HPTN 096

Getting to Zero among Highest HIV Incidence (HHI) Men who have Sex with Men (MSM) in the American South: Testing an Integrated Strategy

DAIDS Document ID: 38561

A Study by the HIV Prevention Trials Network (HPTN)

Sponsored by:

Division of AIDS (DAIDS), United States (US) National Institute of Allergy and Infectious Diseases (NIAID), US National Institutes of Health (NIH)

Non-IND Study

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FINAL Version 5.0

27 JUNE 2025

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I will conduct the study in accordance with the provisions of this protocol and all applicable protocol-related documents. I agree to conduct this study in compliance with United States (US) Health and Human Service regulations (45 CFR 46); applicable US Food and Drug Administration regulations; standards of the International Council for Harmonisation Guideline for Good Clinical Practice (E6); Institutional Review Board/Ethics Committee determinations; all applicable in-country, state, and local laws and regulations; and other applicable requirements (e.g., US National Institutes of Health, Division of AIDS) and institutional policies.

I have read and understand the information in this protocol and will ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about the obligations incurred by their contribution to the study.

_____

Name of Investigator (print name)

_____ _____

Signature of Investigator Date (DD/MONTH/YYYY)

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LIST OF ABBREVIATIONS AND ACRONYMS

ACASI	Audio Computer Assisted Self-Interview
AIDS	Acquired Immunodeficiency Syndrome
AL	Alabama
AOR	adjusted odds ratio
API	Application Programming Interface
ART	antiretroviral therapy
BAC	blood alcohol content
CAB-LA	Long-Acting Injectable Cabotegravir
CABs	Community Advisory Boards
CAG	Community Advisory Group
CSG	Community Strategy Group
CBO	Community-Based Organization
CBPR	Community-Based Participatory Research
CDC	Centers for Disease Control and Prevention
CFIR	consolidated framework for implementation research
CI	confidence interval
CLO	Coalition Lead Organization
COVID-19	Coronavirus Disease 2019
DAIDS	Division of AIDS
DHHS	(US) Department of Health and Human Services
ECHO	Extension for Community Healthcare Outcomes
EHE	Ending the HIV Epidemic: A Plan for America
ESAP	Expanded Syringe Access Program
FHIR	Fast Healthcare Interoperability Resources
FL	Florida
FQHC	federally qualified health center
GA	Georgia
GEE	Generalized Estimating Equation
HCF	health care facility
HHI	Highest HIV Incidence
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HPTN	HIV Prevention Trials Network
HRSA	Health Resources and Services Administration
ICFs	informed consent forms
IRB	Institutional Review Board
IRLM	Implementation Research Logic Model
ITS	Interrupted Time Series
LGB	lesbian, gay, bisexual

LGB+	lesbian, gay, bisexual
LOC	(HPTN) Leadership and Operations Center
MOP	(HPTN) Manual of Operations
MSM	men who have sex with men
NIAID	(US) National Institute of Allergy and Infectious Diseases
NIH	(US) National Institutes of Health
NIR	network-individual-resource
OR	odds ratio
nPEP	non-occupational post-exposure prophylaxis
PHASE	Promoting Human Autonomy Supportive Environments
PrEP	pre-exposure prophylaxis
PTID	participant ID
QI	quality improvement
RCT(s)	randomized controlled trial(s)
SDMC	(HPTN) Statistical and Data Management Center
SDT	self-determination theory
sIRB	single IRB
SMC	(HPTN) Study Monitoring Committee
SMI	social media influencer
SSDOH	Social and Structural Determinants of Health
SSP	Study-specific Procedures (Manual)
STI(s)	sexually transmitted infection(s)
TA	technical assistance
TN	Tennessee
TX	Texas
UK	United Kingdom
US	United States
UTM	Urchin Tracking Module
VL	viral load

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HPTN 096

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SCHEMA

Purpose: The overall purpose of this study is to evaluate a status-neutral integrated strategy to improve access to and uptake of HIV prevention and treatment services for the highest HIV incidence (HHI) men who have sex with men (MSM) in participating communities. The ultimate goal is to establish a strategy to reduce HIV incidence among HHI MSM in the southern United States (US) by increasing the number of HHI MSM accessing prevention and treatment services, increasing uptake and use of pre-exposure prophylaxis (PrEP) among those living without HIV and increasing retention in care, and thus viral suppression, among those living with HIV.

Design: HPTN 096 is a hybrid implementation-efficacy trial that uses a single arm interrupted time series (ITS) design to test whether a status-neutral integrated strategy improves access to and uptake of HIV prevention and treatment services for HHI MSM. ITS measures a change in slope for the primary outcomes pre- and post-intervention using four one-year look backs of EMR data. The integrated strategy will be delivered in up to five selected communities in the southern US.

Integrated Strategy Components: The four study components of the integrated strategy are described below.

- **Health access coalitions:** This component will use a community coalition program as its base model for reducing structural barriers, shaping community social norms and raising awareness to reduce HIV among HHI MSM. This will be achieved through: 1) facilitating a reduction in social, structural, and policy barriers to HIV testing, PrEP, and viral suppression through fostering collective efficacy, promoting norms within the local service sectors (e.g., social, legal, economic, etc.), and advancing advocacy efforts that support the strategic prioritization of access to resources and services for HHI MSM; and 2) amplifying awareness, education, and capacity building around HIV prevention and treatment resources and messaging (including other HPTN 096 components).

- **Social media:** In this component, a robust social media strategy will be used to reach and engage HHI MSM throughout each participating community. Utilizing a multitude of social media communication and marketing tactics, social media content will be used to educate and empower HHI MSM so that they can make informed decisions and behavioral changes to stop HIV acquisition and transmission, with emphasis on accessing HIV prevention and treatment services, the uptake of PrEP and the importance of staying engaged in care and achieving viral suppression. In addition, the strategy will promote other study components, encouraging HHI MSM to engage in care at PHASE healthcare facilities (HCFs), seek help from peer supporters and take advantage of the environmental changes put in place via the health access coalitions.

- **Peer support:** In this component, peer supporters, who may possess a shared and/or lived experience, will provide HHI MSM with emotional and practical support, using a HIV-status neutral approach, as well as share information on locally available sexual health and HIV-related resources and support services. Peers may provide support in-person or virtually and may be housed at local community-based organizations. In addition, when appropriate, the use of PHASE HCFs will be encouraged for those seeking healthcare services.

- **Promoting Human Autonomy Supportive Environments (PHASE).** The PHASE component is an HCF-level training and quality improvement program designed to improve the provision of healthcare services for HHI MSM. PHASE aims to create an autonomy-supportive healthcare environment that supports HHI MSM engagement in HIV-related care and services and helps to promote increased HIV/STI testing, PrEP and ART uptake, retention in care, and viral suppression rates for HHI MSM. The primary study outcomes will be collected at all HCFs participating in PHASE.

Intervention Assessments: Primary outcomes will be measured using facility level evaluations based on electronic medical record (EMR) data from approximately 40 PHASE HCFs that provide HIV prevention services and approximately 20 PHASE HCFs that provide HIV treatment services across all five study communities. Secondary outcomes and primary intervention process outcomes will be measured via EMR data, questionnaires, qualitative data collection and social media metrics from 1) PHASE HCF staff and clients, 2) health access coalition members, 3) peer supporters and their clients, and 4) HHI MSM and other individuals who see and/or engage with the intervention's social media content.

Study Communities: The integrated strategy will be implemented in up to five southern communities, each made up of one or more counties. The five study communities are:

- Dallas, TX
- Montgomery, AL
- Ft. Lauderdale/Miami, FL
- Atlanta, GA
- Memphis, TN

Study Population: The study population will be HHI MSM residing in the five study communities. Primary study outcomes will be measured among HHI MSM at PHASE HCFs. Additionally, a subset of HHI MSM at PHASE HCFs, as well as PHASE HCF staff, community coalition members, peer supporters, and both HHI MSM and other individuals who engage with the intervention's social media content will also be assessed for secondary outcomes and primary intervention process outcomes.

Study Duration: Each study community will participate in the study for approximately 3.3 years, which includes one year of pre-implementation activities, 2 years of implementation of the integrated strategy, and 2.3 years of data collection (see Schema Figure 1). There is a 12-month window during which all five study communities will begin implementation. Therefore, the overall duration of the study is expected to be approximately 4.3 years.

Study Objectives:

Primary Objectives:

- To evaluate whether the HPTN 096 integrated strategy increases the number of HHI MSM clients at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases retention in care among HHI MSM living with HIV at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases PrEP prescriptions for HHI MSM not living with HIV at PHASE healthcare facilities

Secondary Objectives:

- To evaluate whether the HPTN 096 integrated strategy increases viral suppression (<200 copies/mL) in HHI MSM living with HIV at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases PrEP initiation, adherence and persistence for HHI MSM not living with HIV at PHASE healthcare facilities
- To assess changes in the experience of autonomy support among HHI MSM at PHASE healthcare facilities
- To assess how autonomy support, social support, stigma, barriers to healthcare and individual agency among HHI MSM at PHASE healthcare facilities are associated with engagement in care (including PrEP prescriptions and viral suppression)

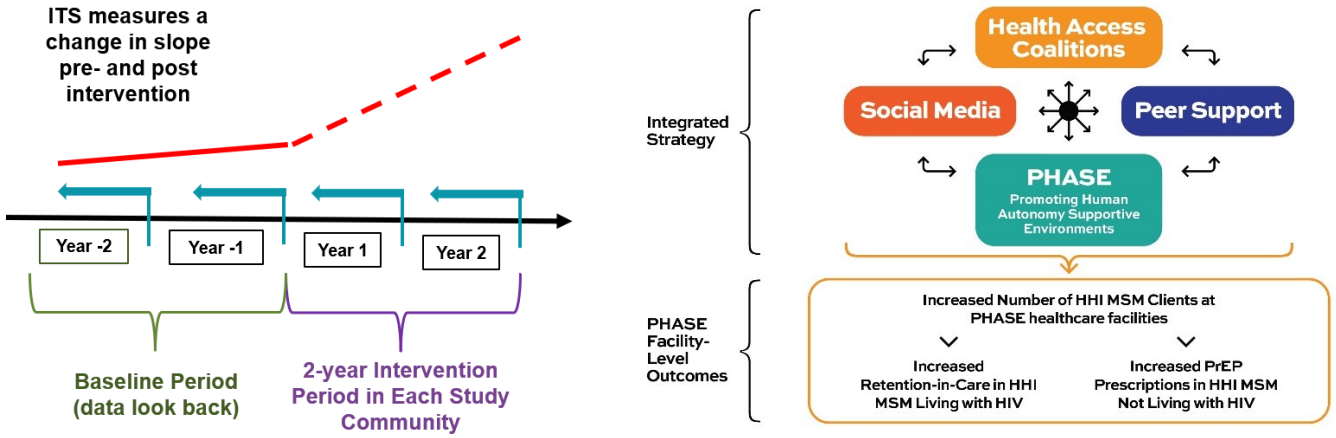
Primary Intervention Process Measures

- Self-reported coalition effectiveness among health access coalitions
- Reach of social media content to intended HHI MSM audience
- Acceptability, satisfaction and perceived usefulness of the peer support component among peer supporters and their clients
- Knowledge and attitudes among staff at PHASE healthcare facilities after completion of PHASE trainings as compared to before training
- Qualitative characterization of staff experiences implementing PHASE

Exploratory Objectives:

- To explore community-level viral suppression in HHI MSM in intervention and selected southern communities using CDC HIV surveillance data
- To use mathematical modeling to assess the potential population-level impact of the integrated strategy on HIV incidence among HHI MSM in the southern US

Schema Figure 1: Overall HPTN 096 Study Design and Study Duration



Study Duration for Each Study Community (approximately 3.3 years)

Color Key: Pre-Implementation (1 year): Intervention Implementation (2 years): Data Collection (2.3 years)

1 INTRODUCTION

1.1 Background

Men who have sex with men (MSM) bear the most disproportionate burden of human immunodeficiency virus (HIV) incidence and prevalence of any community in the United States (US) [1]. Despite the fact that only 4.5% of US men identify as gay or bisexual [2], in 2023, MSM accounted for more than 66% of new HIV diagnoses in the US, which is a percentage that increased by 8% between 2019 and 2023 [1]. Within this relatively small and highly burdened MSM population, there are regions and subgroups in the US that share an even more disproportionate burden. For example, in 2023, the rate of HIV diagnoses was the highest in the southern US (18.4 per 100,000), and within that region, Black MSM accounted for 43% of the new diagnoses, followed by Latino (33%) and White (20%) MSM [1]. In addition, in 2023, young Black MSM made up 47% of the new HIV diagnoses in US MSM, compared to 36% in young Latino and 12% in young White MSM [1]. Relatedly, research shows that multiple social and structural factors undermine prevention and treatment outcomes for MSM subgroups who consistently have the highest HIV diagnoses through their negative effects on health access, healthcare service quality and healthcare seeking behaviors [3]. Consequently, these factors lead to higher rates of undiagnosed and unsuppressed HIV and increased risk for HIV transmissions [4]. These differences make it critical to target HIV prevention activities towards MSM subgroups with the highest HIV incidence (HHI) and prioritize these HHI MSM subgroups for intensified HIV prevention and treatment.

Differences in health outcomes in the HIV epidemic among MSM have persisted unabated by the advent and broad supply of highly effective antiretroviral therapy (ART) and pre-exposure prophylaxis (PrEP) discoveries. It is well-established in the current state of genomic science that the practice of grouping of humans, based largely on skin color, is a social classification system rather than a biological taxonomy [5-7]. This evidence is corroborated by public health epidemiological analyses that determined that genetic factors did not explain the global geographic differences observed in HIV incidence. Given the growing recognition that observed patterns in HIV incidence were “social patterns,” public health officials also began to re-consider previous attempts at searching for biological explanations towards examining social conditions as an explanatory pathway for HIV incidence differences. In the US, the Centers for Disease Control and Prevention has long acknowledged its mounting evidence that overlapping social and structural factors were key contributors to differences in rates of HIV infection [8]. To date, social and structural factors exert determinative influences on the impact of HIV on HHI MSM across the HIV continuum of care. These differences are increasingly understood as the outcomes of social and structural determinants of health (SSDOH) that must be addressed if we are to relieve the epidemic burden on these communities.

Many publications in the epidemiologic, sociologic, and health services literature have described and investigated these SSDOHs and sought to understand and address them. The findings across multiple disciplines have been consistent — individual level behaviors play only modest roles in risks for HIV acquisition and poor clinical HIV outcomes. The critical drivers for HIV outcomes among HHI MSM occur at the social, structural and health care system levels [9-12]. Lower levels of health care access and insurance, lower rates of disease screening, poverty, and multiple stigmas, including stigma in healthcare settings, all also play determinative roles in the

longstanding health outcomes seen among HHI MSM. Yet there are few interventions that seek to address the SSDOH for HHI MSM. HPTN 096 is a pioneering trial of an integrated strategy that seeks to improve HIV prevention and treatment outcomes for HHI MSM across the most HIV-affected region in the country — the South.

1.1.1 HIV Epidemic in the Southern US

The epidemiology of HIV in the US shows an increasing concentration of the epidemic in a relatively small number of high prevalence geographic areas. The US has over 3,100 counties, but just 48, along with the District of Columbia and Puerto Rico, accounted for almost half of all new HIV diagnoses in 2023 [1]. The South has roughly one-third of the US population but accounted for 51% of new infections in 2023 [1, 13]. This is also the region with many of the lowest rates of access to health care services and health insurance. Many southern states where these high prevalence counties are located do not participate in the Medicaid expansion component of the Affordable Care Act, which is designed to increase health care insurance access for low-income individuals [14]. In this region, both HIV testing [15] and viral suppression rates [16] are low. In the most recent CDC surveillance report, the South had a viral suppression rate of only 67% [1]. All these factors have been described as part of a syndemic of multiple overlapping risks and vulnerabilities that have generated and maintain this striking health disparity [17, 18]. The pernicious effects of SSDOH in the region has heightened the awareness that interventions to protect the health of HHI MSM must target the intersecting multi-level systems that impede healthcare access and care.

1.1.2 Ending the HIV Epidemic Initiative

HPTN 096 is designed to strategically align with the US federal initiative "*Ending the HIV Epidemic: A Plan for America,"* referred to as EHE. The EHE plan is based on the current epidemiology of HIV in the US [19]. The plan asserts that we now have the scientific and public health tools to end HIV in the US by 2030, but that a relatively small number of high transmission jurisdictions will require greatly intensified efforts to reduce the health outcome differences at the heart of the US epidemic. It identifies 48 counties, Washington, DC and San Juan, Puerto Rico (which collectively accounted for 46% of new HIV infections in 2023), as well as seven states with disproportionately high HIV incidence in rural areas, as the highest priority areas for these intensified EHE efforts [1, 20]. The plan also recognizes, in the words of former Secretary Azar of the US Department of Health and Human Services (DHHS), that "stigma, which can be a debilitating barrier preventing someone living with HIV or at risk for HIV from receiving the healthcare, services, and respect they need and deserve—still tragically surrounds HIV" [21]. Four key areas are targeted for funding increases to implement the plan: ***Diagnose,*** increase the proportion of Americans living with HIV who know their status and link them immediately to care; ***Treat,*** rapidly and effectively achieve viral suppression; ***Prevent,*** rapidly increase the proportion of at-risk persons on pre-exposure prophylaxis (PrEP); and ***Respond,*** detect and respond to HIV clusters and prevent new infections. HPTN 096 will address the ***Prevent*** and ***Treat*** pillars of EHE in its integrated strategy.

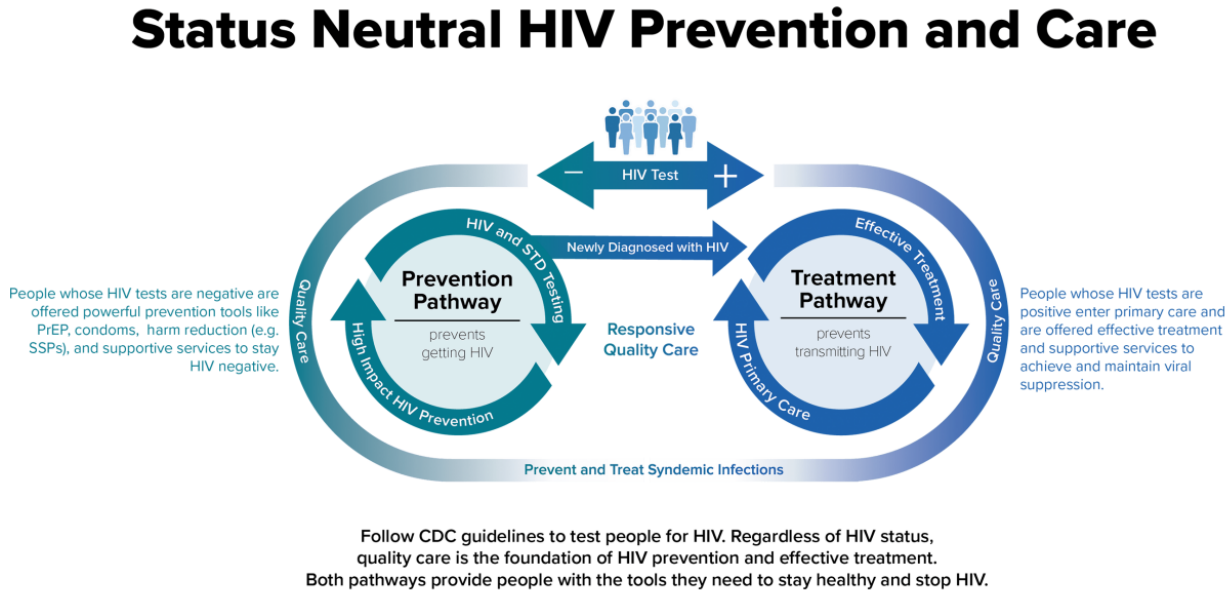
A number of federal agencies are tasked with engagement in the EHE plan and its implementation, including the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Health Resources and Services Administration (HRSA). NIH,

specifically the Division of AIDS (DAIDS) within the National Institute of Allergy and Infectious Diseases (NIAID), will lead the research effort for EHE, which centers on implementation science for the plan. The CDC and HRSA efforts in these counties will be led and funded by the respective agencies, with the CDC taking a lead in enhancing diagnoses and prevention efforts, and HRSA, through its Ryan White Program, supporting enhanced treatment and viral suppression outcomes. HPTN 096 is sponsored by the NIH and will be in collaborative partnership with the other federal agencies above, namely CDC and HRSA. The study will engage with up to 5 communities (some comprised of multiple counties) selected from among the 28 southern EHE counties (see Section 4.1 for additional detail). HPTN 096 will enhance these ongoing EHE efforts by adding a four-component multi-level, status-neutral integrated strategy that targets factors at the interpersonal, organizational, and community levels.

1.1.3 Proven HIV Prevention Methods: A Status Neutral Approach

There now exists an evidence-based repertoire of biomedical strategies for HIV prevention that include HIV PrEP for those who are not living with HIV but are at risk of acquiring HIV, and effective ART and treatment as prevention for those living with HIV. Yet, it has been known for years now that many people – particularly those negatively impacted by SSDOH – are not benefiting from these extraordinary biomedical advances in HIV prevention and treatment science [22]. Identifying people living with HIV who are unaware of their HIV serostatus and linking them to either prevention or treatment services, and reducing differences in HIV prevention and treatment outcomes are important national goals [23].

Figure 1. Status Neutral HIV Prevention and Care [24]



1.1.3.1 HIV Testing

HIV testing (Figure 1) is the entry point into the HIV status neutral prevention and care cascade [24, 25], serving either as the point of diagnosis and opportunity for entry into HIV treatment services or as the point of ruling out an HIV infection and thus presenting the opportunity for entry into prevention services, including PrEP services. There have been important innovations in HIV testing that increases both its ease and accessibility, including rapid point-of-care HIV tests and HIV self-tests [26]. The CDC encourages health departments to consider HIV self-testing as an additional testing strategy to reach persons most affected by HIV [27]. Evidence also indicates that integrating HIV testing services with sexual health screening services is an efficient and effective strategy for identifying undiagnosed people living with HIV for onward linkage to treatment [28, 29]. Moreover, HIV testing is one of the EHE pillars [30], given its essential role in helping to target the appropriate health resources (e.g., prevention or treatment) to the relevant populations at the right time to maximize their clinical impact [31]. Over the years HIV testing has experienced significant scientific innovations (e.g., the development of rapid point of care testing and home-based self-testing) and policy innovations (e.g., opt-out testing, clinical laboratory improvement amendments [CLIA] waivers). Moreover, HIV testing technology has advanced such that testing devices are now produced at a scale and price point that significantly expands its accessibility to individuals regardless of income. HIV testing is now the first step in accessing PrEP and is incorporated in all clinical guidelines for prescribing and managing individuals on PrEP.

1.1.3.2 PrEP

Several randomized clinical trials have demonstrated the efficacy of PrEP in preventing HIV acquisition [32, 33]. The CDC recommends PrEP as an HIV prevention strategy, based on evidence that taking PrEP medication, as prescribed, reduces the risk of HIV transmission via sexual contact by approximately 99% [34]. Currently, there are two oral medications - emtricitabine and tenofovir disoproxil fumarate (brand-name Truvada and generic versions), and emtricitabine and tenofovir alafenamide (Descovy) - approved for daily oral use as HIV PrEP. Furthermore, an off-label use, on-demand oral PrEP, is highly effective at preventing HIV infection among high-risk MSM, is endorsed for MSM by the WHO [35] (although not by the CDC [36]), and represents an alternative to daily PrEP and expanding choices for HIV prevention [37]. However, differences remain, with HHI MSM consistently demonstrating lower levels of PrEP access and use [38]. Moreover, the interaction of multiple stigmas (e.g., PrEP, HIV, and sex) is a widely known barrier in healthcare facilities, with limited interventions developed to address it [39]. Recent and exciting results from HPTN 083, a global randomized, controlled, double-blind study that compared the safety and efficacy of long-acting injectable cabotegravir (CAB-LA) to daily oral Truvada PrEP, showed that CAB-LA was superior to oral daily Truvada for reducing HIV incidence among men who have sex with men [40-42]. CAB-LA was approved for use in HIV prevention by the FDA in 2021, providing an added alternative to oral PrEP. It is critical to ensure that HHI MSM in the South have access to all available HIV prevention strategies, including both oral and injectable PrEP.

1.1.3.3 Viral Suppression

Prompt linkage to and retention in HIV medical care is essential to achieve viral suppression among persons newly diagnosed with HIV and those who were previously diagnosed but are not in care. It is now well established that early ART initiation carries clear short and long-term benefits to anyone living with HIV and also significantly contributes to reduced onward transmission of HIV to sexual partners when there is sustained viral suppression [43]. As with PrEP, differences exist with regard to ART access, uptake, and retention. In an analysis of seven studies from Canada, 13 from the UK, and 174 from the US, HHI MSM in each country were less likely to initiate combination ART [22]. In the US, HHI MSM living with HIV were also less likely to have health insurance, have a low CD4 count, adhere to ART, or be virally suppressed [22]. There were also greater structural barriers (i.e., unemployment, low income, previous incarceration, less education) associated with poor HIV health outcomes among HHI MSM [22]. These structural factors affect availability and choice of sex partners and are also associated with living in neighborhoods with a high background HIV prevalence and community viral load, which increases the odds of sexual exposure to HIV. Elimination of different rates in HIV infection in HHI MSM cannot be accomplished without addressing social determinants of health associated with HIV clinical care access and outcomes, an important focus of our integrated strategies approach in HPTN 096. A long-acting injectable anti-viral regimen, Cabenuva, is also approved for treatment of HIV among adults in the US, and this alternative has demonstrated superiority for maintenance of viral suppression in patients challenged by oral dosing [44]. Regardless of the treatment regimen chosen, a driving predictor of viral suppression is the ability of clinics to retain patients in medical care. Thus, we turn our attention to retention in care for which evidence indicates its failure will eclipse viral suppression goal attainment.

1.1.3.4 Retention in HIV Care

Retention in care is an indicator of quality HIV primary care. When combined with effective anti-retroviral treatment, it leads to HIV viral load suppression. There are a finite number of ART regimens that are known to be effective for the treatment of HIV. The evidence of their efficacy is well-established and, as such, there is very little variation or uncertainty in their expected clinical effect on HIV viral load. However, there is wide variation in the quality of HIV primary care. Poor quality care undermines retention of patients, which interrupts the maintenance of ART treatment and undermines progress towards attainment of viral suppression. There is overwhelming evidence substantiating the link between retention in care and viral load suppression. Overall, the evidence from multiple studies indicates that those who are retained in care are more likely to be virally suppressed [45-49]. For example, there are a few studies on the association of viral suppression with multiple different definitions of retention in care. Retention definitions included (1) having 2 or more HIV visits separated by greater than or equal to 90 days during a calendar year (which is also the definition used by the HRSA Ryan White HIV/AIDS program), (2) having ≥1 HIV visit in each half of the calendar year at least 60 days apart, (3) having ≥6 months between sequential outpatient visits with no gap, and (4) the number of 3-month intervals in a calendar year in which a patient completes at least 1 HIV visit (range, 1–4). Regardless of how it was measured, retention in care was significantly associated with higher likelihood of viral suppression for individuals. The magnitude of these associations was higher for individuals aged 18-29 and 30-39 years, which is significant given the disproportionate HIV incidence in individuals younger than 40 years old [49]. Furthermore, a

study of early retention in care found that it was associated with decreased time to viral suppression among patients newly linked to HIV treatment [47].

Evidence in the research literature also indicates that various indicators of poor retention are associated with detectable HIV viral load [45, 47, 50]. In one study that measured the proportion of scheduled clinic visits that were "no show", researchers found that each "no show" visit added a 17% increased risk of delayed viral suppression [47]. In another study, retention in care was defined as having at least one clinic visit every three months (visit constancy) and viral rebound was defined as a viral load >400 copies/ml. Retention in care was categorized into four groups: (1) optimal retainers (100% retention), (2) suboptimal retainers (75%), (3) sporadic retainers (50%), and (4) poor retainers (<25%) [46]. The odds of a viral load rebound were much greater for suboptimal (odds ratio [OR]: 2.28; 95% confidence interval [CI]: 1.44–3.63) and poor (OR: 15.1; 95% CI: 6.82–33.41) retainers compared to optimal retainers. "Appointment nonadherence" defined as the number of missed appointments over the previous year, was a significant predictor ($p < .05$) of having a detectable viral load among patients in a community -based HIV primary care clinic [45]. Among patients with an undetectable viral load at the earliest visit, the only predictor of declining to a detectable viral load was the number of missed appointments ($p < .003$) [45]. The evidence overwhelmingly indicates that poor rates of retention in quality HIV primary care is a main contributor to detectable viral load. Interventions are needed to address intersectional stigma and other factors in HIV primary care HCFs that contribute to disengagement, disconnection and evasion of care among HHI MSM.

Due to its strong positive association with viral suppression, retention in care has emerged as a viable and more proximal measure of quality HIV primary care than viral suppression. There are several important reasons for this. First, there is a lag time between retention and viral suppression. Therefore, monitoring retention in care is important for early identification of facility's likely progress (or lack of progress) towards reaching viral suppression goals. Monitoring retention in care also affords time to identify and implement improvement measures that can still affect viral suppression outcomes. Second, retention in care is likely to be more sensitive to a change in response to an intervention targeted to improve quality of the HIV primary care experience. For example, the rates of viral suppression among HHI MSM retained in care is very high (approaching 90% in some estimates) [51]. This high proportion of viral suppression is a successful achievement that nonetheless nears a ceiling, which represents a point of diminishing returns on intervention efforts to further improve it. Conversely, retention in care metrics generally trail viral suppression by 10 percentage points or more (because retention metrics include individuals poorly engaged in care who have not received viral load testing), affording ample room for improvement in response to an intervention [51]. In the most recent Ryan White HIV/AIDS annual report of client-level data, 75.6% of HHI MSM were retained in care (defined as 2 visits in the past 12 months at least 90 days apart) and among those HHI MSM retained in care, 86.1% were virally suppressed as measured by the most recent viral load test within the last 12 months [51]. Moreover, situations where intervention activities lead to increases in newly diagnosed HHI MSM entering care (or previously diagnosed HHI MSM returning to care after a significant time gap), will initially depress viral suppression estimates due to the high probability of viremia among the men newly engaged/reengaged in care. However, retention in care is far less susceptible to this type of measurement volatility. Unlike viral suppression, which is a time-independent absolute value, "retention in care" is a relatively

stable indicator of quality in HIV treatment in HCF settings because its fluctuation is minimized by time and activity parameters.

1.1.4 Electronic Health Records: A Promising Tool for Monitoring Prevention, Treatment, and Service Outcomes

Electronic health records (EHRs) have emerged as an indispensable tool that enables the delivery of high-quality services [52-54]. The benefits of EHRs are well-established and include efficiency in data retrieval [55, 56], standardizations that allow for longitudinal monitoring of individual-level health indicators and clinic-level performance indicators [57-59], increased patient ability to access and interact with health data [60-62] and enhanced portability of health data [63, 64]. EHRs have proliferated across the US over the past two decades [65] and are now a cornerstone of the healthcare system. Moreover, their use in research is legitimized by the US Food & Drug Administration that has issued guidance about EHR data practices [66]. Recent advances in computing, statistical analytics, data simulation, and artificial intelligence are fueling a rise in innovations in the use of data that is stored in EHRs [67-69]. For example, a recent study reported on the development and validation of an automated algorithm to identify candidates for HIV pre-exposure prophylaxis indicators, by using EHR data to predict likelihood of a future HIV infection among enrolled patients [69, 70]. EHRs have also been used as an epidemiologic tool such as its deployment as a networked surveillance system for the early detection of trends in disease occurrence [71]. This epidemiologic function can also be helpful in assessing the impact of community- and clinic-delivered interventions whose effects are hypothesized to result in improved clinical (e.g., PrEP use, HIV viral load suppression) and service (e.g., increased patient volume, retention in HIV care) outcomes [72].

Notwithstanding the myriad advantages offered by EHRs, they have some existing limitations. First, EHR databases are still largely dependent on humans to populate them using data that is either collected through direct observation or biometric assessment. Humans can introduce both random and systematic error into EHR data through actions (on inactions) that bias how data are collected, managed, and interpreted [73]. For example, while clinicians make assessments of patient eligibility for PrEP using published clinical guidelines, there is evidence that several major guidelines for PrEP do not sufficiently predict risk of HIV acquisition for all individuals, including HHI MSM [74-76]. Therefore, data that are input into EHRs (or excluded from entry into EHRs) based on biased clinical guidelines will introduce a corresponding bias into the database. Another limitation is that data contained in EHRs may not be a complete representation of social, behavioral and clinical realities of patients in a healthcare facility. There are several important sources for this type of mismatch. One key source is the non-systematic collection of sexual orientation data [77, 78]. Collection of sexual orientation data is important for clinicians to be able to have a more holistic understanding of their patients that inform health screening, health promotion guidance and prevention/treatment planning [79, 80]. However, recent analysis of data from 1,297 federally qualified health centers (FQHCs) found that sexual orientation data was missing for one-quarter to one-third of patients [81]. EHR databases that are incomplete and, consequently, inaccurate will complicate efforts to rely on them as a source for assessing the intervention effects on clinical and service outcomes.

Intervention strategies that are designed to systematize sexual orientation assessments of patients can help to improve both the data completeness (i.e., minimizing the volume of missing fields)

and data quality (i.e., the data accurately characterizes the patient's social, behavioral, and clinical realities). Several recent studies have tested strategies to improve sexual orientation data collection in health care facilities [82, 83]. One quasi-experimental trial tested the effects of a quality improvement collaborative approach combined with a skills-based knowledge exchange model could improve data collection and service outcomes (i.e., STI/HIV screening) [83]. The intervention was conducted in a sample of 123 clinical sites that accounted for 441,387 patients [83]. This resulted in a 276% increase in sexual orientation documentation (from 14% to 51% of patients) [83]. There were also substantial increases in clinical screening of LGB patients for HIV (132% increase), syphilis (87% increase), and gonorrhea/chlamydia (109% increase) [83]. This is evidence of the impact of interventions on sexual orientation documentation and its effect on clinical practice.

Improvements in sexual orientation data completeness may uncover an important conundrum, which is that baseline estimates on clinical outcomes among the LGB census at an HCF are likely to be an overestimate because the "known" denominator of LGB individuals at baseline may be substantially smaller than the "true" LGB census. Over time, as the proportion of the LGB census becomes "known" due to systematic increases in sexual orientation assessments, the gap closes between the known census and the true census. However, as the denominator of LGB census grows due to increased data completeness at later time points, it may have the effect of reducing proportions on clinical outcomes observed at baseline and undermining the ability to detect intervention effects. Take for example a scenario where the known number of HHI MSM in an HCF at baseline is N=10. If nine of these 10 men were prescribed PrEP, then the proportion of PrEP prescriptions among HHI MSM in that HCF is 90%. After increasing the completeness of sexual orientation data, we may later find (after 12-months) that the true number of HHI MSM at the HCF was actually N=90; thus, bringing the proportion of HHI MSM prescribed PrEP down from 90% at baseline to 10% at 12-months post-intervention. The implication of this specific phenomenon is that the positive intervention effects on data completeness could contribute to a null (or inverse) finding on the clinical outcome. To correct this issue, researchers have taken sexual orientation data that were assessed at the end of the intervention period and used it to back-calculate missing data in the earlier period to ensure that both the baseline and end of intervention denominators are more accurate approximations of the HCF's true LGB census [83].

Notwithstanding their range of limitations and complexities, EHRs still represent a modern available tool for assessing the impact of community- and clinic-delivered interventions whose effects are hypothesized to result in improved clinical (e.g., PrEP use, HIV viral load suppression) and service (e.g., increased patient volume, retention in HIV care) outcomes [72]. In fact, collection of sexual orientation data in FQHC EHRs has improved over time and has been documented as being higher in clinics in the Southern US [81]. This higher data completion rate observed in Southern FQHCs may signal that other relevant data fields are more complete than sexual orientation data, thus potentially allowing the use of data on men with the same demographic characteristics as HHI MSM as a back-up/proxy for data on HHI MSM. Multi-level integrated strategies that leverage HCFs to improve HIV prevention, treatment and service outcomes may benefit from harnessing the potential of EHRs to assess intervention effects.

