

WOMEN, GIRLS & HIV: RACE MATTERS

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HIV Prevention Clinical Research

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Disclosures

- Financial disclosures: none
- Investigational products: will be discussed

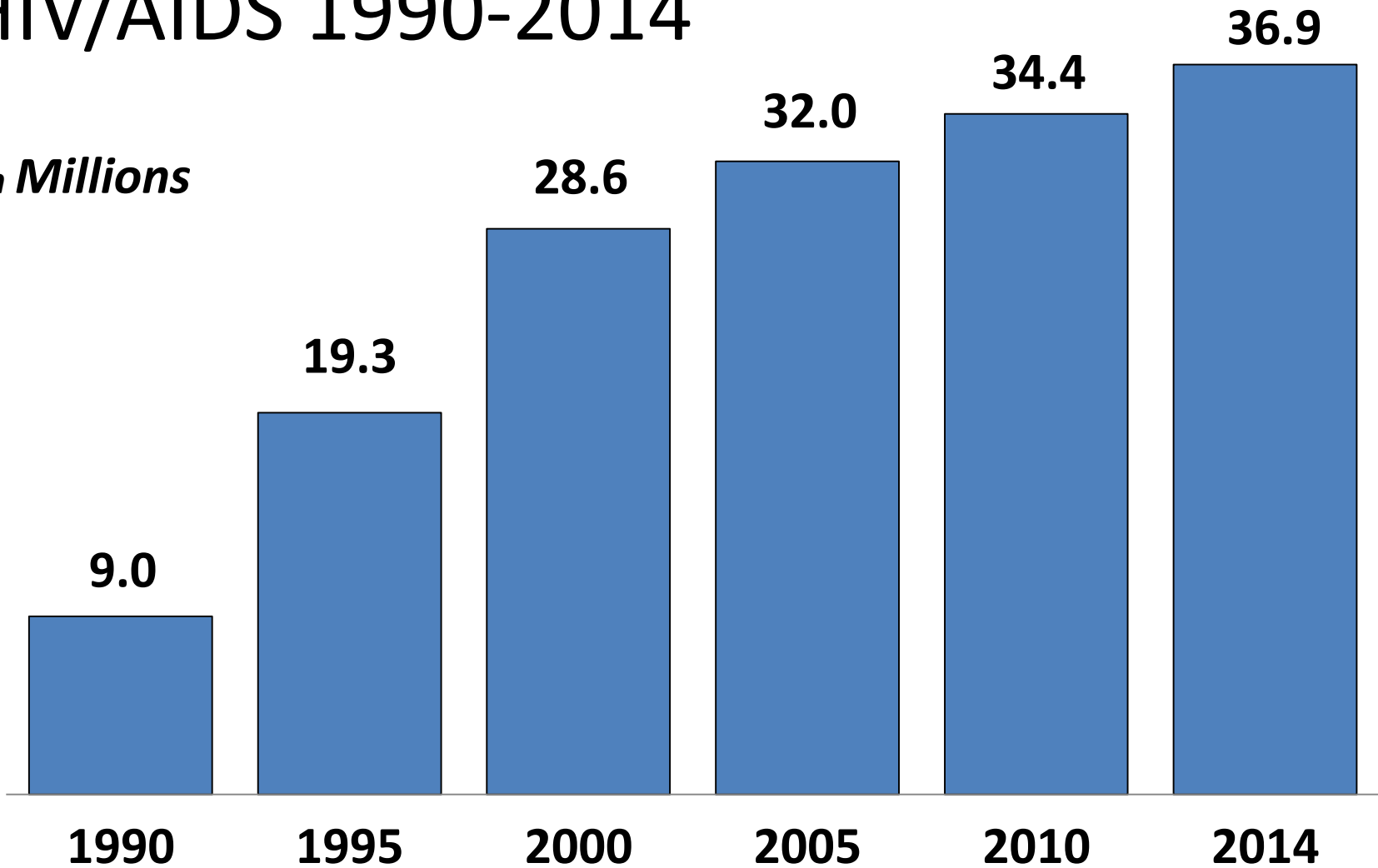
Outline

- Overview of HIV Epidemic
 - Global epidemic and women and girls
 - Scale-up of ART, 90-90-90
 - US epidemic and racial disparities
- Prevention Research Updates
 - Microbicides and adherence
 - Intravaginal rings
 - Injectable PrEP
 - Vaccines: neutralizing antibodies

Global HIV epidemic

Global Estimates of People Living with HIV/AIDS 1990-2014

In Millions



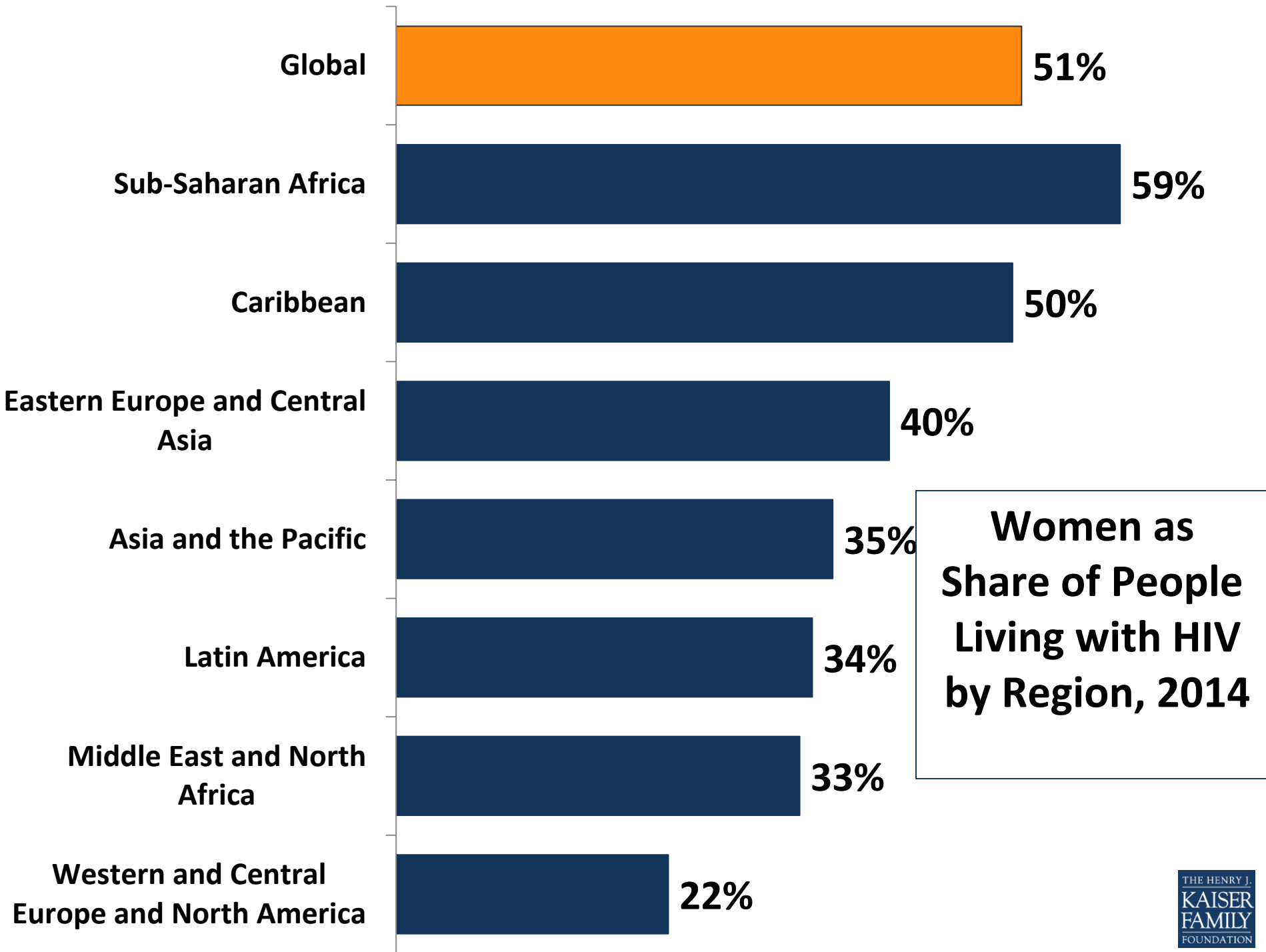
Estimated number of adults and children newly infected with HIV | 2014



