

Towards and AIDS Free Generation

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“We are winning this fight. But the fight is not over, not by a long shot... We just have to keep at it, steady, persistent, today, tomorrow and every day until we get to zero. ...we have come so far; we have saved so many lives. We might as well finish the fight.”

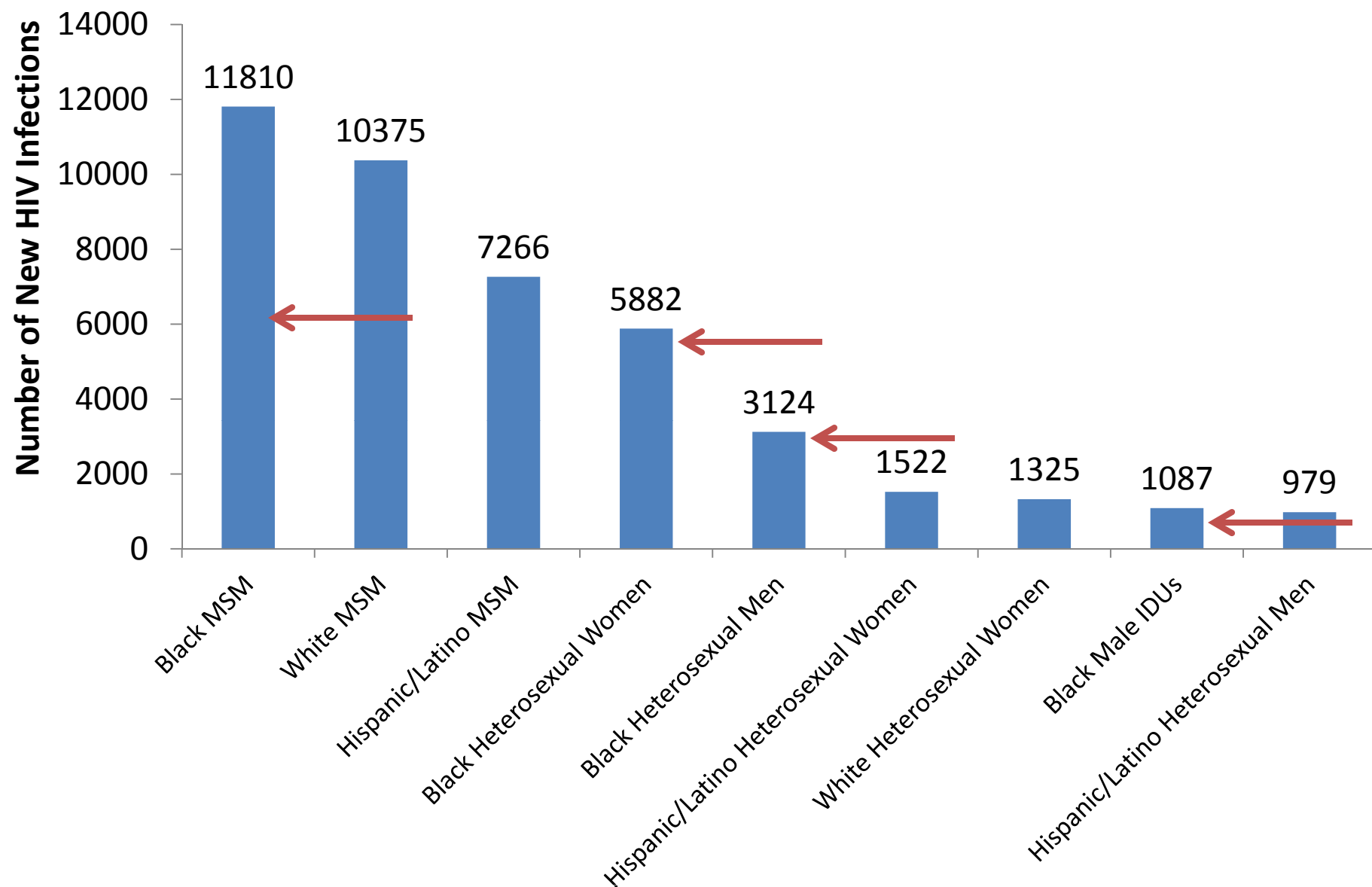
-President Barack Obama ‘12

Overview

- HIV/AIDS Epidemiological Data
- Vaccine
- Treatment as Prevention
- Closing the Gap
- Achieving an AIDS Free Generation