As a technical note, the term "electronic health record" or "EHR" refers to the health information for a person across multiple healthcare providers and organizations. The term "electronic

medical record" or "EMR" refers to the health information for a person within one healthcare clinic. For the purposes of this study, we are using EMR data and will use the term "EMR" throughout the remainder of the protocol.

1.2 Rationale for an Integrated Strategy Approach

HPTN 096 is based on scientific and programmatic evidence that individual-level behaviorally focused interventions alone are insufficient to significantly affect HIV prevention and treatment pathway outcomes among HHI MSM [84-86]. While highly efficacious biomedical HIV prevention tools—such as HIV PrEP and treatment—are available to consumers within the healthcare market [87-89], their broad availability alone has not translated into prevention gains for HHI MSM [90, 91], despite evidence that HHI MSM are interested in and willing to take antiretroviral medication for PrEP and treatment [92, 93]. Cost is a known barrier to accessing PrEP and other healthcare services, but other evidence indicates that healthcare provider attitudes and prescribing practices are also barriers to access to these products and services [92, 94]. These attitudes are manifested in the institutional policies and practices of HCFs as well as HCF staff; and, are not isolated phenomena, but reflect larger social attitudes that stigmatize gayness, HIV seropositive status and HIV-related health-seeking behaviors. In sum, the key factors driving the HIV epidemic among HHI MSM operate at multiple levels that intersect to reinforce barriers that impede the uptake of biomedical HIV prevention and treatment goals [95-97]. These levels include community, organizational and interpersonal levels.

1.2.1 Implementation Framework

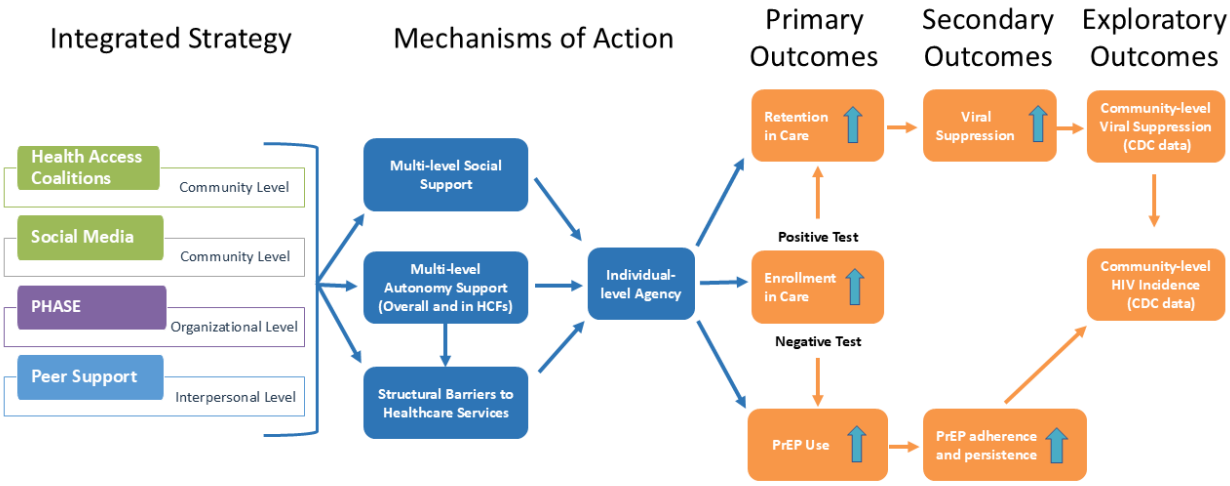
The overall approach to HPTN 096 utilizes the convergence framework (Figure 2) [98, 99] for integrating strategies across multiple levels. The integration of strategies across multiple levels is based on the premise that there are multiple levels of social, political, and economic influencing factors that affect whether implementation will be successful and whether it will improve health outcomes [100]. In HPTN 096, our multi-level implementation approach is centered around the clinical encounter where a desired outcome for the patient is influenced by factors within the HCF and larger healthcare system in a community. It advances the concept that social, political, and economic forces exert strong external pressures that influence implementation at the HCF level and its possibilities for scaling across a broader set of local HCFs. This logic also guides our approach to addressing primary intervention process measures (Section 2.3) that focuses on characterizing the experience of HCF staff implementing autonomy support (an implementation strategy), including examining the dynamics of the HCF contexts and identifying what factors influenced variation in study outcomes between the participating HCFs. It will, as

A Note on Frameworks, Figures, and Theories. The study's integrated strategy supports the implementation of HIV PrEP and workflows that improve retention in HIV care. The figures included in the introduction do not represent competing frameworks. They are provided to give visual illustration of what is descried in the text such as how the components of the integrated strategy function together to affect study outcomes (Figure 2), and the logic for how specific implementation determinants addressed by the integrated strategy are hypothesized to improve implementation of clinical interventions within HCFs (Figure 3). Moreover, each component of the integrated strategy has its own theoretical basis that we articulate in the section where the component itself is described.

well, guide our qualitative exploration of the experiences of patients in participating HCFs (see Section 2.2 Secondary Objectives) and whether or how their experiences influenced PrEP use, ART use, and retention in HIV care.

We have identified four strategies that address factors at multiple (societal/community, organizational, and patient/interpersonal) levels. The four components will be combined into one integrated strategy implemented to address the multi-level drivers of HIV incidence in HHI MSM. Intervening at multiple levels is needed because structural determinants, community-level norms, lack of autonomy support in HCFs, and decreased access to peer-based social support act interdependently to impede health service utilization, PrEP use and retention in HIV care; therefore, intervening at a single level—while necessary—is insufficient to achieve measurable impact among a non-cohort sample of HHI MSM attending real world HCFs [101].

Figure 2. Theorized Pathway of Integrated Strategy Effects on Study Outcomes



Community Level – *Structural Determinants in Local Municipalities Are Barriers to HIV Prevention and Care.* Data from HPTN 061 identified economic, social and legal hardships across six sites that were associated with increased HIV/STI risks among HHI MSM [102]. These economic (e.g., job loss, recent financial crisis) and social (e.g., unstable housing) hardships may have salience for HIV prevention and treatment in communities without robust social safety net programs. Other social hardships (e.g., no health insurance) can have a more severe impact on those who are unemployed in states that did not expand their Medicaid programs under the affordable care act. HPTN 061 also found very high levels of police contact among HHI MSM [103], with an estimated incarceration incidence of 35% (95% confidence interval [CI] 31-38) during the study period [97]. HHI MSM who reported legal hardships (i.e., recent conviction) were more likely to have an STI in the past six months (adjusted odds ratio [AOR]=3.97; 95% CI 1.58-9.94) [102]. In another national sample of HHI MSM (*N*=1,172), a high percentage (43%) reported police discrimination that was associated with recent arrests [104]. Recent arrest and incarceration history were both associated with sexual exposure to HIV. Additionally, incarceration and recent arrests were associated with lower willingness to use PrEP [104]. The impacts of these structural determinants on HIV incidence are problems that are not

solved by either PrEP use or HIV treatment alone; on the contrary, structural determinants thwart the attempts of individuals to prioritize HIV prevention and treatment approaches due to other daily, tangible and immediate threats to their physical health, psychological well-being and survival [105, 106]. Consequently, health promotion approaches that engage multi-sectoral coalition building are needed to mitigate the impact of structural determinants on health service utilization, PrEP use and retention in HIV care among HHI MSM.

Community Level – *Stigmatizing Attitudes and Social Norms Undermine Health Seeking Behaviors.* HHI MSM who live in the South must make decisions whether to seek healthcare services in settings where they can be the subject of mistreatment, discrimination and harassment. In addition, these stigmatizing attitudes are sometimes applied directly to the products (e.g., PrEP), services (e.g., HIV testing) or HCFs (e.g., lesbian, gay, and bisexual (LGB)-centered care) themselves, which can lead to evasion of prevention services to avoid the stigma and potential material consequences (e.g., job loss, housing loss, social exile) of being associated with them. Moreover, these community-level attitudes can be internalized by HHI MSM themselves, which may lead to self-undermining of health seeking behavior [107]. Social media has emerged as a powerful platform that can be leveraged to positively influence community-level social norms—counteracting the stigmatized attitudes and norms that undermine HIV prevention and treatment outcomes for HHI MSM.

Organizational Level – *HCF Policies, Practices and Staff Attitudes and Behaviors Impede Access and Retention in HIV Prevention and Treatment Services.* HCFs are selected as one of the targets for integrated strategy because, even if HHI MSM are sufficiently motivated to attempt access of PrEP or HIV treatment services, these services are typically performed in an HCF. The socio-environmental conditions in HCFs can either be synergistic or antagonistic to the men's motivation to engage in PrEP or engage treatment services [108, 109]. There are numerous studies documenting that stigmas embedded in attitudes, logics and practices of healthcare workers actively impede access to HIV-related services, undermine the quality of the healthcare encounter experience and, consequently, diminishes the effectiveness of healthcare services in improving health outcomes [94, 108, 110, 111].

Interpersonal Level – A peer support component was chosen because of the positive influence that HHI MSM can have on one another. Peers can positively influence the health behaviors of other HHI MSM as well as address the potential negative influence of enacted and internalized forms of stigma [112-117]. Another key reason that the HPTN 096 integrated strategy is targeted to the interpersonal level is because chronic exposure to stigma (whether at the larger community-level or the organizational level) can lead to internalization of the stigmas, which can impede HIV testing and prevention service engagement [118-120]. Stigma can also compromise psychological well-being due to the strain that HHI MSM may experience in response to pressures from peers and families to conform to expectations of masculinity that can often conflict with self expression [121]. Peer support is designed to combat the internalization of stigma through the provision of educative and emotionally supportive encounters with peers, while also guiding men towards autonomy supportive and comprehensive health and social services and supporting PrEP and ART initiation and adherence. Table 1 details the levels of intervention and outcomes described above.

Table 1: HPTN 096 Levels, Drivers, Integrated Strategy Components and Outcomes

LEVEL	DRIVER	COMPONENT	OUTCOMES IMPACTED		
			Health Service Use	PrEP Use	Retention in Care
Community	Structural determinants manifested through economic, social and legal hardships that impede HIV prevention.	Health Access Coalitions	Indirect	Indirect	Indirect
Community	Stigma and social norms non-supportive of HIV-related service use.	Social Media	Indirect	Indirect	Indirect
Organizational	Stigmas and lack of autonomy support institutionalized in policies and practices of HCFs and staff.	PHASE	Direct	Direct	Direct
Interpersonal	Internalized stigma and lack of social support.	Peer Support	Direct	Direct	Direct

1.2.2 The Implementation Research Logic Model: A Method for Explaining the Influence of the Integrated Strategy on Clinical Interventions and Study Outcomes

HPTN 096 is an integrated strategy designed to support the HCF-level implementation of two clinical interventions (HIV PrEP and HIV ART) among HHI MSM attending selected health care facilities that participated in the PHASE intervention component [122]**.** We employ the Implementation Research Logic Model (IRLM) as an explanatory method that accommodates the hybrid implementation-efficacy character of HPTN 096 [123] by framing the relationships between the implementation strategies, the clinical interventions, the mechanisms of action and the study outcomes (implementation, service and clinical). Our use of an implementation science framework necessitates defining "the communities" as the site of implementation. We also take into account the theorized pathway of the integrated strategy's effect on the study outcomes (Figure 2) and situate it within the context of implementation determinants, implementation outcomes and service outcomes (Figure 3). Together these are the core elements of the IRLM: clinical interventions, determinants, strategies, mechanisms and outcomes.

Clinical Interventions are evidence-based practices that have been shown through rigorous research testing to have efficacy in producing a particular health outcome. In HPTN 096, the two clinical interventions are HIV PrEP, which has demonstrated efficacy in preventing the acquisition of an HIV infection; and ART, which has demonstrated efficacy in suppressing viral load and preventing the onward transmission of HIV.

Determinants are factors that can either impede or facilitate the adoption of the clinical intervention. The IRLM uses determinants from the Consolidated Framework for Implementation Research (CFIR) [124]. These determinants are categorized into five domains: intervention characteristics, outer setting, inner setting, characteristics of individuals, and process. These five domains are represented in the HPTN 096 IRLM (Figure 3). We identified

16 relevant determinants from across the five domains. The general conceptual CFIR definitions of each of the selected determinants used in HPTN 096 are listed below. Their corresponding operational descriptions are listed in the HPTN 096 IRLM (Figure 3).

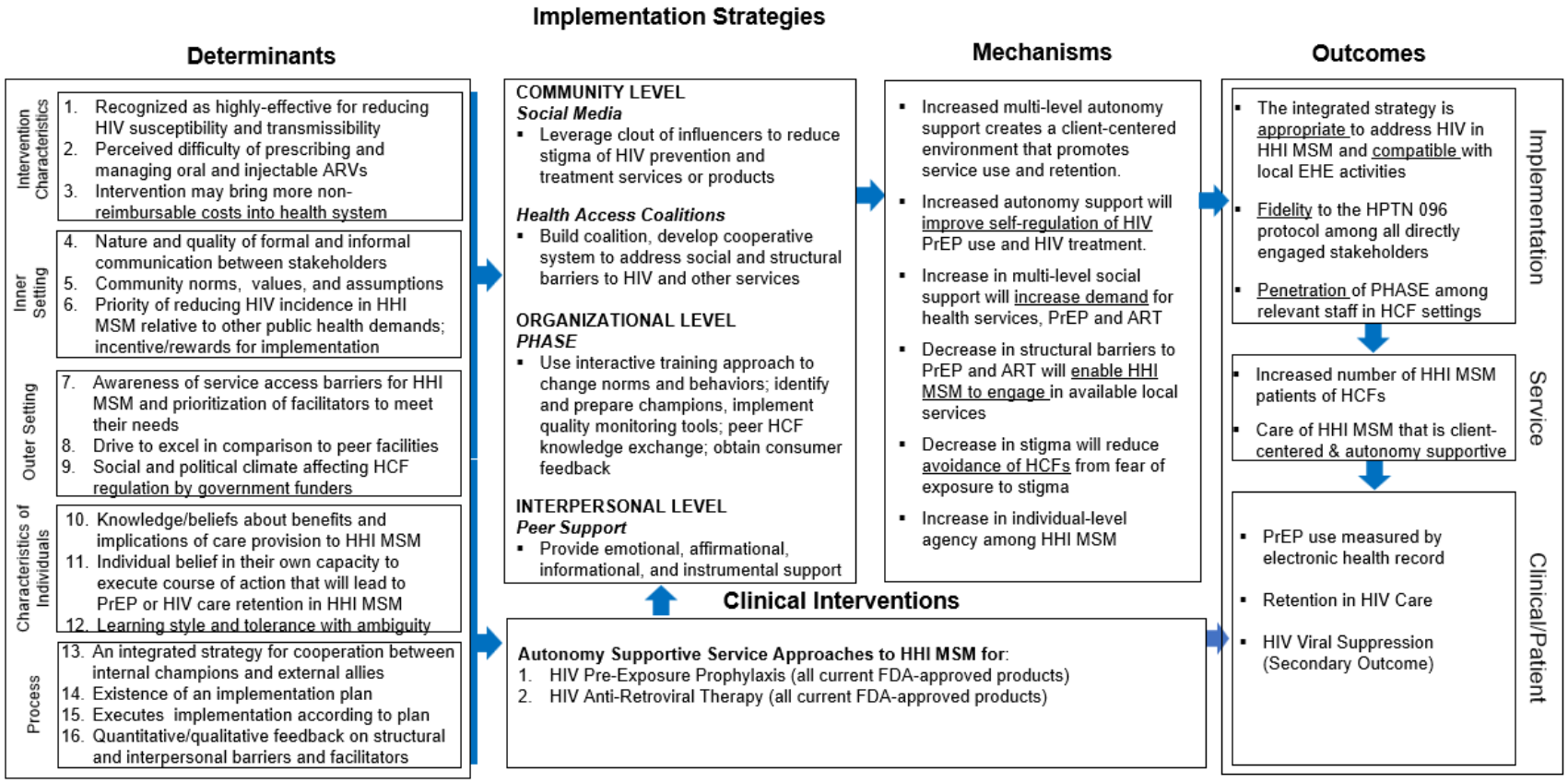
Intervention Characteristics

1. Relative Advantage – Stakeholder's perception of the advantage of implementing the intervention versus an alternate solution.
2. Complexity – Perceived difficulty of implementing the intervention reflected by the radicalness, disruptiveness and intricacy of the steps required to implement.
3. Cost – Costs of the intervention or costs associated with its implementation.

Inner Setting

4. Networks and Communication – The nature and quality of webs of social networks and the formal and informal communications in the implementation context.
5. Culture – Norms, values and basic assumptions in the implementation context.
6. Implementation Climate/Relative Priority – The shared perception of the importance of the intervention and the extent to which the use of the intervention will be supported and rewarded within the implementation context.

Figure 3. HPTN 096 Implementation Research Logic Model



Outer Setting

7. Patient Needs and Resources – The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized in the implementation context.
8. Peer Pressure – Competitive pressure to implement an intervention, typically because key peer implementers have already implemented or are trying to gain a competitive edge.
9. External Policies and Incentives – External strategies to spread interventions, including external mandates and public or benchmarking reporting.

Characteristics of Individuals

10. Knowledge/Beliefs about Intervention – Individuals' attitudes toward and value placed on the intervention as well as familiarity with facts, truths and principles related to the intervention.
11. Self-Efficacy – Individual's belief in their own capabilities to execute a course of action to achieve implementation goals.
12. Tolerance of Ambiguity/Learning Style – The degree to which implementers can cope with and benefit from any needs to "learn as you go" versus knowing in advance exactly what are all the steps.

Process

13. Engaging – Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, training and other similar activities.
14. Planning – The degree to which a scheme or method of behavior and tasks for implementing an intervention are developed in advance and is high quality.
15. Executing – Carrying out or accomplishing the implementation according to plan.
16. Reflecting and Evaluating – Quantitative and qualitative feedback about the progress and quality of the implementation accompanied with regular debriefing on the experience.

Implementation Strategies are techniques and methods used to optimize the implementation of clinical interventions, including products/tools, programs or healthcare practices [125]. Strategies optimize the HCF-level implementation of clinical interventions by addressing determinants—either mitigating determinants that impede implementation or enhancing determinants that facilitate implementation [126]. Research has identified a great number of potential implementation strategies [125, 127]. In HPTN 096, we selected strategies from among the 73 identified in the Expert Recommendations for Implementing Change project [125]. Detailed background (see Section 1.2.5), theoretical rationale (see Section 1.2.6), and description of each component of the integrated strategy (see Sections 5, 6, 7 and 8) are presented in subsequent sections of this protocol. Figure 3 itemizes the specific discrete activities involved in each component of the integrated strategy.

Mechanisms of Action are the ways in which the implementation strategies are theorized to impact on outcomes. The mechanisms of action of HPTN 096 are shown in Figure 2.

Outcomes. In using the IRLM, we are concerned with effecting three types of outcomes: implementation, service and clinical.

Implementation outcomes are the indicators of the success of the process of implementing the integrated strategy and precedes service outcomes and clinical outcomes. Services outcomes relate to the quality of clinical operations and/or patient care, which should be positively affected by successful implementation. The implementation and service outcomes selected for HPTN 096 are drawn from the research evidence-base [123, 128, 129] as well as formative information gained from our consultations with community stakeholders and EHE councils from across the South. Clinical outcomes are individual/patient-level indicators directly impacted by the optimized implementation of the clinical interventions. The general conceptual definitions of each the selected implementation and service outcomes used in HPTN 096 are listed below. Their corresponding operational definitions are presented in the HPTN 096 IRLM (Figure 3).

Implementation Outcomes

- Appropriateness – The perceived fit of the innovation or evidence-based practice to address a particular issue or problem [123, 129].
- Fidelity – The degree to which an intervention was implemented as prescribed in the protocol or as it was intended by the program developers [123, 129].
- Penetration – The integration of a practice within an implementation setting [123, 129].

Service Outcomes

- Proportionality – Providing care that does not vary in quality because of personal characteristics such as sex, geographic location and socioeconomic status [129]. In HPTN 096 this is the co-primary endpoint measuring the proportional increase in HHI MSM healthcare service enrollees (patients) at PHASE HCFs.
- Patient-centeredness – Providing care that is responsive to individual patient preferences, needs and values [129].

Clinical Outcomes.

- In HPTN 096 these are what we have described in this protocol as our co-primary and secondary study endpoints—these are:
    - PrEP use among HHI MSM without HIV
    - Retention in HIV care among HHI MSM living with HIV
    - HIV viral load suppression among HHI MSM living with HIV

1.2.3 Primacy of Community Engagement for an Integrated Strategy

The HPTN 096 integrated strategy also builds skills, supports collective efficacy and harnesses sociocultural assets in the study communities to mobilize coalitions and collective action to identify and address barriers to PrEP use, retention in HIV care and viral suppression among HHI MSM [106, 130]. The study team utilized elements of a community-based participatory research (CBPR) [131, 132] approach by conceptualizing HPTN 096 in collaboration with broad

and frequent input from representatives of the study population, allies and stakeholders from communities across the South.

Additionally, the CBPR process led the HPTN 096 co-chairs to actively avoid approaches that position HHI communities as sites of risk and vulnerability that require external intervention and instead adopted a lens which recognized (a) the resilience and sociocultural assets that already exist in HHI communities and (b) that HPTN 096 would be strengthened by working in partnership with national, southern region and local community organizers to achieve the study objectives. HPTN 096 is further institutionalizing the community engagement process through the intentional inclusion of HHI MSM as members of the protocol team and by incorporating a community engagement component into the infrastructure of the study design via the Community Advisory Group (CAG), as well as the peer support and social media components.

(1) HPTN 096 CAG – The community advisory body for the study, active during pre-implementation and implementation periods, with representation for the study communities as well as national stakeholders. The CAG will guide both the national and local community level community engagement activities for HPTN 096. This group will be the primary point of community input on HPTN 096 study components of the integrated strategy from a community perspective.

(2) Peer Support Component – In consultation with the CAG, peer supporters will develop site-specific community engagement strategies to promote awareness of HPTN 096. They will be encouraged to implement various community engagement strategies in the local communities and across their network to establish and maintain rapport with local community stakeholders.

(3) Social Media Component – The social media advisory group will provide input and guidance specifically for the study's social media strategy and its various campaigns. This group is made up of HHI MSM from each study community with the purpose of bringing a wide range of voices from within the HHI MSM community to support the development and implementation of the social media component.

Community engagement in HPTN 096's integrated strategy builds on successful approaches from previous multi-level studies [93, 106, 130, 133]. This integrated strategy seeks to strengthen partnerships between HHI MSM, HCFs and local community stakeholders and allies whose collaborative efforts will support study implementation.

1.2.4 Critical Partnerships: CDC, HRSA, EHE Committees, Local Health Departments and Third-Party Payers

As outlined in Section 1.1.2, the overall EHE strategy is also influenced by the collaborative work of the CDC, local health departments and EHE committees. It is also influenced by industries that are involved in payment for healthcare services and prescription antiretroviral medication for PrEP and treatment. For this study to work synergistically with these entities, strong partnerships with them are critical. Key colleagues from Division of HIV/AIDS Prevention at the CDC have helped design some aspects of the study, are members of the protocol team and will continue to provide input into ramp-up and implementation activities.

Specifically, the CDC will provide the aggregated data for the study's exploratory endpoints that rely on HIV surveillance data (see Section 2.4). We have sought buy-in for community participation from all EHE committees, which are housed in local health departments, and include representation from community-based organizations (CBOs) and HIV-related service facilities. Members of EHE committees and health departments are invited to serve as protocol team members, actively engage in our working groups, work with the team to identify facilities for the PHASE intervention and participate in the implementation of various aspects of the integrated strategy. We have also built a relationship with Blue Cross Blue Shield of Florida (Florida Blue), which is the major third-party payer of healthcare services in one of the 096 communities (Fort Lauderdale/Miami). Florida Blue contributes insights from an insurer perspective about strategies to maximize the reimbursement of services of HCFs and the use of PrEP benefits among HHI MSM. These insights inform multiple elements of the integrated strategy, including health access coalitions, PHASE and peer support.

1.2.5 Components of the Integrated Strategy

1.2.5.1 Health Access Coalitions

The current (and historically) observed differences in HIV incidence and clinical outcomes are not randomly distributed across the US population but exhibit characteristics that are **systematic** [22, 134-136]. These systematic differences often manifest in patterns of disease between social groups. There are no biologically plausible explanations for why HIV infection rates would be consistently higher among MSM of specific social groups living in the south compared to any other population or region in the US [6, 137-139]. These social patterns of disease are observed across multiple health domains, including Coronavirus Disease 2019 (COVID-19) case and mortality rates [140]. The current state of the science is unequivocal that these differences in health outcomes are the product of structured social arrangements that assign undeserved exposure to risk and hardship (economic, social, legal) to one group while conferring unearned protections and benefits to another group [102, 141]. The character and enforcement of these structured social arrangements, as well as their impacts on health outcomes, may vary from one city to another (or from one region to another). Moreover, the interoperable systems that maintain structural imbalances in health are not only "healthcare systems" but involve (1) multiple human social institutions such as education, law, employment, and housing sectors, [142-144] and (2) multiple processes of exclusion of communities from exercising self-determination over the material conditions of their lives [145, 146]. Therefore, approaches to reducing gaps in disease rates and outcomes must include approaches that extend beyond the healthcare sector to include education, legal, economic, civic, housing, and community development sectors and that are tailored to the realities affecting HIV prevention for HHI MSM in their local context [147, 148].

The current scientific evidence indicates that interventions with the highest impact on reducing social group differences in health involve local community mobilization that foster collaboration with governmental and non-governmental partners inside and outside of the health sectors [149-153]. The patterns that characterize effective interventions are principally (1) information sharing and exchange, (2) optimizing the impact of scarce resources through cooperation between partners, and (3) actively working together in joint coordination to increase efficiency of access to services and resources [152, 154]. One example of an intervention is an intersectoral

partnership formed between CBOs, the local health department and academic institutions in Harlem, New York [155]. This partnership identified HIV prevention as a shared priority and sought to reduce sharing and re-using of injection drug equipment by launching the Expanded Syringe Access Program (ESAP) coalition. The ESAP coalition cooperated on the development of materials describing the benefits of syringe exchange through dissemination of consistent messaging through their individual platforms (e.g., churches, community forums, drug counseling programs) in an effort to raise awareness of ESAP among injecting drug users (IDUs), to sensitize the community to the needs of injection drug users and to reduce stigma [130, 155]. The ESAP coalition developed a survival guide for substance users (information sharing) that included evidence-based health education guidance, a reference list of community services such as drug treatment, housing services and job placement services [130]. The efforts to increase the efficiency of access to clean syringes was accomplished in coordination with local pharmacists who agreed to provide the non-prescription sale of syringes. The multi-sectoral coalition resulted in a significant increase in their awareness of ESAP and decrease in the proportion of pharmacist with unsupportive attitudes about ESAP [130]. Moreover, there was an increase in use of pharmacies for obtaining syringes among IDUs (22% v. 5%, $p<.02$) in the intervention community and no significant change in pharmacy use among IDUs in the comparison community [130].

These three characteristics (sharing, cooperating and coordinating) of successful interventions are observed in other studies that range from an intervention that demonstrated evidence in increasing service engagement among MSM living with HIV through increasing community-level sensitization and acceptance in India [156] to an HIV prevention intervention in San Francisco that engaged gay bar owners to collaboratively provide free self-service access to water and used media inside their bars to share information encouraging the use of water to pace alcohol intake [157]. The bars also coordinated an online networked platform in which patrons who used a breathalyzer could visualize their individual blood alcohol content (BAC) on an iPad alongside real-time comparisons to the average BAC of patrons in the bar as well as the average BACs of patrons in the other intervention bars [157]. The health access coalition model in HPTN 096 is grounded in promoting principles of fairness and justice and is premised on the abundance of scientific evidence that local community coalitions and intersectoral collaborations are the most effective approach to tackling the enduring structural impediments driving HIV outcomes among HHI MSM in the South.

1.2.5.2 Social Media

The social media component of the HPTN 096 integrated strategy is grounded in the Diffusion of Innovation Theory. This theory, developed by E.M. Rogers, explains how new ideas spread throughout a population [158]. Initially new ideas and information may be perceived as risky: individuals may be uncertain about the validity of the assertion, or if this new idea or information is something they should act on for themselves. To overcome this uncertainty, most people seek out others, often people like themselves who they trust and find credible, before adapting the idea for themselves and recommending it to others. Normally this process can take years; however, social media has accelerated this process, allowing information exchange and subsequent behavior change to take place much more rapidly.

The use of social media for health promotion and behavior change [159-161], including for HIV [162], has increased exponentially as more individuals use social media as their primary source of information and method of communication. YouTube and Facebook are the most widely used social media platforms, with half of adults in the US reporting that they use Instagram [163]. Table 2 outlines the use of these top three platforms by demographic characteristics relevant to HPTN 096's study population [163], demonstrating the potential to reach a large majority of the HHI MSM community. In addition, between 21% and 36% of US adults report using Pinterest, TikTok, LinkedIn, WhatsApp, Snapchat, X (formerly Twitter), Reddit and Nextdoor [163]. Furthermore, there are other virtual environments, such as dating apps that are used by the majority of gay men [164], which can be considered non-traditional social media platforms for the purposes of this study.

Table 2: Percentage of US Adults Reporting Use of Top Three Social Media Platforms

Demographic	YouTube	Facebook	Instagram
Age: 18 - 29	93%	68%	76%
Age: 30 - 49	94%	78%	66%
Age: 50 - 64	86%	70%	36%
Age: 65+	65%	59%	19%
Men	87%	61%	44%
Black	88%	73%	52%
White	82%	70%	45%
Hispanic	89%	69%	59%

The HHI MSM community is not homogeneous. It includes a wide variation in HIV knowledge and behaviors, ranging from people who are proud of their sexual orientation, know about HIV prevention tools and use them to those who are ashamed of their sexual preferences and activities, know little about HIV or how to protect themselves or their sexual partners. Using a persona-based methodology, the study's social media strategy will tailor messaging to reach multiple segments of the HHI MSM population. By meeting people where they are and not relying on a one-size-fits-all approach, this component has the potential to reach HHI MSM throughout all study communities.

During the integrated strategy pilot (see Section 3), the team engaged micro-level social media influencers, who were HHI MSM themselves, to create and disseminate HIV-related content. Five influencers from Dallas, TX, Houston, TX, and Montgomery, AL created and disseminated a total of 63 posts. These posts were viewed 39,101 times in Dallas, 921 times in Houston, and 6,467 times in Montgomery. In addition, the study team used some of the influencer-generated video content to create eight social media advertisements. These ads were disseminated to men with interests common to the gay community for a little more than three weeks in Dallas and Montgomery. These ads were seen approximately 250,000 times by roughly 72,000 individuals, of whom about 8,000 clicked on a link to learn more about the advertisement's content (for example to learn more about HIV testing). Table 3 shows the results of the same video, created by an influencer in Dallas, distributed as a social media post versus as a social media advertisement. Given the current targeting and metric reporting capacity of the social media platforms used for the 63 posts and eight ads (Facebook and Instagram), it was not possible to determine how many of the people who saw the post or advertisement were HHI MSM.

However, using 2022 CDC surveillance data and baseline cross-sectional assessment data collected during the pilot, the study team estimates that the number of HHI MSM in Dallas is approximately 17,000. Thus, the combination of social media posts and advertising has the potential to reach a large majority of the HHI MSM population.

Table 3: Social Media Post vs Social Media Advertisement Metrics

HIV-testing video	Distribution time	Views	Reach[1]	Engagement[2]
Social media post	4 weeks	9,464[3]	7,423[3]	516
Social media ad	3.5 weeks	24,038[4]	13,696[4]	998

[1]Reach is the number of unique individuals who saw the post or ad.
[2]Engagment includes reactions (e.g., likes), comments, shares, saves, replies and link clicks.
[3]38% of the SMI's followers were in Dallas, so the posts were seen beyond Dallas.
[4]The social media ad was only seen by those in Dallas.
Note: It was not possible to determine how many of the people who saw the post or ad were HHI MSM given the current targeting and metric reporting capacity of social media platforms used for this video (Facebook and Instagram).

The study team will continue to harness the power of social media to educate, engage and empower HHI MSM using all available social media tools, including but not limited to, the establishment of study-specific social media accounts, utilization of existing content when possible, and the creation and dissemination of new social media content. As before, individuals who are recognized by or are known to have influence in the HHI MSM community will be approached to create content; however, existing content will also be considered, such as HIV-related content made by public health institutions, foundations, public-private partnerships, or other organizations that support HHI MSM. While existing content may be readily available and professionally produced, new content may have the advantage of resonating with the target audience because it is non-establishment, relatable, based on lived experience and unique. This combination of new and existing content will allow the team to ensure a constant stream of content and keep the messaging fresh. Table 4 outlines the advantages, disadvantages and leverage of social media posts, advertising and social medial influencers. While social media has been used by others to disseminate health information with the goal of behavioral change, the innovation of this approach will be that the campaign takes place within a community where the barriers that HHI MSM face with regard to HIV prevention and care are being lowered by the other three study components. The study's social media content will encourage HHI MSM to seek HIV testing, PrEP and care, and they will be doing so in an environment where these options are more accessible and welcoming.

Table 4: Advantages, Disadvantages and Leverage of Posts and Advertisements

	Advantages	Disadvantages	Leverage
Existing content via social media posts and social media advertisement	• Eliminates need to create content; may be readily available • Approach could be easily replicated by Departments of Health, if found to be helpful • Geo-targeting ads allows distribution to specific study communities • Broad community-level reach	• May not be tailored to or able to engage HHI MSM in the southern US • May not be possible to use/license for study purposes • May not be changed or revised	Leverages existing HIV-related content and campaigns
New content via social media posts and social media advertisement	• Broad choice of content creators • Content can be tailored to HHI MSM in the southern US • Geo-targeting ads allows distribution to specific study communities • Broad community-level reach	• Requires resources for content creation; not readily available	Leverages the broad knowledge and lived experience of the community to create content for HHI MSM
Social media posts by social media influencers with HHI MSM followers	• Content can be tailored to HHI MSM from the southern US • Followers have existing relationship with social media influencers	• Requires resources for content creation; not readily available • Limited community-level reach (primarily to followers, unless post goes viral) • Social media influencers may not be willing to create and disseminate HIV-related content	Leverages existing relationship between social media influencers and followers

One of the current limitations of social media advertising is that it cannot be used to target ads based on certain demographics, including sexual orientation. Instead, advertisers try to reach their intended audience by choosing interests – for example specific entertainers or popular celebrities – that the social media algorithms use to distribute the content. However, how social media platforms currently work, it is not possible to determine who sees the ads beyond location, age and sex. For example, an ad can be sent to men in Dallas who have expressed interest in well-known celebrities and entertainers – but social media metrics do not measure and report if HHI MSM have seen the ad. HPTN 096 will attempt to gather data directly from the people who see these ads to determine if they are reaching the study population.

1.2.5.3 Peer Support

Peer support programs in various forms have been an important intervention for HHI MSM in both preventing HIV and maintaining HIV care retention. A recent study focused on the acceptability of peer navigators among HHI MSM in navigating PrEP and other HIV prevention services showed overwhelming openness to peer interventions, particularly if peers were of the same social group [165]. Studies have shown that effective peer support and social networks can increase PrEP awareness, education, trust and help overcome PrEP stigma and misinformation that are contributing to differences in PrEP use for HHI MSM. This study points to the potential role of peers to increase PrEP uptake in this population (107). Several studies have shown that peer support, whether with peer outreach workers proficient in motivational interviewing or other HHI MSM within social networks, is associated with reductions in sexual exposure to HIV [166, 167]. The use of technology in delivering peer support interventions, including through text messaging or through the use of other virtual platforms, has also been proven effective for HHI MSM in HIV care engagement [168].

A recent global meta-analysis of peer interventions for people living with HIV confirmed an overall trend towards increased linkage and retention [169]. The CDC has endorsed multiple peer support interventions for people living with HIV, which have been shown to increase HIV care engagement and treatment adherence [170], and in turn reduce the risk of onward sexual transmission. Successful evidence-informed community-based peer interventions specifically focused on HHI MSM, including d-up: Defend Yourself! and STYLE (Strength Through Livin' Empowered), have shown promising outcomes along the HIV care continuum [171, 172].

