

**Barriers and Facilitators to HIV Prevention, Care, and Treatment among Transgender Women in  
Atlanta, GA, Philadelphia, PA, and Washington, DC (T-Qual)**

**Generic Information Collection Request under OMB #0920-1091**

**Section B: Supporting Statement**

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## **1. Respondent Universe and Sampling Methods**

### **City Selection**

An estimated 0.6% of adults, about 1.4 million, identify as transgender in the United States. However, states vary in the percentage of residents who identify as transgender. Washington, DC is noted for its relatively high percentage of transgender-identified adults (2.8%). Twenty states and Washington, DC are estimated to have a higher percentage of transgender-identified adults than the national average (Flores, Herman, Gates, and Brown, 2016). Georgia (0.75% of adults identify as transgender) and Pennsylvania (0.44% adults identify as transgender) are the selected states, including Washington, DC, for this study. Participants will be selected from three Metropolitan Statistical Areas (MSAs) within these jurisdictions: Atlanta, GA; Philadelphia, PA; and Washington, DC. Each of these MSAs are also noted for their high HIV prevalence.

### **Target Population**

Transgender women are at high risk for HIV infection and transmission. According to a 2008 systematic review of 29 studies measuring HIV prevalence among U.S. transgender populations, pooled data from four studies reporting HIV test results indicated a 28% HIV prevalence among transgender women, and data from 18 studies reporting participants' self-reported HIV status indicated 12% HIV prevalence (Herbst et al., 2008). Furthermore, a higher proportion of African American transgender women have tested positive for HIV infection (56.3%), compared to Latina and White transgender women (Herbst, et al., 2008).

Although HIV incidence is higher among transgender women than other populations, little research has been conducted to understand the unique complexities surrounding transgender women's experiences related to HIV prevention, care, and treatment. To effectively address the HIV epidemic in this population, more must be known and understood about the nature of transgender women's risks for HIV infection, and what evidence-based HIV prevention, care and treatment strategies are available and can be adapted to better meet the needs of transgender women.

### **Sampling Methods**

Due to potential challenges in identifying and recruiting transgender women, we anticipate that multiple sampling and recruitment strategies will be utilized to ensure an adequate number of participants. Sampling approaches and recruitment strategies will vary by target group (i.e., transgender women and healthcare providers) and are described below:

#### *Sampling Plan for Transgender Women*

This study will utilize convenience and snowball sampling to select 40 transgender women to participate in the study (20 HIV-positive transgender women and 20 HIV-negative transgender women). Exhibit 1.1 shows the sampling targets for transgender women participants based on MSA, age group, and HIV status.

Transgender women will be screened for eligibility until each target is met in each MSA. During data collection, study staff will assess whether adjustments to these proposed targets are needed in order to

reach 40 participants. The following inclusion and exclusion criteria will be used to determine eligibility for transgender women to participate in this study:

#### Inclusion Criteria

- Adult (at least 18 years of age)
- Assigned male sex at birth
- Identifies as transgender woman or female
- Self-reported engagement in anal or vaginal sex in the previous six (6) months
- HIV-positive: Self-reported HIV diagnosis for at least 12 months, regardless of current engagement in care
- HIV-negative: Self-reported negative HIV test result within the previous 3-months confirmed by CBO staff or by HIV rapid testing at the CBO

#### Exclusion Criteria

- Non-English speaker
- Current signs of being under the influence of alcohol or illicit substances (e.g. belligerent, slurred speech, swaying, drowsy, stumbling)

#### *Recruitment of Transgender Women*

Given the potential difficulties anticipated in recruiting transgender women, study staff will rely first on convenience sampling and implement two recruitment strategies concurrently:

*Facility-Based Recruitment:* CBO staff will approach potential participants seeking services on site at the CBO facility and administer the eligibility screener (in-person or via phone) to interested individuals.

*Outreach-Based Recruitment:* CBO staff currently conduct outreach activities and provide services at various off-site locations such as mobile units, offsite testing locations, and, if the CBO has previous authorization to conduct outreach in these locations, clubs and bars known to be frequented by transgender women as part of their ongoing CBO activities. As feasible, CBO staff will approach potential participants at these locations and administer the eligibility screener to interested individuals. Study staff will train recruiters and include instructions in script to approach potential participants discreetly if outreach-based recruitment occurs.

In order to identify and enroll a diverse group of transgender women (e.g. age, race/ethnicity), CBOs will be asked to recruit participants using both facility-based and outreach-based recruitment strategies.

