"Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers"

OMB No. 0920-New

Supporting Statement A

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Goal of the study: To deepen our understanding of providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their practices generally as well with populations that have been largely overlooked (e.g., transgender individuals); and how to develop new or enrich existing provider materials to make them more informative, appealing, and usable.

Intended use of the resulting data: CDC can revise and/or develop timely, relevant, clear, and engaging materials to support patient-provider communication.

Methods to be used to collect data: One time in-depth interviews accompanied by a computer-assisted personal interview.

The subpopulation to be studied: Physicians, physician assistants, and nurses who work in primary care, internal medicine, and infectious disease clinics.

How data will be analyzed: Descriptive analyses and thematic or grounded theory analysis of qualitative data.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's Division of HIV/AIDS Prevention, (DHAP) requests a 3-year OMB approval for a formative non-research study entitled, "Formative Research to Develop HIV Social Marketing Campaigns for Healthcare Providers" to support CDC's efforts to develop and refine materials for a social marketing campaign. The purpose of this study is to conduct in-depth interviews with physicians, physician assistants, and nurses who work in primary care, internal medicine, and infectious disease clinics (hereafter, "health care providers") to inform the development of provider-focused social marketing campaigns. The study will consist of a series of in-depth interviews with 600 health care providers in cities with high HIV prevalence. Participants will be recruited from areas with high HIV/AIDS prevalence and incidence, such as New York, NY; Miami, FL; Baton Rouge and New Orleans, LA; and Baltimore, MD.

According to recent estimates, approximately 1.2 million people are living with HIV in the United States. Centers for Disease Control and Prevention (CDC) HIV incidence rates indicate that more than 48,000 people were infected with HIV in 2009 (Prejean et al., 2011). Numerous social, economic, and demographic factors—such as stigma, discrimination, income, education, and geographic region—affect an individual's risk for HIV. Men who have sex with men (MSM), African Americans, Hispanics/Latinos, and transgender communities have higher incidence rates than other populations (CDC, 2013; CDC, 2015).

In 2003, a number of federal agencies, led by the CDC, released a set of recommendations for incorporating HIV prevention in the medical care of persons living with HIV (CDC, 2003). These recommendations are for all persons who provide medical care for HIV-infected persons (e.g. physicians, nurse practitioners, nurses, and physician assistants) and also may be useful to those who deliver prevention messages, such as case managers, social workers, and health educators. This guidance was followed by the release of updated recommendations for HIV counseling and testing in healthcare settings in 2006 (CDC, 2006). As the HIV prevention and treatment landscape evolves, CDC continues to develop new and revised guidance for testing, treatment, and other emerging prevention strategies.

- In May 2014, CDC published guidelines for health care providers on pre-exposure prophylaxis (PrEP). The guidelines provide criteria for determining a person's HIV risk and indications for PrEP use; require that patients receive HIV testing to confirm negative status before starting PrEP; underscore the importance of counseling about adherence and HIV risk reduction, including encouraging condom use for additional protection; recommend regular monitoring of HIV infection status, side effects, adherence, and sexual or injection-risk behaviors; and include a supplement with additional provider materials and tools for use when prescribing PrEP.

- Released in December 2014, the "Recommendations for HIV prevention with adults and adolescents with HIV in the United States, 2014" update and expand on the 2003 recommendations to address the growing number and greater longevity of persons living with HIV in the United States, the availability of a larger set of effective clinical approaches to reduce transmission, and greater experience with promoting adoption of these clinical approaches at an individual or population level. The new recommendations

focus on anti-retroviral therapy (ART) initiation and adherence, retaining HIV-infected patients in care, and reducing HIV transmission by helping patients modify risky sexual behaviors.

The chronic disease literature documents the association between positive patient-provider communication and pro-health behavior (Rubin et al., 2006; Stryker et al., 2010; Garcia-Perez et al., 2013). Yet, less is known about the benefits of patient-provider communication on behavior change among people at risk for or living with HIV. For example, although health care providers may be concerned about their patients' sexual risk factors, studies suggest that patient-provider communication about risk reduction is uncommon, and that when discussions occur, they are often brief (Laws et al., 2011; Morin et al., 2004; Grodensky et al., 2008). Barriers to such discussions include providers' discomfort with the topic, lack of relevant skills, and limited time and competing demand among other things (Drainoni et al., 2009).

