Evaluation Models to Assess Patient Perspectives on Opt-out HIV testing in Clinical Settings

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SECTION B.

Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Non-response
4. Test of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

B. Statistical Methods

1. Respondent Universe and Sampling Methods

The respondent universe will include patients seen in one private practice primary care clinic, one public primary care clinic and one emergency department all estimated to serve patient populations with more than 0.1% HIV prevalence (the threshold estimated to make routine testing sustainable by the CDC) and offering routine HIV screening. Clinical settings will have been chosen to represent a clinical setting targeted for the evaluation models toolkit and to serve patient populations of interest, such as African Americans and Latinos; patient characteristics will not be used to select participants.

Eligibility criteria to participate in the survey are:

- Age 18 years or older
- Able to complete the interview in either English or Spanish
- Offered routine HIV testing as part of their clinical visit the day of the interview
- Willing to participate in a 20 minute interview
- Capable of providing informed consent

Exclusion criteria are:

- Age less than18 years
- Unable to provide consent as determined by clinic staff
- Already known to be HIV-infected

Each of the 3 implementation sites will have a recruitment goal of 150 respondents for a total of 450 eligible respondents. Persons 18 years or older will be offered participation in the study. If a patient accepts participation, they will be taken to a private area of the clinic where the interview will take place. Patients will first be read a brief consent form and will provide verbal consent to participate. A verbal consent process is being used since it is not necessary to collect names or any other personally identifying information from the patient. Once the patient has consented, they will then begin the survey. It is estimated that 85% of patients approached will accept participation in the survey, which means we will approach approximately 177 patients in each setting in order to reach our recruitment goal of 150 patients per setting.

<u>Sampling Methods</u>

This assessment will be administered via ACASI methods to patients exiting appointments in three different types of clinical settings (public primary care, private primary care, and emergency room). A total of 450 persons (150 participants from each of the three sites) will be systematically selected for the survey. We will randomize the data collection timing in order to survey patients attending the clinics at different times, different days of the week, and seeing different providers across the three clinical settings. Patients will be provided with information on the nature of the project and their right to refuse participation prior to taking the assessment. If they consent, the interviewer will help them use a laptop computer to complete the survey.

The survey will include a series of questions related to demographic variables, experiences surrounding informed consent, confidentiality and pre-test information, knowledge related to HIV testing including advantages of testing, potential risks, linkage to care, and right of refusal, fears related to stigma, discrimination and violence related to testing, HIV risk perceptions, risky sexual practices, social support, access to health care, HIV stigma, and relationships with and trust of medical providers. The ACASI survey will take approximately 20 minutes to complete, and patients will receive $10 for participating. Results from the three sites will be compiled and analyzed with particular attention to understanding issues of feasibility and internal and external validity of the included items.

Sample size

CDC will approach patients in each clinic setting until the recruitment goal of 150 respondents in each of the three settings has been reached, for a total of 450 patients. It is estimated that 85% of patients approached will accept participation in the survey, which means we will approach approximately 177 patients in each setting in order to reach our recruitment goal of 150 patients per setting. The sample size has been calculated to provide adequate data to: 1) assess the validity of the specific measures of patient satisfaction through factor analysis; and 2) determine associations between patient characteristics and satisfaction of routine HIV testing.

With a sample of 450 persons, the following differences between subgroups (for example, Latinos or women) on specific questions (i.e. reasons for not testing) can be detected:

- Sub-sample represents half (50%) of the overall sample: Ability to detect a 14% difference in the prevalence of reported reasons.
- Sub-sample represents 25% of the overall sample: Ability to detect a 30% difference in the prevalence of reported reasons.
- Sub-sample represents 10% of the overall sample: Ability to detect a 40% difference in the prevalence of reported reasons.

Each of these estimates assumes a two-sided test, 5% alpha and 80% power.

Expected response rates

It is expected that response rates will be approximately 85%. This is based on the response rate to surveys conducted among patients seen in clinic settings where HIV testing programs are being developed.[3] The response rates will be monitored closely during the data collection. If expected response rates are not reached, project evaluators will evaluate ways to improve the piloted methods, such as recruiting in the clinic at different times of the day or week.

