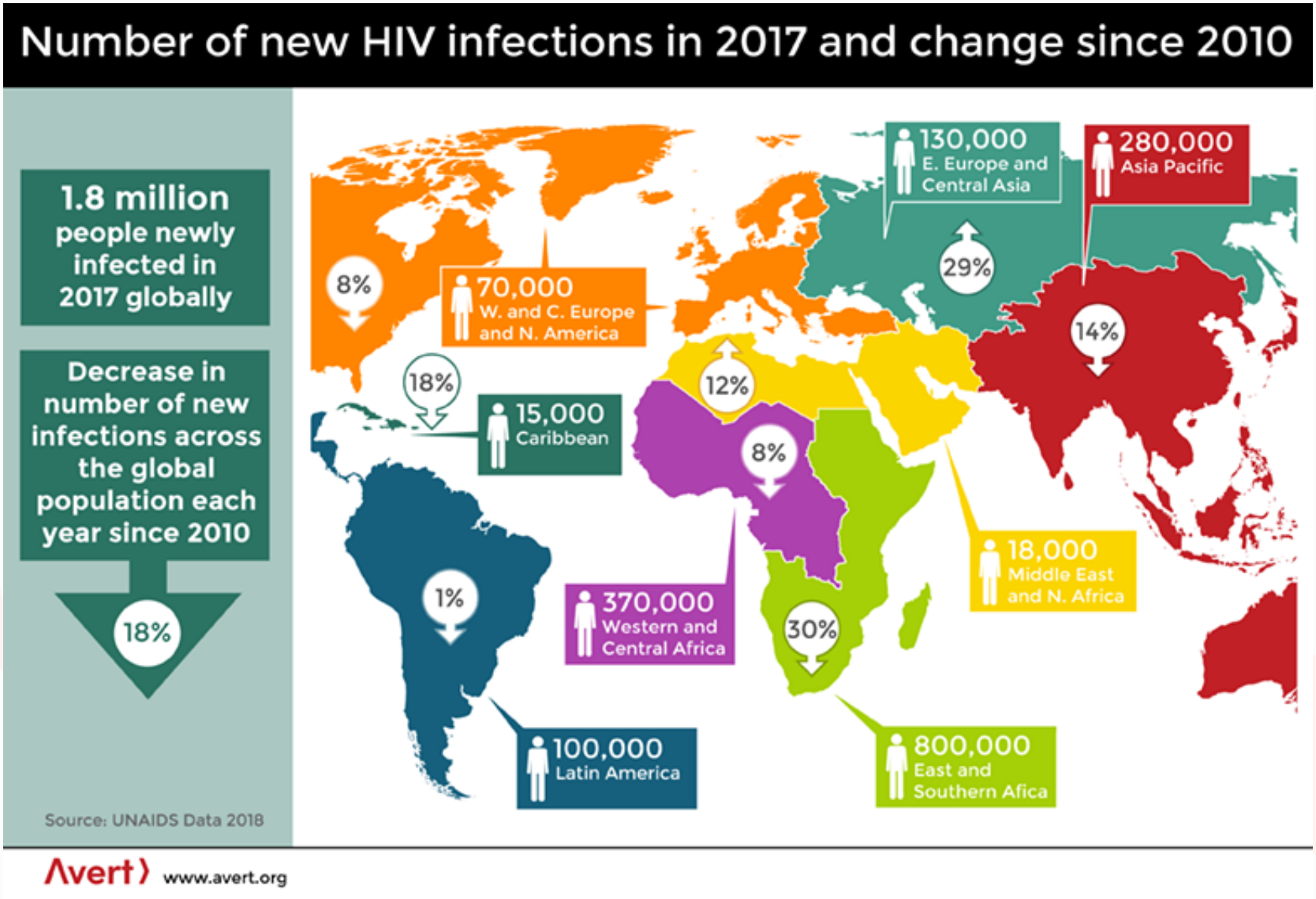
What part of the world leads in HIV disease burden?

A. United States and Europe

B. Asia

C. Africa





https://www.avert.org/global-hiv-and-aids-statistics accessed 11/18/2019

Review of HIV Epidemiology

- Continental Africa still has the majority of HIV infections worldwide, followed by the Americas and Europe
- HIV no longer leading cause of death in Africa
  - #2, after lower respiratory infections
- In Eastern and Southern Africa, the number of people living with HIV on ART has more than doubled since 2010, reaching almost 12.5 million people by June 2017.
- New HIV infections in Eastern and Southern Africa have declined by a third in just six years, while AIDS-related deaths in the region plummeted by 42% over the same period.

http://www.unaids.org/en/resources/presscentre/featurestories/2018/april/turning-point-for-africa

HIV in the United States

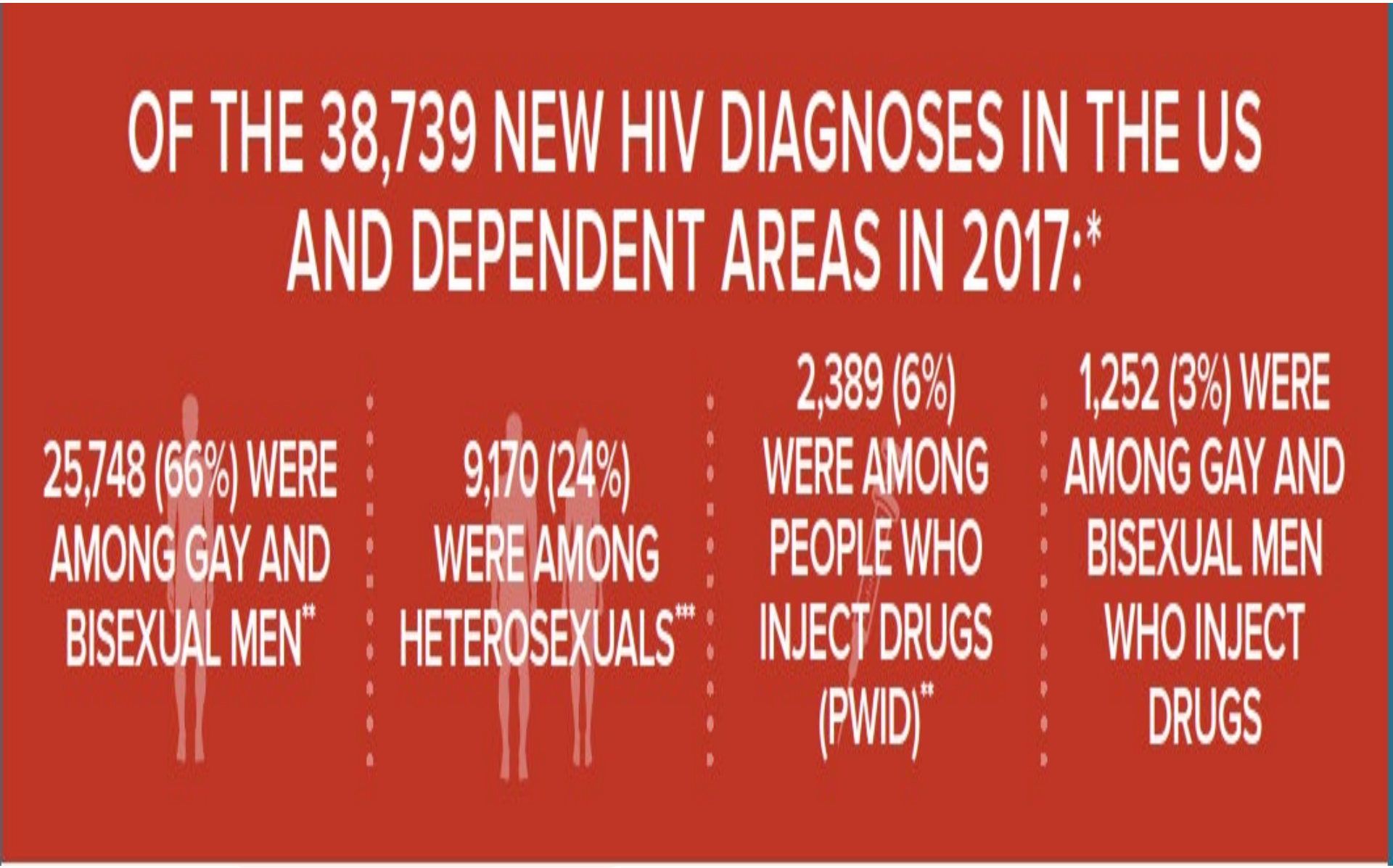
- More than 1.1 million people in the US are living with HIV



https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics accessed 11/18/19

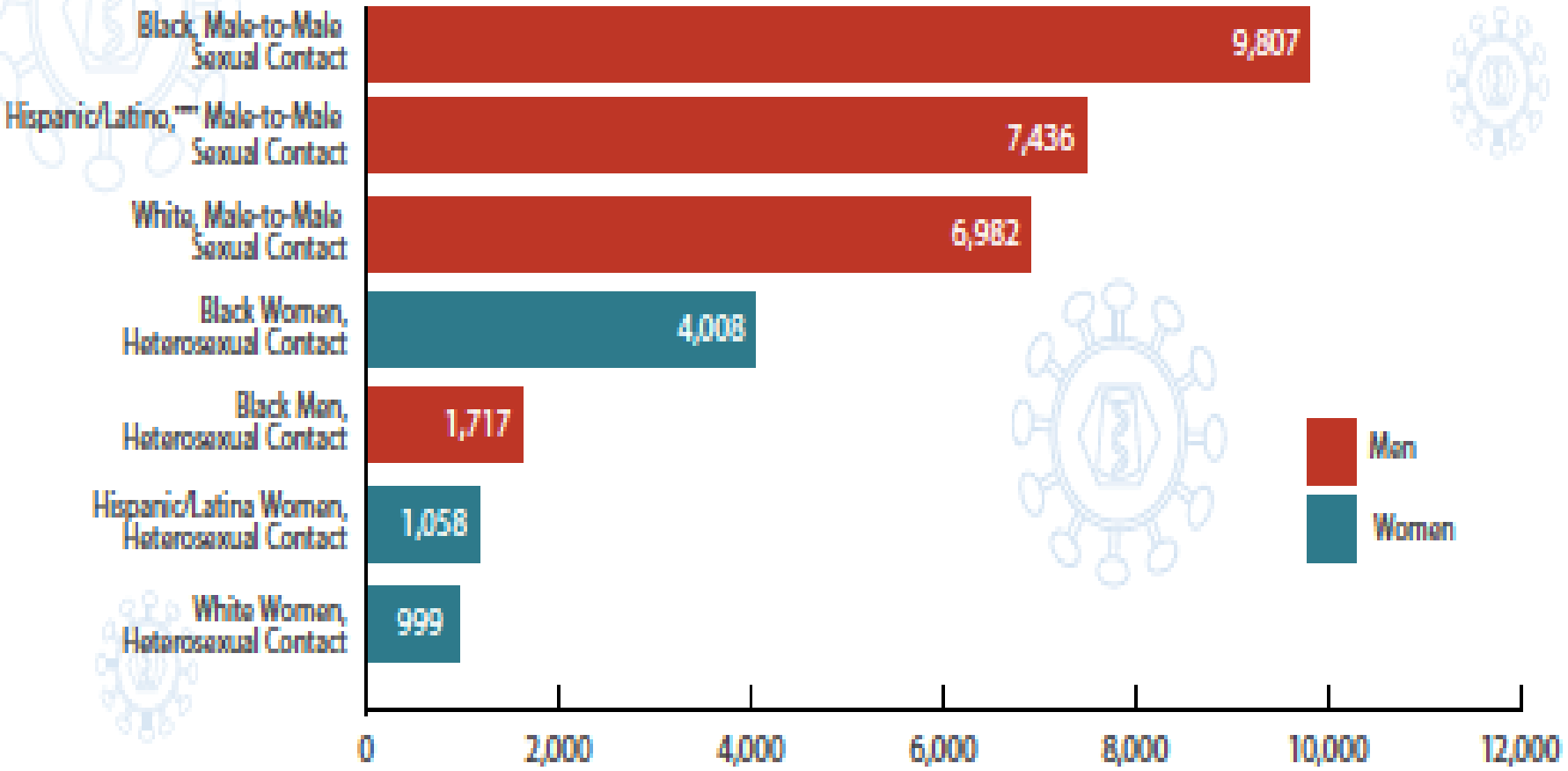
HIV Epidemiology, United States

- More PLWH than ever before
- The epidemic is highly concentrated in the South
- Gay and bisexual men and populations of color are most impacted by HIV infection
  - For African American gay and bisexual men, there is a 1:2 lifetime risk of acquiring HIV
  - For gay and bisexual Latino men, 1:4 lifetime risk of acquiring HIV
- Women of color are disproportionately affected



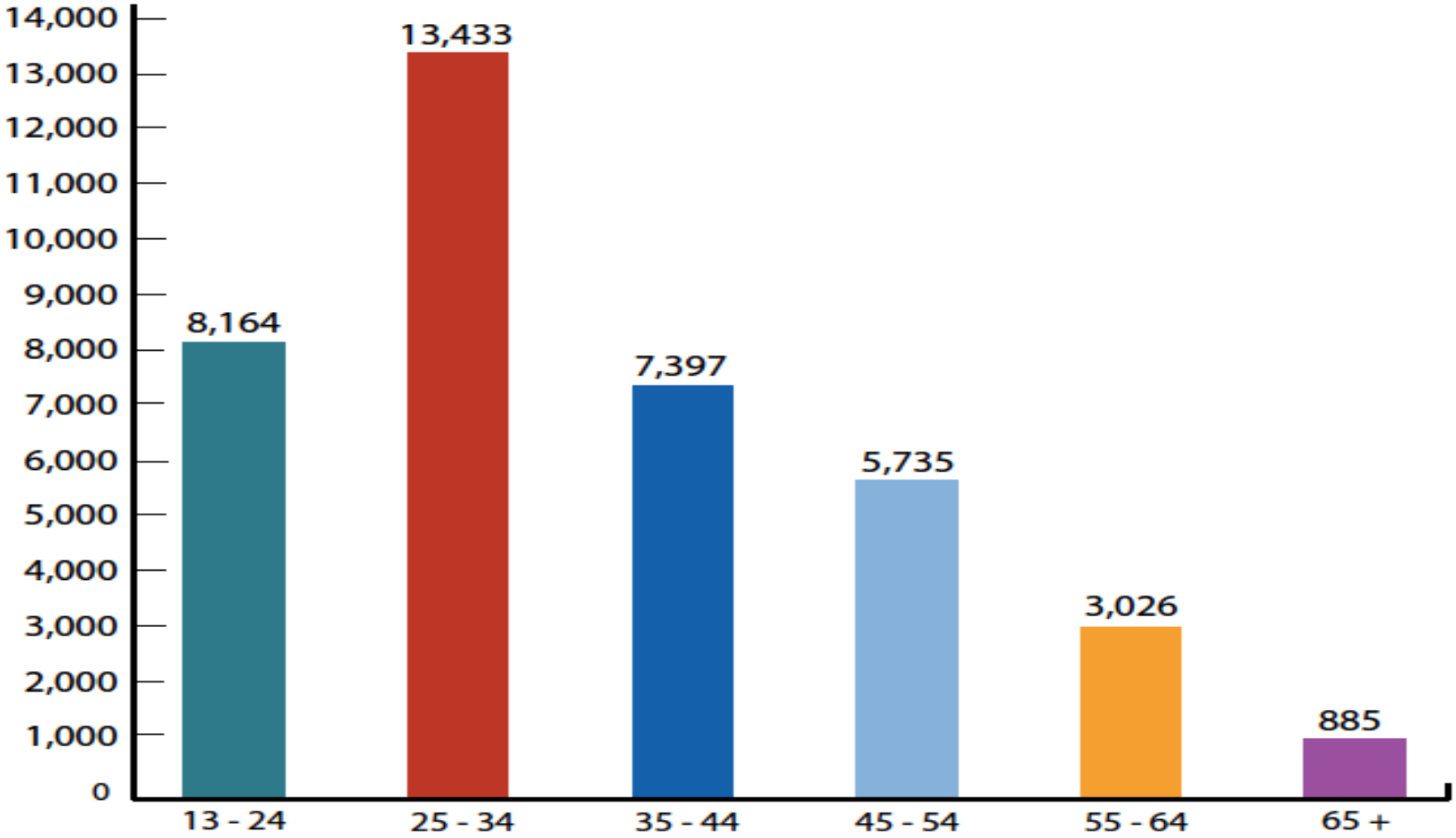
Source: https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf

New HIV Diagnoses in the US and Dependent Areas for the Most-Affected Subpopulations, 2017



Source: https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf

New HIV Diagnoses by Age in the US and Dependent Areas, 2017



Source: https://www.cdc.gov/hiv/pdf/statistics/overview/cdc-hiv-us-ataglance.pdf

AFRICAN AMERICANS are by far the **most affected racial/ethnic group** with a lifetime HIV risk of:



1 IN 2

for African American gay/bisexual men



1 IN 20

for African American men



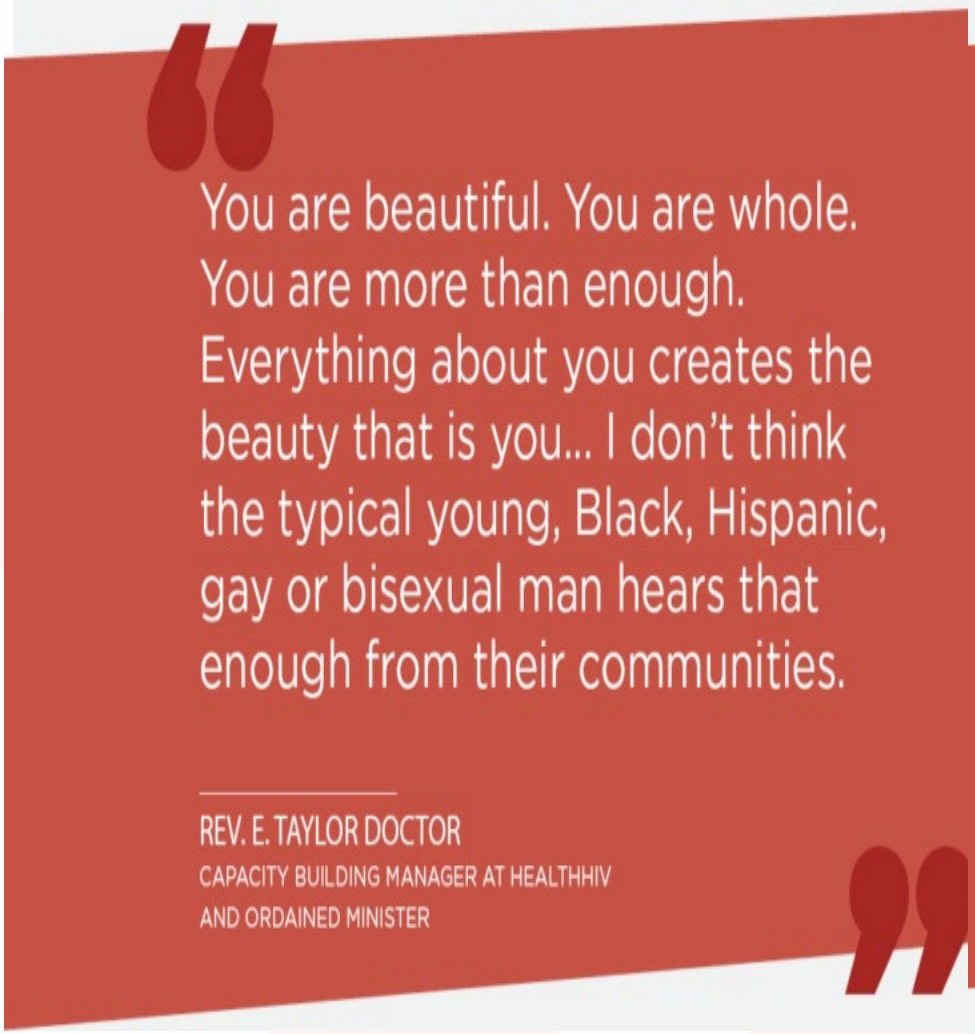
1 IN 48

for African American women

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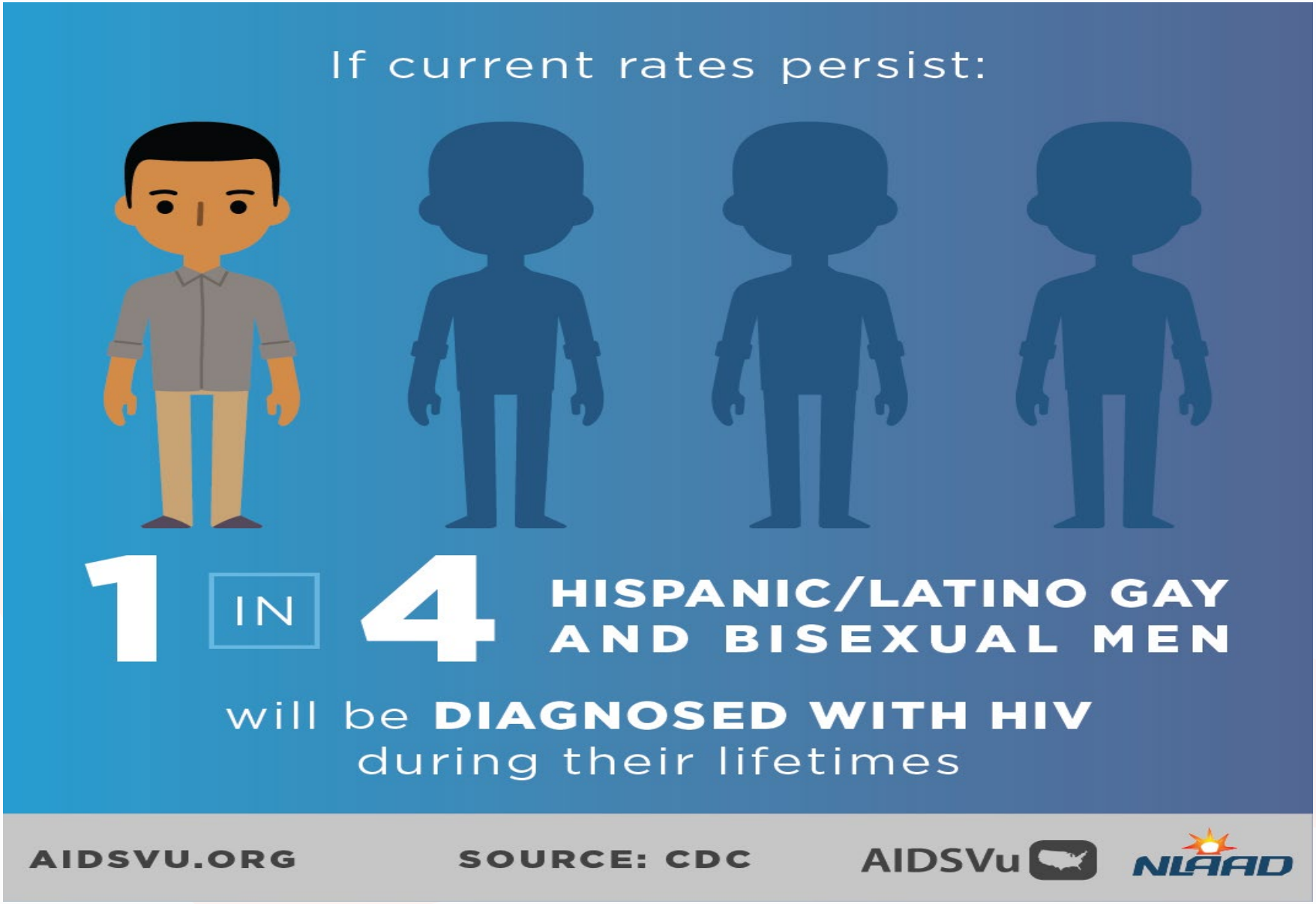
SOURCE: US CENTERS FOR DISEASE CONTROL & PREVENTION

AIDSVu





Source: https://aidsvu.org/etd/


If current rates persist:
1 IN 4 HISPANIC/LATINO GAY AND BISEXUAL MEN
will be DIAGNOSED WITH HIV during their lifetimes
AIDSVU.ORG
SOURCE: CDC
AIDSVu
NLAAD

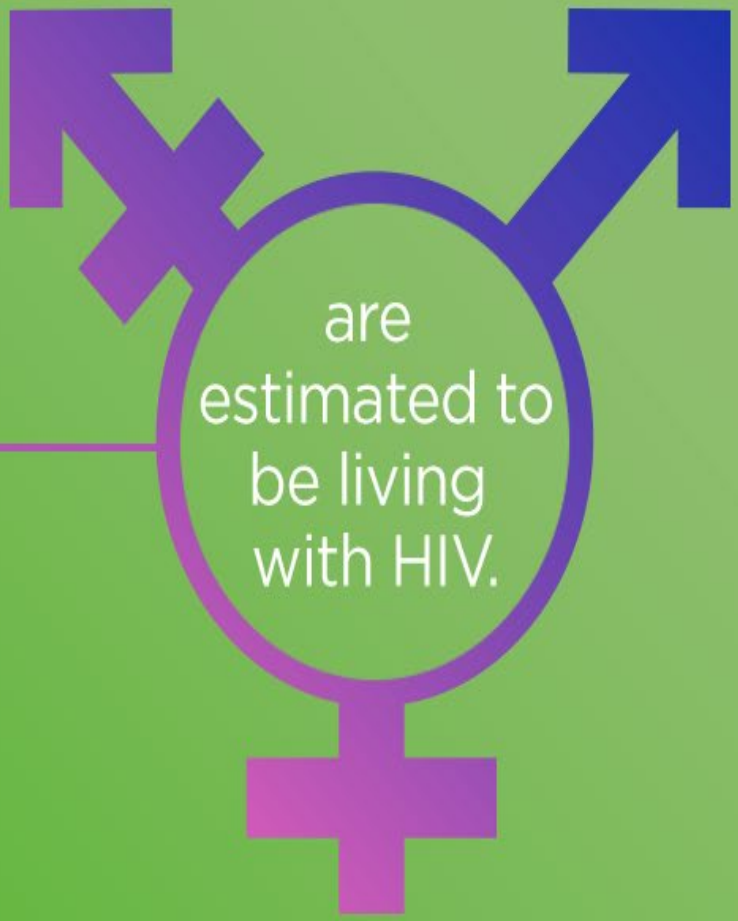


ABOUT 1/4 of all transgender women

&



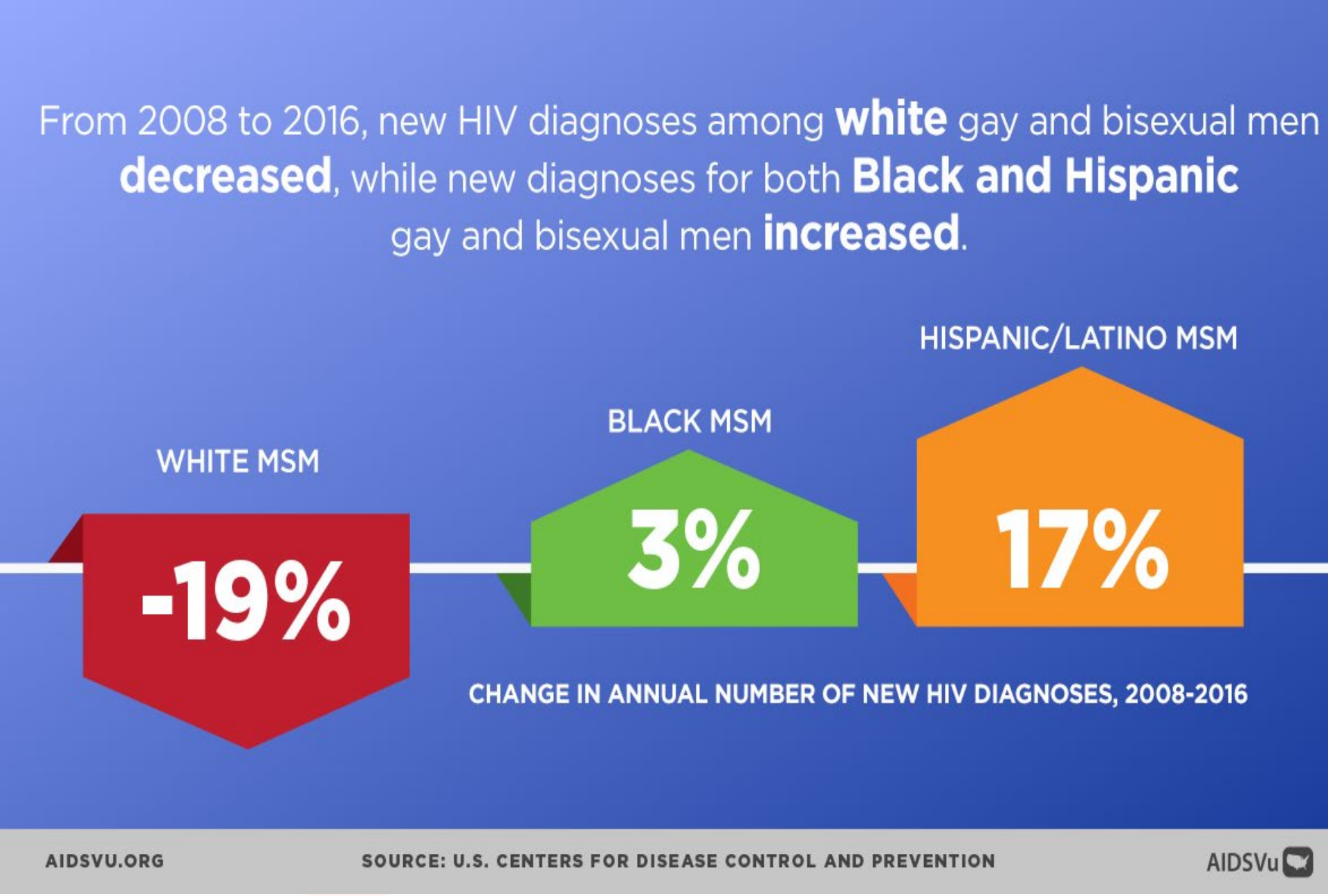
MORE THAN 1/2 of all Black transgender women



AIDSVU.ORG

SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

AIDSVu

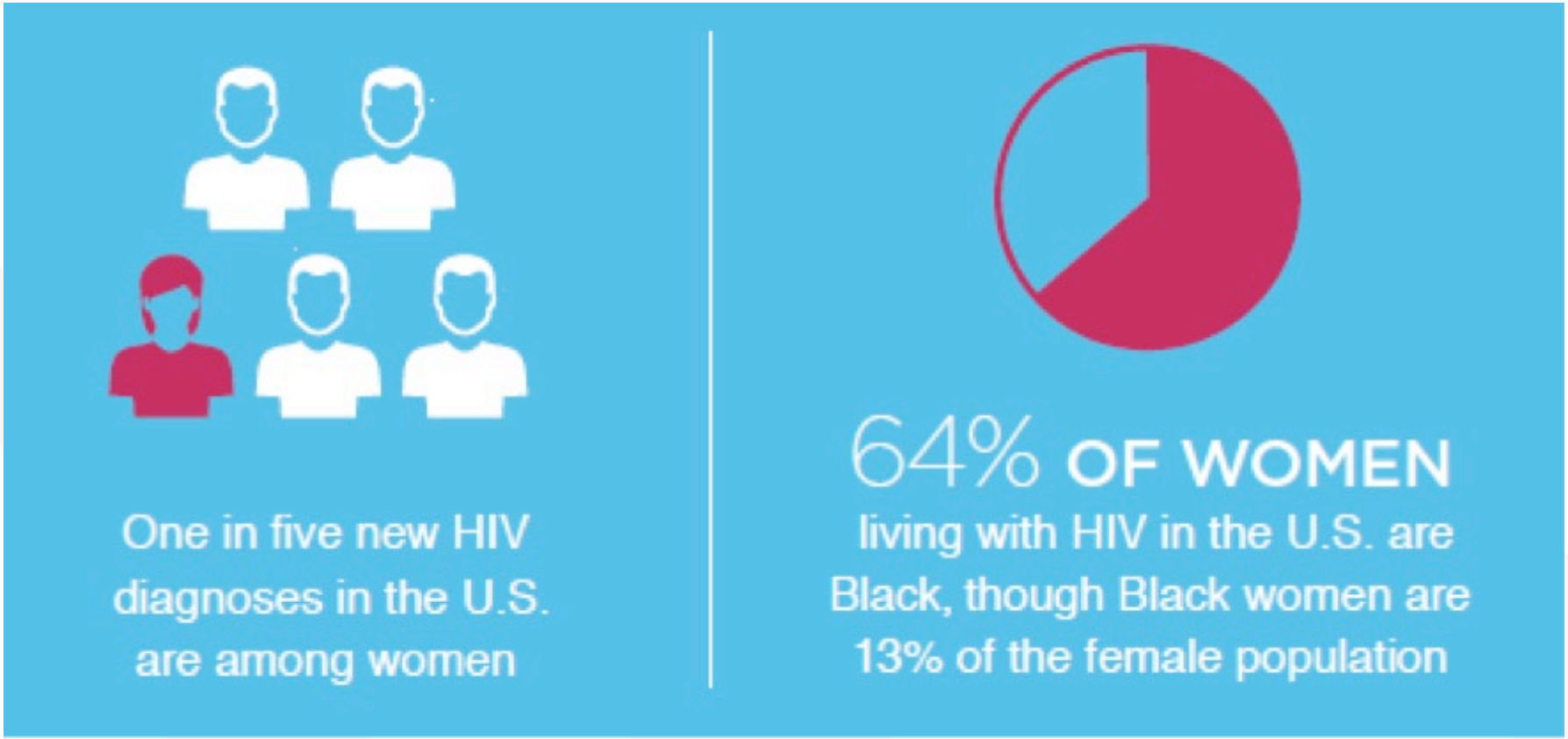

From 2008 to 2016, new HIV diagnoses among white gay and bisexual men decreased, while new diagnoses for both Black and Hispanic gay and bisexual men increased.
WHITE MSM
-19%
BLACK MSM
3%
HISPANIC/LATINO MSM
17%
CHANGE IN ANNUAL NUMBER OF NEW HIV DIAGNOSES, 2008-2016
AIDSVU.ORG
SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION
AIDSVu

New HIV diagnoses in the United States, 2017

- Heterosexual contact : 24% (10,527) of estimated HIV new diagnoses
- Women: 19% (8,328) of estimated HIV diagnoses
  - heterosexual contact (87%, or 7,242)
  - injection drug use (13%, or 1,045)
- Injection drug use: 6% (2,635) of estimated HIV diagnoses

http://www.cdc.gov/hiv/statistics/overview/ataglance.html

Impact on women, 2017



https://www.hiveonline.org/prep4women-disparities/ accessed 11/12/2018



Only **50%**

of women have ever been tested for HIV.

Find a testing site near you



Visit AIDSVu.org/Testing

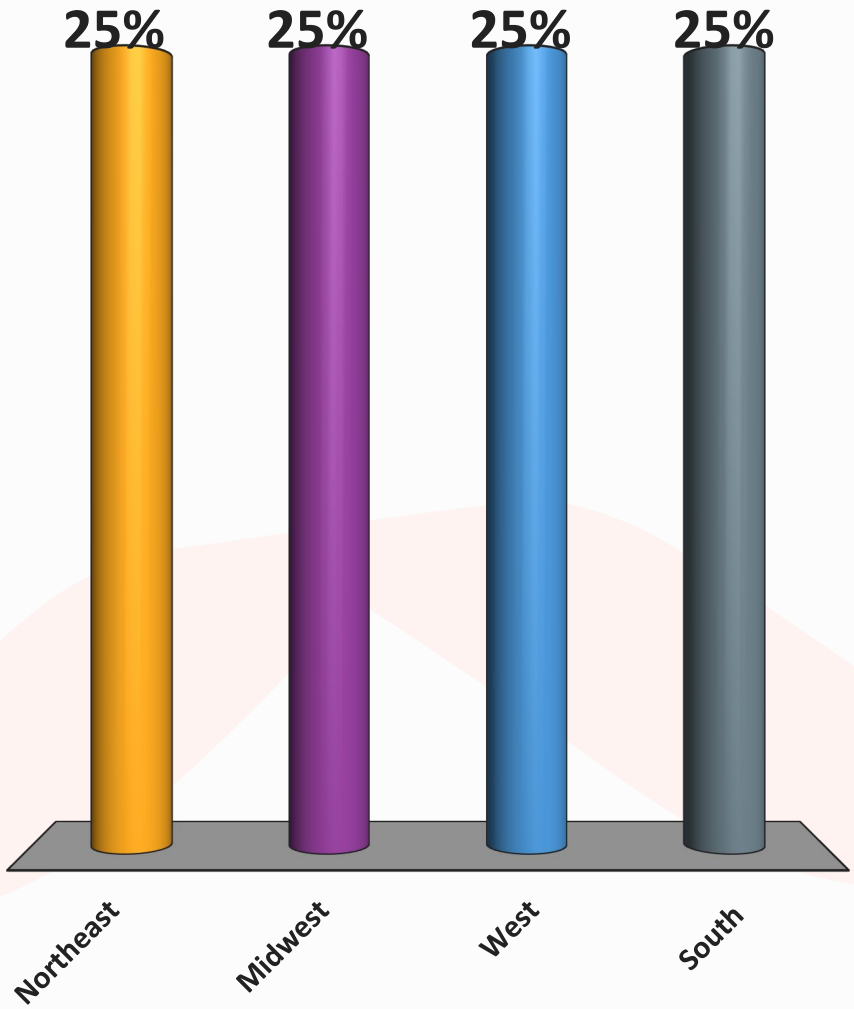
AIDSVU.ORG

SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

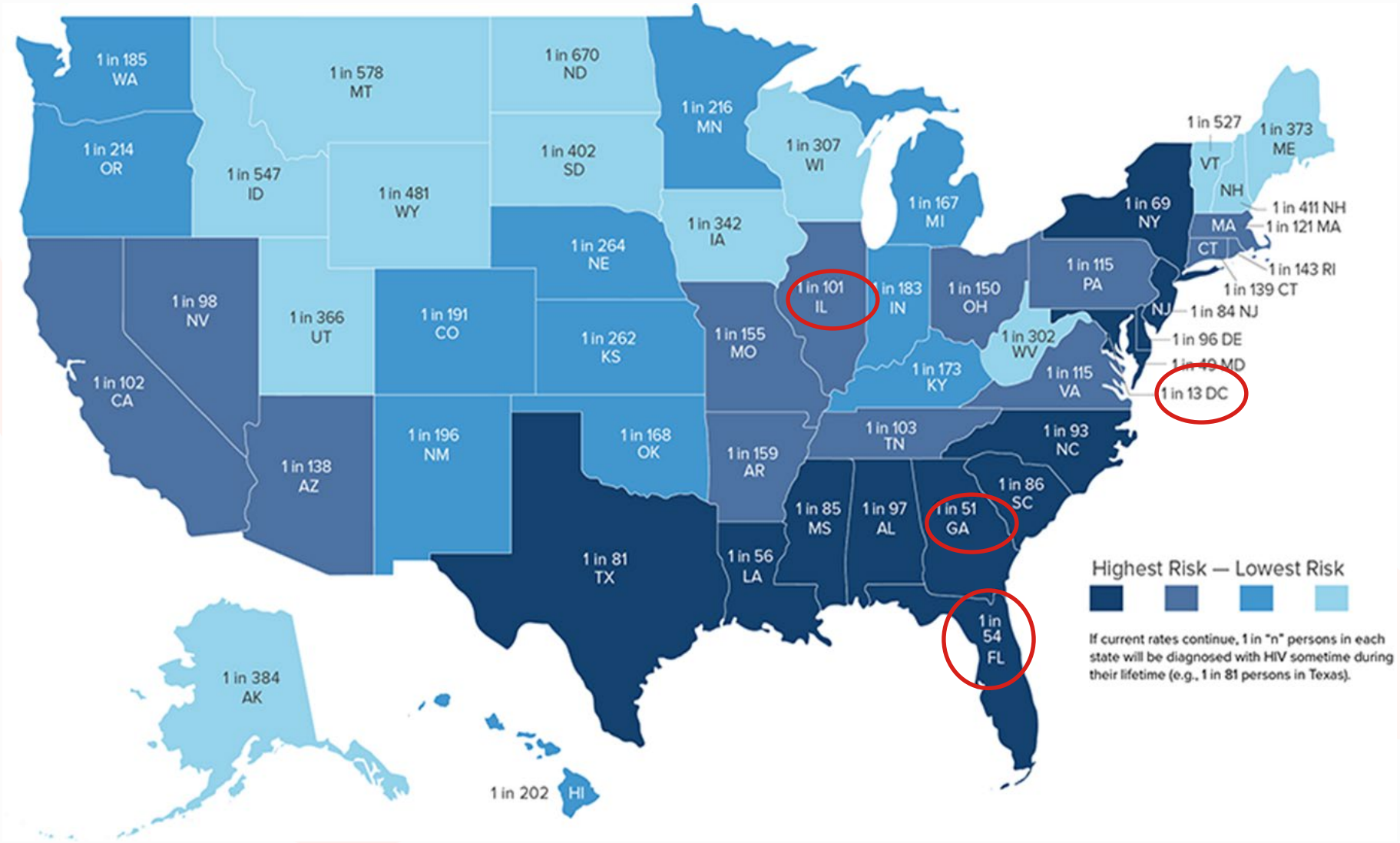
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Where are the most cases of HIV in the US?

