Preferences for Longer-Acting Preexposure Prophylaxis (PrEP) Methods Among Persons in US Populations at Highest Need: A Discrete Choice Experiment

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Program Official/Contact
Dawn K. Smith, MD, MS, MPH
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd. NE | M/S U8-4 | Atlanta, GA 30333
Office: 404639.5166
E-mail: dks0@cdc.gov

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B. Statistical Methods

1. Respondent Universe and Sampling Methods

This study will enroll approximately 1849 participants, including 9 pre-test participants and 1840 survey participants.

Traditional power calculations do not directly translate to preference surveys like discrete choice experiment (DCE) because power is impacted by several factors that are unknown *a priori*.[1] We base our sample size recommendation on Orme's Rule,[2] a widely used rule of thumb that estimates sample sizes for sufficient precision of main effect estimates based on the underlying components of the DCE design: $N > 1000c / (t \times a)$ where (N) is the minimum sample size required for main effects, (c) is the number of analysis cells or the largest number of levels for any one attribute, (t) is the number of choices each participant completes, and (a) is the number of alternative product options per question. Based on these rules, we will require 200 to complete the survey in each of the 8 priority groups: Black MSM, Hispanic/Latino MSM, White MSM, Black heterosexual men, White heterosexual men, transgender women, persons who inject drugs, and clinical providers.

A survey will be considered to be complete for the purposes of reimbursement if the respondent answers at least two choice questions in the DCE and reaches the last screen of the survey. Incomplete surveys will be excluded from the analysis sample. The analysis sample will also exclude data from respondents who complete the survey too quickly or too slowly (with cutoffs determined based on the final DCE design). We estimate that up to 15% of surveys may be rejected due to these quality issues and therefore propose to enroll about 1840 participants to achieve a sample size of 1600 for analysis (Table 1).

The survey uses an experimental design to combine levels from each attribute into hypothetical program profiles and to pair profiles into choice tasks. The number of possible combinations is too large to ask respondents to evaluate all possibilities (for example, a full factorial design for the attributes in the client DCE, each with two to three levels, is 72 profiles). However, robust statistical results can be obtained from a fractional factorial design implemented in far fewer tasks.[3, 4] The experimental design is usually split into a number of blocks or versions. Each equally sized block will have 8 to 12 questions, with only one question repeated across blocks. Participants will be randomly assigned to a block and will see only one block when completing the survey instrument. Using a D-efficient algorithm, we will construct a fractional factorial design that will be sufficiently orthogonal to allow identification (that is, all attribute levels will vary independently, and thus will not be correlated), and have good level balance so that each respondent sees all attribute levels. The experimental-design program in SAS (Cary, NC) will be used to generate potential designs and their diagnostics to assist in evaluating and selecting the most appropriate design.

Table 1. Sample sizes per Priority Population Group (assuming minimum of 200 per group)

Group		Strata 1	Strata 2	Total
Clients	MSM	Black/African American, non-Hispanic/Latino	18-39	150
			≥40	50
		Hispanic/Latino (any race)	18-39	150
			≥40	50
		White, non-Hispanic/Latino	18-39	150
			≥40	50
	Black / African American cisgender heterosexual	Men	18-39	100
			≥40	100
		Women	18-39	100
			≥40	100
	TGW	Black/African American, non-Hispanic/Latino	18-39	75
			≥40	25
		Hispanic/Latino (any race)	18-39	38
			≥40	12
		White, non-Hispanic/Latino	18-39	38
			≥40	12
	PWID	Men	18-39	50
			≥40	50
		Women	18-39	50
			≥40	50
Providers				200
TOTAL				**1600**

2. Procedures for the Collection of Information

Clinician providers and HIV-negative individuals at risk of HIV who are 18 years of age and older and able to complete the survey in English will be eligible for survey participation. The sample will be drawn from cities with high numbers of annual HIV diagnoses within the 57 priority jurisdictions identified as part of the Ending the HIV Epidemic in the US initiative.[5] Resources to be used for identification for specific recruitment sources are as follows:

Safety net clinics: HRSA's *Find a Clinic* website (https://findahealthcenter.hrsa.gov/) and outreach to HRSA BPHC to identify the set of FQHCs for which they provide funding for PrEP provision (see PrEP https://bphc.hrsa.gov/program-opportunities/primary-care-hiv-prevention).