The inclusion of peer support in HPTN 096 is a direct contribution of community input received during the formative phase of developing the concept that was the basis for the HPTN 096 protocol. Multiple members of the HPTN 096 study team (including Drs. Nelson, Beyrer, Gamble, Remien and Driffin) bore witness to community testimony regarding the highly valued yet precarious predicament of peer support due to frequent staff turnover. These abrupt discontinuities in the therapeutic relationships between the peer mentor and their clients were described as painful losses that negatively affected their psychological well-being, often accompanied by experiences of grief and despair. Moreover, HPTN 096 representatives learned that it was not uncommon for HHI MSM to drop out of care for various reasons (e.g., loss of insurance coverage; stigmatizing or discriminatory clinical encounter), which led to the forfeiture of access to any peer support that they may have used as part of the HCF service offering. These real-life community testimonies regarding the need for durable access to peer support was consistent everywhere we convened onsite community listening sessions, including the 2018 Southern Region Ball House & Pageant Conference (Dallas TX), 2019 National CFAR Community Advisory Board Meeting (Chapel Hill, NC), 2019 Saving Our Selves/SOS conference (2019 Charleston, SC), and the 2019 South Carolina MSM HIV Prevention Institute (Columbia, SC). Ongoing community guidance continues to support the need and desire for the availability of peer support for HHI MSM in the HPTN 096 intervention communities. Specifically, communities have advocated for peer support that does not require that they register as a patient/client of a specific organization, and is available during evening, late night and weekend hours. However, the study team did learn during the pilot that it takes considerable time to develop trust in the community before men will take advantage of the HPTN 096 peer support program. Thus, we have adjusted our strategies to more directly and purposefully engage with

established community-based agencies and networks to implement the HPTN 096 peer support component. Additionally, the team will more strongly synergize with other HPTN 096 components to enhance the visibility and trust for men in the community to connect with HPTN 096 peer supporters (See Section 7).

1.2.5.4 PHASE

The intersection of multiple stigmas (e.g., skin color, social status, economic position, sex and health status), produces a unique and synergistic effect on access and engagement in HIV prevention and treatment services. Skin color has been used a basis for a system of structuring opportunity and distributing both privilege and disadvantage based on an individual's or community's assignment to social categories [173]. The system is multi-dimensional in that it operates at societal, institutional, interpersonal and intrapersonal levels [174-177]. Organizing people based on skin color is inherently dehumanizing because it operates on a hierarchy where individuals are assigned value based on the "lightness" (highest) and "darkness" (lowest) of the pigment in their epidermis [178, 179]. HHI MSM are subjected to this social taxonomy intertwined with HIV, sexual and feminine stigmas, and this combined stigma can be experienced, perceived, anticipated, and internalized. At the organizational (HCF) level, stigma [180] is imposed on clients in a range of forms from verbal harassment (e.g., harsh, intrusive, unnecessary questioning) to unwillingness to provide care (or an attitudinal preference not to provide care) to MSM [110, 181]. HIV stigma manifests globally in multiple forms ranging from verbal abuse to refusal to treat and avoidance behaviors like double gloving only with patients living with HIV; the latter driven by unwarranted fears of HIV transmission [182, 183].

The experience of multiple stigmas is a significant barrier to engagement in the HIV prevention and treatment cascades. Stigma prevents HHI MSM from seeking healthcare services and from engaging in HIV prevention practices—such as PrEP use or retention in HIV care that is critical for viral suppression and preventing onward transmission of HIV among people living with HIV. The presence of multiple interacting stigmas, including gossiping and a lack of supportive interpersonal disclosure, leads to guarded disclosures that are disruptive to HIV testing and early linkage to care [184, 185]. Qualitative studies found that sexual stigma is a barrier to seeking general health and HIV treatment services among MSM [110, 186, 187]. Within HCFs**,** negative interactions with staff can discourage MSM from staying engaged in medical care [108]. At the interpersonal and individual levels, perceived stigma can lead MSM to avoid health care services due to fear that someone will discover that they have sex with men. Anticipated stigma can generate fear of potential discriminatory treatment at HCFs, which may lead MSM to avoid or delay accessing services [188, 189]. At the individual level, internalized stigma may undermine motivation for engagement in HIV prevention and care activities and services [190].

The science of intersecting stigmas is not yet mature and is currently characterized by a high level of exploration and innovation . The current evidence-based stigma-reduction interventions in HCFs only address one type of stigma such as HIV stigma, LGB stigma or mental illness stigma [191, 192]. Nonetheless, key insights can be learned from the current stigma-reduction interventions and applied to multiple interacting stigma-reduction interventions. Lessons can also be garnered from the application of Quality Improvement (QI) approaches to reducing stigma and improving quality of care in HIV-related healthcare settings [193, 194].

While not the only element, the provision of intensive, participatory, skills-based training has emerged as an integral piece of comprehensive and effective stigma reduction interventions in HCFs [108, 195]. Approaches that facilitate knowledge exchange, and collaborative peer-learning have also been shown to extend the effects of stigma reduction interventions by translating principles into actions that result in practice improvements and changes in clinical outcomes [196, 197]. Contemporary models, such as the Extending Community Health Outcomes (ECHO) model, fuse videoconference technology and participatory techniques to help reinforce learning by grounding the content in practice-based experiences [198-201]. These types of models also enable the sharing of practical lessons learned between organizations and individuals that may be separated by long distances, but who nonetheless are attempting to achieve similar quality improvement and clinical outcome goals [83].

There is a precedent for an intensive workshop approach addressing stigma reduction in HCFs. For example, the Health Policy Plus Project, a global HIV stigma reduction program funded by United States Agency for International Development (USAID), published an extensive training guide describing a modular training program with prescribed content that can be flexibly implemented and recommended that a base training program be a whole facility approach (training all staff) over a minimum of a two-days [202]. Nyblade et al. describe elements of successful stigma reduction programs, including one in Vietnam that involved a participatory multi-day training [195]. A systematic review of HIV stigma reduction interventions describes the majority as skills-building and delivered over multiple sessions and over the course of many hours or days [203]. While feasibility is an important consideration, changing complex organizational- and healthcare worker-level psychosocial processes and behaviors requires complex training modalities.

1.2.6 Theoretical Premise for Integrated Strategies

The design of this study is informed by the network-individual-resource (NIR) model of HIV prevention with components integrated from self-determination theory (SDT) [204]. The NIR model is a recent innovation in HIV prevention theory development that takes into account the influence of communities, institutional systems and close others (e.g., peers) on an individual's agency (i.e., motivation to act and capacity to act) for enactment of behaviors that contribute to HIV prevention (e.g., PrEP use, retention in HIV care, HIV treatment adherence) [204]. This model also proposes that peers can affect health through social support, social behavioral regulation, and facilitating access to resources. In the NIR model, both mental and tangible resources must be engaged in order to optimize HIV prevention [204]. Tangible resources are assets that structure conditions to facilitate healthy behaviors. Mental resources refer to the psychosocial characteristics of people and networks that serve as assets for the avoidance of HIV/STI exposure behaviors. In this study, we used NIR to guide the selection of integrated strategy components that serve as assets with positive influence at the community (engaging social media content), organizational (increasing autonomy supportive care in HCFs), and interpersonal (peer social support) levels, as well as tangible resources at the community (community coalitions mobilizing to address structural barriers), organizational (reducing stigma as access barriers in healthcare facilities) and interpersonal (decentralized virtual access to peer support) levels.

SDT is a social psychological theory of human motivation that contends that healthy behavior change is optimized in environments that support humans' basic psychological needs for autonomy (freedom from control), competence (acquisition of skills and resources needed to master goal attainment), and relatedness (authentic connection) [205]. In this study, SDT concepts of autonomy, competence and relatedness are integrated into the NIR model by operationalizing them as qualities of the psychosocial assets operating within the HCF and online peer support environments to facilitate PrEP use, retention in HIV care, HIV treatment adherence and viral suppression among HHI MSM. SDT concepts are further integrated by operationalizing them as qualities of tangible resources that support autonomy and competence at the community (addressing local community-identified priority issues impeding PrEP use, retention in HIV care and viral suppression), organizational (increasing proportion of HCF staff trained in autonomy supportive approaches to care) and interpersonal (increased access to various forms of social support including affirmational, emotional, informational and instrumental support) levels. It is also important to distinguish "independence" from the concept of "autonomy" as defined in SDT. Independence is the exercise of thought or action without external input. This is different from autonomy that involves the experience of one's actions as fully willing and without external controls, while accommodating the input and influence of important others such as healthcare providers and peers [206], or via social media. Moreover, as demonstrated in studies across various cultural contexts—including US, Brazil, Canada, China, Ghana, India, Nigeria, Russia and Ukraine—SDT is similar to the local community coalition approach that characterizes the health access coalition component of HPTN 096, in that SDT does not presume "independence" in decision-making [207-211]. Decisions and/or behaviors that are derived from collective-centered thought can still be experienced as willful and volitional (not forced) with those involved assenting to act "together" or in the interest of the group. SDT accommodates the reality that, for many MSM in HHI communities across the American South, even while behaviors are expressed at the individual-level, antecedent psychosocial processes and social/structural determinants are at times influenced at the group or community-level.

2 STUDY OBJECTIVES AND ENDPOINTS

The overall purpose of this study is to evaluate a status-neutral integrated strategy to improve access to and uptake of HIV prevention and treatment services for HHI MSM in participating communities. The ultimate goal is to establish a strategy to reduce HIV incidence among HHI MSM in the southern US by increasing the number of HHI MSM accessing prevention and treatment services, increasing uptake and use of PrEP among those living without HIV and increasing retention in care, and thus viral suppression, among those living with HIV.

The primary and secondary objectives reflect this goal, using a mix of quantitative and qualitative measurements. Explicitly, primary measures are derived based on clinical data routinely available in the electronic medical record (EMR) as follows:

- HIV prevention and treatment services uptake is measured as the number of HHI MSM clients with healthcare visits at PHASE healthcare facilities.

- Use of PrEP is measured as prescriptions given to HHI MSM not living with HIV.

- Retention in care among HHI MSM living with HIV is measured as a proxy for viral suppression because of the high correlation between retention in care and viral suppression.

In addition, primary intervention process measures are designed to capture the implementation of each intervention component. Finally, exploratory objectives are included to investigate the potential impact of the intervention at the community level, as well as the potential contribution of each component to the overall intervention.

2.1 Primary Objectives

The primary objectives of this study are:

- To evaluate whether the HPTN 096 integrated strategy increases the number of HHI MSM clients at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases retention in care among HHI MSM living with HIV at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases PrEP prescriptions for HHI MSM not living with HIV at PHASE healthcare facilities

2.2 Secondary Objectives

The secondary objectives of this study are:

- To evaluate whether the HPTN 096 integrated strategy increases viral suppression (<200 copies/mL) in HHI MSM living with HIV at PHASE healthcare facilities
- To evaluate whether the HPTN 096 integrated strategy increases PrEP initiation, adherence and persistence for HHI MSM not living with HIV at PHASE healthcare facilities
- To assess changes in the experience of autonomy support among HHI MSM at PHASE healthcare facilities
- To assess how autonomy support, social support, stigma, barriers to healthcare and individual agency among HHI MSM at PHASE healthcare facilities are associated with engagement in care (including PrEP prescriptions and viral suppression)

2.3 Primary Intervention Process Measures

The primary intervention process measures of this study are:

- Self-reported coalition effectiveness among health access coalitions
- Reach of social media content to intended HHI MSM audience
- Acceptability, satisfaction and perceived usefulness of the peer support component among peer supporters and their clients

- Knowledge and attitudes among staff at PHASE healthcare facilities after completion of PHASE trainings as compared to before trainings
- Qualitative characterization of staff experience implementing PHASE

2.4 Exploratory Objectives

The exploratory objectives of this study are:

- To explore community-level viral suppression in HHI MSM in intervention and selected southern communities using CDC HIV surveillance data
- To use mathematical modeling to assess the potential population-level impact of the integrated strategy on HIV incidence among HHI MSM in the southern US

2.5 Endpoints and Data Sources for Primary Objectives, Secondary Objectives and Primary Intervention Process Measures

Table 5 below presents the endpoints and data sources for each primary and secondary objective, as well as the primary intervention process measures. The impact of the integrated strategy will be evaluated using repeated EMR-based assessments of the primary and a subset of the secondary endpoints throughout the two years before and the two years during implementation of HPTN 096 integrated strategy. All EMR-based endpoints will be repeated over the 4-year period. Each measurement point will use EMR data from the HCFs participating in the PHASE component over the prior 12 months. The same 12-month periods will be used for all EMR endpoints including the number of HHI MSM clients at participating HCFs, retention in care, PrEP prescriptions and viral suppression. The retention in care and viral suppression endpoints are intended to be consistent with the definitions used for Ryan White HIV/AIDS program reporting [51]. These are widely used measures and will increase the feasibility of ascertainment. In addition, a cross-sectional assessment will be repeated throughout the two-year implementation period to provide data for a subset of the secondary objectives.

Although the primary endpoints (number of clients, retention in care, and PrEP uptake) will be measured among HHI MSM clients at a facility, an analog of these endpoints (termed ‘supportive’ endpoints) will also be collected from all HHI men at each PHASE HCF. Given the implementation nature of this trial, the primary endpoints may be influenced by the quality of the data used to identify HHI MSM within the client population. Thus, in the scenario that the primary endpoints are limited by data availability and completeness, the supportive endpoints will help interpret and understand the effect of the integrated strategy on the primary and a subset of the secondary endpoints.

Table 5: Map of HPTN 096 Objectives and Intervention Process Measures to Endpoints and Source of Evaluation Data

Objective	Endpoints	Data Source
Primary Objectives		
To evaluate whether the HPTN 096 integrated strategy increases the number of HHI MSM clients at PHASE healthcare facilities	• (primary) Number of HHI MSM with a visit at the HCF in the previous 12 months • (supportive) Number of HHI men* with a visit at the HCF in the previous 12 months	Primary: EMR Supportive: EMR
To evaluate whether the HPTN 096 integrated strategy increases retention in care among HHI MSM living with HIV at PHASE healthcare facilities	• (primary) Number of HHI MSM living with HIV with at least two HIV medical visits to the HCF at least 90 days apart within the previous 12 months • (supportive) Number of HHI men* living with HIV with at least two HIV medical visits to the HCF at least 90 days apart within the previous 12 months	Primary: EMR Supportive: EMR
To evaluate whether the HPTN 096 integrated strategy increases PrEP prescriptions for HHI MSM not living with HIV at PHASE healthcare facilities	• (primary) Any PrEP prescription among all HHI MSM without HIV with a medical visit at the HCF within the previous 12 months • (supportive) Any PrEP prescription among all HHI men* without HIV with a medical visit at the HCF within the previous 12 months	Primary: EMR Supportive: EMR

Objective	Endpoints	Data Source
Secondary Objectives		
To evaluate whether the HPTN 096 integrated strategy increases viral suppression (<200 copies/mL) in HHI MSM living with HIV at PHASE healthcare facilities	• (primary) Viral suppression of the most recent viral load (VL) done among all HHI MSM living with HIV who had a VL measurement at the HCF in the previous 12 months • (supportive) Viral suppression of the most recent VL done among all HHI men* living with HIV who had a VL measurement at the HCF in the previous 12 months	Primary: EMR Supportive: EMR
To evaluate whether the HPTN 096 integrated strategy increases PrEP initiation, adherence and persistence for HHI MSM not living with HIV at PHASE healthcare facilities	• Self-report of PrEP initiation and adherence in the previous 12 months • (primary) Repeat PrEP prescriptions among HHI MSM not living with HIV in the previous 12 months • (supportive) Repeat PrEP prescriptions among HHI men* not living with HIV in the previous 12 months.	Cross-sectional assessment in sample of HHI MSM at PHASE HCFs (questionnaires) Primary: EMR Supportive: EMR
To assess changes in the experience of autonomy support among HHI MSM at PHASE healthcare facilities	• Self-reported scale measuring autonomy support • Individual-level qualitative data with a subset of HHI MSM clients exploring autonomy support	Cross-sectional assessment in sample of HHI MSM at PHASE HCFs (questionnaires, healthcare climate section) Cross-sectional assessment in sample of HHI MSM at PHASE HCFs (qualitative interviews)

Objective	Endpoints	Data Source
To assess how autonomy support**,** social support, stigma, barriers to healthcare and individual agency among HHI MSM at PHASE healthcare facilities are associated with engagement in care (including PrEP prescriptions and viral suppression)	• Self-reported data related to autonomy support, social support, stigma, barriers to healthcare, individual agency. • Any PrEP prescription in last 12 months for HHI MSM not living with HIV • Viral load suppression and retention in care in last 12 months for HHI MSM living with HIV	Cross-sectional assessment in sample of HHI MSM at PHASE HCFs (questionnaires) Cross-sectional assessment in sample of HHI MSM at PHASE HCFs (case report forms)
Primary Intervention Process Measures		
Self-reported coalition effectiveness among health access coalitions	• Self-reported data related to coalition effectiveness reported by coalition and CLO members at periodic intervals	Coalition effectiveness inventory tool
Reach of social media content to intended HHI MSM audience	• Social media/website metrics; self-identified demographics and qualitative data from HHI MSM who engage with the campaign; and the number and proportion of reached/engaged who are HHI MSM, if possible.	Social media platforms, website analytics, surveys and qualitative data
Acceptability, satisfaction and perceived usefulness of the peer support component among peer supporters and their clients	• Self-reported data on acceptability, satisfaction, and perceived usefulness of the peer support component	Acceptability, satisfaction, and usefulness surveys among component participants Qualitative and quantitative forms summarizing support activities among peer supporters
Knowledge and attitudes among staff at PHASE healthcare facilities after completion of PHASE trainings as compared to before training	• Individual-level survey data on knowledge and attitudes related to healthcare provision to HHI MSM	Pre- and post-workshop survey in all consenting workshop participants

Objective	Endpoints	Data Source
Qualitative characterization of staff experience implementing PHASE	• Individual-level qualitative data with a subset of HCF staff addressing benefits and challenges of PHASE implementation and facilitators of success	Qualitative interviews – HCF staff

*HHI men will have the same demographic characteristics as HHI MSM, with the exception of sexual orientation.

3 OVERVIEW OF STUDY DESIGN

HPTN 096 is a hybrid implementation-efficacy trial that uses a single arm interrupted time series (ITS) design. The integrated strategy will be delivered in up to five communities in the southern US (See Schema Figure 1 for an overview of the study design). The integrated strategy was piloted for one year in two communities (Dallas, TX and Montgomery, AL) under Version 2.0 and 3.0 of the protocol, and information from the pilot has been incorporated into the study and integrated strategy design.

Study outcomes will be measured at participating healthcare facilities where HHI MSM are receiving HIV-related prevention or treatment services, which will closely link implementation of the integrated strategy to the measured outcomes. An ITS approach was selected as the quasi-experimental design for assessing change in outcomes resulting from the intervention. A time series is a continuous sequence of observations taken on a population over time. In this ITS design, a time series of observations (for client volume, uptake of PrEP and retention in HIV care) for two years prior to the intervention will establish an underlying trend. This trend will be interrupted by the study intervention at a known time point and the subsequent two years of observations during the intervention period will determine if the integrated strategy has changed the expected trend [212, 213].

HPTN 096 is evaluating a four component, multi-level integrated strategy. The four components of the integrated strategy include: 1) a **health access coalition** component using a community coalition model to develop a local community-wide response to improving HIV outcomes for HHI MSM through addressing social and structural barriers, increasing community education and awareness, and implementing local advocacy approaches; 2) use of **social media** to raise awareness, reduce stigma, increase motivation for positive health behaviors, and inform HHI MSM of available HIV-related and other relevant services within their communities; 3) **peer support** for HIV/STI testing, PrEP and HIV prevention, ART initiation and ongoing adherence, and provision of information about access/assistance programs; and 4) a Promoting Human Autonomy Supportive Environments (**PHASE**) training and quality improvement program designed for healthcare facilities to create a supportive healthcare environment that fosters HHI MSM autonomous engagement in HIV-related services and promotes increased HIV/STI testing, PrEP and ART uptake, retention in care, and viral suppression.

The effect of these four components is expected to be synergistic, with each component having the possibility of increasing the impact of the other three (see Section 9, Intervention Component Synergies). As such, these four components will be implemented in parallel together over the

course of two years in each intervention community. Because health access coalitions, social media and peer support activities are expected to increase demand for prevention and care at PHASE healthcare facilities (HCFs), these components will need to be operational at a low level in each community before starting the PHASE component. When PHASE begins, all four components will be fully implemented at scale. These three components will be established during a pre-implementation period, which will begin approximately one year prior to the start of PHASE. Although these components could (and will to some extent) drive demand for services at PHASE and non-PHASE HCFs during pre-implementation, successful (and measurable) healthcare engagement is only expected when the most effective services are provided for HHI MSM at PHASE HCFs. Additionally, it will take time for these components to be built and gain traction within each community. Thus, the impact of pre-implementation activities on baseline measurements is expected to be minimal.

The primary study endpoints will use data extracted from the EMRs of clients seen at the HCFs participating in PHASE. These data will be collected at pre-baseline, baseline, midpoint, and post-intervention for the HHI MSM seen in these HCFs (see Figure 10). The secondary study endpoints will rely on these same EMR data, as well as additional data collected from a subset of HHI MSM. This subset will complete a cross-sectional assessment at baseline, after one year (midpoint) and at the end of the two-year implementation of the integrated strategy (post-intervention) and some will be invited to participate in qualitative interviews. In addition, specific HIV-related clinical data will be abstracted from their medical records and collected via case report forms to assess correlates of successful engagement in HIV care and prevention. There will be a unique and independent subset of HHI MSM for the cross-sectional assessment at each timepoint: no longitudinal data will be collected on any individuals.

Primary intervention process measures will use data inherent to each integrated strategy component to assess key implementation outcomes. The experience of healthcare workers participating in PHASE activities will be collected via surveys and qualitative interviews. The effectiveness of the heath access coalitions will be assessed using data from a coalition effectiveness inventory tool. The experience of peer support component users will be captured via acceptability and usefulness surveys. Lastly, the social media strategy will be assessed using standard social media platform data, website analytics and both quantitative and qualitative data collected from those who engage with the campaign in order to understand the extent to which the strategy reaches and engages HHI MSM in the five communities. In addition to the primary intervention process measures, a number of additional process measures will also be captured for each study component to assess and characterize the fidelity and dose of each component as implemented as compared to the design.

3.1 Study Duration

Each study community will participate in the study for approximately 3.3 years, which includes one year of pre-implementation activities, 2 years of implementation of the integrated strategy, and 2.3 years of data collection (see Schema Figure 1). There is a 12-month window during which all five study communities will begin implementation. Therefore, the overall duration of the study is expected to be approximately 4.3 years.

4 STUDY POPULATION

The primary study population will be HHI MSM residing in the five study communities. All primary study outcomes will be measured among HHI MSM attending a PHASE facility for health care. Additionally, a subset of HHI MSM at PHASE HCFs, as well as healthcare facility staff, health access coalition members, peer supporters and individuals who engage with the social media component will also be assessed for secondary outcomes and primary intervention process measures.

4.1 Description and Selection of the Five Study Communities

This version of the protocol will be conducted in up to five study communities, including a total of approximately 40 HIV prevention and approximately 20 HIV treatment facilities within these communities. A minimum number of three study communities will receive the study intervention, involving approximately 36 healthcare facilities (24 HIV prevention and 12 treatment). For the original community-randomized design (described in protocol Version 1.0), 16 communities were selected from the 28 EHE counties, Washington, DC and the six high-burden rural EHE states in the South, all of which have high burdens of HIV prevalence and recent HIV diagnoses among MSM. These 16 communities were chosen on an epidemiologic basis, using CDC surveillance and other available data on demographics, geographic distance, HIV burdens in men, MSM, and HHI MSM, as well as viral suppression in HHI MSM. Previous versions of the protocol outline the specific process used for study community selection. The five communities selected for the current protocol design represent all states where the original eight intervention communities were located and include the two communities where the study was piloted. These five study communities encompass many of the various cultures and norms found in the southern US. In addition, these five study communities have enough healthcare facilities to provide the pre-specified number (40 HIV prevention and 20 HIV treatment facilities) needed to determine the outcomes for the three primary objectives.

The five study communities are:

- Dallas, TX (Dallas county) (pilot)
- Montgomery, AL (Montgomery, Elmore and Autauga counties) (pilot)
- Fort Lauderdale/Miami, FL (Broward and Miami-Dade counties)
- Memphis, TN (Shelby county)
- Atlanta, GA (Cobb, DeKalb, Fulton and Gwinnett counties)

4.2 Priority Populations for Components of the Integrated Strategy

The population being prioritized for the study through implementation of the integrated strategy is all HHI MSM in the participating five study communities, regardless of HIV status. Each component of the integrated strategy may prioritize additional populations for component activities as described in the subsections below. Populations to be assessed in each component for primary intervention process measures and additional process measures are also described in subsections below.

4.2.1 Health Access Coalition Component Study Population

The health access coalition component activities will focus on broader community members and service providers, including HHI MSM, within each study community. Primary intervention and additional process measures will be assessed among coalition members and coalition lead organization (CLO) staff, as well as the Coalition Manager.

4.2.2 Social Media Component Study Population

Social media component activities will be tailored for HHI MSM within each study community. Primary intervention and additional process measures will be assessed among those who are exposed to and engage with the study's social media content. A subset, based on their level of engagement and willingness to participate, will be invited to participate in surveys and qualitative data collection to determine if the social media strategy is reaching its intended audience.

4.2.3 Peer Support Component Study Population

Peer support component activities will prioritize HHI MSM who reside in the study communities. Peer support will be offered with an HIV-status neutral approach to HHI men who self-report a lifetime history of anal sex with other men (meaning at any time in their life), are 15 years and older, and live in an study community (based on self-reported provision of a county and state of residence). Primary intervention and additional process measures will be assessed among all peer support participants who are willing to provide their feedback, as well as all peer supporters.

4.2.3.1 Recruitment Process for Peer Support Component

Recruitment for the peer support component will be carried out in an ongoing fashion by the peer supporters, the local partner organizations implementing the component, and via the study's website and social media strategy. Participants will be recruited from a variety of sources including, but not limited to, universities, health and social service providers, community-based locations, online websites, and social networking applications. The local partner organizations will be responsible for developing recruitment strategies deemed appropriate for their local communities. Potential participants will be screened for eligibility and offered study participation throughout the entire study. Active recruitment will end at least one month prior to the end of study implementation so that all participants have the opportunity for at least a short period of ongoing support. There is no upper limit for enrollment. Peer supporter workload will be monitored, and the number of peer supporters and active recruitment efforts will be adjusted, as needed, throughout study implementation.

4.2.4 PHASE Component Study Population

PHASE component activities will include staff at each participating PHASE HCF. Primary intervention process measures will be assessed among all HCF staff completing the Foundation workshops as well as those staff members completing each ECHO session who agree to complete the assessments. Additional process measures will be assessed at the facility-level to determine fidelity to program elements of PHASE.

4.3 Study Population for Primary and Secondary Endpoint Data Collection at PHASE HCF

Primary and secondary study endpoints will be measured through EMR data collected from participating PHASE HCFs. In addition, a cross-sectional assessment will be conducted with a subset of HHI MSM clients at participating PHASE HCFs. At a subset of these facilities, qualitative interviews will also be conducted with a subset of HHI MSM clients and PHASE HCF staff. These study populations are further described in sub-sections below.

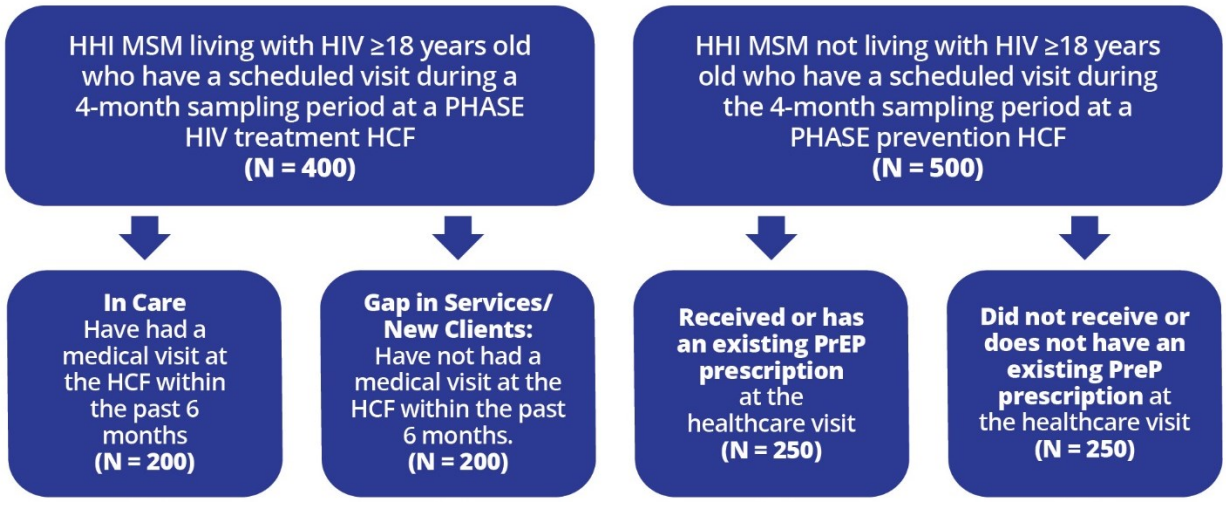
4.3.1 EMR Data Collection Study Population

Primary study endpoints will be assessed using a limited data set from EMR for a subset of clients at all participating PHASE HCFs. This subset will include all clients aged 15 years and older who are identified as male, who have the demographic characteristics that match the demographic characteristics of HHI MSM, and who have at least one encounter recorded in the EMR anytime between the 24 months before the start of PHASE intervention implementation at that HCF and throughout the two years of the intervention (see Figure 10).

4.3.2 Cross-Sectional HHI MSM Client Assessment Study Population

Approximately 900 eligible HHI MSM recruited from HCFs participating in PHASE will be included in a cross-sectional assessment at each of three timepoints (for a total of approximately 2700 HHI MSM). At each timepoint, approximately 400 men living with HIV will be enrolled from PHASE HIV treatment facilities, and approximately 500 men not living with HIV will be enrolled from PHASE prevention facilities. Within each group, participants will be further stratified by care status (for those living with HIV) and PrEP prescription (for those not living with HIV), as shown in Figure 4:

Figure 4. Cross-Sectional HHI MSM Client Assessment Sample Stratification



The stratification definitions are not intended to directly align with primary endpoint definitions, but rather to allow exploration of themes among dichotomous sub-groups of men (e.g., those who have accepted PrEP and those who have not). Participants will be selected for cross-

sectional assessment participation according to criteria in Sections 4.3.2.1 and 4.3.2.2. Participants will be recruited as described in Section 4.3.2.3.

Each cross-sectional assessment cohort will be independent of previous cohorts, although it is possible that individuals may participate in more than one cohort.

4.3.2.1 Cross-Sectional HHI MSM Client Assessment Inclusion Criteria

Individuals who meet all of the following criteria are eligible for inclusion in the cross-sectional assessment:

- At least 18 years of age
- Man
- Self-reports a lifetime history of anal sex with another man (i.e., at any time in their life)
- Determined to be HHI within the study community per CDC surveillance data
- Willing and able to provide consent to participate in the study
- Have a medical visit scheduled during the designated sampling period at a PHASE treatment or prevention healthcare facility

4.3.2.2 Cross-Sectional HHI MSM Client Assessment Exclusion Criteria

Individuals who have any condition that, in the opinion of the Investigator of Record (IoR) or designee, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives, will be excluded from the cross-sectional assessment. There are no co-enrollment restrictions for participation in this assessment.

4.3.2.3 Recruitment Process for the Cross-Sectional HHI MSM Client Assessment

Recruitment of each cross-sectional sample of participants will occur over a 4-month period during or after the PHASE intervention, and there will be a total of three sampling periods: at baseline (1-4 months), midpoint (12-15 months) and post-intervention (24-27 months). Recruitment activities will be conducted by designated site staff at each participating PHASE HCF. All potentially eligible participants will be approached until accrual targets are met to avoid selection bias. PHASE HCFs will be responsible for developing appropriate recruitment processes that are geared toward their respective local communities. They will also be responsible for determining site-specific strategies for identifying all potentially eligible clients and ensuring that all such scheduled clients are approached during the sampling period until target accrual is met.

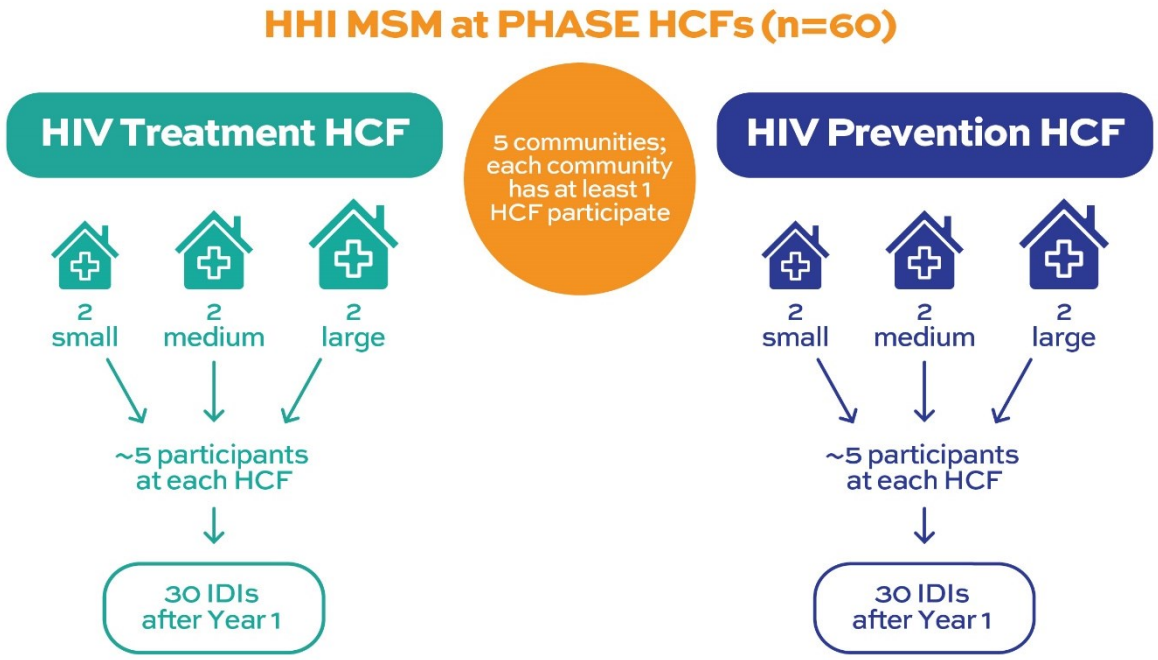
4.3.3 Qualitative Data Collection

An estimated 120 in-depth interviews (IDIs) will be conducted with two sets of participants: 1) HHI MSM who are clients at PHASE HCFs (n=60), and 2) healthcare providers and staff who are participating in the PHASE component of the integrated strategy (n=60). Interviews will be conducted at a subset of PHASE HCF in all five study communities. Participants will be selected based on the criteria outlined in sections 4.3.3.1 and 4.3.3.2.

