Qualitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta, Houston, and Miami

Generic Information Collection Request under OMB #0920-1091

Section A: Supporting Statement

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- **Goals of the study:** The goal of the study is to advance understanding of consumer preferences and opinions about emerging biomedical products (PrEP or pre-exposure prophylaxis) designed to prevent HIV transmission among men who have sex with men (MSM).

- **Intended use:** The primary target audiences for the proposed study findings are MSM, the CDC, health departments, and other HIV prevention organizations that serve MSM. Findings will provide an improved understanding about the HIV prevention products that MSM prefer. Knowledge about preferences may influence development and availability of HIV prevention products that MSM prefer, thereby increasing frequency of use and resulting in fewer opportunities for HIV transmission.

- **Methods to be used to collect data:** Data will be collected through the screening process as well as through in-depth interviews (IDIs), focus groups and brief quantitative surveys.

- **The subpopulation to be studied:** The sample will consist of 120 MSM at high risk of HIV infection residing in the Atlanta, Houston, and Miami metropolitan areas. Of these 120, 60 will be men who are currently using PrEP and 60 will be men who are aware of PrEP but not currently using PrEP. Participants will be evenly grouped to receive the IDI (n=60) or to participate in a focus group (n=60).

- **How data will be analyzed:** We will conduct thematic coding of the 120 IDI and focus group transcripts using computer-assisted qualitative data analysis software. In addition, we will describe the sample's demographic characteristics and preliminary PrEP experiences using statistical software.

Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV/AIDS Prevention, (DHAP) requests OMB approval for 1 year for a qualitative, extramural research study entitled, "Qualitative research to understand consumer opinions and preferences for emerging HIV prevention products among MSM in Atlanta, Houston, and Miami" under the Using Qualitative Methods to Understand Issues in HIV Prevention, Care and Treatment in the United States Generic Clearance (OMB #0920-1091, expires 09/30/2021). CDC will sponsor this data collection activity. Data collection will be carried out by the CDC's contractor, Research Support Services, in conjunction with its subcontracting partners, University of Nevada Las Vegas, and IMPAQ International. Data collection (in-depth interviews and focus groups) will convene when it is permitted by the local and state authorities. Respondents and staff will be appropriately distanced (at least six feet), and all will be required to wear face masks. We will adhere to the CDC guidelines for prevention of COVID-19 at the time that CDC approves in-person (small group) research activities.

This information is collected under the authority of the Public Health Service Act, Section 301, "Research and Investigation," (42 U.S.C. 241); and Sections 304, 306 and 308(d) which discuss

authority to maintain data and provide assurances of privacy for health research and related activities (42 U.S.C. 242 b, k, and m(d)). This information is also being collected in conjunction with the provisions of the Government Paperwork Elimination Act and the Paperwork Reduction Act (PRA). This information will only be used by the Centers for Disease Control and Prevention (CDC) staff to assess MSM preferences and opinions about new HIV prevention products (PrEP or pre-exposure prophylaxis) products currently undergoing, or being considered for, commercial development.

This project will assess consumer preferences and opinions regarding emerging biomedical products designed to prevent HIV infection among high-risk men who have sex with men (MSM) living in the Atlanta, Houston, and Miami metropolitan areas. This project will enable us to learn about the willingness of MSM to consider future prevention options for HIV. This study is timely because even though oral PrEP is efficacious as an HIV prevention option, the uptake is low. Additionally, new products are in development; therefore, it is critical to understand what barriers and facilitators exist that would influence consideration for uptake of emerging biomedical prevention options among MSM.

A proven effective HIV biomedical prevention method is the daily oral pill (tenofovir emtricitabine, brand name Truvada), used for pre-exposure prophylaxis (PrEP).[1] Despite the high efficacy (92% reduction in HIV acquisition)[2] the acceptability of PrEP among MSM is not high in some geographic locations and among some demographic groups.[3] Uptake of PrEP in the southern U.S. overall has been lagging. In 2016, the northeastern U.S. had twice the rate of PrEP use (47.4 per 100,000) as compared to the southern U.S. (22.6 per 100,000).[4] Some studies indicate that specific cities have alarmingly low rates of PrEP uptake (e.g., the estimate for Atlanta is 2%).[5,6] Among PrEP users, only 11% are African American and 13% are Hispanic/Latino despite these populations making up 43% and 26% of those newly diagnosed with HIV in the U.S. respectively.[7] In a recent national study of MSM in the U.S., most (93%) respondents agreed that having to take the PrEP pill everyday was a barrier to PrEP uptake. Of this, 74% indicated that they would take PrEP episodically or for short periods of anticipated increased risk.[8]

