HPTN 096
Building Equity Through Advocacy

HPTN 096 CRISP
Prospective Healthcare Facility Information

HPTN 096

HPTN 096 Building Equity Through Advocacy is a research study conducted by the HIV Prevention Trials Network (HPTN). The study is sponsored by the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID), US National Institutes of Health (NIH).

The purpose of the study is to test an innovative, status-neutral strategy to **improve access to and uptake of HIV prevention and treatment services for Black men who have sex with men (MSM) in the U.S. South**.

Black MSM in the South are among the hardest hit by the HIV epidemic:

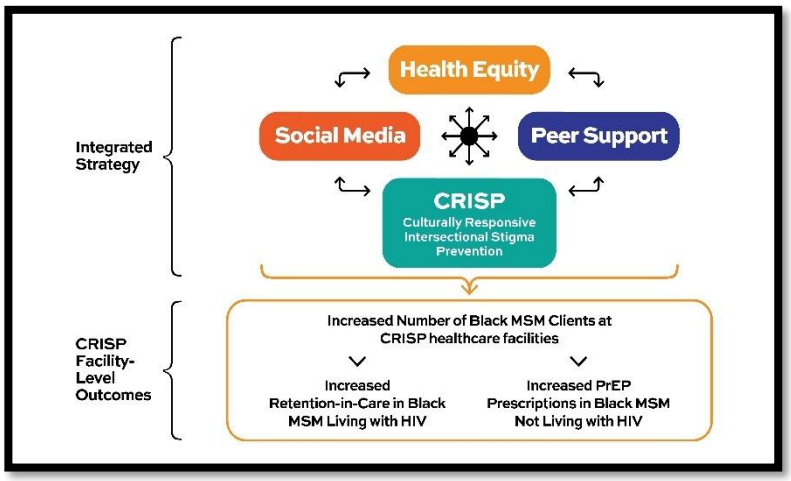
- In 2021, **almost half of MSM who were diagnosed with HIV in the South were Black** – this number is higher than any other racial or ethnic group anywhere in the country.
- The biomedical advances made in HIV prevention science have benefited white MSM but have largely missed Black MSM.

**Terminology note: The term "MSM" (men who have sex with men) is used throughout this document, as this term classifies how some men were (or may potentially be) exposed to HIV. We understand that the term "MSM" is not a social, cultural, or sexual identity. We use this to term to refer to men whose sexual history includes other men, regardless of whether they identify as gay, bisexual, same gender loving, queer, heterosexual, or none of the above. The term 'men' is used to include both cisgender and transgender men.*

Study Design

HPTN 096 is testing a status-neutral integrated strategy intervention comprising four components: **Health Equity Coalitions, Social Media, Peer Support, and Culturally Responsive Intersectional Stigma Prevention (CRISP) for healthcare facilities.** The HPTN 096 integrated strategy is implemented at the community level, including at participating healthcare facilities (referred to as "CRISP facilities"), and outcomes for the entire study are measured at the CRISP facilities. The study uses a **single arm interrupted time series (ITS) design** to test whether the status neutral integrated strategy:

1. Increases the number of Black MSM clients at participating CRISP facilities



2. Increase retention in care among Black MSM clients living with HIV at participating CRISP facilities
3. Increase PrEP uptake among Black MSM clients without HIV at participating CRISP facilities

The ITS design measures the change in slope for these primary outcomes (listed above) pre- and post-intervention using four one-year look backs of electronic medical record (EMR) data.

Integrated Strategy Components

The four components of the integrated strategy intervention are:

- **Health Equity Coalitions** – Locally established coalitions will develop solutions to reduce health disparities through capacity-building, community engagement, education, advocacy, and partnerships. This component will also focus on working with local service providers to help them better meet the needs of Black MSM. The study will partner with local organizations to lead these community mobilization efforts.
- **Social Media** – We know social media can profoundly impact individual health behaviors. In this component, a robust social media strategy will provide accurate messaging on HIV testing, PrEP, and the benefits of viral suppression to Black MSM in the study communities while promoting related study activities and partnerships.
- **Peer Support** – Peer support can help to remove power imbalances and potentially reduce the negative influence of discrimination and stigma sometimes seen and experienced by Black MSM when seeking services and/or support in their community. Black GTBMSM will be trained to provide emotional and practical support to their peers in their community one-on-one.
- **Culturally-Responsive Intersectional Stigma Prevention (CRISP)** – Stigma is a persistent barrier to equitable healthcare, especially for Black MSM. This component will provide evidence-based training, support, and quality improvement to healthcare facilities to help them optimize their service delivery to better respond to sexual diversity among Black men.

