

Understanding Barriers and Facilitators to HIV Prevention, Care, and Treatment

Generic Information Collection request under 0920-0840

Section B: Supporting Statement

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PART B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection request is for the 1) in depth interviews of thirty (30) HIV providers, 2) eighty (80) Persons living with HIV (PLWH) and 3) twenty (20) of their HIV-discordant partners, in order to understanding barriers and facilitators to HIV prevention, care, and treatment PLWH.

1. Respondent Universe and Sampling Methods

Target Population and City Selection

This study offers the opportunity to explore the reported facilitators and barriers among HIV prevention, care, and treatment in some of the most impacted geographical regions in the country. We have chosen to focus our study on five metropolitan areas in the United States with some of the heaviest burdens of HIV/AIDS – Atlanta, Baltimore, Chicago, Los Angeles, and Washington, D.C. These cities are also among the twelve cities participating in the CDC Enhanced Comprehensive HIV Prevention Planning (ECHPP) Project’s metropolitan HIV/AIDS statistics. The demographic layout of these cities will enable project staff to recruit heavily from racial and ethnic minority populations. Although not specifically targeted, these cities may also provide project staff with hard-to-reach groups such as homeless PLWH, young adult PLWH, and injection drug users who are also men who have sex with men (MSM). The sampling approach will have three components and includes 1) the selection of (n=30) HIV providers, 32) (n=80) PLWH and 3) (n=20) HIV-discordant partners. This section serves to briefly summarize the sampling plan for this project.

HIV Provider sampling

In-depth interviews will be conducted with HIV care providers defined as “a physician, physician assistant, clinical nurse specialist, nurse practitioner, or other health care professional certified in his or her jurisdiction to prescribe antiretroviral (ARV) therapy” (Ryan White AIDS Program Services Report, 2013), case managers, and social workers. To select HIV providers for the interviews members of contractor project staff will contact a diverse pool of providers selected within each city partner facilities (Atlanta, GA, Baltimore, MD, and Washington, DC) with an aim to maintain diversity across cities. For example if we are unable to interview the only physician at facility A1, we will replace this physician with a nurse practitioner. Instead of interviewing a nurse practitioner at facility A2 or A3, we might interview another physician. This will depend on the flow of data collection. We will be continuously checking and updating Exhibits B1.1-1.3 to ensure that the sample is diverse.

Exhibit B1. 1. Atlanta HIV Provider Sample by Facility

Types of Providers	Facility 1A: Absolute CARE Med. Center		Facility 2A: AID Gwinnett		Facility 3A: Ponce De Leon		Atlanta Sample
	# of providers	# sampled	# of Providers	# sampled	# of providers	# sampled	Total MSA

							Sample
Physician	5	1	1	1	11	2	4
Nurse Practitioner	2	1	2	1	0	0	2
Registered Nurse	4	0	1	0	19	2	2
Case Manager/ Social Worker	1	1	3	1	3	0	2
Total # of Interviews		3		3		4	10

Exhibit B1.2. Baltimore HIV Provider Sample by Facility

Types of Providers	Facility 1B: JACQUES Initiative		Facility 2B: People Community Health Center		Facility 3B: Chase Brexton Randallstown Center		Baltimore Sample
	# of providers	# sampled	# of Providers	# sampled	# of providers	# sampled	Total MSA Sample
Physician	2	1	7	1	5	2	4
Nurse Practitioner	0	0	4	1	1	1	2
Registered Nurse	2	1	0	0	0	0	1
Case Manager/ Social Worker	3	1	5	1	1	1	3
Total # of Interviews		3		3		4	10

Exhibit B1.3. Washington HIV Provider Sample by Facility Facility

Types of Providers	Facility 1W: Carl Vogel Center		Facility 2W: Dupont Circle Physician's Group		Facility 3W: Whitman Walker		Washingt on Sample
	# of providers	# sampled	# of providers	# sampled	# of providers	# sampled	Total MSA Sample
Physician	1	1	2	2	13	1	4
Nurse Practitioner	0	0	1	1	7	1	2
Registered Nurse	0	0	0	0	2	0	0
Case Manager/Social Worker	1	1	0	0	7	1	2
Total # of Interviews	3	1	0	0	3	1	2
Physician		3		3		4	10