4.3.3.1 HHI MSM Clients

IDIs will be conducted around the midpoint (12-17 months) of the intervention after one year of implementation with 30 clients from six PHASE treatment facilities and 30 clients from six PHASE prevention facilities (N=60 total). Participants will be purposively sampled aiming for balance of individuals across prevention and treatment strata (e.g., those prescribed PrEP and not prescribed PrEP, those engaged in care, retained in care, newly diagnosed, etc.). (See Figure 5 below)

Figure 5. HHI MSM Client IDIs



The following criteria will be used:

Inclusion Criteria:

- Met inclusion criteria for the cross-sectional HHI MSM client assessment (defined in Section 4.3.2.1)
- Completed the cross-sectional HHI MSM client assessment
- Willing and able to provide assent/consent

Exclusion Criteria:

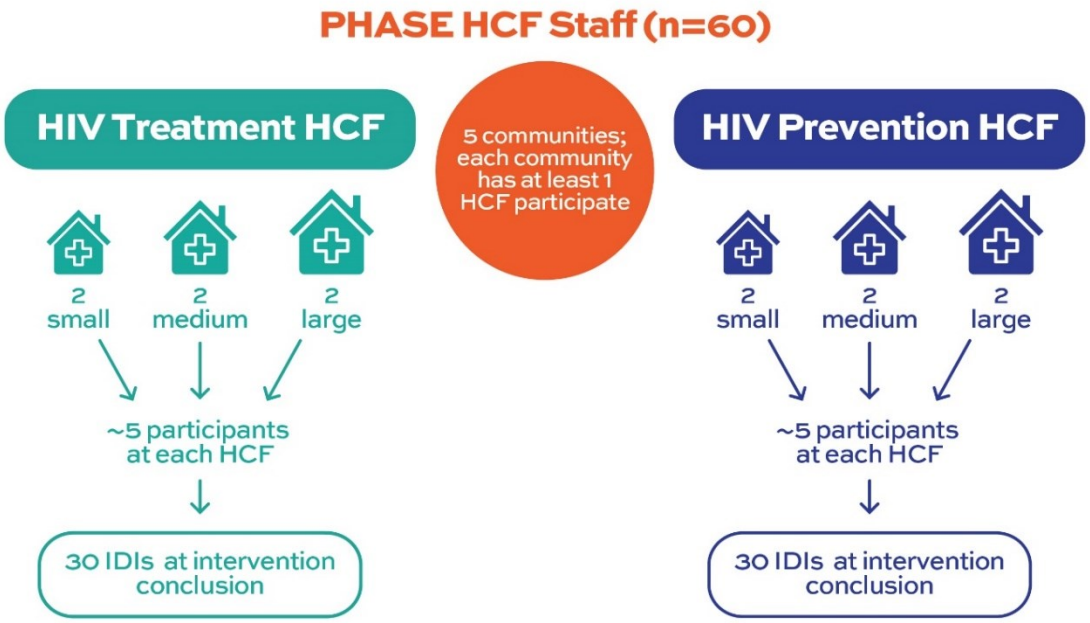
- Individuals who have any condition that, in the opinion of the Investigator of Record (IoR) or designee, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives, will be excluded from the qualitative interview.

There are no co-enrollment restrictions for these interviews.

4.3.3.2 PHASE HCF Staff

IDIs will be conducted at the conclusion of the PHASE intervention (months 18-23) with 30 staff from six PHASE treatment facilities and 30 staff from six PHASE prevention facilities (total N=60). Staff will be purposively sampled based on their engagement with PHASE, aiming for a subset of clinical providers (including physicians, advanced practice provider, etc.), social support staff (peer navigators, social workers, etc.), quality improvement staff, data managers, and administrative and executive staff (receptionists, C-Suite, etc.) (see Figure 6 below).

Figure 6. PHASE HCF Staff IDIs



The following criteria will be used:

Inclusion Criteria:

- Is a staff member at a participating PHASE facility
- Participated in at least one PHASE activity (e.g., attended a PHASE Foundation training, participated in ECHO training, member of PHASE quality improvement team)
- Willing and able to provide consent

Exclusion Criteria:

- Individuals who have any condition that, in the opinion of the Investigator of Record (IoR) or designee, would make participation in the study unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives, will be excluded from the qualitative interview.

There are no co-enrollment restrictions for these interviews.

5 HEALTH ACCESS COALITIONS COMPONENT

5.1 Component Description

The health access coalitions component will use a community coalition program as its base model for reducing structural barriers, shaping community social norms and raising awareness to reduce HIV among HHI MSM. The coalition model will do this through:

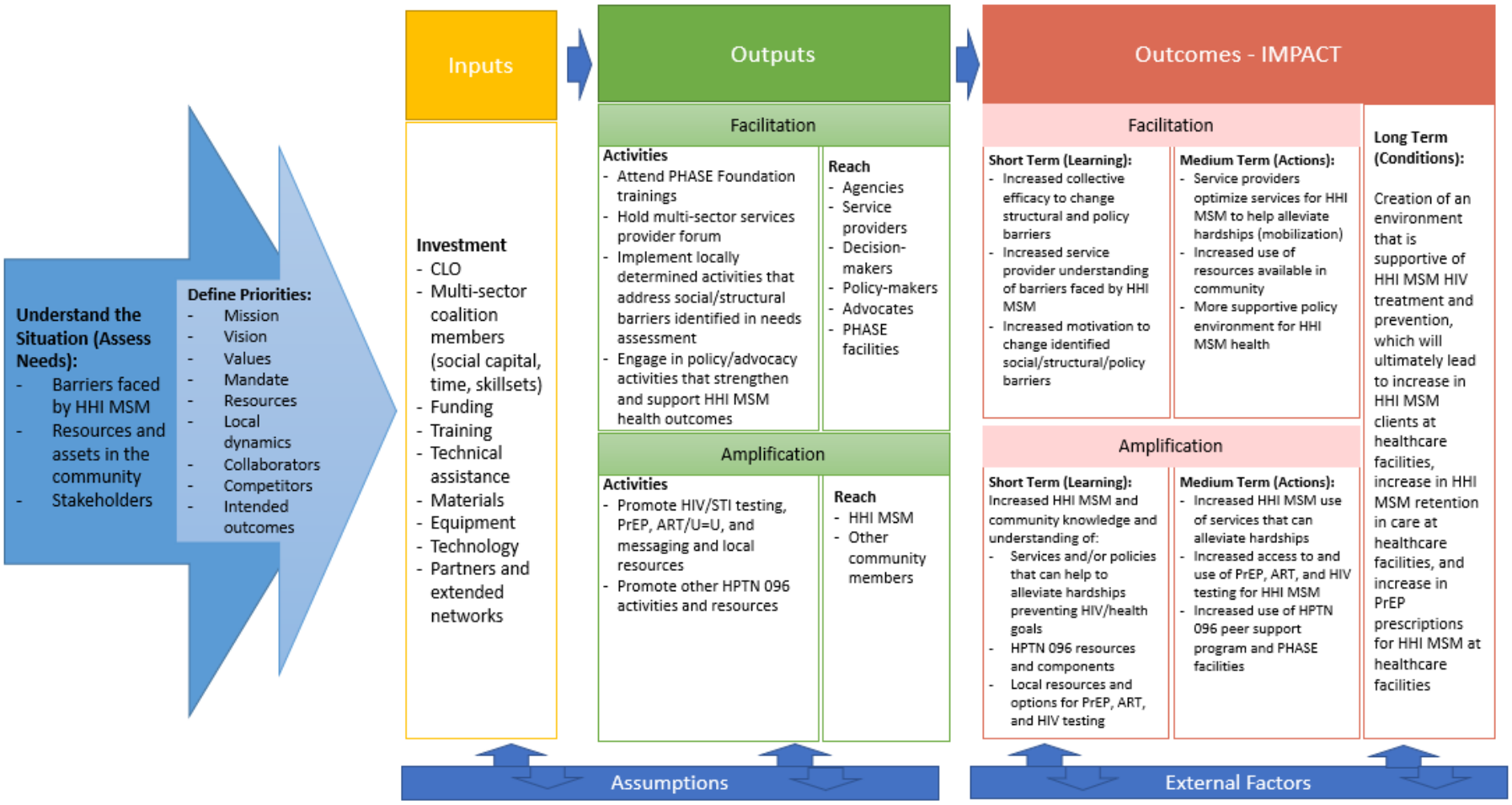
- Facilitating a reduction in social, structural, and policy barriers to HIV testing, PrEP, and viral suppression through fostering collective efficacy, promoting norms within the local service sectors (e.g., social, legal, economic, etc.), and advancing advocacy efforts that support the strategic prioritization of access to resources and services for HHI MSM.

- Amplifying awareness, education, and capacity building around HIV prevention and treatment resources and messaging (including other HPTN 096 components).

The community coalition program will be initially implemented through partnership with local CBOs contracted in each community, referred to as the Coalition Lead Organization (CLO), to build and establish the coalition in their community. After the coalitions are established, they will transition to be largely self-governing, but a continuing contracted Coalition Manager role will ensure that there is ongoing administrative support for each coalition.

The coalition model will impact the study outcomes through the two strategy pathways of facilitation and amplification [100]. A logic model depicting how the coalition program is expected to achieve short-, medium-, and long-term objectives through facilitation and amplification pathways is shown in Figure 7.

Figure 7. Health Access Coalition Program Logic Model



5.1.1 Implementers

The health access coalition component will be implemented by the CLO initially, and after establishment, by each local coalition and their Coalition Manager. Coalition activities may be implemented in partnership with other CBOs and service providers in the communities as well.

5.1.1.1 CLO and Coalition Manager Role

The CLO is primarily responsible for building and establishing the coalition. Until the coalition is fully established and self-governing, the CLO will assume the role of convening the coalition and will assume significant responsibility for its operations. The ultimate goal will be for the coalition to transition to being fully self-governing with respect to their efforts to realize the study goals and drive their activities, with a Coalition Manager playing a support role throughout the duration of the study period. The coalition will be determined to be self-governing after completion of all study-specific training activities, and upon approval from the study team.

A competitive selection process will be used in each community to select the organization best suited for the CLO role. The Coalition Manager may be affiliated with the CLO or independent from the organization. The Coalition Manager will be responsible for ensuring continued administrative and logistical support for the coalition to implement the study-specific activities (see Section 5.2.2) after the coalition is established and has transitioned fully to self-governance.

5.1.1.2 Formative Work and CLO Selection Process

In many HPTN 096 communities, it is likely that at least some efforts are already ongoing by grassroots community organizations for HHI MSM with similar goals as this study. Prior to selecting CLOs through a competitive contracting process, formative work will take place to better understand the existing community structures and organizations in each intervention community that are currently operating within the HIV field and/or doing work related to HHI MSM. Attempts will be made to engage with existing organizations and groups to increase their awareness of the HPTN 096 study and its goals, and to ensure they are informed of and have the opportunity to participate in the competitive CLO selection process. The selection process will be standardized across communities. Selection will be done by committee, and the evaluation criteria and selection process will be fully documented and transparent to community members. CLO selection will occur in the study pre-implementation period.

5.1.1.3 Coalition Role

For the purpose of HPTN 096, a coalition is defined as multiple relevant organizations and/or individuals who have agreed to work together towards a common goal, in this case, to create an environment that is supportive of HIV treatment and prevention goals for HHI MSM. The CLO will be responsible for recruiting and assembling the initial coalition members. Coalition recruitment will occur in the study pre-implementation period. There is no minimum or maximum required number of coalition members; however, membership should be varied and comprised of traditional and non-traditional partners of different demographic groups, representing sectors from across the social determinants of health. The coalition members are responsible for carrying out the overall mission of the coalition and its activities. The coalition will develop its own identity (name/branding) and has autonomy to govern itself in accordance

with HPTN 096 study guidance and its own by-laws. The Coalition Manager is tasked with ensuring that the coalition's operations and activities are consistent with the study guidelines and maintaining direct lines of communication with the study team.

5.1.2 Location

One coalition will be established in each study community. Coalition activities may take place at any location deemed suitable or necessary in the community or that would benefit and/or reach members of the community. Coalition meetings and/or activities may also take place virtually.

5.1.3 Health Access Coalition Toolkit

Study-specific operational guidance for CLOs, Coalition Managers, and coalitions will be outlined in the HPTN 096 Health Access Coalition Toolkit and associated supporting documents that will be made available to all CLO staff and coalition members. The Toolkit will serve as an implementation guide for CLOs, coalition managers, and coalition members on coalition building and recruitment, governance, and operations of the coalition (including leadership and committee structure), training expectations and plans, activity expectations and processes, monitoring and evaluation, and sustainability planning. The purpose of the Toolkit will be to provide consistency in guidance and structure across all coalitions, alleviate administrative burden, streamline establishment of coalition leadership and governing by-laws, and generally facilitate and support successful functioning of the coalition in alignment with study goals and the study protocol.

5.2 Health Access Coalition Component Activities

5.2.1 CLO Activities

After selection, CLOs will complete study-specific training prior to any coalition recruitment activities. CLOs will be expected to build an initial coalition within the pre-implementation period, and to transition its management to the coalition, with support of a Coalition Manager, for the majority of the implementation period. CLOs will be expected to lead initial community engagement and recruitment activities for coalition building. CLOs will work in collaboration with, and with supportive technical assistance (TA) and consultation from, members of the HPTN 096 study team. CLOs will communicate closely with key study team leads about all study-related coalition establishment activities in their community.

5.2.2 Coalition Manager Activities

Coalition Managers will provide administrative and logistical support to the coalitions. Coalition Managers will submit coalition activity proposals to the study team, monitor and track coalition activities and attendance, and report process data to the study team monthly. The Coalition Manager will attend all coalition meetings and activities and serve as a representative in the coalition leadership body, as well as attend protocol team meetings and calls.

5.2.3 Coalition Activities

Once established, each coalition will be expected to implement a minimum set of study-specific activities, as shown in the Coalition Logic Model (Figure 7) and further described in the Toolkit. These activities are summarized in the sub-sections below; however, each coalition will have the flexibility to implement the activities in the ways in which they believe will be most effective in their community. All activities will be documented as part of process measures (Section 5.4) to enable activity characterization, and to assess levels of uniformity and adherence to the health access coalition model.

5.2.3.1 Trainings and Initial Coalition Meetings

Prior to implementing coalition activities, each CLO/coalition, will receive study-specific training on topics such as the HPTN 096 study components and design, study objectives (especially primary objectives), structural competency [214-216], HIV 101 and epidemiology of HIV in the South, conducting needs assessments, policy and advocacy approaches, coalition governance, and other topics as detailed in the Toolkit. The initial training will also include a team building element. The structure of the first several coalition meetings will be pre-determined per the Toolkit and will be utilized for ongoing study-specific training as well as pre-specified coalition business. At the conclusion of these pre-specified trainings/meetings, coalitions will be expected to have leadership structures and identity (i.e., name/brand) in place, and full management of coalition meetings will be transitioned to coalition leadership. Supplemental training will be provided on an as-needed basis.

5.2.3.2 Needs Assessment

Coalitions will first work to understand the local situation by conducting a rapid needs assessment exercise to identify local services and resources that address social determinants of health, as well as assessing the barriers experienced by HHI MSM in their community. The rapid needs assessment is the first required activity that coalitions will undertake and will serve as the basis for all future activities. This needs assessment will help coalitions use facts and data to decide what activities should be prioritized. The needs assessment process will include evaluating existing needs assessments that have been done in the community, as well as potential collection of supplemental information. Supplemental information that is collected will be for the purposes of helping coalitions make decisions about which activities to implement and how best to do so in their community. Information collected from the needs assessment is not considered HPTN 096 study data and will not be analyzed by the HPTN 096 team for the purposes of assessing study outcomes, nor will it be presented as such in study publications. Once the coalition has determined that sufficient information has been collected and reviewed and unmet needs have been identified, the coalition will begin the work of priority setting and action planning within the two activity pathways of facilitation and amplification.

5.2.3.3 Facilitation Component

Facilitation activities will primarily be locally determined activities that can help to address or offset underlying social and structural issues such as poverty, homelessness, substance use, and access to education, which can impact the risk of HIV transmission and the ability to access care.

As a starting point for these activities, after the needs assessment, coalitions will convene a Service Provider Forum(s) to bring together multi-sector service providers representing resources and/or needs identified that are key to supporting a more comprehensive community system for HHI MSM. The goals of the Forum(s) will be to:

- Raise awareness of service providers to differences in HIV outcomes experienced by HHI MSM;
- Raise awareness of service providers of the needs of HHI MSM to create better health outcomes;
- Discuss together ways in which services can be optimized to better meet the needs of HHI MSM as they relate to HIV outcomes; and
- Develop an action plan to address barriers that can be implemented by forum attendees, as well as next steps for reporting back on progress and outcomes.

Coalition members will also be expected to identify representatives to participate in PHASE Foundation training workshops along with PHASE HCF staff in their community once full study implementation begins. During these workshops, barriers to HCF access will be raised and discussed and coalition members will have an opportunity to be part of these conversations and learning. Coalitions will determine appropriate activities to address HCF-related barriers in their community after participation in these workshops.

Additionally, coalitions will work to support or recommend causes or policies that strengthen HIV services, human rights, and/or foster patient-centered healthcare practices for HHI MSM in their community. Coalitions may engage in policy and advocacy related activities through advocating for/against new policies and/or laws, suggesting ways in which implementation of existing policies and/or laws could be improved, and monitoring to ensure agencies are held accountable to what they are funded to do in their community.

5.2.3.4 Amplification Component

To amplify the effects of the other HPTN 096 activities as well as local HIV prevention/treatment and health/wellness strategies, and to address barriers related to knowledge, awareness, understanding, and stigma, coalitions will conduct activities that relate to the following domains:

- Promoting HIV education and awareness, including HIV testing, engagement in care, viral suppression or U=U, and PrEP messaging.
- Destigmatizing HIV, PrEP, and HIV testing.
- Promoting other HPTN 096 study resources and activities, specifically, the PHASE intervention with participating HCFs in the community, the peer support component, and amplifying HPTN 096 messaging using multimedia channels where appropriate, including social media and traditional (e.g., print, radio, television) media, and online (websites, webinars) media channels.

- Establishing local coalition brand identity, social media presence, and a strategy for clout-building activities that will increase their influence and enhance their ability to steer public attention to HPTN 096 activities.

Additionally, coalitions will engage in targeted leadership development and capacity building efforts with HHIM in their community, implemented in partnership with the study team, with the goal of equipping HHIM with the skills, knowledge, and connections to be leaders in their communities.

5.2.3.5 Timeline of Activities

CLO selection and award will occur early in the pre-implementation period such that coalition building may also occur during the pre-implementation period. Once the coalition is assembled, the initial training and coalition meetings will begin as specified in Section 5.2.2.1 and the Toolkit. These initial meetings are likely to, but are not required to, occur during the study pre-implementation period. The initial meetings and trainings will follow the schedule specified in the Toolkit. If a coalition completes the pre-specified initial meetings and trainings and moves into self-governance during the pre-implementation period, the coalition may commence planning and executing coalition activities. However, it is expected that in most communities, the implementation period will begin (or will be close to starting) by the time the initial meetings and trainings have been completed, at which point coalition activities are expected to start ramping up. Other details specific to timing of activities will be specified in the Toolkit.

5.3 Primary Intervention Process Measure for the Health Access Coalition Component

The primary intervention process measure for the health access coalition component will be self-reported coalition effectiveness among health access coalition members. This information will be captured via the Coalition Effectiveness Inventory tool [217] implemented biannually with each coalition.

5.4 Additional Process Measures Related to the Health Access Coalition Component

Additional process measure data will be collected monthly to evaluate fidelity to and penetration of the planned health access coalition component. These measures are intermediary between the implementation of the component activities and achievement of the expected health access coalition outcomes and reflect key implementation outcomes of the overall implementation research logic model framework (see Section 1.2.2). Thus, they will be important in understanding the role that this particular strategy may (or may not) have in producing the primary and secondary outcomes. Coalition Managers will be responsible for providing monthly process data reports to the study team. Further, all process measure data may be reviewed by the study team and/or the Study Monitoring Committee (SMC) during the study period to make real-time adjustments to the deployment of the component to improve its effectiveness. Additional process measures for health access coalitions will include:

- Measures of penetration of the component activities:
    - Agreement in place with a local organization to serve as CLO in each intervention community

- CLO establishment of community coalition in each community and length of time required for establishment
- Number of meetings and attendance at each meeting for each coalition
- Composition and demographics of each coalition (number of people, number and types of organizations represented, roles/positions of members, sexual orientation, and sex of members)
- Metrics of engagement of coalition members (e.g., number and percentage of members who participate in each type of coalition activity)
- Number of sectors and agencies represented in the multi-sector service provider forum (including % that agree to be on a resource list)

- Measures of fidelity to the planned implementation of the component:
  - Number, type, and timing of coalition activities completed by each coalition within the study pre-implementation and implementation periods

6 SOCIAL MEDIA COMPONENT

6.1 Component Description

The social media component is a robust social media strategy designed to reach and engage HHI MSM throughout each participating community. The purpose of the strategy is to educate and empower HHI MSM so they can make informed decisions and behavioral changes to stop HIV acquisition and transmission. The strategy will utilize a multitude of social media communication and marketing tactics, such as campaigns and advertisements. Messaging will be ultimately designed to impact the outcomes of the primary and the first two secondary objectives, which include increasing the number of HHI MSM who are engaged and retained in prevention and care, the uptake of PrEP and the achievement of viral suppression. Simultaneously, the social media strategy will promote other study components, with the intention of creating inter-component synergy to amplify the benefit of these components. For example, a social media campaign will encourage HHI MSM to engage in care at PHASE HCFs (if the HCFs agree to be identified in a campaign), seek help from peer supporters, and take advantage of the environmental changes put in place via the health access coalitions. Ultimately, the social media strategy will take advantage of the features of social media that make it so powerful. Built into this component are ways to determine if the campaign is reaching the intended audience and what characteristics of creators, distribution and content are most successful. Finally, an outcome of this component will be a guidance document for future implementors: this guidance document will provide the details for how to execute a successful social media campaign for HHI MSM.

6.1.1 Content Description

All social media activity produced by this component will use tailored, HIV-status-neutral, resonant messaging that prioritizes HHI MSM and recognizes that this is not a monolithic audience. In particular, the strategy will recognize that HHI MSM are on a spectrum from fully transparent about their sexuality to completely secretive; thus, a wide range of approaches must

be included to reach the entire study population. The HIV-status-neutral approach allows for messaging that is relevant for those living with HIV, those not living with HIV and those who are not aware of their HIV status. In addition, other variables for audience segmentation (such as messages tailored for age or the stages of change) may be considered when determining content. Ultimately, content will promote HIV testing, engagement in prevention and care services, PrEP uptake and the benefits of viral suppression. In addition, the promotion of the other three study components will be integrated seamlessly into the social media strategy. An example of this would be that messaging about HIV-related services will provide information about the PHASE HCFs (not just "get tested" but rather "get tested here").

6.1.2 Types of Content

All modes of social media communication will be used in the campaign: posting and re-posting newly created and existing content, social media advertisement, and the engagement of social media influencers. There will be various sources of content including *event-driven* (e.g., conferences, Pride or college events), *credible authorities* (e.g., the CDC, health departments), HPTN 096 *partner-driven* (e.g., content created by social media partners participating in other study components), *campaign-driven* (content created specifically for the study's social media campaign), and *user-generated* (created by users in response to a campaign). Content from these streams may be in any format (e.g., short video, long video, image, text) that is supported by the social media platforms selected for the study.

6.1.3 Content Platforms

The social media campaign will be distributed across traditional (e.g., Facebook, Instagram) and non-traditional (e.g., gay dating apps, websites) social media platforms. As these platforms and their audiences evolve over time, the exact platforms will be determined in an ongoing fashion. When appropriate, specific HPTN 096 social media accounts will be created for the dissemination of content. For example, study specific HPTN 096 Facebook and Instagram accounts will be created centrally for content distribution to local communities (via advertising) and more globally (posting to all followers). Each partner will have the option to use existing social media accounts or create study-specific accounts; however, it will be encouraged for partners to use their existing accounts that already have an established following. All partners will be informed of the central, study-specific social media accounts, and asked to provide information about their own social media presence.

6.1.4 Implementers

A core social media working group will be established and responsible for implementation and oversight of the social media strategy. This group will be made up of members of the HHI MSM community (including individuals from the study communities), HPTN Leadership and Operations (LOC) staff, social media experts and a standing member of the study's CAG. In addition, a social media advisory group will be established to provide insight and guidance to the core social media working group from a wider range of voices within the HHI MSM community.

6.2 Social Media Component Activities

6.2.1 Creation of a Social Media Strategy Document

The core social media working group will create a social media strategy document that will outline the goals, tactics and metrics of the social media strategy. As the strategy is expected to evolve over the course of the study, a living document will be created that will capture this evolution. The social media strategy document will guide all activities and be the foundation of the guidance document created for future implementors.

6.2.2 Establishment and Maintenance of Content Creation Streams

Five content creation streams will be established prior to full implementation, as outlined below:

- *Event-driven:* The core social media working group will work closely with community engagement staff and other team members to provide information and a presence at local, regional and national events. Examples of local events include colleges homecoming, festivals/fairs and HIV-related fundraising events. Examples of regional and national events include conferences such as the Annual Alabama AIDS Symposium, the Saving Ourselves Symposium (SOS), the US Conference on HIV and AIDS (USCHA), HIV Implementation Science to Optimize Research Impact (HISTORI), and the Association of Nurses in AIDS Care (ANAC) conference. Content will be generated for distribution via social media before, during and immediately after these events, highlighting new information and the study's presence at the meeting. Event-driven content will often overlap with partner-driven content, as this content stream may highlight events implemented by partnering organizations.

- *Credible authorities:* The core social media working group will identify sources of credible health information to generate content. This stream may be re-posting existing content made by these credible authorities (e.g., the CDC, HRSA, local health departments) or content made by the study team that summarizes new and/or factual information (e.g., summarizing information from a newly published study, the various kinds of PrEP options).

- *HPTN 096 partner-driven*: There will be two types of partner-driven content. The first will be made by external partners who are already participating in the study. For example, healthcare facilities may generate content about their participation in PHASE or the peer supporters may generate content to promote the peer support component. The second will be partnerships formed specifically for the social media campaign. An example of this may be a partnership with a popular food or fashion brand that is willing to promote the study's key messages. This content stream will be distributed in one of two ways: 1) it will be distributed by these partners and then re-posted and/or reacted to by the HPTN 096 social media accounts, or 2) it will be provided to the core social media working group for initial distribution with partners then re-posted and/or reacted to the content.

- *Campaign-driven*: The core social media working group will oversee the generation of original content for multiple campaigns. Examples of how this might be done include

working with recognized members of the study communities, those with expertise in the sub-cultures of the HHI MSM community, those with specific knowledge and experience with HIV-related prevention and care topics, and social media influencers who have established relationships with the study population on social media platforms. The core social media working group will work with experienced photographers, videographers, graphic designers and other professionals to create a comprehensive look and feel for each campaign.

- *User-driven*: User generated content is created in response to any of the content created by the streams outlined above. This content is expected to be generated spontaneously or may be encouraged by the campaign – for example by asking social media users to upload videos in response to specific content.

The individuals selected to create campaign-driven content will be evaluated on both their experience with the HHI MSM community in the southern US and their familiarity with creating content for social media. Ideally, these content creators will have a basic understanding of HIV; however, extensive knowledge is not required, as training will be provided on HIV-related topics, as required. In addition, individuals who represent the broad and varied sub-cultures of the HHI MSM population in the southern US will be chosen. Content creators will be selected in an on-going basis driven by the need for new content creation. Partnering organizations, such as the PHASE HCFs, the health access coalitions, and the local peer support partner organizations, will select and manage their own content creators.

6.2.3 Training

Study-specific training will be provided to any content creators making campaign- or partner-driven content who need it. This training may include information about the study and/or technical information related to HIV, such as testing, PrEP uptake and the benefits of viral suppression. Content creators will be assumed to have the technical skills to create content themselves, or the study team will engage professional services (e.g., photographers, videographers, graphic designers, etc.). All content creators will receive guidance on the creative and technical parameters of the content (for example, the elements that describe the look and feel of the campaign or the expected video length).

6.2.4 Content Creation

6.2.4.1 Existing Content

Event-driven, credible authorities and partner-driven content streams will all take advantage of existing content by re-posting information put out by other creators on social media. The core social media working group is responsible for identifying this type of content with input from the social media advisory group and study CAG. Priority will be given to content that resonates with and engages HHI MSM. Existing content may be created by, but is not limited to, event and conference organizers, study partner organizations, organizations that support and represent HHI MSM, the CDC, U.S. Department of Health and Human Services (HHS), health departments, foundations, public-private partnerships, and HIV-related organizations.

6.2.4.2 Newly Created Content

Event-driven, credible authorities, partner-driven and campaign-driven content streams will all require the creation of new content. The core social media working group is responsible for overseeing the generation of newly created content with input from the social media advisory group and study CAG. A wide range of individuals will be approached to make new content, including HHI MSM, who may or may not be social media influencers, individuals who are recognized by or are known to have influence in the HHI MSM community (e.g., women, recognized artists, or entertainers), experts in HIV or other aspects of the study (HIV-providers, peer supporters and peer support partner organizations, PHASE participants and organizations, health access coalition members), and study members and staff (e.g., those attending community events and conferences). The study team will provide the content creators with guidance for content-related information (e.g., talking points or resources for specific topics), as well as any technical specifications required for the content (e.g., format, duration). In addition, the study team will provide professional services (photographers, videographers, graphic designers) when needed. Content creators will be asked to create both situational/local/short-lived and "evergreen" content, meaning that it could be used in multiple communities or multiple times throughout the duration of the study.

6.2.5 Review

All existing content that is re-posted and all newly created content will be reviewed and approved prior to distribution on HPTN 096 social media accounts by at least one member of the core social media working group to ensure relevance and accuracy. There may be some exceptions, such as posts made by study staff attending conferences and events, when timeliness is critical. The specific review process and any exceptions will be described in the social media strategy document. Partner organizations will be provided with guidance for the creation of their own content for the study; however, they will be responsible for ensuring that accurate and appropriate information is being distributed for the study.

6.2.6 Distribution

All content (both pre-existing and newly created) will be distributed via social media by either posting, re-posting or advertising. The way that posts and ads appear to users will be dictated by the social media platform used for distribution.

Whenever possible, social media platform tools will be used to target distribution, for example social media ads can be geotargeted to the study communities. Any other available and relevant parameters will be used to reach the study population (e.g., for Facebook and Instagram, sex, age, and interests can be used to target content). When identifying interests is an option, the core social media working group will work with the social media advisory group and the study CAG to determine any interest lists required for distribution. In addition, tools such as hashtags will be used to help individuals looking for certain social media content to find the study's content, when appropriate.

In order for posts and re-posts to reach the study population, it will be critical to create a recognized and trusted brand and to build the HPTN 096 social media following over time. This

approach will take advantage of the full power of social media, allowing content to reach the majority of HHI MSM in each community.

Some content will be distributed centrally, via HPTN 096 specific social media accounts or via paid advertising, and other content will be distributed by partner organizations. For example, it is expected that the peer support component (either by the peer supporters themselves or by the peer support partner organizations) will create and distribute their own social media content to promote themselves. The core social media working group will work closely with all study partners to provide guidance for their social media content and amplify their efforts. In return, local partners will be expected to amplify central messaging. Amplification can happen in different ways, depending on the social media platform and the original post; for example, on most social media platforms original posts can be re-posted, commented on, responded to, liked, shared, etc. Partners will be expected to provide information about their use of social media to the central team. The mechanism for reporting partner social media activities and engagement to the social media core working group will be outlined in the social media strategy document.

All content distributed centrally will be assessed to determine if it should be delivered to all study communities or only specific study communities. For example, information that is only relevant to a specific community will only be distributed to that community.

6.2.7 Frequency of Messaging

The core social media working group will establish a content calendar that will dictate the timeframe for content creation and dissemination. The frequency of posting, re-posting and ad distribution will depend on ongoing activities – for example event-driven content will be tied to local events and conferences – and on the overall goal of building and sustaining an active social media presence. The team will use social media campaign management tools, which can recommend optimal frequency and days/times to post content. Social media ads will be run for a limited time (never longer than three months) in any given study community. The general principle will be to continuously refresh the content being distributed for the study to strengthen engagement.

6.2.8 Evaluation of Reach and Engagement

All social media posts, re-posts and advertisements distributed via the HPTN 096 social media accounts will be monitored for reach, engagement and the response to calls to action. These data will be captured in real-time and used to adjust content and content distribution. Whenever possible, all content will contain a link back to an HPTN 096 webpage; therefore, the team will also be able to monitor website metrics. A list of both social media and website metrics is included in the Sections 6.3 and 6.4. This monitoring will include the temporal relationship between social media content distribution and engagement.

In addition, the team will try different ways to collect information from at least a subset of individuals who engage with the social media content to determine if HHI MSM are being reached. This data collection will include surveys ranging from very short and non-invasive (e.g., a pop-up window that asks, “Is the information on this website useful to you?” to longer, more personal questionnaires (e.g., brief surveys that include questions about sexual orientation). The

team will explore using various qualitative methods and user experience techniques, such as individual interviews and/or focus groups, to collect more nuanced information about how the content is able to engage the study population. The details of the minimal level, frequency and schedule for these evaluations will be included in the social media strategy document.

In addition to determining whether the social media ads are reaching the study population, the team will conduct A/B testing to compare different ads, or different distribution elements (e.g., the interests used to target the ads), to determine which approach works best. Some social media platforms (e.g., Meta, which includes Facebook and Instagram) have the capacity to distribute two ads simultaneously to two equivalent segments of the intended audience, ensuring that no one sees both ads. This allows for a head-to-head comparison of the performance of each ad. Whatever is learned from this testing will be incorporated into the next iterations of ad distribution.

Finally, those that enroll into the peer support component or who participate in the cross-sectional surveys will be asked if they have seen examples of recent content being disseminated for the social media campaign. This measurement may provide some insight into the impact the social media campaign is having on behavior.

6.2.9 Timeline of Activities

The social media component will be implemented in an ongoing fashion with the following activities taking place continuously:

- Establishment and maintenance of HPTN 096 social media platform accounts
- Identification and review of existing content for re-posting
- Identification of events and conferences for event-driven content
- Identification of individuals and organizations as credible authorities, or to create partner- or campaign-driven content
- Content creation, review and approval from all content streams
- Content distribution via posts, re-posts and ad distribution
- Use social media and website metrics to monitor engagement and process measures
- Use quantitative and qualitative feedback to determine if the social media content is reaching the study population

The specific details for all these activities will be included in the social media strategy document. The study team will continuously incorporate improvements to the process of content selection, creation and distribution to optimize HHI MSM engagement.

6.3 Primary Intervention Process Measure for the Social Media Component

The primary intervention process measure for the social media component will be the reach of the social media content to the intended HHI MSM audience. This information will be captured via quantitative and qualitative assessments as described in the Section 6.2.8.

6.4 Additional Process Measures for the Social Media Component

Additional process measure data will be collected to evaluate fidelity to and penetration of the planned social media activities. These measures are intermediary between the implementation of the social media component and achievement of the primary and first two secondary outcomes and reflect key implementation outcomes of the logic model framework (see Section 1.2.2). They will be important in understanding the role that this component of the integrated strategy may (or may not) have in producing the primary and first two secondary outcomes. Further, all process measure data may be reviewed by the study team and/or the SMC during the study period to make real-time adjustments to component implementation in order to improve its effectiveness. Additional process measures for social media will include:

- Measures of penetration of the social media content:
  - Number, topic, type (e.g., video, text-based, etc.) and the social media platform used for distribution of all social media posts, reposts and advertisements deployed in each study community
  - Metrics of social media engagement, including the following:
    - Impressions (number of views) and reach (number of unique individuals viewing each post, re-post or ad)
    - Clicks on embedded links
    - Number and types of other engagement (e.g., saves, likes, comments, reposts, etc.)
- Measures of engagement with and use of the HPTN 096 website
  - For all content that includes links back to the HPTN 096 website, website analytics will be used to capture engagement. The engagement parameters may include, but are not limited to:
    - New and repeat visitors
    - Page views and duration
    - Engagement
    - Session tracking (captures information about page views that last a certain amount of time)
    - Event tracking (captures actions visitors do on the page, for example clicking a link or playing a video)
- Estimates of the number of HHI MSM in the study communities reached and engaged:
    - Derived from the overall number of people reached and engaged as measured by social media metrics and the responses to surveys and individual interviews.
    - These data will be compared to the estimated number of HHI MSM in each study community.
- Measures of fidelity to the planned social media activities:

- Creation and distribution of social media content compared to the social media strategy
- When possible, partner-driven content will include a link to the HPTN 096 website in their social media posts and ads. These links will include a special code (called a UTM [Urchin Tracking Module]), which will allow the team to distinguish if a website visitor arrived via content distributed by partner organizations.

