Assessing the acceptability and adoptability of HIV-1 pre-exposure prophylaxis (PrEP) technologies with and without contraceptive formulation among African American women in the southeastern United States

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Section B: Supporting Statement

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B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

1A City Selection

This proposed data collection will be carried out in three (3) sites from comparable metropolitan statistical areas in the southeastern United States (US) with moderate to high HIV-1 prevalence among African American women: Atlanta, GA; Jackson, MS; and Baton Rouge, LA.

Georgia (Atlanta): Georgia ranked 5th in the US in the number of HIV diagnoses in 2015. In Atlanta, the rate of African American females living with HIV was 14.7 times that of white females in 2016. Fifty-six percent of female transmission of HIV was attributed to heterosexual contact with an additional 7.9% attributed to injection drug use.[1] When reviewing the 5-year combined estimated percent of new HIV diagnoses among women by transmission category, 48.2% are attributed to heterosexual contact while 49.8% are attributed to various issues including hemophilia, blood transfusion, perinatal exposure, or other factors not reported or identified.[2]

Louisiana (Baton Rouge): Louisiana ranked the 2nd in the nation for highest rates of HIV cases, with Baton Rouge and New Orleans both representing significant portions of new HIV diagnoses in 2016. In Baton Rouge, the rate of African American females living with an HIV diagnosis was 24.5 times that of a white female in 2016.[3] Transmission of HIV among African American females was attributed to heterosexual contact in 38.1% instances, and another 51.5% of diagnoses were attributed to "other" causes or risk factors that were not reported or identified. About 42.7% of females living with HIV in New Orleans had attributed transmission caused by heterosexual contact with another 10.7% attributed to injection drug use.

Mississippi (Jackson): In 2014, Mississippi had the 9th highest new HIV diagnoses and 30.9% of cases were among women.[4] In 2016, 30.3% of persons living with HIV in Jackson were female and 22.6% of new HIV diagnoses were among women. African American individuals represented 87.6% of new HIV diagnoses in Jackson in 2016. In Jackson, African American women experience HIV diagnoses at 11.3 times the rate of white women. While female transmission was attributed to heterosexual contact in 38.7% of cases, 54.2% of cases had no identified risk factor attributed to HIV transmission.[5]

1B Target Population

This study plans to select 75 respondents to participate in qualitative, in-depth interviews across the three sites (25 per site): Atlanta, GA; Jackson, MS; and Baton Rouge, LA. The target population for this study is African American women who meet the following inclusion criteria:

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[1] AIDSVu. Local data: Atlanta. 2016; https://aidsvu.org/state/georgia/atlanta/. Accessed October 18, 2018.
[2] Frew PM, Parker K, Vo L, et al. Socioecological factors influencing women's HIV risk in the United States: qualitative findings from the women's HIV SeroIncidence study (HPTN 064). *BMC public health.* 2016;16(1):803.
[3] AIDSVu. Local data: Baton Rouge. 2016; https://aidsvu.org/state/louisiana/baton-rouge/. Accessed October 18, 2018.
[4] AIDSVu. Local data: Mississippi. 2016; https://aidsvu.org/state/mississippi/. Accessed October 18, 2018.
[5] AIDSVu. Local data: Jackson. 2016; https://aidsvu.org/state/mississippi/jackson/. Accessed October 18, 2018.

- Self-identify as African American
- Are 18-34 years of age
- Were born in the US
- Have resided at the targeted site for at least 12 months
- Were female sex at birth and currently identify as female
- Have engaged in vaginal or anal sex without a condom with a man in the past 12 months
- Are HIV-negative or HIV status-unknown (based on self-report)
- Are conversant in English

Exclusion criteria:

- Women who are foreign-born (Black but not African American)
- Non-English speakers

This is a qualitative research study and is not designed to make comparisons between groups or to generalize findings. We intend to use a standard qualitative sampling methodology that ensures a wide range of experiences are captured. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest.