PLWH sampling

We plan to enroll 80 PLWH, 50 Black/African-American MSM and 30 Hispanic/Latino MSM living with HIV. Ethnic minorities and MSM are disproportionately affected by HIV/AIDS. Although African Americans and Latinos comprise only 12% and 16% of the United States population respectively, 44% of people in the US with HIV are African American and 21% are Latino.¹ Achieving the National HIV/AIDS Strategy (NHAS) goal to reduce population disparities in HIV/AIDS cases requires research among those disproportionately affected by the epidemic. Our study focuses on Black/African-American and Hispanic/Latino MSM, who bear the greatest burden of disease², are more likely to face structural barriers to care³, and are at greater overall risk for treatment non-adherence and resulting treatment failure².

Among this sample, we will target PLWH who represent the entire treatment continuum, including those who, since their diagnosis, have always been in treatment, those who have at some point dropped out or dropped out and reengaged in treatment, and those who have never been in treatment. Thirty (n=30) will be in treatment while fifty (n=50) will not be currently in ARVT.

HIV-discordant Partners sampling

Finally, we plan to enroll 20 HIV-discordant partners. We are interested in examining the effects of HIV-discordant partners on treatment adherence among PLWH. Studies of treatment partnering, wherein partners of diagnosed PLWH are treated prophylactically, find that the involvement of HIV-negative partners in the treatment process can also (1) encourage disclosure, (2) combat stigma, (3) restore hope, and (4) reduce social disparities.⁹ In recognition of the potential of HIV-negative primary partners to facilitate treatment adherence among vulnerable groups, we intend to interview 20 HIV-discordant partners across all five metropolitan areas.

Exhibit B1.6 below describes our recruitment targets for treatment status of PLWH and their discordant partners.

Exhibit B1.6 Summary of Recruitment Targets by Treatment Status

Treatment Status	Male MSM PLWH			Partners	Total
	Black/ African- American	Latino (Both English & Spanish Speaking)	Total	Male HIV- discordant (HIV-)	
Currently In treatment	20	10	30	10	
Currently not In treatment	30	20	50	10	
Total	50	30	80	20	100

2. Procedures for the Collection of Information

This project will use qualitative data collection methods. Prior to the in-depth interviews of HIV providers, PLWH, and HIV-discordant partners, members of contractor project staff will administer a demographic questionnaire to each respondent in the study. Demographic data will not be linked to qualitative interview data, and will only be reported in aggregate summary form. The study design integrates three qualitative methods: 1) direct observation of the facility physical environment (no pictures of patients or staff will be taken); 2) in-depth document review of annual reports, new hire orientation materials, blank copies of patient charts and related materials, protocols related to patient care (e.g. engagement, retention, referral), aggregated patient information (e.g. average waiting time to see providers), social media protocols, MOAs, and MOUs; and 3) in-depth interviews with HIV providers, PLWH and their HIV-discordant partners.

We will recruit PLWH and their HIV-discordant partners from different cities, and different types of clinics (urban/suburban/rural, Ryan White vs. non Ryan White funded). Each subgroup will be sufficient for qualitative analysis yet not sufficient to be generalized to the larger population. Therefore, recruiting a probability sample is unnecessary and would be misleading. To elicit the most themes related to barriers to care, we intend to use a convenience sample designed to ensure that a wide range of experiences are available. As described above, providers and organizations will be categorized by type, including if they are a Ryan White clinic or not, in order to ensure respondents have a diversity of clinic and organization experiences. Our procedures for determining eligibility, recruiting facilities and respondents, sampling and screening are described below.