6.5 Guidance for Future Implementors

As the study team will gain valuable experience in the creation and implementation of a social media campaign designed to reach and engage HHI MSM, the study team will generate a guidance document to capture what they find to be best practices. This guidance document will include information such as:

- How to find and work with content creators and partners to create engaging content for HHI MSM
- The elements of social media content that optimize engagement with HHI MSM
- The overall costs affiliated with a social media campaign that engages HHI MSM
- The advantages and disadvantages of different content streams when engaging HHI MSM
- Technical details about content distribution, for example, interest lists that help target social media ads to HHI MSM

7 PEER SUPPORT COMPONENT

7.1 Component Description

The peer support component will promote and provide peer support to HHI MSM for HIV prevention in the intervention communities. Peer supporters will accomplish this by supporting and enhancing motivation for positive health behaviors, as well as facilitating linkage to HIV prevention and treatment, and other needed social and support services. Peer support may be provided in-person or virtually using a third-party communication platform (such as Google Voice, WhatsApp, etc.).

The peer support component will not serve as, nor is it intended to replace any traditional peer navigation or case management services. Peer navigators serve to guide peers through the healthcare system and work to overcome obstacles that are in the way of the peer receiving the care and treatment they require, including but not limited to health financing obstacles that could be overcome with insurance solutions. They help to identify needs and link peers to appropriate resources and health care. Similarly, case managers provide an assessment of care needs, provides referrals, and coordinates and ensures client access to a range of comprehensive medical care and social services.

Peer supporters will work collaboratively with applicable community resources (including identified peer navigators and case managers) to ensure comprehensive support services are

extended beyond the reach of the clinical setting and reachable for all seeking responsive and sustained care and support. This support seeks to augment their current network of support and reinforce positive and healthy behavior change.

Peer supporters who use their experiential knowledge which will be supplemented with formal training. Peer supporters will provide practical motivational, emotional, and informational support to peers who may be matched based on limited characteristics (e.g., age, location) and availability, taking client preference into account when possible. Once enrolled, program participation will continue throughout study implementation and will end when the study concludes.

7.2 Training

Peer supporters will be trained on the core skills and competencies of peer support as well as the scope and expectations of their role. They will also be trained on the following topics, including but not limited to:

- HIV, PrEP, non-occupational post-exposure prophylaxis (nPEP), other current HIV prevention options, and antiretroviral therapy (ART) education
- Adherence to PrEP, ART and medical care
- HIV/STI testing
- New HIV diagnosis
- Addressing stigma
- Self-care
- Resources and programs (at the national, state, and local level, as applicable) that prioritize HHI MSM in the provision of healthcare and other supportive services, including those that assist with healthcare coverage and insurance options, and accessing preventive and treatment medications and care services
- Multicultural competency (as it relates to the heterogeneity of the HIV epidemic for HHI MSM in the southern US)

The peer supporters will also be trained to share information about local resources and organizations that provide additional support resources including, but not limited to, legal, social, food, housing, substance use, mental health, and health care and insurance assistance programs available in the community. A resource directory of local organizations that provide HIV prevention and care services, as well as other support resources in each community will be established and maintained for use by peer supporters.

Peer supporters will receive standardized oversight, which will consist of ongoing monitoring and check-ins. In addition, they will receive ongoing support from a licensed mental health professional that will routinely assess their well-being and whether they are experiencing distress or any negative impacts from providing peer support. During check-ins, resources and tools for self-care (e.g., managing support fatigue or vicarious trauma), support for difficult scenarios, and guidance for maintaining appropriate boundaries will be provided.

Peer supporter training (initial and ongoing development) as well as supervision may take place virtually or in person.

7.3 Collaborators

This component of the integrated strategy will be implemented by peer supporters located in each community as well as those who oversee the program centrally. In addition, community-based organizations (CBOs) may serve as implementing partners to support the implementation of the peer support component locally and provide operational and administrative oversight for HPTN 096 study-specific activities. The implementing partner will also support community engagement efforts to expand the network of service provision in the community. Local CBOs have existing community or social service delivery programs serving HHI MSM, thus, coordinating a collaborative approach with local service providers will ideally strengthen and facilitate a holistic approach to service and support delivery. This approach is essential to building and sustaining trust and in providing autonomy support and tailored strategies in the provision of peer support for HHI MSM. Collaborating with a local community organization in support of the peer support component offers the added benefit of having care providers, social workers, counselors, nurses, etc. in close proximity to further support the peer supporters, as well as their engagement in referring participants to the program.

7.4 Promotion and Community Engagement

The peer support component will be promoted via various types of community engagement and outreach to raise awareness about the component and to support participant recruitment. This includes, but is not limited to, listservs, study website and newsletter, printed promotion materials (brochures, flyers), in-person engagement activities, webinars, conferences, social media, social networking sites and online dating sites and applications as appropriate.

Potential recruitment strategies may include, but are not limited to, tabling and conducting educational presentations at local universities/academic institutions, wellness fairs, community forums, public health conferences and disseminating promotion materials throughout the community (i.e., on local community bulletin boards and in public areas on college campuses as well as in common areas in clinics and local service providers). This collective outreach could also enact the identification of potential and key stakeholders for the peer support component.

The peer support component and/or its staff may be integrated throughout the other HPTN 096 study components, furthering the objective of implementing a successful integrated strategy approach. This includes, but is not limited to, peer supporters participating in the PHASE training activities and collaborating with participating PHASE HCFs to ensure care and support services are appropriately in place for participant care coordination, unifying community engagement efforts to promote the peer support component to and within the care facilities, and liaising with the health access coalitions (by participating in associated coalition activities including attending coalition meetings, trainings and service provider forums as appropriate).

7.5 Location

The peer support component will take place virtually or in-person. All communication between the participant and peer supporters will be private and confidential. If a support session is

conducted virtually, all communications will be facilitated using a third-party communication application (such as Google Voice) that permits voice and/or video calls or short service messaging [i.e., texting]). Local organizations that serve as implementing partners for the peer support component may provide a venue for face-to-face support sessions.

When in-person support sessions occur, the peer supporter (with necessary support/resources provided by the local partnering organization) and client will discuss and agree upon the desired date, time, and safe and accessible location to meet. Before the meeting, the peer supporter and participant will set expectations for their face-to-face meeting, such as deciding what the purpose of the meeting is, or what they are and are not comfortable discussing. Peer supporters will be trained in best practices for protecting the identity and privacy of anyone they work with, including in the context of face-to-face meetings.

7.6 Component Size

We anticipate that at least 10% of the minimum number of new HHI MSM clients needed to detect an intervention effect in each PHASE HCF will come from peer support referrals that originated in the community. The primary endpoint of increasing HHI MSM census at PHASE HCFs is powered to detect a 17% increase from baseline. The actual number will vary between HCFs because baseline HHI MSM census will vary. Moreover, the baseline HHI MSM census is likely to also vary within a PHASE HCF over time as EMR data are backfilled to address the data limitations described in Section 1.1.4.

In support of peer support's contribution to the primary endpoint, our first goal is to raise awareness of the peer support component among at least 50% of the estimated HHI MSM in each study community. The community-specific estimates for 50% of HHI MSM are 13,150 in Atlanta, 8,500 in Dallas, 4800 in Memphis, 900 in Montgomery and 5,600 in Ft Lauderdale/Miami. These figures are based on population size estimates from the CDC based on census and CDC surveillance data, and from data collected during the study pilot (see Section 3) in Dallas and Montgomery. We expect that by reaching this awareness goal for HHI MSM population in a community, we will reach a spillover tipping point where awareness of peer support expands beyond those directly reached by HPTN 096. This spillover phenomenon is a naturally occurring characteristic of how information is socially transmitted through communities via networks [218, 219]. Evidence from HPTN 037 indicated a spillover (unintended exposure to HPTN 037 content by individuals who were not in direct contact with HPTN 037 study personnel) of 39% [220]. Informed by these data from HPTN 037, we project that "awareness" of peer support in the remaining 50% of HHI MSM that are not directly reached will be approximately 25% to 35%. Achieving a high degree of awareness of peer support in the community (50% to 85% of the HHI MSM population) enables a synergy with the PHASE component wherein: (1) most HHI MSM at any given PHASE HCF will have at least heard of HPTN 096 peer support and (2) HHI MSM's familiarity with HPTN 096 peer support will increase their likelihood of enrollment in the component when PHASE HCF staff offers to connect them to peer support. Regarding clinic-based awareness, we anticipate that 60% to 75% of HHI MSM at PHASE HCFs will have the peer support component discussed with them (see Section 9, Intervention Component Synergies). We conservatively estimate that the uptake of the peer support component from the clinic setting will range between 10% and 25% (defined as enrollment into peer support and at least one interaction with a peer supporter).

Accrual into the peer support component is expected to increase over the course of the study, which may be enhanced through the increased number of organizational partnerships established and/or the utilization of impactful community outreach and engagement by the local peer support team. The number of implementing partner organizations and/or the number of local peer supporters in each community will also be scaled to increase over time to ensure adequate coverage for program needs and demands.

The level of effort required by the peer supporters will vary based on their individual capacity and the fluctuation in needs of the program participants assigned to them. The conduct of community engagement and outreach activities will also contribute to the peer supporters' level of effort. It is anticipated that there will be a wide variety of support sessions (from one-time to repeat support sessions and durations ranging from a few minutes to potentially lasting an hour). The effort spent by each peer supporter will be monitored throughout study implementation and adjusted as needed.

7.7 Primary Intervention Process Measure for the Peer Support Component

The primary intervention process measure for the peer support component will be assessed via self-reported satisfaction, acceptability and perceived usefulness of the peer support component among peer supporters and their clients. This information will be captured via qualitative and quantitative forms summarizing support activities among peer supporters.

7.8 Additional Process Measures related to the Peer Support Component

Additional process measure data will be collected to evaluate program implementation and penetration of the peer support component activities. These measures are intermediary between the implementation of the component and achievement of the secondary outcomes. They will be important in understanding the role that this component may (or may not) have in producing the secondary outcomes. Further, all process measure data may be reviewed by the study team and/or the SMC during the study period to make real-time adjustments to deployment of the component to improve its implementation and impact.

The additional peer supporter-level process measures may include:

- Measures of penetration:
  - Number of peer/client matches
  - Number of interactions with clients (e.g., to assess penetration/reach across communities)
- Measures of implementation:
  - Completion of acceptability assessment (at intervals throughout implementation and at the end of program participation); frequency to be outlined in the implementation manual
  - Measurement of the type of support provided during each session (e.g., topic areas)

Peer supporters may also be asked to provide input about the component throughout implementation and to share their experiences with providing peer support. The component will

also be assessed to determine whether the component is progressing towards its goals and what the overall impact the component is having for those being served. The areas of the component felt to be most and least effective, areas for improvement and supporting roles and responsibilities across the component will be evaluated.

The additional participant-level process measures may include:

- Measures of penetration:
  - Number of participants engaged in the program, sociodemographic characteristics, and frequency of program use
  - Measurement of where participants learned about the program
- Measures of implementation:
  - Satisfaction survey (e.g., brief assessment evaluating participant satisfaction with the program and overall feedback)
  - Acceptability and usefulness assessment (e.g., assessment evaluating the participant's overall experience with the program including, but not limited to, how accessible the program is, satisfaction with the support received, etc.)

Participant-level acceptability measures will be administered after each support session at varying intervals as outlined in the implementation manual. The team will also explore various qualitative methods, such as individual interviews and/or focus groups, to elicit and capture additional information about the experiences of participants who engaged with the peer support component. This includes, but is not limited to, assessing their overall experience obtaining peer support and engaging with a peer supporter, any barriers they experienced accessing services, which elements were seen to be most beneficial and appealing, as well as those elements found least beneficial and least attractive. This will also serve as an opportunity for the participants to cross-share their experiences and identify themes across their experiences that will provide valuable insights and knowledge into how the participants perceived and responded to receiving peer support.

8 PROMOTING HUMAN AUTONOMY SUPPORTIVE ENVIRONMENTS (PHASE) COMPONENT

8.1 Component Description

The PHASE component is a health care facility (HCF)-level training and quality improvement program designed to improve autonomy supportiveness in the provision of health care services for HHI MSM. PHASE aims to create an autonomy-supportive healthcare environment that supports HHI MSM engagement in HIV-related care and services and helps to promote increased HIV/STI testing, PrEP and ART uptake, retention in care, and viral suppression rates for HHI MSM.

PHASE will take place at selected HCFs (see Section 8.1.3) in each study community. The PHASE component is designed to optimize the healthcare environment for HHI MSM by

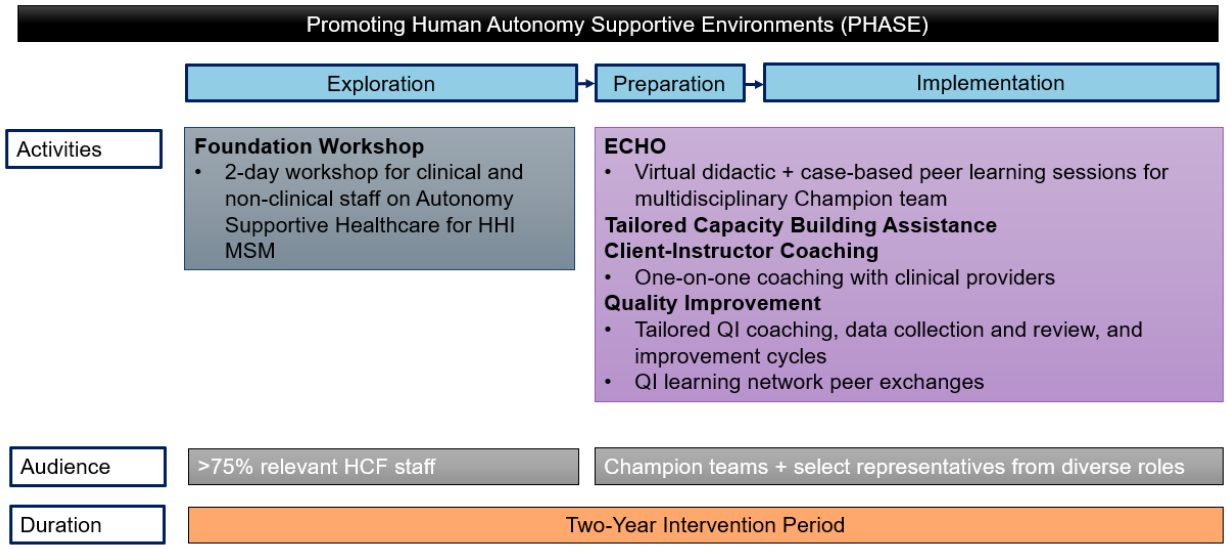
addressing the multiple key intersecting factors that undermine autonomy support. This will be accomplished through a comprehensive package of five activities that are aligned with the EPIS (exploration, preparation, implementation and sustainment) model [221] delivered over the course of a two-year implementation period in each community:

- **Exploration:** A majority of *relevant* staff (e.g., the clinical staff who directly provide HIV treatment or prevention services, and the non-clinical staff who support or provide administrative leadership to them) at each HCF will participate in the PHASE **Foundation workshop** on autonomy supportive HIV prevention and treatment services for HHI MSM, including content on informed decision-making, stigma, structural competency, skills practice, and accountability.
- **Preparation Phase:** HCF representatives from key clinical and non-clinical roles will engage in continued learning and skills application within their HIV prevention and/or treatment practice settings, achieved through participation in an Extension of Community Healthcare Outcomes (**ECHO**) distance learning curriculum; **tailored capacity building assistance** such as state-level seminars on insurance options, financing, and business development; **quality improvement** (QI) preparatory and data collection activities; and **client-instructor mentoring** for providers.
- **Implementation Phase:** HCFs will develop, implement, and monitor site-specific **QI interventions** [222], and share lessons learned through **QI peer learning networks** that will foster practice transformation by facilitating knowledge exchange and technical assistance between the HCFs participating in PHASE.

The PHASE model is shown below in Figure 8 and further described in Section 8.2. The PHASE component will generally employ a "whole facility" approach, recognizing the sources of intersectional stigma do not only come from clinical providers, but also any HCF staff that may encounter clients/patients, such as front desk and administrative personnel.

It is important to differentiate between PHASE component activities that are part of the integrated strategy intervention, and data collection activities taking place at PHASE HCFs that are intended to measure the outcomes of the overall integrated strategy. The latter are described in Section 11.0. This section describes only those activities that are considered part of the PHASE component of the integrated strategy.

Figure 8: PHASE Model



8.1.1 Implementers

PHASE will primarily be implemented by teams of interventionists who may include, but are not limited to, individuals with expertise in various types of stigma, training methodologies used with HCFs, clinical provision of HIV prevention and treatment services, and working with HCFs to improve the quality of the services provided for HHI MSM.

Expertise of interventionist teams will be supplemented by external ECHO and capacity building faculty and experts, QI coaches, and HHI MSM who will be trained to implement the client-instructor methodology.

8.1.2 Location

The Foundation phase of the PHASE component will involve multiple offerings of a synchronous workshop that will take place, in person, at central locations in each community accessible to participating HCF staff. All other PHASE activities will take place at each HCF and will involve a combination of virtual synchronous and asynchronous web-based activities as well as virtual or on-site technical assistance and coaching.

8.1.3 Health Care Facility (HCF) Selection

A total of approximately 40 HIV prevention and approximately 20 HIV treatment facilities across the five study communities will participate in the PHASE component (with intent of selecting facilities that yield a baseline average of 90 HHI MSM per HIV treatment facility and 54 HHI MSM per prevention facility). At these facilities, both PHASE intervention activities, as well as study endpoint data collection and assessment activities, will take place. HCF selection must thus be undertaken with a goal of selecting HCFs that are appropriate for both types of activities (intervention and assessment).

HCF selection will involve six core steps that may be iterative:

1. General study community engagement will be conducted at the local level to raise awareness about the study and the PHASE component, particularly among healthcare providers.
2. HCFs that provide HIV-related treatment and/or prevention services in each study community will be identified.
3. Identified HCFs may be prioritized for recruitment.
4. Targeted recruitment of identified and/or prioritized HCFs will be undertaken in order to gain their buy-in and willingness to participate.
5. Recruited HCFs will be requested to submit information about their facility to ensure they meet criteria to participate and to assist in selection decisions.
6. If more HCFs express interest than are needed to participate in the study, a sub-committee of the study team will review submitted information from all interested HCFs in each community and determine which HCFs to select for participation.

8.1.3.1 HCF Identification and Prioritization

HCFs may include any type of facility that provides HIV-related treatment and/or prevention services, including but not limited to primary care clinics, health system and/or hospital outpatient clinics, health department sexual health clinics, FQHCs, Ryan White-funded clinics, general medicine clinics, private health care offices, infectious disease clinics, pharmacies providing walk-in clinic services, and CBOs within the PrEP continuum. Eligible HCFs must be located within an HPTN 096 study community (see Section 4.1).

An iterative and formative HCF identification process will use a combination of information from quantitative databases and qualitative data sources. Efforts will be made to identify all HIV primary care facilities and all facilities that provide PrEP – or have the capability of providing PrEP – to HHI MSM in each study community; through an iterative process, some facilities (prevention and treatment) may be ruled out of selection if they serve relatively few HHI MSM to ensure that HCFs across all five communities can participate.

Data sources include:

- Facility-based viral suppression and care surveillance data for HHI MSM (CDC)
- Ryan White-funded clinics (HRSA)
- Health Center Program Awardee Data (HRSA)
- HIV care and PrEP service locations (AIDSVu)
- Sexually transmitted infection (STI) surveillance data (local/state jurisdictions)
- Census tract data

Supplemental qualitative information will be elicited from the sources below:

- HCF preferences and perceptions survey data (pre-pilot formative web-based survey implemented with HHI MSM in potential HPTN 096 communities)

- HPTN 096 CAG input
- EHE planning council and local expert (e.g., community groups, health department, etc.) recommendations

Additional sources may be used to supplement information about current facilities or identify potential new facilities/providers (e.g., of PrEP). The existing data sources will then be used to prioritize identified facilities for recruitment, taking into consideration those facilities that are most likely to serve (and those with the capacity to serve) HHI MSM, where the majority of HHI MSM diagnosed with HIV received care, and where the majority of HHI men or HHI MSM were diagnosed with STIs, as well as those that demonstrate the most need for improvement in services to HHI MSM. Prioritization will also take into consideration population size of each study community and ensure a representative number of facilities across each community (for example, larger communities may have more HCFs prioritized for recruitment than smaller communities). Prioritized HCFs will be approached first for recruitment, but all identified HCFs in each community may be informed about PHASE and asked to express interest in participating.

8.1.3.2 HCF Recruitment and Selection

A comprehensive HCF recruitment strategy will be developed with input from community members, partners (i.e., CDC, HRSA, local health departments and EHE councils), and individuals with expertise in health care leadership and quality improvement, practice transformation, and provision of HIV services in the southern US. The strategy will be informed by the HPTN 096 pilot lessons learned and include proactive measures to address feasibility, such as soliciting HCF feedback on incentives (e.g. financial compensation, continuing education credits, facility certification, access to technical assistance, etc.) that may facilitate their participation, and how the training approach could be tailored to meet their preferences. The strategy will also emphasize how participation in this component can help communities achieve EHE goals. Recruitment strategies may be tailored to each study community.

The recruitment strategy will be implemented with the identified HCFs by study team members during the study pre-implementation period. Recruitment will begin with broad community education and engagement activities in each community, in order to gain trust and establish a presence among those providing healthcare in the community, before moving into targeted discussions around the details of study participation with specific HCFs.

Recruitment of HCFs will explain expectations around participation in the PHASE component of the integrated strategy, as well as expectations related to research partnership for data collection and study endpoint assessment activities that will occur at PHASE HCFs but are not considered PHASE intervention activities.

In order to participate in PHASE, HCF must agree to participate in all PHASE intervention activities as well as all HPTN 096 data collection activities at PHASE HCFs, including provision of EMR data for study endpoint assessments.

Interested HCFs will be asked to provide basic information about their facility, including recent HHI MSM patient census data, and information to ensure that data provision requirements for study endpoint assessments can be met. HCFs that do not meet these basic criteria and/or that

would be unable to contribute to study endpoint assessments will not be eligible to participate. If more HCFs express interest than there are available spots, a selection process will be implemented based on information collected about each facility to prioritize facilities that would have the highest probability of serving HHI MSM in that community, and to ensure fair, representative, and adequate coverage of HCFs across communities to meet the study needs.

8.2 PHASE Intervention Activities

The PHASE intervention involves an integrated package of five activities that each PHASE HCF will participate in. As many PHASE activities will involve multiple HCFs either within a community or potentially across communities, PHASE will not begin in a given community until all participating HCFs in that community are prepared to begin PHASE activities. PHASE will be implemented over a period of two years concurrently in each community, dependent upon when each community begins PHASE. The PHASE activities are further described below. Data collection activities that will take place at PHASE HCF to measure study outcomes but are not considered part of the PHASE intervention are described in Section 11.0.

8.2.1 Foundation Workshop

Staff from each participating HCFs will take part in a community-wide (i.e., inclusive of multiple participating HCFs in a given community) synchronous training on autonomy supportive healthcare for HHI MSM across the HIV continuum. This two-day workshop will be frequently offered during Year 1 of PHASE implementation in each community. Additional workshops may be offered into Year 2 if requested to provide an opportunity for new staff to complete the training. A target of >75% of relevant (i.e., clinical and non-clinical staff related to provision and support of HIV services) staff at each participating HCF will be trained. Multiple workshop dates will be offered in each community to allow HCF staff to cycle through the training in a way that does not place undue burden on clinic operations and provides enough opportunities to ensure the target number of HCF staff are reached. Continuing education credits will be provided.

The standard curriculum to be used for this Foundation workshop will be derived from existing evidence-based training curricula on autonomy supportiveness, HIV stigma reduction, human-centered practices in health care, contributions and resilience of HHI MSM in the southern US and similar topics, but will be tailored by the PHASE training team to meet the specific needs of this study. Topics covered in the training will include (but are not limited to) the following:

- Presentation of HIV epidemiological data for HHI MSM, including intersectional patterns of demographics, transmission category, and geography with an emphasis on the southern US
- Review of evidence related to health outcomes of HHI MSM in relation to PrEP, general HIV prevention, viral suppression, and HIV testing
- Understanding intersecting stigmas
- Identification of sociocultural assets of HHI MSM
- Building structural competency in HIV prevention and treatment services

- Skills practice for supportive provider-client interactions
- Creating autonomy supportive health care settings for HHI MSM
- Overview of the PHASE intervention and synergies with the other components of HPTN 096

As a lead-in to the Foundation workshop, each HCF will be offered an opportunity to receive a simulated patient prior to the start of the Foundation workshops. This simulated patient visit will involve a trained individual with lived social experience and similar demographic characteristics as HHI MSM in their community, including same-sex experience. The visit entails enacting a full simulation of a typical visit for the initiation of HIV PrEP and/or treatment (depending on services offered by that HCF). The simulated patient will use a quantitative and qualitative feedback tool (adapted from the healthcare climate questionnaire) to characterize their experience of the clinic environment, including their interactions with HCF personnel in various roles. Summaries of the simulated experience will be used in the Foundation workshop training to provide HCF-specific feedback that workshop participants can use to curate draft menus of stigma-reduction options for their respective HCFs. Summaries will characterize the simulated patients' general experiences of the HCF and are not an assessment or evaluation of any individual employed by or otherwise affiliated with the PHASE HCF.

8.2.2 Extension for Community Healthcare Outcomes (ECHO)

The Extension for Community Healthcare Outcomes (ECHO) component will build on themes highlighted in the Foundation Workshop by using an ECHO-based model for case-based learning and knowledge exchange [223, 224] to facilitate translation of the Foundational workshop concepts into best practices for providing HIV prevention and care services to HHI MSM within HCF settings. The ECHO-based model will employ a train-the-trainer approach and will be delivered over a series of synchronous web-based sessions to a subset of HCF staff, called a Champion Team, who represent key clinical and non-clinical roles in the facility. ECHO content will build on content covered in the Foundation training by extending it to clinical application and will include a brief didactic presentation on a pre-specified theme followed by a related case presentation and discussion related to that theme. A standard thematic curriculum for the ECHO sessions will be developed centrally and related cases will be submitted by the participating HCFs to reflect actual clinical and systems-level challenges they are experiencing. During ECHO sessions, discussion of challenges may lead to identification of potential solutions that can inform the QI work. For example, identification of systems-level processes that can address barriers to retention in care or PrEP prescription. A minimum of 12 sessions will be offered beginning in the first year of the PHASE implementation period, after the Foundation workshops are completed. Continuing education credits will be offered for each session, and sessions will be recorded and housed on the PHASE web-based portal for future viewing.

Champion teams will be assembled at each HCF and will include at least one representative from key functional areas at each facility; for example, a combination of clinical staff, front-line staff, peer navigator, C-suite member, data manager, and human resources representative. Champion team composition specific to each HCF will be based on organizational composition of each HCF and determined as part of the onboarding process with the HCF. Champions must complete the Foundation workshop of PHASE as a pre-requisite to ECHO participation.

8.2.3 Tailored Capacity Building Assistance

Tailored capacity building assistance will be offered to PHASE HCFs in order to meet additional extracurricular needs not addressed through the existing training curricula or QI work. The primary focus of this capacity building will be to provide additional training and technical assistance related to navigating insurance coverage for PrEP and ART as well as using PHASE to enhance business development of HCFs. At a minimum, the following capacity building assistance will be provided:

- Supplemental state-specific workshops, similar to the ECHO model, will be offered and geared towards executive and administrative roles, in addition to clinical roles, that will focus on insurance options and financing of PrEP and HIV treatment options. Technical assistance will also be available from the external faculty experts leading the workshops.
- Access to technical assistance related to increasing clinicians' knowledge of documentation practices that support billing to maximize revenue.
- Access to training on implementing a long-acting injectable PrEP program, with a connection to one-on-one technical assistance when needed provided by the PrEP manufacturer, ViiV.

Assistance may be provided on other topics as needs are identified by participating HCFs

8.2.4 Client Instructor Coaching

Clinical providers at each HCF will be offered an opportunity to practice and reinforce the skills learned in the Foundation workshop through the Client Instructor (CI) supportive feedback methodology (analogous to "standardized patients" in the medical literature) [225-227]. CI will act as independent raters of structural, procedural, and interpersonal manifestations of stigma and provide supportive feedback on strengths-based communication skills based on client readiness specifically in the context of ART and/or PrEP initiation communications. CI will be individuals with lived experience and similar demographic characteristics as HHI MSM in their community who are and trained to assess and coach providers and provide constructive and supportive feedback to HCFs using the study-specific methodology. The CI coaching component will seek to reach a majority of clinical HIV-related providers at each HCF. The number of providers targeted to complete CI coaching sessions at each HCF will depend on the clinical workforce composition of each participating HCF and is expected to be between 2 and 10 providers each. Eligible clinicians must have completed the Foundation workshop prior to their coaching session and will be offered an initial coaching session with optional additional follow-up coaching sessions provided upon request throughout the two-year intervention period.

8.2.5 Quality Improvement (QI)

Defined QI approaches and methodologies will be used to assist HCFs in translating their learnings from PHASE trainings into improvements in outcomes for HHI MSM related to HIV testing, PrEP use, engagement and retention in care, and viral suppression. PHASE QI methods and learning networks will support HCFs in addressing stigma as a barrier to improving care and prevention outcomes for HHI MSM. Through the QI work, HCFs will identify root causes of stigmas affecting HIV prevention and care for HHI MSM and accelerate the adoption of targeted

interventions to address them, as well as be supported in adopting evidence-based strategies for increasing HIV testing, PrEP use, retention in care, and viral suppression among HHI MSM. Application of QI methods at participating HCFs will offer an innovative approach to identify the complex and confluent multifaceted factors and root causes contributing to intersectional stigma, enabling them to be addressed through data-informed adaptation of interventions in a local setting. Through continuous measurement and tests of change, facilities will develop interventions that reduce stigma, thereby improving care-seeking and sustained engagement, which, in turn, may lead to individual and population-health aims. When supported by strong leadership, process improvement methodology, peer-to-peer learning, and coaching, QI activities can strengthen participating organizations' capabilities to predictably deliver prevention and care services that are effective, equitable, people-centered, and outcomes-oriented. The PHASE QI approach is based on cycles of continuous measurement with testing of changes targeting gaps identified from the data and will be guided by five activities: 1) QI pre-work; 2) QI data collection; 3) tailored QI coaching; 4) QI learning network peer exchange; and 5) QI action periods. QI activities will be detailed in HPTN 096 QI Operational Manual and are summarized in the sub-sections below.

8.2.5.1 QI Pre-Work

Participating HCFs will begin their PHASE QI process with four pre-work activities: 1) PHASE QI orientation; 2) assembly of a site-specific team of QI stakeholders (if not already in existence); 3) QI organizational assessment; and 4) QI measurement pre-work. The pre-work stage will set expectations for the QI activities; introduce QI coaches and supporting staff, as well as terminology and alignment with overall PHASE programming; allow QI coaches to assess and determine baseline competency for QI work; introduce the QI principles and methodology to be used; determine HCF capacity to collect relevant data, including disaggregated data (i.e., stratified) by demographic variable; facilitate customization of standardized QI data collection tools including both the healthcare worker survey and client/patient assessments; and define the project scope. Pre-work activities are further detailed in the QI Operational Manual.

8.2.5.2 QI Data Collection

Data collection will be required at the clinic level for QI as part of routine performance measurement based on the PHASE QI indicators (specified in the QI Operational Manual) so that an HCF can understand whether its efforts are having an impact. HCF collection and self-monitoring of data is an important part of the QI process. PHASE QI data collection activities will include:

1. HIV prevention and treatment cascade clinical performance measures related to study primary and secondary endpoints, disaggregated by demographics
2. Healthcare worker stigma survey
3. Patient experience and health literacy data

The QI Operational Manual will guide QI data collection methods and definitions of measures. Data collection will be expected to occur approximately quarterly. QI coaches will work with

HCFs to review QI data to help determine root causes and areas for targeting QI interventions. In addition to the above data sources, site-specific summary reports generated from the Foundation workshops supplement collected QI data to inform root cause analysis and QI interventions. Data collected as part of QI activities will not be submitted to or retained in the study database and will not be considered study data for endpoint assessment.

8.2.5.3 Tailored QI Coaching

Each HCF will be supported by a QI coach who will facilitate discussions and appropriate peer exchange and provide feedback on application of QI tools and methods. To foster the application of varied and scalable QI concepts, coaching will utilize interactive, project-based learning with relevant examples addressing gaps along the HIV care and prevention continuum. Recognizing that each HCF will have different baseline QI experience and capacity, and some may have robust ongoing QI initiatives, coaching will be tailored to the level of need determined for each HCF during the QI pre-work organizational assessment stage, with the coaching scheduled determined between coach and HCF. Each HCF will designate at least one staff member to serve as QI contact to lead their local QI efforts and work directly with the QI coach throughout the duration of the PHASE intervention.

8.2.5.4 QI Learning Network Peer Exchanges

QI learning network peer exchange sessions will further support practice transformation, the accomplishment of PHASE goals, and improvement in clinical outcomes through sustaining connections with other participating HCFs workings towards similar goals. HCFs within the same PHASE cohort will form a QI learning network and participate together in quarterly peer exchange sessions. This approach will facilitate learning and sharing of best practices across these HCFs, and will allow for additional targeted training, technical assistance, or other skills-building activities in support of related goals over the intervention period. QI learning networks will be facilitated by QI coaches and members of the QI team with expertise in QI methods. Additional details about the QI learning network sessions are provided in the QI Operational Manual.

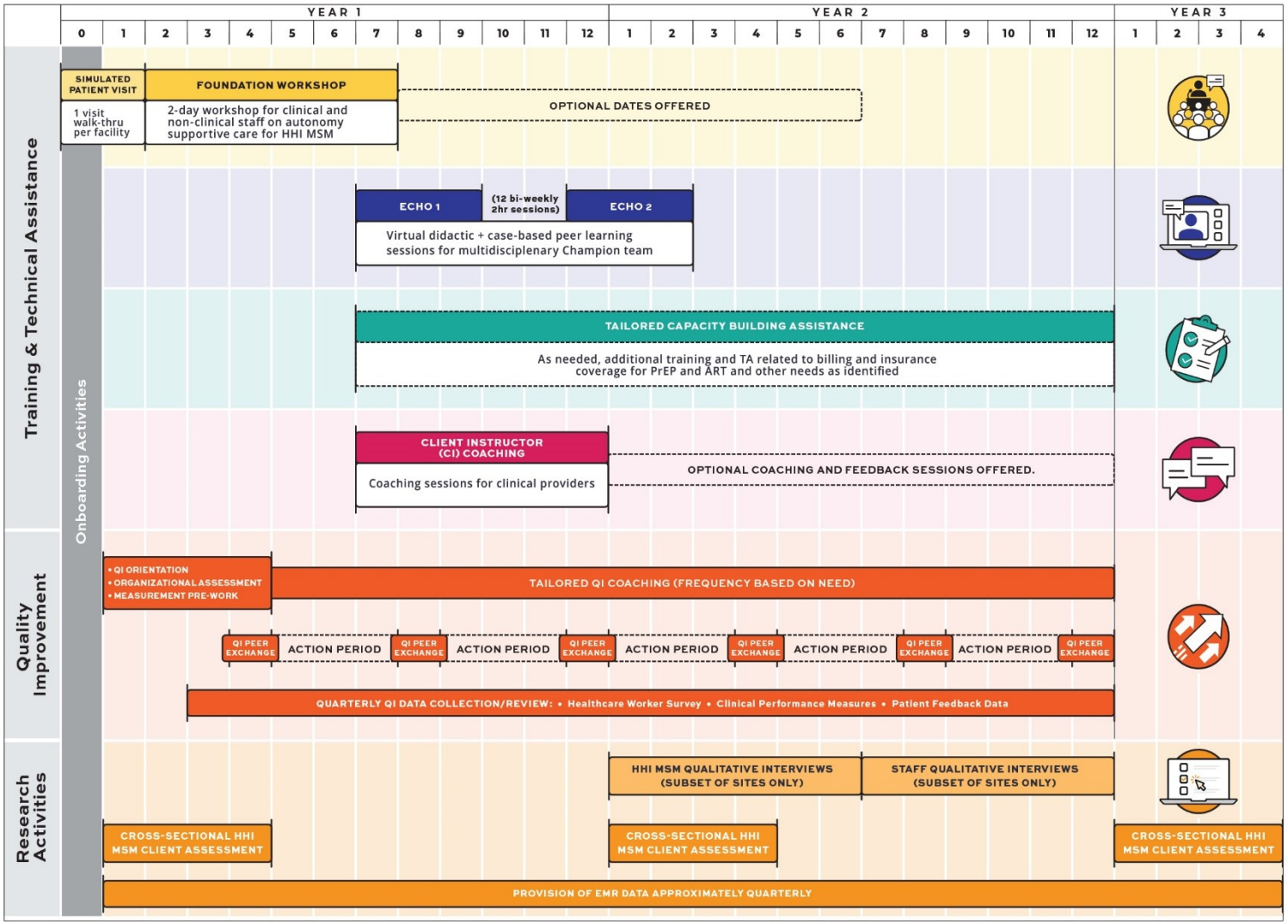
8.2.5.5 Action Periods

Action periods are the time frame between QI learning network peer exchange sessions, where the local HCF PHASE QI team plans and carries out a QI project(s). During the action periods, teams are expected to implement tests of interventions based on data and root cause analysis and monitor their data on the outcomes and custom measures relevant to tests of change. The tests of change are intended to be very small tests of improvement ideas such as changing or adding a step in the process in response to data and feedback. QI efforts are directed towards objectives of addressing stigma for HHI MSM and to improve their clinical outcomes related to HIV prevention (PrEP prescription) and HIV treatment (retention in care and viral suppression).