Global total = 2 million in 2014

Almost 6000 new infections per day

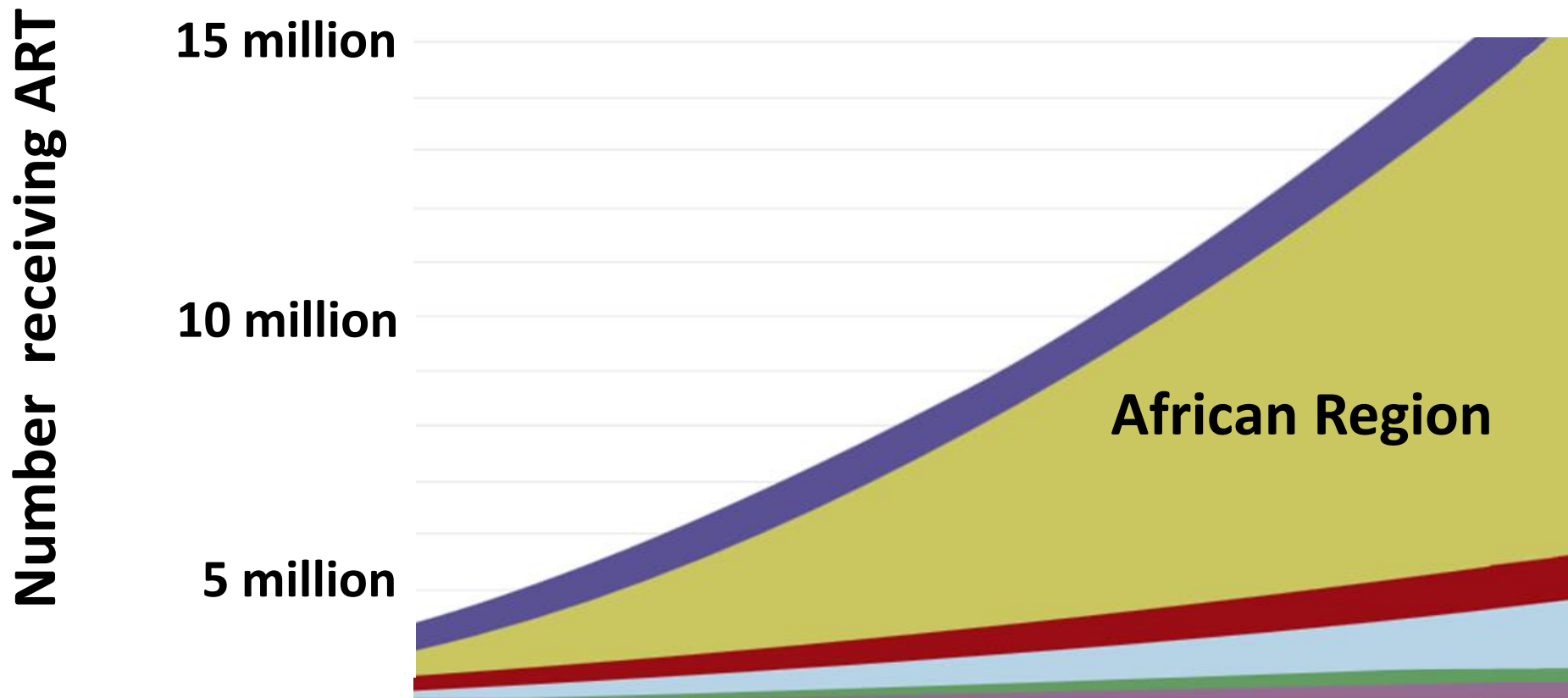
$\frac{1}{2}$ in women and $\frac{1}{3}$ in youth, age 15-24 y



HIV estimates: Transgender women

- Global
 - 19% prevalence, almost 50 x higher than general population
 - Based on a summary of 39 studies (2000-2011) in 19 countries

