

# *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.”*

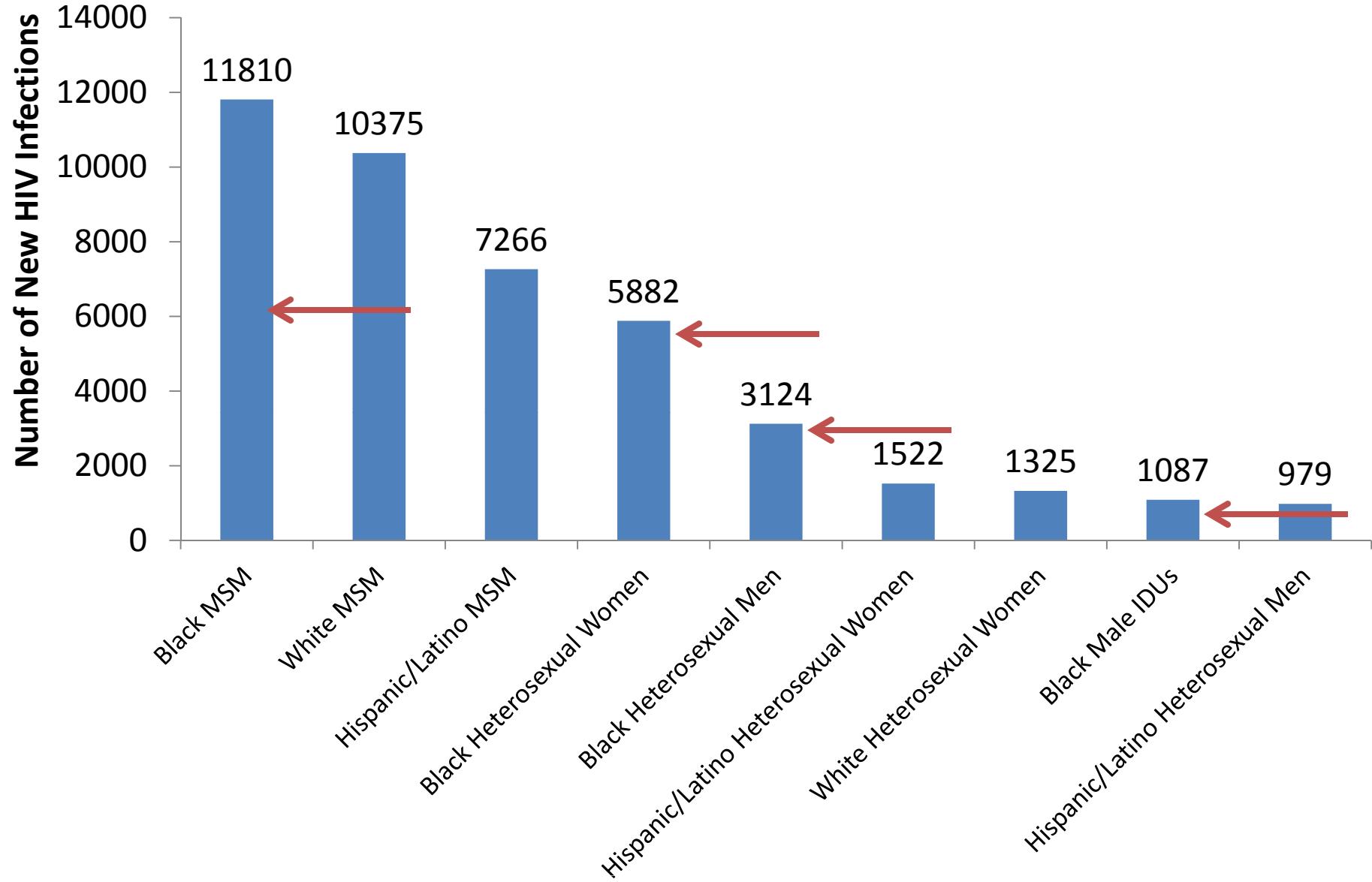
*-President Barack Obama '12*

## 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

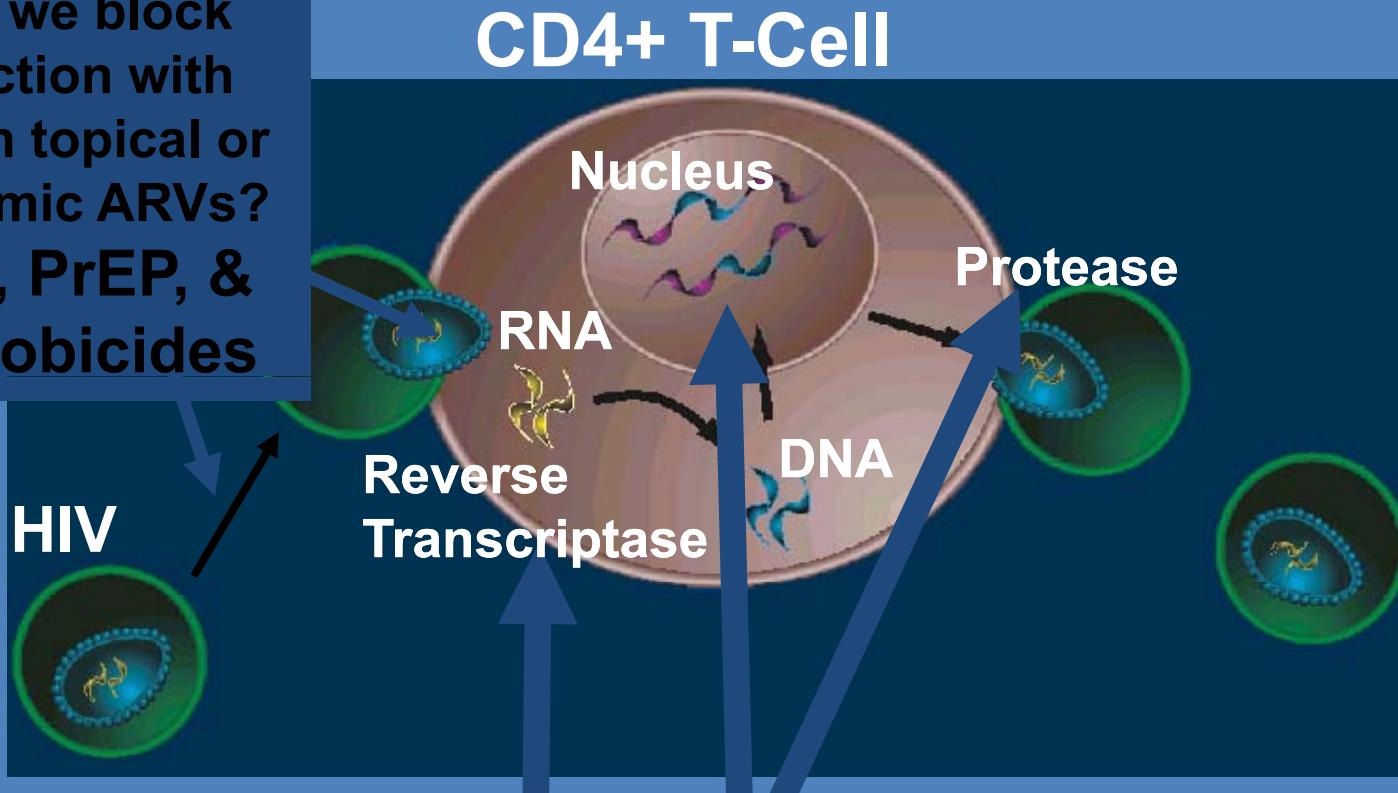
- Education and behavior modification
- HIV counseling and testing
- Access to condoms
- Partner notification and referral services
- Behavioral interventions (DEBIs) - individual, small-group, and community
- Substance abuse treatment and needle exchange
- Screening and treatment for other STDs