As part of *Act Against AIDS (AAA)*, a 5-year communication campaign to address complacency about HIV and AIDS in the United States, CDC has developed four campaigns targeted to health care providers:

- ***HIV Screening. Standard Care.*** gives primary care providers new tools to help ensure all patients are tested for HIV at least once in their life.
- ***Prevention is Care.*** encourages health care providers who treat patients with HIV to screen them for risky transmission behaviors and reiterate to HIV-infected patients the importance of protecting themselves and others by reducing risky behaviors.
- ***One Test. Two Lives.*** encourages health care providers to test pregnant women for HIV infection and help reduce the number of infants born with HIV.
- ***HIV Treatment Works*** encourages people living with HIV to get in care, stay in care, and live well.

The materials developed for these campaigns have made great strides in addressing health care providers' information needs. More research is needed, however, to deepen our understanding of providers' interpretation and understanding of existing and emergent HIV prevention science; how providers use guidance or evidence-based approaches in their practices generally as well with populations that have been largely overlooked (e.g., transgender individuals); and how to develop new or enrich existing provider materials to make them more informative, appealing, and usable. The information gathered through this data collection will allow CDC to develop timely, relevant, clear, and engaging materials to support patient-provider communications related to HIV prevention. For this study, CDC will oversee the data collection to be carried out by a contractor, assist in interpreting research findings, and spearhead dissemination activities.

This study is authorized under U.S. Federal Code, 42 USC 241, Section 301 of the Public Health Service Act (see **Attachment 1**).

2. Purpose and Use of the Information Collection

The purpose of this study is to conduct semi-structured, in-person, in-depth interviews with health care providers to inform the development of health-care provider-focused social marketing campaign materials. A contractor will conduct the interviews. We will use the interview results to develop, refine, and pretest campaign concepts, messages, and materials. We

will interview each participant only once and will develop and refine all campaign materials through the one-time interviews. The data collection will provide a deeper understanding of participants' information needs.

Key research questions for this formative research are presented in **Exhibit A.2.1**. The brief web-based survey is shown in **Attachment 3** and the discussion guides are shown in **Attachments 4-7**.

Exhibit A.2.1. Research Questions

1. What are providers' current practices for HIV testing, behavioral screening, partner notification, primary and secondary prevention, retaining HIV positive patients in care and promoting ART adherence, prescribing PrEP, and working with transgender populations?
2. What are providers' knowledge, attitudes and beliefs about current recommendations for HIV testing, behavioral screening, and prevention strategies (e.g., partner notification, PrEP)?
3. What are providers' perceived and actual barriers to implementing guidelines and recommendations?
4. What types of materials do providers need in order to test for HIV, screen for different behaviors, retain HIV positive patients in care and promote ART adherence, prescribe PrEP, and work with transgender populations?
5. What are providers' initial reactions to campaign materials (e.g., visual appeal, format, design, content, usefulness, credibility)?
6. What are providers' preferred channels for obtaining new information on guidelines or practices?
7. To what extent are providers interested in provider resources and patient education materials?

3. Use of Improved Information Technology and Burden Reduction

Where possible and upon participant consent, we will audiotape the interviews to capture all information and assist with report preparation. Our data collection requires that we employ qualitative research methods through the use of one-time, in-person, in-depth interviews. The responses from the participants are as important as the interviewers' observation of the participant and the overall interview. The qualitative data collection will be supported by quantitative data collected through a brief web-based survey. Use of web-based surveys reduces respondent burden by automating "skip" instructions rather than asking participants to interpret and implement the instructions themselves. This approach is less cognitively demanding and reduces the amount of time it will take participants to complete the survey. In addition, the survey will automatically place results in a format that can be read by our statistical analysis software. This functionality eliminates the potential for key stroke errors since research staff do not have to transcribe the data manually. See **Attachment 3a** for screenshots of the web-based survey.

4. Efforts to Identify Duplication and Use of Similar Information

In order to identify duplication and use of similar information, we conducted an extensive review of the literature by examining several large periodical journal databases. In addition to reviewing published information, we searched for "gray" literature through an Internet search.

Searches were performed on several Internet search engines, including Google, Yahoo, AltaVista, Medline, and Science Direct. We were unable to find duplication or the use of similar information. Therefore, we have confirmed the need for the present study.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

6. Consequences of Collecting the Information Less Frequently

The activities involve a one-time collection of data over a 3-year period.

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

There are no other special circumstances that require the data collection to be conducted in a manner inconsistent with 5 CRF 1320.5 (d)(2). This data collection request fully complies with the regulation.

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

A 60-Day FRN was published on March 21, /2016, Vol. 81, No. 54, pp. 15111 - 15113 (**Attachment 2**). Two non-substantive public comments were received and the standard CDC response was sent (**attachment 2a**).

