

HPTN 096
Getting to Zero among Black MSM in the American South:
Testing the Efficacy of an Integrated Intervention Strategy

The HIV Prevention Trials Network, HPTN, is conducting a large-scale study in selected Ending the Epidemic (EHE) initiative communities with a focus on improving HIV outcomes for Black men who have sex with men (MSM) in the U.S. South. The project, HPTN 096: Building Equity Through Advocacy, is being led by three co-chairs, Dr. LaRon Nelson from Yale University, Dr. Robert Remien from Columbia University, and Dr. Chris Beyrer from Johns Hopkins University, along with a multi-disciplinary team which includes researchers from U.S. universities, the Centers for Disease Control and Prevention (CDC), the Health Services Research Administration (HRSA), the National Institutes of Health (NIH), Fred Hutchinson Cancer Research Center, FHI 360 and several community partners.

We are seeking to conduct HPTN 096 in collaborative partnership with EHE Planning Committees, health departments, community stakeholders and health service facilities. We believe that by working together to improve outcomes among Black MSM, we will increase our chances of success in achieving the goals of EHE. A brief description of the project is included below.

Purpose: The purpose of HPTN 096 is to assess an integrated, HIV status-neutral, population-based approach designed to reduce HIV incidence among Black MSM in the U.S. South by increasing HIV testing, pre-exposure prophylaxis (PrEP) use among Black MSM living without HIV, and viral suppression rates among Black MSM living with HIV.

Design: This will be a community-randomized intervention package that includes a combination of community-, organizational-, interpersonal-level interventions, as outlined in the table below. Cross-sectional baseline and endpoint assessments will be conducted at the start and end of the 3-year intervention period to measure study outcomes.

Intervention	Health Equity	Social Media Influencers	Intersectional Stigma Reduction	Peer Support
Level	Community	Community	Organizational	Interpersonal
Increased HIV testing	X	X	X	X
Increased PrEP uptake and adherence	X	X	X	X
Increased ART uptake and viral suppression	X	X	X	X

Prior to implementation of the full study, the team will conduct a pilot in order to establish partnerships within each participating community, test out implementation of the intervention components, identify challenges, improve the interventions and refine the implementation strategy. The pilot will take place in a subset of both intervention and standard-of-care (control) communities (2 pairs, 4 study communities). During the pilot phase, all communities will be preparing for full study implementation after the pilot ends.

Interventions: The four study components that make up the intervention package are described below.

- **Health equity:** This community-level intervention will use a replicable and scalable community coalition model to promote health equity for Black MSM through capacity-building for leadership and advocacy in achieving health equity, community mobilization and education to amplify other HPTN 096 components, cross-sector cooperation and sensitization of local service providers to the needs of Black MSM, and facilitating linkage of Black MSM to those service providers.
- **Social media influencers:** In this community-level intervention, social media influencers (SMI) will provide tailored messaging prioritizing Black MSM in intervention communities on the topics of HIV testing promotion, PrEP awareness and promotion and the benefits of viral suppression messaging.
- **Intersectional stigma reduction:** This organizational-level intervention will take place in healthcare facilities and is designed to optimize the healthcare environment for Black MSM by addressing the intersectional experience of racism, sexual stigma, gender nonconformity stigma, and HIV-related stigma through training, collaborative quality improvement and technical assistance.
- **Peer support:** In this interpersonal-level intervention, Black MSM will be trained as HIV peer support workers to provide emotional and practical support to Black MSM. Once trained, they will have demonstrated competencies in HIV testing and diagnoses, PrEP uptake, ART adherence, intersectional stigma, local resources, the multi-cultural facets of the epidemic and the provision of emotional support.

Baseline and Post-intervention Cross-Sectional Assessments: Two cross-sectional assessments will be conducted for this study: one at baseline, the other after the three-year intervention ends. A starfish sampling approach (the combination of venue-time-based and respondent-driven sampling) will be employed to recruit and enroll individual participants in both intervention and standard-of-care (control) communities to complete the cross-sectional assessments. These brief assessments will include optional HIV rapid testing, blood collection and the completion of two surveys.

- Baseline: 16 communities, 100 Black MSM per community, 1600 total
- Post-intervention: 16 communities, 200 Black MSM per community, 3200 total

Study Sites: Sixteen communities were selected from the southern counties and states identified in the EHE plan. Eight communities were randomized to the interventions and eight communities were randomized to serve as the standard-of-care (control) communities.

Study Population: Adolescent (≥ 15 years old) and adult Black MSM (including both cis- and transmen).

Study Duration: Once the pilot is complete, full study implementation will take place over three years.

