Evaluation of Rapid HIV Self-Testing: Qualitative and User Proficiency Assessments

Generic Information Collection request under 0920-0840

Supporting Statement
Part B

November 5, 2012

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

Part 1
Focus group will be conducted in both Chicago and Atlanta. The Principal Investigator (Patrick Sullivan) is from Emory University in Atlanta and will manage focus groups in Atlanta. Co-investigators (Brian Mustanski and Michael Newcomb) are from Northwestern University in Chicago and will manage them in Chicago.

The focus group and in-depth interview participants will be primarily recruited through online banner advertisements displayed on social networking sites such as Facebook. The inclusion criteria for Part 1 focus groups are: (1) male sex at birth; (2) currently identify as male; (3) at least 18 years of age; (4) resident of Atlanta or Chicago; (5) self-reported anal intercourse with a man in the past 12 months; (6) able to provide informed consent; and (7) English speaking.

The aim is to have four focus groups in Atlanta (three groups with HIV-negative participants and one group with HIV-positive participants) and two groups in Chicago (mostly Hispanic participants). A total of 60 participants will participate in the focus groups; 40 (predominately black and white) in Atlanta and 20 (predominately Hispanic) in Chicago. We will over-recruit for each focus group by 50% to allow for participants who do not report to their scheduled focus group.

In-depth interviews will be conducted only in Atlanta. The Principal Investigator (Patrick Sullivan) is from Emory University in Atlanta and will manage focus groups in Atlanta. The inclusion criteria for Part 1 in-depth interviews are: (1) male sex at birth; (2) currently identify as male; (3) at least 18 years of age; (4) resident of Atlanta; (5) self-reported anal intercourse with a man in the past 12 months; (6) able to provide informed consent; and (7) English speaking.

We will conduct in-depth interviews with 15 participants, recruiting up to 20 participants, if necessary. If saturation is

reached prior to interviewing 15 men we will stop recruitment and not conduct any more interviews. Sample sizes for the focus groups and in-depth interviews are based on the number of participants that were needed to reach data saturation in previous qualitative research studies.

Part 2
Part 2 will be conducted only in Atlanta and will be managed by the Principal Investigator (Sullivan).
The inclusion criteria for Part 2 user proficiency assessment are: (1) male sex at birth; (2) currently identify as male; (3) at least 18 years of age; (4) resident of Atlanta; (5) self-reported anal intercourse with a man in the past 12 months; (6) able to provide informed consent; and (7) English speaking.

The aim is to conduct proficiency assessment with 30 known HIV-negative men and 10 known HIV-positive men for a total of approximately 40 participants. We will over-recruit by 50% to allow for participants who do not report to their proficiency assessment session. Thus, we will recruit 45 known HIV-negative men and 15 known HIV-positive men and expect 30 and 10, respectively, to consent to participate. Based on prior formative research on evaluation of materials for research studies, the proposed number will be sufficient to determine if subjects are able to follow directions and complete activities correctly.

B.2. Procedures for the Collection of Information

B.2.1. Recruitment

Part 1
Online recruitment will be our main source of recruitment for Part 1 focus groups and in-depth interviews. The goal is to recruit participants who would be typical users of HIV self-test kits in Parts 3 and 4. Therefore, recruitment will be conducted through banner advertisements displayed on social networking sites such as Facebook.

Recruitment for focus groups will be targeted towards men who indicate in their social networking profile that they are interested in men, whose profile age is at least 18 years and who report their city of residence as Atlanta or Chicago. Recruitment for in-depth interview participants will be targeted towards men who indicate in their social networking profile that they are

interested in men, whose profile age is at least 18 and who report their city of residence as Atlanta.

If the desired sample size is not reached through online recruitment, we will recruit men through current or past research studies conducted by study investigators—Sullivan in Atlanta and Mustanski and Newcomb in Chicago. Currently, Sullivan's Involve[MEN]t (IRB00042405) and MAN Project (IRB00047855) studies together have enrolled approximately 850 black and white MSM in Atlanta. The majority of these participants have agreed to be contacted for future research. Mustanski's and Newcomb's studies (STU00046626/STU00046626 and STU00047881/STU00047881) together currently have approximately 450 MSM enrolled and the majority of these participants have agreed to be contacted for future research. Recruitment for focus groups will occur from the Atlanta-based studies and Chicago-based studies while recruitment for in-depth interviews will only occur from the Atlanta-based studies.