As needed, CDC will continue to conduct ad hoc consultations with subject-matter experts to obtain broad input from key experts early in the campaign development process to identify strengths and areas for improvement; and broadly discuss experts' recommendations for working with potential partners and leveraging pre-existing efforts to complement the campaigns.

Exhibit A.8.1. Individuals Consulted

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9. Explanation of Any Payment or Gift to Respondents

Initially, we will provide a token of appreciation of $100 for all providers and then we will offer a refusal conversion of $250 if response rates are lower than expected. Token of appreciation amounts were determined based upon the time that providers may have to take time away from their practice to come to the focus group facility and the types of providers who are invited to participate. We plan to recruit five different types of providers: (1) infectious disease specialists, (2) primary care physicians, (3) internal medicine specialists, (4) nurses, and (5) physician assistants.

Recruiting physicians and other health care providers to participate in research has been shown to be difficult for reasons related primarily to the time burden (Asch, Connor, Hamilton, & Fox, 2000). Health care providers are a specialized, unique group of people whose time is limited and, thus, quite valuable. Therefore, professional recruitment firms that recruit primary care providers and infectious disease specialists recommend a high token of appreciation to ensure adequate participation. In addition, in our experience, a high token of appreciation has been more successful than lower tokens of appreciation in recruiting health care providers for research studies. Use of a lower token of appreciation may result in higher recruiting fees from

the professional recruitment firms or refusal or withdrawal of some facilities from the bidding process for the research. Kim Johanson, a Vice President of recruiting for Schlesinger Associations, a market research firm that conducts over 6,000 healthcare studies annually, states "These are the [tokens of appreciation] needed to insure success for recruiting in the markets specified. From our extensive history of recruiting, the amounts are based on the lowest amounts that have proven to be successful." (K. Johanson, personal communication, September 10, 2014).

In addition to the fact that health care providers are a population that is difficult to recruit for research studies, there are several other factors that offer justification for the provision of a token of appreciation:

1. A token of appreciation of up to $250 for primary care physicians and infectious disease specialists was recently approved under the OMB package #0920-0840.
2. Removing the token of appreciation would incur significant costs and timeline delays which could threaten the launch of this important campaign.
3. A token of appreciation will ensure participation from a cross section of physicians which will improve data quality by improving validity and reliability.
4. This token of appreciation is consistent with those used in past interview studies between the contractor and the professional recruitment firm.

Provider participation is critical to the success of this research.

10. Assurance of Confidentiality Provided to Respondents

Prior to data collection, participants will be given time to read the consent (**Attachment 8**) and ask questions. Providers will be given two copies of the informed consent: one to keep and one to sign or indicate consent and return. During the introduction to the interview, the moderator will go over key parts of the informed consent which will include informing participants of the following:

1. The interview is voluntary; participants may choose not to answer any question and end participation at any time.
2. The contractor will report findings in summary form so that participants cannot be identified and that their identifiable information will be kept secure and separate from the interview notes and audio recordings.
3. There is a note-taker behind a one-way mirror and that CDC staff may be watching in person or via a live video stream.

The informed consent includes both the number for the contractor's IRB office, in case participants have questions about their rights as a study participant, as well as the project director, should participants have questions about the study itself.

Privacy Impact Assessment Information. A contractor will implement all phases of this study. The respondents for this project will be 600 health care providers recruited from cities with high HIV prevalence over a 3-year period. Each health care provider will be recruited by contractor staff or through local professional recruitment firms (hereafter referred to collectively as "recruiters") under contract with the contractor using a standardized screening instrument (**Attachment 9**). Personally identifiable information (PII), including names, email and physical

addresses, and telephone numbers, will be maintained by the recruiters and destroyed at the end of each interview. The entire data collection system will be a one-time in-depth individual interview and a one-time web-based survey per individual. Contractor staff will take notes and audio tape each interview. All audio files will be destroyed three years after completion of the project.

The recruiters will screen participants to determine if they meet the study criteria. Participants will be asked questions about themselves (specialty and subspecialty if applicable) and their practice (e.g., number of years in practice, practice setting, age, gender) and the number of patients in their case load (overall and HIV-positive patients). CDC and the contractor will have access to this information but records will not be stored with PII, and procedures will be followed to limit the linkage of this information to response data. All participants will be asked to complete a web-based survey prior to their interview (**Attachment 3**). The survey will ask more detailed questions about participants' medical practices, caseload, interest in HIV/AIDS-related topics, use of electronic media, patient resources, CME utilization, and communication practices with patients. Participant will also be sent a reminder email prior to their scheduled interview.

The qualitative data collected by the contractor will vary based on testing round. The questions for the exploratory round of research will span multiple topics: HIV testing, HIV prevention, prevention with positives, retention in care, pre-exposure prophylaxis (PrEP), and transgender health. See **Attachments 4a-4c** for the exploratory research guides.