In the recent state of the union address, President Trump announced a new public health initiative, "Ending the HIV Epidemic: A Plan for America".[9] One of the four key strategies to end the HIV epidemic is protecting individuals at risk for HIV using proven prevention approaches, including increasing PrEP use among high-risk groups.[9] Additionally, part of the vision for the National HIV/AIDS Strategy (NHAS) is that the U.S. will become a place where new HIV infections are rare.[10] Emerging biomedical HIV prevention products may contribute substantially to reducing HIV incidence among MSM.[11] With the low uptake rates of daily oral PrEP and associated barriers to use, research is needed on the opinions about and preferences for emerging prevention products among sexually active, HIV-uninfected MSM – particularly different subgroups of MSM (e.g., by current users and non-users of daily oral PrEP or race/ethnicity).[12] To reduce HIV burden among MSM, it is important to identify factors that may facilitate or hinder the acceptability and adoptability of emerging biomedical products.

2. Purpose and Use of the Information Collection

There is limited information about how different populations may perceive PrEP and other biomedical technologies.[12] The purpose of this study is to advance understanding of consumer preferences and opinions about emerging biomedical products designed to prevent HIV infection among MSM who (a) have heard of PrEP but are not using it to assess whether the emerging products would lead them to be more inclined to adopt PrEP or (b) those who are currently using daily oral PrEP to assess whether the emerging products would be more or less favorable options as compared to their current PrEP regimen.

MSM who are unfamiliar with PrEP are ineligible to participate. This study is not meant to be an introduction to PrEP as consumer preferences and opinions of the biomedical tool to those who are PrEP naïve is beyond the scope of this study. This study is an advanced discussion on usability and will explore preferences and opinions about specific PrEP delivery products currently in development (**Attachments 2a-f, 7, and 8**).

The project will help address two NHAS goals: preventing new infections (through consumer acceptability of new prevention technologies), and reducing HIV-related disparities and health inequities (by focusing eligibility and data collection among MSM in Atlanta, Houston, and Miami, particularly MSM of color) [10]. Additionally, this study will build on data collected from a previous qualitative study. The 2015 Pulse study asked 150 HIV-uninfected black/African American and Hispanic/Latino MSM about their PrEP knowledge. Findings suggest just over half of the sample were aware of PrEP and had concerns that it promoted promiscuity. Black/African American MSM were more likely to be concerned about side effects, access, and cost, but were also more likely to think of PrEP as an insurance policy against HIV. Hispanic/Latino MSM were more likely to believe they did not need PrEP and to express their dislike of taking pills as a barrier to PrEP use [13]. The previous study explored general knowledge and perceptions about PrEP; this study will explore preferences and opinions about specific PrEP delivery products currently in development.

The primary target audiences for the proposed study findings are MSM, the CDC, health departments, and other HIV prevention organizations that serve MSM. Findings will provide an improved understanding about the HIV prevention products that MSM prefer. This knowledge is important, as knowing more about preferences and acceptability may influence the development and availability of products and improve client-centered counseling about PrEP. Increased acceptability may result in more frequent use of prevention products and thereby a reduction of HIV transmission.

Exhibit 2.1: Overview of Key Variables

Key Topics	Emerging Prevention Products
• Sociodemographic variables • PrEP use • PrEP knowledge • Opinions regarding emerging PrEP products	• Weekly pill • Sexual episode-based pill • Suppositories • Anal douching • Injections • Implants

3. Use of Improved Information Technology and Burden Reduction

The contracted research team will recruit and screen potential participants by telephone or in-person. The contracting team will conduct small (n=5) focus groups and one-on-one interviews at a time and location that is publicly accessible and convenient for the participants. Telephone or visual remote interviews or focus group attendance (utilizing tools such as Skype) are not good vehicles for developing rapport between the interviewer and participant or between focus group participants, especially when discussing topics that may be viewed as sensitive (e.g. disease status and risk behaviors). Body language and facial cues are critical to interviewers to help them understand where

additional questions may be needed and to focus group guides to help them steer group discussions. Telephone or web participation limits a researcher's ability to read and respond appropriately to participants. Thus, the research team will conduct the interviews and focus groups in person.