8.2.6 Timeline of Activities

PHASE activities over the 2-year implementation period for any given cohort are depicted in Figure 9: PHASE Journey Map.

Figure 9. PHASE Journey Map



8.3 Primary Intervention Process Measures for PHASE

The primary intervention process measures for the PHASE component will be knowledge and attitudes of staff at PHASE HCF after completion of PHASE trainings as compared to before trainings, and qualitative characterization of staff experience implementing PHASE. Knowledge and attitude change information will be captured via pre- and post-test surveys administered to HCF staff participating in PHASE trainings and workshops. Qualitative information will be captured via qualitative in-depth interviews with a subset of staff at PHASE HCFs.

8.4 Additional Process Measures related to the PHASE Component

Additional process measure data at the HCF level will be collected on an ongoing basis to evaluate fidelity to and penetration of the planned implementation of the PHASE component. These measures are intermediary between the implementation of the PHASE component and achievement of the primary and secondary outcomes and reflect key implementation outcomes of the logic model framework (see Section 1.2.2). Thus, they will be important in understanding the role that this particular strategy may (or may not) have in producing the primary and secondary outcomes. Further, all process measure data may be reviewed by the study team and/or the SMC during the study period to make real-time adjustments to deployment of the component to improve its effectiveness. The additional process measures for PHASE will include:

- Measures of penetration of the component activities:
  - Number and types of participating HCF in each intervention community
  - Number and types of staff who complete PHASE Foundation workshop
  - Number of PHASE Foundation workshops conducted
  - Numbers and roles of staff participating as ECHO Champions at each HCF
  - Number and roles of providers completing Client Instructor coaching sessions at each HCF, and proportion of providers completing Client Instructor coaching sessions out of all eligible providers
- Measures of fidelity to planned implementation of PHASE
  - Proportion of staff completing PHASE Foundation workshops at each HCF
  - Proportion of total ECHO sessions completed by HCF staff
  - Ability of HCF to collect specified QI data
  - Number and type of QI interventions implemented at each HCF in QI action periods
  - Number of QI learning network peer exchanges sessions completed
  - Number of QI coaching sessions completed at each HCF

9 INTERVENTION COMPONENT SYNERGIES

The four components of the integrated strategy are designed to work synergistically, with each component having the potential to enhance the effect of the other three components. In addition, the health access coalition, social media and peer support components are designed to help

motivate and facilitate HHI MSM who are not engaged in healthcare to access HIV prevention and treatment services, particularly at HCFs participating in the PHASE component of the intervention. Throughout the study, the team will consistently look for ways to identify and implement potential synergies.

9.1 Synergies to Enhance Health Access Coalitions

The overall goal of the health access coalition component is to lower the barriers that HHI MSM face accessing HIV prevention and treatment services at the structural, community and policy-level.

- Through attending the PHASE Foundation Workshop, health access coalition members will gain a better understanding of the barriers that PHASE HCFs face in serving HHI MSM and the barriers that HHI MSM face in accessing HIV prevention and treatment services.

- The peer support component will amplify health access coalition engagement with the local HHI MSM community. For example, peer supporters may serve as non-voting members of the coalitions.
- Social media can be used to advertise health access coalition activities to increase participation and inform the HHI MSM community how they can take advantage of any environmental changes put in place via the health access coalitions.

9.2 Synergies to Enhance Social Media

The overall goal of the social media component is to educate and empower HHI MSM to make informed decisions and behavioral changes to stop HIV acquisition and transmission. There are three primary ways that the other three components can enhance the social media component, including:

- Consistently encouraging HHI MSM to follow the HPTN 096-specific social media accounts.
- Informing the social media team of upcoming events and ongoing services or programs for HHI MSM so that they can be promoted via social media centrally.
- Having local HPTN 096 partners use their own social media accounts to inform HHI MSM about their services as well as other HPTN 096 activities and programs.

9.3 Synergies to Enhance Peer Support

The goal of the peer support component is to provide individual HHI MSM with the support they need to access HIV prevention and treatment services.

- Peer supporters will attend PHASE Foundational workshop to strengthen their understanding of how stigma impedes obtainment of care and support.

- PHASE HCF staff may promote the peer support component and make referrals to it, when appropriate.
- The health access coalitions may also promote the peer support component and help to overcome barriers to accessing peer support.
- Social media will be used to promote the peer support component locally and centrally.

9.4 Synergies to Enhance PHASE

The goal of PHASE is to change the healthcare environment so that more HHI MSM can access HIV prevention and treatment services, take PrEP and remain in HIV care.

- Health access coalitions will work to lower the barriers to HIV prevention and care services for HHI MSM. Working to lower medical mistrust and addressing local structural, community and policy-level barriers are examples of this type of synergy.
- The peer support component will serve as a resource for PHASE HCFs to leverage as much or as little as they choose and will provide referrals to PHASE HCFs, when appropriate. Including PHASE HCFs in the resource guide used by the peer support component and peer supporters sharing resources and information with their clients about preventive, treatment and/or care resources, including programs that assist with healthcare coverage and insurance options, are examples of the potential synergistic efforts between PHASE and peer support.
- Social media is expected to drive the demand for HIV-related services by raising awareness about HIV status and increasing knowledge about PrEP and ART. This is particularly important for HHI MSM who are not currently engaged in HIV prevention or treatment services. It can also be used to promote the PHASE HCFs to HHI MSM, both locally by the PHASE HCFs themselves and centrally via the HPTN 096 social media accounts.

10 COMMUNITY ENGAGEMENT

Given the community stigma and discrimination related to homosexuality in the southern US, innovative community involvement approaches will be utilized to proactively address concerns related to social harms, strengthen community rapport, and plan for community engagement. Utilizing core principles for Community Based Participatory Research (CBPR) is key to incorporating community input into the development and conduct of the HPTN 096 study through meaningful community engagement. CBPR is an approach to public health and environmental research that aims to increase the value of research for both researchers and the community for whom or in which the research is conducted [228]. This approach is particularly useful when dealing with persistent problems related to disparate health care outcomes among a variety of populations (e.g., socioeconomic status sexual orientation) [228]. Through the sharing of knowledge and experiences, CBPR builds bridges between scientists and communities [228]. Furthermore, this collaboration facilitates the development of appropriate measurement instruments, thereby increasing the efficiency and effectiveness of projects [228]. Finally, CBPR fosters mutual trust that increases both the quality and quantity of data collected [228].

Collaborations of this type of result in a deeper understanding of the unique circumstances of a particular community [228].

The HPTN 096 team recognized, through community forums and community input, the need for a multilevel, comprehensive community engagement strategy. The goals of community engagement are to build trusting relationships, create partnerships, share resources, create and improve communications, and improve health outcomes [229]. The NIH defines community engagement as "a process in research of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community focus" [229]. Community engagement will be directed at two levels: 1) general awareness of the study and 2) component-specific engagement. Each level of engagement will specifically target appropriate audiences using various methods of engagement.

10.1 Levels of Engagement

10.1.1 General Awareness

The main purpose for general awareness-raising community engagement is to generate awareness around and support for HPTN 096 to raise the level of community acceptability of the study presence and the intervention components that will be implemented. Community engagement for the purposes of general awareness-building will focus on the creation of awareness. These activities are separate from how community engagement will be conducted for the specific study components and the cross-sectional assessment (described further in sections below).

The establishment and use of community advisory boards (CABs) is a critical strategy in achieving the goals of community engagement [230-232]. CABs, which typically include a representative group of non-researchers, have been a part of HIV research since the late 1980s [230, 233]. Originally, CABs provided consultation and communicated community needs, which later expanded to a collaborative relationship with researchers [230, 232, 234].

Although establishing a Community Advisory Board (CAB) is a vital component of community engagement, this method alone does not comprise a comprehensive community engagement strategy [232, 233, 235]. Additional community engagement approaches include planning with community input, increased and consistent communication to the community and study participants, providing community resources, and involving researchers representative of the community [231-233, 235]. Some other ways to engage and greatly impact the community are to provide trainings on health or resources available to bring awareness and increase its capacity; support events by attending or volunteering; foster collaborative programs such as health fair; and create ongoing, sustainable partnerships [235].

The HPTN 096 Community Advisory Group (CAG) will serve as the CAB to the protocol team and will support stakeholder engagement activities and planning for HPTN 096. The group includes HHI MSM from each of the HPTN 096 study communities. It will meet monthly to discuss stakeholder engagement strategies and receive regular updates on the progress of the study. CAG members will provide high-level input and guidance to the HPTN 096 study team

related to community awareness and acceptability. The CAG will bring a variety of perspectives and expertise, connecting issues and opportunities across stakeholder engagement, agencies, and local stakeholder sectors. Recognizing that there is no one-size-fits-all community awareness strategy, each CAG member will work with the HPTN 096 study team and local community stakeholders to find ways to create opportunities for continued engagement of new stakeholders and raise awareness for HPTN 096 overall.

10.1.2 Component-Specific Community Engagement Activities

Each study component will involve tailored community engagement activities for the purposes of gaining participation in, awareness of, or acceptability for each component. These community engagement activities are largely integrated into the activities of the study components themselves, and as such, the success of community engagement as it relates to specific components will be assessed from a subset of outcome measures already identified for each component. A CAG representative will serve as a liaison for each of the HPTN 096 study components to provide real time guidance and enhance communication between the team working on each component and the HPTN 096 CAG.

10.1.2.1 Health Access Coalitions

Community engagement activities for the health access coalitions component will be carried out in conjunction with local CBOs to establish community coalitions in each intervention community. Guidance on organizations and individuals to engage for membership in the coalitions will be provided by the local CAG representative and local peer support staff.

10.1.2.2 Social Media

Community engagement activities for the social media component will be focused on identifying and vetting appropriate social media content; providing messaging on HIV-related topics; and promotion of the other study components. The HPTN 096 CAG will provide guidance on the identification and creation of social media content, and strategies for disseminating social media messages.

10.1.2.3 Peer Support

Community engagement methods will be used for promotion of the peer support component. In consultation with local CBOs and other stakeholders, peer supporters from each intervention community will develop site-specific community engagement strategies to promote awareness of HPTN 096 and the peer support component. They will be encouraged to implement various community engagement strategies in the local communities and across their network through the following (including but not limited to): peer outreach/word of mouth referrals, formal/informational educational sessions, and distribution of promotional materials at local venues and events. Community engagement activities may also leverage invaluable networks such as the CAG members and other community partners to raise awareness and generate interest in the peer support component.

10.1.2.4 PHASE

Community engagement activities for the PHASE component will be focused on supporting the recruitment of healthcare facilities who provide service to HHI MSM and relationship building with targeted facilities to gain their agreement to participate in the component activities. The HPTN 096 CAG may provide guidance to the PHASE component on identification of healthcare facilities.

11 STUDY PROCEDURES FOR DATA COLLECTION AT PHASE HEALTHCARE FACILITIES

This section provides an overview of data collection procedures that will be conducted at PHASE HCFs. Data collection activities include the EMR endpoint data collection (see Schema Figure 1), a cross-sectional HHI MSM client assessment (inclusive of a questionnaire and chart extraction), and qualitative data collection with HHI MSM clients and HCF staff. A summary of these data collection activities is shown in Figure 10. In addition, a brief schedule of evaluations is provided in Appendix I. Additional detailed instructions to guide and standardize procedures across PHASE HCFs are provided in the HPTN 096 PHASE HCF Study-Specific Procedures (SSP) Manual (Participant Accrual, Informed Consent, Enrollment Section and Visit Procedures and Visit Checklists Section).

Figure 10: Summary of Data Collection Activities at each PHASE HCF

		Pre-Implementation	Intervention Implementation (All Four Study Components Ongoing At Scale)		Post-Implementation
	Year -2	Year -1	Year 1	Year 2	Year 3
EMR Endpoint Data	Baseline	Baseline	Intervention Year 1	Intervention Year 2	
HHI MSM Client Assessment			Baseline M 1-4	Midpoint M 12-15	Post M 24-27
HHI MSM Qualitative Interviews				M 12-17	M* 24-27
HCF Staff Qualitative Interviews				M 18-23	

* May extend to M 24-27 if needed to complete accrual

11.1 Cross-Sectional HHI MSM Client Assessment

11.1.1 Pre-Screening

It is the responsibility of each PHASE HCF to determine the best approach to screen potential participants for the cross-sectional HHI MSM client assessment. Generally, it is expected that each HCF will have a designated study coordinator (e.g., a nurse or manager) who will be responsible for pre-screening client records. Study coordinators will identify and flag charts of clients who appear to meet eligibility criteria in Section 4.3.2, and who have a scheduled appointment during one of the four-month sampling timeframes: baseline (1-4 months), midpoint (12-15 months) or post-intervention (24-27 months).

11.1.2 Recruitment, Screening and Eligibility Confirmation

Generally, it is expected that potential participants will be recruited, screened, enrolled, and will complete their questionnaire all in the same day as their scheduled medical visit. Before enrollment takes place, stratification must be determined by the study coordinator based on information in the medical record. Each PHASE HCF will be assigned a target accrual number for each stratification category during each sampling timeframe (see Section 4.3.2.1 for stratification), and study coordinators will be expected to locally track enrollment and stratification of each participant.

To mitigate selection bias, all individuals who were flagged during the pre-screening process as potentially eligible will be approached at their regularly scheduled medical visit by the study coordinator until the desired sample size is achieved within each 4-month sampling timeframe. The study coordinator will invite each approached individual to participate in the study and will review a study information sheet with them.

The questionnaire will be accessible via a web-based platform. If the participant is interested in moving forward, the study coordinator will confirm the eligibility criteria (per section 4.3.2.1) within the web-based platform. Potential participants who meet the eligibility criteria and stratification will be prompted to provide electronic consent via a checkbox within the questionnaire platform (see Section 15.7.1).

11.1.3 Questionnaire Completion and Enrollment

Once the participant has consented, the participant will be prompted to complete the questionnaire.

The questionnaire will ask participants their thoughts and personal experiences/perspectives on a variety of topics, including, but not limited to:

- Structural barriers to healthcare access
- Healthcare climate and autonomy support
- PrEP use initiation, adherence, and persistence
- Individual agency & PrEP/HIV care barriers
- U=U knowledge
- Multi-level social support
- Stigma
- Mental health
- Sexual behavior and vulnerability
- Exposure to the integrated strategy
- Demographics

An audio computer-assisted self-interview (ACASI) will be offered as well as a Spanish translation of the questionnaire. The questionnaire will be reviewed by the CAG prior to implementation.

Once the questionnaire is completed, the participant will be offered compensation for their time. A participant is considered enrolled into the cross-sectional HHI MSM client assessment once the questionnaire is complete and submission is confirmed.

11.1.4 Chart Abstraction

The study coordinator will abstract protocol-required medical history and laboratory results information from the participant's medical record and enter them into an electronic case report form (eCRF) after the participant has completed the questionnaire. The eCRF data will also be used for the purposes of stratification of each sample during the analysis, per Section 4.3.2.1. Data entry can be completed immediately after the participant's questionnaire is submitted or at a later date, but must be completed within a seven-day window from questionnaire submission.

Data elements to be abstracted at HIV treatment HCFs (for HHI MSM living with HIV) include:

1. Demographics (not to include any direct identifiers)
2. HIV diagnosis and date
3. ART prescriptions within the past 12 months
4. Viral load results within the past 12 months
5. STI diagnoses within the past 12 months
6. Retention in care over the past 12 months
7. Date of first medical visit to the HCF

Data elements to be abstracted at HIV prevention HCFs (for HHI MSM not living with HIV) include:

1. Demographics (not to include any direct identifiers)
2. Most recent HIV test date and result
3. PrEP prescriptions/injections within the past 12 months
4. STI diagnoses within the past 12 months
5. Medical visits over the past 12 months
6. Date of first medical visit to the HCF

Accrual by stratification status will also be monitored across PHASE HCFs through the study database once data elements are entered from the medical record for each participant. Accrual targets may be adjusted across HCFs based on actual enrollment.

11.2 Collection of Electronic Medical Record (EMR) Data

11.2.1 EMR Data Collection Elements

A limited data set (deidentified per 45 CFR 164.514e), will be abstracted periodically over the PHASE intervention period from EMRs of all 60 PHASE HCFs to evaluate primary and secondary study objectives. Section 4.3.1 defines the subset of clients whose records will be abstracted from the EMR.

The general data elements to be abstracted within the study period include:

1) HHI male and MSM clients
    a) Age
    b) Cultural identity
    c) Sex
    d) Sexual orientation
    e) Type (e.g., primary, HIV prevention or treatment, STI testing, lab, medical) and date for each visit/encounter
    f) Other MSM-behavioral variables as available
2) HIV care
    a) HIV viral load and CD4 test dates and results
    b) Medication information (medication name, type of record, dose, quantity and date for each HIV treatment medication)
    c) Diagnosis codes related to AIDS/HIV infection and date for each diagnosis
    d) Other HIV care variables as available
3) HIV prevention
    a) HIV diagnosis tests results and dates
    b) PrEP medication (medication name, type of record, dose, quantity and date for each prescription)
    c) Other HIV prevention variables as available
4) Indicators of substantial risk of HIV acquisition
    a) High risk diagnosis code and dates for each visit/encounter
    b) STI tests within the study period (test description, test result and date)
    c) STI diagnosis and date for each diagnosis
    d) Other HIV acquisition risk variables as available

Specific EMR data codes and other details about data to be extracted will be provided in the PHASE HCF SSP (Data Collection and Management Section) and data extraction guide.

11.2.2 EMR Data Collection Procedures for PHASE HCFs

Each HCF will use an Application Programming Interface (API) to connect their EMR system to a secure third-party platform designated to capture EMR data from the HCF. Once the integration is complete, the third-party vendor will be responsible for accessing the EMR data on a periodic basis as directed by the study team (approximately quarterly), deidentifying the data, creating a limited dataset per protocol specifications, and transferring it to a central database that is accessible to the HPTN SDMC for analysis and reporting. Any direct patient identifiers and medical record identifiers will be replaced by the third-party vendor with study specific participant identifiers (PTIDs) such that no direct identifiers are available in the central database. A business associates' agreement and data use agreement will be in place between the third-party vendor and each HCF to allow the third-party vendor to generate and share the limited data set with the HPTN SDMC for research purposes; a data use agreement in place between the third-party vendor and HPTN SDMC will govern the HPTN SDMC's use of the data. Additional

operational procedures will be provided to HCFs in the PHASE HCF SSP (Data Collection and Management Section) and via technical training.

11.2.3 EMR Data Quality and Completeness

EMR data are expected to evolve and improve during the study due to the PHASE intervention and EMR data verification processes. EMR data will be continuously assessed for quality and completeness, using, for example, consistency checks across repeated data transfers from the same clinic, monitoring for increased completeness of critical data elements (e.g., MSM defining fields), direct verification of accuracy (e.g., number of clients) with participating clinics, and comparison of pre-intervention outcome proportions and trends between sites.

11.3 Qualitative Data Collection

11.3.1 Qualitative Data Collection with PHASE HHI MSM Clients

At a subset of PHASE HCF (see Section 4.3.3.1), participants completing the cross-sectional client assessment will be invited to participate in qualitative interviews. Participants who agree will be asked for permission to provide contact information to study team members conducting the qualitative interviews. These participants will be contacted by study team members trained in qualitative data collection methods. Qualitative IDIs with HHI MSM clients will take place around the midpoint (12-17 months) and, if necessary to reach accrual targets, post-intervention (24-27 months).

Qualitative research staff who are members of the HPTN 096 study team will contact potential qualitative IDI participants and confirm that they are willing to participate. Interviews will be arranged at a time and location convenient to the participant and interviewer. All IDIs will be conducted in a private setting, either virtually or in-person, based on the participant's preference.

Prior to proceeding with the interview, verbal consent will be obtained. IDIs will explore HHI men's (specifically men with a history of same-sex sexual practices) experience with stigma, client-centeredness, and service satisfaction in healthcare-related settings including at the PHASE HCF. To further elucidate these experiences, interviews will explore:

- What effect, if any, have autonomy supportive efforts of the PHASE HCF had on their uptake of antiretrovirals for PrEP or HIV treatment?
- How could PHASE HCFs improve their client-centeredness?
- What structural barriers do they face when seeking care for HIV prevention or treatment?
- What individual (self) agency do they feel to access PrEP or HIV treatment services despite the existence of barriers? What has contributed to their sense of (increased, decreased, or static) agency?

Interviewers will use a semi-structured interview guide to provide a general structure to the discussion. However, the interview guide will include the flexibility to ask probing questions as needed or welcomed. Interviewers will be encouraged to let the interview participants expound on their experience in a way that's most comfortable to them – guided by the interview topics.

Interviews will last approximately 45-60 minutes. All interviews will be digitally recorded and transcribed. Interviews will be conducted in English or Spanish, depending on the participant's preference. Interviews conducted in Spanish will be translated and transcribed into English.

11.3.2 Qualitative Data Collection with PHASE HCF Staff

At a subset of PHASE HCFs, staff who meet the criteria outlined in section 4.3.3.2 will be invited by a member of the qualitative research team to participate in an interview. Staff members who agree to participate will provide contact information to study team members conducting the qualitative interviews for follow-up and interview scheduling. Qualitative IDIs with HCF staff will take place prior to the study conclusion (between 18-23 months).

Interviews will be arranged at a time and location convenient to the participant and interviewer. All IDIs will be conducted in a private setting, either virtually or in-person, based on the participant's preference.

Prior to proceeding with the interview, verbal consent will be obtained. IDIs with PHASE HCF providers and staff will be conducted to help interpret and understand implementation barriers when implementing the PHASE integrated strategy. To characterize the experience of implementing the PHASE component among HCF providers and staff, interviews will examine:

- How relevant is PHASE to the HCF providers and staff?
    - What aspects of PHASE benefit HCF staff? What aspects of PHASE are difficult to implement?
- How does PHASE training affect clinical encounters or client/patient-provider interactions?
- What factors have contributed to successful outcomes?
    - What has been integrated into the HCFs workflow?
- In what context does the PHASE intervention work best/worst (e.g., hospital settings, CBOs, FQHCs, etc.)? Why?
- Factors that may lead to sustainability of any PHASE effects at the HCF.

Interviewers will use a semi-structured interview guide informed by the convergence framework and constructs from the implementation science literature (see section 1.2.2). While interviewers will ask questions about the implementation process, they will have the flexibility to ask probing questions as needed or appropriate. Interviewers will be encouraged to let participants expound on their experiences with PHASE to help build rapport and facilitate discussion.

Interviews will last approximately 30-45 minutes, depending on availability and workflow. All interviews will be digitally recorded and transcribed. Interviews will be conducted in English or Spanish, depending on the participant's preference. Interviews conducted in Spanish will be translated and transcribed into English.

12 USE OF CDC HIV SURVEILLANCE DATA

One of the exploratory objectives of the study is to see if there is any evidence that the integrated strategy is having an impact on community-level viral suppression in HHI MSM using CDC HIV

surveillance data. As such, a comparison will be made of community-level viral suppression in HHI MSM between the five study intervention communities and the five communities with which they were matched for a previous version of the study design (see V3.0 of the protocol). The five study intervention communities were matched with standard-of-care communities based on demographics (community size and percent of the population that are HHI) and baseline rates of viral suppression (based on CDC HIV surveillance data). All ten communities were included in the EHE counties and states designated as those with the highest burden of HIV prevalence and new HIV infections in the US.

The comparisons will be made between the following matched pairs:

- Dallas, TX (Dallas county) vs Houston, TX (Harris county)
- Montgomery, AL (Montgomery, Elmore and Autauga counties) vs Greenville, SC (Greenville and Spartanburg counties)
- Fort Lauderdale/Miami, FL (Broward and Miami-Dade counties) vs New Orleans/Baton Rouge, LA (Orleans, Jefferson and East Baton Rouge parishes)
- Memphis, TN (Shelby county) vs Charlotte, NC (Mecklenburg county)
- Atlanta, GA (Cobb, DeKalb, Fulton and Gwinnett counties) vs Washington DC/MD suburbs (Washington DC, Montgomery and Prince George's counties)

HPTN 096 will use data from the CDC's National HIV Surveillance System to conduct this exploratory analysis. The CDC maintains the National HIV Surveillance System, which is the primary source of data for monitoring HIV-related trends in the US [236]. The CDC does this by funding and assisting state and local health departments to collect information about the diagnosis and prevalence of HIV infection. In turn, these health departments report de-identified data to the CDC so that HIV-related information from around the country can be consolidated and analyzed. Some of the critical parameters collected include basic demographic information, date of diagnosis, acquisition risk and laboratory values (CD4 and viral load measurements) [236]. The ultimate goal of this surveillance system is to provide an integrated database that includes diagnosed HIV infection, disease progression, and the behaviors and characteristics of people with diagnosed HIV infection. The CDC uses this living database to understand the HIV epidemic in the US and to direct HIV prevention and treatment funding where it is needed most.

In addition to guiding public health policy, the CDC's National HIV Surveillance System can be used for research purposes, as data are continuously collected in a prospective manner. As the data are geographically linked, they can be categorized by location (e.g., state, county, city, facility), which allows the data to be used to measure outcomes for interventions made at the community-level. The use of surveillance data for this exploratory objective is feasible because the study intervention and their matched standard-of-care communities are contributing data to the CDC's National HIV Surveillance System.

For the exploratory analysis, viral load data from HHI MSM with diagnosed HIV who are alive at the end of each year will be used to compare rates of viral suppression between the study intervention and standard-of-care communities at various timepoints.

All data for this analysis will be collected and maintained by the CDC and CDC staff will conduct the analysis. The decision to pursue the analysis will be made in collaboration with the protocol team, including the DAIDS Medical Officer. If pursued, the analysis will be performed in collaboration with the protocol team.

13 STATISTICAL CONSIDERATIONS

13.1 Review of Study Design

HPTN 096 is a hybrid implementation-efficacy trial the aim of which is to evaluate a status-neutral integrated strategy to improve access to and uptake of HIV prevention and treatment services for HHI MSM. A single arm interrupted time series (ITS) design will be implemented to evaluate the integrated strategy, which will be delivered in up to five selected communities in the US South.

13.2 Objectives and Endpoints

The overall goal of this study is to establish a strategy to reduce HIV incidence among HHI MSM in the southern US by increasing the number of HHI MSM accessing prevention and treatment services, increasing uptake and use of preexposure prophylaxis (PrEP) among those living without HIV and increasing retention in care, and thus viral suppression, among those living with HIV in the study communities. The primary and secondary objectives reflect this goal, using a mix of quantitative and qualitative measurements. Explicitly, primary measures will be derived based on clinical data routinely available in the EMR.

It is expected that sexual orientation and/or sexual behavior data may not be complete within all EMR records. As such, supportive endpoints will be measured among the population of "HHI men," who will have the same demographic characteristics as HHI MSM except for sexual orientation/sexual behavior.

13.2.1 Primary Study Objectives and Endpoints

- To evaluate whether the HPTN 096 integrated strategy increases the number of HHI MSM clients at PHASE healthcare facilities.

  Endpoint:

  - (Primary) Number of HHI MSM with a visit at the HCF in the previous 12 months (**Source:** EMR).
  - (Supportive) Number of HHI men with a visit at the HCF in the previous 12 months (**Source:** EMR).

- To evaluate whether the HPTN 096 integrated strategy increases retention in care among HHI MSM living with HIV at PHASE healthcare facilities.

Endpoint:

- (Primary) Number of HHI MSM living with HIV with at least two HIV medical visits to the HCF at least 90 days apart within the previous 12 months (**Source:** EMR).
- (Supportive) Number of HHI men living with HIV with at least two HIV medical visits to the HCF at least 90 days apart within the previous 12 months (**Source:** EMR).

- To evaluate whether the HPTN 096 integrated strategy increases PrEP prescriptions for HHI MSM not living with HIV at PHASE healthcare facilities.

  Endpoint:

  - (Primary) Any PrEP prescription among all HHI MSM without HIV with a medical visit at the HCF within the previous 12 months (**Source:** EMR).
  - (Supportive) Any PrEP prescription among all HHI men without HIV with a medical visit at the HCF within the previous 12 months (**Source:** EMR).

13.2.2 Secondary Study Objectives and Endpoints

- To evaluate whether the HPTN 096 integrated strategy increases viral suppression (<200 copies/mL) in HHI MSM living with HIV at PHASE healthcare facilities.

  Endpoint:

  - (Primary) Viral suppression of the most recent VL done among all HHI MSM living with HIV who had a VL measurement at the HCF in the previous 12 months (**Source**: EMR).
  - (Supportive) Viral suppression of the most recent VL done among all HHI men living with HIV who had a VL measurement at the HCF in the previous 12 months (**Source**: EMR).

- To evaluate whether the HPTN 096 integrated strategy increases PrEP initiation, adherence and persistence for HHI MSM not living with HIV at PHASE healthcare facilities.

  Endpoint:

  - Self-report of PrEP initiation and adherence in the previous 12 months (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [questionnaires])
  - (Primary) Repeat PrEP prescriptions among HHI MSM not living with HIV in the previous 12 months. (**Source**: EMR).
  - (Supportive) Repeat PrEP prescriptions among HHI men not living with HIV in the previous 12 months. (**Source**: EMR).

- To assess changes in the experience of autonomy support among HHI MSM at PHASE healthcare facilities.

  Endpoint:

  - Self-reported scale measuring autonomy support (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [questionnaires, healthcare climate section])
  - Individual-level qualitative data with a subset of HHI MSM exploring autonomy support (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [qualitative interviews]).

- To assess how autonomy support, social support, stigma, barriers to healthcare and individual agency among HHI MSM at PHASE healthcare facilities are associated with engagement in care (including PrEP prescription and viral suppression).

  Endpoint:

  - Self-reported data related to autonomy support, social support, stigma, barriers to healthcare, individual agency (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [questionnaires])
  - Any PrEP prescription in last 12 months for HHI MSM not living with HIV (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [case report forms])
  - Viral load suppression and retention in care in last 12 months in HHI MSM living with HIV (**Source**: Cross-sectional assessment in sample of HHI MSM at PHASE HCFs [case report forms]).

13.3 Considerations for Power

For five study communities, the number of HCFs for assessing power for each objective is fixed: 60 in total, with 20 PHASE HIV treatment HCFs and 40 PHASE HIV prevention HCFs. We assess the effect sizes for which we have 80% power to detect for each objective, under a range of assumptions. The power assessments for the primary objectives are performed for an interrupted time series (ITS) design through simulations, the details of which are given below.

13.3.1 Simulation for Number of Clients at a Healthcare Facility (HCF)

The simulations evaluating the power for the endpoint of number of HHI MSM visiting the PHASE (both HIV prevention and HIV treatment) HCFs were performed under the interrupted time series (ITS) design. The number of clients visiting the i^{th} clinic ($i = 1, .., N$) during the assessment timepoint T_j was generated as a Poisson random variable with mean:

$$E(n_{ij}) = \exp(\lambda_{i0} + \lambda_{i1}T_j + \lambda_{i2}(T_j - T_0)I[T_j > T_0] + \lambda_{i3}F_i + e_{ij}) ,$$

Where T_0 is the baseline time period, $\text{expit}(x) = \frac{1}{1+e^{-x}}$, F_i indicates whether the i^{th} HCF is a HIV prevention facility or not, and $(\lambda_{i0}, \lambda_{i1}, \lambda_{i2})$ is a vector of random coefficients that was simulated as a multivariate normal random variable with mean $(\lambda_{00}, \lambda_{01}, \lambda_{02})$ and variance Σ_λ.

Here $\exp(\lambda_{02})$ is the intervention effect, the relative increase in the average number of HHI MSM presenting for service at the PHASE HCFs per year during the intervention periods and $\exp(\lambda_{03})$ is the ratio of the number of HHI MSM at PHASE HIV prevention HCFs versus PHASE HIV treatment HCFs. Also, $e_{i1}, \ldots, e_{it}$ are normally distributed and correlated random variables with mean zero that were generated such that $e_{ij} = \rho e_{ij-1} + v_{ij}$ $(j = 2, \ldots, t)$ with $e_{i1} \sim N(0, \sigma_e^2)$ and $v_{ij} \sim N(0, \sigma_v^2)$. Here $\rho = 0.25, \sigma_e^2 = 0.0025, \sigma_v^2 = 0.0025$.

The power assessment was based on a Wald test (testing $\lambda_{02} = 0$) using a generalized estimating equation (GEE) modification of the segmented Poisson model with the log link function and facilities as clusters and assuming an AR-1 correlation structure. The following additional assumptions were made:

- There were 4 evaluation time periods (T_j , $j = -1, 0, 1, 2$) with T_{-1} and T_0 being the pre-baseline and baseline time periods, respectively.
- The number of PHASE HIV prevention HCFs was 40.
- The number of PHASE HIV treatment HCFs was 20.
- No pre-intervention secular time trend: $\lambda_{01} = 0$.
- The average number of HHI MSM at PHASE HIV treatment HCFs at baseline was assumed to be 30, 50, 90 and 120 at baseline ($\lambda_{00} =$ $\log(30), \log(50), \log(90), \log(120)$). This was based on the average number of HHI MSM living with HIV and receiving HIV care at HIV treatment HCFs in Atlanta, Birmingham, Memphis, Mobile and Montgomery, which was used as a proxy for potential PHASE treatment HCFs. This average number was 89 based on the CDC 2020 estimates of facility-level number of HHI MSM, aged 13 years or older receiving HIV medical care at this set of facilities.
- The average number of HHI MSM not living with HIV at the PHASE HIV prevention HCFs was assumed to be smaller than the average number of HHI MSM at HIV treatment HCFs at baseline. In particular, it is assumed that the average number of HHI MSM clients at the PHASE HIV prevention HCFs at baseline was 60% of that at PHASE HIV treatment HCFs at baseline ($\lambda_{i3} = -0.5$): $18, 30, 54, 72$.
- The variability of the number of HHI MSM at PHASE HCFs varies from low (diag(Σ_λ) = (0.01, 0.001, 0.001)), medium (diag(Σ_λ) = (0.025, 0.0025, 0.0025)), and high (diag(Σ_λ) = (0.1, 0.005, 0.005)),
- Type I error rate = 5% (two-sided).
- The number of simulation replicates for each scenario was 1000.

13.3.2 Simulation of Retention in Care and PrEP Prescription

The number of HHI MSM client/patients visiting the i^{th} PHASE HCF during the baseline period (n_{i0}) was generated as a Poisson random variable with mean $\exp(\alpha_{i0})$, where $\alpha_{i0} \sim N(\alpha_{00}, \sigma_\alpha^2)$.