Questions on the message (**Attachment 5**), concept (**Attachment 6**), and materials (**Attachment 7**) testing guides will be the same across all individuals and assess providers' initial reactions to campaign materials (e.g., visual appeal, format, design, content, usefulness, credibility); preferred channels for obtaining new information on guidelines or practices; and interest in provider resources and patient education materials.

The final evaluation reports will be the central focus of dissemination efforts and will be written in clear language that is understandable by a wide range of audiences (i.e., the target audience, practitioners, policy makers, and researchers). The evaluation reports will include an executive summary, a report of less than 100 pages (including an overview of background literature to provide contextual information about the purpose of the campaign and evaluation approach; a detailed summary of evaluation methods and activities; the evaluation results; a discussion of findings in comparison with those of other relevant program evaluations; strengths and limitations of the evaluation; and recommendations for future evaluations of this scope for practitioners, evaluators, and policy makers), and appendices. The results of our study also will be used to develop at least one peer-reviewed journal article (e.g., American Journal of Public Health, Journal of Health Communication) that summarizes findings on the overall effectiveness of the AAA campaign.

Even though we will collect personally identifiable information (PII), the proposed data collection will have no impact on the respondents' privacy. PII will be kept separate from survey and interview and survey data so that participants' responses cannot be linked with their names; the only linkage between forms is a randomly generated unique identification number. Thus, study findings can only be reported in summary form. The recruiters will be asked to sign a privacy agreement prior to the start of the study (**Attachment 10**).

The informed consent process was covered above. In brief, the moderator will inform participants of the voluntary nature of the interview and their right to refuse to answer any question and to end participation at any time; that the findings will be reported in aggregate form

so that individual participants cannot be identified; that their PII will be kept secure and separate from the interview notes and audio recordings; and that a note-taker is sitting behind a one-way mirror and that CDC staff may be watching in person or via a live video stream. The informed consent forms include contact information for the contractor's IRB and project director should they have concerns about their rights as a study participant or have questions about the study itself.

The contractor will retain notes, audio files, and any other project-related documents on secure servers or in locked file cabinets; only project staff members will be able to access the servers via password-protected computers. A system of records is not being created under the Privacy Act. Websites will not be used in this study.

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

This project received approval through a Project Determination from that was reviewed by the National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (**Attachment 11**). IRB approval was also obtained through the evaluation contractor.

For the in-depth interviews, the evaluation contractor will utilize POC's names, phone numbers, and email addresses to send reminder emails and make reminder telephone calls, as well as for conducting the telephone interviews; however, the information will not be recorded elsewhere. All participants will be informed that any information they provide will be completely voluntary and they can end their participation at any time. We will obtain verbal consent for the telephone interviews. Once a potential participant provides verbal consent, we will proceed with the interview.

For the survey, CDC and the evaluation contractor will receive data for analysis in aggregate form. The participant ID itself will only be used to track the survey completion pattern (i.e., how many people complete a survey). Information in identifiable form (IIF) is not shared with anyone, including CDC and CDC's contractor. It is stored separately from the survey data file and is not linked in any way to participant responses.

All respondents will be assured that the information will be used only for the purpose of this research and will be kept secure to the extent allowable by law, as detailed in the sample study consent form (**Attachment 8**). Respondents will be assured that their answers to screener and survey questions will not be shared with anyone outside the research team and that their names will not be reported with responses provided. Respondents will be told that the information obtained from all of the surveys will be combined into a summary report so that details of individual questionnaires cannot be linked to a specific participant.

We will not collect sensitive information from participants. However, there is a minimal risk that some questions may make respondent feel uncomfortable. The informed consent form includes a statement about this risk and informs participants that they may choose not to answer a particular question if they wish and/or end the study at any time without penalty (**Attachment 8**).

12. Estimates of Annualized Burden Hours and Costs

We estimate the total annualized response burden at 950 hours. **Exhibits 12.1** provides details about how this estimate was calculated. Timings are based on our previous experience conducting research with this population.

Screening is estimated to take 10 minutes (**Attachment 9**); 1,200 health care providers will be screened to achieve the desired sample size of 600. The time burden for screening is

estimated to be 200 hours. An estimated 600 participants will complete a 15-minute web-based survey (**Attachment 3/3a**). The time burden for the survey is estimated to be 150 hours. After completing the survey, participants will take part in a 1-hour interview (**Attachments 4a, 4b, 4c**). The time burden for all interviews combined is estimated to be 600 hours.