These four components work synergistically such that the overall impact of the integrated intervention is greater than the impact of each components being implemented alone.

CRISP Participation

HPTN 096 is seeking healthcare facilities to participate in CRISP. CRISP healthcare facilities will also serve as research partners for HPTN 096 by providing data that is needed to assess the study outcomes.

What does participation in the CRISP intervention involve?

CRISP is a package of training, capacity building, and quality improvement activities that will be implemented for a period of 2 years at participating CRISP facilities. All participating healthcare facilities in a study community will undergo the CRISP intervention together as a cohort. The core CRISP activities include the following:

1. **Foundation Workshop** on Culturally Responsive Services for Black MSM along the HIV Continuum: this *whole-facility* powerful and transformative workshop includes content on integrative anti-racism and intersectional stigma, structural competency, skills practice, and accountability.
    - The workshop is two full days and will offer 10 CME credits to participants.
    - Each clinic will have a goal of at least 75% of all relevant clinical and non-clinical providers at the facility completing the workshop.
    - Multiple workshop dates will be offered in each community over a multi-month period to allow for each facility to send staff on an ongoing basis over time and reduce disruptions to clinic schedules.
    - A pre-activity to this workshop involves a simulated patient visit walk-through at each healthcare facility (arranged by the study team), where a trained Black MSM study team members will do a full visit walk-through for a PrEP or ART visit. Observations from this visit will directly inform an exercise in the workshop.

2. **ECHO Sessions:** A smaller subset of up to 6 staff per facility will attend additional training sessions delivered in the ECHO (Extension for Community Healthcare Outcomes) model. Twelve 2-hour virtual sessions will comprise the core ECHO curriculum and will further explore various topics relevant to successful healthcare engagement and outcomes for Black MSM.
    - Sessions will include a short didactic presented by expert faculty, followed by case presentations shared by ECHO participants, and peer-to-peer discussion.
    - Some sessions will be divided into clinical and non-clinical cohorts, and some will include both clinical and non-clinical staff.
    - The staff members participating in ECHO from each facility should represent a variety of clinical and non-clinical roles/functions at the facility.

3. **Client-Instructor Coaching**: Black MSM "client-instructors" will hold one-on-one in-person coaching sessions with clinical providers. This activity will provide a safe space for providers to practice and receive feedback on interpersonal communication skills around PrEP and/or ART initiation with Black MSM.
    - Coaching sessions are offered after providers have completed the Foundation Workshop.
    - Each facility will determine, with the study team, the number of coaching sessions needed, dependent on the number of clinical providers on staff.
    - Providers may request additional coaching sessions and/or additional feedback provided to more staff members (e.g., during a lunch and learn session).

4. **Tailored Capacity Building Assistance**: As needed, additional training and technical assistance (TA) will be offered to facilities, with a primary focus on navigating insurance coverage for PrEP and ART and using CRISP strategies to enhance business development. Needs may be identified and addressed through CRISP, but initial planned assistance includes:
    - Supplemental optional community-specific sessions, similar to the ECHO model, will be offered to focus on insurance options and financing of PrEP and HIV treatment options. TA will be available from external faculty experts leading the sessions.
    - Access to TA for documentation practices that support billing to maximize revenue.

- Access to training and TA on implementing long-acting injectable PrEP programs, with connection to ViiV field reimbursement managers for support.

5. **Quality Improvement:** A tailored quality improvement (QI) approach will be used to implement small tests of change within participating facilities and self-monitor improvement data. Each facility will designate a small QI team within their facility to participate in the QI activities. QI support is provided by a matched QI coach and specialist team, and tailored to the needs of each facility and can build upon on-going efforts. QI activities include the following:
   - QI pre-work, including orientation, organizational assessment, and preparation of self-monitoring measurement tools.
   - QI coaching sessions, with frequency tailored to the need of the facility.
   - Guided and tailored QI data collection and review (approximately quarterly), with data sources including clinical performance measures, healthcare worker surveys, and patient feedback.
   - Action periods, where small tests of change are determined in consultation with the QI coach, and self-implemented and monitored at the facility.
   - Periodic peer learning sessions, to support practice transformation and facilitate sharing of best practices across participating CRISP facilities.