A. Northeast
B. Midwest
C. West
D. South



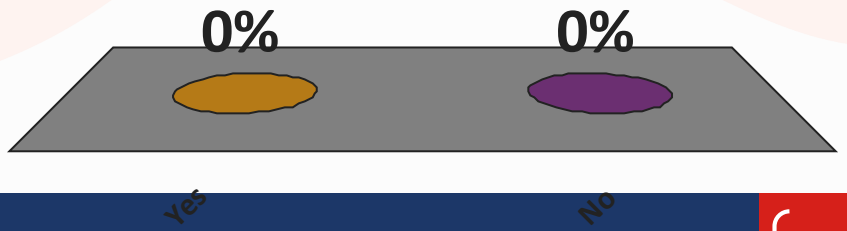
Lifetime risk of HIV (2016, CDC)



Are people still dying of HIV/AIDS?

A. Yes

B. No



Chicago data (2017)

HIV Prevalence

Number of people living with HIV, 2017
19,704

Percent of people living with HIV, by Race/Ethnicity, 2017
51.0% Black | 20.9% Hispanic/Latinx | 22.0% White

Percent of people living with HIV, by Sex, 2017
81.2% male | 18.8% female

New HIV Diagnoses

Number of new HIV diagnoses, 2017
743

Number of new HIV diagnoses, by Sex, 2013-2017
84.2% male | 15.8% female

Number of new HIV diagnoses, by Race/Ethnicity, 2013-2017
54.2% Black | 21.8% Hispanic/Latinx | 18.5% White

HIV Mortality

Number of deaths of people with HIV in Chicago, 2017
171

Number of deaths of people with HIV in Illinois, 2016
539

https://aidsvu.org/local-data/united-states/midwest/illinois/chicago/ accessed 11/18/19

Chicago (2017)

- 752 persons were newly diagnosed with HIV
- 367 persons were newly diagnosed with AIDS
- 23,824 persons living with HIV, highest it has ever been
- More HIV infection diagnosis occurring among men than women
- Largest proportion of HIV infection diagnoses occurred among in Non-Hispanic (NH) blacks
- Persons age 20-29 years were 38TH% of all new diagnoses
- Burden of disease is in young black gay and bisexual men
- Highest rates of new HIV diagnosis: Uptown, Chatham, and Washington Park
- Highest rates of PLWH: Uptown, Edgewater, Rogers Park, and South Shore

CDPH 2018 HIV/STI Surveillance Report

HIV IN ILLINOIS

In 2015, an estimate

38,314

people were living with HIV in Illinois

New HIV transmissions in Illinois dropped by nearly

28%

over the decade from 2006-2015

Illinois has nearly

ELIMINATED

perinatal HIV transmission

1/3

of people living with HIV in the state are covered by the ACA and Medicaid

Gay, bisexual and other men who have sex with men made up

63%

of persons living with HIV in the state in 2015

Source: https://gtzillinois.hiv

https://gtzillinois.hiv/



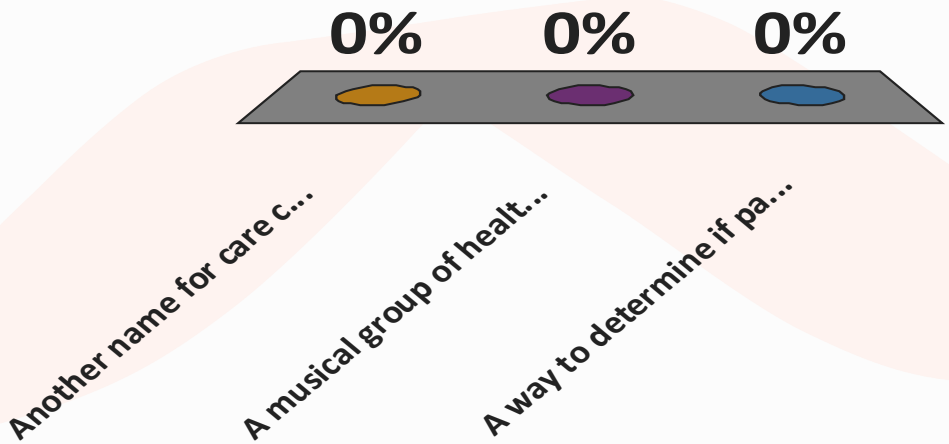
Conclusions Thus Far

- Chronic, manageable illness
- Mortality from HIV/AIDS decreasing
- New infections declining overall
- Highest impact
  - Gay and bisexual men
  - Persons of color
  - Communities of high economic hardship
  - Chicago has new infection rate equal to the southern states

HIV CARE CONTINUUM

What is the treatment cascade?

A. Another name for care continuum
B. A musical group of healthcare professionals
C. A way to determine if patients receive duplicate treatments for the same illness



What is it for?

- It is a way of measuring PLWH along the pathway from diagnosis to viral suppression
  - Diagnosis
  - Engaged in Care
  - Prescribed ART
  - Virally Suppressed

https://www.aids.gov/federal-resources/policies/care-continuum/

https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf

HIV Transmission Stage of Care



HIV TRANSMISSIONS IN 2016

% OF PEOPLE WITH HIV	STATUS OF CARE	ACCOUNTED FOR X% OF NEW TRANSMISSIONS*
15%	didn't know they had HIV	38%
23%	knew they had HIV but weren't in care	43%
11%	in care but not virally suppressed	20%
51%	taking HIV medicine and virally suppressed	0%

*Values do not equal 100% because of rounding

SOURCE: Vital Signs, 2019

ENDING THE HIV EPIDEMIC: A PLAN FOR AMERICA



Diagnose HIV as early as possible	**Treat** HIV quickly and effectively	**Protect** people at risk	**Respond** quickly to clusters of new cases

bit.ly/2DW9Deb

CDC Vitalsigns™

www.cdc.gov/vitalsigns/end-HIV

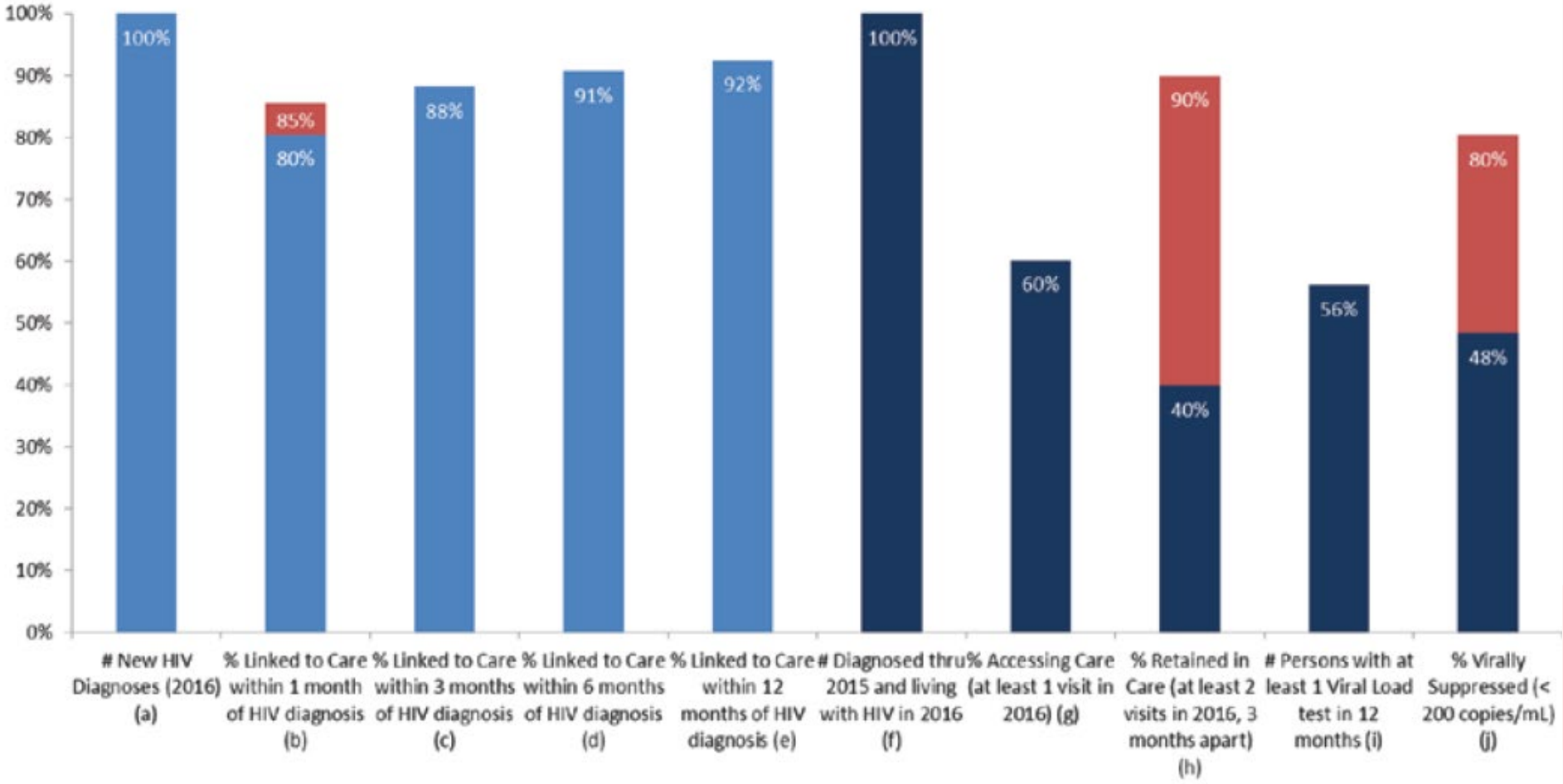
CS296484-I

HIV Continuum of Care, Chicago, 2017

- 82% of those diagnosed w HIV were linked to HIV medical care within one month of diagnosis
- By 12 months post-diagnosis, 92% of the newly diagnosed had been linked to medical care
- 63% had accessed care (having at least 1 medical visit)
- 36% were retained in care (having at least 2 visits)
- Less than 50 % were considered to be virally suppressed (HIV viral load < 200 copies/mL)

STI/HIV Surveillance Report 2018, City of Chicago CDPH

Figure 1.1: HIV Continuum of Care Among Cases 13 Years and Older, Chicago, 2016 (as of 9/26/2017) with 2020 National HIV/AIDS Strategy Indicators #4-6(red)



https://www.chicago.gov/content/dam/city/depts/cdph/HIV_STI/HIV_STISurveillanceReport2016_12012017.pdf

National HIV Prevention Objectives for 2020

- Increasing the percentage of PLWH who are diagnosed to 90%
- Increasing the percentage of persons newly diagnosed PLWH who are linked to care within one month to 85%
- Increasing the percentage of PLWH who are retained in care and taking ART to 90%
- Increasing the percentage of PLWH with viral suppression to 90%, with an emphasis on youth and persons who inject drugs

https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview

National HIV/AIDS Strategy Goals

- Reduce new infections
- Increase access to care and improve health outcomes for people living with HIV
- Reduce HIV-related health disparities and health inequities
- Achieve a more coordinated national response to the HIV epidemic

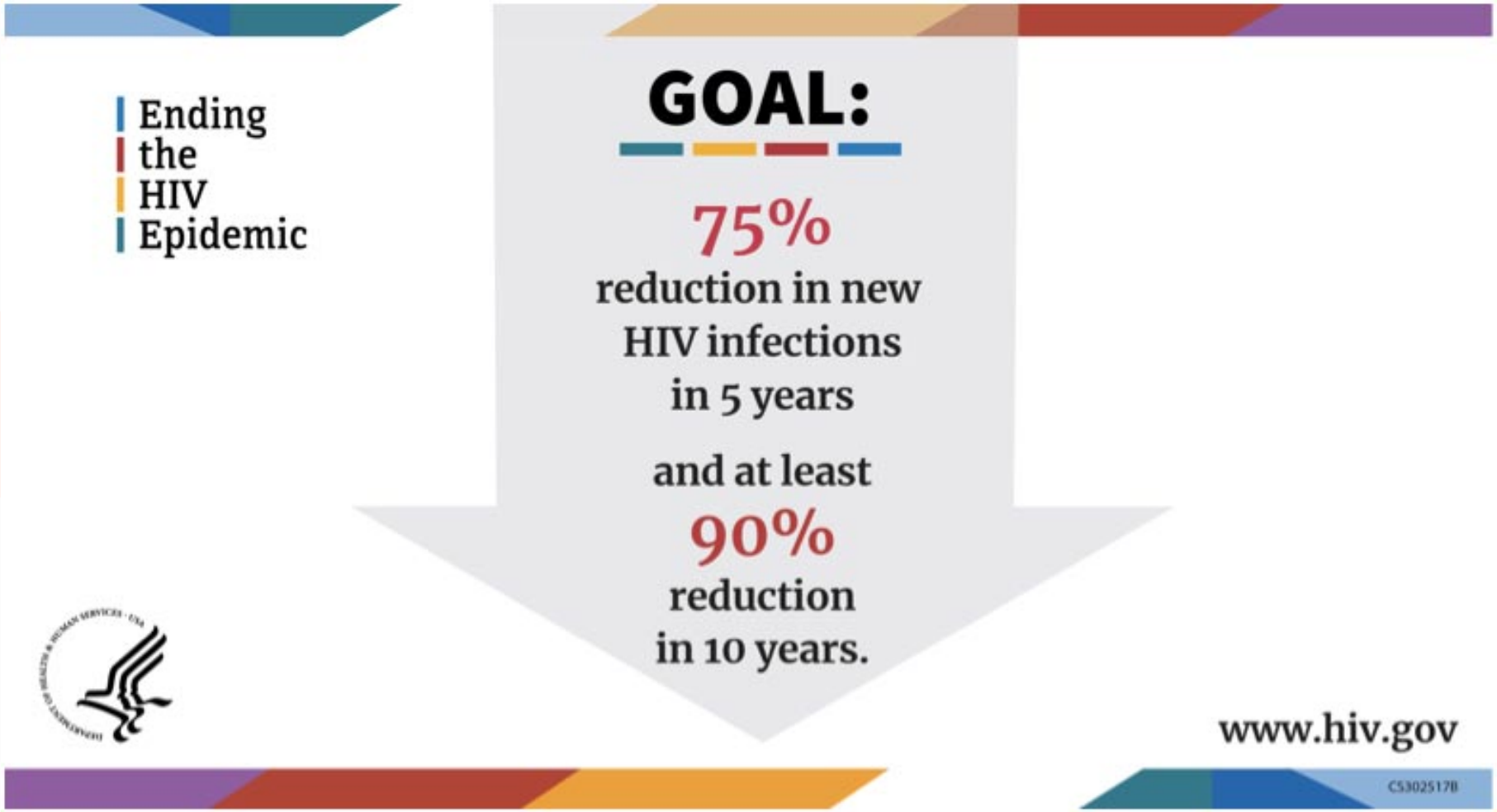
https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview

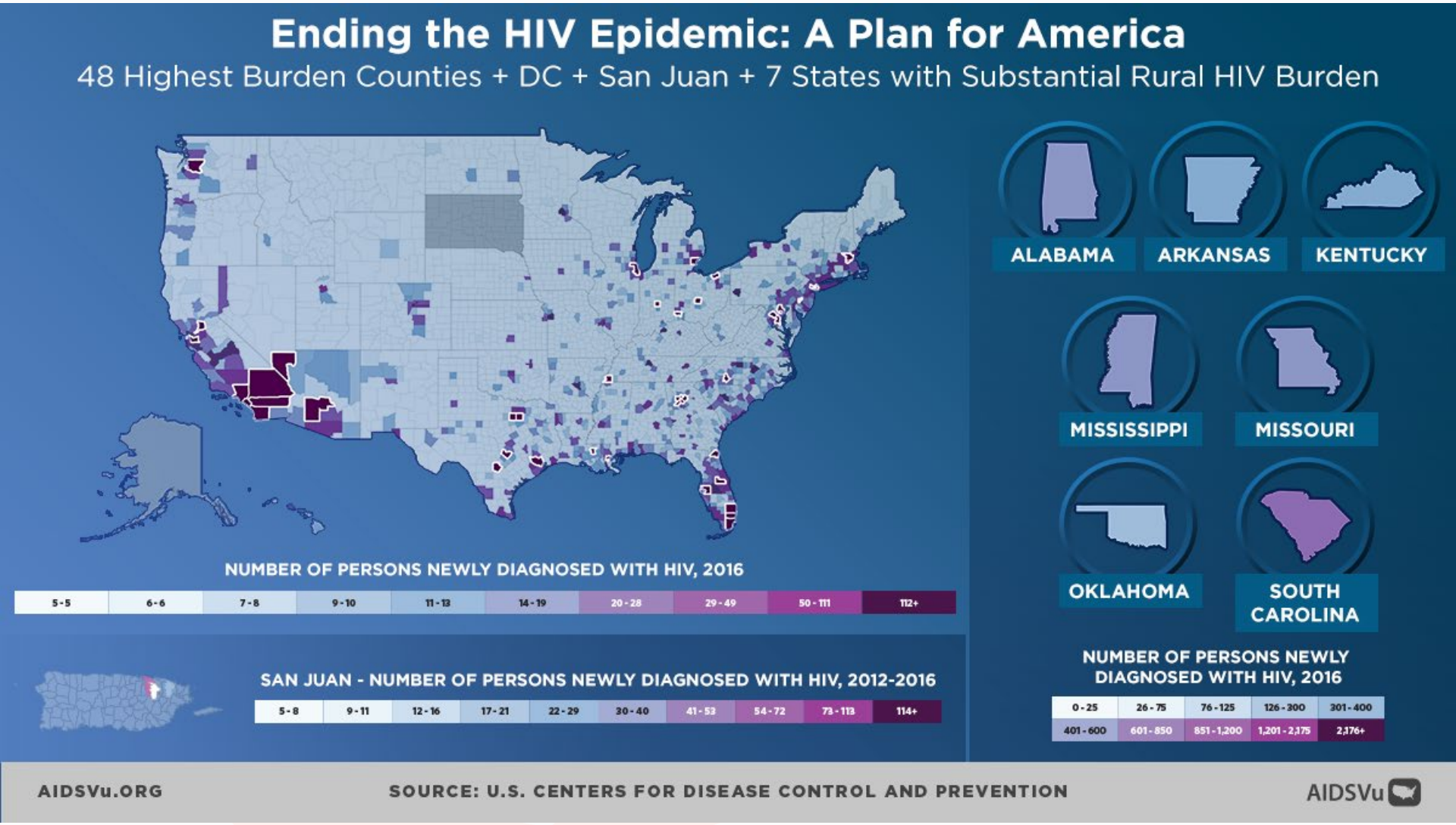
Ending The Epidemic: A Plan for America

The plan will fund three major areas of action:

- Increasing investments in **geographic hotspots** through our existing, effective programs, such as the Ryan White HIV/AIDS Program, as well as a new program through community health centers that will **provide medicine to protect persons at highest risk** from getting HIV.
- Using **data to identify where HIV is spreading most rapidly** and guide decision-making to address prevention, care and treatment needs at the local level.
- Providing funds for the creation of a local **HIV Health Force** in these targeted areas to expand HIV prevention and treatment.

