Evaluation of Rapid HIV Self-Testing: Field-Performance study

Generic Information Collection request under 0920-0840

Supporting Statement
Part B

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CONTACT

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B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

This information collection request does employ statistical methods. The following is a description of data collection procedures.

B.1. Respondent Universe and Sampling Methods

Participants will be recruited through online banner advertisements displayed on social networking sites such as Facebook.

For this study, we plan to enroll 900 persons who are unaware of their current HIV status. If the true prevalence of unidentified HIV infection is 5% or 10%, then we have a 24% or near 100% chance of recruiting at least 50 HIV positive persons. With 50 HIV positive persons and a long-run sensitivity of the test of 0.9, the half-width of the 95% confidence interval will be approximately 0.083. If 45 of 50 people correctly test positive (and 5 people incorrectly test negative), then the 95% confidence interval for sensitivity will be (0.782, 0.967). We will monitor the number of newly diagnosed HIV positive men during the study to estimate the total number of men to enroll, and if necessary, will continue recruitment up to 1,000 HIV status negative or unaware men to identify 50 newly diagnosed HIV-positive men.

Participants to be included will include current residents of Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan. Enrollment of men from Atlanta, Chicago or New York City will be limited to 50 in each city to control enrollment of potential participants in our 3 primary cities for Part 4. We will ensure that at least 20% of participants are black and at least 15% are Hispanic.

The inclusion criteria for this formative study are (1) male sex at birth; (2) currently identify their sex as male; (3) able to provide informed consent; (4) at least 18 years of age; (5) resident of Atlanta, Baltimore, Chicago, Dallas, the District of Columbia, Houston, Los Angeles, Miami, New York City, Philadelphia, San Francisco, and San Juan; (6) able to read instructions and complete study survey instruments in English; (7) self-reported unprotected anal sex with at least one man in the past 12 months; (8) never diagnosed with a bleeding disorder; (9) not part of an HIV vaccine trial; (10) not taking antiretroviral medication for HIV; and (11) not known to be HIV-infected.

B.2. Procedures for the Collection of Information

B.2.1. Recruitment

Our goal in Part 3 (formative study) is to recruit participants online who would be typical users of HIV self-test kits in Part 4 (the next phase – not covered by this generic information request). Therefore, recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook and dating and sex-seeking sites such as Manhunt and Adam4Adam (**Attachment 4b**). Banner advertisements will be displayed in English. Recruitment will be targeted only towards those men who indicate in their Facebook profile that they are interested in men, and towards all men on Manhunt and Adam4Adam, whose profile age is at least 18 years. Depending upon the language of the banner advertisement men clicked on, they will be taken to a page containing basic study information including a short description of study activities.

B.2.2. Screening and Scheduling Procedures

If men express an interest in participation they will be taken to a consent form (**Attachment 2a**), and if they consent they will be directed to a short eligibility screener (**Attachment 1a**), which will confirm that they meet the eligibility criteria. Men who do not consent or do not meet the eligibility criteria will be taken to a screen thanking them for their interest and directing them to AIDSVu, an online tool that allows users to visually explore the HIV epidemic alongside critical resources such as HIV testing center locations and NIH-Funded HIV Prevention and Vaccine Trials Sites. Men who are eligible will then be prompted to complete the registration process (**Attachment 1b**). During the registration process they will provide their contact information including an email address, a cell phone number and a mailing address and will also be asked to provide a nickname or name of choice. Once a participant submits an email address as part of the registration process, an email containing a code will be immediately sent to that address. The purpose of this email is to ensure that participants provide a valid email address. Also, a text message containing a code will be immediately sent to the cell phone number provided by the participant. The participant must then enter this code as part of the registration process in order to continue. The purpose of sending this code is to verify that the participant has provided a valid cell phone number. Men who successfully register will be provided with a link to the study web site where they will set up an account by selecting a user

name, password and security questions, and complete the baseline survey.

After taking a baseline survey (**Attachment 1c**), the test kit package containing: 1 oral fluid test (OraQuick), 1 DBS specimen collection kit, and 1 finger-stick blood test (Sure Check), will be mailed to the participant. All study test kits will be affixed with a barcoded sticker to enable the kit to be tracked. Kits will be scanned prior to distribution to study participants, which will link the test kit information (the type of test) with the ID number of the participant it was sent to. Participants will be required to scan or enter a test kit barcode number into the study website or secure cell phone application to verify the test kit is part of the eSTAMP Part 3 study; recognition of the test kit will then allow the user to report their test results. Emory study staff will keep a log of the test kit lot number, the barcode number and the participant ID that the test kit was sent to for each test kit. Emory study staff will monitor the progress of the delivery and tracking system. The test kit package instructions will guide participants through the process of first conducting the oral fluid test, second collecting a DBS specimen, and third conducting the finger-stick blood test.

B.2.3. Data Collection Methods

Men who consent to participate will take a short baseline survey (**Attachment 1c**). They will have the option of accessing the survey online or downloading a secure cell phone application. The baseline survey will collect information on demographic characteristics, prior laboratory training or experience, and HIV testing history. They will also have the option of entering their rapid self-test results (**Attachment 1d**) and taking the follow-up survey (**Attachment 1e**) online or through a secure cell phone application.