2. Procedures for the Collection of Information

Main steps in data collection

All interviews will be conducted by trained, bilingual evaluators, in a location that assures patient privacy while respondents complete the interview process. Participation in this project will be voluntary; a decision not to participate will not affect patient care. Respondents may refuse to answer questions or stop participation at any time without penalty. Verbal consent will be obtained from patients before the start of the interview. Once a patient has shown interest in participating, they will be brought to a private room, where project staff will explain the study to the patients. If they still choose to participate, they will provide verbal consent to project staff and staff will provide an information sheet to the patient. We will not request written informed consent from patients because the signature would be the only link between the patient and the survey. Because this study is a survey in which no identifiable information is collected on the patient, it poses minimal risk to participants.

Persons who consent to be interviewed will be administered a standardized, structured questionnaire (Attachment 3). The structured interview will include a series of questions related to demographic variables, experiences surrounding informed consent, confidentiality and pre-test information, knowledge related to HIV testing including advantages of testing, potential risks, linkage to care, and right of refusal, fears related to stigma, discrimination and violence related to testing, HIV risk perceptions, risky sexual practices, social support, access to health care, HIV stigma, and relationships with and trust of medical providers. For persons who refuse HIV testing during their visit, reason(s) for refusal will be collected.

The patient survey will not collect any identifying information. Data collected through the survey are stored and accessed by a survey identification number. The interview instrument will be programmed into a secure laptop and administered through ACASI methods. The laptops will be password protected and data from the laptop will be uploaded to a secure server at the University of California, San Francisco. Electronic data will be destroyed at the end of the analytic phase

Quality Control

Data quality is ensured by use of computer-assisted interviewing, interviewer training and monitoring and data editing. Computer-assisted interviewing improves data quality because:

a) Respondent errors are reduced. Consistency checks are programmed into the questionnaire so that inconsistent answers or out of range values can be corrected or explained while the interview is in progress.
b) Use of computer-assisted interviewing also reduces coding and coding errors, which makes it possible to prepare the data for analysis faster and more accurately.

Trained evaluators will implement the patient surveys in each of the three pilot sites. Evaluators conducting the survey process have extensive training in interviewing skills and have the ability to provide technical assistance to respondents who have problems with the ACASI questionnaire.

The data from the provider surveys and the ACASI patient surveys will be pre-coded and only identified with a number. No identifying information will be collected during the surveys.

3. Methods to Maximize Response Rates and Deal with Non-response

As stated above, it is expected that response rates will be approximately 85% based on previous patient surveys in health-care settings developing or implementing routine HIV screening programs. In order to maximize response rates, project evaluators will first meet with clinic staff to build support for project activities and to encourage clinic staff to let patients know about the survey. If patients perceive that the survey is "endorsed" and supported by the clinic staff, this may assist in increasing patient participation. Staff will hand out flyers in both English and Spanish that will let patients attending clinic appointments know about the survey. The flyer will be given to the patient prior to the patient being approached for the survey. Clinic staff will also be consulted to ensure persons who are unable to provide consent (e.g. patients who are seriously ill) are not approached for the study. Patients will then be approached after their clinic visit and given a brief overview of the survey and asked if they would like to participate in the survey.

To address non-response for specific survey items, evaluators will conduct formative interviews with fewer than 10 persons prior to the pilot study to ensure questions are understandable to patients. Questions that are unclear will be modified to increase response rates for all included items.

4. Test of Procedures or Methods to be Undertaken

The data collection instrument will be undergoing field testing as part of this project. Prior to implementation in the field, project evaluators will test the skip patterns and responses both electronically and using paper versions of the data collection instruments. Evaluators will also conduct mock interviews with other staff members using laptop computers to identify any issues with the questionnaire prior to implementing pilot testing activities with patients.

Patient surveys will be conducted using ACASI with patients leaving their primary care visits at 3 different clinics. The data resulting from the quantitative ACASI assessment in the three clinics will be combined into one data set for analysis to assess the variables of interest. We anticipate that the analyses will use standard statistical techniques to measure the magnitude of patient satisfaction, perceptions and attitudes, including barriers and facilitators to receiving screening. These include ANOVA, chi-squared tests, Kruskal-Wallis, and Fisher's exact tests, among other statistics. Additionally, factor analysis will be conducted to assess the validity of included survey items.

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

Dr. Starley Shade, Principal Statistician for the AETC National Evaluation Center at the University of California, San Francisco was consulted about the statistical aspects of the project, including the sampling strategy, analytic methods and sample size calculations.

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