Table A.12.1. Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses Per Respondent	Average Burden per Response (in hours)	Total Burden Hours*
Health care providers	Screener (Att 9)	1,200	1	10/60	200
	Web-based survey (Att 3, 3a)	600	1	15/60	150
	Exploratory guide – PwP** and retention in care (Att 4a)	50	1	1	50
	Exploratory guide – Transgender health (Att 4b)	50	1	1	50
	Exploratory guide – HIV prevention (Att 4c)	50	1	1	50
	Message testing guide (Att 5)	150	1	1	150
	Concept testing guide (Att 6)	150	1	1	150
	Materials testing guide (Att 7)	150	1	1	150
	TOTAL				**950**

**Rounded to the nearest hour.*
***PwP=Prevention with positives.*

In calculating annualized costs to health care providers, we used $90.00 per hour as an estimate of the average hourly wage rate. To establish this amount, we used the mean hourly wage for physicians and surgeons released from the United States Department of Labor, Bureau of Labor Statistics (May 2014; available online at http://www.bls.gov/oes/current/oes291069.htm). Actual hourly wage rates will vary by credentials (e.g., wage rates for infectious disease specialists will be higher than the wage rates for nurses). The estimated annual cost to participants will be $85,500.

Exhibit A.12.2 Estimated Annualized Burden Costs

Form Name	No. of Respond-ents	No. of Responses Per Respondent	Average Burden per Response (in hours)	Total Burden Hours*	Hourly Wage Rate	Total Respondent Costs**
Screener	1200	1	10/60	200	$90.00	$18,000
Web-based survey	600	1	15/60	150	$90.00	$13,500
Exploratory	50	1	1	50	$90.00	$4,500

guide – PwP*** and retention in care						
Exploratory guide – Transgender health	50	1	1	50	$90.00	$4,500
Exploratory guide – HIV prevention	50	1	1	50	$90.00	$4,500
Message testing guide	150	1	1	150	$90.00	$13,500
Concept testing guide	150	1	1	150	$90.00	$13,500
Materials testing guide	150	1	1	150	$90.00	$13,500
Total						$85,500

**Rounded to the nearest hour.*
***Rounded to the nearest dollar.*
****PwP=Prevention with positives.*

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

There are no start-up or maintenance costs. We do not require any additional record keeping.

14. Annualized Cost to the Federal Government

The annualized estimate cost to the federal government is $484,033, which is based on the contractor's costs for carrying out the data collection activities, analysis, and reporting and CDC's oversight of the contractor and project (**Table A.14.1**). CDC personnel, including a Contracting Officers' Representative (COR), will be responsible for obtaining CDC approvals, providing project oversight and participating in analysis and dissemination of the results. This project will be executed as part of Contract No. HHSD2002013M53964B/Order No. 200-2015-F-88167.

Table A.14.1 Government Costs

Item/Activity	Details	$ Amount
Direct Costs to the Federal Government	60% of FTE GS-13 Behavioral Scientist and 15% of FTE GS-13 Health Communication Specialist: CDC oversight of contractor and project	$84,033
	Subtotal, Direct Costs	**$84,033**
Cooperative Agreement or Contract Costs	Contract No. HHSD2002013M53964B/Order No. 200-2015-F-88167 (RTI International): Recruitment, data collection, analysis, and reporting	$400,000
	Subtotal, Cooperative Agreement or Contract Costs	**$400,000**
	TOTAL COST TO THE GOVERNMENT	**$484,033**

15. Explanation for Program Changes or Adjustments

No change in burden is requested, as this is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

During data collection, the note-taker will enter data from the interviews into an electronic data matrix, which will be stored on a password-protected computer. Analysis of the interview data will start immediately after completion of data collection in each city and will be conducted under the supervision of a senior staff member with extensive experience in qualitative research. The contractor will conduct thematic or grounded theory analysis of the data to understand participants' reactions to the campaign messages in as rigorous and detailed manner as possible. The contractor and CDC will review the preliminary data within 1 week after data collection is completed in each city via a debriefing conference call. Contractor staff will further analyze the data in the matrices and summarize results in four separate summary reports by city and one final report. Survey data will be reported in descriptive data tables with accompanying narrative in the summary and final reports. **Exhibit 16.1** lists the key events for this project.

Exhibit A.16.1. Project Time Schedule for each City

Activity	Time Schedule
Identify and reserve professional recruitment firms	1 month after OMB approval
Begin recruitment	1 month after OMB approval
Conduct first round of interviews	2 months after OMB approval
Topline report due	4 months after OMB approval
Summary report due	6 months after OMB approval

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

OMB Expiration Date will be displayed on necessary materials and documents.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.

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