The outcome of interest (PrEP prescription or retention) for a participant visiting the i^{th} clinic during the time period T_j was simulated based on the following model:

$$E(Y_{ijk}) = \text{expit}(\beta_{i0} + \beta_{i1}T_j + \beta_{i2}(T_j - T_0)I[T_j > T_0] + e_{ij}),$$

where T_0 is the baseline time period, $\text{expit}(x) = \frac{1}{1+e^{-x}}$, $(\beta_{i0}, \beta_{i1}, \beta_{i2})$ is a vector of random coefficients that was simulated as a multivariate normal random variable with mean $(\beta_{00}, \beta_{01}, \beta_{02})$ and variance Σ_β. β_{02}, the change in slope during the intervention period, is the intervention effect. Here $\text{expit}(\beta_{00} + \beta_{01})$ is the PrEP prescription (retention) proportion at the first assessment time period, β_{01} is the slope of the logit-transformed PrEP prescription (retention) proportion pre-intervention (before baseline) and β_{02} represents the change in slope during the intervention period. As before, $e_{i1}, \ldots, e_{it}$ are normally distributed and correlated random variables with mean zero that were generated such that $e_{ij} = \rho e_{ij-1} + v_{ij}$ *(j=2,…,t)* with $e_{i1} \sim N(0, \sigma_e^2)$ and $v_{ij} \sim N(0, \sigma_v^2)$. Here $\rho = 0.25, \sigma_e^2 = 0.0025, \sigma_v^2 = 0.0025$, and $\sigma_\alpha^2 = 0.01$. It is worth mentioning that retention in care and PrEP prescription were modeled separately in the simulations based on the model given above. Moreover, the simulations were performed separately for the retention in HIV care and PrEP prescription endpoints. Also, the intervention effects on retention in care and PrEP prescription are not expected to be the same.

PrEP prescription (retention) proportion at the i^{th} facility and time period T_j was calculated as

$$p_{ij} = \sum_k y_{ijk} / n_{ij}$$

where n_{ij} is the number of HHI MSM visiting the i[th] PHASE HCF during the assessment time period. For the power simulation no increase in client/patient volume was assumed, (i.e. $n_{ij} = n_{i0}$). The power calculation for the intervention effect under the ITS design was based on a Wald test: testing for no change in slope in post-intervention PrEP prescription proportion (or retention), that is, $\beta_{02} = 0$, using a generalized estimating equation (GEE) model for the logit-transformed proportions p_{ij} with the identity link function, facilities as clusters and assuming an AR-1 correlation structure for repeated facility observations. The following additional assumptions were made:

- All time periods had a duration of a calendar year, with the baseline period the year before the intervention implementation.
- There were 4 evaluation time periods ($T_j, j = -1, 0, 1, 2$) with T_{-1} and T_0 being the pre-baseline and baseline timepoint (pre-intervention), respectively.
- The number of PHASE HIV prevention HCFs was 40.
- The number of PHASE HIV treatment HCFs was 20.
- The average number of patients at PHASE HIV treatment HCFs was $exp(\alpha_{00}) = 30, 50, 90, 120$ at each time period.
- The average number of clients at PHASE HIV prevention HCFs was $exp(\alpha_{00}) = 18, 30, 54, 72$ at each time period.

- The average PrEP prescription proportion at baseline was 18% ($\beta_{00} = -1.5$). This assumption was based on the HPTN 096 pilot study data. The average proportion of Self-reported current use of PrEP among HHI MSM in the four study communities (Houston, Dallas, Greenville and Montgomery) was 21.5% with much smaller proportions from the two smaller communities (13% and 17.5%, respectively for Greenville and Montgomery) when compared with the larger communities (Dallas and Houston). It is expected that several PHASE HIV prevention HCFs will be from small communities, and it is possible that the baseline proportion of PrEP prescriptions for HHI MSM at the PHASE HIV prevention HCFs would be smaller than the observed 21.5% of PrEP use in the sample of HHI MSM from the four communities in the pilot study.
- The average retention proportion at baseline was 77% ($\beta_{00} = 1.2$). This was based on the HRSA Ryan White HIV/AIDS program services reports 2020 (Table 12b) and 2021 (Table 12b) showing overall retention proportions of 77.7% and 75.6% for 2020 and 2021, respectively for HHI MSM aged 13 years or older receiving HIV care at Ryan and White HIV care clinics.
- The time trend for PrEP prescription pre-intervention varies from no-trend ($\beta_{01} = 0$), small trend ($\beta_{01} = 0.1$), moderate trend ($\beta_{01} = 0.2$) and substantial trend ($\beta_{01} = 0.3$).
- The time trend for retention varies from no-trend ($\beta_{01} = 0$), small trend ($\beta_{01} = 0.05$), moderate trend ($\beta_{01} = 0.1$) and substantial trend ($\beta_{01} = 0.15$).
- The between-clinic variability varies from low (diag(Σ_β) = (0.01, 0.001, 0.001)), medium (diag(Σ_β) = (0.25, 0.025, 0.025)) and high (diag(Σ_β) = (0.5, 0.05, 0.05)).
- Type I error rate = 5% (two-sided).
- The number of simulation replicates for each scenario was 1000.

13.3.3 Power for Primary Endpoints

Simulation-based power results are provided in Table 6 for the endpoint of number of HHI MSM clients at the PHASE HCFs, Table 7 for the retention in care endpoint and Table 8 for the PrEP prescription endpoint. The following power statements are derived from the results displayed in the tables:

If the PHASE HIV treatment HCFs served an average of 90 HHI MSM and the PHASE HIV prevention HCFs served an average of 54 HHI MSM, with medium variability in number of clients between HCFs and assuming no background trend in client volume, we would have 80% power to see a relative increase of 17.4% in patient numbers between the baseline period and the second year of the intervention.

If the PHASE HIV treatment HCFs served an average of 90 HHI MSM and average retention in care during the baseline period is 77% with a medium variability in retention proportion between HCFs and a background improvement in retention of 1% in the absence of an intervention, we would have 80% power to see a relative increase of 15% [(expit($\beta_{00} + 2\beta_{01} + 2\beta_{02}$)/ expit($\beta_{00}$) $= 1.15$] in retention, translating to a 11.6% increase (from 77.0% during the baseline

period to 88.5% during the last year of the intervention) as a result of the intervention, compared to 1.7% increase (from 77.0% to 78.7%) in the absence of an intervention.

If the PHASE HIV prevention HCFs served an average of 54 HHI MSM, and we assume a medium variability in PrEP prescription proportion between HCFs and a 9% background relative increase in PrEP prescriptions in the absence of an intervention, we would have 80% power to see a relative increase of 120% ($\text{expit}(\beta_{00} + 2\beta_{01} + 2\beta_{02})/ \text{expit}(\beta_{00}) = 2.2$) in PrEP prescriptions, translating to a 22% increase (from 18.0% during the baseline period to 40% during the last year of the intervention) as a result of the intervention, compared to 3.2% increase (from 18.0% to 21.2%) in the absence of an intervention.

Table 6. Power simulations for Objective 1. Relative increase from baseline (Alt. Hypothesis) in number of HHI MSM presenting at the PHASE HIV treatment HCFs and PHASE HIV prevention HCFs with 80% power over the two years of the implementation of the intervention based on a Wald test using a segmented generalized estimating equations (GEE) model for count data with the log-link function, assuming an AR-1 correlation structure, alpha=0.05 (two-sided) and no underlying time trend (before the start of the intervention). The evaluation assumes 60 HCFs: 20 PHASE HIV treatment HCFs and 40 PHASE HIV prevention HCFs.

Size of PHASE HIV treatment HCF[1]	Size of PHASE HIV prevention HCFs[2]	SD_btwf[3]	SD_total[4]	SD_care_bsl[5]	SD_prep_bsl[6]	Intervention effect (λ_{02})[7]	Relative increase[8]
Variability of the number of HHI MSM at PHASE HCFs = Low							
30	18	2.54	5.94	6.36	4.66	0.140	1.323
50	30	4.21	8.17	8.80	6.39	0.110	1.246
90	54	7.46	12.26	13.51	9.41	0.080	1.174
120	72	9.89	15.27	16.89	11.49	0.075	1.162
Variability of the number of HHI MSM at PHASE HCFs = Medium							
30	18	4.13	7.08	7.37	5.21	0.140	1.323
50	30	6.73	10.18	10.88	7.44	0.105	1.234
90	**54**	**11.91**	**16.25**	**17.66**	**11.62**	**0.080**	**1.174**
120	72	15.70	20.68	22.64	14.69	0.070	1.150
Variability of the number of HHI MSM at PHASE HCFs = High							
30	18	8.67	10.83	11.75	7.58	0.130	1.297
50	30	14.15	16.78	18.60	11.76	0.105	1.234
90	54	24.89	28.36	32.31	20.08	0.075	1.162
120	72	32.96	37.06	42.71	26.27	0.065	1.139

[1]Size of PHASE HIV treatment HCF is the average number of HHI MSM presenting at the PHASE HIV treatment HCFs during the baseline period.

[2]Size of PHASE HIV prevention HCF is the average number of HHI MSM presenting at the PHASE HIV prevention HCFs during the baseline period.

[3]SD_btw is the between facility standard deviation of the number of HHI MSM presenting at the PHASE HCFs.

[4]SD_total is the square root of the total variance (between facility variance + within facility variance) of the number of HHI MSM presenting at the PHASE HCFs.

[5] SD_care_bsl is the standard deviation of the number of HHI MSM with HIV presenting at the PHASE HIV treatment HCFs during the baseline period.

[6]SD_prep_bsl is the standard deviation of the number of HHI MSM without HIV presenting at the PHASE HIV prevention HCFs during the baseline period.

[7]Intervention effect is the effect size., which is $\boldsymbol{\lambda_{02}}$.

[8]Relative increase is the relative increase from baseline in the number of HHI MSM presenting at the PHASE HCFs at the end of the study. This was obtained as $exp(2\lambda_{02})$.

Table 7. Power simulations for Primary Objective 2. Increase in retention in care proportion at the end of the implementation of the intervention for which we have 80% power based on a Wald test using a segmented GEE model for the logit transformation of the retention in care proportion, assuming an AR-1 correlation structure and alpha=0.05 (two-sided). The number of PHASE HIV treatment HCFs was fixed at 20. The baseline retention in care proportion is assumed to be 77%.

Size[1]	Time trend(β_{01})	Relative increase (background) from baseline of 77%	Intervention effect(β_{02})[2]	Total increase[3] under alternative	Total increase[4] under null	Increase due to the intervention only[5]
Variability of retention in care proportion across PHASE HIV treatment HCF = Low						
30	0	1	0.65	15.6%	0.0%	15.6%
	0.05	1.01	0.64	16.1%	1.7%	14.4%
	0.1	1.02	0.63	16.6%	3.4%	13.2%
	0.15	1.04	0.62	17.1%	4.9%	12.2%
50	0	1	0.46	12.4%	0.0%	12.4%
	0.05	1.01	0.46	13.4%	1.7%	11.6%
	0.1	1.02	0.46	14.2%	3.4%	10.8%
	0.15	1.04	0.47	15.1%	4.9%	10.2%
90	0	1	0.33	9.7%	0.0%	9.7%
	0.05	1.01	0.33	10.8%	1.7%	9.1%
	0.1	1.02	0.33	11.8%	3.4%	8.5%
	0.15	1.04	0.33	12.8%	4.9%	7.9%
120	0	1	0.29	8.7%	0.0%	8.7%
	0.05	1.01	0.3	10.1%	1.7%	8.4%
	0.1	1.02	0.29	11.0%	3.4%	7.6%
	0.15	1.04	0.3	12.2%	4.9%	7.3%
Variability of retention in care proportion across PHASE HIV treatment HCF = Medium						
30	0	1	0.72	16.5%	0.0%	16.5%
	0.05	1.01	0.71	17.0%	1.7%	15.2%
	0.1	1.02	0.69	17.3%	3.4%	13.9%
	0.15	1.04	0.68	17.7%	4.9%	12.8%
50	0	1	0.48	12.8%	0.0%	12.8%
	0.05	1.01	0.48	13.7%	1.7%	12.0%
	0.1	1.02	0.48	14.5%	3.4%	11.2%
	0.15	1.04	0.47	15.1%	4.9%	10.2%
90	0	1	0.37	10.6%	0.0%	10.6%
	0.05	**1.01**	**0.37**	**11.6%**	**1.7%**	**9.9%**
	0.1	1.02	0.37	12.6%	3.4%	9.3%
	0.15	1.04	0.37	13.5%	4.9%	8.6%
120	0	1	0.33	9.7%	0.0%	9.7%
	0.05	1.01	0.33	10.8%	1.7%	9.1%
	0.1	1.02	0.33	11.8%	3.4%	8.5%
	0.15	1.04	0.32	12.6%	4.9%	7.7%
Variability of retention in care proportion across PHASE HIV treatment HCF = High						
30	0	1	0.83	17.7%	0.0%	17.7%
	0.05	1.01	0.81	18.0%	1.7%	16.3%
	0.1	1.02	0.81	18.5%	3.4%	15.1%
	0.15	1.04	0.79	18.8%	4.9%	13.8%
50	0	1	0.53	13.7%	0.0%	13.7%
	0.05	1.01	0.52	14.4%	1.7%	12.6%
	0.1	1.02	0.51	15.0%	3.4%	11.6%
	0.15	1.04	0.51	15.7%	4.9%	10.8%
90	0	1	0.38	10.8%	0.0%	10.8%
	0.05	1.01	0.38	11.8%	1.7%	10.1%
	0.1	1.02	0.38	12.8%	3.4%	9.4%
	0.15	1.04	0.38	13.7%	4.9%	8.8%
120	0	1	0.36	10.4%	0.0%	10.4%
	0.05	1.01	0.35	11.2%	1.7%	9.5%
	0.1	1.02	0.36	12.4%	3.4%	9.1%
	0.15	1.04	0.35	13.2%	4.9%	8.3%

[1]Size is the average number of HHI MSM at the PHASE HIV treatment HCFs during baseline period.

[2]Intervention effect (β_{02}) detectable with 80% power

[3] Increase in the retention proportion at the end of the study with the intervention from baseline. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01} + 2\beta_{02})$- $\text{expit}(\beta_{00})$.

[4]Projected increase in the retention proportion at the end of the study without the intervention from baseline. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01})$- $\text{expit}(\beta_{00})$.

[5]Difference between the increase in the retention proportion at the end of the study with the intervention and the projected increase in the retention proportion at the end of the study without the intervention. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01} + 2\beta_{02})$ - $\text{expit}(\beta_{00} + 2\beta_{01})$.

Table 8. Power simulations for Primary Objective 3. Increase in proportion with PrEP prescription at the end of the implementation detectable with 80% power, based a Wald test using a segmented GEE model for the logit-transformation of the PrEP prescription proportion with the identity link function, assuming an AR-1 correlation structure and alpha=0.05 (two-sided). The number of PHASE HIV prevention HCFs was fixed at 40. The baseline PrEP prescription proportion is assumed to be 18%.

Size[1]	Time trend(β_{01})	Relative increase (background) from baseline of 18%	Intervention effect(β_{02})[2]	Total increase[3] under alternative	Total increase[4] under null	Increase due to the intervention only[5]
Variability of PrEP prescription proportion across PHASE HIV prevention HCF = Low						
18	0	1	1.05	46.3%	0.0%	46.3%
	0.1	1.09	1.14	54.5%	3.2%	51.3%
	0.2	1.18	1.20	60.3%	6.7%	53.6%
	0.3	1.29	1.25	65.0%	10.7%	54.3.%
30	0	1	0.61	24.8%	0.0%	24.8%
	0.1	1.09	0.68	33.3%	3.2%	30.1%
	0.2	1.18	0.75	41.6%	6.7%	34.9%
	0.3	1.29	0.81	49.0%	10.7%	38.4%
54	0	1	0.33	11.9%	0.0%	11.9%
	0.1	1.09	0.34	16.7%	3.2%	13.6%
	0.2	1.18	0.35	21.9%	6.7%	15.2%
	0.3	1.29	0.39	28.8%	10.7%	18.1%
72	0	1	0.28	9.8%	0.0%	9.8%
	0.1	1.09	0.28	14.1%	3.2%	10.9%
	0.2	1.18	0.29	19.0%	6.7%	12.3%
	0.3	1.29	0.30	24.3%	10.7%	13.7%
Variability of PrEP prescription proportion across PHASE HIV prevention HCF = Medium						
18	0	1	1.09	48.1%	0.0%	48.1%
	0.1	1.09	1.16	55.3%	3.2%	52.1%
	0.2	1.18	1.20	60.3%	6.7%	53.6%
	0.3	1.29	1.22	64.1%	10.7%	53.4%
30	0	1	0.74	31.3%	0.0%	31.3%
	0.1	1.09	0.80	39.2%	3.2%	36%
	0.2	1.18	0.87	47.2%	6.7%	40.5%
	0.3	1.28	0.94	54.5%	10.7%	43.8%
54	0	1	0.42	15.8%	0.0%	15.8%
	0.1	**1.09**	**0.45**	**21.9%**	**3.2%**	**18.7%**
	0.2	1.18	0.49	28.8%	6.7%	22%
	0.3	1.29	0.55	36.7%	10.7%	26.1%
72	0	1	0.33	11.9%	0.0%	11.9%
	0.1	1.09	0.34	16.7%	3.2%	13.6%
	0.2	1.18	0.35	21.9%	6.7%	15.2%
	0.3	1.29	0.37	27.8%	10.7%	17.1%
Variability of PrEP prescription proportion across PHASE HIV prevention HCF = High						
18	0	1	1.10	48.6%	0.0%	48.6%
	0.1	1.09	1.15	54.9%	3.2%	51.7%
	0.2	1.18	1.20	60.3%	6.7%	53.6%

Size[1]	Time trend(β_{01})	Relative increase (background) from baseline of 18%	Intervention effect(β_{02})[2]	Total increase[3] under alternative	Total increase[4] under null	Increase due to the intervention only[5]
	0.3	1.29	1.22	64.1%	10.7%	53.4%
30	0	1	0.84	36.2%	0.0%	36.2%
	0.1	1.09	0.87	42.6%	3.2%	39.4%
	0.2	1.18	0.95	50.8%	6.7%	44%
	0.3	1.29	1.01	57.2%	10.7%	46.5%
54	0	1	0.51	20.0%	0.0%	20%
	0.1	1.09	0.55	26.8%	3.2%	23.6%
	0.2	1.18	0.59	33.8%	6.7%	27%
	0.3	1.29	0.64	41.1%	10.7%	30.5%
72	0	1	0.39	14.5%	0.0%	14.5%
	0.1	1.09	0.42	20.5%	3.2%	17.3%
	0.2	1.18	0.44	26.3%	6.7%	19.5%
	0.3	1.29	0.50	34.3%	10.7%	23.6%

[1]Size is the average number of HHI MSM at the PHASE HIV prevention HCFs at baseline.

[2]Intervention effect means effect size (β_{02}) detectable with 80% power.

[3]Total increase in proportion of PrEP prescription at the end of the study with the intervention from baseline. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01} + 2\beta_{02})$- $\text{expit}(\beta_{00})$.

[4]Projected increase in proportion of PrEP prescription at the end of the study without the intervention from baseline. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01})$- $\text{expit}(\beta_{00})$.

[5]Difference between the increase in the retention proportion at the end of the study with the intervention and the projected increase in the retention proportion at the end of the study without the intervention. This was calculated as $\text{expit}(\beta_{00} + 2\beta_{01} + 2\beta_{02}) - \text{expit}(\beta_{00} + 2\beta_{01})$.

A simulation study was also performed to evaluate the type 1 error rates of the tests assessing the intervention effects on the primary endpoints under the ITS design. The data generation in the simulations was done similarly as for the power assessment for each endpoint except that this was done under the null hypothesis of no intervention effect. The simulations results indicated non-substantially inflated type 1 error rates for the endpoints ranging between 0.036 and 0.088 with the assumed nominal significance level of 0.05 under the different scenarios that were considered.

For a minimum of three communities and 36 HCFs (12 PHASE HIV treatment and 24 PHASE HIV prevention HCFs), using similar methods, there would be 80% power to detect the following differences: for the number of HHI MSM clients at all PHASE HCFs, a relative increase of 23.4%; for retention in care (PHASE HIV treatment HCFs), a relative increase of 18% (absolute change of 13.7%, from 77% at baseline to 90.7% at end of intervention); for PrEP prescription (PHASE HIV prevention HCFs), a relative increase of 136% (absolute change of 25%, from 18.0% at baseline to 43% at end of intervention).

13.4 Accrual and Retention

Primary outcomes will be measured over different time periods in this study using facility level evaluations based on electronic medical record data from approximately 40 PHASE HIV prevention HCFs providing HIV prevention services and approximately 20 PHASE HIV treatment HCFs providing HIV treatment services across these five study communities. Given that primary data collection will rely on cross-sectional facility level evaluations (obtained from

the EMRs), no consideration for accrual and retention of participants is necessary for these endpoints.

On the other hand, there are secondary study endpoints that are based on recruitment into the cross-sectional assessment data collected from a subset of HHI MSM at baseline, after one year (midpoint) and at the end of the two-year implementation of the integrated strategy (post-intervention); a subset of these participants will be invited to participate in qualitative interviews. For the cross-sectional assessment, it is generally expected that potential participants will be recruited, screened, enrolled, and complete their questionnaire all in the same visit. Each PHASE HCF will be assigned a target accrual number for each stratification category during each sampling timeframe (see Section 4.3.2.1 for stratification), and study coordinators will be expected to locally track enrollment and stratification of each participant. Accrual by stratification status will also be monitored across PHASE HCFs through the study database once data elements are entered from the medical record for each participant. Accrual targets may be adjusted across PHASE HCFs based on actual enrollment.

13.5 Data and Feasibility Monitoring and Interim Analyses

A multi-tiered data and feasibility monitoring approach will be followed for the duration of this study. Data and Safety Monitoring Board oversight is not planned for this study. The monitoring approach will include 1) regular ongoing oversight of study implementation activities by component-specific and cross-cutting working groups comprised of protocol co-chairs, statisticians, key LOC and SDMC staff members, sub-groups of protocol team members, implementing partners, and NIH representatives; 2) monthly protocol leadership oversight with key members of the protocol leadership team and NIH representatives; and 3) HPTN SMC review. The HPTN SMC will conduct interim reviews of study progress, including tracking of PHASE HCF participation and EMR data transfer, rates of participant accrual for cross-sectional assessments, measures of integrated strategy delivery and uptake (i.e., process measure data), and completion of primary and secondary endpoint collection. The frequency and content of protocol leadership oversight and HPTN SMC reviews will be determined prior to the start of the study as outlined in the HPTN Manual of Operations (MOP) (Section 15.5 Study Monitoring Committee (SMC) Oversight) and the Study-Specific Monitoring Plan. The Study-Specific Monitoring Plan will outline the key parameters and performance standards that will be monitored for both monthly protocol leadership oversight and SMC review.

Implementation of the intervention is a critical component of protocol leadership oversight and HPTN SMC review for this study. Standards for implementation of each of the four components will be outlined in the Study-Specific Monitoring Plan with key parameters and performance standards to be developed in collaboration with the SMC and NIH representatives. The implementation metrics available for each component are described in Protocol Sections 5.3 and 5.4 (for health access coalitions), 6.3 and 6.4 (for social media), 7.3 and 7.4 (for PHASE) and 8.7 and 8.8 (for peer support). If the study team is not meeting the agreed upon standards, the study team would undergo a remediation/modification process with the SMC and NIH, including the potential to stop the study if the implementation of the intervention is so poor that it is judged improbable that it could result in substantive change in any of the primary study endpoints.

13.6 Statistical Analysis

This section briefly describes the statistical analyses of the primary objectives. Detailed technical specifications of the statistical analyses, including secondary objectives will be described in a separate Statistical Analysis Plan.

13.6.1 Primary Analyses

This trial is designed to assess the effect of the integrated intervention on the following endpoints (i) number of HHI MSM clients established in care at these healthcare facilities, (ii) retention in care in HHI MSM living with HIV, and (iii) PrEP uptake in HHI MSM not living with HIV. Note that although the primary endpoints of number of clients, retention in care, and PrEP uptake will be measured among HHI MSM clients, we have also included analogs of these endpoints (supportive endpoints) that will be measured among all men with the same demographic characteristics as HHI MSM except for sexual orientation and/or sexual behavior who are clients at the facilities. Given this is an implementation project, the primary endpoints may be influenced by the quality of the data that will be used to identify HHI MSM within the client population. Thus, in the scenario that the primary endpoints are limited by data availability and completeness (regarding MSM status), the supportive analyses will help for interpretation and understanding of the effect of the intervention on the endpoints.

13.6.1.1 Interrupted Time series (ITS) Model

All three primary endpoints will be measured over four distinct time periods in this study. Of these, two will be pre-intervention measures, collected before the start of the intervention, and two will be post-intervention measures, collected in the period between the start of the intervention and its conclusion after two years. For notational ease, we define the two-year long integrated intervention to be Year 1 and Year 2, starting after the baseline (Year 0), and continuing up through the end of Year 2. One of the pre-intervention measures will be the baseline period, that is, prior to the start of the integrated intervention, named Year 0. We will have another (retrospective) one year pre-baseline period, namely Year -1. Each year will rely on EMR data accumulated in the 12-month period. The definition of the end of the baseline year will be defined during the first intervention year and may vary by facility but will pre-date conducting any PHASE training at the facility.

The repeated evaluation of the endpoints at these participating PHASE HCFs, including multiple pre-intervention and during-intervention measurements, will allow us to implement the interrupted time series design [213, 237-239] to assess intervention effect. The pre-intervention timepoints will establish a background level and trend. This trend will be interrupted by the study intervention and the subsequent two years of observation during the intervention period will determine if the integrated strategy has changed the expected trend.

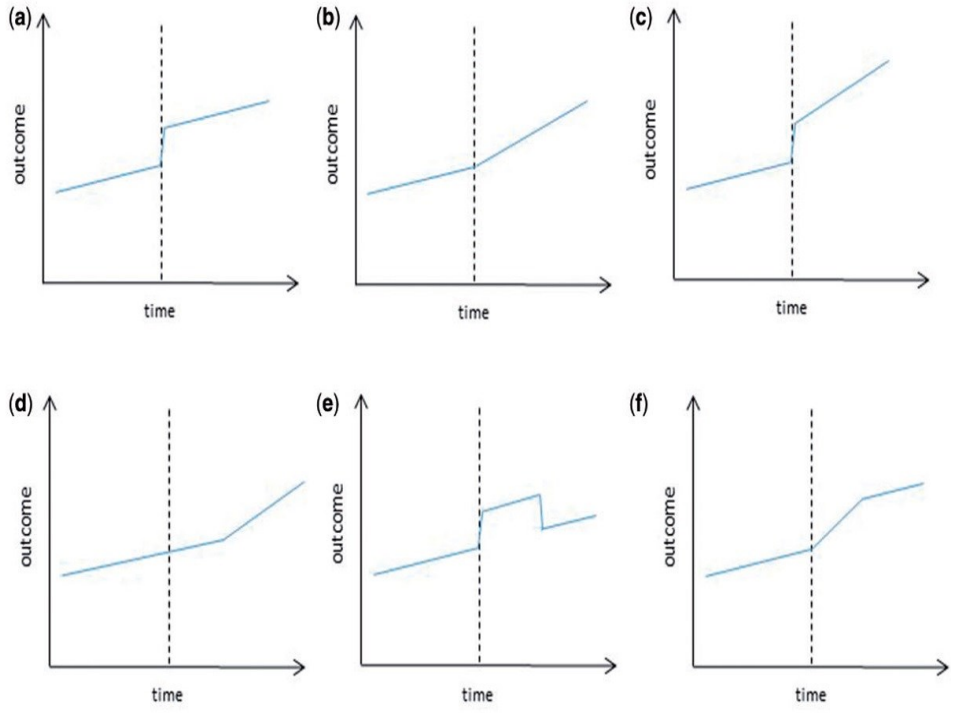
HPTN 096 is a quasi-experimental study. Quasi experimental designs (QEDs) are non-randomized designs used for evaluating the effect of interventions, implemented in scenarios when randomization is not feasible, as in HPTN 096. The interrupted time series (ITS) design is considered the strongest among QEDs and a powerful tool for evaluating the impact of interventions implemented in healthcare [237]. Under the ITS design, endpoints are measured at

different time points before and after implementing an intervention, allowing the change in level and trend of endpoints to be compared, to evaluate the intervention effect. Note that the ITS design has internal validity even in the presence of a secular time-trend. That is, if there is a background rate of improvement of the endpoints even without the intervention the ITS design allows modelling background trend (based on the 2 pre-intervention years) separately from the intervention effect, so that background changes are not falsely attributed to the intervention itself. This design can correctly estimate the intervention effect even in the presence of a background time trend, i.e. to detect if the intervention has an additional effect than the underlying trend. One necessary assumption of the ITS design is that the temporal trend observed in the endpoint in the pre-intervention period would remain the same if the intervention is not implemented.

13.6.1.2 Impact Model for the Interrupted Time Series (ITS) Design

One important step in an ITS analysis is the selection of the intervention-impact model, that is, to hypothesize how the intervention will impact the endpoints if it were effective. Examples of some possible impact models are given below (illustration taken from Bernal et al. 2017 – see Figure 11 in [238], for (a) level change; (b) slope change; (c) level and slope change; (d) slope change following a lag; (e) temporary level change; (f) temporary slope change leading to a level change.

Figure 11. Slope and Level Changes



It is usually recommended that the impact model is selected a priori based on existing literature and knowledge of the intervention and the mechanism by which it is expected to act on the endpoints. Based on our knowledge of the study setting and implementation process of the integrated intervention in HPTN 096, we do not expect any sudden level change in these

endpoints just following start of the intervention or anytime later, rather we expect the intervention to slowly show its impact on these endpoints over time. Hence, impact model (b) slope change (from the above figure) is deemed most appropriate for analysis of the HPTN 096 data, and this model will be implemented in analysis of all three endpoints.

Endpoint measures from a participating facility will be correlated over time. This correlation is due to (i) facility-wise random effect: random fluctuation of these endpoints due to facility-specific practices, clients, and a varying degree of implementation of the intervention at a given facility, and (ii) autocorrelation: consecutive measurement of the endpoints may be more similar to one another than measurements that are further apart.

13.6.1.3 Number of HHI MSM Served at PHASE HCFs

Our primary measure of the number of HHI MSM at PHASE HCFs will be based on electronic medical record (EMR) data (containing the number of clients and visit information) from approximately 20 PHASE HCFs that provide HIV treatment services and 40 PHASE HCFs that provide HIV prevention services across the five intervention communities. The number of HHI MSM will be measured for each participating PHASE (HIV treatment or prevention) HCF at each of the four assessment timepoint (pre-baseline, baseline, midpoint and postintervention) as the number of HHI MSM with a visit at the HCF in the previous 12 months.

The primary interest lies in the estimation of the average effect of the implementation of the package of interventions on the number of HHI MSM across the HCFs. We will fit the following segmented regression model, assuming no immediate level-change, using Generalized Estimating Equations (GEE) with autoregressive order 1 (AR-1) correlation structure, clustering at the health facility level to estimate and test for the intervention effect:

$$E(n_{ij}) = \exp(\gamma_0 + \gamma_1 T_j + \gamma_2 (T_j - T_0) I[T_j > T_0] + \gamma_3 F_i) \quad (1)$$

where n_{ij} be the number of clients evaluated at facility $i,\ i = 1, \dots, N$, at time periods $T_j, j \in \{-1,0,1,2\}$. N $(approximately\ 60)$ is the total number of participating PHASE HCFs (20 PHASE HIV treatment HCFs and 40 PHASE HIV prevention HCFs). T_{-1} and T_0 are pre-baseline and baseline, Years -1 and 0, respectively; T_1 and T_2 are intervention, Years 1 and 2, respectively. Note that T_0 is the time when the intervention is implemented. F_i indicates the facility type for the i^{th} HCF, that is, $F_i = 1$ if it is a PHASE HIV prevention HCF and $F_i = 0$ if it is a PHASE HIV treatment HCF. exp (γ_0) is the mean number of HHI MSM clients with at least one visit at baseline, $\gamma_1$is the coefficient associated with the effect of secular (time) trend on the logarithm of the number of HHI MSM clients seen at a facility (slope), and γ_2 is the coefficient associated with the slope change due to the intervention, and hence is the intervention effect on the logarithm of the average number of HHI MSM visiting any PHASE HCF, and exp (γ_3) is the ratio of the average number of HHI MSM with a visit at PHASE HIV prevention HCFs divided by the average number of HHI MSM with a visit at PHASE HIV treatment HCFs.

From model (1), we will provide a 95% CI for the intervention effect γ_2 and a p-value for testing the hypothesis H_0: $\gamma_2 = 0$ using α = 0.05 (two-sided). We will also provide model-based estimates for the number of HHI MSM seen at a PHASE HCF (separately for HIV treatment and HIV prevention HCFs) and their CI at each time point under the intervention and under the

counterfactual condition of no intervention. This will facilitate interpretation of the impact of the intervention on the number of clients. We will use γ_2, the intervention effect in the transformed scale, to estimate a total intervention effect (given as Δ) and its 95% CI for each type of PHASE HCF, as the difference between the estimated number of HHI MSM clients seen at a given type of PHASE HCF at the post-intervention timepoint Year 2 (end of intervention) and model predicted estimates at that timepoint under the counterfactual condition of no intervention:

$$\Delta_{\text{PrEP}} = E(n_{i2}|\text{intervention, HIV prevention HCF}) - E(n_{i2}|\text{no intervention, HIV prevention HCF})$$

$$= \exp(\gamma_0 + \gamma_1 T_2 + \gamma_2(T_2 - T_0) + \gamma_3) - \exp(\gamma_0 + \gamma_1 T_2 + \gamma_3)$$

$$\Delta_{\text{HIV}} = E(n_{i2}|\text{intervention, HIV treatment HCF}) - E(n_{i2}|\text{no intervention, HIV treatment HCF})$$

$$= \exp\big(\gamma_0 + \gamma_1 T_2 + \gamma_2(T_2 - T_0)\big) - \exp(\gamma_0 + \gamma_1 T_2)$$

As a sensitivity analysis, we will also repeat the above analyses after adjusting for potential confounders in the segmented regression model (1), including the HCF size, and characteristics (such as average age) of HHI MSM at any PHASE HCF at baseline.

13.6.1.4 Retention in Care

Our primary measure of retention in care among HHI MSM living with HIV will be measured as the number of HHI MSM living with HIV with at least two HIV medical visits to the PHASE HIV treatment HCFs at least 90 days apart within the previous 12 months at each assessment timepoint based on EMR data containing HIV medical visit information from approximately 20 PHASE HIV treatment HCFs that provide HIV care services across the five intervention communities.

The proportion of HHI MSM living with HIV who are retained in care will be measured for all participating PHASE HIV treatment HCFs at each of the four measurement windows (Year -1, Year 0, Year 1 and Year 2). The primary interest is in estimating the average intervention effect on the retention in care proportion across the PHASE HIV treatment HCFs. We will use a segmented GEE model for the logit-transformation of the retention in care proportion using the identity link function, assuming no immediate level-change, an AR-1 correlation structure and clustering at the healthcare facility-level to test for the intervention effect on the retention in care proportion. The GEE model is formulated as follows.

$$\big(\text{logit}(\text{E}(r_{ij})\big) = \alpha_0 + \alpha_1 T_j + \alpha_2\big(T_j - T_0\big) I\big[T_j > T_0\big], \qquad (2)$$

where r_{ij} is the retention in care proportion for HIV care facility *i* at the assessment timepoint T_j which is defined similarly as in model (1) for $j = -1, \ldots, 2$; and $logit(x) = \log(x/(1-x))$. Also, average of the logit-transformed retention proportion at baseline, α_1 is the coefficient associated with the effect of secular (time) trend on the logit-transformation of the retention in care rate (slope), and α_2 is the coefficient associated with the slope change due to the intervention, and hence is the intervention effect on the logit-transformed retention in care.

