Multi-Site HIV Testing in Community Mental Health Settings Serving African Americans

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B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Method

The sampling frame for persons selected to participate in this project will be clients at one of the six participating implementation sites. The six mental health settings will be located in Philadelphia and Baltimore, through a cooperative agreement with the University of Pennsylvania. In each city, testing and linkage to treatment services will be offered to individuals receiving mental health services in a general medical hospital psychiatry inpatient unit; a community-based outpatient mental health clinic; and a community-based mental health outreach program.

Eligibility will be determined according to information provided by clients. The population of interest for this project is clients at the selected mental health sites. Eligible persons will be selected prospectively, as described below in the section titled, "Selection of Participants." Through an informed consent process, selected persons will be asked to participate in an interview and to provide an oral swab or fingerstick blood specimen for rapid HIV testing.

Respondent eligibility criteria

Eligible persons are those who:

- Are an adult, age 18 or older
- Are able to speak and understand English
- Are willing to receive rapid HIV and other STI testing regardless of known status
- Have the capacity to provide informed consent for participation.

Ineligible persons are those who:

- Do not have the capacity to provide informed consent for participation (including a lack of capacity secondary to active psychiatric symptoms or intoxication).
- Are a prisoner or correctional detainee
- Are unable to speak English

Selection of Participants

An interviewer and counselor/tester will be present in the selected implementation sites and will seek to recruit clients systematically according to the sampling plan for the survey and testing. The overall response rate will be calculated as the percentage of clients approached who agree to participate. The overall response rate is expected to be approximately 90%.

In the in-patient setting, the interviewer will obtain a roster of new admissions since the interviewer was last at the facility. Providers will be given the opportunity to recommend exclusion of any potential participant whom they feel is medically or psychologically unstable and unable to participate. From the remaining patients on the roster, staff will approach persons based on the length of time they have been on the unit, starting with those who have been on the unit longest (but not previously approached) and ending with those who have been admitted to the unit most recently.

In community mental health clinics, the interviewer will approach persons who have checked in for their appointment at the facility. As with the in-patient setting, clinic staff may exclude certain persons from being approached if staff feels the individual is medically or psychologically unstable or unable to participate. The interviewer will choose patients based on the time they checked in for their appointment, beginning with those who have been in the waiting room the shortest period of time and ending with those that have been in the waiting room the longest period of time.

For recruitment in the outreach setting, outreach staff members will approach all clients whom they feel are medically and psychologically stable enough to participate in the study and will offer them HIV testing. Staff will then provide information on which clients would like to receive testing to the project HIV counselor. The mobile van will be able to travel to various locations in each city to accommodate the testing schedule for a given day. Following recruitment, the study personnel will explain the study and review the consent form.

Sample Size

The number of interviews has been set based on the estimated number of clients approached, the time and resources available for this project, and the expected level of precision for the sample. Research staff will attempt to enroll a total of approximately 600 new participants annually and will likely meet or exceed this goal. Because this project is mainly descriptive, power calculations, which are used in sample size determinations for testing specific hypotheses, were not performed. Instead, the level of precision, i.e., the estimated 95% confidence interval (CI) half-width that can be expected, was examined. The expected level of precision for a systematic sample was calculated for all six mental health sites (n = 1200 over the 2-year data collection period). The following table shows the expected level of precision for an estimate from these data, such as, for example, an estimate of the proportion of persons with a given mental health diagnosis who report a given risk behavior. A design effect of 2 was chosen for the calculations because that level of design effect is commonly encountered in similar surveys. The CI half-widths in the table are the maximum that would be expected for estimates for a total sample size of 1200 for the project over the 2-year data collection period. The table shows the level of precision to be expected not only for estimates for the entire population (column 2), but also for subpopulations (e.g. racial/ethnic groups) that comprise 50%, 25%, 15% and 10% of the total population (columns 3, 4, 5, and 6, respectively).

N	CI half-width total population	CI half-width subpopn = 50%	CI half-width subpopn = 25%	CI half-width subpopn = 15%	CI half-width subpopn = 10%
1200	4.00%	5.66%	8.00%	10.33%	12.65%
1400	3.70%	5.24%	7.41%	9.57%	11.71%

Project staff will attempt to recruit these 1200 clients by direct contact at clinical sites. This sample size goal has been established based upon the above precision estimates, the resource limitations of the project, and the estimated number of clients approached in the clinical settings.

2. Procedures for the Collection of Information

Personal Interview

All interviews will be conducted by trained project staff, in a location that assures privacy in the mental health care setting. Participation in this project is voluntary; a decision not to participate will not affect an individual's right to mental health, medical, or other services. Respondents may refuse to answer questions or stop participation at any time without penalty. Informed consent must be obtained as required by CDC's IRB and state/local IRBs in the project areas. Each person approached will be invited to be interviewed and to provide an oral swab specimen or finger stick blood specimen for rapid HIV testing. Persons approached can elect not to participate in the survey and still provide a specimen for testing. However, no one who refuses all testing will be asked to participate in the interview.