Part 2
Sullivan's current and previous research studies will be the sole source of recruitment for Part 2 user proficiency assessment. As described above, Sullivan's Involve [MEN]t (IRB00042405) and MAN Project (IRB00047855) studies have together enrolled approximately 850 black and white MSM in Atlanta. The majority of these participants have agreed to be contacted for future research.

B.2.2. Screening and Scheduling Procedures

For part 1, men who are interested in participating in the focus groups or in-depth interviews will be given a link to provide consent (**Attachments 2a and 2c)** and those who consent will complete a short eligibility screener **(Attachment 1a)**, which will confirm that they meet eligibility criteria to participate in a focus group or in-depth interview. Men who are determined by the screener to meet eligibility criteria will be asked to provide a nickname or name of choice, email address and telephone number so they can be contacted to be scheduled for the focus group or in-depth interview.

Emory study staff will contact men who are residents of Atlanta and Northwestern study staff will contact men who are residents of Chicago for participation in the focus groups at Emory University or Northwestern University. Staff in both cities will provide basic information about the study procedures, and schedule men for a time to attend focus group discussions. Emory

study staff will contact men for participation in an in-depth interview, provide basic information about the study procedures, and schedule men for a time to attend an individual interview at Emory University.

For part 2, men who are interested in participating will be given a link to consent, and those who consent will be taken to a short eligibility screener **(Attachment 1a)**, which will confirm that they meet eligibility criteria to participate in the proficiency assessment. Men who are determined by the screener to meet eligibility criteria will be asked to provide a nickname or name of choice, email address and telephone number so that they can be contacted. Emory study staff will contact men who have indicated their interest in participating, provide basic information about the study procedures, and schedule men for a time to attend a study session for Part 2 at Emory University.

B.2.3. Data Collection Methods

a) Part 1 *Focus Groups (Qualitative interviewing)*

Men who agree to participate in a focus group will be registered upon arrival and assigned a unique identifying number. Those selected to participate will be consented prior to the focus group **(Attachment 2b)** and informed that the focus group discussion will be audio recorded. Participants will be called by their number into the room where the focus group will be conducted. Thirteen chairs will be arranged in a circle (up to 12 participants and the moderator), and the note taker will sit at the side of the room. The moderator will begin by explaining the purpose of the focus group, and will ask permission from the participants to tape record the discussion. It will be made clear that no names will be used in the discussion and that tapes will be destroyed after their content has been transcribed. The facilitator will then outline some guidelines for the discussion: no names to be used, one person talking at a time, all opinions are valid. The discussion will then follow the focus group discussion guide **(Attachment 1b)**.

Focus group participants will examine the test kit packaging to be provided to participants in Parts 2, 3 and 4. The test kit package for Part 2 will include two rapid tests (one OraQuick In-Home HIV Testand one, SURE CHECK® HIV 1/ 2 Assay currently distributed as Clearview Complete HIV-1/2 rapid test) and one dried blood spot (DBS) specimen collection kit. Participants will be asked to provide their opinions

regarding issues relevant to the research study including: recruitment and willingness to provide contact information, barriers to participation, receiving test kits in the mail, their perception of the accuracy of the test kits, and their willingness to use the test kits and give them to others in their sexual and social networks. Participants will be asked to talk about their ideas about how the kits could be packaged or provisioned to increase the likelihood that the participant would be comfortable both using and distributing the kits.

b) Part 1 *In-depth Interviews (Qualitative Interviewing)*
Men who arrive for an in-depth interview will be registered upon arrival and assigned a unique identifying number. Those selected to participate will be consented prior to the beginning of the interview **(Attachment 2c)**. The interviewer will begin by explaining the purpose of the interview, and will ask permission from the participant to video and audio record the interview. It will be made clear that no names will be used in the interview and that tapes will be destroyed after their content has been transcribed. Each participant will be administered an individual qualitative interview, according to the interview guide included in **Attachment 1c**.