From model (2), we will provide a 95% CI for the intervention effect α_2 and a p-value for testing the hypothesis $H_0: \alpha_2 = 0$ using $\alpha = 0.05$ (two-sided). We will also provide model-based estimates for retention in care rates and their CI at each time point under the intervention and under the counterfactual condition of no intervention. This will help us understand how the retention in care rates have been impacted by the background trend as well as the intervention over the period of the study. Using large sample approximation for asymptotic behavior of functions (that is, the delta method), we can use α_2, the intervention effect, to estimate a total intervention effect (given as Δ), as the difference between the estimated retention rates at Year 2 (end of intervention) and model predicted rates at Year 2 under the counterfactual condition of no intervention:

$$\Delta = E(r_{i2}|\text{intervention}) - E(r_{i2}|\text{no intervention})$$

$$= \text{expit}\big(\alpha_0 + \alpha_1 T_2 + \alpha_2 (T_2 - T_0)\big) - \text{expit}(\alpha_0 + \alpha_1 T_2),$$

As a supportive analysis, we will also repeat the above analyses after adjusting for potential confounders in the regression model, including HCF size, and characteristic (such as average age) of HHI MSM living with HIV at the PHASE HIV treatment HCFs at baseline.

13.6.1.5 PrEP Prescription

Our primary measure of PrEP prescription among HHI MSM living without HIV will be measured based on EMR data containing visit, STI diagnosis and PrEP prescription information from approximately 40 PHASE HIV prevention HCFs that provide PrEP services across the five intervention communities.

PrEP prescriptions issued will be assessed in HHI MSM living without HIV seen at each PHASE HIV prevention HCF. Evaluations will be based on visit history and PrEP prescriptions recorded in the EMR of these facilities. PrEP prescription proportion at a facility will be defined as the proportion of HHI MSM living without HIV with at least one visit in the past 12 months with a PrEP prescription.

PrEP prescription proportion will be measured for all participating PHASE HIV prevention HCFs at each of the four measurement windows (Year -1, Year 0, Year 1 and Year 2). The primary interest is in estimating the average intervention effect on the PrEP prescription proportion across the HIV prevention health facilities. We will use a segmented GEE model, similar to model (2) for the logit-transformation of the PrEP prescription proportion, using the identity link function, assuming no immediate level-change, an AR-1 correlation structure and clustering at the healthcare facility-level to test for the intervention effect on the PrEP prescription proportion. The GEE model is formulated as follows.

$$E\big(\text{logit}(p_{ij})\big) = \big(\beta_0 + \beta_1 T_j + \beta_2 (T_j - T_0) I[T_j > T_0]\big), \qquad (3)$$

where p_{ij} is the PrEP prescription proportion for PHASE HIV prevention HCF *i* at the assessment timepoint T_j which is defined similarly as in model (1) for $j = -1, ...,2$. Also, β_0 is the average of the logit-transformed PrEP prescription proportion at baseline, $\beta_1$is the coefficient associated with the effect of secular (time) trend on the logit-transformed PrEP prescription

(slope), and β_2 is the coefficient associated with the slope change due to the intervention, and hence is the intervention effect on the logit-transformed PrEP prescription proportion.

After fitting model (3), we will provide a 95% CI for the intervention effect β_2 and a p-value for testing the hypothesis H_0: $\beta_2 = 0$ using α = 0.05 (two-sided). We will also provide model-based estimates for PrEP prescription proportion and their CI at each timepoint under the intervention and also under the counterfactual condition of no intervention. This will help us understand how the PrEP prescription proportions have been impacted by the background trend as well as the intervention over the period of the study. Similarly, as for retention, we can use the estimate of γ_2, the intervention effect (for PrEP prescription proportion), we will estimate the total intervention effect (given as Δ) as the difference between the estimated PrEP prescription at Year 2 (end of intervention) and model predicted proportion at Year 2 under the counterfactual condition of no intervention, and will be evaluated as the following:

$$\Delta = E(p_{i2}|\text{intervention}) - E(p_{i2}|\text{no intervention})$$

$$= \text{expit}\big(\beta_0 + \beta_1 T_2 + \beta_2 (T_2 - T_0)\big) - \text{expit}(\beta_0 + \beta_1 T_2)$$

As a supportive analysis, we will also repeat the above analyses after adjusting for potential confounders in the regression model, including HCF size, and characteristic (such as average age) of HHI MSM at the PHASE HIV prevention HCFs, and level of completeness of sexual behavior and sexual orientation information at baseline.

13.6.2 Secondary Analyses

Details of the analysis plan for the secondary endpoints will be provided in the separate Statistical Analysis Plan.

14 SOCIAL HARMS REPORTING

It is possible that some elements of the study may result in a social harm. A social harm is defined as an undesired change in a person's relationships, experiences, interactions, rights and/or community status that occurs as a direct result of participating in a research study. Participants will be enrolled into the peer support component, as well as the cross-sectional assessment and qualitative data collection activities that will take place at PHASE HCFs. It is possible that those enrolled into these parts of the study may experience social harms, particularly if there is a breach of confidentiality. For these aspects of the study, social harms will be reported by participant identification number to the study database.

Individuals who participate in other PHASE, health access coalitions and social media component activities may also experience negative impacts. For example, the PHASE component is designed to increase the level of sexual orientation data collected in medical records, which may lead to social harms due to clinic staff having access to this information. In addition, social harms may also occur to implementers of the integrated strategy components. For example, social media content that is developed for the purposes of the study may cause the content creators to be negatively targeted or bullied by members of the online community. The study team will be vigilant for evidence of such incidents and will report them to the study

database in association with the relevant intervention component. Implementers will also be instructed on how to report such incidents to the study team – for either themselves or on behalf of others who may have been negatively impacted by the study activities – for documentation in the study database.

A summary of all social harms will be reported to the single institutional review board (sIRB) and the SMC at least annually. The protocol team and SMC will review the social harms and watch for any trends. If needed, adjustments will be made to study conduct. In addition, the study's CAG may be consulted to help minimize the potential occurrence of specific types of social harms if trends are discovered.

15 HUMAN SUBJECTS CONSIDERATIONS

15.1 Ethical Review

This protocol will be reviewed and approved by the HPTN Scientific Review Committee and NIAID Prevention Science Review Committee with respect to scientific content and compliance with applicable research and human subjects regulations.

The protocol, participant education and recruitment materials (including electronic and verbal consent language), and other requested documents — and any subsequent modifications — also will be reviewed and approved by the HPTN single IRB (sIRB), as the IRB responsible for oversight of this research study.

The HPTN Leadership and Operations Center (LOC) will make progress reports to the sIRB as needed and within three months of study termination or completion. All changes in research and all unanticipated problems involving risks to human subjects or others will also be provided to the NIH and sIRB.

15.2 Orientation to the Human Subjects Consideration Section

Human subjects considerations for each component of the integrated strategy and the data collection activities are detailed in the sub-sections below separately for each activity.

15.3 Health Access Coalition Component Human Subjects Considerations

In general, data collection activities for the health access coalition component are limited to descriptive, aggregate organizational and activity information about coalitions in each community and do not include collection of data or private identifiable information on any individual coalition members. Coalition members are not considered study participants. However, coalition members will be expected to complete periodic anonymous coalition effectiveness inventory surveys to self-report the effectiveness of their coalition. These surveys are considered to be human subjects research, but in this case, they are expected to meet the definition for exempt under 45 CFR 46.104(d)(2)(i), as data will be collected anonymously.

15.3.1 Health Access Coalition Component Informed Consent

As the health access coalition component is expected to be exempt under 45 CFR 46(d)(2)(i), written informed consent will not be collected. However, as part of standardized coalition training, all coalitions members will be informed that their participation in the coalition is part of a research study. The training will also cover the kind of information that will be collected and reported about their coalition and its activities, as well as the coalition effectiveness inventory survey. Members will also be informed that no data or identifiable information about individual members will be stored by the HPTN 096 study team, analyzed, or included in any publication.

15.3.2 Health Access Coalition Component Risks

Though not considered study participants, coalition members involved in HPTN 096 study activities may face some risks. These include possible social harms, stigmatization, or risks related to unwanted disclosure of HIV status or sexual orientation due to association with an HIV- and MSM-related research study. To minimize these risks, no personal identifying information about individual coalition members will be stored as study data, analyzed, or included in any HPTN 096 publications. All social harms will be reported and monitored as described in Section 14.

15.3.3 Health Access Coalition Component Benefits

Coalition members and communities may benefit from involvement in this study. Coalition activities may change social norms around HIV and foster collective efficacy of local organizations to improve the social and healthcare environments in which individuals exist and receive HIV care and preventive services. Coalition members may also benefit from an increase in knowledge and awareness related to HIV prevention and treatment, as well as from capacity-building and professional networking that may result from coalition participation.

15.3.4 Health Access Coalition Component Incentives

Coalition members will be compensated for their time spent towards coalition activities. Coalition member compensation structures will be equal across all communities, determined by the study team at rates assessed to be comparable to market value, and transparently communicated to all coalition members.

15.4 Social Media Component Human Subjects Consideration

This section addresses only educational social media content created, posted and advertised as part of the social media component intervention and does not address social media used for recruitment purposes for the peer support component (this is addressed in the peer support human subjects section).

Data will be collected from a subset of individuals exposed to social media content to determine if the social media content is reaching the intended audience of HHI MSM. These data will be collected via:

- anonymous and/or confidential pop-up questions or surveys (with or without incentives)

- individual interviews
- focus groups

Surveys and interviews are considered to be human subjects research, but in this case, they are expected to meet the definition for exemption under 45 CFR 46.104(d)(2)(i) (because the data are collected anonymously) or 45 CFR 46.104(d)(2)(iii) (because there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data).

If incentives are used for pop-up question or survey completion, limited identifying information (for example, an email address) will be collected and a unique code will be used to prevent someone from completing the surveys or interviews more than once for fraud prevention purposes. Measures will be taken to protect the privacy and confidentiality of contact information and the data collected. Each survey will be authenticated by a unique code that participants must use to begin the survey and request their incentive. If collected, limited contact information to receive the incentive will be stored separately from the data. Those who complete these incentivized pop-up questions or surveys will be informed that their limited contact information will only be used to provide the incentive. This limited contact information will not be able to be linked to survey data.

For individual interviews and focus groups, limited identifying information (name, address, phone, email) will be collected to set up the interview/focus group session and to provide incentives. A link-log will be maintained to provide a unique identifier for each participant and to ensure that no one participates in the interviews or focus groups more than once. Interviews and focus groups will be recorded and transcribed using the unique identifier; once an accurate transcription is obtained, the recording will be destroyed. Names and other identifying information will be redacted from transcripts. Once all interviews and focus groups are complete and accurately transcribed, the link-log will be destroyed.

All social media data collection tools, including pop-up questions, surveys and individual interview and focus group guides will be submitted and approved by the sIRB prior to use.

15.4.1 Social Media Component Informed Consent

As the social media component is expected to be exempt under 45 CFR 46.104(d)(2)(i) or 45 CFR 46.104(d)(2)(iii), written informed consent will not be collected. However, individuals completing pop-up questions or surveys, and participating in interviews or focus groups, will be informed that they are providing information for a research study.

15.4.2 Social Media Component Risks

While measures will be taken to protect the privacy and confidentiality of contact information and the data collected from individuals taking part in social media data collection activities, it is possible that the data could be linked to the contact information. In addition, it is possible that individuals may experience social harm by participating in the social media campaign, for example if people recognize them in a social media post or ad and harass them for assumptions made about their sexual orientation or HIV status. All social harms will be reported and monitored as described in Section 14.

15.4.3 Social Media Component Benefits

There may be no direct benefits to individuals exposed to social media content as part of this study or participating in social media data collection activities. However, individuals who see the messaging may benefit from learning HIV-related information and acting on it. The information learned from the study may also improve how HIV-related social media messaging reaches and appeals to HHI MSM.

15.4.4 Social Media Component Incentives

Compensation will not be provided to any individual social media users for viewing the content distributed for the study. However, appropriate compensation will be provided, pending sIRB approval, for pop-up questions (if incentivized), surveys (if incentivized), interviews and focus groups used to determine if the social media content is reaching HHI MSM.

15.5 Peer Support Component Human Subjects Considerations

Participants enrolled in the peer support component will not be followed as in a typical clinical trial. Once enrolled, participation in the peer support component can continue until the study ends, in that peer support participants are eligible to contact peer supporters and receive peer support services at their desired frequency throughout the duration of the study. Data will be collected on individual participants and their use of the program, and as such, participant-level data collection activities constitute non-exempt human subjects research, and 45 CFR 46 applies. All peer support recruitment materials, including content to be utilized via social media as appropriate and print materials, will undergo sIRB review and approval.

Adolescents aged 15 to 17 years of age are eligible to participate in the peer support component. Per the US Code of Federal Regulations (CFR), the HPTN sIRB must consider the potential risks and benefits to these participants as described in 45 CFR 46 Subpart D. With respect to 45 CFR 46 Subpart D, the specifications of 45 CFR 46.404 are expected to apply to adolescent participants not of legal age to consent in the peer support component. The study involves no more than minimal risk to any participant.

Personal information (such as place of residence, name, age, contact information, etc.) will be obtained from participants to determine program eligibility and to link the participant with a peer supporter. This information will be maintained confidentially and stored securely in a separate area of the database from where data for analysis is stored. As necessary, implementers including peer supporters will have the names and contact information of participants to identify them and provide appropriate support services. The peer supporters, in collaboration with the study team and the local organizations, will implement confidentiality protections and identify potential confidentiality issues and strategies to address them. Training will also emphasize the importance of protecting the confidentiality of participants and the data collected about the participants. Peer support sessions may be conducted virtually and/or in person. The platform by which the peer supporter will conduct virtual support sessions with the participants will allow secure two-way messaging (for text) and audio and/or video calling. All communication between the participant and the peer supporter will be conducted privately, and every effort will be made to protect participant’s privacy and confidentiality to the extent possible.

Study data in the form of surveys and assessments will be completed by participants following peer support sessions. This data will be identified by a coded number to maintain client confidentiality. All participants will be authenticated and assigned a study identification number within the study database; thus, no linkage log will be maintained. All reports summarizing peer support process data will include aggregate data only and will not include any participant identifying information. For individual interviews and/or focus groups, limited identifying information (such as name, contact information) will be captured to coordinate the interview/focus group session and to provide reimbursement for participation. These sessions will be recorded and transcribed; and any identifying information will be redacted from transcripts to protect participant identity. All tools and guides used in the conduct of any interviews and/or focus groups will be submitted and approved by the sIRB prior to use.

Participants' information will not be released without their written permission, except as necessary for study review, monitoring, and/or auditing purposes.

15.5.1 Peer Support Component Informed Consent

Per 45 CFR 46.117, participation in the peer support component poses no more than minimal risk of harm to participants because the peer support activities are low risk, involve no procedures for which written consent is normally required outside of the research context, and participants would not be deprived of any clinical care for which they would otherwise be entitled. Therefore, a waiver of documented written consent will be requested for all participants. However, all potential participants will review the consent text (electronically) prior to enrolling in the peer support component. The consent text will include a checkbox where the participant must acknowledge their willingness to participate in the peer support component. All participants will be offered the ability to download a copy of the consent text for their records. The consent language will be submitted to and approved by the sIRB prior to implementation. All peer supporters will be trained to properly conduct and ensure the integrity of the informed consent process. Participants requested to participate in an interview and/or focus group will be reminded that they are participating in these sessions as part of a research study and their permission to participate will be documented.

Per 45 CFR 46.408(a), it is expected that adolescents participating in this study would be deemed capable of providing assent, as all participants will be at least 15 years of age. However, per 45 CFR 46.408(e), a waiver of documented assent will be requested in accordance with the same criteria for adult participants given that the study is low risk. Additionally, a waiver of parental/guardian permission will be requested for these adolescents per 45 CFR 46.408(c). This is because the study is designed for a population for which parental or guardian permission is not a reasonable requirement to protect the study participants. There is concern that parent/guardian knowledge of a participant's involvement in the study may pose significant risk to participant's privacy and confidentiality, particularly for those whose parents are not aware or supportive of their sexual orientation, and stigma may prevent these adolescents from participating in the study.

It is the responsibility of the HPTN sIRB to determine the level of risk to adolescents in the categories specified in 45 CFR 46.404-407. The risk category assigned by the sIRB will ultimately determine the parental informed consent and assent requirements for the study.

Additionally, it will be the responsibility of the sIRB to require any additional mechanisms to protect adolescent participants in lieu of parent/guardian permission, per the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual: Informed Consent of Participants:

https://www.niaid.nih.gov/sites/default/files/score-informed-consent.pdf.

15.5.2 Peer Support Component Risks

It is not expected that this study component will expose human subjects to unreasonable risk. Participation in this research includes the risks associated with the loss of confidentiality and discomfort with the nature of topics when discussing sexual behaviors and other practices.

Discussion topics covered during support sessions may cause program participants discomfort given their personal nature. Feelings of embarrassment may arise from thinking or talking about one's own behavior or attitudes on sensitive topics, such as discussing one's sexual behavior and ways to protect against or manage HIV. Disclosure of one's HIV and STI status may cause worry, sadness, or depression. Trained peer supporters and a mental health professional will be available to help participants deal with these feelings and answer any questions the participants may have.

Although the study team will make every effort to protect participant privacy and confidentiality, it is possible that participants' involvement in the study could become known to others, and that social harms may result. For example, participants may experience stigma and could be treated unfairly or discriminated against or could have problems being accepted by their families and/or communities because they assume that they have HIV, or their sexual orientation is assumed, by taking part in the study. All social harms will be reported and monitored as described in Section 14.

Support sessions may take place in person or via the participant's personal device (cell phone, computer, etc.). There is a possibility that the participant may exceed their data plan limit on their personal device if used to access the program.

15.5.3 Peer Support Component Benefits

There may be no direct benefits to program participants in this study, however, program participants will be able to engage with peers who possess similar lived experience and talk about what they are going through or why support is being sought. Additionally, participants and others may benefit in the future from information learned from this study. Specifically, information learned in this study may lead to the development of effective prevention programs improving HIV prevention, care and support services for HHI men. Participants also may appreciate the opportunity to contribute to the field of HIV prevention research.

15.5.4 Peer Support Component Incentives

Pending sIRB approval, peer support component participants will be compensated for their time and effort in the study. They will be compensated for taking part in an initial support session, for responding to brief surveys about their experiences obtaining peer support and for taking part in

any interviews and/or focus group sessions. Specific reimbursement amounts will be outlined in the study informed consent text and information sheet and will be explained to participants.

15.6 PHASE Component Human Subjects Considerations

The PHASE component of the integrated strategy involves intervening on healthcare facilities and their staff, and will include collection of various types of data, each of which have different human subjects' considerations:

1. **Pre-/post-training assessments for Foundation and ECHO:** Surveys to assess knowledge and attitude change related to healthcare provision to HHI MSM will be implemented with HCF staff pre- and post-training for the Foundation workshops as well as the ECHO sessions. These assessments are considered to be human subjects research, but they are expected to meet the definition for exemption under 45 CFR 46.104(d)(2)(i), as data will be collected anonymously. Pre and post responses will be linked via a participant-created unique code that will be known only to the participant and will not be retained on a link-log. All participants are expected to be of legal age to provide consent.

2. **Participant experience training evaluations:** Participant evaluations will be administered after the Foundation workshops and ECHO sessions. As these evaluations are for internal quality assurance and improvement purposes, they do not meet the definition of human subjects research under 45 CFR 46.102(l).

3. **Quality Improvement (QI) data:** QI clinical, client/patient, and provider data are collected (as described in Section 8.2.5) by each HCF for QI purposes only and are not collected in the study database or systematically analyzed for this study. As these data collection activities are for each HCF's quality improvement purposes, they do not meet the definition of human subjects research under 45 CFR 46.102(l), which is defined as "…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge…"

15.6.1 PHASE Component Informed Consent

The pre-/post-training assessments are the only activities considered human subjects research as a part of the PHASE intervention. As they are expected to meet the definition for exemption under 45 CFR 46.104(d)(2)(i), informed consent will not be collected. However, HCF staff participating in the trainings will be shown a brief online informational form within which they must acknowledge their agreement to participate in the assessment prior to entering the web-based assessment and will be permitted to opt out of the assessments.

Additionally, in the interest of transparency, all HCF staff participating in PHASE activities will be informed of the nature of their clinic participation as part of a research study. Individual HCF staff will not be required to participate in any specific activities of PHASE and are permitted to opt out.

15.6.2 PHASE Component Risks

It is not expected that PHASE participation will expose HCF staff to unreasonable risk. However, participants may feel uncomfortable, worried, sad, or anxious when discussing stigma and discrimination or experience other types of social harms because they provide services to HHI MSM related to HIV. The PHASE training team will be available to help address these feelings as they come up in trainings. All social harms will be reported and monitored as described in Section 14.

15.6.3 PHASE Component Benefits

There may be a wide range of benefits from PHASE participation. Preventing or reducing intersectional stigma and changing organizational norms around providing HIV services can improve the social and healthcare environments in which individuals exist and receive HIV care and preventive services. Staff members may benefit from an increase in knowledge and awareness related to service provision to HHI MSM, as well as from capacity-building and professional networking that may result from PHASE participation.

15.6.4 PHASE Component Incentives

HCFs will be provided with a small compensation package that is intended to offset, but not entirely compensate for, any revenue loss or staff time expended as a result of participation in PHASE activities. Individual staff members will not be compensated for participation in PHASE activities or for completion of PHASE training assessment surveys or evaluations.

15.7 Cross-Sectional HHI MSM Assessment Human Subjects Considerations

The cross-sectional HHI MSM client assessment is considered human subjects research and 45 CFR 46 Subpart A applies. Individuals participating in the cross-sectional assessment will be considered study participants and will be enrolled into the study. Cross-sectional assessment participation will include completion of a behavioral questionnaire by the participant as well as collection of limited medical record information abstracted from the participant's medical chart and submitted via case report form to the study database to be linked with questionnaire data. Study participation will not involve investigational drugs or devices, nor will directly identifying data be collected; thus, the cross-sectional HHI MSM client assessment involves no more than minimal risk to any participant.

15.7.1 Cross-Sectional Assessment Informed Consent and Authorization to Use Protected Health Information

A waiver of written informed consent will be requested under 45 CRF 46.117(c)(1)(ii) as this study activity presents no more than minimal risk to participants. Prior to enrolling in the study, a study information sheet will be reviewed with each participant as part of the recruitment process and participants will be offered a copy. The information sheet will be submitted to and reviewed by the sIRB. Potential participants deemed eligible who agree to participate will be required to review a brief electronic consent form and enter their agreement to participate into the electronic consent form prior to proceeding to the survey. The consent language will be submitted to and approved by the sIRB prior to implementation along with the survey tool.

As data collection involves abstraction of medical record information that is considered protected health information (PHI), such as medical visit and diagnosis dates, a Health Insurance Portability and Accountability Act (HIPAA) authorization will be obtained from each participant prior to enrollment. The HIPAA authorization will be captured on an sIRB-approved form that meets requirements of 45 CFR 164.508.

15.7.2 Cross-Sectional Assessment Risks

It is not expected that this study activity will expose participants to unreasonable risk. Participation in the cross-sectional assessment includes the risks associated with the loss of confidentiality and discomfort with the nature of topics when answering questions related sexual behaviors, barriers to healthcare, and HIV and other STIs.

Although the study team will make every effort to protect participant privacy and confidentiality, it is possible that participants' involvement in the study could become known to others, and that social harms may result. For example, participants may experience stigma and could be treated unfairly or discriminated against or could have problems being accepted by their families and/or communities because their HIV status or sexual orientation may be assumed by taking part in the study. All social harms will be reported and monitored as described in Section 14.

15.7.3 Cross-Sectional Assessment Benefits

There may be no direct benefits to participants in this study. However, participants may benefit indirectly. The information gathered from the assessment may show how healthcare services can be provided more successfully to HHI MSM, which may impact healthcare provision to participants and other members of their community.

15.7.4 Cross-Sectional Assessment Incentives

Pending sIRB approval, participants will be offered compensation for their time and effort in this study activity. Specific information regarding compensation, including how compensation will be provided and the amount, will be specified in the electronic consent text and explained to participants.

15.8 EMR Data Collection Considerations

Collection of EMR data at PHASE HCFs for study endpoint assessment is expected to meet the definition for human subjects research because such data may include identifiable private information. Data collected will be limited to information collected as part of the medical record for client care and will not be generated specifically for this study. This activity is expected to meet the criteria for exemption under 45 CFR 46.104(d)(4)(ii), in that it involves only secondary research using identifiable private information that will be recorded in such a manner that the identity of the human subjects cannot readily be ascertained directly or through linked identifiers, human subjects will not be contacted through the use of this data or because of their affiliation with the dataset, nor will they be re-identified.

Any information available to the SDMC in the central database will first be stripped of client identifiers and identified only by a unique study code. However, as visit and laboratory test dates

will be retained in the study database, the data is considered a limited data set [240] under the HIPAA Privacy Rule per 45 CFR 164.514e, meaning that it would not be considered fully deidentified. Only the minimum necessary information needed to assess study endpoints will be extracted from the medical record and used to generate the limited dataset for analysis. It is expected that use of the limited data set will meet requirements for a waiver of individual authorization under the Privacy Rule per 45 CFR 164.512(i) [241].

Specifically, the use of the data involves no more than minimal risk; the transmitted data will be stripped of all direct identifiers and plans will be in place with the participating HCFs both to protect the identifiers and destroy them after the study; the dataset provided to the HPTN SDMC will not be reused or disclosed to any other person or entity outside of the use for this research study except as required by law; the research could not practicably be conducted without this waiver as assessment of study endpoints necessitates a complete set of data on all HHI MSM and men with the same demographic characteristics except for sexual orientation and/or sexual behavior who are clients at the participating HCFs, and this may not be possible to obtain if individual authorization were required; and the study design requires this limited data set of identified elements from the medical record in order to assess study endpoints.

The third-party vendor will be responsible for retaining a link-log in order to link client-level deidentified data across all study timepoints; however, the HPTN SDMC, as receiver of the data, will never have access to this link-log. As such, the identity of clients will not be readily ascertained by the investigators through the link-log. Agreements will be established between each participating HCF and the third-party vendor. These agreements will meet the standards specified in the Privacy Rule under HIPAA.

15.8.1 EMR Data Collection Informed Consent

As collection of EMR data for this study activity is expected to be exempt under 45 CFR 46.104(d)(4)(ii), written informed consent will not be collected.

15.8.2 EMR Data Collection Risks

All efforts will be made to protect the privacy, security and confidentiality of medical record data obtained for the study; however, there is a small risk that a privacy or security breach may occur when de-identifying medical record information. Data systems and data handling procedures for capturing, transferring, and storing electronic data obtained from EMRs by the third-party vendor have been developed to preserve client confidentiality, privacy, and security. However, if a privacy or security breach does occur, it will be captured as a social harm. All social harms will be reported and monitored as described in Section 14.

15.8.3 EMR Data Collection Benefits

There may be no direct benefits to clients/patients whose data are used for this research study. However, clients whose data are used in this study may benefit indirectly, as well as future clients/patients. The information learned from the study may positively impact how healthcare services are provided to HHI MSM.

15.8.4 EMR Data Collection Incentives

Clients whose medical records are accessed for this study will receive no compensation.

15.9 Qualitative Data Collection Considerations

Qualitative data collection activities (specifically, IDIs) with PHASE staff members and PHASE healthcare facility clients/patients are considered human subjects research, and 45 CFR 46 Subpart A applies. For PHASE clients/patients, a subset of individuals who participated in the cross-sectional HHI MSM client assessment will be selected for interviews; they will already be considered study participants and will be enrolled in the study. Contact information for cross-sectional participants who agree to be contacted about qualitative interviews will be stored in a separate database from assessment data and will not be linked to assessment data.

15.9.1 Qualitative Data Collection Informed Consent

A waiver of written informed consent will be requested under 45 CFR 46.117 (c)(1)(ii), as participation in qualitative interviews presents no more than minimal risk to participants. Additionally, for staff members, 45 CFR 46.117(c)(1)(i) applies, as a signed informed consent document would be the only information linking the participant to the research. Before proceeding with interviews, participants will be verbally informed about the study and provide oral consent. The oral consent language will be submitted for sIRB review with the drafted interview guide.

Adolescents participating in this study would be deemed capable of providing assent as described in 45 CFR 46.408(a). A waiver of parental/guardian consent will be requested for those not of legal age to consent, per 45 CFR 46.408(c). This study is designed for a population (HHI MSM in the southern US) for which parental or guardian permission is not a reasonable requirement to protect the study participants. There is concern that parent/guardian knowledge of a participant's involvement in the study may pose a significant risk to participant's privacy and confidentiality, particularly for those whose parents are not aware or supportive of their sexual orientation, and stigma may prevent these adolescents from participating in the study.

Per 45 CFR 46.408(e), the sIRB will be requested to waive documented assent in accordance with the same criteria for adult participants.

15.9.2 Qualitative Data Collection Risks

Participants may feel uncomfortable or embarrassed by some of the questions asked in interviews; however, they can refuse to answer any question or leave the discussion at any time.

15.9.3 Qualitative Data Collection Benefits

There may be no direct benefits to participants in this study. However, participants (both clients/patients and staff), other clients/patients, and other healthcare organizations may benefit from the information learned about stigma and providing care for HHI MSM through the interviews.

15.9.4 Qualitative Data Collection Incentives

Pending sIRB approval, participants will be compensated for their time and effort participating in the qualitative data collection activities. Reimbursement amounts will be specified in the verbal consent text and explained to participants.

15.10 Confidentiality for all Study Activities

All study-related information will be stored securely. Electronic documents will be stored using appropriate computer security protections. All other participant information such as forms, lists, logbooks, appointment books, and any other listings that link participant ID numbers to other identifying information will be stored in a separate, locked file in an area with limited access to study staff. All reports, study data collection, process, and administrative forms will be identified by a coded number to maintain participant confidentiality. All databases will be secured with password-protected access systems.

Interviews and focus groups will be conducted in a private location or through a video conferencing platform. Interviews and focus groups will be recorded and then transcribed by qualified personnel. All participant identifiers will be removed from transcripts, and all reports and publications will be carefully redacted to ensure that identification of interview or focus group participants is not possible.

Reports and public use datasets produced from data collected will present only completely deidentified data in compliance with HIPAA Safe Harbor standards [242] for de-identification of data.

15.11 Study Discontinuation

The study may be discontinued at any time by NIAID, the HPTN, and/or the sIRB.

16 ADMINISTRATIVE PROCEDURES

16.1 Source Documentation and Direct Data Entry

Direct data entry or direct data capture of study data into the study database is only allowed when capturing information directly from the participant (participant self-report). Other study data will be sourced from electronic or paper source documents prior to being entered into the database. Source documentation tables will be finalized prior to implementation.

16.2 Protocol Registration

There will be no protocol registration requirements for this study because it does not include an investigational agent and there are no informed consent forms. There will also be no safety or medically related adverse event data collection and participating organization (e.g., PHASE HCFs) will not undergo traditional monitoring.

16.3 Study Activation

For the integrated strategy components, a formal study activation process will not be followed. However, for any given study component, operational feasibility conditions will be met prior to the start of implementation of that component. For example, health access coalitions, CLOs, and peer support implementing partners must complete study-specific training prior to study activities. Further, financial agreements with any implementing partners must be in place prior to the initiation of study activities. Given that PHASE HCFs will be involved in data collection for endpoint assessment, these organizations must undergo a training and activation process prior to implementation. Specific operational and fiscal tasks required prior to initiation of integrated strategy intervention implementation and data collection activities will be determined and monitored by HPTN LOC staff and documented internally.

16.4 Study Coordination

Study implementation will be directed by this protocol as well as the implementation manuals specific to each component of the integrated strategy and data collection activities. The implementation manuals will outline study procedures; how data will be captured and processed; management and reporting; intervention oversight and monitoring; and other study operations.

For the data collection activities, including EMR data extraction, study electronic case report form (eCRF) completion, questionnaire administration, qualitative data collection and other study instruments, instructions will be developed by the protocol team and HPTN SDMC. Data will be submitted to the HPTN SDMC or the HPTN LOC, as appropriate, for cleaning, reporting and analysis. Quality control data queries will be generated on a routine schedule for verification and resolution by local data management staff.

Close coordination between protocol team members will be necessary to track study progress, respond to queries about proper study implementation, and address other issues in a timely manner.

16.5 Study Monitoring

Because there will be minimal data collected via eCRFs, no signed informed consent forms, no long-term follow-up of individual participants, and the components of the integrated strategy are all expected to be deemed low risk, no traditional on-site study monitoring will take place for the study. However, oversight will be provided for each component, including, but not limited to, monitoring the process measures, routine protocol team monitoring of component engagement, and HPTN SMC review. The HPTN LOC, HPTN SDMC, DAIDS and their designees may visit the implementing partner organizations and PHASE HCF sites. Site visits may be used to:

- verify compliance with human subjects and other research regulations and guidelines;
- assess adherence to the study protocol and procedural manuals;
- inspect study-related documentation; and
- confirm the quality and accuracy of information collected at the site and entered into the study database.

16.6 Protocol Compliance

The study will be conducted in full compliance with the protocol. The protocol will not be amended without prior written approval by the Protocol Chairs and DAIDS Medical Officer. All protocol amendments must be submitted to and approved by the sIRB and the DAIDS Regulatory Support Center prior to implementing the amendment.

16.7 Study Records

All study records will be maintained and stored in a secure, complete and accurate manner throughout the study. The responsible parties are outlined below:

- sIRB-related documentation and approval: HPTN LOC
- Health access coalitions component: HPTN LOC Coalition Managers, CLO
- Social media component: HPTN LOC
- PHASE component: HPTN LOC, implementing partners and interventionists, and the participating HCFs
- Peer support component: HPTN LOC, HPTN SDMC and implementing partners
- Data collection activities at PHASE HCFs: HPTN LOC, HPTN SDMC and PHASE HCFs

Under the US DHHS regulations, the responsible parties are required to retain all study records relating to research for at least three [3] years after completion of the research, or longer if needed to comply with local regulations.

Completion of a clinical research study occurs when the following activities have been completed:

- All research-related interventions or interactions with human subjects (e.g., when all subjects are off study).
- All protocol-required data collection of identifiable private information described in the sIRB-approved research plan.
- All analysis of identifiable private information described in the sIRB-approved research plan.
- Primary analysis of either identifiable private or de-identified information.

Study records include administrative documentation — including all reports and correspondence relating to the study — as well as documentation related to each participant screened and/or enrolled in the study — including locator forms, eCRFs, notations of all contacts with the participant, and all other source documents.

All study records (including participant records) may be reviewed by study staff and other staff employed by the HPTN, NIH, sIRB, and the US Office for Human Research Protections.

16.8 Use of Information and Publications

Publication of the results of this study will be governed by the HPTN MOP (Section 21 Publications and Data Sharing Policy). Any presentation, abstract, or manuscript will undergo review by the HPTN Manuscript Review Committee and DAIDS prior to submission.

16.9 ClinicalTrials.gov

This protocol is not subject to the Food and Drug Administration Amendments Act of 2007. However, it will be registered in ClinicalTrials.gov to meet International Committee of Medical Journal Editors requirements and as a requirement of the sponsor (NIH).

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APPENDIX I: SCHEDULE OF EVALUATIONS FOR DATA COLLECTION ACTIVITIES AT PHASE HCF

Administrative and Behavioral Procedures	1-4 months (Baseline)	12-15 months (Midpoint)	18-23 months (prior to study conclusion)	24-27 months (Post-Intervention)
Screening/Confirmation of eligibility and stratification	X	X		X
Electronic (checkbox) consent	X	X		X
Completion of questionnaire	X	X		X
Chart abstraction/eCRF data entry[1]	X	X		X
Qualitative Interviews (HHI MSM clients)[2]		X[3]		(X)[4]
Qualitative Interviews (HCF staff)			X	

[1]eCRF data must be entered within seven days of questionnaire completion. Completed for participants of the cross-sectional HHI MSM client assessment only.
[2]Recruitment for qualitative interviews will take place at a subset of HCF only with a subset of HHI MSM; at these selected HCFs, participants will be invited to participate upon completion of the questionnaire. Those who agree will be contacted for an interview at a later date.
[3]Midpoint qualitative interviews with HHI MSM clients will take place through 18 months.
[4]Recruitment for HHI MSM qualitative interviews will continue into the post-intervention sampling timeframe if qualitative accrual targets are not met at midpoint.