2a. Eligibility

HIV Providers

In order to include only those providers with a significant understanding of the possible barriers and facilitators to HIV care within the selected facility, we have limited our recruitment to providers who work at the facility for at least 20 hours per week and at with at least 12 months of experience providing HIV care. Providers who work fewer hours may not have the necessary familiarity with processes and procedures at the facility to provide the level of detail needed for the interviews. We have also limited our sample of providers to those who are English-speaking due to data collection and analysis resource constraints associated with translation between English and other languages. Below are the inclusion and exclusion criteria for HIV Providers;

Inclusion criteria

- Practitioner type (Physician, Nurse Practitioner, Physician Assistant, Registered Clinical Nurse Specialist, Registered Nurse, or Case Manager)
- At least 12 months providing HIV care
- Consent (verbal) to participate in the study
- Adult (over the age of 18)

Exclusion criteria

- Employed less than 20 hours per week at the facility
- Non-English speaker

PLWH and HIV-discordant partners

We will determine eligibility for the cohort of 80 PLWH based on both demographic characteristics and placement in the treatment continuum. Demographic eligibility will be based on respondents' HIV status, ethnic/racial identification, age, language proficiency, gender, and MSM. Eligibility for the cohort of 20 partners includes the same characteristics except for ethnic/racial identification. These criteria are detailed in Exhibit B2.1.

Exhibit B2.1. Summary of Demographic Eligibility Criteria

	Persons Living with HIV (PLWH)	HIV-discordant Partners
<i>HIV Status</i>	Diagnosed HIV-positive	Not tested or diagnosed HIV-negative
<i>Race/Ethnicity</i>	Black/African-American, or Hispanic/Latino	No race/ethnicity requirements, monitor for diversity
<i>Age</i>	18 years of age and over	18 years of age and over
<i>Language</i>	Proficient in English or Spanish	Proficient in English or Spanish
<i>Gender</i>	Male-identified	Male-identified
<i>Other</i>	Men who have sex with Men	Men who have sex with men

	(MSM)	(MSM)
		In a 6-month or more sexual relationship with a study respondent who is MSM PLWH

Our study focus requires PLWH to identify as African American or Latino; however, their HIV-discordant partners will not be selected on the basis of their own race or ethnicity. All respondents will be individuals who identify as males and have sex with men. Due to our small sample size, inclusion of multiple subpopulations (e.g., transgender, women) would yield extremely small cells for analysis. As a result, we have chosen to focus on the highest burden population, i.e., Black/African-American and Hispanic Latino MSM.

We expect that HIV-discordant partners will also be primarily racial or ethnic minorities. We will monitor for diversity but not limit eligibility of HIV-discordant partners to African American and Latinos. HIV-discordant partners should also identify as male and as men who have sex with men (MSM). By our definition, HIV-discordant partners will be HIV negative or not tested (that is, not known to be HIV positive).

We include language proficiency as an eligibility criterion in order to conduct the face-to-face interview. Respondents must be able to understand either Spanish or English. (Consent forms and interview protocols will be available in both languages, and will be read aloud to respondents if they are unable to read.) Spanish or English administration will be determined over the course of the screening interview. Since fluency in communication is important for a successful in-depth interview, we will interview the respondent in the language in which he is most fluent.

Respondents must be over 18 years of age to be eligible for the study; minors will be excluded. Inclusion of minors may lead to mandatory reporting (e.g., relationships between a minor and an adult over 18 years of age), which would in turn require releasing of private information. In order to minimize any scenario in which a respondent’s private information must legally and ethically be released, we have restricted our respondent pool to individuals 18 years of age or older, including HIV-discordant partners. In order to verify age, respondents will be asked to bring a photo ID with their date of birth to the interview session.

2b. Recruitment of Respondents

Gaining referrals of potential respondents

HIV Providers

Among our partner facilities, we will request a complete roster of eligible staff and identify potential HIV providers based on our inclusion and exclusion criteria. HIV providers will be contacted first by phone followed by email and invited to participate in the study (See **Attachment 5a** for provider recruitment script).

We will recruit HIV providers who work at least 20 hours per week at the facility and regularly care for HIV patients by providing HIV care services. Study procedures will include an in-depth interview regarding perceived barriers and facilitators experienced when providing HIV care and demographic questionnaire. Members of contractor project staff will work with each HIV provider to identify a mutually convenient time for the interview. If a provider is unavailable during the previously scheduled time, we will reschedule at the provider's convenience. We will accept two cancellations from a provider, before scheduling the interview with another provider with similar training. This process will ensure that we give providers a fair opportunity to participate but also that we stay on schedule with the study. In-depth interviews will be completed at the facility location in a quiet area where others cannot overhear the interview (to maintain privacy) or alternate location if preferred or requested by the provider.