Global Scale-up of HIV Treatment



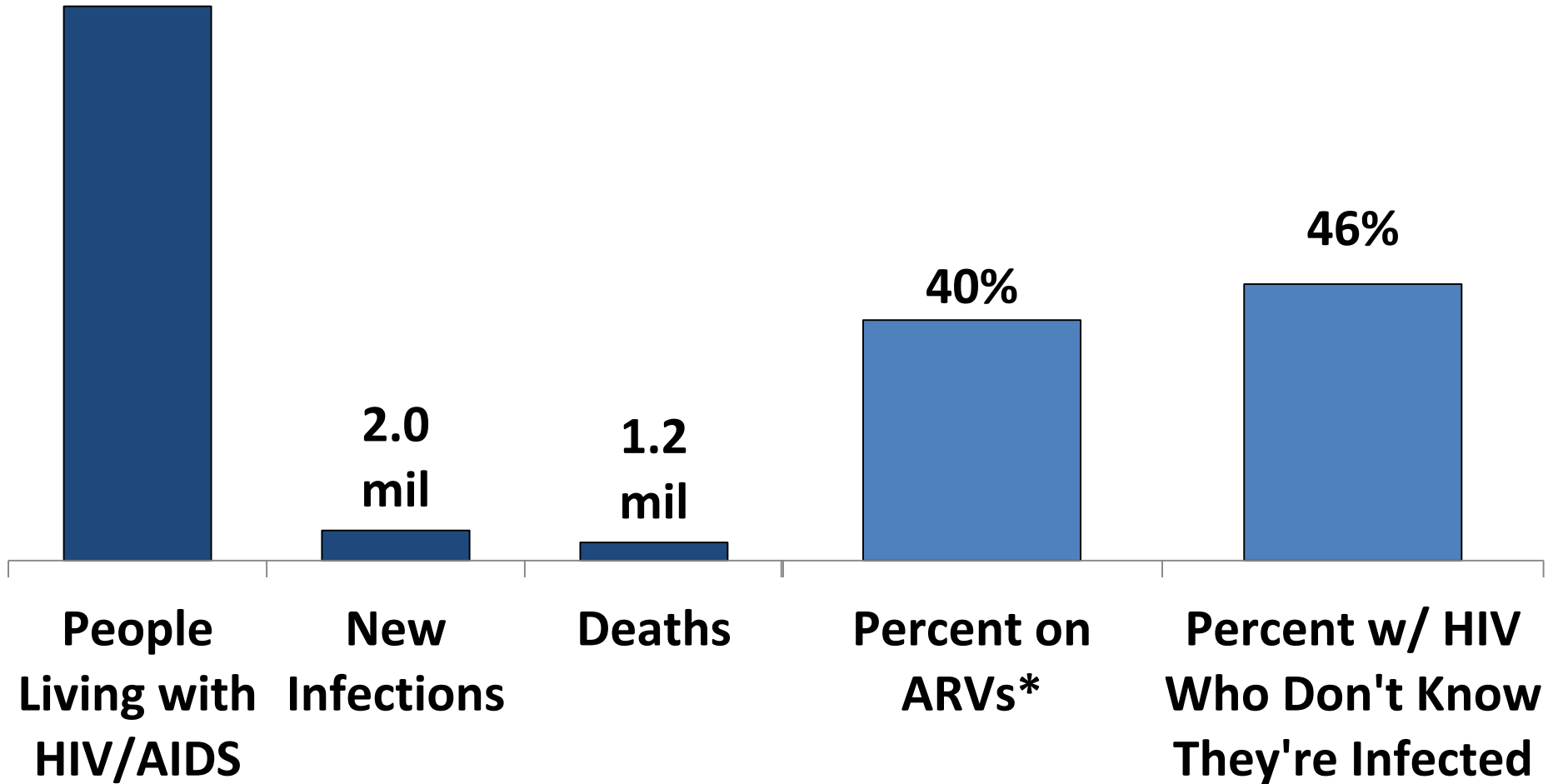
African Region

Adapted from: Global AIDS Response Progress Reporting (WHO/UNICEF/UNAIDS)

- High-income
- African Region
- Region of the Americas
- South-East Asia Region
- Europe
- Eastern Mediterranean Region
- Western Pacific Region

Snapshot of the Global Epidemic

36.9 million



*Of people living with HIV.

SOURCES: UNAIDS, How AIDS Changed Everything; 2015.

Race to the End HIV Treatment-- Global Targets By 2020

90%
of all people
living with HIV
will know their
HIV status

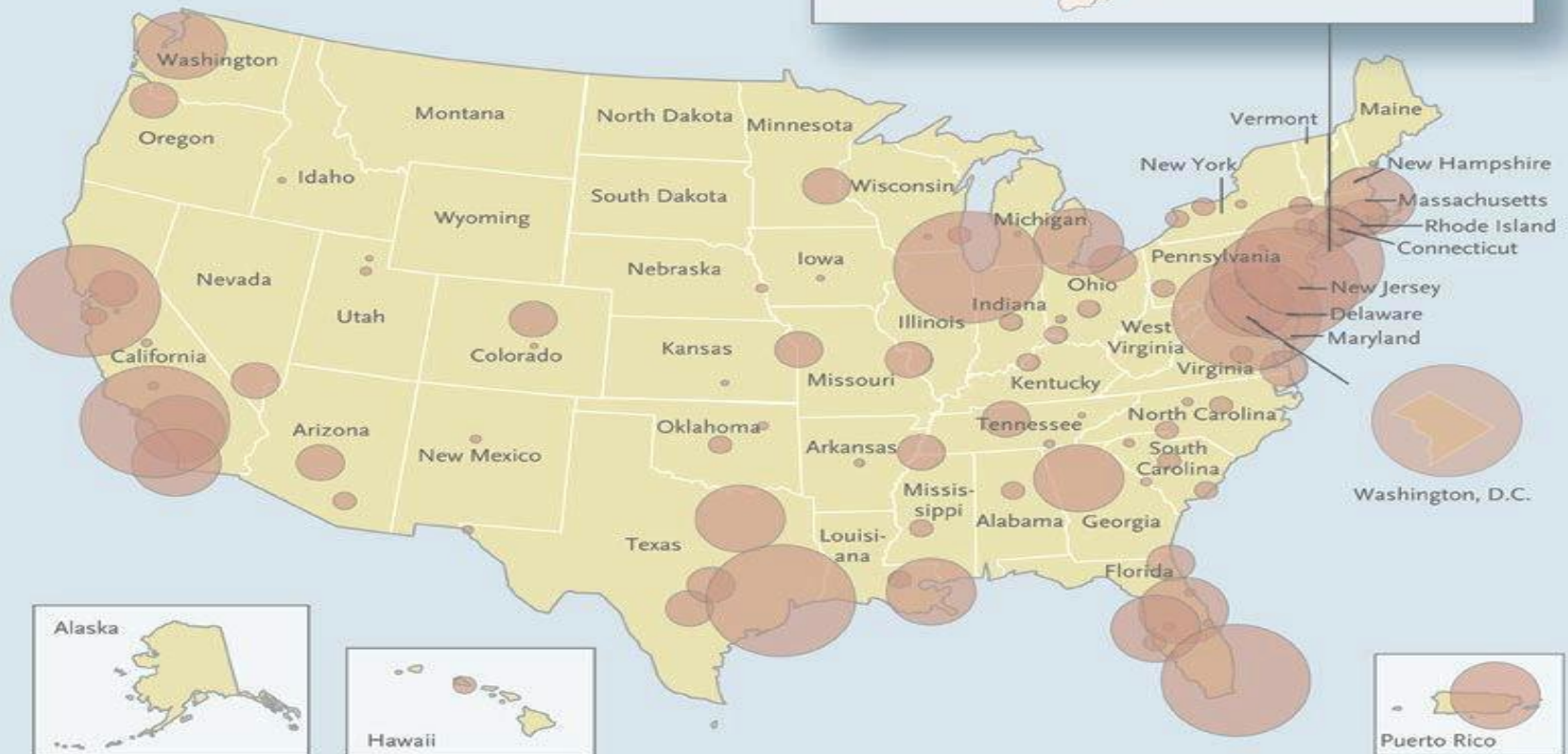
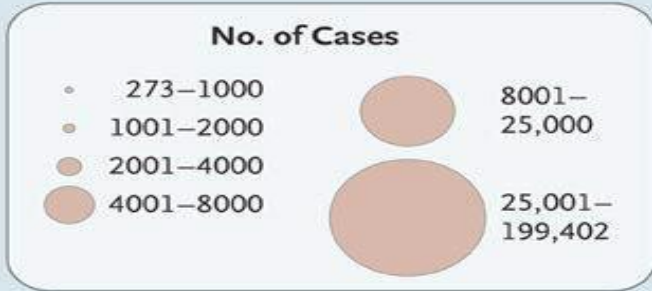
90%
of all people
diagnosed with
HIV will receive
sustained
antiretroviral
therapy.

90%
of all people
receiving
antiretroviral
therapy will have
durable
suppression.