# 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

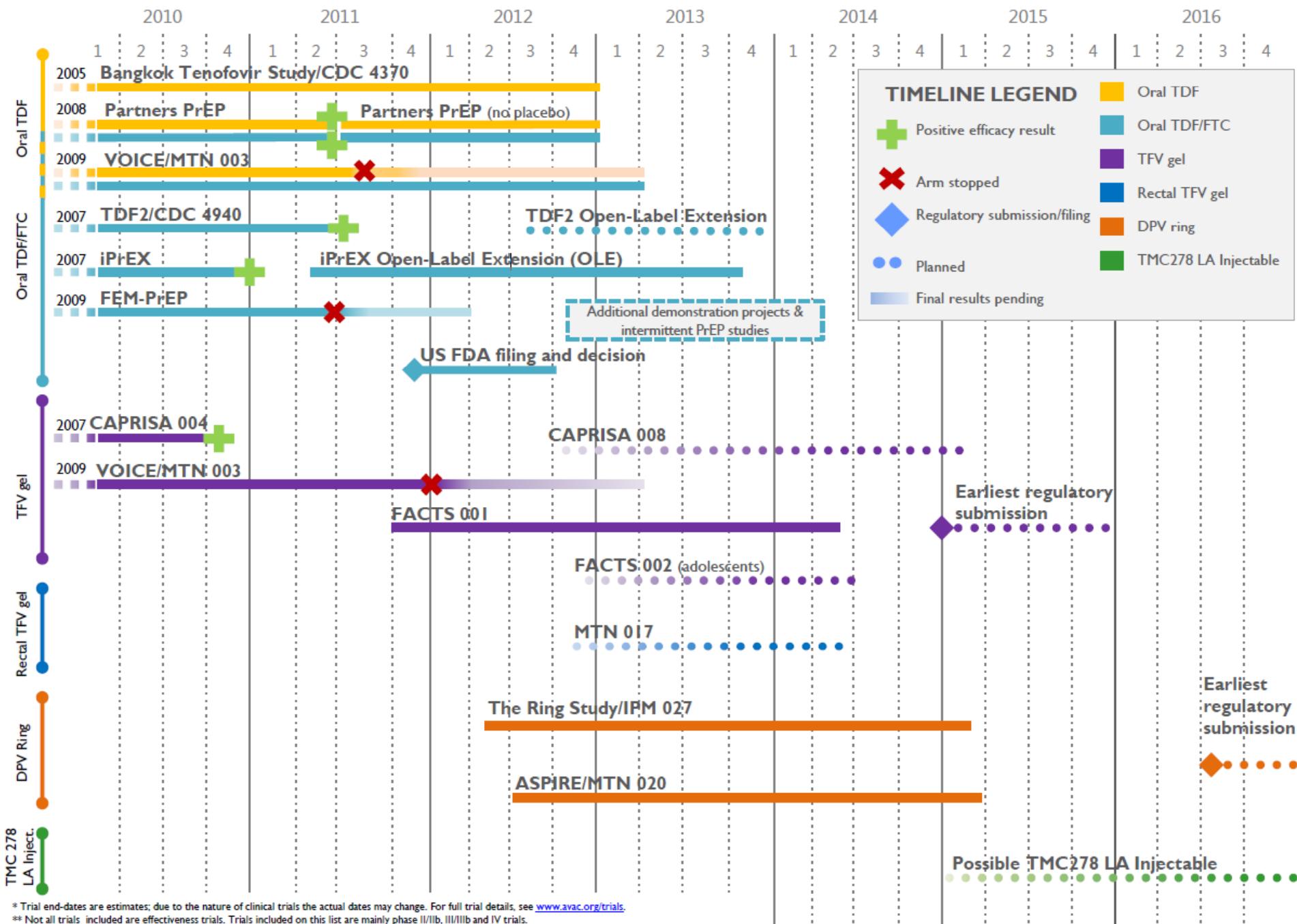
- Follow-up of volunteers continues
- The study is ongoing, study visits and procedures (except vaccinations) continue as scheduled.
- Participants continue to receive risk reduction counseling at every visit.
- Work continues to determine the reason for the results we have seen.

# PREP, PEP, MICROBICIDES



# ARV-Based Prevention Options Timeline \*\*\*

AVAC, September 2012



\* Trial end dates are estimates; due to the nature of clinical trials the actual dates may change. For full trial details, see [www.avac.org/trials](http://www.avac.org/trials).

\*\* Not all trials included are effectiveness trials. Trials included on this list are mainly phase II/IIb, III/IIIb and IV trials.