PLWH

The main cohort of eighty (n=80) MSM must be diagnosed HIV positive. In order to verify HIV status, we will focus our recruitment on treatment centers, clinics, and community organizations that primarily serve PLWH. We will distribute a variety of recruitment flyers in these locations (See **Attachments 5c-5t**). We will also speak to healthcare providers such as doctors or nurses who can identify PLWH and provide them information about our research study. By working closely with providers and treatment clinics geared towards PLWH, we can be sure of HIV status without requesting a release of medical records. Our team will provide criteria that will help venue staff and HIV care providers identify potential respondents at each stage of the treatment continuum. Care providers will be able to approach potential respondents without releasing to the study any HIPAA-protected information.

In order to identify treatment-naïve PLWH, we will again work closely with providers who can refer their patients to our study. These providers can review their records to identify patients who are eligible for treatment but not currently on treatment, including those who are eligible for treatment but have ever missed an appointment, missed multiple appointments, or never attended or made an appointment. Providers can also identify individuals that have difficulty staying on medication, refuse medication, or do not follow provider recommendations.

We will also work closely with community-based organizations, which may be able to identify individuals that have disclosed their HIV status within the organization but receive no care nor have any relationship with providers. These organizations can refer such individuals to our research study.

Finally, because respondents who refuse care or drop in and out of care may be more difficult to recruit through treatment centers and clinics, we plan to make use of online listservs, advertisements, community outreach, and non-treatment community organizations to target those who do not actively engage in treatment and care. Thus, we anticipate that close relationships with HIV treatment and care providers as well as community-based organizations will facilitate identification of PLWH in various stages of treatment.

HIV-discordant partners

We anticipate that most HIV-discordant partners will be identified through a PLWH recruited into the study. PLWH respondents will be asked to identify a primary partner who may be interested in study participation. Respondents interested in having us interview their partner must understand and be comfortable with their partner discussing the respondent's HIV status and engagement in treatment and care.

Service providers may be able to assist in the recruitment of HIV-discordant individuals and their PLWH partner by identifying those HIV-negative patients who are at risk for infection and taking pre-exposure prophylaxis (PrEP). Although we would not ask providers to refer these patients directly, we would ask them to provide information to the HIV-discordant individual to pass on to his PLWH partner. If the PLWH partner is recruited, we would then ask him if the HIV-discordant patient was also interested in the study.

Focusing efforts while maintaining diversity

Among the service providers and community organizations that work with PLWH, we will focus on those that work with the populations of interest to the study such as: the Black AIDS Institute, Clinica Monseñor Oscar A. Romero, or other organizations minority PLWH are more likely to frequent. We will ask organizations that are willing to assist in recruitment to distribute flyers that invite the target population to participate in the study. The flyers provide email and phone contact information for those interested in participating, and will include information about the \$40 offered in appreciation.

In order to incorporate the desired demographic groups, we will recruit respondents in each city as follows:

1. Chicago: Recruitment will be aimed at Black and Hispanic/Latino MSM, including Spanish speaking MSM. Potential recruitment locations include but are not limited to VidaSIDA, Bonaventure House, and Heartland Alliance.
2. Atlanta: Recruitment will be aimed at younger MSM and African-American MSM. Potential recruitment venues include but are not limited to: the AIDS Research Consortium and the AIDS Survival Project. We also hope to include hard-to-reach, homeless, or injection drug using MSM populations by networking with community organizations across metropolitan areas (e.g., AID Atlanta, Positive Impact, Someone Cares Inc.).
3. Washington D.C./Baltimore: Recruitment will target younger MSM and African-American MSM. Potential recruitment venues include but are not limited to: Hearts and Ears and University of Maryland STAR TRACK. Recruitment of younger adult MSM can also be achieved by targeting specific community organizations that focus on young adult health, such as Metro Teen AIDS (which also serves young adults) and Advocates for Youth.
4. Los Angeles: Recruitment will target younger MSM, African-American MSM, and Hispanic/Latino MSM. Potential recruitment venues with a focus on Black/African-

American and Hispanic/Latino populations include but are not limited to: APLA, Latino Coalition Against AIDS, and the Black AIDS Institute.