Our efforts will focus on four key strategies that together can end the HIV epidemic in the U.S.: **Diagnose, Treat, Protect, and Respond**


Ending
the
HIV
Epidemic
GOAL:
75%
reduction in new
HIV infections
in 5 years
and at least
90%
reduction
in 10 years.
www.hiv.gov
C53025178


Ending the HIV Epidemic: A Plan for America
48 Highest Burden Counties + DC + San Juan + 7 States with Substantial Rural HIV Burden
ALABAMA
ARKANSAS
KENTUCKY
MISSISSIPPI
MISSOURI
OKLAHOMA
SOUTH CAROLINA
NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2016
5 - 5
6 - 6
7 - 8
9 - 10
11 - 13
14 - 19
20 - 28
29 - 49
50 - 111
112+
SAN JUAN - NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2012-2016
5 - 8
9 - 11
12 - 16
17 - 21
22 - 29
30 - 40
41 - 53
54 - 72
73 - 113
114+
NUMBER OF PERSONS NEWLY DIAGNOSED WITH HIV, 2016
0 - 25
26 - 75
76 - 125
126 - 300
301 - 400
401 - 600
601 - 850
851 - 1,200
1,201 - 2,175
2,176+
AIDSVu.ORG
SOURCE: U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION
AIDSVu

Ending The Epidemic

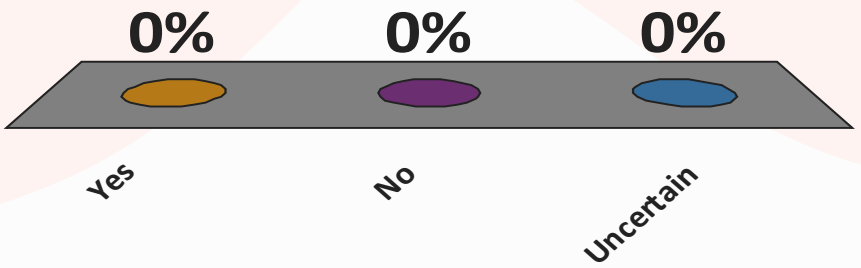
- Of the 48 highest burden counties targeted by the initiative, 48% are in the South.
- In 67% of the 48 target counties and DC, the percent of people living in poverty is higher than the national average.
- Most of the 48 target counties fall in states with a high unmet need for PrEP.

https://aidsvu.org/resources/ending-the-hiv-epidemic/ accessed 11/18/2019

HIV screening

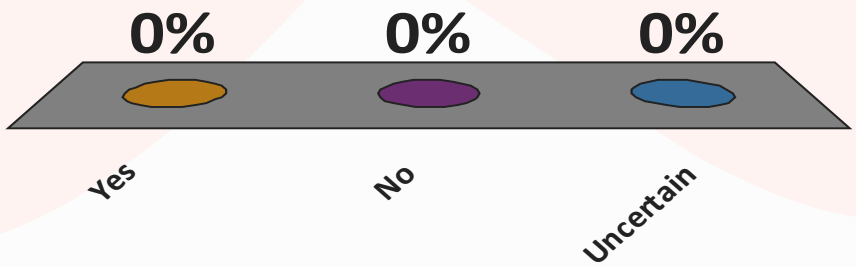
Have you, as a health care consumer, ever been offered an HIV test?

A. Yes
B. No
C. Uncertain



Have you ever had to advocate for yourself and request an HIV test?

A. Yes
B. No
C. Uncertain



Routine HIV Screening

- Since 10/2006, CDC has recommended routine HIV screening in all health care settings for all patients 13-64 years of age
- Repeat screening is recommended annually for those at continuing risk
- Illinois now permits HIV testing based on a patient's verbal consent after being given mandatory pretest information

In practice, why test?

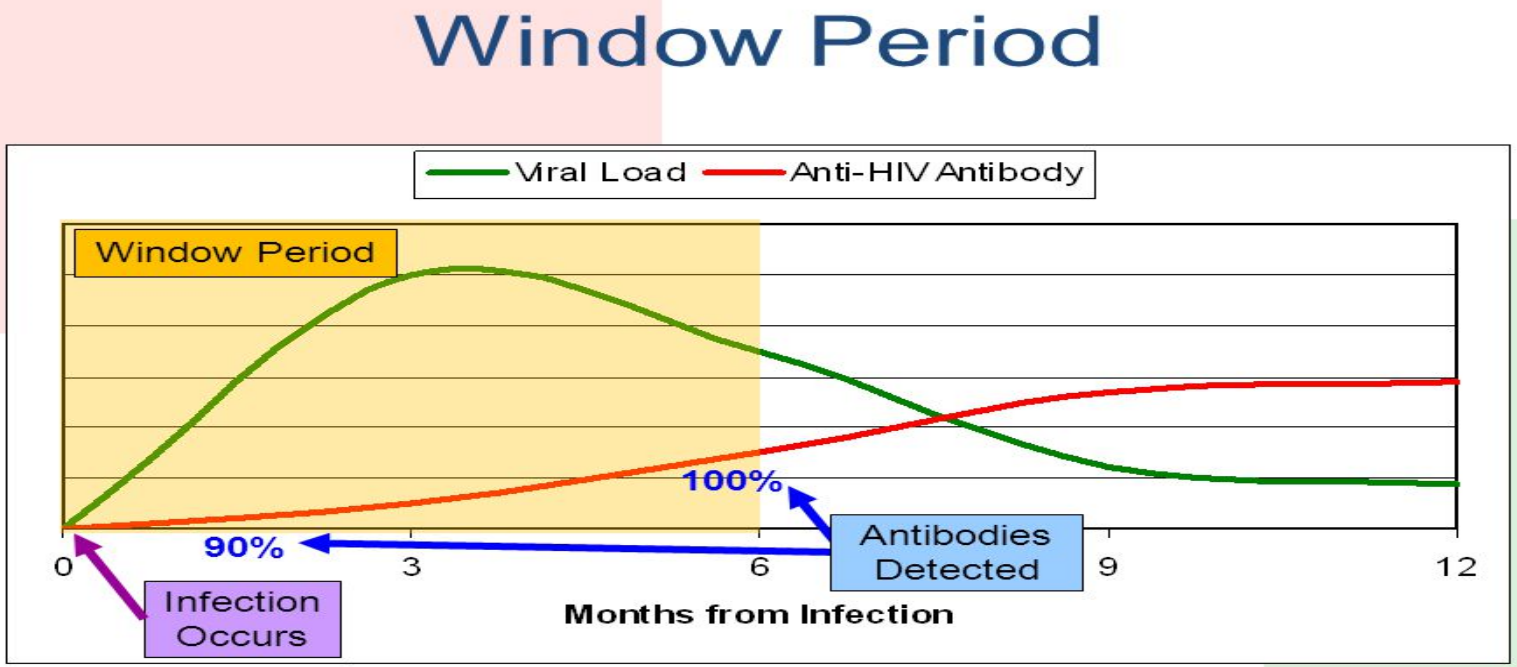
- ~ 14% HIV cases are undiagnosed
- Routine testing reduces HIV-related stigma
- Awareness of sexual risk factors leads to reduced high-risk sexual behaviors and fewer new infections
- Early initiation of ART (antiretroviral therapy) is now the standard of care
- Getting patients enrolled in routine care early helps maintain optimal health
- Sustained ART achieves viral suppression and reduces further transmission (treatment as prevention-TasP)

DISCUSS: Challenges of Implementing CDC HIV Testing Guidelines

- Why have we been so slow and ineffective in implementing CDC HIV testing guidelines in all practice settings?
- Brainstorming: What can we, as HIV care providers and coordinators of care, do to promote the uptake of HIV testing?
- What impact would increased HIV testing potentially have "downstream"?

HIV Diagnosis Challenge

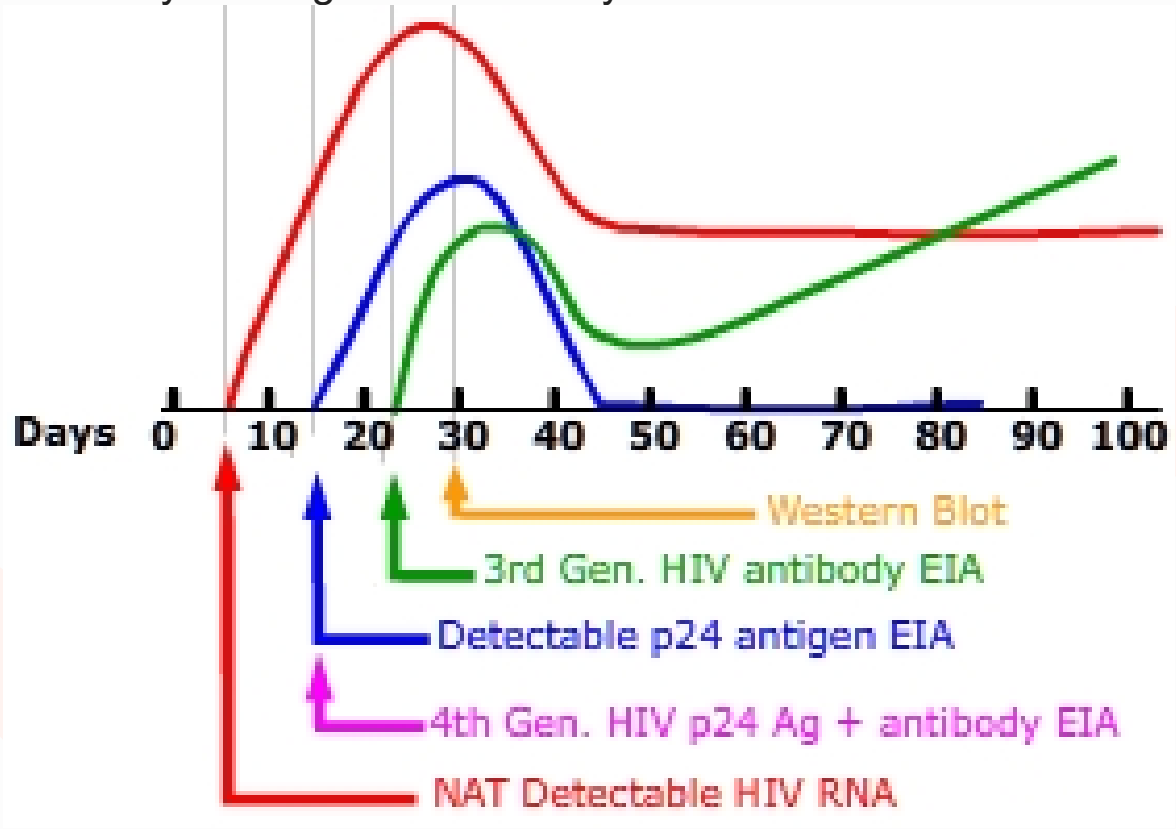
- The challenge with HIV diagnosis is the time it takes the body to develop antibodies



(90% diagnosed by 3 months, 100% diagnosed by 6 months)

Generations of HIV Tests

- In response to this delay, multiple “generations” of HIV testing have been developed
- Each generation has improved on the time from actual infection to being able to detect antibody or antigen dramatically

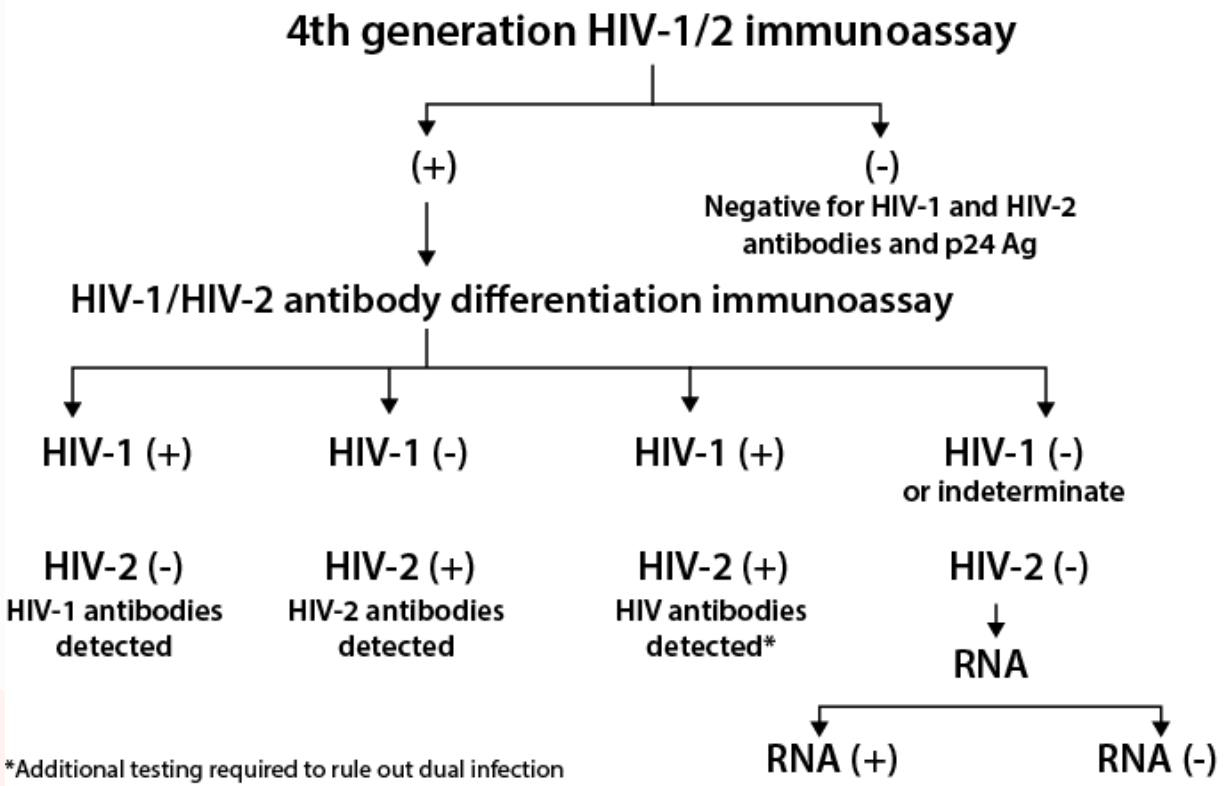


Diagnostic Tests for HIV Infection

	Assay Type	Indicated Uses
4th generation dual assay	Determine® HIV-1 / HIV-2 Ab / Ag	screening for both acute and chronic HIV infection

- detects p24 antigen within 10-14 days of infection
- detects antibodies to HIV-1 or HIV-2 within 4 wks
- positive Ag must be confirmed with NAT
- positive Ab must be confirmed with Multi-spot

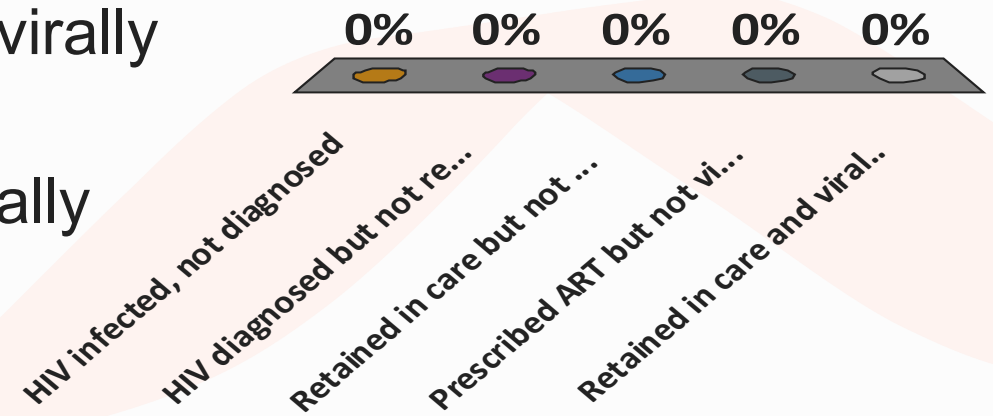
4th Generation Testing



https://aidsetc.org/guide/expedited-hiv-testing

Which group accounts for most HIV transmissions?

A. HIV infected, not diagnosed
B. HIV diagnosed but not retained in care
C. Retained in care but not prescribed ARV
D. Prescribed ART but not virally suppressed
E. Retained in care and virally suppressed



Answer

- PLWH not retained in care accounted for the most transmissions (61.3%).