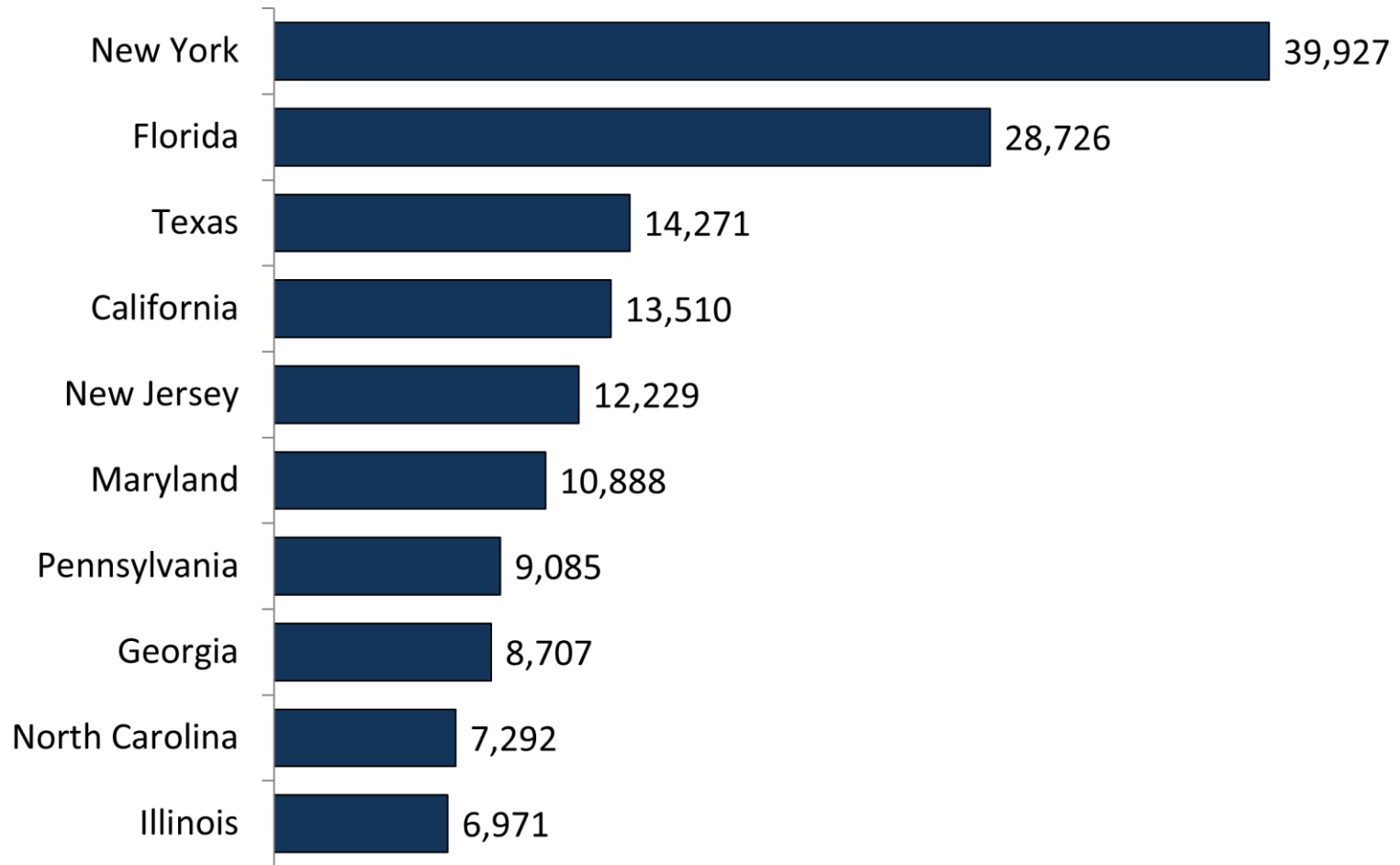
US HIV epidemic

Reported AIDS Cases By Metropolitan Area

El-Sadr W et al. N Engl J Med 2010;10.1056



Number of Women & Girls Estimated to be Living with an HIV Diagnosis, Top 10 States, year-end 2010

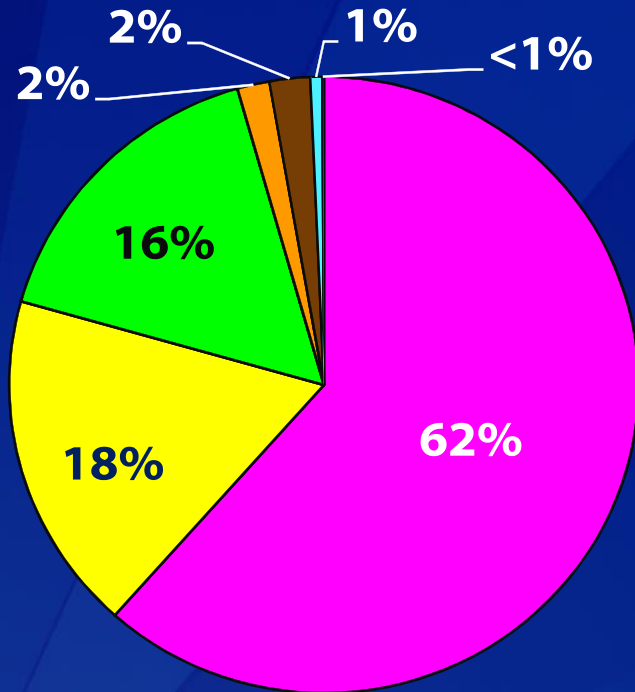


NOTES: Data are estimates for adults/adolescents ages 13 and older in all 50 states, the District of Columbia, and Puerto Rico.
SOURCE: CDC, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention Atlas.

Diagnoses of HIV Infection and Population among Adult and Adolescent Females, by Race/Ethnicity 2014, USA

