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

OMB Control Number 0920-New

Supporting Statement: Part A

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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: 404.639.5166
E-mail: dks0@cdc.gov

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Supporting Statement: Summary

Goal of the project: The goal of this study is to understand preferences for long-acting pre-exposure prophylaxis (LA-PrEP) products for HIV prevention among potential users and providers, including product characteristics and other service delivery factors that may facilitate or hinder future uptake of these products.

Intended use of the resulting data: Results from this experiment will be used to identify key factors for adoption and implementation of LA-PrEP products. The information collected will also be used to increase implementation efficiency by identifying strategies to support decision making and address potential challenges with early use of LA-PrEP products.

Methods to be used to collect: Data will be collected via two separate self-administered online cross-sectional surveys; one for potential LA-PrEP users ("clients") and one for clinicians. The study design is comprised of a discrete choice experiment (DCE) and additional questions to directly elicit participant preferences and gather data on socioeconomic, behavioral, and attitudinal factors. Data collection will last approximately six months.

The subpopulation to be studied: The study's target population includes clinical providers ages 18 and older who prescribe PrEP and clients from the following priority population groups who were selected because they have the highest rates of HIV acquisition and are in need for HIV prevention services:

- Gay, bisexual, and other men who have sex with men (hereafter MSM) subdivided by race/ethnicity
  - Black / African American
  - Hispanic / Latino
  - White
- Black / African American heterosexual persons subdivided by biological sex:
  - Men
  - Women
- Transgender women
- Persons who inject drugs

How the data will be analyzed: A random-parameters logit (RPL) regression model will be used to analyze the data collected in this DCE and to estimate the primary and secondary endpoints. In addition, descriptive statistics will be calculated to summarize acceptability and direct elicitation of preference measures, overall and by priority population. Differences in direct preference measures by subgroup will be tested using chi-square for categorical measures and ANOVAs or t-tests for continuous measures.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests OMB approval for 2 years for a NEW information collection request (ICR) entitled Preferences for Longer-Acting Preexposure Prophylaxis (PrEP) Methods Among Persons in US Populations at Highest Need: A Discrete Choice Experiment. Approval is requested for 2 years to identify key factors for adoption and implementation of LA-PrEP products.

Despite successes in development and scale of up daily oral pre-exposure prophylaxis (PrEP) as a biomedical HIV prevention product, studies consistently show obstacles to its uptake and continuation. Median persistence of oral PrEP use in the United States is around 1 year, with high HIV incidence after discontinuation.[1] Further, rates of PrEP initiation remain low in key populations: a 2018 study found that nationally, females, young people <24 years, and all groups in the U.S. South had lower PrEP use relative to epidemic need.[2] Although the proportion of men who have sex with men (MSM) reporting PrEP use in the National HIV Behavioral Surveillance System increased from 6% to 35% between 2014 and 2017, this proportion was substantially lower among Black/African American and Latino MSM (26% and 30%, respectively) than white MSM (42%).[3] Efforts focused on increasing PrEP use among MSM of color might substantially reduce the overall incidence, and persistent racial/ethnic disparities, of HIV.[4, 5] Transgender women (TGW) are disproportionally affected by HIV, with new diagnoses occurring mostly in Black and Latina TGW[6, 7]; although few studies have been conducted on PrEP uptake and continuation in this population, existing data describe challenges to acceptability and adherence.[8-10] The 2022-2025 National HIV/AIDS Strategy includes a goal of increasing PrEP coverage to 50% among persons with indications, from a 2017 baseline of 13.2%.[11] Achievement of this goal will be contingent on addressing social, behavioral, and biological barriers experienced or perceived by both potential users (clients) and providers, including fatigue associated with daily product use, cost, frequency and duration of clinic visits, side effects, provider knowledge and training, and stigma.[8, 12-18]

The Centers for Disease Control and Prevention (CDC) and its partners must engage in early planning for the implementation of longer-acting (LA)-PrEP agents to help achieve the U.S. Ending the HIV Epidemic (EHE) goal of reducing incident HIV infections by 90% by 2030. Understanding providers' and priority populations' preferences for different LA-PrEP agents and perceived advantages and disadvantages of each product will be critical to estimating future uptake and market share of the various products that are likely to come to market.