Please refer to the CRISP Journey Map at the end of this document for a description of all CRISP activities and their sequence over the 2-year intervention period.

In addition, CRISP facilities will be asked to help synergize their activities with other intervention components – for example to be aware of and promote the peer support program, if and when appropriate.

What is involved in the research partnership?

CRISP healthcare facilities will support study data collection in up to three areas:

- **Provision of electronic medical record (EMR) data for assessment of study outcomes:** Under an agreement with an expert healthcare analytics organization, an Application Programming Interface (API) will connect to the EMR system of participating facilities to access limited EMR datasets approximately quarterly, deidentify them, and transfer them to the study database for analysis. Transferred data will not include direct patient identifiers and will meet the requirements for a waiver of individual authorization under the HIPAA Privacy Rule per 45 CFR 164.512(i). A representative from each facility will be designated to assist the analytics partner in the EMR data access and work with the study team to ensure data quality and accurate interpretation.

- **Recruitment of a small cross-sectional sample of Black MSM at three timepoints:** Each facility will be responsible for recruiting and enrolling a small sample of Black MSM into a cross-sectional assessment which will take place at three timepoints (baseline, mid-intervention, post-intervention). Facilities will be assigned some participants to recruit and enroll based on the facility size (anticipated between 10-20 men at each timepoint). Enrolled participants will complete a self-administered online questionnaire during a regularly scheduled medical visit. After the visit,

designated facility staff will abstract limited data from the participant's medical record and enter it onto study forms. No follow-up is needed with these participants, and no laboratory samples are collected.

- **Qualitative interviews:** At a subset of facilities, a small number of Black MSM will be recruited directly from the cross-sectional assessment questionnaire to participate in one qualitative interview, which will be conducted by a member of the study team. Participating facilities will not be required to assist with these interviews. At these facilities, however, a small number of staff members will also be asked to participate in a qualitative interview towards the end of the intervention period. Facility representatives will be asked to help recruit and put the study team in touch with these staff members.

What commitment is being asked of your healthcare facility?

HPTN 096/CRISP is a two-year intervention, with preparatory work required before intervention start, and some data collection activities extending approximately 6 months beyond the end of the intervention. While participation is voluntary and facilities may withdraw at any time, our hope is that each facility will be able to participate in the full CRISP intervention and data collection activities (as described above) over this period of time, as this level of participation is critical to the success of the study.

What are the requirements for participation?

The CRISP intervention is for healthcare facilities that are serving, or have the capacity to serve, Black MSM for HIV prevention and/or treatment needs. In addition to providing these services, facilities must:

- Be located in an HPTN 096 study community
- Be willing and able to accept new Black MSM clients
- Be willing to allow extraction of limited EMR data for study outcomes assessments
- Be willing to participate in the CRISP intervention activities
- Be willing to recruit Black MSM into the cross-sectional assessment
- Be willing and able to incorporate PrEP into the facility practice (if prevention services are provided)

Because there is a maximum number of healthcare facilities that can be supported to participate in the study, if more facilities express interest than the study needs, the study team will select the facilities to participate based on information provided and interest expressed. Consideration will be given to the number and type of clients served by each facility, their location, and the type of facility, to ensure heterogeneity in the mix of participating facilities and equitable and representative coverage of healthcare facilities across the study communities.

What benefits are there to participating in CRISP/HPTN 096?

HPTN 096 a study of high strategic national significance. If the strategy is successful, your healthcare facility will be part of the story about how we stopped this epidemic. Participating healthcare facilities will be part of this larger, historic effort within their community, and will benefit from the shared

experiences, knowledge exchange, and peer learning with the other participating healthcare facilities in all of the study communities.