2c. Sampling and Screening

HIV Providers

We will also use purposeful sampling to create a diverse list of HIV providers at contacted HIV partner facilities within Atlanta, GA; Baltimore, MD; and Washington, DC. We will request a complete roster of eligible staff and identify potential HIV providers based on our inclusion and exclusion criteria. The use of purposeful sampling to create a pre-determined list of HIV providers will eliminate the need for additional screening of HIV facilities as all partner facilities will already have been previously determined to meet inclusion criteria. Like the partner facility, HIV providers will be contacted first by phone followed by email and invited to participate in the study (See **Attachment 5b** for provider recruitment script).

The recruiter will describe the interview process and answer any questions from the respondent. The potential respondent must indicate she/he understands that she/he is being asked to complete a demographic questionnaire and face-to-face interview that combined lasts one hour. The recruiter will also inform HIV providers that the interviews are recorded, are completely voluntary, that the respondent can refuse to answer any question and stop the interview at any time.

PLWH and HIV-discordant partners

PLWH and their HIV-discordant partners will be recruited from Atlanta, GA; Baltimore, MD; Chicago, IL; Los Angeles, CA; and Washington, DC. Interested respondents who received flyers or other information from the organizations mentioned above will complete a screening questionnaire over the phone to determine eligibility (see Exhibit B2.2, below). During the screening, trained recruiters from the project staff will also assess whether the caller will be able to participate in an open-ended in-depth interview. Recruiters will exclude otherwise-eligible callers if they feel the caller may be non-responsive or confrontational during the interview.

During the screening process, the demographic and treatment continuum questions discussed above will be used to determine if the caller is eligible for the study. Using these eligibility criteria, callers who are determined to be eligible will be invited to complete an in-depth interview in person. The recruiter will describe the interview process the potential respondent and answer any questions from the respondent. The potential respondent must indicate he understands that he is being asked to complete a face-to-face interview that lasts at least one hour. The recruiter will also inform him that the interviews are recorded, are completely voluntary, that he can refuse to answer any question and stop the interview at any time, and that if the respondent chooses to participate in the study, he will receive \$40 or a \$40 gift card in appreciation for the interview (even if he chooses not to answer specific interview questions or chooses to stop the interview at any time). If the respondent chooses to participate, the recruiter will use a separate form to gather contact information (name and telephone number) needed to schedule the interview (see Exhibit B2.3 below). This information will be stored separately from the screener responses.

We will also screen eligible PLWH callers for the presence of a HIV-discordant partner until saturation is determined for partner targets as detailed in Exhibit B1.6. PLWH callers will be asked about sex partners of any kind and then asked to identify primary partners in order to recruit a sufficient number of HIV-discordant partners. We are most interested in respondents' main partner, primarily because the partner must know of the respondent's HIV status prior to joining the research study. Respondents are most likely to disclose their HIV status to primary or main partners^{1,2}. Furthermore, respondents may feel most comfortable discussing treatment engagement with a primary partner, who may offer additional insight into the role of partners in HIV treatment and care. Although main or primary partners are of greatest interest for the purposes of this study, if we encounter difficulty recruiting twenty main partners of PLWH in our sample, we are prepared to alter eligibility criteria with the agreement of the CDC COR. Possible alternatives include broadening the criteria to short-term or casual partners, shifting cases from the partner to PLWH cohort, or including HIV-discordant partners of PLWH not in the study.

We will ask eligible respondents who identify a primary partner whether the partner might be interested in participating in the study, and if the partner is aware of their HIV status. If so, we will ask the respondent for permission to contact the partner. A recruiter will contact the partner to ask if they are interested in participating in the interview. As with PLWH, we will inform interested partners that if they choose to participate, the study is voluntary, they can choose to not answer any question or stop the interview at any time, and that they will receive \$40 in cash or a gift card following the interview, regardless of how many questions they answer. If they are interested, the partners will be screened to determine their eligibility as described above in Exhibit B2.1.