The goal of this study is to understand preferences for LA-PrEP products for HIV prevention among potential users and providers, including product characteristics and other service delivery factors that may facilitate or hinder future uptake of these products. The study's target population includes clinical providers ages 18 and older who prescribe PrEP and potential PrEP users ("clients") from the following priority population groups who were selected because they have the highest rates of HIV acquisition and are in need

for HIV prevention services: 1) Gay, bisexual, and other men who have sex with men (hereafter MSM) subdivided by race/ethnicity 2) Black / African American heterosexual persons subdivided by biological sex 3) Transgender women 4) Persons who inject drugs.

This information collection activity is authorized under the Public Health Service Act, (42 USC 241) Section 301 (**Attachment 1**).

2. Purpose and Use of the Information Collection

The proposed information collection will include two separate discrete choice experiment (DCE) surveys: one for priority populations; and one for clinicians. The survey uses an experimental design to combine levels from each attribute into hypothetical product profiles and to pair profiles into choice tasks. The experimental design will be split into several 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.

The study design is comprised of a DCE and additional questions to directly elicit participant preferences and gather data on socioeconomic, behavioral, and attitudinal factors. Data collection will last approximately six months. Results from this experiment will be used to identify key factors for adoption and implementation of long-acting pre-exposure prophylaxis (LA-PrEP) products. The information collected will also be used to increase implementation efficiency by identifying strategies to support decision making and address potential challenges with early use of LA-PrEP products.

The study's target population includes clinical providers ages 18 and older who prescribe PrEP and the following priority population groups who were selected because they have the highest rates of HIV acquisition and are in need for HIV prevention services:

- Gay, bisexual, and other men who have sex with men (hereafter MSM) subdivided by race/ethnicity
  - Black / African American
  - Hispanic / Latino
  - White
- Black / African American heterosexual persons subdivided by biological sex:
  - Men
  - Women
- Transgender women
- Persons who inject drugs

To be eligible for the study, potential participants in each of the priority population groups must be 18 years of age and older, living without HIV, and meet the U.S. Public Health Service (USPHS) indications for offering PrEP as described in the 2021 USPHS Clinical Practice Guidelines.

The study sample will be recruited from organizations in cities with high numbers of annual HIV diagnoses within the 57 priority jurisdictions identified as part of the Ending the HIV Epidemic (EHE) initiative using the client and provider invitation emails (**Attachments 3 & 4**). Data collection will last approximately six months. Participants will be randomly assigned to a block when they are sent their unique DCE survey link and will only complete the set of choice tasks in that block. Throughout the study, we will closely monitor recruitment and data collection to ensure that screening criteria are being met, key demographic groups are adequately represented, and survey completion rates are acceptable. Participants will be given a $20 token of appreciation upon completion of the DCE. A Visa gift card will be sent electronically or mailed via the postal system based on the participant's choice.

The primary objectives of the study are:

1. To elicit preferences from potential LA-PrEP users ("clients") for LA-PrEP product and delivery program characteristics to understand what attributes maximize willingness to use LA-PrEP among people in need of HIV prevention methods.

2. To elicit preferences from PrEP providers for LA-PrEP product and delivery program characteristics to understand what attributes maximize willingness to prescribe LA-PrEP to people in need of HIV prevention methods.

3. Use of Improved Information Technology and Burden Reduction

This study will rely on web-based survey data collection to collect primary data to understand preferences for LA-PrEP products for HIV prevention among potential users and providers. Using an online survey allows the respondent to be candid with their responses. This increases accuracy of the data because respondents provide more honest responses than when other types of data collection methods are employed, especially when it is clear that the answers will remain private. In addition, using a survey will allow for more participants to respond in a cost-effective and timely manner. The self-administered, web-based survey permits greater expediency with respect to data processing and analysis (e.g., a number of back-end processing steps, including coding and data entry). Data are transmitted electronically, rather than by mail. These efficiencies save time due to the speed of data transmission, as well as receipt in a format suitable for analysis. An added benefit is increased data protection by limiting the amount of personally identifiable information (PII) collected from participants, reducing the risk of data security issues. Finally, as noted above, this technology permits respondents to complete the survey in privacy. The use of a more private data collection method makes reporting potentially embarrassing or stigmatizing behaviors (e.g., sexual behaviors and injection drug use) less threatening and enhances response validity and response rates.