Men will be shown the test kit packaging to be provided to participants for use in Parts 2 and 3. The test kit package will contain: one oral fluid test (OraQuick Advance), one finger-stick blood test (Sure Check), and one DBS specimen collection kit. Participants will be asked to interact with the packages and provide feedback about their understanding of the sequence of conducting the individual tests in the package from the package layout and instructions. They will also be asked to examine the written and video instructions for each individual test within the kit, including “placemats” (instructional sheets designed to guide the placement of materials and the steps for administering and interpreting each test)developed by the study team for each individual test kit that will guide participants through the test procedures for that specific kit. They will be asked to describe to the interviewer their understanding of how to administer each test, and how to collect, package and ship the DBS specimen. They will also be observed as they interact with the package to visually confirm if package instructions are followed. The interview will be conducted to elicit men’s understanding of and reactions to the packaging that will be used in Parts 2 and 3, and the

instructional materials for the individual tests that will be used in Parts 2, 3 and 4. Participants will be asked to share their ideas about how the instructions could be clearer and how the packaging could be changed to increase the likelihood that the participant would be comfortable using the test kits.

c) Part 2 User Proficiency Assessment

Men who meet the eligibility criteria will be consented to having their hands video recorded and their voice audio recorded (**Attachment 2d**). Men in the HIV negative/unaware group will be informed that if any of their tests are reactive, they will have their blood drawn by the trained counselor for confirmatory supplemental EIA testing, and will be provided with counseling which includes referrals to local HIV care services. Information will be collected by study staff for HIV reporting purposes (name, mailing address and phone number) and if they are confirmed HIV-positive, this information will be reported by telephone to the Georgia Department of Public Health. If the confirmatory supplemental EIA testing is negative, this information will be destroyed. All men will be informed that a trained HIV counselor on the Emory study team will be available following each proficiency assessment session to provide HIV testing to men who want to learn or confirm their status, and to provide counseling. Emory staff will use a finger-stick OraQuick rapid test. Test results and counseling will be conducted in a private, secure area.

All men participating in the proficiency assessment will be assigned a participant number that will be associated with their test results, but not linked to their contact information. The proficiency assessment sessions will be conducted to determine men’s ability to understand the sequence of use of the testing package components and the instructional materials for each of the individual rapid tests and the DBS specimen collection instructions included in the package.

Each participant will be given the same testing kit package as will be distributed to home testing participants in Part 3 containing: one oral fluid test (OraQuick Advance), one finger-stick blood test (Sure Check), and one DBS specimen collection kit. Participants will open the test kit package and follow the package instructions to begin the process of first collecting a DBS specimen, second conducting the oral fluid test, and third the finger-stick blood test.

Participants will use the written instructions included with each individual test and will also have access to an electronic application that will provide video instructions and timers specific to each test. Participants will conduct the testing process following the kit instructions, and will have the option to document test times and results on the individual test kit "placemats" (instructional sheets designed to guide the placement of materials and the steps for administering and interpreting each test) or in the electronic application. Following each rapid test administered and interpreted by the participant, a study staff member trained in HIV testing will interpret the participant's test results. Researchers will observe the men's ability to conduct the tests and interpret the results of each self-test, and to collect the DBS specimen and properly package it for transport, and will document their observations. Men will package a prefabricated DBS specimen for transport. Participants' DBS specimen cards will be collected by Emory study staff and transported to CDC for laboratory testing. Considerations for further educational materials or provisions to packaging will be assessed. Following the self-testing component, participants will complete a survey about the self-testing process (**Attachment 1d**). Finally, each participant will review a panel of test result images for OraQuick Advanced and either Sure Check (**Attachment 1e**). At the end of their session, participants will have the option to receive counselor provided HIV screening from training Emory study staff and to speak to the trained HIV counselor or other study staff.

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

Researchers involved in this study have extensive experience recruiting MSM online. Emory study staff will contact men who are residents of Atlanta and Northwestern study staff will contact men who are residents of Chicago for participation in study activities at Emory University or Northwestern University. Staff in both cities will provide basic information about the study procedures, and schedule men for a time to attend and follow-up with men prior to their scheduled focus group, in-depth interview, or user-proficiency assessment.

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 instrument development.

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 are:

Patrick Sullivan
A.D. McNaghten
Alexandra Ricca
Akshay Sharma

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

Lisa Belcher
Arin Freeman
Darrel Higa
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