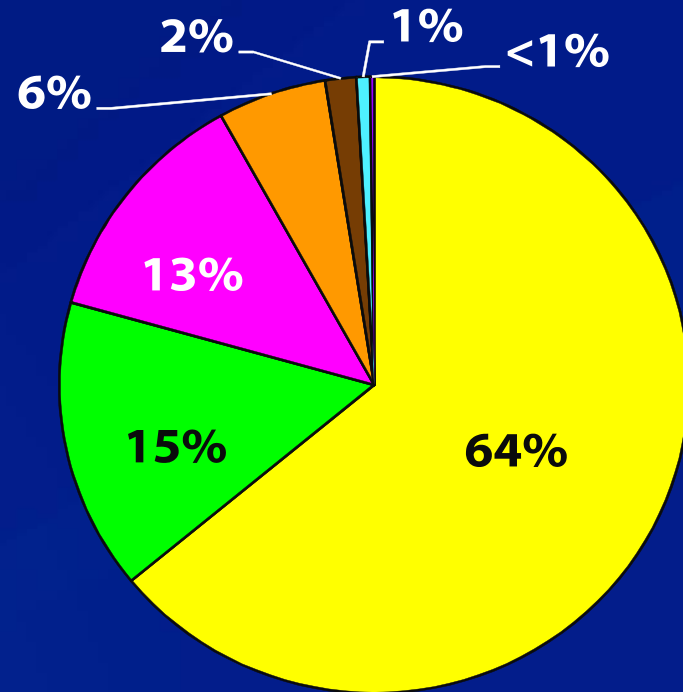
Diagnoses of HIV Infection

N = 8,328



Female Population, United States

N = 136,147,401



American Indian/Alaska Native

Asian

Black/African American

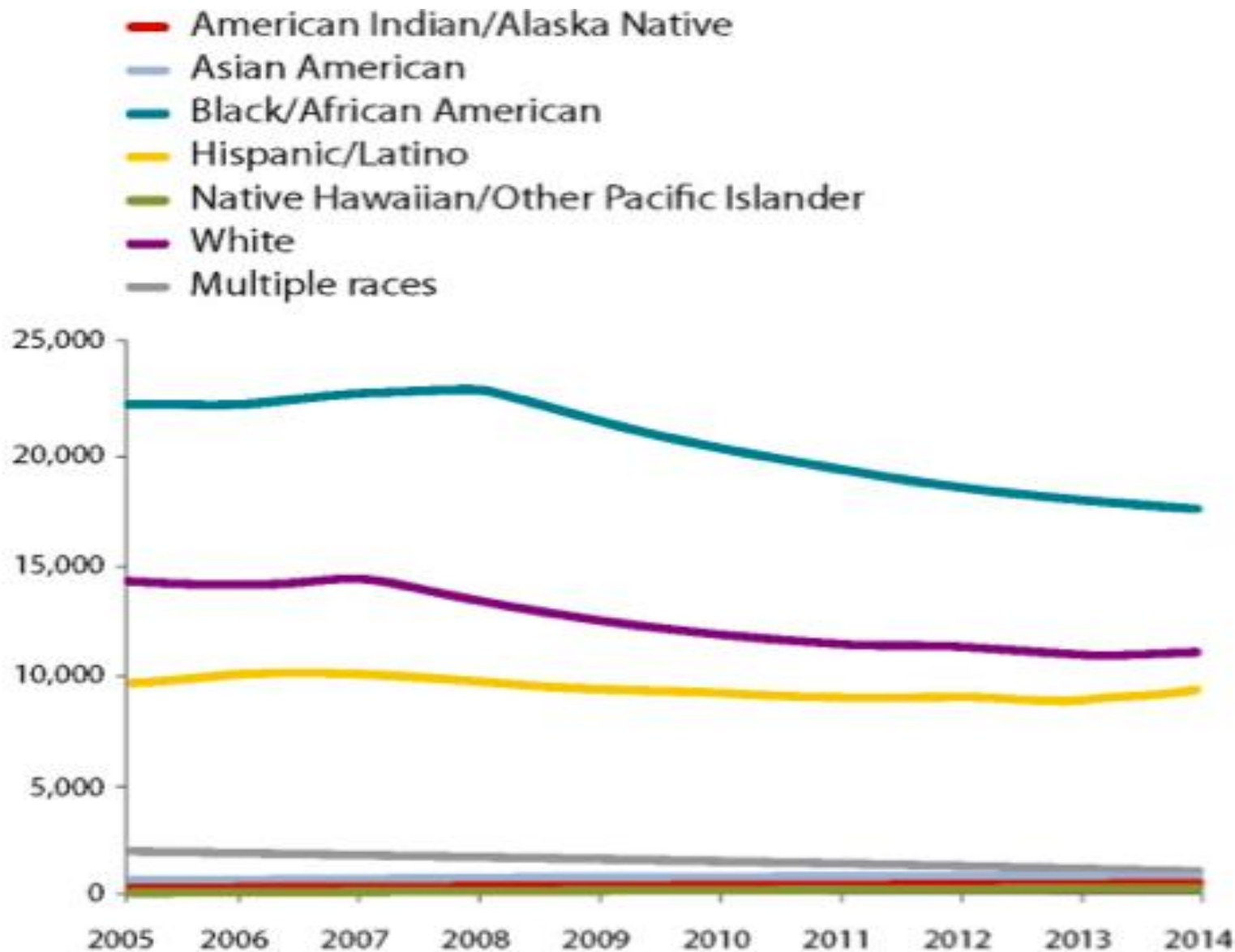
Hispanic/Latino^a

Native Hawaiian/other Pacific Islander

White

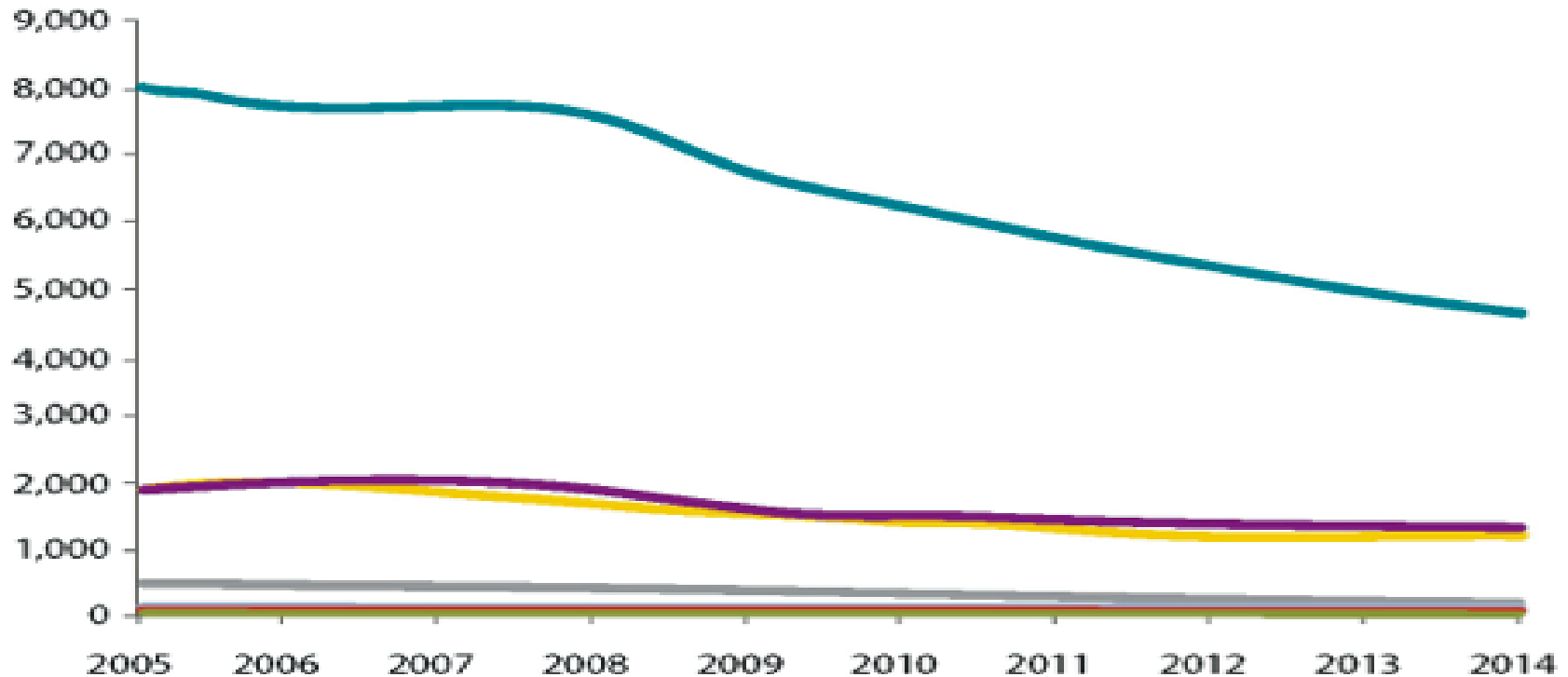
Multiple races

HIV Diagnosis by Race/Ethnicity, 2005-2014



HIV Diagnosis among Women by Race/Ethnicity, 2005-2014

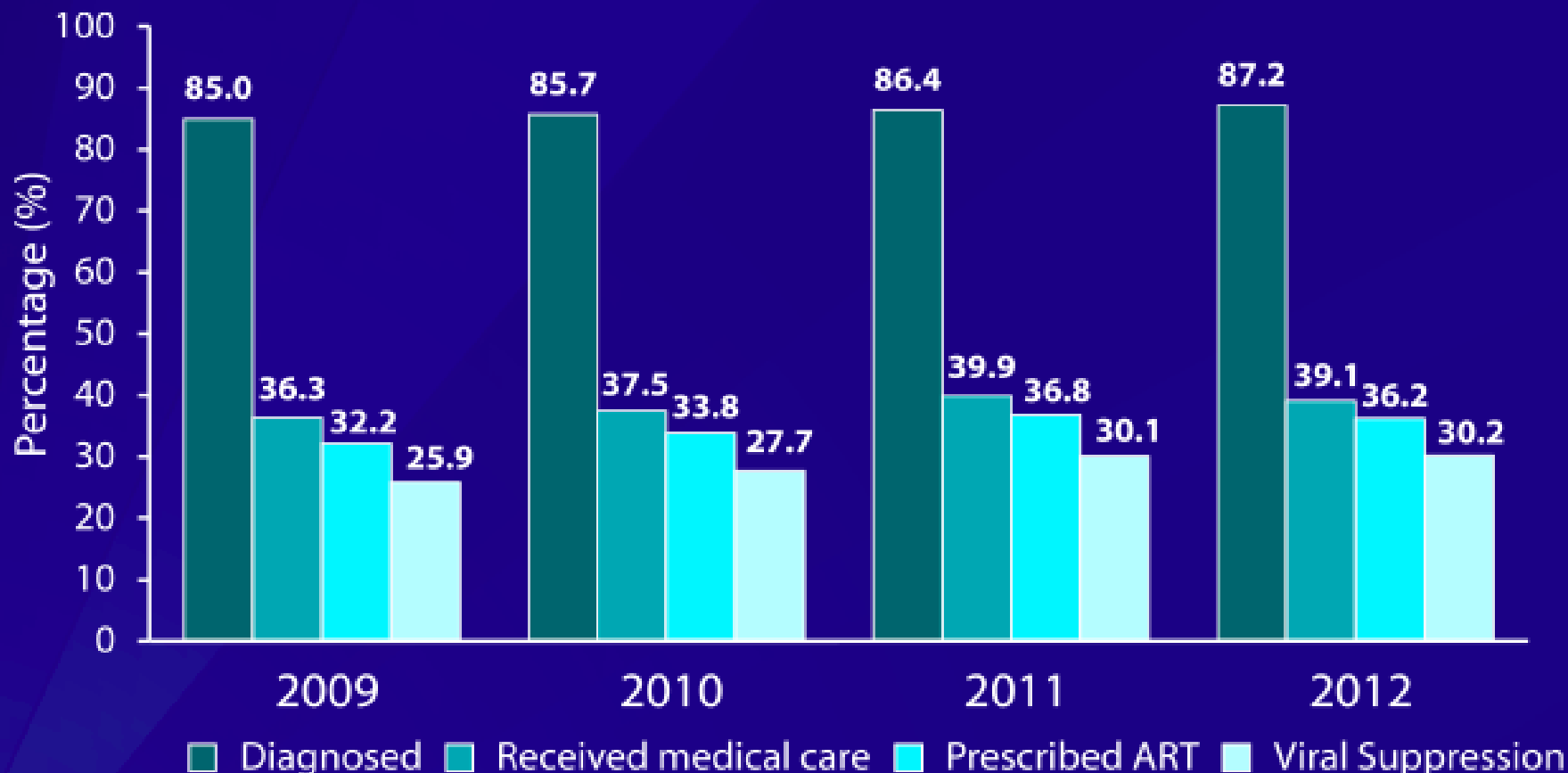
- American Indian/Alaska Native
- Asian American
- Black/African American
- Hispanic/Latino
- Native Hawaiian/Other Pacific Islander
- White
- Multiple races



HIV estimates: Transgender women