4. Efforts to Identify Duplication and Use of Similar Information

CDC's effort to understand preferences for LA-PrEP products for HIV prevention among clients and providers, including product characteristics and other service delivery factors that may facilitate or hinder future uptake of these products is new. To date, there have been no in-depth research studies examining preferences between specific LA-PrEP

products that are currently available or likely to be available within the next few years, to identify strategies that support decision making and address potential use challenges early on. Eliciting preferences not only from potential LA-PrEP users but also providers of LA-PrEP products will allow an understanding of what attributes contributes to preferences, and the relative importance of each attribute, and how they differ by priority population group.

We carefully reviewed existing data sets and the literature to determine whether any of them are sufficiently similar or could be modified to address CDC's need for information on providers' and priority populations' preferences for different LA-PrEP products. The data sources that we examined for this purpose include the ongoing national surveillance system the National HIV Behavioral Surveillance System. We also reviewed the literature to determine what PrEP agents are in development or have been recently approved by the U.S. Food and Drug Administration (FDA), and what studies have been conducted on preferences for these products. We concluded that these sources do not include the information needed to elicit provider and clients' preferences for characteristics of LA-PrEP delivery programs. Other data sources monitor the safety and efficacy of LA-PrEP products, measure the barriers to uptake and continuation of daily oral PrEP products, assess preference among different sets of products without attention to delivery program features, or assess preferences for programs delivering daily oral PrEP only, and most studies focus only on preferences among MSM. None of these sources can be used to identify key factors for adoption of newly available LA-PrEP methods to inform implementation planning.

5. Impact on Small Businesses or Other Small Entities

This data collection will not involve small businesses. .

6. Consequences of Collecting the Information Less Frequently

Each respondent to this data collection will complete only one survey to ensure the participant burden is as low as possible. Without the information collection requested for this research study, it would be difficult to determine the preferences for LA-PrEP products for HIV prevention among clients and providers. Failure to collect these data could reduce the effectiveness or efficiency of CDC's programmatic efforts to increase uptake of LA-PrEP agents to help achieve the U.S. ending the HIV epidemic (EHE) goal of reducing incident HIV infections by 90% by 2030. Careful consideration has been given to the experimental study design and the intended audience. We believe the cross-sectional research design will provide sufficient data to detect product and service delivery characteristics the inform preferences for LA-PrEP products among potential users and providers.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-day Federal Register Notice was published in the Federal Register on March 1, 2022, vol. 87, No. 40, pp. 11445-11446 (see **Attachment** 2). No public comments were received.

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: jmungo@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

9. Explanation of Any Payment or Gift to Respondents

There is no incentive or gift for completing the screening survey. Respondents deemed eligible based on the screening survey (**Attachments 5 & 6**) are invited to take the main survey with the DCE. Respondents who complete the main survey (**Attachments 7 & 8**) will be given $20 visa gift card as a token of appreciation. The token of appreciation will be provided to survey respondents who complete the survey. The Visa gift card will be sent electronically or mailed via the postal system based on the participant's choice.

Organizations that assist with passive recruitment will be offered a token of appreciation in recognition of their time. Organizations who post flyers or send out information about the survey via email or social media will be sent a Visa gift card worth up to $50, depending on project budget. All organizations will receive the same amount. The gift card will be sent electronically or mailed via the postal system based on the organization's preference.

The tokens of appreciation are intended to encourage participation and convey appreciation for contributing to this important study and are comparable to tokens offered for most surveys of this type. A similar CDC study also provided $20 tokens of appreciation to interview participants.[19] Studies suggest that this token approach increases response rates and reduces costs. Numerous empirical studies have shown that tokens can significantly increase response rates in cross-sectional surveys [20,21]. HIV prevention research studies that recruit similar populations to ours have shown that tokens improve completion of online surveys. Hall and colleagues found that tokens improved online survey completion for behavioral HIV prevention research among MSM.[22] MSM participants were more likely to complete a 15-minute online HIV survey when they were given a $20 Amazon gift card in comparison to those who were not provided a token. Khosropour and Sullivan found that MSM who were offered a token of appreciate had increased likelihood of participating in a follow-up internet survey examining HIV behavioral risk factors.[23]

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The Privacy Officer for CDC / ATSDR has assessed this package for applicability of 5 U.S.C. § 552a and has determined that the Privacy Act does apply. The CDC Privacy Office reviewed and approved the Privacy Impact Assessment (PIA) form (**Attachment 10**).