<u>Online surveys</u>

Men who take the baseline survey online will enter responses to survey questions directly into their computer via a web interface. On completing this survey, they will be informed that a package containing: 1 DBS specimen collection kit, 1 oral fluid test (OraQuick), and 1 finger-stick blood test (Sure Check) is being sent to the mailing address they provided. They will be instructed on how they can log into the study web site to access the survey online or use the secure cell phone application to enter results of their rapid HIV self-tests that they conduct at home. They will also be asked for their preference of how they want to be contacted with reminders to report the results of

their HIV tests and to send in the DBS specimen if they are not received within 3 weeks after the test kit package was mailed.

Cell phone application surveys

Men who take the baseline survey using their cell phone will interact with and enter responses to survey questions directly into the cell phone application. On completing this survey, they will be informed that a package containing: 1 DBS specimen collection kit, 1 oral fluid test (OraQuick), and 1 finger-stick blood test (Sure Check) is being sent to the mailing address they provided. They will be instructed on how they can use the secure cell phone application to enter results of their rapid HIV self-tests that they conduct at home. They will also be asked for their preference of how they want to be contacted with reminders to report the results of their HIV tests and to send in the DBS specimen if they are not received within 3 weeks after the test kit package was mailed.

Each participant will receive a package containing: 1 oral fluid test (OraQuick), 1 DBS specimen collection kit, and 1 finger-stick blood test (Sure Check). Participants will open the test kit package and follow the package instructions to begin the process of first conducting the oral fluid test, second collecting a DBS specimen, and third conducting the finger-stick blood test. Participants will follow the written instructions included with each individual kit to conduct DBS specimen collection and self-testing. They will be asked to log into the study web site or start the electronic application prior to starting the testing process so they can report their self-test results at the time of testing and take the follow-up survey immediately after testing. They will also have the option of viewing video instructions online or on a cell phone application, both of which will provide timers specific to each test. Participants will document test times and results on the individual test “placemats” (instructional sheets designed to guide the placement of materials and the steps for administering and interpreting each test). After conducting each rapid test they will report their results online or using the secure cell phone application and select an image of the test kit device that most closely resembles their results. They will receive messages based on their results (positive, negative or invalid) that will direct them to the study referral support system or HIV testing services if they want or need supplemental HIV testing. They will be instructed to dry the DBS card, package it in a Ziploc bag, and return it to Emory in a pre-paid shipping envelope provided in the kit for transport to the CDC for laboratory-testing with

EIA. Once they have reported their results they will be directed to the follow-up survey.

B.3. Methods to Maximize Response Rates and Deal with Nonresponse

Researchers involved in this study have extensive experience recruiting and retaining MSM for research studies. We plan to obtain maximum response rates by collecting and validating contact information and by providing tokens of appreciation. During the registration process they will provide their contact information including an email address, a cell phone number and a mailing address and will also be asked to provide a nickname or name of choice. Once a participant submits an email address as part of the registration process, an email containing a code will be immediately sent to that address. The purpose of this email is to ensure that participants provide a valid email address. Also, a text message containing a code will be immediately sent to the cell phone number provided by the participant. The participant must then enter this code as part of the registration process in order to continue. The purpose of sending this code is to verify that the participant has provided a valid cell phone number.

Participants who have not entered their self-test results within three weeks after the test kit package was mailed will be sent a reminder email by Emory study staff. Emory study staff will send up to 3 email reminders to participants who have not reported their self-test results, and then will contact the participant by phone to request that the results be entered. Similarly, participants who have not sent their DBS specimen to CDC for laboratory testing within three weeks after the test kit package was mailed will be sent a reminder email by Emory study staff. Emory study staff will send up to 3 email reminders to participants who have not sent their DBS specimen, and then will contact the participant by phone to request that the DBS specimen be sent.

Men will also receive tokens of appreciation upon completing specific tasks at four stages during Part 3. Upon completion of the baseline survey, men will be given $20. They will be given an additional $10 for reporting the results of both the oral and blood finger-stick self-administered and interpreted HIV rapid tests, $10 for completing the follow-up survey, and an additional $20 for returning the DBS specimen. The tokens of appreciation will be provided by PayPal or by Amazon.com gift card, depending on participant preference.

B.4. Tests of Procedures or Methods to be Undertaken

This submission is a request for authorization to conduct tests of procedures and methodologies typical in methods and field-performance studies.

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

The contractor and subcontractors were involved in designing the study and will implement study procedures. The persons involved at Emory University are:

Patrick Sullivan, Principal Investigator
A.D. McNaghten, Study Manager
Alexandra Ricca, Research Assistant
Akshay Sharma, Research Assistant

The federal (CDC) staff members who are involved with the various aspects of designing and implementing the study are listed below.

Lisa Belcher
Arin Freeman
Darrel Higa
Wayne Johnson
Heather Joseph
Robin MacGowan
Andrew Margolis
David Purcell
Jerris Raiford
Kristina Bowles
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