Development of a Mobile Messaging Intervention for Men who have Sex with Men: Formative Study

GenIC Information Collection Request under OMB #0920-0840

Section B: Supporting Statement

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CONTACT
Gordon Mansergh, PhD
Project Officer
Centers for Disease Control and Prevention
Division of HIV/AIDS Prevention
1600 Clifton Road, NE, Mailstop E-37
Atlanta, GA 30333
Phone: 404-639-6135
Fax: 404-639-1950
E-mail: gcm2@cdc.gov

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EXHIBITS

1. Respondent Universe and Sampling Methods

City Selection

This study will be carried out in three metropolitan areas in the United States: Atlanta, GA, Detroit, MI and New York City, NY. These cities were selected not only because they have high rates of HIV, but also because significant disparities in HIV have been observed by race/ethnicity and age.

Atlanta is the southern study site. The South accounts for about half of all new HIV diagnoses in the United States; Georgia, as a state, ranks second in the rate of HIV diagnoses among US states,[1] and as a city, Atlanta ranks second in the number of new HIV diagnoses among black/African American MSM.[2] Marked racial disparities in HIV prevalence have been observed in the Atlanta metro,[3] and HIV incidence among young black MSM has been estimated at nearly 11% per year.[4]

The Detroit Metro Area (DMA) is one of the most racially segregated areas in the United States,[5] and it is the state of Michigan's HIV epicenter, accounting for 67% of all HIV/AIDS cases in the state.[6] MSM account for 60% of HIV cases and more than two thirds of HIV-positive MSM statewide reside in Southeast Michigan.[6] In 2010, black MSM accounted for 59% of all MSM cases, while White and Latino MSM account for 34% and 3%, respectively. Further, while the rate of new HIV infections in the DMA remained stable for most age groups from 2006 to 2010, incidence among youth (13-29) doubled.

New York City (NYC) was selected as a study site because it remains an area of high transmission in the HIV epidemic in the United States, with MSM accounting for the majority of infections. NYC surveillance data from the Department of Health and Mental Hygiene (DOHMH) show that approximately 58% of all new HIV diagnoses in 2013 were among MSM, with 46,562 residents living with diagnosed HIV.[7] The HIV diagnosis rate among black males was 1.5 times higher than the rate among Hispanic males and >2 times higher than white males, and men aged 20-29 accounted for more than 40% of new HIV diagnoses.

Target population:
This study plans to sample 135 MSM living in the Atlanta, GA, Detroit, MI, or New York, NY metropolitan statistical areas to participate in either a focus-group discussions (n=90, average 10/group) or an in-depth interview (n=45).

Inclusion criteria:
* Assigned male at birth
* Current, self-reported gender identity as "Male"
* Aged 18 or over
* Resides in or near Atlanta, GA, New York, NY, or Detroit, MI.
* Self-reported sex with a male partner in the past 6 months
* Owns an Android or iOS smartphone
* Is included in one of the following risk groups:
   - HIV seropositive
   - HIV seronegative at higher risk (less than 100% consistent condom/PrEP use)
   - HIV seronegative at lower risk (self-reported 100% consistent use of condoms/PrEP)

Exclusion criteria:
* Assigned female at birth

* Current, self-reported gender identity is not "Male"
* Aged 17 or under
* Does not reside in or near Atlanta, GA, Detroit, MI or New York, NY
* No sex with male partners in the past 6 months
* Does not own an Android or iOS smartphone

45 MSM will be selected for participation in each of the three study sites (Atlanta, GA, Detroit, MI or New York, NY). As shown in Exhibit 1.1, three risk-groups of 45 MSM will be recruited across all study sites: 1) MSM living with HIV, defined as eligible MSM who self-report their HIV status as HIV-positive; 2) HIV-negative MSM at higher-risk, defined as eligible MSM who self-report HIV status as "HIV negative" while also indicating incomplete or inconsistent use of condoms and/or PrEP; 3) HIV-negative MSM at lower-risk, defined as eligible MSM who self-report HIV status as "HIV negative" while also indicating complete and consistent use of condoms and/or PrEP.

Exhibit 1.1: Summary of Recruitment Targets

	Atlanta				Detroit				New York City				
	Focus Groups		Interviews		Focus Groups		Interviews		Focus Groups		Interviews		
	#	#MSM	#	#MSM	#	#MSM	#	#MSM	#	#MSM	#	#MSM	Total MSM
HIV-positive	1	10	5	5	1	10	5	5	1	10	5	5	45
High-risk HIV-negative	1	10	5	5	1	10	5	5	1	10	5	5	45
Low-risk HIV-negative	1	10	5	5	1	10	5	5	1	10	5	5	45
Total	3	30	15	15	3	30	15	15	3	30	15	15	135

Our recruitment goal will be to recruit a study-wide sample with at least half MSM of color (participants indicating American Indian or Alaska Native, Asian, black or African American, Hispanic or Latino, or Native Hawaiian or Pacific Islander), or a maximum of 50% white participants in the study-wide sample. Our recruitment goal for age diversity is to recruit a sample in which at least 50% of participants are aged 18 to 29 at the study-wide level. Given the possibility that racial and ethnic compositions vary from site to site, we will not set fixed, within-site proportions for race or ethnicity, but on a study-wide basis. We expect that our participants of color will be present in roughly similar racial proportions as found nationally among people of color. As with race and ethnicity, the possibility for variable proportions of age strata from across study sites led us to apply this recruitment goal at the study-wide level and not for individual study sites.