We will interview HIV-discordant partners in a separate interview than the PLWH, with experienced and trained qualitative interviewers regarding their role in, and perception of, treatment care and adherence issues. We will ask both the PLWH and his HIV-discordant partner to refrain from discussing the particulars of the interview with each other at least until both have been interviewed.

Exhibit B2.2. Recruitment Screening Summary

¹ Mimiaga, M. J., Closson, E. F., Kothary, V., & Mitty, J. A. (2013). Sexual partnerships and considerations for HIV antiretroviral pre-exposure prophylaxis utilization among high-risk substance using men who have sex with men. *Archives of sexual behavior*, 1-8.

² Sullivan, K. M. (2005). Male self-disclosure of HIV-positive serostatus to sex partners: a review of the literature. *Journal of the Association of Nurses in AIDS Care*, 16(6), 33-47.

 Screener section	PWLH	HIV-discordant partner
Section 1 – Establish why R is calling to participate	Three questions to determine the reason the person thinks they qualify. Provides an opportunity for the recruiter to determine if the person might be eligible and appropriate for the study.	Two questions to determine the reason the partner believes they qualify. Provides an opportunity for the recruiter to determine if the person might be eligible and appropriate for the study if they call. <i>If the recruiter calls an identified SDP these questions are skipped.</i>
Section 2 – Demographic eligibility	Six questions that determine initial eligibility (see Exhibit 2.1). These questions will be asked of all callers. Although it may be determined that a caller is not eligible during this portion of the screener, it is important that all questions are asked. This prevents legitimate callers from feeling they have given a ‘wrong answer’ and thus ‘failed’. It also prevents ‘professional respondents’ who might provide false answers from knowing which answers disqualify them. Persons who do not qualify will be skipped to Section 3	Four questions required to determine eligibility. (See Exhibit 2.1.)
Section 2 cont. Secondary Eligibility – Treatment Continuum	One or two questions (depending on responses) that will determine the person’s status in the treatment continuum. Persons who are in already filled cohorts will be skipped to Section 3	No questions, although if there are enough partners available, we will attempt to solicit partners of PLWH to represent all treatment continuum experiences.
Section 2 cont. – Identifying HIV-discordant Partner	Up to ten questions to determine partner’s eligibility if PLWH wishes him to be contacted, and contact information. Callers will be skipped out once the partner is determined to be ineligible or PLWH prefers he not be contacted. Questions are designed to elicit a long-term male partner. Once saturation of the target is met (20 partners) these questions will be skipped.	NA

Screener section	PWLH	HIV-discordant partner
Contact Information Form – Providing additional information about the project, answering respondent questions, collecting information necessary to set up an interview.		

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- HIV facilities and HIV providers will be identified through past and existing partnerships with facilities.
- A token of appreciation of \$40, in cash or gift card, will be provided to PLWH and HIV discordant partners upon completion of the interview.
- Telephone screening of interested individuals will be used to determine eligibility and to further identify and recruit HIV-discordant partners. Screening questions will be used to determine eligibility by demographic criteria, status in treatment continuum, and type and length of HIV-discordant relationship.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from individual respondents.

4. Tests of Procedures or Methods to Be Undertaken

Our team includes experts with the HIV population and qualitative research, including screening and interview development and testing. We will conduct pretesting of the screening tool and interviews on three to five qualified respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and screener.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit B5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC Project Officer/COR and Technical Monitors are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews (ABT, Emory); working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC Project Officer/COR and Technical Monitors will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed below in Exhibit B5.1 (ABT, ATLAS, RSS, IMPAQ, and Emory). No individual identifiers will be linkable to

collected data, and no individually identifiable private information will be shared with or accessible by CDC staff.

Exhibit B5.1. Statistical Consultants

Jim Carey	CDC	404-639-1903	jfc9@cdc.gov
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