Sexual health clinics: CDC's *GetTested* website (https://gettested.cdc.gov/) and the National Prevention Information Network (NPIN) website (a comprehensive, national directory of more than 1,800 public and private providers in the U.S. that offer PrEP, The NPIN website powers the "HIV testing sites & care services locator" service on HIV.gov (https://locator.hiv.gov/map). CDC will also provide a list of sexual health clinics that they fund for PrEP provision.

Family planning clinics: Title X Family Planning Clinic Locator developed and maintained by the Office of Public Affairs (https://opa-fpclinicdb.hhs.gov/).

Syringe service programs: North America Syringe Exchange Network directory (https://www.nasen.org/map/).

Other community-based organizations: AIDS Service Organization/Community-Based Organization (ASO/CBO) National Online Directory (https://healthhiv.org/resources/aso-cbo-national-directory/).[6]

Hospital emergency rooms: American Hospital Directory (https://www.ahd.com/search.php).

Non-residential alcohol and drug treatment organizations: SAMHSA's treatment locator (https://dpt2.samhsa.gov/treatment/directory.aspx) and opioid treatment program directory (https://findtreatment.gov/).

Approximately 200 organizations will be selected for study recruitment with attention to balance by geography, program type and other factors. Eligible participants will be included in the sampling pool and stratified based on analysis groups. Additional stratification will be done using data collected on the screening form to ensure that the survey respondents represent the groups in greatest need of HIV prevention products and services.

The recruitment materials will provide potential participants with a brief overview of the project and a link to the secure consent form via a QR code or web link. Interested individuals will access the website on their own device (tablet, computer, or smartphone) in the location of their choice. Recruitment sites also will be encouraged to facilitate survey completion for clients who have limited internet access, e.g., through access to a site computer.

The web link and QR code provided on the recruitment materials will send participants to an online consent form, with separate links for the PrEP clients and providers. Because screening requires asking sensitive questions about sexual and drug use behaviors, consent will be obtained prior to screening for all potential participants. Individuals will be provided detailed information about the study and asked to provide electronic informed consent for the screener and preference questionnaire in compliance with CFR 45 Part 46 and IRB requirements. We will assure participants that participation is voluntary and that their responses will be confidential.

All participants will complete the consent form online in the same manner, at a time and location of their choice. Participants who are eligible, via the screening form, and who are invited to participate in the main survey will be reminded of the key elements of consent when beginning the main survey.

We anticipate that survey recruitment will occur over a 6-month period (from September 2022 to March 2023). RTI will ask sites to engage in passive recruitment by forwarding email flyers to their listservs, putting up posters in their facilities, and posting

announcements to their websites and social media pages. We will recruit clinicians from the same clinical sites that we approach to recruit clients so that the clinicians represent those serving the priority populations, however we will also recruit clients from non-clinical organizations as described above.

3. Methods to Maximize Response Rates and Deal with Nonresponse

The ability to obtain the cooperation of potential participants for the survey will be important to the success of this study. To ensure that each DCE has the desired sample size and assuring balanced representation across subgroups of interest, we will develop a sampling pool of potential participants deemed eligible based on data from online screener forms.

Eligible participants will be included in the sampling pool and stratified based on analysis groups. Additional stratification will be done using data collected on the screening form to ensure that the survey respondents represent the groups in greatest need of HIV prevention products and services:

- **Black, Hispanic/Latino, and White MSM:** Younger age is associated with higher HIV risk across race/ethnicity groups among MSM. Therefore, we will aim to over-sample younger men by targeting ~75% men aged 18-39 and 25% aged ≥40 within each race/ethnicity group described above.

- **Black Heterosexual Cisgender Men and Women:** HIV risk is evenly distributed across the lifespan among Black/African American women and men at risk of heterosexual HIV transmission. Therefore, ensure sample representativeness, we aim to enroll approximately equal numbers of women and men aged 18-39 and ≥40.