# 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

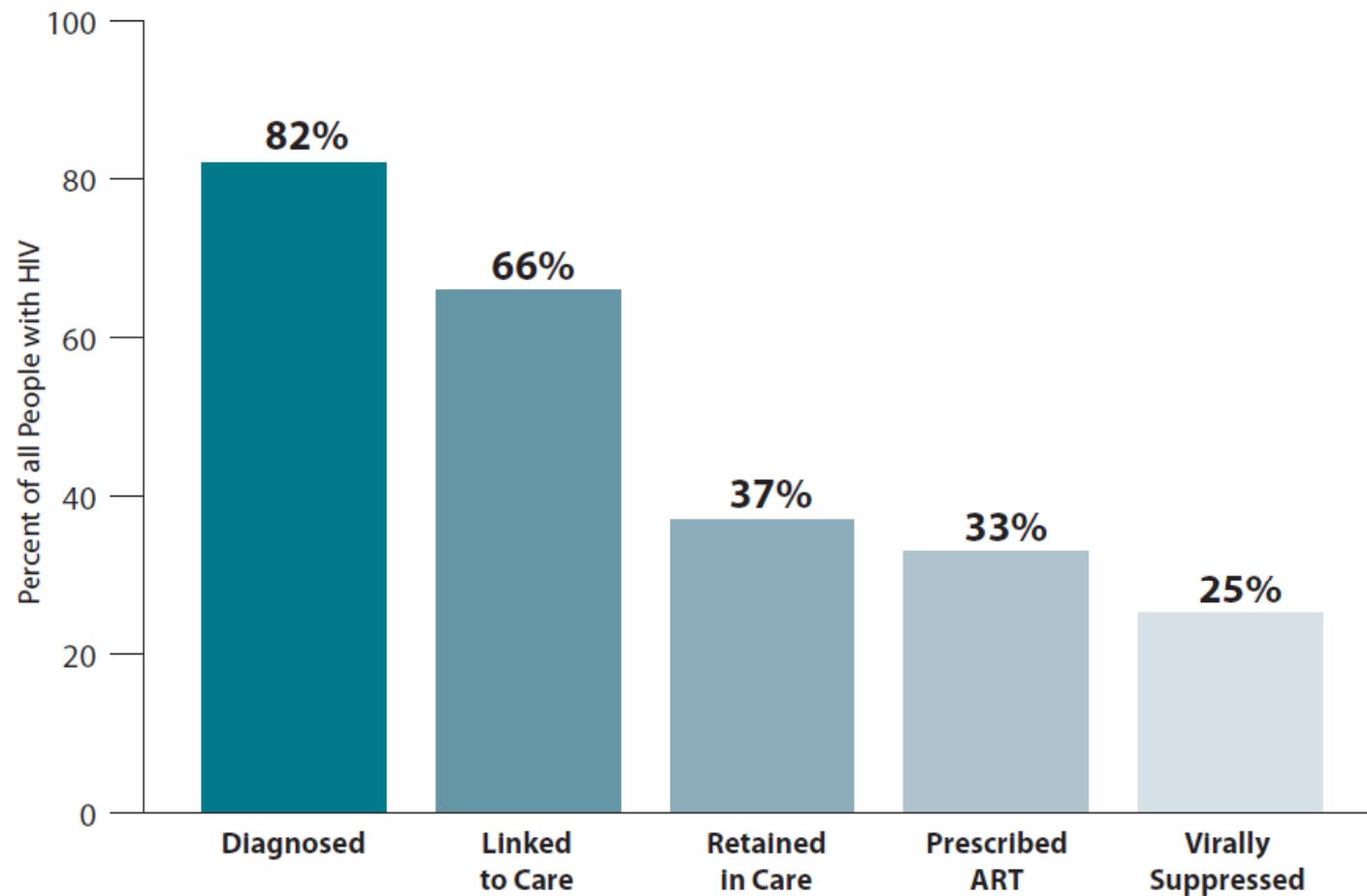
# TREATMENT AS PREVENTION



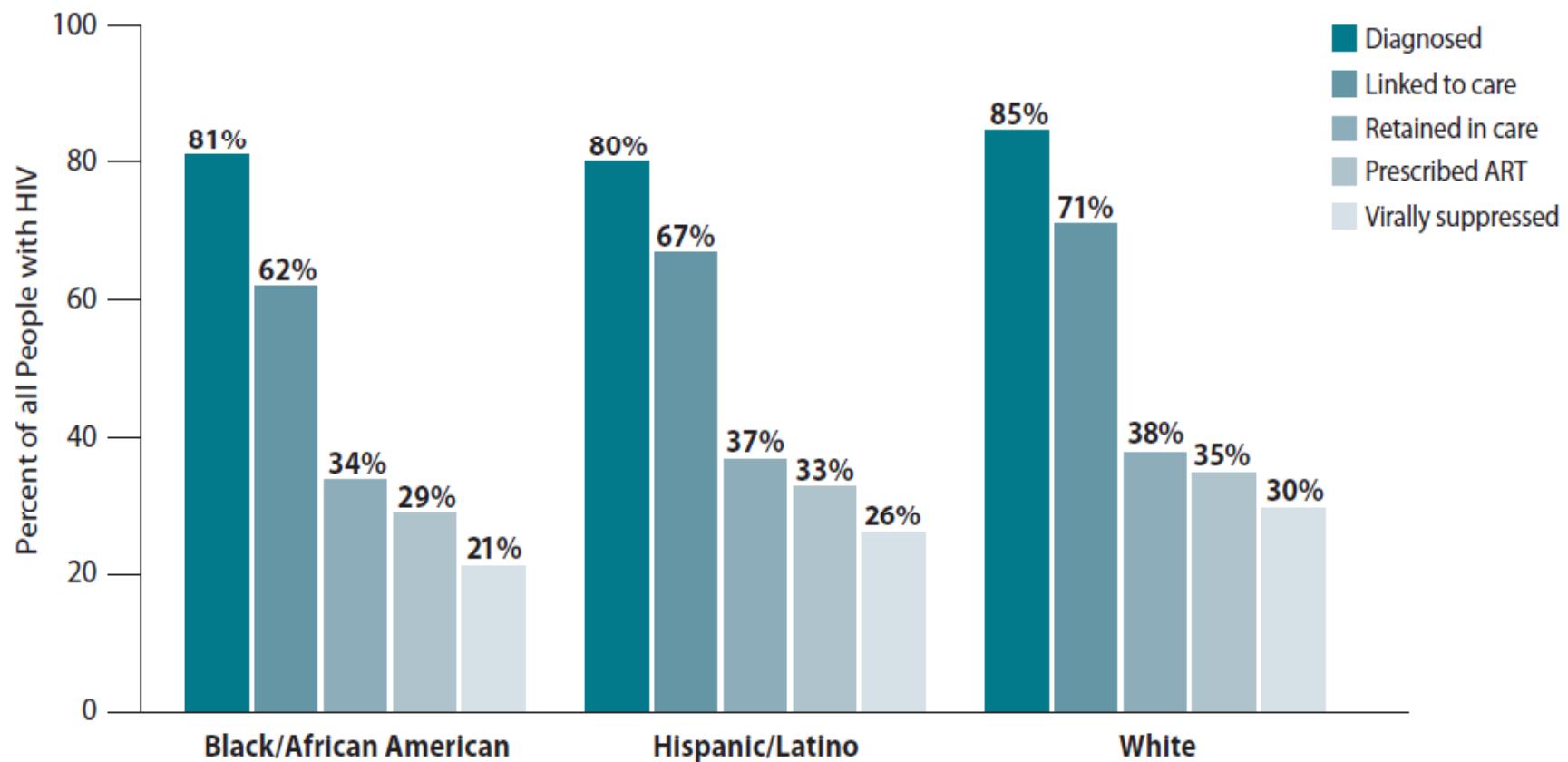
## What is TaSP?

- 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.**



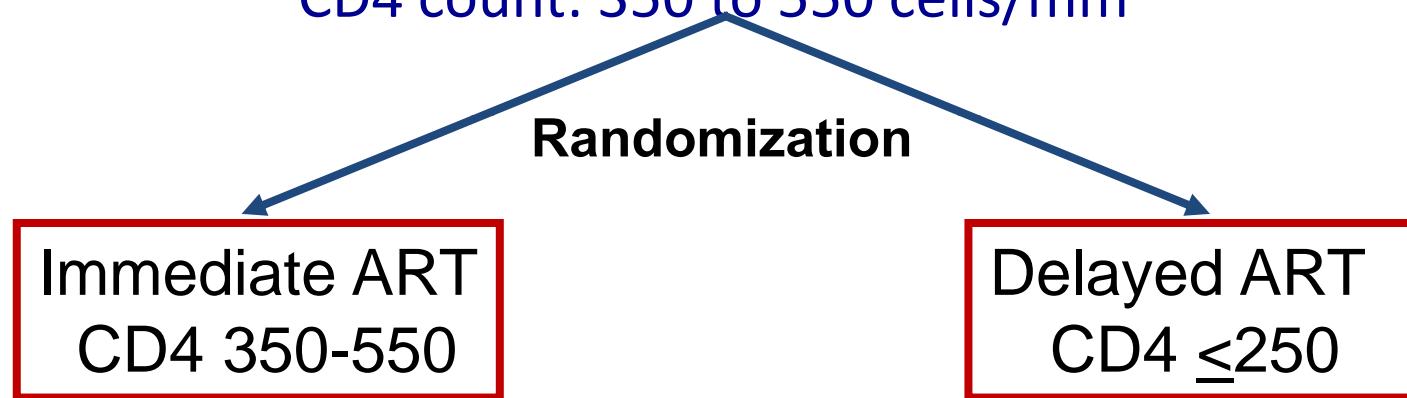
**BY RACE/ETHNICITY: African Americans are least likely to be in ongoing care or to have their virus under control.**



# HPTN 052 Study Design

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

CD4 count: 350 to 550 cells/mm<sup>3</sup>



**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/ $\mu$ L
- **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](http://www.avac.org)
- [www.hptn.org](http://www.hptn.org)
- [www.nih.gov](http://www.nih.gov)
- [www.cdc.gov](http://www.cdc.gov)

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