#### *Sampling Plan for Healthcare Providers*

The study will use a purposive sampling approach to identify healthcare providers who provide routine care, hormone therapy, and/or HIV treatment and care to transgender women participants (n=10) (e.g. physicians, nurse practitioners (NPs) and physician assistant (PA)). The study target is to recruit three providers in Atlanta, GA, four providers in Philadelphia, PA, and three providers in Washington, DC. These targets are modifiable by MSA based on accessibility of providers during recruitment efforts. A pool of healthcare providers within each MSA will be identified through 1) interviews with transgender women participants asked to indicate their providers for general health care, hormone

therapy, or HIV treatment or care services, 2) internet searches and 3) study staff’s previous experience with clinics indicating provision of services to transgender women within each MSA.

We will purposively sample healthcare providers from this pool taking into account type of provider (e.g., infectious disease physician primary care physician, endocrinologist), number of transgender women participants that cited the provider during their interview, number of years providing HIV care and/or HRT to transgender women, and number of transgender women patients where feasible.

The following inclusion and exclusion criteria will be used to determine eligibility for healthcare providers to participate in this study:

Inclusion Criteria

- At least 6 months of experience providing care to transgender women
- Referred by a transgender study participant as her health care provider or known provider of services to transgender women based on previous work by study staff or subject matter experts

Exclusion Criteria

- Non-English speaker

*Recruitment of Healthcare Providers*

Providers will be recruited using multiple recruitment strategies:

*Referral-Based Recruitment:* The primary recruitment strategy will be to obtain referrals from transgender women participants. We will request that transgender women participants identify their general health care, hormone therapy, and HIV treatment and care providers. Following the interviews, our team will contact the providers to assess interest in participating in the study and recruit for participation.

*Outreach-Based Recruitment I:* The secondary recruitment strategy will be to recruit healthcare providers that the contractor team (including subject matter expert consultants) has identified through an Internet search as having experience providing care to transgender women in each of the MSAs.

*Outreach-Based Recruitment II:* The third recruitment strategy will be to utilize study staff’s previous experience with clinics indicating provision of services to transgender women within each MSA to identify and recruit healthcare providers that provide care to transgender women.

**Exhibit 1.1: Summary of Recruitment Targets**

Age Groups	Atlanta, GA		Philadelphia, PA		Washington, DC		Total
	HIV positive	HIV negative	HIV positive	HIV negative	HIV positive	HIV negative	
18-24 years	3	3	3	4	3	4	20
25+ years	3	3	4	3	4	3	20
<b>Total per HIV status</b>	<b>6</b>	<b>6</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>7</b>	<b>40</b>
<b>Providers</b>	<b>3</b>		<b>4</b>		<b>3</b>		<b>10</b>
<b>Total per</b>	<b>15</b>		<b>18</b>		<b>17</b>		<b>50</b>

MSA				
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The distribution of respondents will vary somewhat from place to place based on local particularities, but we will strive for diversity of respondents within each of the jurisdictions. This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. 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.

**2. Procedures for the Collection of Information**

CBO staff will be provided and instructed to utilize recruitment flyers to garner participation in the study (**Attachment 1**). In an effort to minimize risk to participants the flyer will be the size of an index card. Study staff will train CBO recruitment staff not to push potential participants to accept the flyers. Each participant will be provided one to three flyers with information about the study and a phone number to call to be screened for study eligibility. If the potential participant is eligible for the study, the individual will be scheduled for an interview at the CBO facilities in a secure and private space or, if requested, the participant can request to meet at a quiet and safe public location (e.g., library) which has been verified by the CBO and contractor staff as safe and with enough privacy to conduct the interview. If study staff do not feel comfortable, they will not be required to conduct the interview in this location. At the time of the interview, staff will review the study procedures, after which participants will complete the informed consent (**Attachment 2**). If a potential participant misses an interview appointment, up to three attempts will be made by CBO staff to reschedule the interview. If a potential participant leaves a voice mail for CBO staff with contact information, up to three attempts will be made to screen them and schedule them for an interview. Study staff will accept two cancellations from a participant before scheduling the interview with an alternate participant. This process will ensure that each potential participant is given fair opportunity to participate while also maintaining the study schedule. Study staff will provide designated blocks for CBO recruitment staff to schedule interviews each week. If an eligible potential participant is unable to participate during the pre-established times, the study staff will try to accommodate the potential participants schedule though it will not be guaranteed. If a healthcare provider declines participation, they will be replaced with a similar provider from the pool of provider and clinic names. For example, if an infectious disease provider in Atlanta is unable to participate, we will attempt to contact another infectious disease provider in Atlanta.