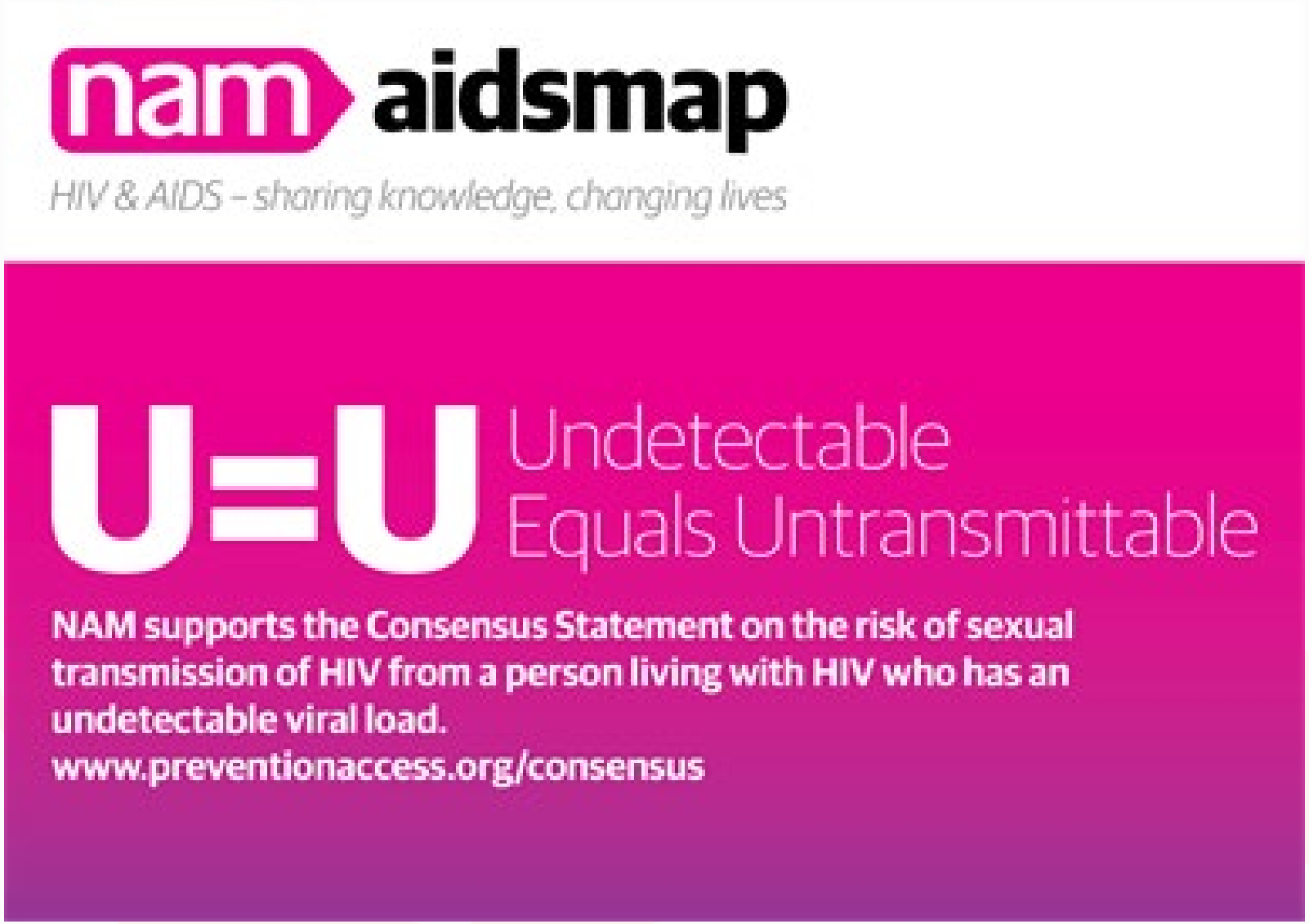
Skarbinski, et al. JAMA Intern Med. 2015;175

Treatment as Prevention

People living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners.

https://www.cdc.gov/hiv/risk/art/index.html

updated 11/3/2017

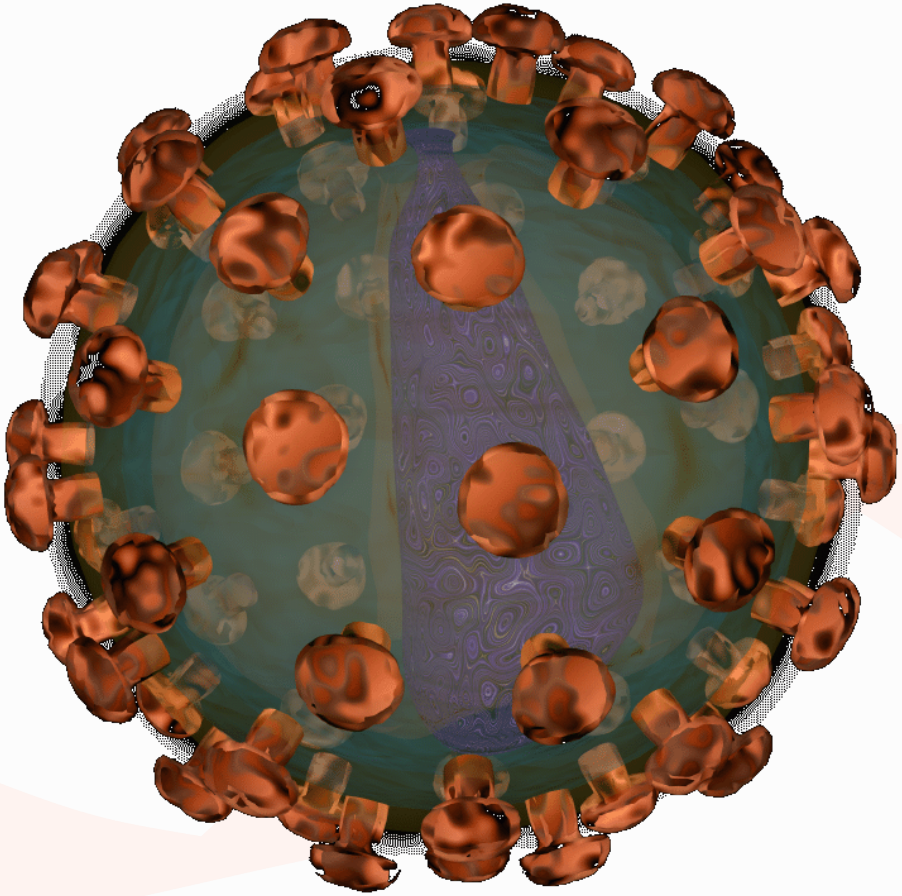


Published 07 February 2017

Treatment as Prevention

- Not all persons taking ART are undetectable
- Relies on partner's report
- Part of prevention toolkit
  - Condoms
  - Seroselecting partners
  - PrEP
- We don't want to further stigmatize those for whom becoming undetectable may not be an achievable goal or a personal goal.
- If it is, we should do our best to connect them to the resources to enable them pursue their goals.

Clinical Spectrum of HIV Disease



HIV/AIDS

- HIV: Human Immunodeficiency Virus
- AIDS: Acquired Immuno-Deficiency Syndrome

- Virus attacks CD4 or (T-cells), CD4 cells die
- Low CD4-cells causes body to lose ability to fight infections
- CD4-cells less than 200 is an AIDS diagnosis

Fast facts

- HIV cannot multiply on its own
- HIV attaches to an immune system cell - the CD4 cell
  - it then fuses with the cell
  - it releases viral RNA into the cell
  - it uses the cell's machinery to make a DNA copy of the RNA
  - it integrates the DNA copy into the cell's DNA
  - it uses the DNA to make HIV proteins and new HIV RNA
  - these assemble into full HIV viruses as they are released
- Different HIV treatment medications stop these steps: attachment, fusion, copying the RNA into DNA, integration, protein assembly, and maturation

Destruction of CD4 Cells by HIV

- HIV uses CD4 cells' genetic material to create more HIV virions
  - HIV virions bud off the host cell, utilizing the CD4 cell membrane, destroying it
- When CD4 cells are destroyed, multiple functions of the immune system are lost
  - Eventually PLWH become vulnerable to opportunistic infections
- Antiretroviral therapies can interfere with the replication process, inhibit viral production and prevent further CD4 cell destruction

Relationship between CD4 Count and Viral Load

T-Cell Count+ distance to crash, HIV RNA= speed of train



Viral load = Speed

1000

10,000

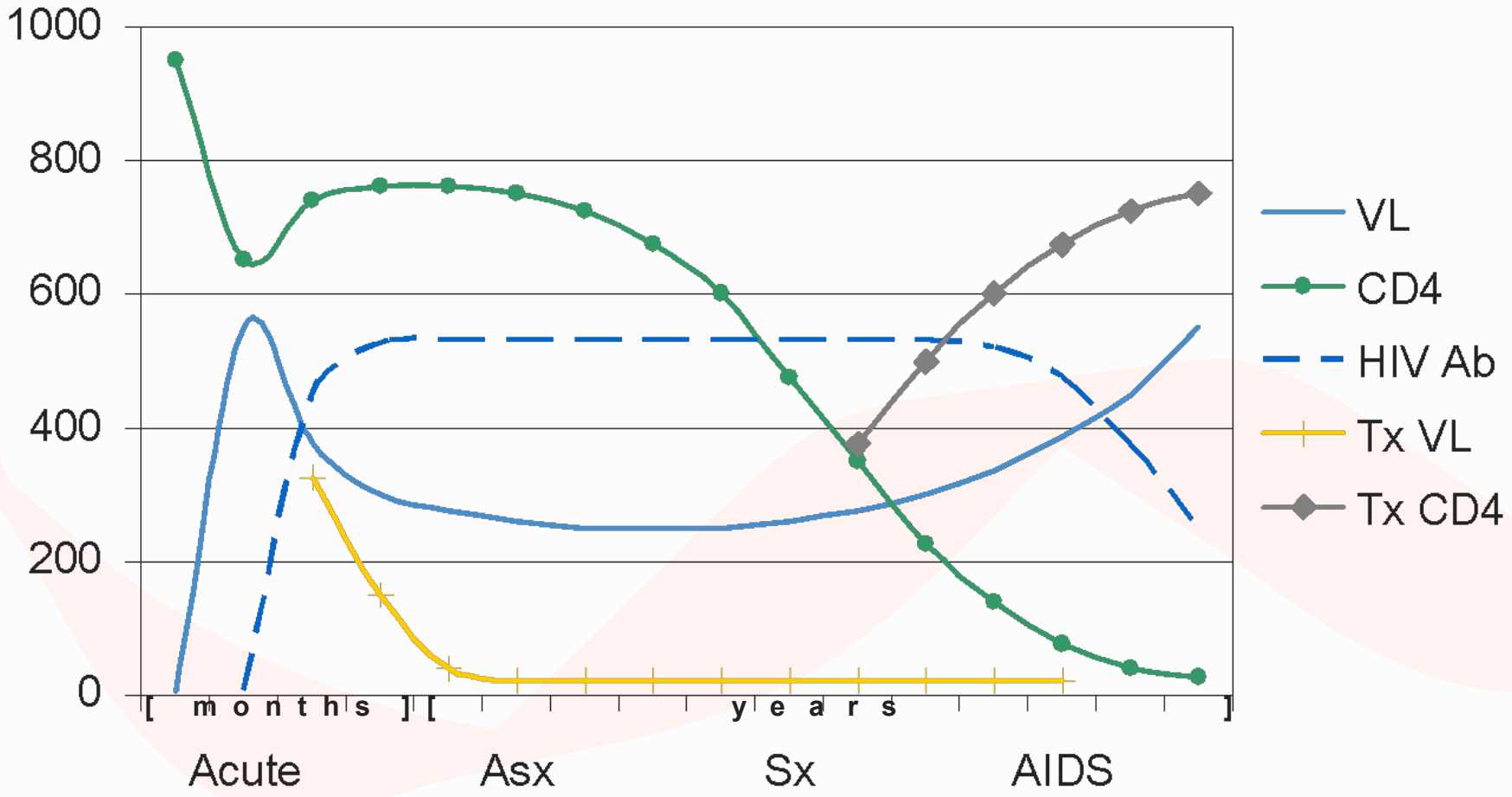
100,000

AIDS

1000 900 800 700 600 500 400 300 200

CD4+ Count = Distance

Course of HIV Disease



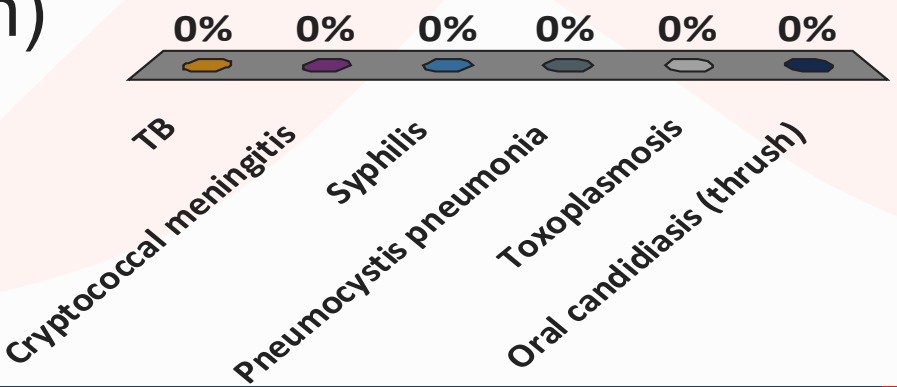
Acute / Primary HIV Infection

Most patients have an acute symptomatic illness:

Fever	96%	Headache	32%
Swollen lymph node	74%	Diarrhea	32%
Sore throat	70%	Oral or genital ulcers	28%
Rash	70%	Nausea/vomiting	27%
Malaise	68%	Abnormal liver/spleen	14%
Muscle aches	54%	Weight loss > 5 lbs.	13%
Low platelets	51%	Neurologic symptoms	12%
Low white cells	38%	Oral thrush	12%

Which of the following is NOT considered an opportunistic infection?

A. TB
B. Cryptococcal meningitis
C. Syphilis
D. Pneumocystis pneumonia
E. Toxoplasmosis
F. Oral candidiasis (thrush)



Recognizing HIV-related Conditions

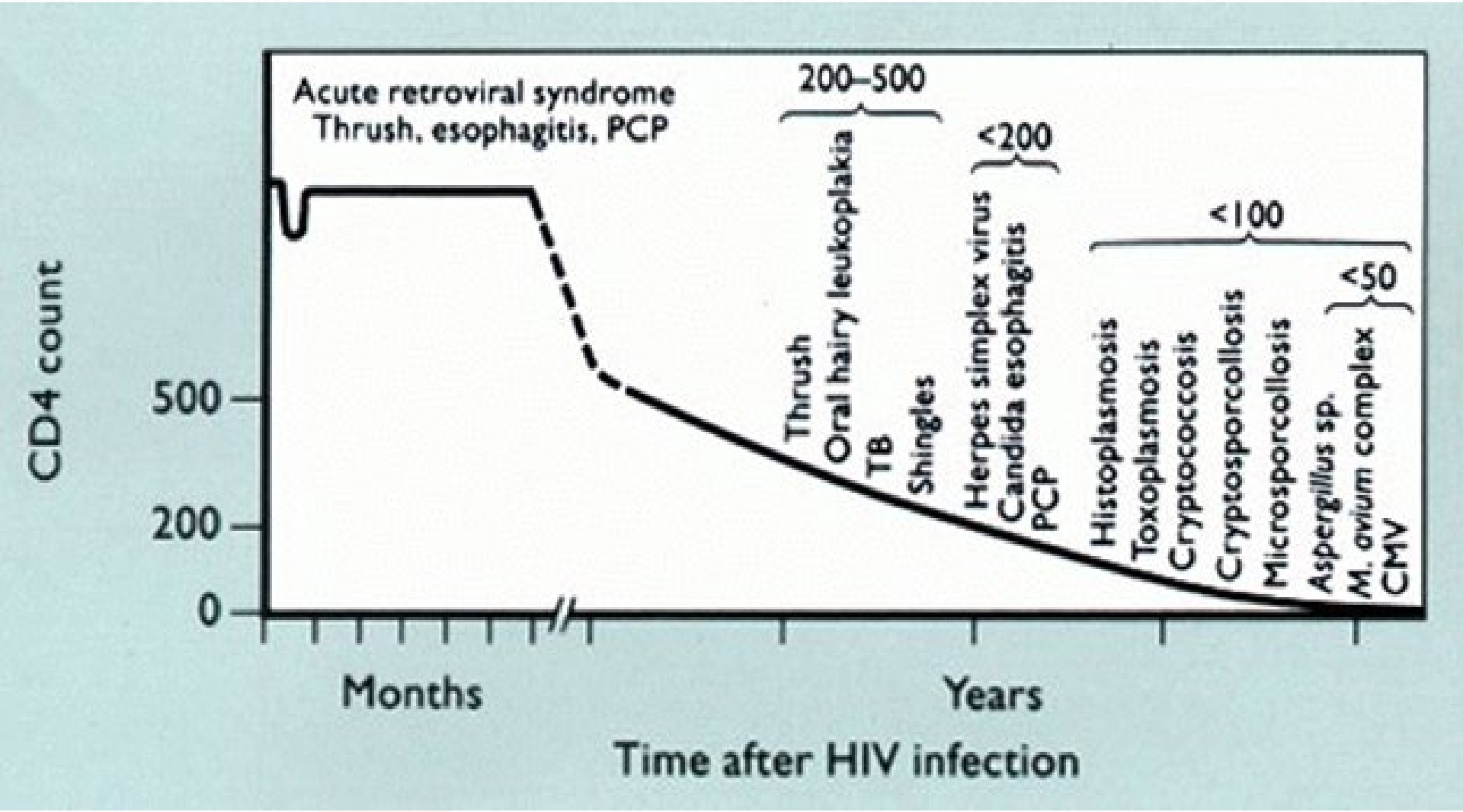
Common Symptoms

- Persistent fatigue
- Recurrent fevers
- Chills/night sweats
- Persistent diarrhea
- Weight loss
- Rashes
- Possible STIs
- Oral infections
- Body aches
- Swollen lymph nodes

Late Symptomatic Disease / AIDS

- Pneumocystis pneumonia (PJP)
- Toxoplasma encephalitis
- Candida esophagitis (thrush)
- Mycobacterium avium complex (MAC)
- CMV Retinitis

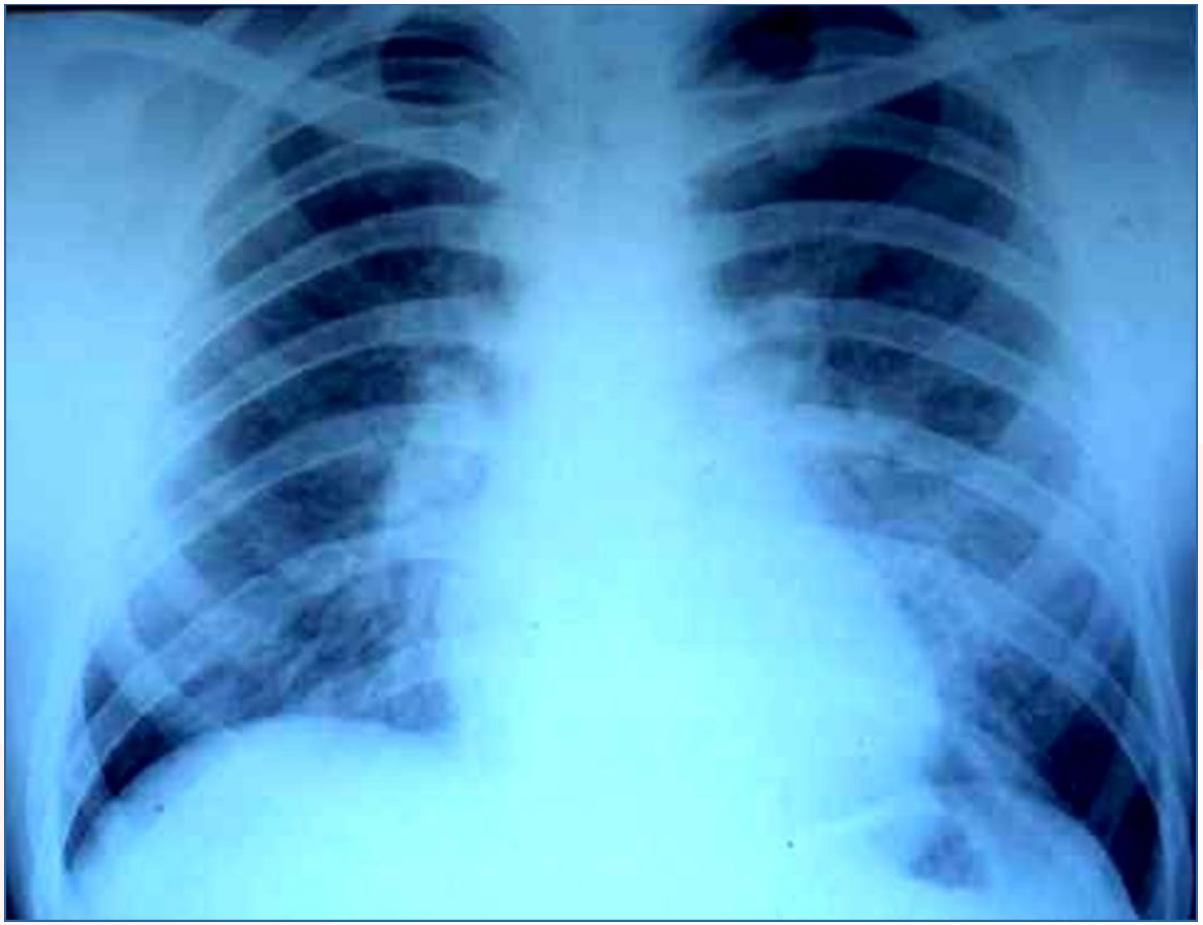
CD4 & Risk of Clinical Disease



Coordination of Care

- What are some tests and screenings that patients typically need when they have a CD4 < 200?
- What are best practices for helping patients stay healthy and live well until their CD4 count increases > 200?

Pneumocystis pneumonia (PJP)



PJP

- What are some things that you should be thinking about when assessing a patient for PJP?
- What is an easy clinical test a clinician can do if you suspect PJP pneumonia in your patient?
- As a case manager or health educator, what kinds of things are you thinking about to promote improved health and well-being?