HIV in the United States

- More than 1.1 million people in the U.S. are living with HIV infection
- Almost 1 in 5 (18.1%) are unaware of their infection
- By race, Blacks/African Americans face the most severe burden
- Gay, bisexual, and other men who have sex with men (MSM), particularly young Black/African American MSM (BMSM), are most seriously affected



Estimated New HIV Infections in the United States and 6 Dependent Areas, 2011, for the Most Affected Subpopulations - CDC

HIV in African Americans

- Experience the most disproportionate burden compared with other races and ethnicities
- Represent approximately 12% of the U.S. population, but accounted for 46% of new HIV infections in 2011
- Since the epidemic began, more than 260,800 Blacks with an AIDS diagnosis have died

Traditional HIV Prevention Activities

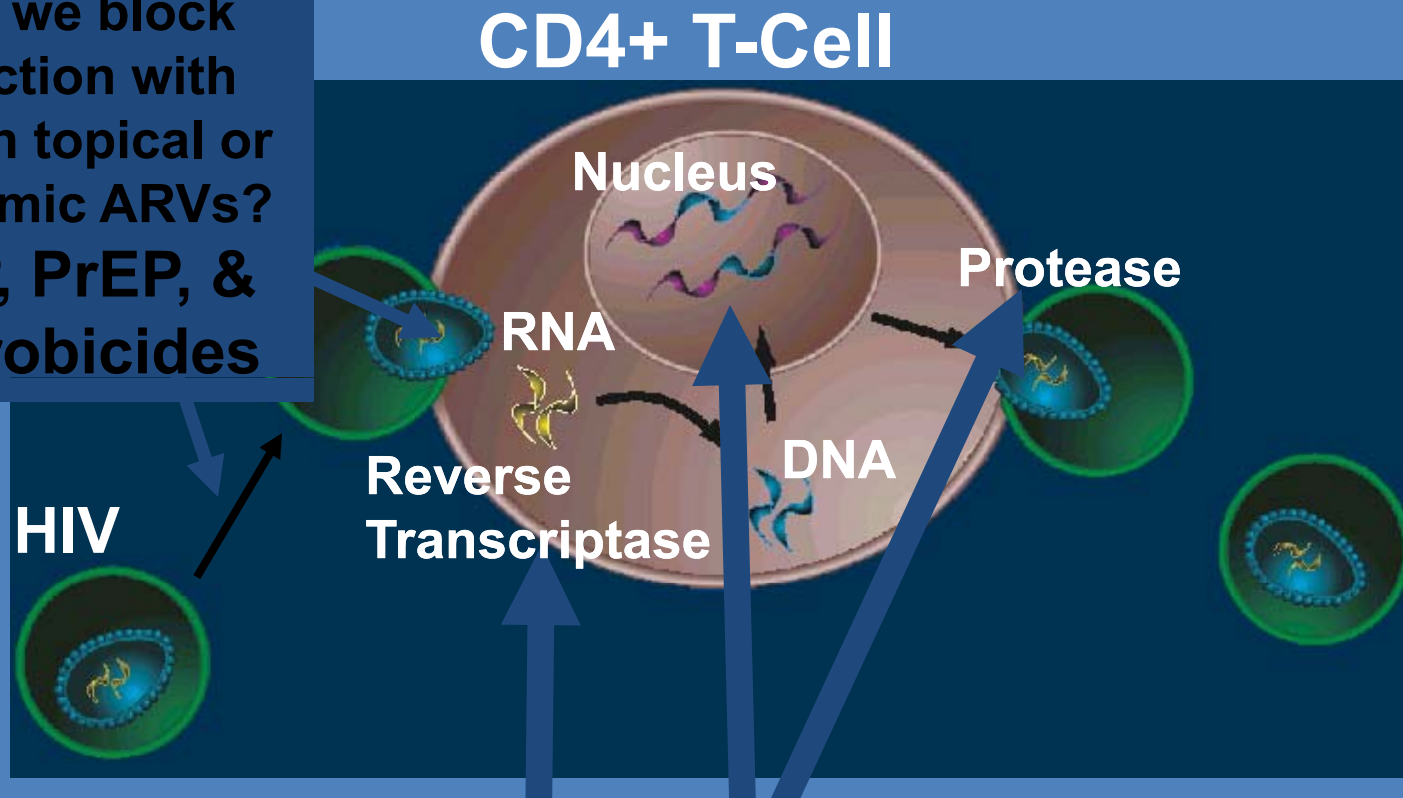
- Education and behavior modification
- HIV counseling and testing
- Access to condoms
- Partner notification and referral services
- Behavioral interventions (DEBIs) - individual, small-group, and community
- Substance abuse treatment and needle exchange
- Screening and treatment for other STDs