Benefits also include:

- **Improved Patient-Provider Communication:** CRISP will help healthcare providers enhance their ability to communicate effectively with Black MSM patients from diverse backgrounds, leading to better understanding and trust.
- **Enhanced Patient Care and Satisfaction:** Participating facilities will be empowered to optimize services to better meet the needs of Black MSM, which will in turn, improve patient satisfaction and engagement, and retention in care, ultimately leading to improved healthcare outcomes and reduced health disparities for this population.
- **Enhanced Community Trust:** CRISP facilities will demonstrate a commitment to ensuring their practices align with the cultural contexts and preferences of Black MSM patients, thereby earning the trust and respect of these communities and enhancing their reputation as culturally competent healthcare providers.
- **Market Differentiation and Competitive Advantage:** CRISP facilities will distinguish themselves in the marketplace as responsive to Black MSM's needs, which will help them attract a broader patient base and gain a competitive advantage in an increasingly diverse healthcare landscape.
- **Increased patient volume:** Components of the integrated strategy will direct Black MSM clients to CRISP facilities, which will increase patient volume and revenue.
- **Improved EMR data quality for Black BGTMSM:** Participation in this study will improve every clinics' ability to capture and track health data for Black MSM, resulting in better tools to improve their health outcomes.

Additionally, CRISP is designed to synergize with the three other study components, so CRISP facilities will benefit from connection to and promotion by these activities: peer support will serve as a resource to CRISP facilities with peer supporters referring clients to CRISP facilities, CRISP facilities will capitalize upon the systemic changes being made by health equity coalitions and ensure their needs are factored in to the coalition efforts, and the robust social media strategy will also ensure that community members are aware of the important efforts underway at CRISP facilities and cross-promote them.

Is IRB approval required?

Yes, the study is overseen by a single IRB, Advarra. All participating facilities will undergo IRB review by Advarra. Facilities with their own local IRB must establish a reliance agreement with Advarra. Local ethics committee reviews are permitted in addition to Advarra review if institutionally required. The study team will manage the single IRB process and work closely with each facility to complete IRB submission and approval requirements.

Will CRISP facilities be compensated for their participation?

Yes, all participating facilities will receive a compensation package totaling up to $260,000 over the period of performance. This amount was determined based on the following:

1. A participation incentive for CRISP intervention activities totaling up to $100,000;
2. Funding to support staffing effort required for data collection activities;
3. Reimbursement per participant enrolled in the cross-sectional assessment.

Funding disbursements will be tied to achieving specific milestones throughout the study period. The funding is unrestricted.

How to participate

Interested facilities should complete the CRISP Prospective Facility Interest Form. The form should be returned to 096crisp@fhi360.org, no later than September 15, 2024.

Once all completed forms have been received, the study team will review interested facilities and make selection decisions. All facilities will be informed of selection decisions by October 15, 2024.