Oral Thrush



Oral Candida (Thrush)

- What are some things that you should be thinking about when assessing a patient for oral candida?
- What is an easy clinical test one can do if you suspect thrush in your patient?
- As a case manager or health educator, what kinds of things are you thinking about to promote improved health and well-being?
- What are some things that you may need to advocate for if your patient has thrush?

HIV Conditions Independent of CD4

Infections:

- Syphilis
- Tuberculosis
- Hepatitis C

Nervous System:

- HIV-associated neurologic disease
- Neuropathy

Malignancies:

- Kaposi Sarcoma (KS)
- Lymphoma
- HPV Dysplasias
  - Cervical dysplasia/carcinoma
  - Squamous cell carcinoma of anus

Syphillis







Early Syphilis

Primary → **Secondary** ⟷ **Late Syphilis**

Latent → **Tertiary**



~ 3 weeks after infection



~ 6 weeks after infection

Early | Late

Weeks to years after infection



Years to Decades after infection

Can be transmitted congenitally, most likely during early stages

Neurologic complications can occur at any stage of syphilis

ODPHP | Office of Disease Prevention and Health Promotion

CDC

Syphilis: Screening, Treatment

- STI rates are at a record high in the US, make one more vulnerable to HIV
- RPR is the standard test for syphilis, concentration of infection is based on a titer of 1:?
- Previous screening and treatment history is needed to make treatment decisions; goal of treatment is a four-fold decrease in titer
- Benzathine penicillin G 2.4 MU IM single dose for primary and secondary
- No previous screen > 1 year requires 1 dose x 3 weeks
- With higher titers, consider assessment for neuro and ocular complications

Primary and Secondary Syphilis

Presentation

- chancre; rash (palms/soles)

Diagnosis:

- RPR
- LP if neuro symptoms (per guidelines), assess for vision changes
- some experts recommend LP if titer >1:32 or CD4 <350

Treatment:

- benzathine penicillin G: 2.4 mil units IM
- If rash, can treat as secondary, regardless of screening hx
- monitor titer: 4-fold ↓ in 12-24 months

Kaposi Sarcoma







Kaposi Sarcoma

A cancer that develops from cells that line lymph or blood vessels.

- usually appears as tumors on the skin or on mucosal surfaces such as inside the mouth
- tumors can also develop in other parts of the body (lymph nodes, lungs, or digestive tract
- abnormal cells of KS form purple, red, or brown blotches or tumors on the skin called lesions
  - skin lesions of KS most often show on the legs or face
  - may look bad, but they usually cause no symptoms
  - some lesions on the legs or in the groin area may cause the legs and feet to swell painfully

KS can cause serious problems or be life threatening when the lesions are in the lungs, liver, or digestive tract.

HIV-Associated Neurologic Disease

Stage 1: Mild

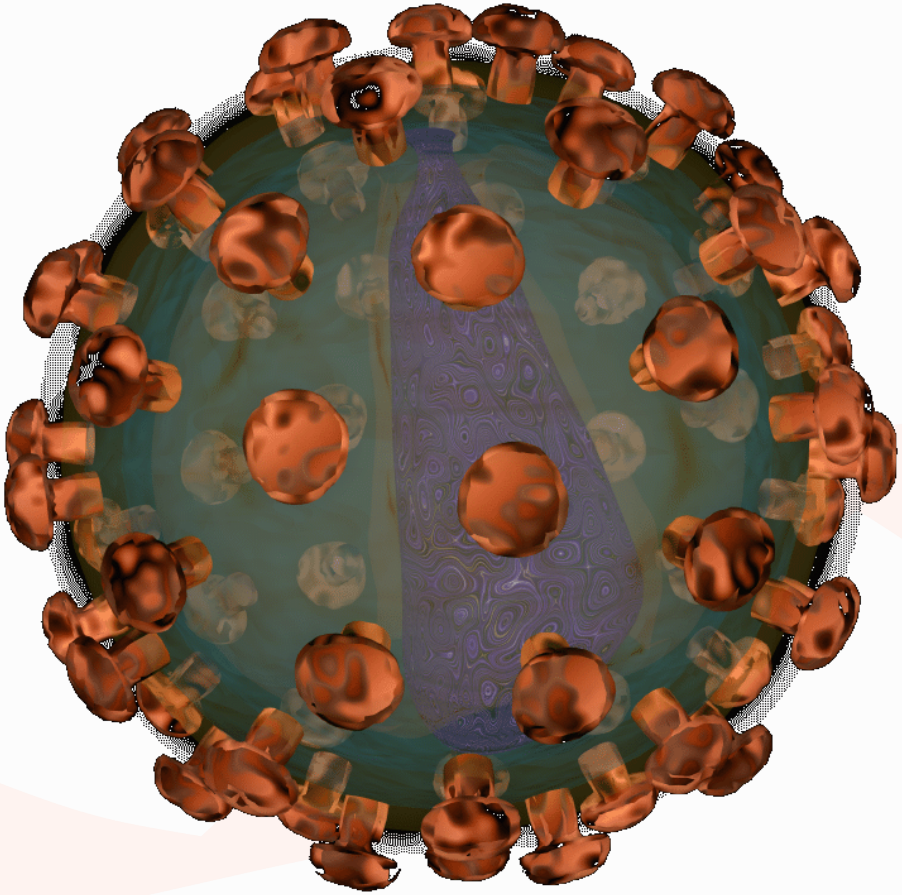
- fatigue, appetite and sleep disturbances
- decreased concentration, attention, short-term memory
- apathy, decreased interest, social withdrawal

Stage 2: Moderate

- decreased cognitive and / or gross motor functioning
- long-term memory deficits, slowed mentation/speech

Assess and REFER to neurologist when appropriate

Diagnosis & Baseline Assessment



Diagnosis and linkage to care

- Diagnosis of HIV given to patient with linkage to care
- Offer mental health services, assess patient's psychological response to diagnosis, stabilize, educate, refer
- Initial lab tests
  - Routine health labs (lipids, blood counts, chemistry (kidney and liver function)
  - HIV genotyping
  - Baseline hepatitis, STIs (3-site), tuberculosis testing
  - CD4 count and viral load
- HIV treatment recommendations are to treat all patients, some consideration should be given to high VL or low CD4 counts

ART and Opportunistic Infection Treatment Guidelines

- ART should start as soon as possible after diagnosis
- Opportunistic infection prophylaxis will be initiated if CD4 counts are under 200, additionally if below 100 and 50
- Newer recommendations offer flexibility of PJP prophylaxis for patients with undetectable viral loads whose CD4 count is between 150-200 for 3 months
- It is important to assess for drug allergies (Sulfa drugs) for patients who are prescribed SMP/TMX (Bactrim), and do a G6PD for those who are prescribed dapsone

https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/354/primary-prophylaxis

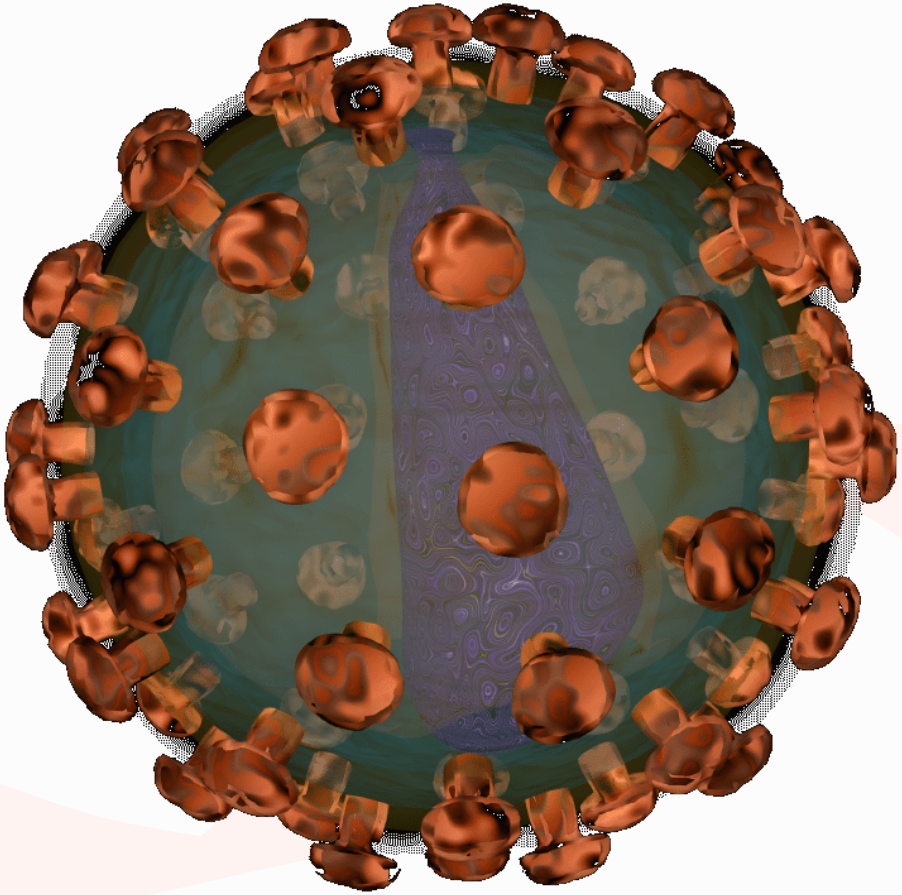
Baseline Laboratory Assessment

- CBC (diff & platelets)
- T-lymphocyte subsets (CD4 count / CD4 %)
- HIV-RNA PCR (viral load assay)
- Chem panel / GFR (LFTs, glucose, kidney function)
- Fasting lipids (NNRTIs & PIs can cause ↑ lipids)
- Resistance test (genotype to check for mutations)
- HLA B-5701 [hypersensitivity to abacavir], optional
- Calculate renal clearance (may impact choice of ART)

Baseline Laboratory Assessment

- Hepatitis panel (check for immunity/infection)
- Urinalysis (check for proteinuria)
- Quantiferon or PPD (check for latent TB)
- RPR
- Chlamydia and Gonorrhea
- Toxoplasma IgG titer if low CD4 (+ means risk of toxoplasmosis)
- Pap test (refer for colposcopy if abnormal)
- Anal Pap test (if hx of anal sex)
- Chest X-ray (optional)
- Stool cultures (optional)

Primary Care Management of HIV



Objectives

- Explain the clinical management of the person living with HIV (PLWH)

Opportunistic Infection Prophylaxis

- PCP (CD4 <150-200) = TMP-SMX, dapsone
- Toxo (CD4 <100) = TMP-SMX, dapsone
- MAC (CD4 <50) = (no longer recommended)
- TB (if PPD+) = INH + B_6 x 9 months
- Recurrent Candida = fluconazole, clotrimazole
- Recurrent HSV = acyclovir, valacyclovir

Vaccinations

▪Prevnar	prior to Pneumovax
▪Pneumovax	>2-12 months after Prevnar, then in 5y & age 65
▪Influenza	injection only
▪Hepatitis A	for all patients w/out documented immunity
▪Hepatitis B	for all patients w/out documented immunity
▪HPV	for males & non-preg females age 9 – 45y
▪Tdap	as indicated and/or Td booster
▪Polio	inactivated vaccine only
▪MMR	for unvaccinated born after 1957 & non-preg; contraindicated if CD4 <200
▪Varicella	for non-immune born after 1980 & non-preg; contraindicated if CD4 <200
▪Zoster	for patients >age 50 with CD4 >200 (Shingrex)
▪MCV	meningococcal conjugate vaccine (Menactra® or Menveo®)

Table 1 Recommended Adult Immunization Schedule by Age Group United States, 2019

Vaccine	19–21 years	22–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or **Influenza recombinant** (RIV)	1 dose annually				
or					
Influenza live attenuated (LAIV)	1 dose annually				
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td booster every 10 yrs				
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)				
Varicella (VAR)	2 doses (if born in 1980 or later)				
Zoster recombinant (RZV) *(preferred)*				2 doses	
or					
Zoster live (ZVL)				1 dose	
Human papillomavirus (HPV) **Female**	2 or 3 doses depending on age at initial vaccination				
Human papillomavirus (HPV) **Male**	2 or 3 doses depending on age at initial vaccination				
Pneumococcal conjugate (PCV13)	1 dose				
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication				1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine				
Hepatitis B (HepB)	2 or 3 doses depending on vaccine				
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, then booster every 5 yrs if risk remains				
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication				
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication				

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

No recommendation

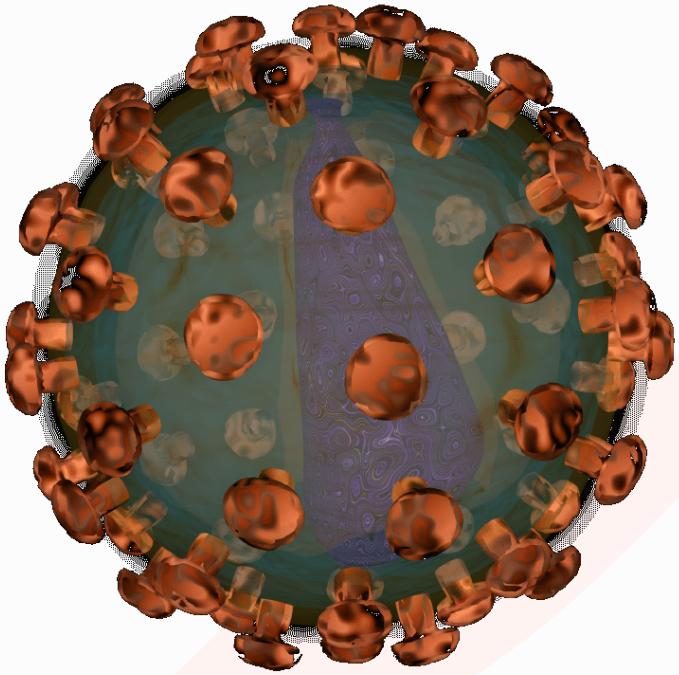
Routine Laboratory Tests

Viral load	q3-4 mo after achieving undetectable VL, then every 6 months to a year if suppressed consistently, and in care
CD4 count	q3 mo until undetectable VL and > 200, then q3-6 mo until undetectable VL x 2yrs. May be extended to every 6-12 months with suppressed viral load, good adherence and consistent care. ADAP requires q 6 months labs to recertify
CMP/lipids	q6 mo x 1yr on ART, then yearly if stable
Pap	cervix: upon initiation of care, repeated at 6 months and annually thereafter if results are normal. Women with atypical squamous cells , glandular cells, low or high-grade intraepithelial lesions or squamous carcinoma should undergo colposcopy and directed biopsy, with further treatment as indicated anal: institutional protocols, ANCHOR study
PPD or Quantiferon	q6 mo, then yearly if neg x 2, or Quantiferon Gold TB testing
UA	baseline urinalysis and calculated creatinine clearance or estimated glomerular filtration rate. UA & calculated creatinine clearance assay should be done prior to initiation of nephrotoxic drugs
RPR, site specific gc/ct	Every 3 months if risk exists

Health Maintenance

- Regular medical, dental and vision visits
  - Non-HIV chronic conditions may require more frequent health care visits
- Routine mental health assessment / referrals
- Medication Adherence
- Smoking cessation, limit alcohol, and other drug use
- Proper diet / nutritional counseling
- Adequate exercise and rest
- Safer sex / STI prevention practices
  - Regular testing (q3-6 months) with high-risk behaviors
- Family Planning
- Disclosure of Status/Recommend PrEP for partners

Antiretroviral Therapy



Objectives

- Describe the goals & indications of antiretroviral therapy (ART)
- Discuss the classes of antiretroviral therapy (ART)
- Illustrate the prescription and management of antiretroviral therapy (ART) regimens
- Review side effect and resistance management

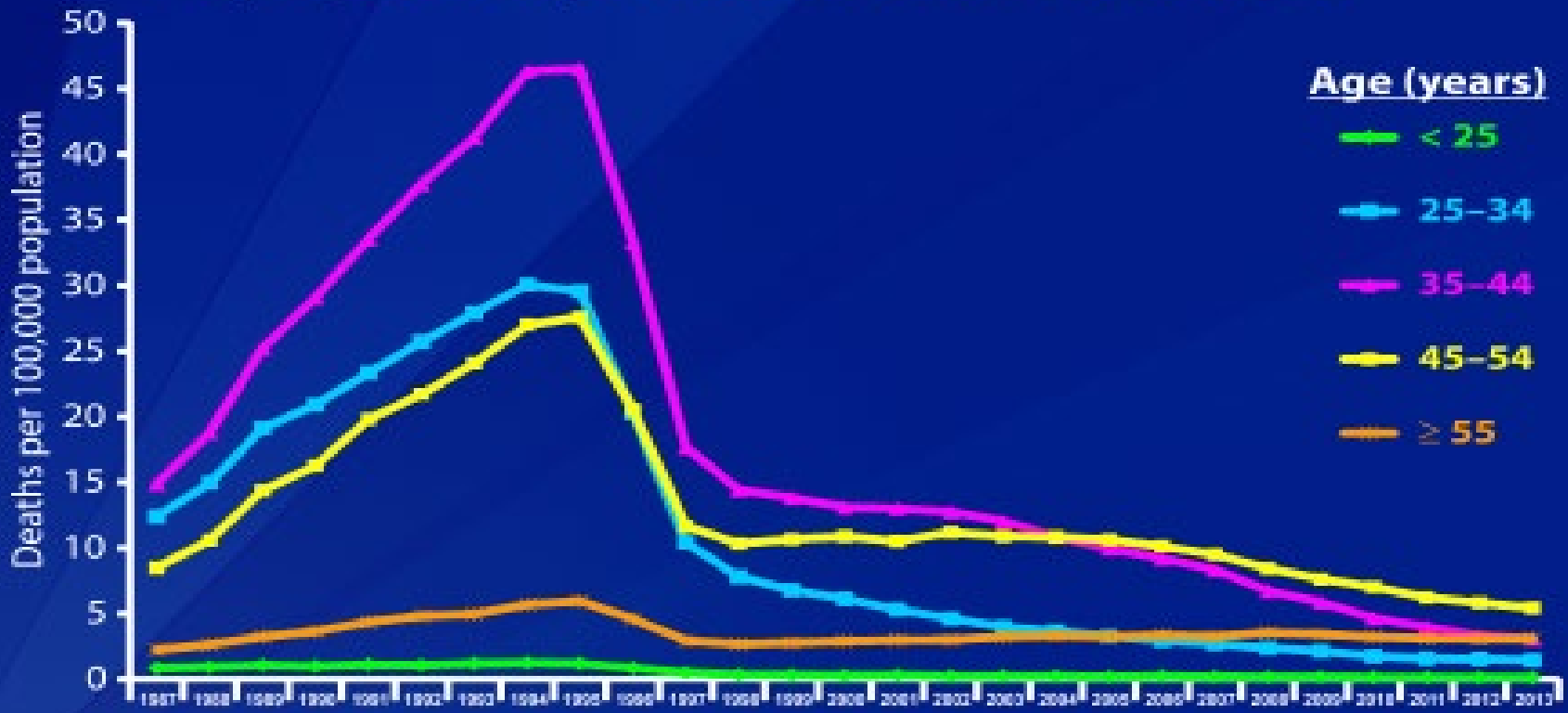
Goals of Therapy

- Maintenance of Viral Suppression
- Restore/Preserve Immunologic Function
- Reduce Morbidity and Mortality
- Improve Quality of Life

Surrogate Markers:

- Reduced Viral Load (viral suppression, undetectable viral load)
- Increased CD4 count, Monitor CD4 Percentage

Trends in Annual Rates of Death due to HIV Infection by Age Group, United States, 1987–2013



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.