- Global
 - 19% prevalence, almost 50 x higher than general population
 - Based on a summary of 39 studies (2000-2011) in 19 countries
- US
 - 22% prevalence, highest in transwomen of color

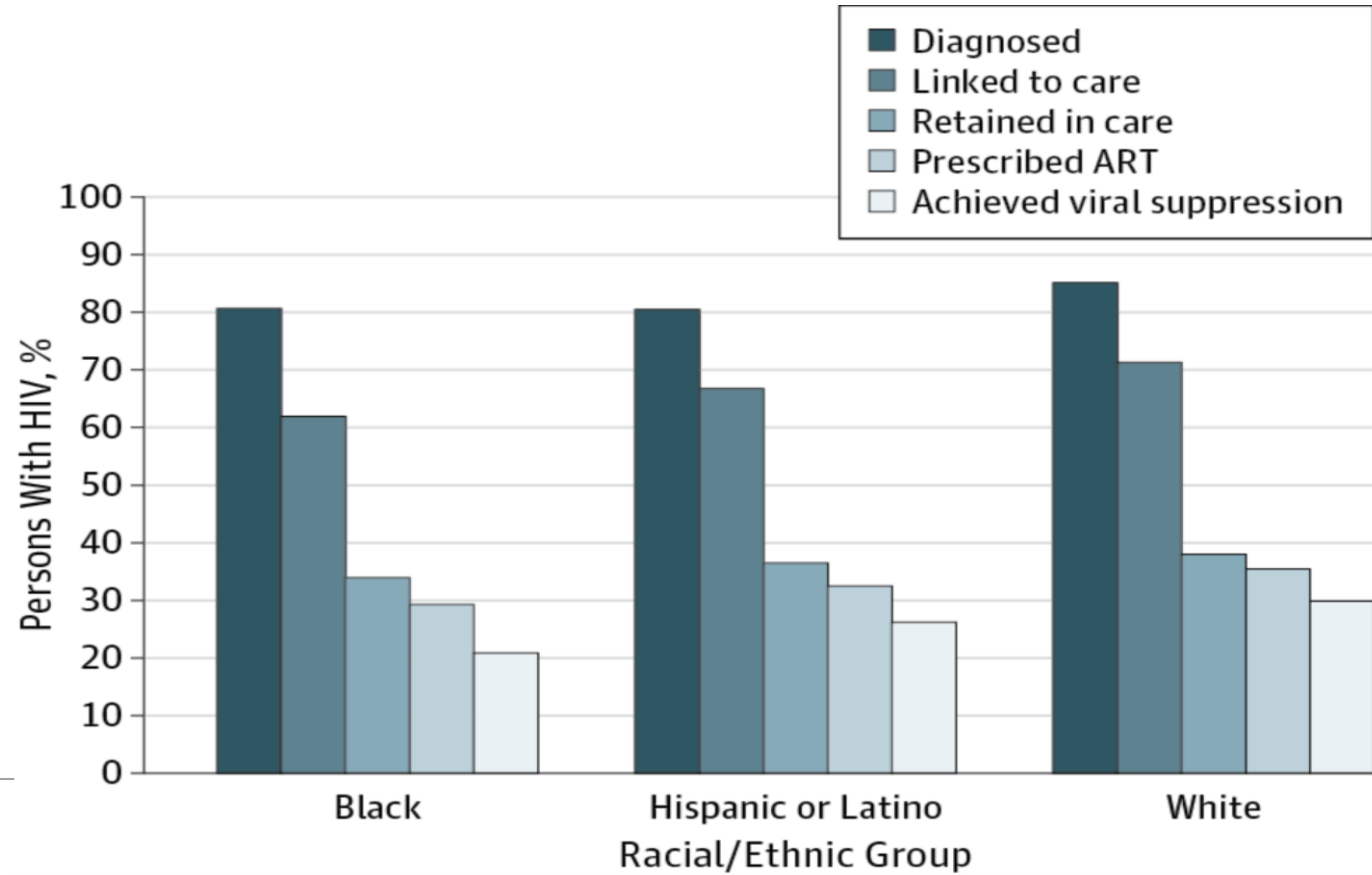
Persons Living with Diagnosed or Undiagnosed HIV Infection HIV Care Continuum Outcomes, 2009, 2010, 2011 and 2012 United States and Puerto Rico



National HIV Surveillance System: Estimated number of persons aged ≥ 13 years living with diagnosed or undiagnosed HIV infection (prevalence) in the United States at the end of the specified year. The estimated number of persons with diagnosed HIV infection was calculated as part of the overall prevalence estimate.