The following data collection instruments will be used in this study:

*Eligibility Screeners for Transgender Women:* Eligibility screeners will be utilized to identify eligible transgender women and take approximately 5 minutes to complete (**Attachment 3a**). All eligibility screeners will be managed by CBO recruitment staff. As potential interview participants are identified, CBO recruitment staff will administer hard copies of the eligibility screener either in-person or over the phone. CBO recruitment staff will be trained to administer the screener completely. CBO recruitment staff will not provide a justification nor feedback for why an individual is ineligible for the study. The intent of this strategy is to minimize the possibility that individuals provide false information for the purpose of being selected into the study. All HIV-negative potential participants will be required to

bring their written HIV test result to their interview so that contractor and CBO recruitment staff can verify status. CBO recruitment staff will not maintain a copy of HIV test result brought in by potential participants as a part of study records. If a potential participant self-reports being HIV-negative and chooses to test for HIV at the CBO in an effort to verify their status and they subsequently receive an HIV-positive result, then they are immediately linked to care and are ineligible for the study because participants living with HIV are required to have known their status for at least 12 months to answer some of the research questions regarding HIV care and treatment. If an HIV-negative participant is recruited after HIV testing as part of regular services provided by the CBO, then CBO staff will follow their standard record keeping for HIV-testing procedures.

*Demographic Questionnaires:* Study staff will administer one of two demographic questionnaires to all interview participants) for transgender women and healthcare providers (**Attachments 3b-c**). It is estimated that the questionnaire will take approximately 5 minutes to complete. The questionnaires for transgender women will include variables related to: demographics, education, and length of time living in the jurisdiction. The questionnaire for healthcare providers will include variables related to demographics, provider practice type and training, gender status, sexual orientation, number of years in position, and organizational affiliations. These data will be entered by study staff into a database which will be stored on encrypted and password-protected laptops.

*In-Depth Interviews:* All interviews will be conducted by study staff using one of three separate interview guides for HIV-positive transgender women, HIV-negative transgender women, and healthcare providers (**Attachments 3d-f**). One-hour interviews will be conducted with transgender participants and healthcare providers in a private setting such as a CBO private room or a provider's office. All interview data will be recorded by study staff using an encrypted digital audio-recorder (not video-tape) with the consent of interview participants. Upon completion of an interview, a member from the study staff will upload interview recordings on password protected/encrypted laptops and encrypted flash-drives. Participants will be reminded by the interviewer not to use full names or identifying information during the interview. Study staff will perform the transcription of all audio-recordings and maintain all transcripts on password protected/encrypted laptops. During the interview, responses related to close-ended interview questions will be recorded manually by study staff onto paper forms. These data will be entered by study staff into a database which will be stored on encrypted and password-protected laptops.

Transcripts will be coded and analyzed used the NVivo qualitative data analysis software program. Information from the structured response questions will be analyzed using the Microsoft Excel and SPSS software programs. Individual transcripts, NVivo files, and other structured response data files will be stored on and edited from a CDC-approved encrypted USB drive plugged into a standalone, non-networked computer without Internet access. Only project staff will have access to the records, study documents, and data.

### **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:

- Transgender women will be identified through CBOs that do transgender-relate work in each of the jurisdictions.

- Healthcare providers will be recruited via direct referrals from participants and study staff.
- A token of appreciation of \$40, in the form of gift card/money order, will be provided to participants upon completion of the interview.
- 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 transgender women

#### 4. Tests of Procedures or Methods to be Undertaken

Our research team includes experts with experience conducting HIV research with health departments, CBOs, LGBT populations and qualitative research, including screening and interview development and testing. The contractor will conduct pretesting of the screening tool and interviews on three to five mock respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and to estimate response burden for each respondent. Non-CDC members of the research team will be responsible for recruiting respondents and collecting the data in the three cities 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 Project Determination and local IRB reviews; 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	Email
Damian Denson	CDC	Dvd5@cdc.gov
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#### References

Flores, A. R., Herman, J. L., Gates, G. J., & Brown, T. (2016). How Many Adults Identify As Transgender In The United States?. The Williams Institute. Los Angeles. Available online:



<http://williamsinstitute.law.ucla.edu/wp-content/uploads/How-Many-Adults-Identify-as-Transgender-in-the-United-States.pdf>