HPTN 096: BETA

CRISP JOURNEY MAP

Version 4.0 | Mar 2024

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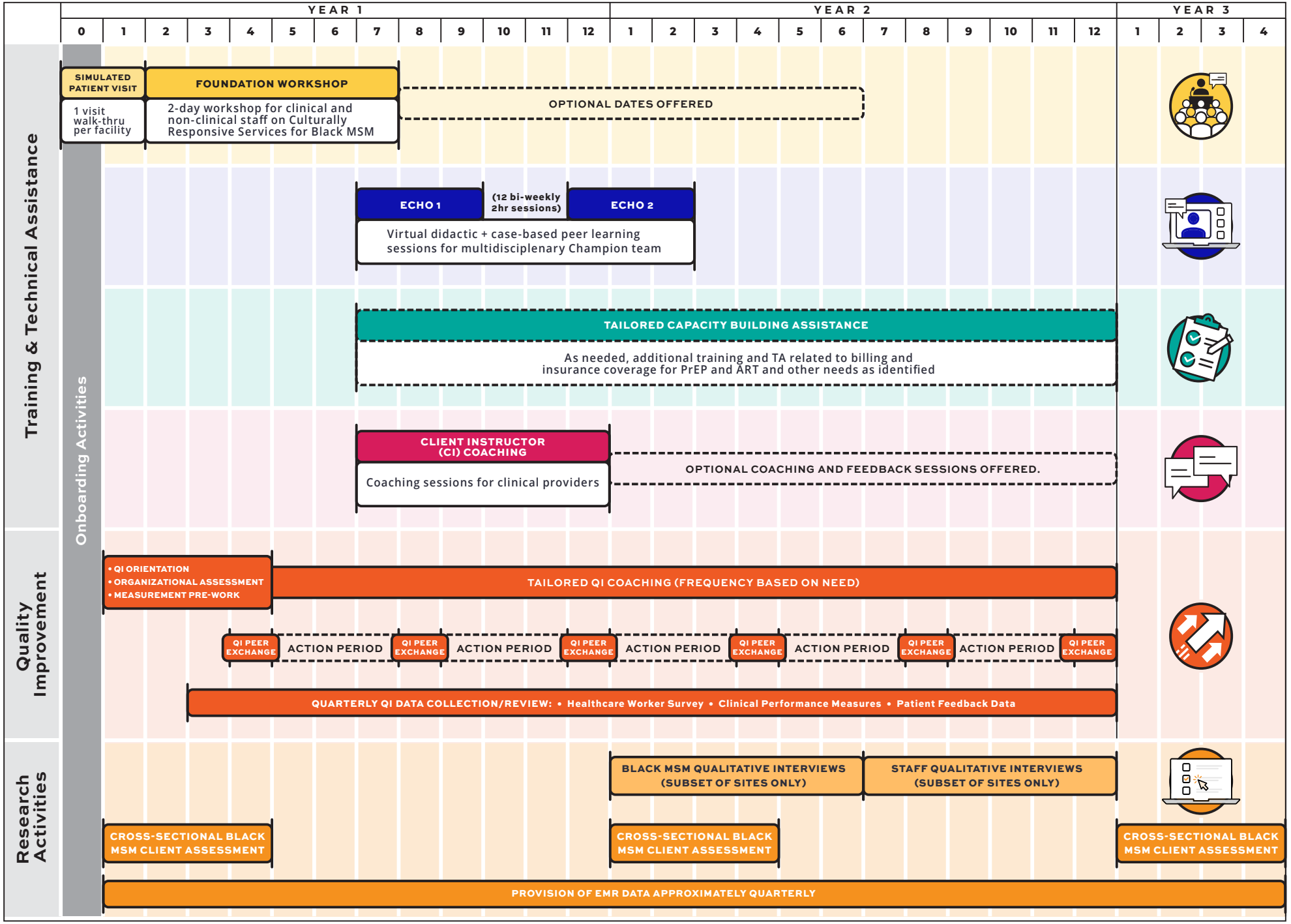

HPTN 096: BETA

CRISP DESCRIPTIONS

Version 4.0 | Mar 2024

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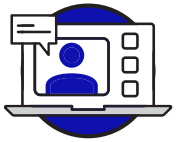
FOUNDATION WORKSHOP

A 2-day workshop for clinical and non-clinical staff that aims to enhance cultural responsiveness in providing HIV/STI services for Black MSM through greater awareness and understanding of how anti-Black racism and other intersectional stigmas affect their HIV/STI health behaviors. Prior to the workshop, each facility will have a simulated patient visit, where a trained Black MSM will conduct a full visit walk-through of a PrEP or ART initiation visit. Observations will inform a site-specific exercise in the Foundation training.

ECHO

A smaller subset of staff (referred to as a Champion team) will attend additional training sessions held virtually, focusing on a variety of topics to explore more deeply after the Foundation training and featuring case-based peer-to-peer learning.



TAILORED CAPACITY BUILDING ASSISTANCE

As needed, additional training and TA will be offered to facilities with a primary focus on navigating insurance coverage for PrEP and ART as well as using CRISP to enhance business development, and other support as needs are identified.

CLIENT INSTRUCTOR (CI) MENTORING SESSIONS

Black MSM Client-Instructors will hold one-on-one coaching sessions with providers to offer a safe space for providers to practice and receive feedback on interpersonal communication skills around PrEP and/or ART initiation with Black MSM clients.

QUALITY IMPROVEMENT (QI)

A tailored quality improvement approach is taken to implement small tests of change and self- monitor improvement data over time. Each participating facility is paired with a quality improvement coach and will be part of a peer learning network to help foster ideas and provide guidance throughout the QI process. QI support is tailored to the need of the healthcare facility and QI activities can build upon ongoing efforts.

RESEARCH ACTIVITIES

As research partners, healthcare facilities will recruit Black MSM clients to complete a cross-sectional assessment at three time-points over the study and provide electronic medical record data approximately quarterly to assess study outcomes. Some facilities will be selected to participate in qualitative interviews as well.