The contractors will use multiple sources to obtain their samples of participants. Partnerships with health departments, universities, and community-based organizations and HIV and STD testing sites and health clinics and agencies will be made in each recruitment site. Partnering agencies at each site will assist our recruiting efforts by distributing flyers (**Attachment 2**) to potentially eligible clients at agency points of contact, by posting flyers for agency clients to see, and by sharing flyers through social media. Partnering agencies will be asked to identify potential venues and settings frequented by African American women 18-34 years of age. Study staff will assess venues and settings to select those most appropriate for reaching our target population, and request permission to post flyers and undertake active recruitment, as appropriate. We will also encourage snowball sampling by generally encouraging a non-incentive-based recruitment by word-of-mouth. Recruitment in venues or settings (e.g., beauty salons, laundromats, parks, community centers) and word-of-mouth referrals may also be used. Respondents will be directed to contact study staff for telephone or in-person screening.

Because the samples are not randomly selected, they may not fully represent the entire study population. Participants will represent some segments of the communities from which they are drawn, but not all, of the target population. The qualitative study's participants may be different when compared with the entire population of interest. Information on participant characteristics will be gathered via brief structured-response questions. Basic socio-demographic information limited behaviors will be included in the brief structured-response question so that we can describe the study sample and discuss limitations of generalizability to other populations.

The study methods are intended to allow researchers to gather information for a specific geographic area or subpopulation and are not being done in a way that is generalizable to other areas or the national population. Study outcomes will be communicated to local stakeholders and organizations in positions to consider and implement site-specific improvements in HIV prevention for each of the study sites examined. For stakeholders, organizations, or agencies outside the local affected communities, all communications will include clear discussion of the limitations of the geographic-specific, qualitative methods and the non-generalizability of the study outcomes. In presenting our findings, given the study methods, it will be clearly stated that any of the practical antidotes developed are not being recommended as policy recommendations or appropriate for widespread adoptions.

Our sample design is based purposeful sampling recruitment strategies for the target populations. Based on previous studies using similar methodological approaches we conservatively estimate that out of 150 potential participants screened at least 60% will be eligible for participation, and among those eligible to participate, 83% will agree to participation. **Exhibit 1.1** below outlines recruitment targets.

Exhibit 1.1 Summary of Recruitment Targets

	Atlanta, GA	**Jackson, MS**	**Baton Rouge, LA**	**Total**
Screened for Eligibility	50	50	50	150
Eligible to Participate	30	30	30	90
Consented and Enrolled	25	25	25	75
Total				150

2. Procedures for the Collection of Information

Recruiters will consist of contractor staff members of the project team. Partner organizations such as health clinics and community organizations that serve the target populations in the respective geographic locations may be contacted for their assistance in recruitment of potential candidates. In addition, word-of-mouth peer referrals by members of the target population will be sought. Lastly, Participants may also be recruited using recruitment materials such as but not limited to flyers, emails, ads on websites or referrals from partner organizations until the target total of participants indicated in each study is met.

Individuals who are interested in participating will be screened by members of the contractors' recruitment team using an eligibility assessment tool (**Attachment 3a**). If they are eligible, they will be invited to provide their contact information (name, phone, email), in order to schedule the face-to-face, in-depth interview. This contact information will be hand-written on paper (**Attachment 3b)**, and not be computerized on a form. When not in active use, the papers containing the contact information will be stored in locked cabinets separate from other study data at the contractor's office facility. These papers with the participant's contact information will be destroyed at the end of the study and will never be given to CDC.

At the beginning of the scheduled in-depth interview, a member of the contractor team will review the purpose of the study with the participant and answer any questions she might have. The participant will be asked to provide signed informed consent (**Attachment 4**) that will include an explanation of the study, risks and benefits of participation, duration of participation, the voluntary nature of participation, the right to withdraw without penalty, permission to audio record the interview, and contact person for the research. If she chooses to participate and sign the consent form, she will be given a copy of the form for her records. After the consent process is finished, the interview will begin.

On average, the qualitative in-depth interviews, including use of showcards (**Attachments 3c**). will last about 60-minutes, and collection of the demographic and behavioral information for this study will require approximately an additional 6 minutes (**Attachments 3d**). The data collection will take place at a time and place that is convenient to the participant. Locations will be private. The in-depth interviews will be audio-recorded with the consent of the participant, and transcribed. Location will also be selected based on low ambient sound when possible so as not to interfere with the recording quality. Two recording devices will be used to ensure no data is lost secondary to an inferior recording.