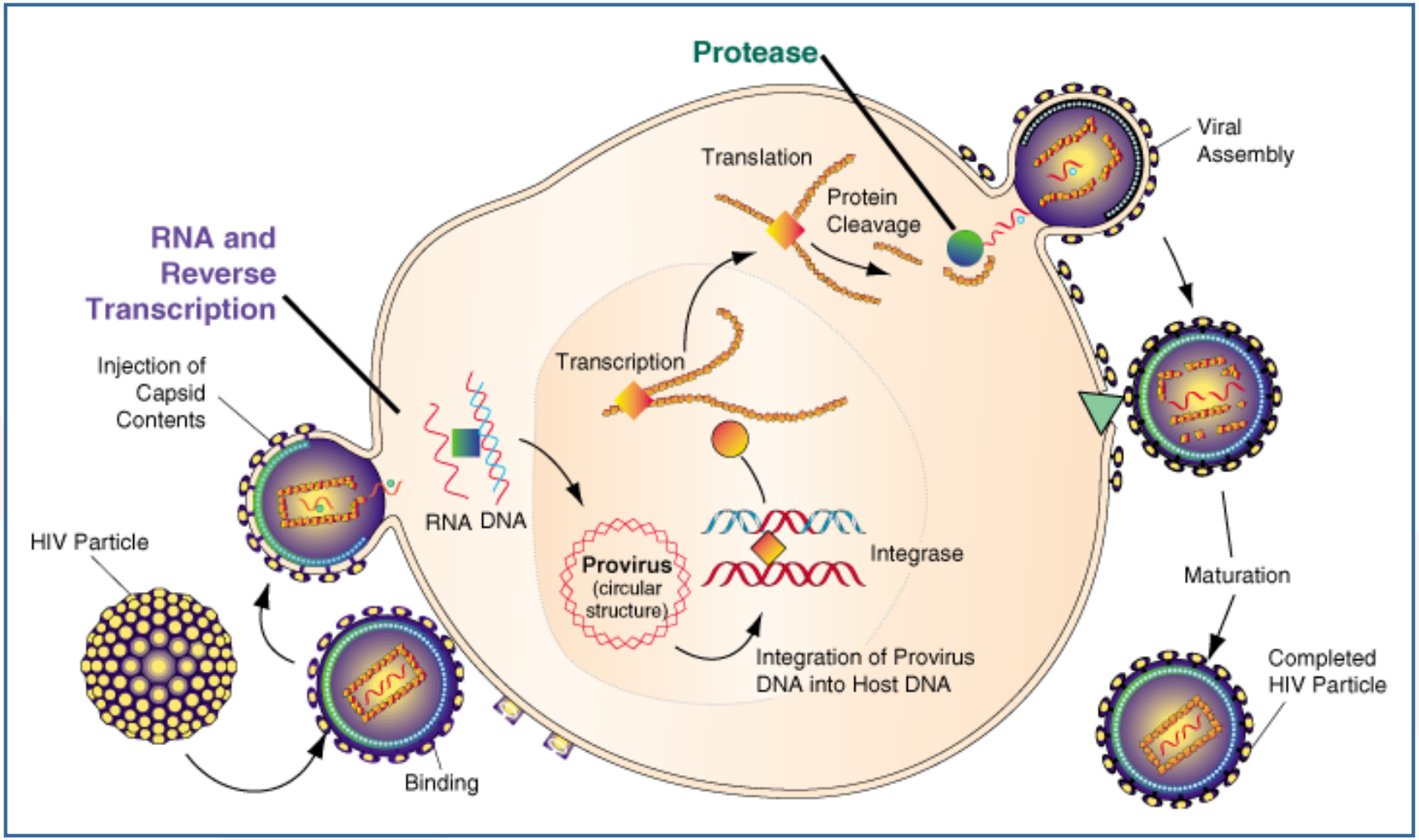
CDC

Indications for Initiating ART

- Antiretroviral therapy (ART) is recommended for all HIV-infected individuals, regardless of CD4 T lymphocyte cell count, to reduce the morbidity and mortality associated with HIV infection (AI).
- ART is also recommended for HIV-infected individuals to prevent HIV transmission (AI).
- When initiating ART, it is important to educate patients regarding the benefits and considerations regarding ART, and to address strategies to optimize adherence. On a case-by-case basis, ART may be deferred because of clinical and/or psychosocial factors, but therapy should be initiated as soon as possible.

https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/10/initiation-of-antiretroviral-therapy

Lifecycle of HIV



Current ART Medications

NRTI

§ Abacavir (ABC)
§ Didanosine (ddI)
§ Emtricitabine (FTC)
§ Lamivudine (3TC)
§ Stavudine (d4T)
§ Tenofovir DF (TDF)
§ Tenofovir alafenamide (TAF)*
§ Zidovudine (AZT)

NNRTI

§ Delavirdine (DLV)
§ Efavirenz (EFV)
§ Etravirine (ETR)
§ Nevirapine (NVP)
§ Rilpivirine (RPV)
Doravirine (DOR)

PI

§ Atazanavir (ATV)
§ Darunavir (DRV)
§ Fosamprenavir (FPV)
§ Indinavir (IDV)
§ Lopinavir (LPV)
§ Nelfinavir (NFV)
§ Saquinavir (SQV)
§ Tipranavir (TPV)

Integrase Inhibitor

§ Dolutegravir (DTG)
§ Elvitegravir (EVG)
§ Raltegravir (RAL)
§ Bictegravir (BIC)

Entry Inhibitor

§ Enfuvirtide (ENF, T-20)
§Maraviroc (MVC)
§Trogarzo (Ibalizumab)

Pharmacokinetic (PK) Booster

§ Ritonavir (RTV)
§ Cobicistat (COBI)

*** TAF available only in coformulations: TAF/FTC, RPV/TAF/FTC, EVG/COBI/TAF/FTC**

Antiretroviral Agents

- Entry Inhibitors
  - Enfuvirtide = *Fuzeon*

    binds to HIV blocking attachment to CD4 receptors
  - Maraviroc = *Selzentry*

    after binding to a CD4 receptor HIV must bind to one of two co-receptors: CCR5 (R5) or CXCR4 (X4)

    binds to R5 co-receptors (but not X4 co-receptors) on CD4 cells blocking fusion of the virus to the cell

    requires a tropism assay to determine the patient's virus is R5 tropic and not R5/X4 dual/mixed tropic

Antiretroviral Agents

Nucleoside Analog Reverse Transcriptase Inhibitors (NRTIs) “Nukes”

(structurally altered substitutes for DNA building blocks)

Abbreviation	Generic	Brand
AZT/ZDV	Zidovudine	Retrovir
TDF	Tenofovir (Disoproxil Fumarate)	Viread
TAF	Tenofovir (alafenamide)	Only available in co-formulations, Descovy, Genvoya and Odefsey, Biktarvy
3TC	Lamivudine	Epivir
FTC	Emtricitabine	Emtriva
ABC	Abacavir	Ziagen

Antiretroviral Agents

Non-nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

"Non-nukes" (chemically bind to RT to prevent assembly of viral DNA)

Abbreviation	Generic	Brand
NVP	Nevirapine	Viramune
EFV	Efavirenz	Sustiva
RPV	Rilpivirine	Edurant
ETV	Etravirine	Intelence*
DOR	Doravirine	Pifeltro*

* approved for patients with demonstrated resistance to other NNRTIs

Antiretroviral Agents

Integrase Inhibitors

(block the integration of proviral DNA into the host genome)

Abbreviation	Generic	Brand
RAL	Raltegravir	Isentress
DTG	Dolutegravir	Tivicay
EVG	Elvitegravir	Vitekta
BIK	Bictegravir	Only in STR

Antiretroviral Agents

Fixed Dose Combination (FDC) NRTIs

Abbreviation	Generic/*Brand*	FDC Brand
TDF/FTC	Tenofovir/Emtrictabine ***Viread/Emtriva***	**Truvada**
TAF/FTC	Tenofovir Alafenamide/Emtricitabine ***Tenofovir Alafenamide/Emtriva***	**Descovy**
ZDV/3TC	Zidovudine/Lamivudine *Retrovir/Epivir*	**Combivir**
ABC/3TC	Abacavir/Lamivudine ***Ziagen/Epivir***	***Epzicom***
ZDV/3TC/ABC	Zidovudine/Lamivudine/Abacavir ***Retrovir/3TC/ABC***	**Trizivir**

Single Table Regimens (STRs)

Abbreviation	Generic/*Brand*	FDC Brand
TDF/FTC/EFV	Tenofovir/Emtricitabine/Efavirenz ***Truvada + Sustiva***	**Atripla**
TDF/FTC/EPV	Tenofovir/Emtricitabine/Rilpiverine ***Truvada/Edurant***	**Complera**
TDF/FTC/EVG/COBI	Tenofovir/Emtricitabine/Elvitegravir/COBI ***Truvada/Vitekta/Tybost***	**Stribild**
TAF/FTC/EVG/COBI	Tenofovir Alafenamide/Emtricitabine/ Elvitegravir/ COBI ***Descovy/Vitekta/Tybost***	**Genvoya**
TAF/FTC/RPV	Tenofovir Alafenamide/Emtricitabine/ Rilpiverine ***Descovy/Edurant***	**Odefsey**
ABC/3TC/DTG	Abacavir/Lamivudine/Dolutegravir ***Epzicom/Tivicay***	***Triumeq***
BIC/FTC/TAF	Bictegravir/Emtricitabine/Tenofovir Alafenamide ***Bictegravir/Descovy***	***Biktarvy***
DTG/RPV	Dolutegravir/Rilpiverine ***Tivicay/Edurant***	***Juluca***
DRV/COBI/TAF/EVG	Darunavir/COBI/Tenofovir Alafenamide/ Emtricitabine ***Prezista/Tyboost/Descovy***	***Symtuza***

Antiretroviral Agents

Protease Inhibitors (PIs)

(block cleavage of viral proteins & assembly of new virions)

Abbreviation	Generic/*Brand*	FDC Brand
DRV	*Darunavir*	Prezista
AZV	*Atazanavir*	Reyataz
LPV	*Lopinavir/r*	Kaletra
RTV	*Ritonavir*	Norvir

Newer FDCs of PIs:
Atazanavir (Reyataz) + Cobicistat = Evotaz
Darunavir (Prezista) + Cobicistat = Prezcobix

Appropriate Antiretroviral Regimens: How to Decide?

- Appropriate ART prescriptions should be client centered: What does this mean to you?
- Dependent on patient profile, a regimen may match the DHHS guidelines exactly
- If a patient has been highly treated or has a high degree of resistance, regimens may consist of uncommon combinations of drugs that match patient's needs
- Assess patient's potential for successful adherence, patient's preference of taking with food or without food, time of day, QD (once daily) vs BID (twice daily) dosing

Medication Adherence

- Assessment of patient's potential for and barriers to consistent med adherence is extremely important
- Providing ongoing monitoring of med adherence is integral and essential; practice with multivitamins!
- Providing support and technical assistance can promote optimal adherence, promote patient empowerment
- Assessing patient's knowledge, attitudes and beliefs about ART can provide useful insight into motivation
- Providing appropriate medication teaching, what to anticipate with side effects, missed doses, empower to manage medication refills and pharmacy skills are helpful

Appropriate Antiretroviral Regimen

- All regimens need to contain at least 3 drugs from at least 2 different classes of ARVs (except new DTG/RPV or DTG/3TC regimens)
- A regimen may have combinations that look like this:
  - 1 INSTI + 2 NRTIs
  - 1 INSTI + 1 NNRT for long-term well controlled?
  - 1 PK-boosted PI + 2 NRTIs
  - 1 NNRTI + 2 NRTIs

Basic ART Recipes

For treatment-experienced patients:

At least 2 fully active medications (preferably 3) from different drug classes

- Integrase Inhibitor
- Active NRTIs
- Active NNRTI (ie, *Intelence*)
- Active PI
- Entry Inhibitor

- Intelence is indicated for BID dosing (twice daily dosing); Isentress has typically been BID dosing, recently received indication for one daily, high-dose (HD) dosing

Initial Regimens: Recommended

INSTI plus 2 NRTIs:

Note: For individuals of childbearing potential, discuss childbearing intentions, consider avoiding dolutegravir-based regimens.

- BIC/TAF/FTC **(AI)**
- DTG/ABC/3TC **(AI)—if HLA-B*5701 negative**
- DTG plus tenofovir/FTC (**AI** for both TAF/FTC and TDF/FTC)
- RAL plus tenofovir/FTC (**BI** for TDF/FTC, **BII** for TAF/FTC)

3TC can be used in place of FTC and vice versa; TDF: caution if renal insufficiency

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials, observational cohort studies with long-term clinical outcomes, relative bioavailability/bioequivalence studies, or regimen comparisons from randomized switch studies; III = Expert opinion

Recommended Initial Regimens in Certain Clinical Situations

INSTI plus 2 NRTIs:

Note: For individuals of childbearing potential, see Table 6b before prescribing one of these regimens.

- EVG/c/tenofovirb/FTC (**BI** for both TAF/FTC and TDF/FTC)
- RALc plus ABC/3TCa **(CII)—if HLA-B*5701 negative and HIV RNA <100,000 copies/mL**

Boosted PI plus 2 NRTIs: (In general, boosted DRV is preferred over boosted ATV)

- (DRV/c or DRV/r) plus tenofovirb/FTCa **(AI)**
- (ATV/c or ATV/r) plus tenofovirb/FTCa **(BI)**
- (DRV/c or DRV/r) plus ABC/3TCa **—if HLA-B*5701 negative (BII)**

3TC can be used in place of FTC and vice versa; TDF: caution if renal insufficiency

Rating of Recommendations: A = Strong; B = Moderate; C = Optional
Rating of Evidence: I = Data from randomized controlled trials; II = Data from well-designed nonrandomized trials, observational cohort studies with long-term clinical outcomes, relative bioavailability/bioequivalence studies, or regimen comparisons from randomized switch studies; III = Expert opinion

Evolution of the STR (Single-Tablet Regimen)

Name	Year	Classes	Drugs
Atripla	2006	NNRTI + 2 NRTIs	Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate (TDF)
Complera	2011	NNRTI + 2 NRTIs	Rilpivirine/ Emtricitabine/Tenofovir Disoproxil Fumarate (TDF)
Stribild	2012	INSTI + COBI + 2 NRTIs	Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Disoproxil Fumarate (TDF)
Triumeq	2014	INSTI + 2 NRTIs	Dolutegravir/Abacavir/Lamivudine
Genvoya	2015	INSTI + COBI + 2 NRTIs	Elvitegravir/Cobicistat/ Emtricitabine/Tenofovir Alafenimide (TAF)
Odefsey	2017	NNRTI + 2 NRTIs	Rilpivirine/ Emtricitabine/Tenofovir Alafenimide (TAF)
Juluca	2017	INSTI + NNRTI	Dolutegravir/ Rilpivirine
Biktarvy	2018	INSTI + 2 NRTIs	Bictegravir/ Emtricitabine/Tenofovir Alafenimide (TAF)
Symtuza	2018	PI + COBI + 2 NRTIs	Darunavir/Cobicistat/ Emtricitabine/Tenofovir Alafenimide (TAF)
Delstrigo	2018	NNRTI + 2 NRTIs	Doravirine/Lamivudine/ Tenofovir Disoproxil Fumarate (TDF)
Dovato	2019	INSTI + NRTI	Dolutegravir/ Lamivudine

Combination Antiretrovirals

Atripla
(EFV/TDF/FTC)



Biktarvy
(BIC/TAF/FTC)



Combivir†
(ZDV/3TC)



Complera
(RPV/TDF/FTC)



Delstrigo
(DOR/TDF/3TC)



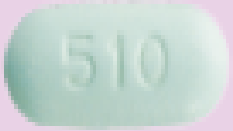
Descovy
(TAF/FTC)



Epzicom†
(ABC/3TC)



Genvoya
(EVG/COBI/TAF/FTC)



Juluca
(DTG/RPV)



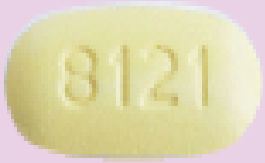
Odefsey
(RPV/TAF/FTC)



Stribild
(EVG/COBI/TDF/FTC)



Symtuza
(DRV/COBI/TAF/FTC)



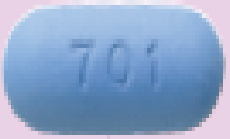
Triumeq
(DTG/ABC/3TC)



Trizivir†
(ABC/3TC/ZDV)



Truvada
(TDF/FTC)



Managing Adverse Effects

With all new ART, nausea and diarrhea are possible

Integrase Inhibitors: class effect = mostly well tolerated, now believed may cause weight gain

Dolutegravir has been associated with headaches and insomnia

NRTIs: class effect = fat wasting, lipodystrophy

- Zidovudine = bone marrow suppression
- Tenofovir DF = bone thinning, renal issues*
- Abacavir = hypersensitivity reaction*, do an HLA B5701 before starting; concern for increased risk for cardiovascular events

*Indicates Black Box warning

Managing Adverse Effects

NNRTIs: class effect = CNS, elevated lipids

- Efavirenz = CNS effects: vivid dreams, insomnia, depression
- Rilpivirine = CNS effects (HA, insomnia, depression)
- Nevirapine = liver toxicity*; avoid in men with CD4 >400 and women with CD4 > 250
- Etravirine = Generally well tolerated

PIs: class effect = metabolic complications: elevated liver enzymes, blood sugar / diabetes, elevated lipids, lipodystrophy, bone thinning

- Atazanavir = elevated bilirubin

*Indicates Black Box warning

Monitoring Response to Treatment

- Remote follow-up @ 1-2 weeks for side effects and adherence
- Repeat VL @ 4-8 weeks after starting therapy; then q8 weeks until undetectable (w/in 2-6 mo)
- CD4 count @ 3 months then q3-6 months once undetectable

- Indications for changing therapy
  - Inadequate viral suppression
  - Sustained viral rebound after full suppression
  - Declining CD4 count or clinical deterioration

Barrier to Resistance for HIV Medications

- In general: NNRTI's have a lower barrier to resistance
  - One resistance mutation makes most of drug class ineffective
  - Not always the same mutation for every drug in the same class
- In general: protease inhibitors have a high barrier to resistance
  - Multiple resistance mutations must be present to make drug ineffective
  - Exception is Atazanavir- one mutation causes drug resistance
- Among the integrase inhibitors, dolutegravir and bictegravir have high barriers to resistance, raltegravir and elvitegravir have lower barriers
  - A rare integrase mutation, often confers resistance to all integrase inhibitors as well

2018 IAS–USA Antiretroviral Guidelines: Key Updates

- Recommend initial regimens focus primarily on unboosted (InSTI) regimens
- Encourage rapid initiation of ART, including 'same day' initiation, if feasible
- Recommend against routine use of *Mycobacterium avium* complex prophylaxis for those with advanced disease on effective ART
- Recommend discontinuation of routine CD4+ counts once a patient has sustained undetectable HIV RNA for a year and has a CD4+ count >250 cells/uL
- Expand alternatives for preexposure prophylaxis for MSM who are uninfected with HIV but remain at risk for infection to include an episode-based "2-1-1" approach, where at risk individuals can take 2 ART pills prior to exposure followed by 1 pill once daily for 2 days after exposure (2-1-1)

Saag, Benson, Gandhi, et al. *JAMA*, 2018.

New IAS-USA Guidelines 2018

Recommended Laboratory Monitoring (Cont.)

- Once HIV RNA level is <50 c/mL, monitor **every 3 months until virus is suppressed for at least a year**. Then, monitoring can be reduced to **every 6 months** if the patient maintains adherence
- CD4 cell counts every 6 months until counts >250/μL for at least 1 year with concomitant viral suppression; **Then no longer monitor CD4 counts unless virologic suppression is lost**
- Age- and risk-appropriate screening for STIs at various anatomical sites, anal or cervical dysplasia, TB, general health, and medication toxicity is recommended
- Once a viral load is >50 c/mL, repeat test within 4 weeks and reassess for adherence and tolerability
- Measurement of viral load at 4 to 6 weeks after starting a new ART regimen is recommended

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Saag, Benson, Gandhi, et al. *JAMA*. 2018.