Biomedical Approaches to Prevention

- Vaccines
- Male circumcision
- Pre-exposure prophylaxis (PrEP)
- Female-controlled barrier methods/
Microbicides
- Antiretroviral treatment

ARVs for Prevention

Can we block infection with ...with topical or systemic ARVs? PEP, PrEP, & Microbicides



Can we treat the infected partner with cART and protect the sexual partner?
ART for prevention



VACCINES

What is a Vaccine?

- A substance that teaches the immune system how to protect itself against a virus/bacteria
- AIDS vaccines cannot cause HIV
- No vaccine is 100 effective

HPTN 505

Overview of Study Design

- Randomized (1:1 vaccine: placebo), double-blind, placebo-controlled, test of concept trial
- 2500 healthy, HIV-uninfected men, and transgender women, who have sex with men
- Eligibility:
 - Adenovirus serotype 5 neutralizing antibody negative
 - Fully circumcised
 - Ages 18-50 years
- Primary follow-up: 24 months post-entry
 - HIV testing every 3 months after month 9 visit
- Co-primary endpoints
 - HIV acquisition
 - Post infection viral load setpoint
 - Safety

Study Questions

- **Safety**
 - Is this vaccine well-tolerated by people who receive it?
- **Efficacy**
 - Does this vaccine prevent infection with HIV?
 - Does this vaccine reduce the amount of HIV in the blood (viral load) of people who become infected with HIV?

Status of HVTN 505

- The vaccine did not protect against HIV infection
- The vaccine did not reduce the viral load in people who became infected
- Futility criteria were met, so vaccinations were stopped
- Participants were unblinded to their treatment assignment and are in active follow-up