PII Collection

As part of this study, RTI International, the contractor acting on behalf of CDC, is collecting and maintaining personally identifiable information (PII) about participants who provide informed consent for two purposes: to distribute the unique survey link (via email or SMS) to participants who are eligible and selected to participate, and to distribute incentives to those who complete the online survey. As part of the informed consent, participants are asked to provide the following PII: first and last name, email address or phone number to receive the link to the online survey, and email address or

mailing address to receive the incentive as either a virtual gift card or physical gift card. On the screener survey, participants are asked to provide information on their gender, race/ethnicity, HIV status, and age (to determine eligibility); thoughts and actions regarding HIV prevention; sexual and drug use behaviors; and interest in using PrEP. The main online survey does not collect any PII; however, the following non-PII is collected from participants: education level, employment status, insurance status, marital status, gender, race/ethnicity, zip code, HIV prevention behavior, experience with HIV prevention products, source for obtaining HIV prevention products, type and cost of HIV prevention products, thoughts and actions regarding HIV prevention, sexual and drug use behaviors, and interest in using PrEP.

No personally identifiable data will be shared with the CDC, any technical reports or publications will only include aggregate respondent data. The fully de-identified dataset will be stored by the National Archives and Records Administration (NARA). Prior to release, the investigators will consult with the CDC Informatics team to conduct a re-identification risk analysis to determine whether data can be publicly released without restriction. If necessary, we will apply statistical limitation techniques to prevent re-identification, such as suppressing small cell counts, generalizing geographic areas, grouping variables, top or bottom coding, or blurring data. If these techniques are not sufficient or would compromise the value of the dataset, CDC will release the dataset under a data sharing structure that would make it accessible only to particular parties under a special data-use agreement with CDC. Therefore, there is no impact of this study on individual respondents' privacy.

Data Minimization

The PII collected for this study is limited to the minimum necessary to achieve the authorized purpose and produce a valid study.

Data Management and Security

Study data will include the information collected on the online informed consent form, online screening form, and online main survey form. The RTI study team will verify that all data captured from the online surveys (including informed consent) have been recorded correctly by thoroughly checking the programmed survey instruments. In addition, test scripts will be run on the online survey instruments to ensure that test data match the data recorded using the online survey instrument. These data-quality steps will be conducted before administering the online survey instruments and collecting any data.

To protect our client's data, RTI implements National Institute of Standards and Technology (NIST) 800-53 controls within our Federal Information Processing Standards (FIPS)-Moderate Network and maintains compliance with the Federal Information Security Modernization Act (FISMA). We will use Voxco Online software installed on secure servers in our FIPS Moderate network to ensure secure data collection. All survey data will be identified by a participant identification number (PTID) and stored on secure, password-protected servers where only RTI study team members working on the project will have access to the files. Personal identifying information (PII) collected for distributing survey invitations and incentives will be stored at the same security level but separately from questionnaire responses and will only be accessible to the Programming

and Data Management Team. This PII will be destroyed by the end of the contract, as soon as it is no longer needed for study procedures. The datasets provided to the analysis team will be deidentified and will be structured to have one row for each respondent including all the information collected in the survey.

RTI will permit study-related monitoring, audits (including quality assurance audits), IRB/IEC review, and regulatory inspection(s), providing direct access to source data/documents.

At the end of the contract, RTI will transfer a deidentified study dataset and documentation to CDC via Secure Data Network (SDN), which requires use of a 128-bit encryption digital certificate for authentication. All PII will be removed, including study PTIDs that could be linked back to identifying information. The Programming and Data Management Task Leader, along with the Data Security Officer will produce all datasets, and the Data Quality and Delivery Quality Control Specialist and the PD will review them. We will conduct a test data export to provide the opportunity for feedback on the formatting of data and to ensure future successful transfers. Subsequently, there will be one final transfer of data and documentation.

Notice and Transparency

All participants are provided notice regarding the collection and use of the information they provide. The mechanism that will be used for notice or consent is called Consent to Participate Form (see **Attachments 5 & 6**) and will apprise respondents that participation is voluntary and that they need not answer any question that makes them feel uncomfortable or that they simply do not wish to answer. Specifically, when respondents access the survey, they must read and acknowledge an informed consent form that explains the study and their rights as a respondent providing information. The informed consent form notes that

> *"Many precautions have been taken to protect your information. We have procedures in place to limit who can connect you/your name to your answers. We will remove your name and any other information that could directly identify you from your survey responses. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your survey responses in a secure location. Only a few research staff from RTI International who are working on this study will know your name and your code number. If findings from this study are presented at scientific meetings or published, your name will not be used.*
>
> *This study has a Certificate of Confidentiality from the CDC. Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings"*

To affirm that consent is obtained, participants will be asked to check one of two boxes in the electronic survey, to indicate whether they agree to participate in the study or do not participate in the study.