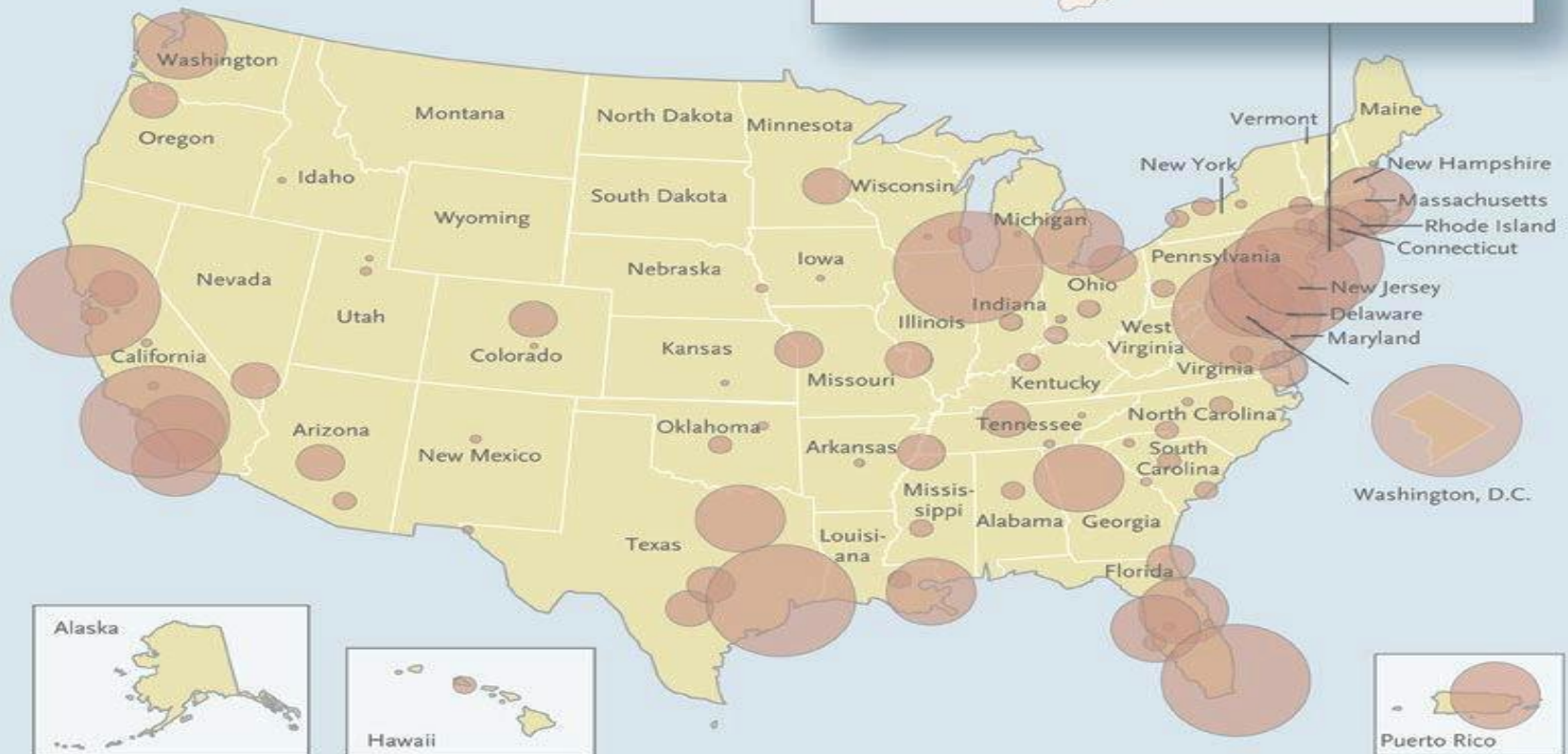
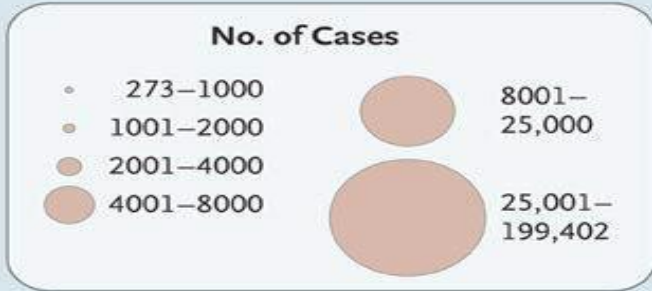
Medical Monitoring Project: Estimated number of persons aged ≥ 18 years who received HIV medical care during January to April of the specified year, were prescribed ART, or whose most recent VL in the previous year was undetectable or <200 copies/mL—United States and Puerto Rico.

Differences in HIV Care and Treatment by Race/Ethnicity in the US



Reported AIDS Cases By Metropolitan Area

El-Sadr W et al. N Engl J Med 2010;10.1056



HIV Prevention Research

Evidence-based Methods of HIV Prevention

Prevention for Negatives

- Condoms
- Male Circumcision
- PEP
- PrEP
 - Truvada once daily

Prevention for Positives

- HIV Testing
- Treatment as Prevention

Investigational Methods of HIV Prevention: Microbicides

- A substance that can reduce transmission of sexually transmitted infections (STIs), including HIV, when topically applied in the vagina or the rectum
- Gel, cream, or ring
- All microbicides are investigational at this time



CAPRISA 004

Tenofovir vaginal gel



889 women, 18-40 y in South Africa

randomized



tenofovir gel or placebo gel

Two years later:

39% Protection

July 2010:

Moderate protection and no safety concerns

Coital use:

