

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

The group of respondents in the HIV-R MPEP is the universe for these surveys. This includes 750 testing sites that were recruited using CDC databases of sites currently performing HIV testing, reagent manufacturers' customer lists, and respondents recruited from announcements made at national meetings.

Because HIV rapid tests are new in the U.S., and because there is no other substantial proficiency testing program currently available that target these tests, we believe our recruitment efforts have covered, as closely as possible, the universe of U.S. testing sites. Foreign testing sites are generally those involved in other CDC collaborations or are national reference laboratories. There is no claim that these are representative of all foreign testing sites.

Since the most common test used in the U.S. is waived under CLIA, it is uncertain which types of testing sites will tend to enroll in HIV-R MPEP. For this reason it is uncertain whether or not the HIV-R participants will be a truly representative sample of all testing sites. However, we are currently offering the HIV-R MPEP service to all types of testing sites in an effort to obtain a sample of the universe of potential respondents. We anticipate a 95% response rate from all active HIV-R participants. The surveys are designed in such a way that the information gained will benefit all HIV-R testing sites. The information gained from the surveys is available to all HIV testing sites and associated organizations through public domain.

2. Procedures for the Collection of Information

Data is collected from respondents who return either the hard copy of the HIV Rapid Testing Form EZ (mailed in June and December) and LPQ surveys (mailed in December) or respondents who answer the surveys via electronic web site. Hard copy surveys are returned to the contractor through mail in a postage-paid envelope to Constella Group, LLC, Contract # 200-2003-F-01325. Hard copies of the HIV Rapid Testing Form EZ and LPQs are secured in locked, fire-proof file and storage cabinets whose access is strictly limited to approved personnel. The contractor will download the online data from the electronic website and combine it with the data resulting from keypunch of the hard copy data. All data is treated in a secure manner and will not be released in identifiable form, unless compelled by law.

Non-respondents receive one follow-up call from Constella three weeks after the initial surveys are mailed, as a reminder. During this call they ask the participant to respond by submitting their forms. Since this program is the only aggregate quality assurance information specifically directed to HIV rapid testing, we expect a 95% response rate, and sufficient interest from participants to complete these surveys.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Because all of the respondents are voluntary participants in the HIV-R MPEP and are keenly interested in further information about the performance of the tests and testing practice procedures, we anticipate a 95% response rate. Through outside and CDC consultation with organizations involved in HIV counseling and testing centers, the language used in the surveys has been adjusted so as to be broadly understood by all types of testing sites and personnel. The HIV Rapid Testing Form EZ has been designed as a 2-page collection instrument with the first page being of foremost importance. The LPQ has been designed to collect the minimum amount of information needed for improving CDC prevention and control efforts regarding HIV-R testing. Adequate choices of categorical answers have been provided to minimize uncertainty in answering questions. Numerical variables have been linearized for simplification in answering. All answers are voluntary. There should be a minimal number of answers that need to be “looked up.”

This approach is analogous to other unique and successful CDC project surveys. Participants who have not responded within 3 weeks of receipt of the survey will be called by the contractor (Constella) as a reminder. In an effort to minimize public burden, we assume that if participants decline to respond after the follow-up phone call, they are unable to respond, and we therefore drop them from the participant cohort. We expect this to be rare, and fully expect adequate participation to constitute a valid project survey.

4. Tests of Procedures or Methods to be Undertaken

These surveys were developed by public health scientists, statisticians, epidemiologists, and program managers from the Division of Laboratory Systems, CDC. The survey design was directed by Project Officers who are public health scientists and epidemiologists with experience in HIV testing and in survey design and analysis. In addition, microbiologists, physicians and public health scientists from the National Center of HIV, STD, and TB Prevention (NCHSTP) and from the National Center for Infectious Diseases (NCID) were consulted. The comments and advice from these experts were incorporated into the survey designs.

The survey was sent to the director of a community-based HIV counseling and testing center for advice as to its practicality for use by non-scientist, non-laboratory based personnel. The surveys were also reviewed by an experienced HIV counselor. Based upon this collective advice, the wording of questions was modified so as to be broadly understood by volunteers or other persons with limited technical qualifications. Feedback from all consultants was incorporated into the survey designs.

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

Statistical consultation for the surveys was provided by Dr. Harvey Lipman, Senior Statistician, CDC/DLS. The comments of Dr. Lipman were assessed and

incorporated into the survey design by the Project Officers. Project Officer, Dr. Laurina Williams has extensive training and experience in public health, epidemiology, survey design, and statistical analysis. Project Officer, Mr. David Cross, has extensive experience in testing practice, survey design and analysis for HIV-related testing.

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