Next Steps

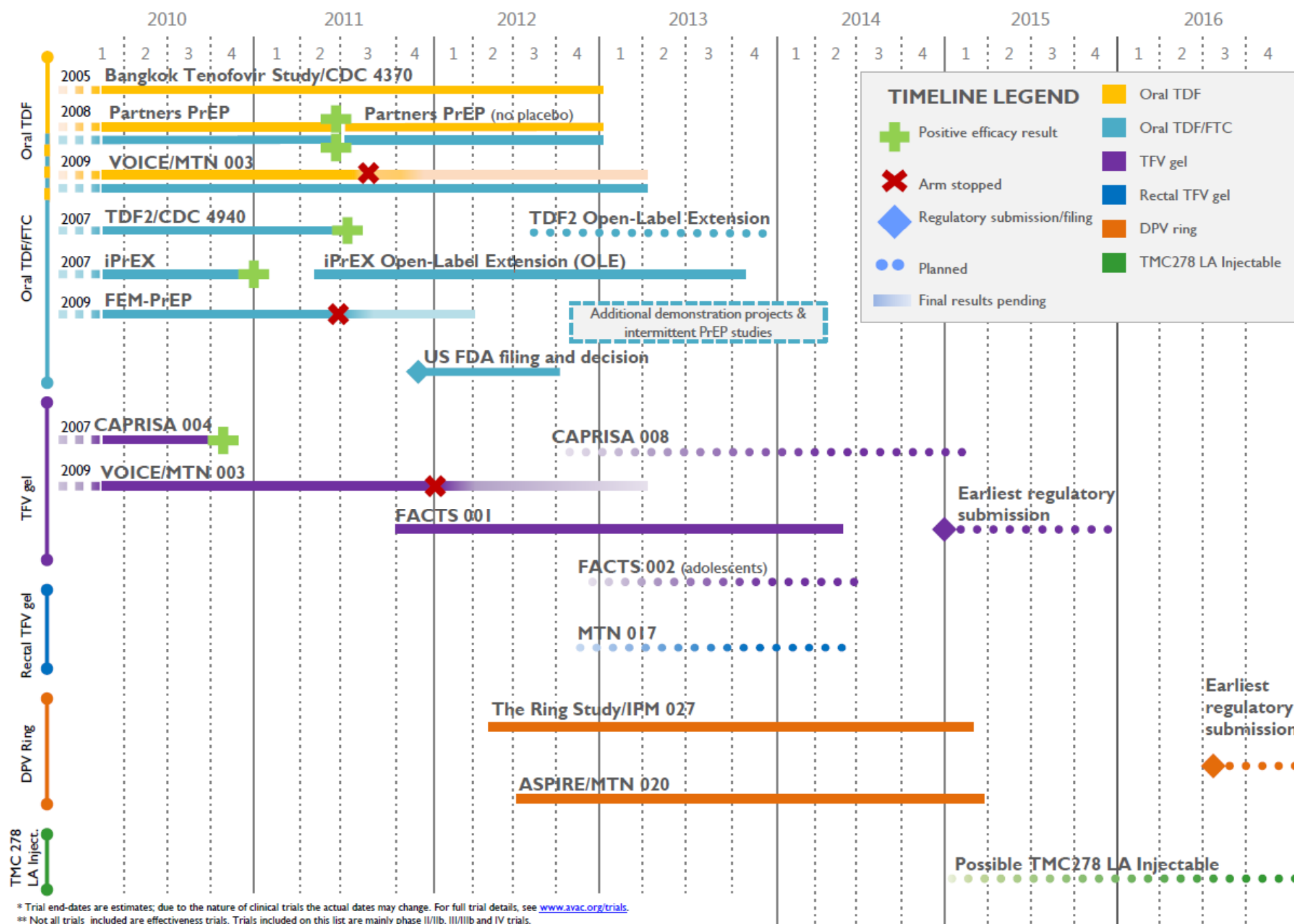
- Follow-up of volunteers continues
- The study is ongoing, study visits and procedures (except vaccinations) continue as scheduled.
- Participants continue to receive risk reduction counseling at every visit.
- Work continues to determine the reason for the results we have seen.



PREP, PEP, MICROBICIDES

ARV-Based Prevention Options Timeline **

AVAC, September 2012



Efficacy Trials

Study Population	PrEP Agent	#of HIV Infections		PrEP Efficacy
		PrEP	Placebo	
iPREX – MSM (Brazil, Ecuador, Peru, South Africa, Thailand, US) n=2499	FTC/TDF	36	64	44% (15-63%) Grant et al N Engl J Med 2010
Partners PrEP Heterosexual Couples Kenya, Uganda n=4758	TDF	17	52	67% (44-81%)
	FTC/TDF	13		75% (55-87%) Baeten et al. N Engl J Med 2012
TDF2 Study Heterosexual Botswana n=1219	FTC/TDF	10	26	62% (16-83%) Thigpen et al N Engl J Med 2012