We will recruit men into the study through a combination of approaches, including online advertisement, traditional print advertisement, referral, in-person outreach, and through word of mouth (Attachment 1). If we notice that our recruitment is falling short of these goals, we will direct the recruitment contractor to change the mix of selected venues and recruitment strategies to increase recruitment where there are shortfalls and to discontinue recruitment in groups where group maxima have been reached. This will involve weekly review of recruitment data and weekly meetings with recruitment staff to assess efforts.

This is a qualitative research study and is not designed to make comparisons between groups or to make generalizations. We intend to use a standard qualitative sampling methodology that ensures a wide range of experiences are captured. Rather than using probabilistic methods (i.e., random selection with known, non-zero chances of selection for each unit in the population) to generate a sample, non-probability sampling requires researchers to use their subjective judgments, drawing on theory (i.e., the academic literature) and practice (i.e., the experience of the researcher and the evolutionary nature of the research process). Unlike probability sampling, the goal is not to achieve objectivity in the selection of the

sample, or necessarily attempt to make statistical inferences from the sample being studied to the wider population of interest.

2. Procedures for the Collection of Information

Two qualitative methodologies will be used to collect information for this study: focus group discussions and in-depth interviews (**Attachment 2c-d**). We will recruit 45 men from each of the cities using a variety of methods, with approximately half recruited online through ad placements on websites and the other half recruited through in-person methods, including outreach at gay venues, health fairs, gay pride parades or other events where the population may be reached, print advertisements, referrals or word of mouth. Study-wide, we expect that approximately half of participants will be MSM of color and that approximately half will be young MSM. Within each city, we will stratify sampled MSM by those who are HIV-positive, high-risk HIV-negative, and low-risk HIV-negative, with a third of men selected from each group, as shown in Exhibit 1.1 above. While our subgroup sizes will be sufficient for qualitative analysis, their size is too small for generalization to the larger population. Recruiting a probability sample is unnecessary for this type of research and findings could be misleading to the broader scientific community and the general public.

All potential participants will complete a brief, two-phase screening process for eligibility (**Attachment 2a-b**), which includes initial screening and reverification of eligibility prior to consent and data collection, as outlined in Exhibit 2.1 below. In the first phase of screening, men will consent to screen and complete a brief screening online screening questionnaire (**Attachment 2a**). Eligible men will be asked to provide contact information (name, phone number and email address) through a separate online questionnaire (**Attachment 2b**). In the second phase of screening, men will be asked to verify their eligibility before completing the in-person interview or focus group discussion. Those who remain eligible will complete the corresponding informed consent (**Attachments 3a-b**) and will then participate in either a focus group discussion or in-depth interview.

Exhibit 2.2: Recruitment and Screening Procedures
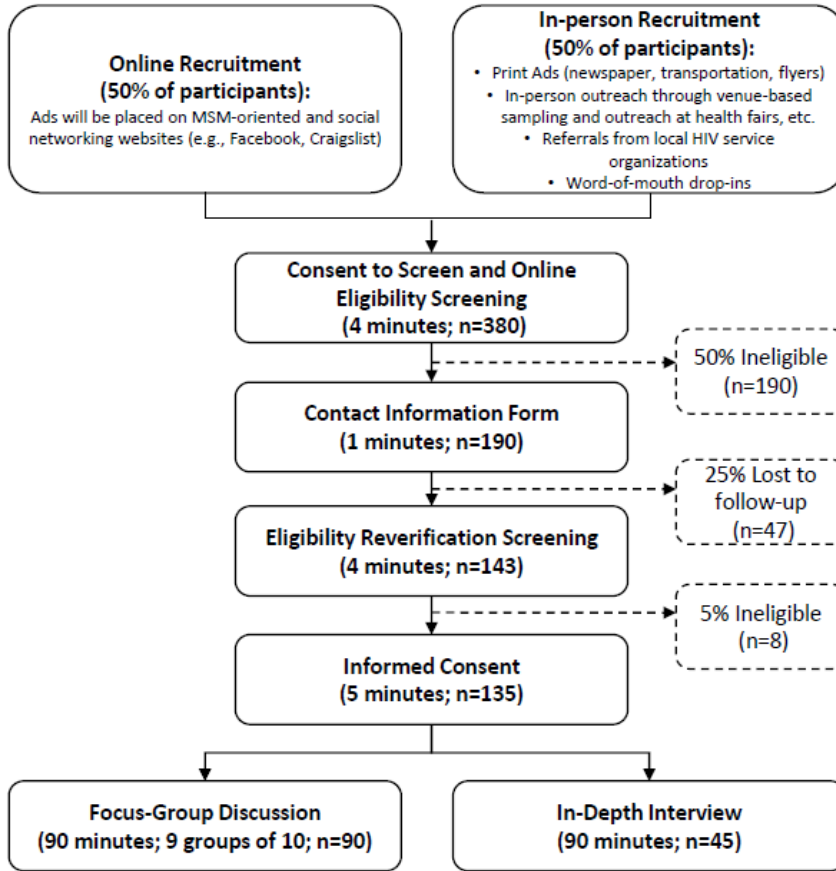
Focus groups will be small groups with an average of 10 participants, selected based on the above inclusion criteria, and approximately 90-minutes in length. Focus groups will be conducted by a trained moderator using a semi-structured interview guide (**Attachment 2c**). Focus-group discussions will address MSM's acceptability of mobile messaging, focusing primarily on message format and delivery, and secondarily on supplemental message content by HIV status and risk group. FGDs will incorporate a pile sorting activity to generate discussions that address MSM's perceptions and general preferences for mobile messaging. During the pile sorting activity, participants will be provided with cards that represent the characteristics for each key domain and characteristics will be sorted based on preference for inclusion in a mobile messaging intervention. The moderator will validate and challenge depend on the content of the message. At stated preferences in order to generate additional discussion and understand what would need to occur for preferences to change (for example, if participants put PrEP at the bottom of the list of preferred messages, the moderator would ask what would need to change for PrEP to be an acceptable message).