- **Transgender Women:** Among TGW, Black/African American TGW experienced 46% of the total number of HIV infections in 2019 (n=289), followed by Hispanic/Latino (of any race; n=219) and White (n=80) TGW. We will therefore aim to over-sample Black/African American and Hispanic/Latino TGW by enrolling ~50% Black/African American, 25% Hispanic/Latino and 25% Other Race/Ethnicity. Because younger age is also highly associated with higher HIV among TGW, we will aim to over-sample young TGW by enrolling ~75% aged 18-39 and 25% aged ≥40. Age over-sampling will be conducted within Race/Ethnicity strata.

- **PWID:** Because HIV risk is evenly distributed across the lifespan among PWID and between men and women, we seek to enroll approximately equal numbers of women and men, and within those strata, approximately equal numbers of individuals aged 18-39 and ≥40.

- **Providers:** Because prescribing practices and preferences may vary by provider type, we will aim to enroll participants from the following three categories: 1) family practice and general internal medicine physicians (about

40% of sample), 2) nurse practitioner and physician assistants (about 20%), and 3) infectious disease/HIV specialist (about 20%) and OB-GYN providers (about 20%).

Within each strata, we will randomly select members of the sampling pool to participate in the DCE survey. If, during the study, the rate of survey completion from unique email/SMS invitations is too low, we will implement an alternate plan by which all participants who are eligible for study participation at the time of screening form completion will be routed directly to the online survey. In this scenario, when enrollment targets are reached for each priority population group and substrata, the survey programming will be updated to inform other eligible participants from the same group that enrollment has closed.

4. Test of Procedures or Methods to be Undertaken

Prior to programming the electronic version of the DCE, RTI will pretest the self-administered paper version of the survey with a small group of 9 or fewer eligible respondents to ensure that participants understand the survey content. We plan to recruit 1 client from each of the 7 priority groups plus 2 providers. The pretest procedures, informed consent, and DCE survey instrument have been approved by RTI's institutional review board (IRB), prior to pretesting. Pretest participants will be assigned a number that is used to record pretest observations.

The primary objective of the pretests is to evaluate the survey instrument and use the findings to refine the survey instrument. The semi-structured interviews will include a variety of approaches (e.g., think-aloud protocol, open-ended questions, debriefing) to examine whether pretest participants understand the survey content.

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

The following individuals inside the agency have been consulted on the design of the campaign research plan, questionnaire development, or intra-agency coordination of information collection efforts:

Dawn K. Smith
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd. NE | M/S U8-4 | Atlanta, GA 30333
Phone: 404-639-5166
E-mail: dks0@cdc.gov

Damian J. Denson
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

1600 Clifton Rd. NE | M/S U8-4 | Atlanta, GA 30333
Phone: 404-639-6125
Email: dvd5@cdc.gov

Karen Hoover
Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Rd. NE | M/S U8-4 | Atlanta, GA 30333
Phone: 404-639-8534
E-mail: ffw6@cdc.gov

The following individuals outside the agency have been consulted on questionnaire development. Additionally, input has been solicited and received from CDC on the design of this study, including participation by CDC in meetings with OMB.

Sarah Roberts
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 510-665-8255
E-mail: sroberts@rti.org

Alexandra Minnis
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 415-848-1323
E-mail: aminnis@rti.org

Dallas Wood
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-7206
E-mail: dwood@rti.org

Erica Browne
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 510-665-8268
E-mail: ebrowne@rti.org

Jackie Mungo
RTI International
3040 Cornwallis Road

Research Triangle Park, NC 27709
Phone: 919-541-6562
E-mail: bgarner@gmail.com

Anwar Mohammed
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 919-541-7308
E-mail: amohammed@rti.org

Emily Moore
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 580-761-3284
E-mail: emoore@rti.org

David Tweedy
RTI International
3040 Cornwallis Road
Research Triangle Park, NC 27709
Phone: 256-655-6804
E-mail: dtweedy@rti.org

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