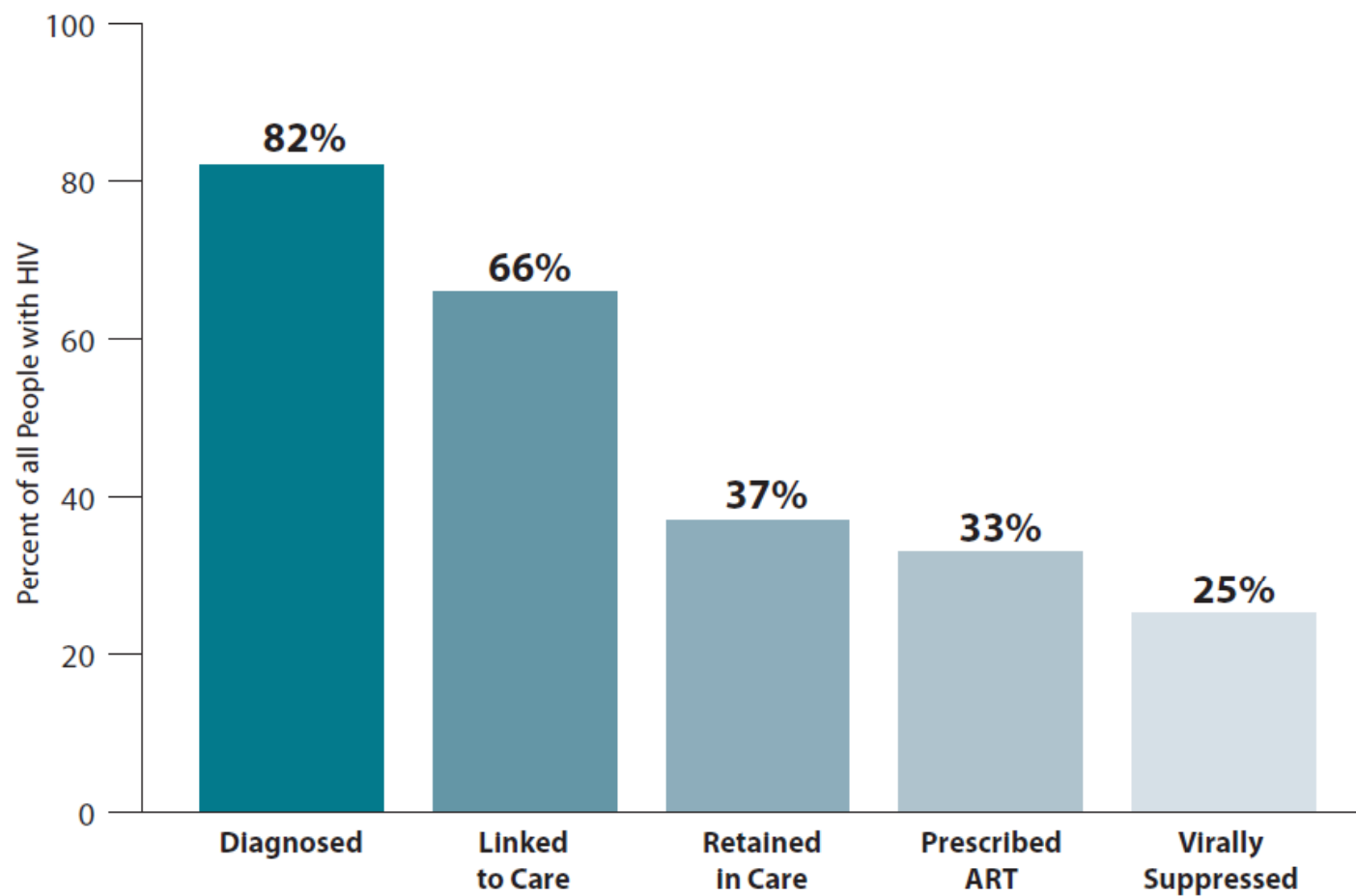


TREATMENT AS PREVENTION

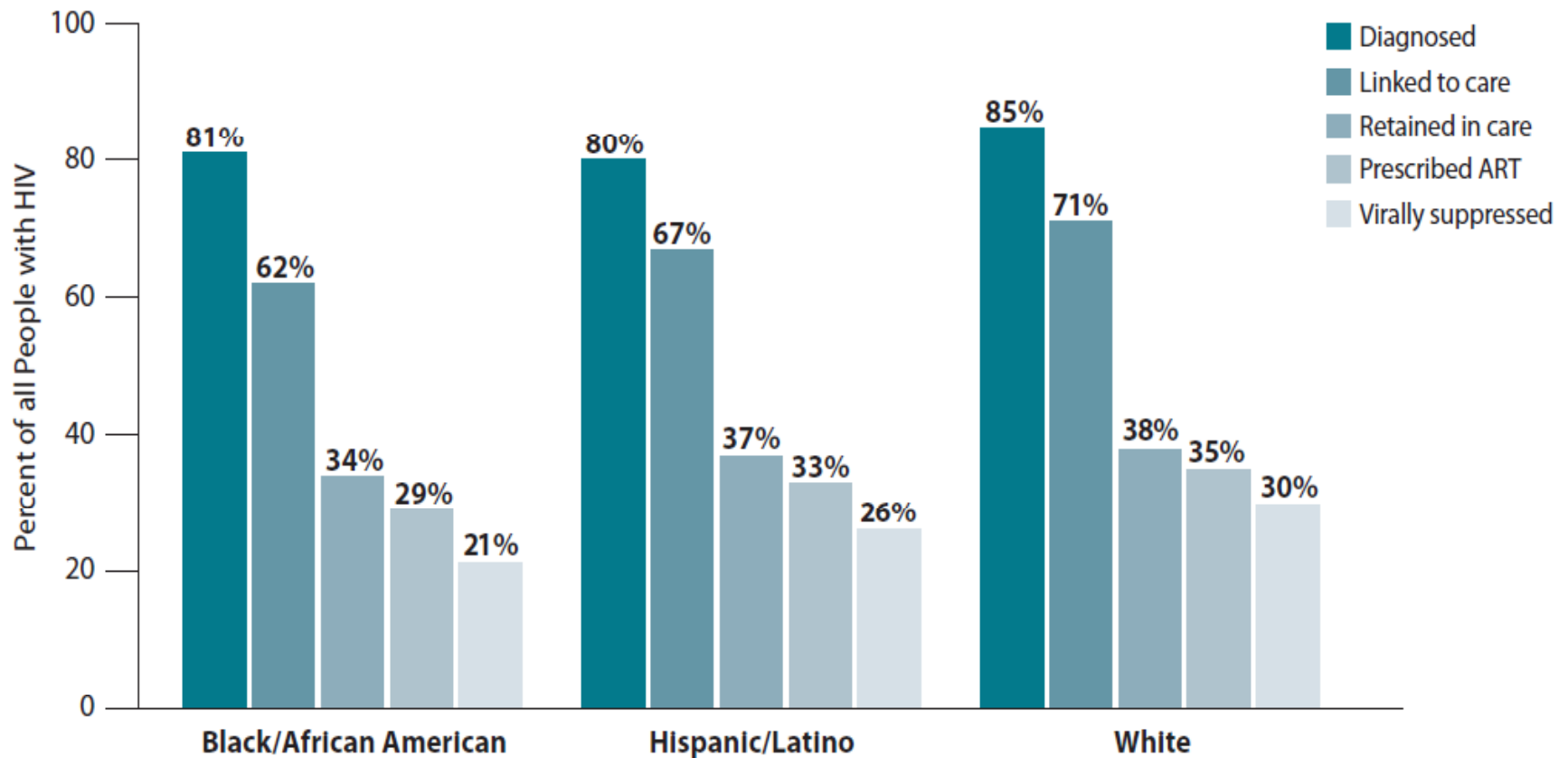
What is TaSP?

- Treatment as prevention is the use of medications for the tx of HIV to reduce the transmission of HIV
- A key tool for accelerating an “AIDS Free Generation”
- Does not work overnight
- Is not impossible

OVERALL: Of the 1.1 million Americans living with HIV, only 25 percent are virally suppressed.



BY RACE/ETHNICITY: African Americans are least likely to be in ongoing care or to have their virus under control.



HPTN 052 Study Design

Stable, healthy, African, Asian and American serodiscordant couples, sexually active

CD4 count: 350 to 550 cells/mm³

Randomization

Immediate ART
CD4 350-550

Delayed ART
CD4 ≤ 250

Primary Transmission Endpoint

Virologically-linked transmission events

Primary Clinical Endpoint

WHO stage 4 clinical events, pulmonary tuberculosis, severe bacterial infection and/or death

HPTN 052 Prevention Results

- 28 linked infections – within the dyad
 - 27 delayed arm
 - 1 immediate arm

> $p < 0.001$ **96% efficacy**

➤ 17 of 27 transmissions in delayed arm occurred when the index partners' CD4+ was >350 cells/ μL
- 7 unlinked infections – from outside
 - 4 delayed arm
 - 3 immediate arm
- 4 additional infections still being evaluated, all in delayed arm

WHERE TO NEXT?

Closing the Gap

- Improvements are needed at each stage of the process
- HIV testing
- Ensuring Access to care
- Achieve and maintain viral suppression
- Remove stigma

Engaging Community

- Address poverty
- Increase Awareness
- Become open and honest
- Engage our communities

For More Information

- www.avac.org
- www.hptn.org
- www.nih.gov
- www.cdc.gov

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