Participants will be informed of their privacy and confidentiality rights and protections prior to participation. In addition, they will be asked to provide a signed informed consent prior to the interview or focus group **(Attachment 3a-b)**. After receiving permission from the participant, the contracting team will audio-record the focus groups and interviews and transcribe the recordings shortly after the interview. This limits the burden on the participant (no additional burden after completing the interview or focus group) and allows the interviewer and focus group guide to focus on building and maintaining rapport with the participants.

4. Efforts to Identify Duplication and Use of Similar Information

There is limited research of MSM's perception of PrEP and emerging biomedical products.[12]This study is an advanced discussion on usability and will explore preferences and opinions about specific PrEP delivery products currently in development. Past studies usually focus on one emerging biomedical product, whereas, our studies focuses on the acceptability of six. There was a study that evaluated the acceptability of the skin injection, but it took place in New York and San Francisco.[14] Yet, over half of all new U.S. HIV diagnoses in 2016 occurred in the South[15] and in Atlanta, GA, for instance, 70% of people living with HIV were African American and 7% were Hispanic/Latino.[16] Therefore, it is critical to understand what barriers and facilitators exist that would influence consideration for uptake of emerging biomedical prevention options among this unique population of MSM residing in the Southern U.S. Our evaluation indicates the collection of this new primary data is unique. There would be no reason for another Federal Agency to evaluate these research questions.

5. Impact on Small Businesses or Other Small Entities

This information collection does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This information collection will provide the qualitative data needed by the developers of these emerging biomedical products as well as by HIV prevention researchers, health departments and other HIV prevention organizations to understand barriers and facilitators among MSM for potential uptake of emerging prevention products. Information from this study can help guide the development and prioritization of emerging biomedical products. If this study were not conducted, it would not be possible to form an understanding of the acceptability of these emerging biomedical products in the South, where HIV prevalence is high. The length of data collection is 6 months and data will only be collected once.

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

This data collection effort does not involve any special circumstances.

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

A 60-day FRN notice to solicit public comments was published for the Generic umbrella collection (0920-1091) in the Federal Register on 03/13/2018, Volume 83, Number 49, Page Number 10853-10855. No public comments were received.

In addition, University of Nevada Las Vegas, Research Support Services, and IMPAQ International were consulted for the development of this study. There were no unresolved issues associated with the consultation process. Aside from the official 60-day public comment period for the Generic data collection, there were no other public contacts or opportunities for public comment on this information collection.

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9. Explanation of Any Payment or Gift to Participants

Respondents will receive $40 in the form cash or a gift card as a token of appreciation for completion of the survey and in-depth interview (which will be a total of 60 minutes). Respondents who participate in focus groups and survey will receive $60 in the form of cash or gift card, due to the focus groups being longer (90 minutes). Offering tokens of appreciation helps recruit historically underrepresented and stigmatized groups, [17] such as African American and Latino MSM. A recent study of recruitment and retention found it difficult to obtain information from participants because many were reluctant to provide their names and contact information because of concerns about being seen giving these personal details to the researchers. In this study, offering a token of appreciation improved participation.[18] Further, a meta-analysis found that studies using tokens of appreciation yielded an average increase in response rates of 19.1 percentage points, representing a 65% average increase in response.[19] In light of these findings, we hope to enhance our response rate in populations with the greatest need.

Forty U.S. dollars is a generally approved amount for OMB-approved qualitative interviews (such as the Insight OMB#0920-0840-14PA, LEAP OMB#0920-0840-15AQL, and LEAP2 OMB#0920-1091-

16AQA studies) and is not considered a coercive amount for participation. The $60 token of appreciation is similar to that of recently approved Prepare for PrEP (P4P) study (OMB #0920-17AZI) that offers the same amount for a 90-minute in-depth interview and behavioral assessment among MSM in Atlanta.