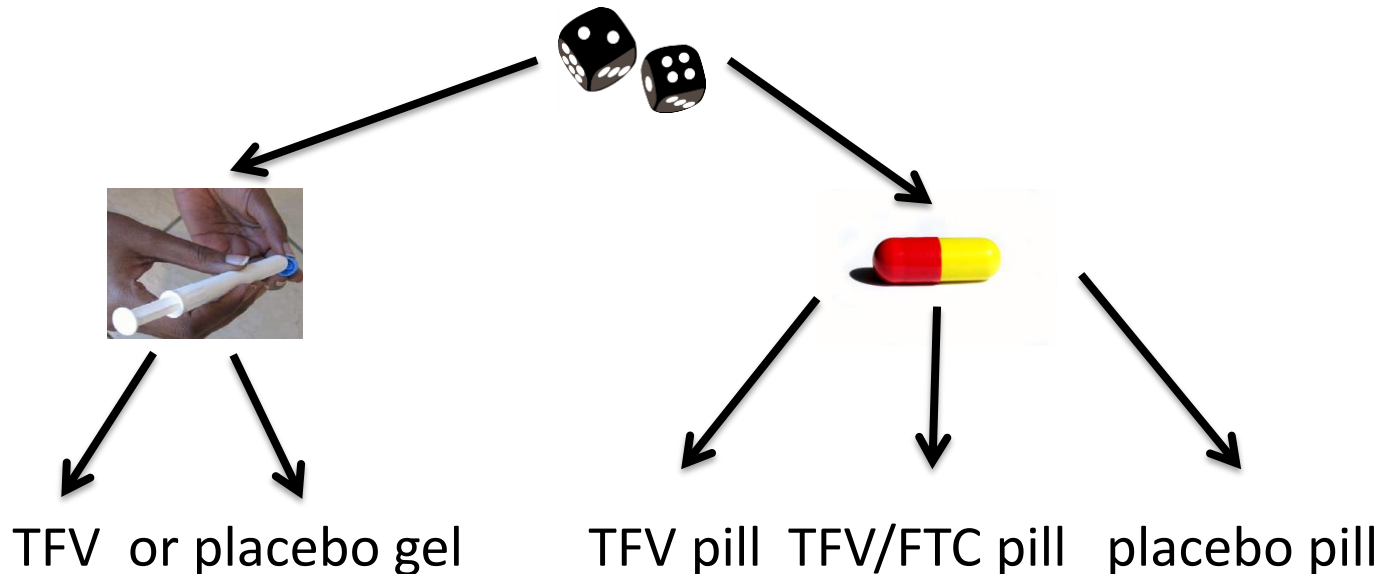
once within 12 hours before sex
and again 12 hours after sex,
and
no more than 2 doses in 24 hrs

VOICE Study

Vaginal & Oral Interventions to Control the Epidemic

First study to compare *daily* oral and vaginal PrEP

5,029 HIV-negative African women, 18-45 years of age



- September 2011: tenofovir pill arm stopped for futility
- November 2011: tenofovir and placebo gel stopped for futility

MTN-020-ASPIRE

Dapivirine Ring Study



2629 women, 18-45 y in Malawi, SA, Uganda, Zimbabwe

randomized



Dapivirine Ring *or* Placebo Ring

Dosage:
Once per month with
replacement

3 years later:

Feb 2016
No safety concerns

**27% protection; 37% with
higher adherence; 61% among
women > 25 y**

IPM: The Ring Study

Dapivirine Ring Study



1959 women, 18-45 y in South Africa and Uganda

randomized



Dapivirine Ring *or* Placebo Ring

Dosage:
Once per month
with replacement

3 years later:

31% protection; 37% among women > 21 y

Feb 2016:

No safety concerns

Injectable PrEP: HTPN 076 rilpivirine (TMC278 LA) Safety Study



120 women 18-45 y in SA, Zimbabwe, Bronx, Newark

randomized



TMC278 LA

or Placebo

Dosage:
2 injections every 8 weeks



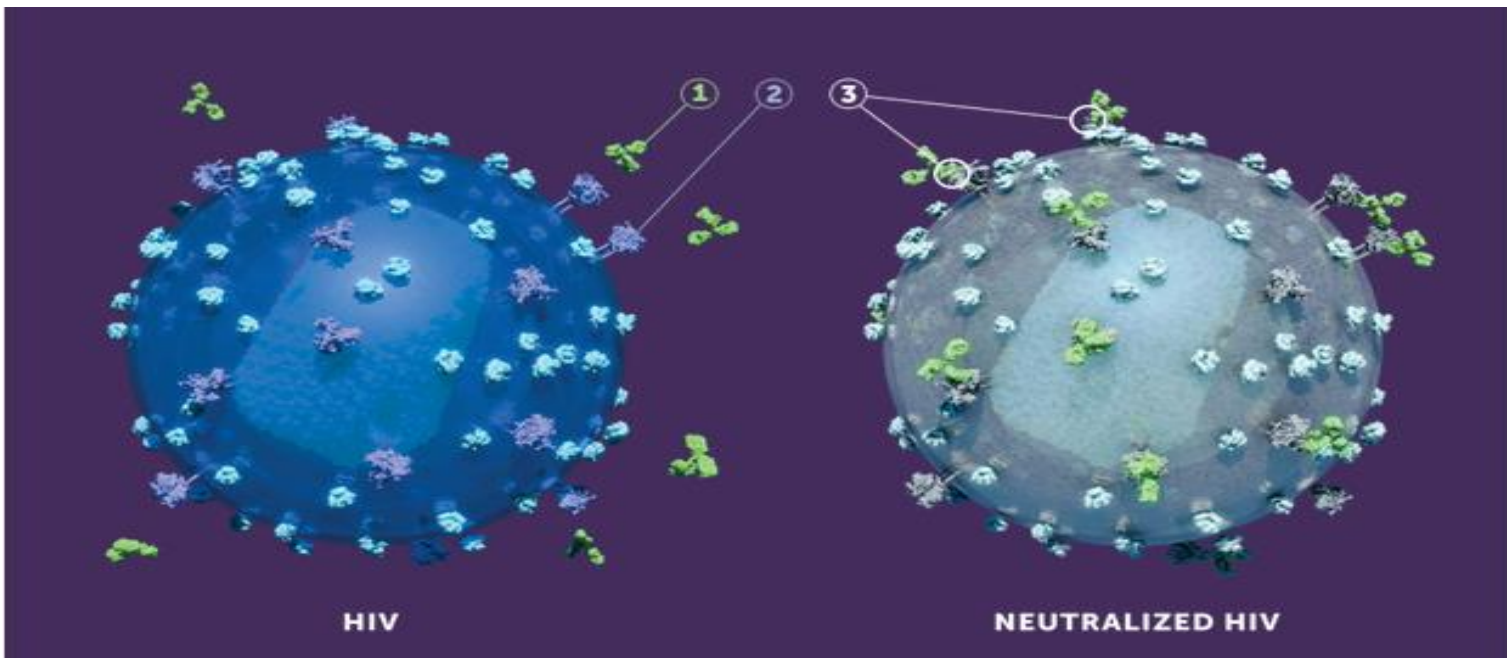
1.5 years later:

Ongoing

Vaccines and HIV Prevention Research

Neutralizing Antibodies: VRC01

- VRC01 attaches to HIV at CD4 binding sites and prevents the virus from binding to T-cells



HVTN 704/HTPN 085

“Antibody Mediated Prevention “ efficacy study



2700 MSM or TGPSM in US, Brazil, Peru

randomized



VRC01 (bnAb)

or

Placebo



Dosage:
Intravenous infusion
every 8 weeks

1.5 years later:

Ongoing

- A parallel study, HVTN 703/HPTN 081, will be initiated later this year in sub-Saharan Africa and will enroll 1500 sexually active HIV-neg women

Summary

Global epidemic, ART scale-up and 90-90-90

-an opportunity to 'race to the end'

US epidemic and race

-will ART scale-up lessen the disparities?

Prevention research

-evidence-based methods and adherence

-investigational methods: less adherence needed

-will these methods offer enough protection?

-importance of making them accessible to those who need them the most

Thank you!

More info on HIV prevention interventions and research:

www.mtnstopshiv.org

www.avac.org

www.hptn.org

Thanks to Ivy Mushamiri