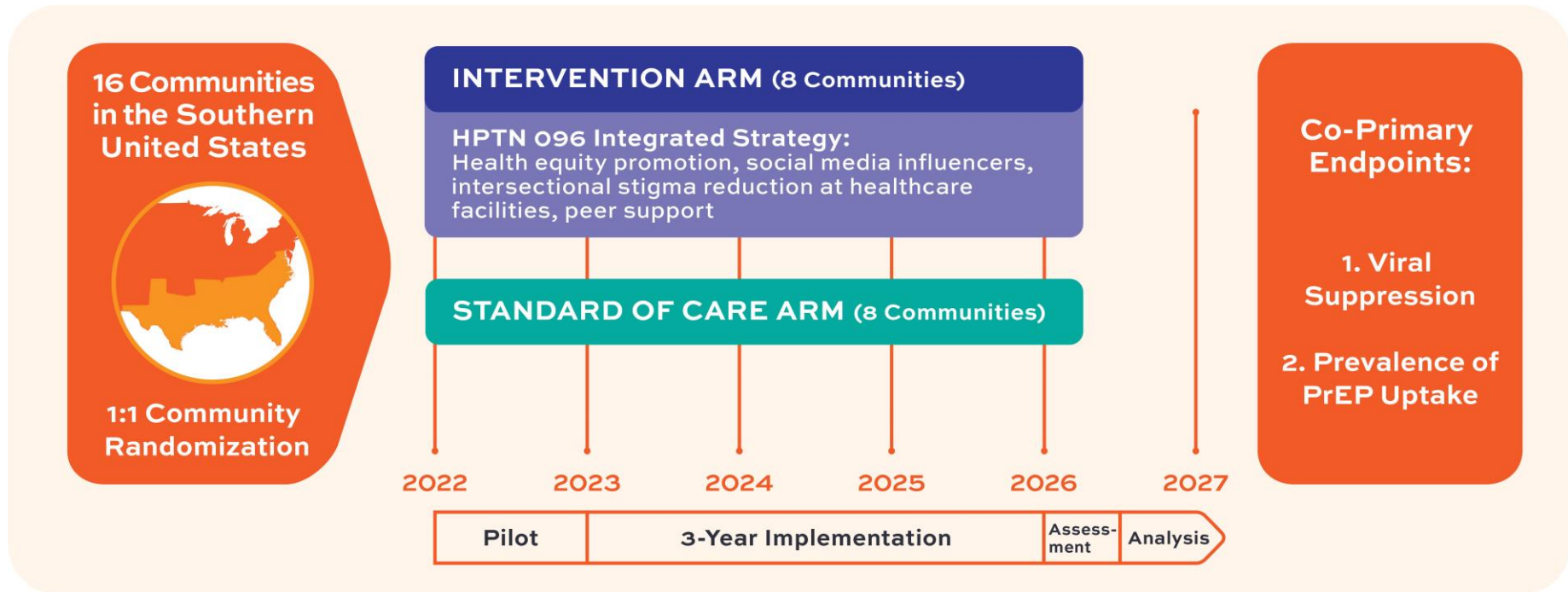
Activities for Intervention and Standard-of-Care (Control) Communities

Activities	Intervention Communities	Standard-of-Care (Control) Communities
Standard-of-care and EHE activities	X	X
Cross-sectional assessments	X	X
Community coalition building for health equity	X	
Increased SMI messaging	X	
Intersectional reduction at local healthcare facilities	X	
Access to peer support	X	

HPTN 096: Participating Communities and Pairs

Pair	Community	City	State	County
PILOT STUDY COMMUNITIES				
1	1	Greenville	SC	Greenville County
			SC	Spartanburg County
	2	Montgomery	AL	Montgomery County
			AL	Elmore County
			AL	Autauga County
2	3	Dallas	TX	Dallas County
			TX	Tarrant County
	4	Houston	TX	Harris County
NON-PILOT STUDY COMMUNITIES				
3	5	Atlanta	GA	Cobb County
			GA	DeKalb County
			GA	Fulton County
			GA	Gwinnett County
	6	DC/MD suburbs	DC	Washington DC
			MD	Montgomery County
			MD	Prince George's County
4	7	Columbia	SC	Lexington County
			SC	Richland County
			SC	Sumter County
	8	Birmingham	AL	Jefferson County
			AL	Shelby County
			AL	Tuscaloosa County
5	9	Charlotte	NC	Mecklenburg County
	10	Memphis	TN	Shelby County
6	11	Charleston	SC	Charleston County
			SC	Dorchester County
			SC	Berkeley County
	12	Mobile	AL	Mobile County
			AL	Baldwin County
			MS	Jackson County
7	13	Ft. Lauderdale	FL	Broward County
			LA	East Baton Rouge Parish
	14	Baton Rouge/New Orleans	LA	Orleans Parish
			LA	Jefferson Parish
8	15	Jackson	MS	Hinds County
			MS	Madison County
			MS	Rankin County
	16	Orlando	FL	Orange County

Study Design and Estimated Timeline



How Does the Integrated Strategy Work?