In light of the President's new public health initiative, "Ending the HIV Epidemic: A Plan for America", a $40-$60 token of appreciation is also justified by public health need. To prevent disease spread and progression, product developers, researchers and public health professionals need to know the attitudes and perceptions of populations at-risk of contracting HIV infection and their desirable delivery methods for HIV pre-exposure prophylaxis. MSM in the southern U.S., especially racial and ethnic minorities, are an underrepresented and highly affected community who would be incentivized by a token of appreciation for sharing sensitive information on a personal and stigmatizing topic. The token of appreciation is for providing valuable insight directly from communities and populations that are greatly affected by the HIV epidemic.

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

The Privacy Officer for CDC/ASTDR has reviewed this ICR and determined the Privacy Act applies to this collection of information. However, participant names and contact information will not be transmitted to the CDC. CDC has completed a Privacy Impact Assessment of the data system used by the study contractor team (**Attachment 6**).

The contractor, Research Support Services, UNLV and IMPAQ, will be responsible for collecting all data for this study. We will inform participants that their responses will be kept private to the extent permitted by the law. All participants interviewed will be informed that the information collected will not be attributable directly to the participant and will only be discussed among members of the research team. Terms of the CDC contract authorizing data collection require the contractor to maintain the privacy of all information collected. Accordingly, individuals' data will be kept private and protected to the extent permitted by law. This information collection is covered under the Privacy Act system of records notice 09-20-0136, "Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC", which enables CDC officials to collect information to better understand disease patterns in the United States, develop programs for prevention and control of health problems, and communicate new knowledge to the health community.

Given this information collection is to learn about consumer preferences and opinions regarding emerging biomedical products designed to prevent HIV infection among men who have sex with men (MSM), we are sensitive to the need to protect personal health information (PHI) as well as personally identifiable information (PII), including name and contact information. To ensure that participants' PHI and PII is protected, we will take several measures to separate name and contact information from study-related data. All researchers with access to PHI and PII will be required to read and sign a "Rules of Behavior." Contact information collected for the purposes of recruitment (i.e., name, telephone number, and email address) will be collected via paper form only, will be used only for the purpose of scheduling interviews. All participants will be assigned a unique study identification number, which will be the only link between the PHI and PII contained on the contact information sheet and the interview responses. Both contact information and interview responses will be stored securely in locked cabinets, separately from one another. All research documents and audio recordings will be kept in a locked file cabinet in a secure place. The participant interview transcript will be kept in a password-protected file and only authorized staff will be able to access the information. If any personal characteristics are accidently

disclosed by the participant during the interview, that information will be fully redacted from the interview transcripts and data sets used for analysis. We will train researchers who play a role in data collection and analysis in proper procedures for data handling. A limited number of key staffs authorized by the contractors will have access to personal identifiers, and this information will be destroyed as quickly as possible after it no longer is required for study purposes, no later than the end of the contract. The contractors will be prepared to describe these procedures in full detail and to answer any related questions raised by interviewees. CDC will never have access to any participant names or contact information.

In conjunction with the data policy, members of Contractor project staff are required to:

- Comply with a privacy pledge and security manual procedures to prevent improper disclosure, use, or alteration of private information. Staff may be subjected to disciplinary and/or civil or criminal actions for knowingly and willfully allowing the improper disclosure or unauthorized use of information.
- Access information only on a need-to-know basis when necessary in the performance of assigned duties.
- Notify their supervisor, the project director, and the organizational security officer if information has either been disclosed to an unauthorized individual, used in an improper manner, or altered in an improper manner.
- Report immediately to both the project director and the organizational security officer all contacts and inquiries concerning information from unauthorized staff and non-research team personnel.

The security procedures implemented by project staff cover all aspects of data handling for hard copy and electronic data. Transcripts of interviews (stripped of personal identifying information) will be stored on encrypted flash drives. The contractor will investigate immediately if any item is delayed or lost. When not in use, all completed hardcopy documents will be stored in locked file cabinets or locked storage rooms. Unless otherwise required by CDC, these documents will be destroyed when no longer needed for the project.

Public access to the data will be provided at the completion of the study and after the dissemination of the main outcome findings. Any data made publicly available after the completion of the study will be de-identified and will not be linked to participant names or contact information (**Attachment 5**).

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

IRB Approval

This study has been approved by the CDC IRB (**Attachment 4**).