In-depth interviews will be conducted in-person and will be approximately 90-minutes in length. All the in-depth interviews will be conducted by a trained interviewer using a semi-structured interview guide (**Attachment 2d**). In-depth interviews will assess the extent to which messages need to be customized and tailored to address contextual differences and variations in prevention needs. Prevention needs will be assessed based on: *local contexts, demographic contexts* (e.g. race, age, socioeconomic status, sexual orientation), *risk group,* and *relationship context* (e.g. single versus in a relationship, monogamy versus non-monogamy). The principal goal of the in-depth interviews is to assess participants' reactions to messages that were adapted based on the data collected in the focus-group discussions. Participants will

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be asked about their reactions to several messages, including their comprehension, willingness to view or read the message, appropriateness of the message and their perception of the ability to enact behavioral change. Participants will also be asked about how desired messages would change based on differences in relationship types and sexual activities.

3. Methods to Maximize Response Rates and Deal with No Response

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Participant accrual rates will be monitored by the recruitment contractor to maintain consistent and accurate procedures. Age and race/ethnicity will be tracked across all study sites to ensure that approximately 50% of participants are MSM of color and that approximately 50% are young MSM. Within each study location, we will monitor MSM recruitment by targeted risk group to ensure that 15 HIV-positive MSM, 15 high-risk HIV negative, and 15 low-risk HIV negative MSM are recruited within each location. We anticipate a sample size of 135 for analysis with targets.
- If recruitment falls short we will work with the recruitment contractor and study staff to determine the best course of action, including recruiting additional participants at alternative MSM venues or changing the mix of recruitment strategies in the city or cities where additional participants are needed.
- A $50 token of appreciation will be provided to respondents upon completion of the interview.
- Online screening of interested individuals will be used to determine initial participant eligibility.
- All recruitment materials indicate the voluntary nature of the study and high participation is due in part to interest in the study and participation from individual respondents.

4. Tests of Procedures or Methods to be Undertaken

Our team includes experts with the HIV population and qualitative research, including screening and interview development and testing. We will conduct pretesting of the screening tool and interviews on three to five qualified respondents to assess question wording, skip patterns, question sensitivity, and overall flow of the interview and screener.

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

Exhibit 5.1 below lists the project team members who were consulted on the aspects of research design and those who will be collecting and analyzing the data. Please note: The CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. The staff will neither collect data from nor interact with research participants. Data will be collected by members of contractor project staff listed. No individual identifiers will be linkable to collected data, and no individually identifiable private information will be shared with or accessible by CDC staff.

Exhibit 5.3: Statistical Consultants

Team Member	Organization	Phone	Email
Gordon Mansergh	CDC	404-639-6135	gcm2@cdc.gov
Deborah Gelaude	CDC	404-639-1905	zoi1@cdc.gov
Brittney Baack	CDC	404-639-6297	jcx3@cdc.gov
Evelyn Olansky	CDC	404-639-5203	ism9@cdc.gov
Patricia Bessler	CDC	404-639-8239	vey4@cdc.gov
Patrick Sullivan	Emory University	404-727-2038	pssulli@emory.edu
Aaron Siegler	Emory University	404-712-9733	asiegle@emory.edu
Eli Rosenberg	Emory University	404-712-8897	esrose2@emory.edu
Jennie McKenney	Emory University	404-712-1269	jennie.l.mckenney@emory.edu
Jose Bauermeister	University of Michigan	734-615-8414	jbauerme@umich.edu
Rob Stephenson	University of Michigan	734-615-0149	rbsteph@med.umich.edu
Sabina Hirshfield	Public Health Solutions	646-619-6676	shirshfield@healthsolutions.org
Martin Downing	Public Health Solutions	646-619-6528	mdowning@healthsolutions.org
Mary Ann Chiasson	Public Health Soluations	646-619-6411	machiasson@healthsolutions.org

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