Dolutegravir in Pregnancy: Background

- No fetal toxicity or teratogenicity in animal studies described in manufacturer's submission for regulatory approval[1]
- High placental transfer of DTG relative to other ARVs in an ex vivo study[2]
- "*Unexpected placental transfer of DTG with fetal accumulation and then slow neonatal clearance*"[3]
- ***18 May 2018: Report of Neural tube defects in 4/426 (0.9%) babies born to women taking DTG in Botswana…compared to 14/11,173 (0.1%) non-DTG[4]***

DOI: 10.1056/NEJMc1807653 ; 24 July 2018

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In response to the FDA alert, interim guidance has been issued by the HHS Antiretroviral Guidelines Panels regading dolutegravir (DTG).[2] The Office of AIDS Research Advisory Council will be reviewing for proposed guideline changes. The interim recommendations of the Panels are as follows[3]:

- Health care providers are encouraged to counsel women of childbearing age with HIV currently receiving DTG about this newly identified potential risk.
- Pregnant women with HIV who are currently taking DTG should not stop their ARV therapy and should speak with their health care provider for additional guidance.
- Women of childbearing age with HIV who desire to become pregnant should discuss alternative ARV regimen options with their health care provider.
- Women of childbearing age with HIV who are not planning to become pregnant may be on DTG-based regimens provided their pregnancy test before initiation of therapy is negative, and they consistently use a reliable contraceptive method.
- Health care providers are encouraged to report all pregnancy data to the Antiretroviral Pregnancy Registry (1-800-258-4263; http://www.apregistry.com).

https://hivcareconnect.com/wp-content/uploads/Dolutegravir-risk-HAB-5-23-18.pdf

What's new in the pipeline?

FDA approved

- Juluca- 2 drug regimen (Dolutegravir/Rilpivirine) approved for persons who have long been virally suppressed. Less medication is better?
- Biktarvy- 2nd generation Integrase Inhibitor, Bictegravir, no booster
- Symtuza- Single-tablet regimen which is PI based (Prezcobix, Descovy)
- Dovato, latest 2-drug single tablet regimen (STR), for naïve & switch
- New generation of NNRTI: Doravirine, Delstrigo (STR)
- TAF/FTC for PrEP; shown to be non-inferior, recently approved in MSM only, not tested on women

Coming soon

- Long acting injectables for HIV management: Cabotegravir/Rilpivirine
- Long acting injectable for PrEP?

Rapid Start

Initial Visit ARV start – 3-4 hour visit

RAPID Visit: ART Start

- Disclosure, counseling
- Registration
- Insurance
- Assess housing, substance use, mental health needs
- Labs
- HIV education
- Counseling
- Medical evaluation
- Assess preparedness
- ART dispensed
- Telephone follow-up

AETC Pacific HIV LEARNING NETWORK
A TELEHEALTH PROGRAM OF THE PACIFIC AETC

Hot Topics

"Truvada Lawsuit"

- Tenofovir disoproxil fumarate (TDF) may cause worsening kidney function and decreased bone mineral density
- Newer version of tenofovir is tenofovir alafenamide (TAF)
- Labs are monitored on a regular basis, and changes are made if concerns arise.
- Patients should be switched off of TDF or offered switch and documented
- What is the impact of this on patients' adherence? Mistrust?

Long-acting injectables

- Currently will be monthly, large dose IM gluteal shot for HIV management, no need to take pills anymore. Concerns?

U = U: Undetectable = Untransmittable

It is now generally widely accepted that PLWH who have an undetectable viral load are not able to transmit the virus to others (PARTNERS 1 & 2 study).

- importance of retention in care of PLWH
- Importance of medication adherence to maintain viral suppression (in addition to reducing morbidity and mortality)

As a broad public health goal, increasing the prevalence of PLWH who are virally suppressed, and linking those who are still HIV negative to PrEP services, would promote a reduction in new HIV infections by reducing transmission and ability of HIV negative persons of acquiring HIV.

Results of Partners 2 Study Presented at AIDS 2018 Conference

TITLE

Risk of HIV transmission through condomless sex in MSM couples with suppressive ART: The PARTNER 2 Study extended results in gay men

Background: Although zero cases of HIV transmission in gay men have been reported in observational studies (PARTNER1 and Opposites Attract) of serodifferent couples where the positive person was on suppressive ART, the level of evidence for gay men remained less than for heterosexual couples. The aim of PARTNER 2 was to provide more precise estimates of transmission risk through condomless-sex in serodifferent gay male couples where the HIV-positive partner was on suppressive ART.

Conclusions: Despite almost 75,000 condomless-sex acts in gay serodifferent couples where the positive partner was on suppressive ART, we found zero cases of within couple HIV transmission. PARTNER 2 provides a similar level of confidence for gay men as for heterosexual couples in PARTNER 1.

Rodger A et al. *Risk of HIV transmission through condomless sex in gay couples with suppressive ART: the PARTNER2 study expanded results in gay men.* 22nd International AIDS Conference, Amsterdam, abstract WEAX0104LB, 2018.

Getting to Zero Campaign, Illinois

GOAL & VISION

We want to make sure that the HIV epidemic is no longer able to sustain itself by achieving both HIV prevention and access to care goals.
We want to see:

1. Zero new HIV transmissions

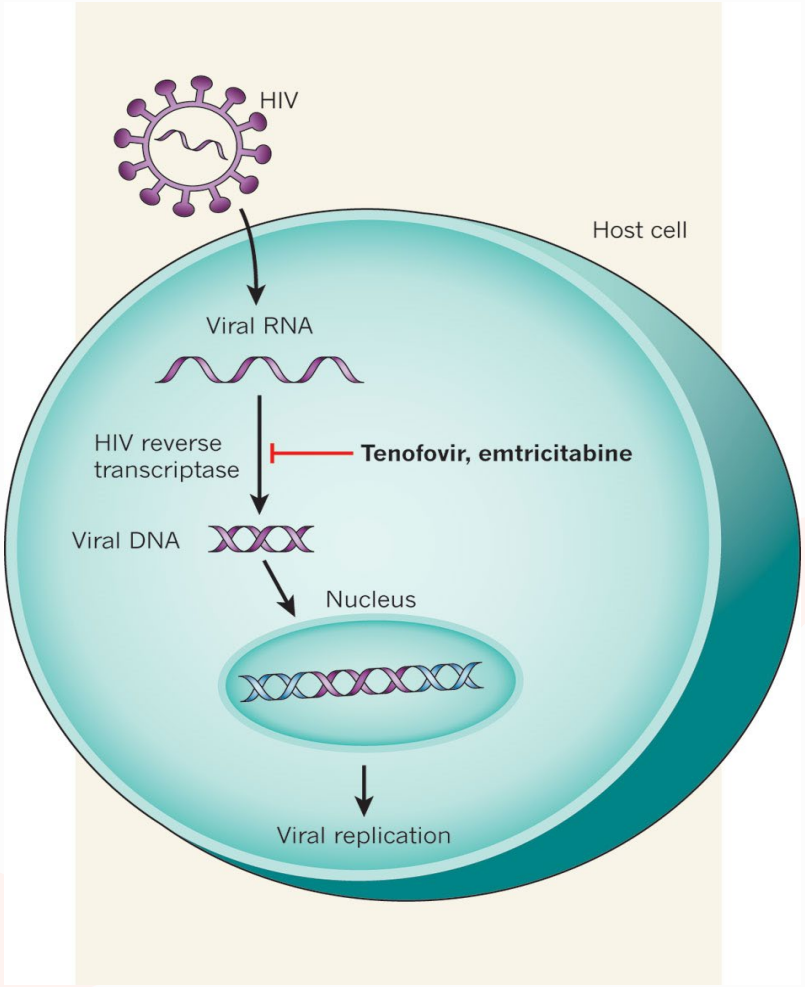
2. Zero people living with HIV who are not receiving treatment

Through increasing access and uptake of PrEP (pre-exposure prophylaxis), retaining more people living with HIV in care and the continued funding of ongoing supportive services, we can get to zero.

PEP vs. PrEP

PEP	PrEP
Post-Exposure Prophylaxis	Pre-Exposure Prophylaxis
Prevention of HIV infection	Prevention of HIV infection
HIV medication given within 72 hours of exposure	Medication given prior to exposure to prevent HIV infection
Medication taken for a period of a month	Medication taken as long as needed
Antivirals prescribed based on exposure	Truvada (tenofovir DF/emtricitabine) or Descovy (tenofovir AF/emtricitabine)

How PrEP Works



PrEP

- Must have enough medication in cells to be effective
- Different body parts need different amounts of medication
  - 6-7 days for rectal/back parts (anal) protection
  - 20 days for vaginal/front parts protection
  - 20 days (estimated) for injection drug use protection

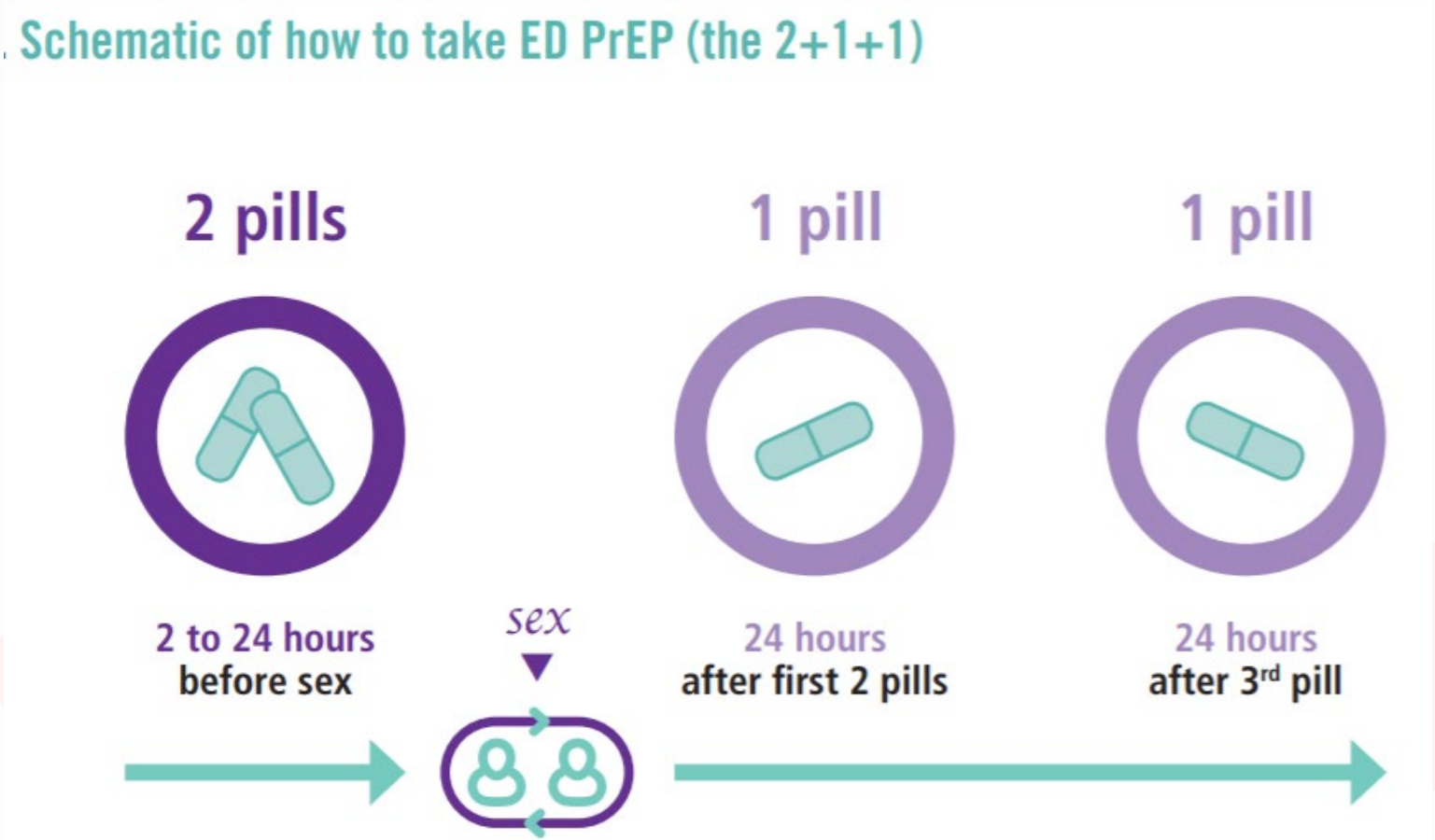
Using PrEP (daily dosing)

- TDF/FTC (Truvada)
  - or TAF/FTC (Descovy) for rectal/back parts sex in men
- one pill every day by mouth
- Labs, clinic visit every 3 months
  - Review use, desire to continue
  - HIV screening
  - STI screening
  - Kidney health screening
  - Pregnancy testing (vaginal/front parts sex)

On-demand or Event-driven PrEP

- Only for anal/back parts sex between men
- Not approved by the FDA, but recommend by the World Health Organization
- 2+1+1
  - Two tablets taken 2-24 hours before sex
  - One tablet 24 hours after first dose
  - One tablet 48 hours after first dose
    - May extend by continuing one tablet every 24 hours if sex continues beyond one day
- Labs and clinic schedule same as daily PrEP

On-demand or Event-driven PrEP



What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: Update to WHO's recommendation on oral PrEP. Geneva: World Health Organization; 2019 (WHO/CDS/HIV/19.8).

Daily or Event-driven PrEP?

- How often sex occurs
  - 2 times per month was average in on-demand study
  - If more than 2 times per week, switch to daily PrEP
- How predictable is sex
  - Or, can sex be delayed by at least 2 hours to take dose
  - Sex cruise vs. Saturday night sex
    - Plan for the cruise, start daily at least a week before!
- Concerns about kidney health or bone density (may prefer on-demand)

Off label use of medication

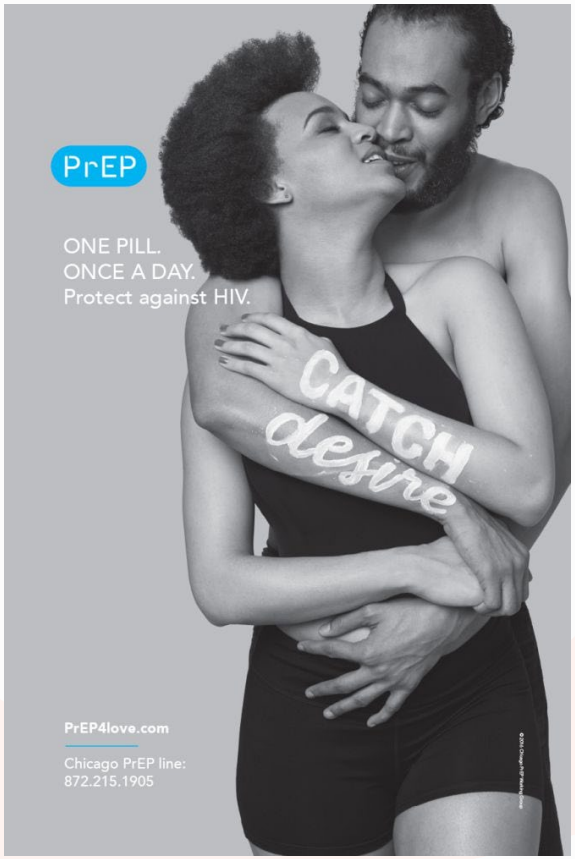
- Off-label use of medication: “event driven PrEP” or “2-1-1 PrEP” is not approved by the FDA

Why take PrEP?

Sex should be fun, enjoyable, and pleasurable to all partners.

PrEP (taken as directed) is 99% effective at preventing sexual HIV transmission.

Pre-Exposure Prophylaxis (PrEP)



US Public Health Service

PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES - 2014

A CLINICAL PRACTICE GUIDELINE



UCSF Clinician Consultation Center

- **Call for a Phone Consultation**
- **(855) 448-7737** or **(855) HIV-PrEP**
- Monday – Friday, 11 a.m. – 6 p.m. EST

Family Planning

- Almost anything is possible with regard to family planning goals for PLWH
- PLWH should be undetectable when trying to conceive
- HIV negative female partner may elect to be on PrEP
- Ideally, female partner should be undetectable at time of conception, chose a regimen that is safe for pregnancy in anticipation of conception (raltegravir-based)
- If a female is undetectable in early pregnancy, maintain regimen (except for dolutegravir?) and viral suppression
- Consult high-risk pregnancy specialist, PACPI, registry

PrEP continues during pregnancy

- Recommended by World Health Organization
- Large study (1530 women exposed to PrEP) found "Pregnancy outcomes and early infant growth did not differ by PrEP exposure.
- PrEP Implementation for Mothers in Antenatal Care (PrIMA) 20 African clinics expected end 5/2020

https://www.who.int/hiv/pub/toolkits/prep-preventing-hiv-during-pregnancy/en/

https://www.ncbi.nlm.nih.gov/pubmed/31498563

https://clinicaltrials.gov/ct2/show/NCT03070600

ECHO study

- 7829 African women HIV negative at start of trial
- Randomly assigned DMPA-IM, a copper IUD, or an LNG implant
- “no substantial difference in HIV risk”
- All methods safe, highly effective, well accepted by women who used them
- New HIV infection rate 397 (3.8% per year)

http://echo-consortium.com/ accessed 11/20/2019

WHO updates recommendations for contraceptive eligibility for women at high risk of HIV

29 August 2019 ¦ WHO has changed its recommendations for progestogen-only injectables and intrauterine devices (IUDs) for women at high risk of HIV from a Category 2 to a Category 1.

MEC Category 1: A condition for which there is no restriction for the use of the contraceptive method

https://www.who.int/reproductivehealth/contraceptive-eligibility-women-at-high-risk-of-HIV/en/ accessed 11/20/2019

MIDWEST AIDS TRAINING + EDUCATION CENTER

Legal Issues Impacting HIV Clients

Social determinants of health

Conditions in the places where people live, learn, work, and play affect a wide range of health risks and outcomes. These conditions are known as social determinants of health (SDOH). CDC definition

- Poverty
- Stigma
- Racism
- Trauma
- Education

Brainstorming

- What legal challenges have your clients shared that they have had with you?

Case 1

- Jamie is a 12 year-old boy who has burning on urination.
- Can he get STI treatment without his parents consent?
- An HIV test?
- What about PrEP?

Case 2

- Sandra sues her fiancée's parents because they knew his HIV status and didn't tell her.
- Did the parents have an obligation to disclose his status?

Case 3

- Joachim has HIV and has sex with a condom with all his partners but does not share his status.
- Is he at risk of prosecution for HIV criminal transmission?

Illinois law

- Opt-out testing since 6/1/08
- Minors age 12 and older may consent for testing
  - If positive, provider may but NOT REQUIRED to inform parents
- Only sexual partner who provider may notify is legal spouse (NOT REQUIRED, high intimate partner violence risk)
- Test results must be delivered “by personal contact” whenever possible
- Persons who test positive must be referred for counseling and appropriate HIV care
- Although not required by law, high-quality screening and treatment programs will also counsel HIV negative patients about risk-reduction
- PLWH are not required to disclose status if using condoms

https://www.aidschicago.org/resources/legacy/pdf/2008/adv_HIV_testing_guide_clinicians.pdf

Legislation for Legal Issues

- AIDS as a Handicap Under the Illinois Human Rights Act
- HIV Testing and Disclosure
- IL Perinatal Prevention Act
- IL Criminal Transmission Act
- IL AIDS Confidentiality Act
- Resources
  - http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1550&ChapterID=35
  - http://aidslegal.com/wp-content/uploads/2014/05/HIV-and-Confidentiality.pdf
  - LEGAL COUNCIL NOT AIDSLEGAL

Legal Resources for Patients

- Legal Council for Health Justice
  - http://legalcouncil.com/
- Lambda Legal, Illinois
  - http://www.lambdalegal.org/states-regions/illinois
- Prairie State Legal Services
  - http://www.pslegal.org/

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QUESTIONS?

Thank you!