All materials, including recordings, will be kept in locked cabinets in secure locations. All personal identifiable information (PII) will be maintained on paper. The exception will be any possible PII provided by the participant inadvertently in the recorded interview. Transcripts of the data collection will exclude participant names or contact information. Participant names and contact information required to schedule interview appointments, will be kept in separate locked cabinets away from the paper materials or recordings.

Although the majority of data will be collected by using qualitative, open-ended questions, use of brief structured response questions will collecting descriptive information on topics such as the participants' age, race/ethnicity, sex and gender identity, HIV risk behaviors, and socio-economic status (e.g., education, income, employment). Use of closed-ended questions to obtain descriptive information will help minimize time burden on the participant. All data collection methods will be pre-tested and conducted by trained personnel. For in-depth interviews, questions are open-ended so that participants can reply freely of their own accord. For this type of interview, the trained data collector will guide the discussion with probing questions as needed. In the event of an emotional or anxious response from the participant, participants will be provided with a city-specific list of mental health care referral services that they may consult as needed. Participants will also be informed that they may stop the data collection at any time without penalty.

All interview audio files will be stored on the recorders; transcription will be done in-house by contractor team members by listening to the recording device and transcribing to stand-alone computers that are non-networked, taking care to remove any PII that may have been transcribed accidentally. Each interview will be transcribed into an MS Word document. Transcripts and NVivo files for individual cases will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer (without Internet access) at study offices. No final interview transcript or other computerized data file will contain any PII from the participant.

Analysis will include descriptive demographic characteristics of participants and other relevant data obtained from structured response questions. The bulk of the analysis will be done as traditional qualitative analysis, describing how participants with different characteristics (e.g. demographics, city, etc.) inform the research question posed within the relevant qualitative study. NVivo analysis files will be stored in a FISMA-compliant enclave on a dedicated data server. Backup files will be encrypted and maintained on flash drives securely kept under lock and key.

The contractor will keep paper and audio files of the interviews as well as the completed interview guides, screeners, contact information, and other project materials through the period of transcription, quantitative data entry, and QA/QC processes. Participant contact information will be destroyed at the end of the study. All consent documents will be maintained in locked cabinets within a secured, physical space, separate from other study data, of which only key study staff have access to records (i.e., PI, project director, study coordinators). All electronic study data (transcripts without PII) will be kept in encrypted or password protected files. Analysis will be done on secure network systems or stand-alone (non-networked) password-protected computers in secure locations. Study participants will only be labeled with unique numeric ID numbers in the final computerized data sets.

To protect study participant confidentiality, CDC has completed a Privacy Impact Assessment of the data system used by the contractor team (**Attachment 7**). Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. The study data sharing and use agreement describes in detail how data access will be provided and provisions for protection of privacy, confidentiality, security, intellectual property, or other rights (**Attachment 6**).

Only project staff will have access to the records, study documents, and original (raw) data records.

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

The following procedures will be used to maximize cooperation and to achieve the desired high response rate:

- Potential participants will be identified through targeted recruitment efforts or purposive selection of respondents selected from the relevant study population.
- A $40 incentive of in cash or gift card, will be provided to participants.
- Telephone or face-to-face screening of interested individuals will be used to determine eligibility and to further identify and recruit potential participants. Screening questions will be used to determine eligibility.
- All recruitment materials indicate the voluntary nature of the study.

4. Tests of Procedures or Methods to Be Undertaken

The research team includes experts with experience conducting HIV research with health departments, community-based organizations, vulnerable populations, and qualitative research, including screening and interview development and testing. The contracting team will conduct

pre-testing of the screening tool and interviews on up to nine mock participants to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each participant. Staff of partner organization staff will help the contracting team identify strategies for recruiting participants but will not be responsible for their actual recruitment. Non-CDC members of the research team will be responsible for collecting data, as well as for generating transcripts that contain no PII.

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

Exhibit 5.1 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 staff 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 IRB review; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The CDC staff will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff. All members of the research team will work together to analyze the data and generate reports containing summaries of the findings.

Exhibit 5.2 Statistical Consultants

Team Member	Organization	Phone	Email
James P. Carey	CDC	404-639-1903	jfc9@cdc.gov
Eleanor McLellan-Lemal	CDC	404-639-6147	egm4@cdc.gov
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