Participation in this study is completely voluntary. The respondent may choose not to take part in the study or leave the study at any time without any consequences. The voluntary nature of the information collection is described in the introductory section of the consent to participate form (**Attachments 5 & 6**) and the survey (**Attachments 7 & 8**).

Although unlikely, there is also a potential risk of disclosure of individuals' responses. Many efforts will be made to protect the information, but absolute confidentiality cannot be guaranteed. At the start of the screening form and the main survey, participants will be reminded that the survey questions cover sensitive topics and advised to complete the survey in a location where no one else can see their responses. We will also recommend that they use headphones to listen to the video content, if possible.

Third-Party Accountability

RTI is held accountable for complying with privacy and security procedures (including reporting data breaches) by its contract with CDC, which requires that RTI complies with 45 CFR part 46 and with the contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. RTI agrees to provide certification that the Institutional Review Board has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance. RTI also has an established protocol in place for privacy breaches that includes the Project Director notifying RTI's IRB and CDC. In addition, RTI has an Incident Response and Breach Notification Plan in place that activates first responders when an incident occurs, and, as required by law, a breach notification policy with respect to protected health information. RTI subcontractors are accountable via contract terms for all data that it handles, uses, shares and maintains as part of this survey.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

All procedures have been developed in accordance with federal, state, and local guidelines to ensure that the rights and privacy of participants are protected and maintained. The authorized Institutional Review Board (IRB) of RTI International reviewed and approved all instruments, informed consent materials, and data collection and management procedures (see RTI IRB approval notice in **Attachment 9**).

Sensitive Questions

It is necessary to ask some questions that participants may consider sensitive to is to understand preferences for long-acting pre-exposure prophylaxis (LA-PrEP) products for HIV prevention among potential users and providers. These questions are essential to the objectives of this information collection. Questions concerning sexual and drug use behaviors that determine risk of HIV acquisition, HIV prevention product characteristics and other service delivery factors that may facilitate or hinder future uptake of these

products and some demographic information, such as race, ethnicity, and income, could be considered sensitive as well. To address concerns about potential inadvertent disclosure of sensitive information, respondents are fully informed of the applicable privacy safeguards. The screener and the consent to participate form (**Attachments 5 & 6**) informs participants that potentially sensitive questions will be asked in the survey. The research employs several procedures to minimize potential negative reactions to potentially sensitive questions, including the following:

- Respondents are informed that they can skip any question that makes them uncomfortable or that they do not wish to answer.
- Web surveys are self-administered and maximize respondent privacy without the need to verbalize responses.
- Participants are provided with a toll-free phone number to call RTI's IRB Office if they have a question or concern about a sensitive issue.

Finally, as with all information collected, these data will be presented with all identifiers removed. This safeguard encourages candid responses to questions that may be considered sensitive by a portion of respondents.

12. Estimates of Annualized Burden Hours and Costs

Annualized Hour Burden Estimate

The study sample will be recruited from cities with high numbers of annual HIV diagnoses within the 57 priority jurisdictions identified as part of the Ending the HIV Epidemic (EHE) initiative. Data collection will last approximately six months. Participants will be randomly assigned to a block when they are sent their unique DCE survey link and will only complete the set of choice tasks in that block. Throughout the study, we will closely monitor recruitment and data collection to ensure that screening criteria are being met, key demographic groups are adequately represented, and survey completion rates are acceptable.

Participation is voluntary. For this study, we intend to screen 8,050 clients (**Attachment 5**) and 1,150 providers (**Attachment 6**) and enroll 1,610 clients (**Attachment 7**) and 230 providers (**Attachment 8**). We estimate that approximately 15% of enrolled participants will be removed from the analysis due to fraud or incomplete data, resulting in a final analysis sample size of 1,600 participants (1400 clients and 200 providers). At 25 minutes per survey for clients and 20 minutes per survey for providers, and 10 minutes per combined screener and consent, this would provide us with a total of 2,282 annualized burden hours.