Sensitive Questions

This study aims to learn about consumer preferences and opinions regarding emerging biomedical products designed to prevent HIV infection among MSM. As such, our information collection involves measuring sensitive information about sexual health and prevention practices. All contracting staff will be trained to provide participants with city-specific contact information for HIV and mental health care organizations, as needed. We will inform all participants that they may skip any question or stop participation at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. **Estimated Annualized Burden Hours**

Exhibit 12.2: Estimated Annualized Burden Hours

Type of Participant	Form Name	No. of Participants	No. of Responses Per Participant	Average Burden Per Response (in Hours)	Total Burden Hours
General Public-Adults	Screener (Att. 2a)	240	1	10/60	40
General Public-Adults	Contact Information Form (Att. 2b)	120	1	5/60	10
General Public - Adults	In-Depth Interview Guide (Att. 2c)	60	1	1	60
General Public - Adults	Focus Group Guide (Att. 2d)	60	1	1.5	90
General Public - Adults	Survey on PrEP (Att. 2e)	60	1	10/60	10
General Public – Adults	Survey not on PrEP (Att. 2f)	60	1	10/60	10
				Total	**220**

12B. **Estimated Annualized Burden Costs**

The annualized costs to the participants are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May 2018 (https://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rate for the general public for the purpose of this GenIC request. The total estimated cost of the burden to participants is approximately $5495.60. This cost represents the total burden hours of general participants multiplied by the average hourly wage rate ($24.98).

Exhibit 12.3: Estimated Annualized Burden Costs

Type of Participant	Form Name	Total Burden Hours	Hourly Wage Rate	Total Participant Costs
General Public-Adults	Screener (Att. 2a)	40	$24.98	$999.20
General Public-Adults	Contact Information Form (Att. 2b)	10	$24.98	$249.80
General Public-Adults	In-Depth Interview Guide (Att. 2c)	60	$24.98	$1498.80
General Public-Adults	Focus Group Guide (Att. 2d)	90	$24.98	$2248.20
General Public-Adults	Survey on PrEP (Att. 2e)	10	$24.98	$249.80
General Public-Adults	Survey not on PrEP (Att. 2f)	10	$24.98	$249.80
				Total $5495.60

13. Estimates of Other Total Annual Cost Burden to Participants and Record Keepers

There are no other costs to participants for participating in this survey.

14. Annualized Cost to the Federal Government

The annualized cost to the government is $651,072. Direct costs include the salaries of CDC staff. The contract cost is $554,614.

Exhibit 14.4: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (GS-13 0.10 FTE)	$11,301
	CDC Contracting Officer (GS-13, 0.30 FTE)	$27,985
	CDC Contracting Officer (GS-13, 0.30 FTE)	$30,238
	CDC Contracting Officer (GS-15, 0.10 FTE)	$17,944
	CDC Scientist (GS-12, 0.10 FTE)	$8,990
	Subtotal, Direct Costs	**$96,458**
Contract Costs	**Annual Contract Costs (RSS, #200-2013-57341)**	**$** 554,614
	TOTAL COST TO THE GOVERNMENT	**$ 651,072**

15. Explanation for Program Changes or Adjustments

This is a new GenIC information collection request (ICR).

16. Plans for Tabulation and Publication and Project Time Schedule

Tabulation will include descriptive characteristics of participants collected during screening (e.g., age, race/ethnicity, job category). Data collection will occur between March and August 2020, analyses will be carried out in September – February 2021, and the final data set and report will be submitted March 2021. The project timeline is detailed in exhibit 16.1.

Exhibit 16.5: Project Time Schedule

Activity	Time Schedule
Develop data collection tools, sampling and data plans, study protocol	September 2018 – December 2019
OMB Submission	January 2020
Recruitment	1-6 months after OMB approval (anticipated March – August 2020)
Data Collection	1-6 months after OMB approval

	(anticipated March – August 2020)
Data analysis finalized and report drafted	7-12 months after OMB approval (anticipated Sept 2020 – Feb 2020)
Final data set and final report submitted to CDC	13 months after OMB approval (anticipated March 2021)

In compliance with the CDC policy on data management and access, we will develop a final, de-identified (names and contact information will be removed) qualitative database for this study along with the corresponding data documentation, which will be made publicly available within 30 months of the end of data collection.

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

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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