A brief eligibility questionnaire will be administered to determine if the person is eligible to participate in the study (Attachment 3a). The eligibility questionnaire will take approximately one minute to complete.

If a person is eligible to participate, s/he will be asked to provide informed consent process. Informed consent may be obtained by any of the following methods, as determined by the project areas:

- having the participant read and sign the informed consent form;
- having the interviewer read the form to the participant and asking the participant to sign the form; or
- having the interviewer read the form to the participant and indicating on the form that the participant provided verbal consent.

After reviewing the informed consent form (Attachment 8) with the study personnel, potential participants will be encouraged to ask questions about the consent form and the study. Once all the questions have been answered, study personnel will assess the capacity of the client to provide consent for participation by asking the candidate five questions about the project to check his/her comprehension (Attachment 3b). If any question is explained more than two times and the respondent still does not answer the question correctly, correctly then s/he will be determined to be unable to provide

informed consent and so will be ineligible to participate. The consent process will take approximately 10 minutes to complete.

Persons who pass the consent comprehension interview will be administered a standardized, structured questionnaire (Attachment 3c). The structured questionnaire consists of questions designed to collect self-reported demographic characteristics, mental health symptoms, and risk and testing behaviors. The survey incorporates validated assessment instruments for psychiatric symptoms, including the Behavior and Symptom Identification Scale-24 (BASIS-24) and the standard multi-purpose short-form generic measure of health status (SF-12). Questions on demographics, risk behaviors, and HIV testing behaviors are modeled on questions from the National HIV Behavioral Surveillance System (NHBS, OMB 0920-0990 exp. 3/31/2011). The interview instrument will be programmed into a secure web-based interview program. The interview will be administered face-to-face using the web-based survey interview via a laptop computer.

The laptops will be password protected and the data on them will be encrypted using software approved by the Department of Health and Human Services. No personal identifiers will be included. Interviews will be administered using hard copies of the questionnaire in the event of an equipment malfunction. The hard copies of the questionnaire will not contain personal identifiers, and will be kept in a locked briefcase while being transported to and from interview appointments. The structured interview is expected to take approximately 20 minutes.

Participants will receive HIV prevention materials at the end of the interview, referrals to local HIV prevention and care services, and also prevention information from project staff, as requested.

Quality control/assurance

For quality assurance, the field coordinator will observe each interviewer conduct at least three trial interviews, and 1 in 30 actual interviews, and will evaluate administration, accuracy, and completeness. Additionally, interviewers will periodically review each other's administration techniques to ensure consistency across interviewers.

In order to avoid data loss, and to ensure data security, at the completion of each interview the data is automatically uploaded via the secure website to the main project database. Once the uploading has occurred, all interview data will be deleted from the laptop computer’s hard drive before beginning the next interview.

Project staff will regularly train the interviewers and convene "lessons learned" meetings to understand the problems that can occur with the software and hardware that is used for conducting the interviews. Automated edit checks will be built into the survey interview program used to collect the structured interview data, as a further quality control measure.

3. Methods to Maximize Response Rates and Minimize Nonresponse

Because the interview will take approximately 20 minutes to complete, to increase response rates, potential participants will be offered reimbursement for their participation. Participants will be reimbursed approximately $20 in cash for participation in the interview. If local regulations prohibit cash reimbursement, equivalent reimbursement may be offered in the form of personal gifts, gift certificates, or bus or subway tokens. As described above, a similar reimbursement was used in CDC's Supplement to HIV/AIDS Surveillance (SHAS) project (OMB 0920-0262, exp 06/30/2004) to help achieve adequate response rates for persons who agreed to participate in the interview. Such financial incentives are also useful for populations that are difficult to interview, such as among persons with SMI who might not respond to other means of motivation. In addition, monitoring of response rates will be done through conference calls on a regular basis with the implementation sites, offering the opportunity to share additional strategies for improving response rates on an on-going basis.

4. Tests of Procedures or Methods to be Undertaken

The data collection instruments were developed using validated psychiatric assessment instruments and questions from the National HIV Behavioral Surveillance System, demographics and HIV testing history sections (NHBS, OMB 0920-0990 exp. 3/31/2011). Since these questions comprising the data collection instrument have been previously validated, tested, and/or used, only internal testing by project staff was needed. Overall pilot testing of the instrument was done; not more than 9 persons were involved in this testing.

CDC and local project staff will test the skip patterns and responses both electronically and using paper versions of the data collection instruments. CDC and local project staff will also conduct mock interviews of staff members using the web-based program to interview other project staff.

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

Drs. Chris Johnson and Patrick Sullivan were consulted about the statistical aspects of the project, including the sampling strategy, sample size, and analytic methods. The following individuals were also consulted:

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