Table 1. Estimated Annualized Burden Hours

(Type of) Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden (in Hours)
Potential LA-	**Client Screening**	8,050	1	10/60	1,342

PrEP users or Clients	**Survey & Consent Form (Attachment 5)**				
	C4P Client DCE Survey (Attachment 7)	1,610	1	25/60	671
Clinical providers who prescribe PrEP, in the United States	**Provider Screening Survey & Consent Form (Attachment 6)**	1,150	1	10/60	192
	C4P Provider DCE Survey (Attachment 8)	230	1	20/60	77
Total					2,282

Annualized Cost Burden Estimate

Respondents participate on a purely voluntary basis and there are no start-up or maintenance costs. According to the U.S. Department of Labor (DOL) Bureau of Labor Statistics as of May 2021,[24] the national average hourly wage is $28.01[25]. Thus, assuming an average hourly wage of $28.01, the estimated annualized cost to participants will be $63,869. The estimated value of respondents' time for participating in the information collection is summarized in Table 2.

Table 2. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Total Burden Hours	Hourly Wage Rate	Total Respondents Cost
Potential LA-PrEP users or Clients	**Client Screening Survey & Consent Form**	1342	$28.01	$37,539
	C4P Client DCE Survey	671	$28.01	$18,795
Clinical providers who prescribe PrEP, in the United States	**Provider Screening Survey & Consent Form**	192	$28.01	$5,378
	C4P Provider DCE Survey	77	$28.01	$2,157
Total				$63,869

13. Estimates of Other Total Annual Costs Burden to Respondents or Recordkeepers

There are no other costs to respondents and no capital, start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Government

The annualized cost to the government is $646,424. This information collection is funded through a contract with RTI. There are additional contract-funded activities occurring before and after this data collection that include project planning and data analysis. Other activities outside this data collection include coordination with CDC; research plan development; instrument development; reporting; review of survey protocols by RTI's IRB; and progress reporting and project management. This information collection is projected to occur from September 2022 through March 2023.

Table 3. Itemized Cost to the Federal Government

Government Personnel	Time Commitment	Average Annual Salary	Total
Dawn K. Smith (GS 14/10)	0.10	**$152,998**	$15,300
Damian Denson (GS 13/8)	0.05	**$122,832**	$6,140
Karen Hoover (GS 14/10)	0.02	**$152,998**	$3,060
Latasha Sims (GS 13/6)	0.05	**$116,193**	$5,810
		Total Salary Costs	**$30,310**
		Contract Cost	$616,114
		Total	**$646,424**

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Data from this information collection will be used to estimate preferences for long-acting pre-exposure prophylaxis (LA-PrEP) products for HIV prevention among potential users and providers. These estimates will take the form of self-reported product preferences and a series of discrete choice questions where they will be asked to choose between PrEP options. Following the DCE, participants will be asked more direct questions about factors that could influence their choice of LA-PrEP products and delivery features. The survey questionnaires will focus on the following primary and secondary endpoints:

- Relative preference weight estimates for all attribute levels of LA-PrEP products included in the DCE, estimated separately for clients and providers.
- Conditional relative importance estimates for all attributes in the DCE, computed separately for clients and providers.
- Relative preference weight estimate for the neither option and proportion of clients and providers not choosing one of the presented LA-PrEP options.
- Acceptability rating scores for products and specific aspects of LA-PrEP and product rankings, overall and by subgroup.

Exploratory endpoints will include:

- Differences in preference weight estimates and direct elicitation questions salient to preferences by sociodemographic, behavioral, and attitudinal factors within the priority populations and among providers.

Traditional power calculations do not directly translate to preference surveys like DCEs because power is impacted by several factors that are unknown *a priori*.[26] We base our sample size recommendation on Orme's Rule,[27] 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. Data from respondents who complete the survey too quickly or too slowly (with cutoffs determined based on the final DCE design) will also be excluded from analysis sample (see section 5.4.2). 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.

The reporting and dissemination to CDC will consist of these primary components: (1) a comprehensive report summarizing findings from this information collection; and (3) at least two peer-reviewed journal articles that document the results of the provider and client DCEs. The project time schedule is summarized in Table 4.

Table 4. Project Schedule

Project Activity	Time Schedule
Complete web survey programming	Prior to OMB approval
Identify and confirm recruitment sources for each target population	Prior to OMB approval
Initiate online recruitment and data collection	Within 1 month of OMB approval
Complete online data collection	6 months after OMB approval
Preparation of analytic data file	7 months after OMB approval
Data analysis	8 months after OMB approval
Report writing and dissemination	9 months after OMB approval
Transfer dataset and documentation to CDC	1 year after OMB approval

Final report	1 year after OMB approval
Drafting of up to 2 primary manuscripts	1 year after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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