Minority AIDS Initiative Rapid HIV Testing
Clinical Information Form

Implementation with Ethnic and Racial Minorities at Risk for Substance Use and HIV/AIDS

SUPPORTING STATEMENT

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

This section presents information about SAMHSA's collection of rapid HIV test data as a requirement of funded grantees and the use of the RHT form. The information collected using the RHT form will assist in the enhancement of preventive services for those who test HIV-negative and referral to high-quality treatment/medical care for those who test HIV-positive.

It is expected that each grantee will offer a rapid HIV test to all its clients and complete the RHT form for each client. In addition, clients may be offered a second test if they continue to engage in high-risk sexual and drug-taking behaviors or if they have been recently exposed or suspect that they have been exposed to HIV.

Many prior studies have had to rely on self-report of HIV status in trying to determine the predictors of infection. They also often also rely on other self-reported behaviors important to understanding HIV infection. However, research in assessing the validity of the self-report of HIV status has shown that anywhere from 10% to as high as over 40% (Latkin and Vlahov, 1998; Strauss et al., 2001) of HIV positive individuals give a false answer when asked about their status. Few individuals report a positive test and consequently turn out to be negative, but false negative answers vary widely (Strauss et al., 2001) Research finds that this variation is based on the wording and placement of the question (separate from question about risk behaviors), the in introductory statements (more accurate disclosure if preceded by a statement that many people in the area are HIV positive) and the setting itself (high prevalence versus low prevalence areas). Some of the variation in answers can also be due to timing of tests; that is, an individual may have been tested in the past, testing negative and since seroconverted.

The structure of the RHT form and the locations in which the tests are offered may help to mitigate some tendency of persons to report inaccurately. The question regarding whether the individual had a previous test (Section B: 5) precedes any questions regarding risk behavior (Section D). In addition, MAI-TCE grantee cities were selected as the US cities with the highest rates of HIV infection, settings in which the stigma of HIV may be reduced to some degree. This also may be mitigated by the fact that the funds for this program are to target those persons who are HIV positive, who test positive through rapid testing, or who are at risk for HIV. Grantees are charged with providing rapid testing to as many untested or not recently tested individuals as

possible to assure that MAI-TCE funds are used appropriately. For this reason, we assume that most persons will be tested as a first step in screening processes (rather than relying simply on self-report) so that the appropriate services and/or medication can be developed for them. Because programs are charged with providing the best treatment and prevention services related to HIV during the course of each client's participation, it is highly likely that persons who state that they have been tested and tested negative will be retested in the course of their receipt of services, both to verify the original information and to determine if any reinfection may have occurred since last testing.

There are also programs in the MAI-TCE system that are already only serving persons who are HIV positive and/or living with AIDS. Those clients in those programs have already been tested and tested positive. We assume that data on Section B5 of the RHT form (filled out for all clients in the MAI-TCE system) will be verified and that the individual filling out the form will have access to clinical information or referrals.

While not a perfect solution to the issue of the reporting of false results, the combination of the placement of the question, the high prevalence of HIV in the targeted population and SAMHSA's charge that grantees provide as close to universal coverage in rapid testing should significantly minimize this issue.

SAMHSA is now adding the Minority AIDS Initiative Targeted Capacity Expansion Program (MAI-TCE). The purpose of the MAI-TCE program is to facilitate the development and expansion of culturally competent and effective integrated behavioral health and primary care networks, which include HIV services and medical treatment, within racial and ethnic minority communities in the 11 Metropolitan Statistical Areas (MSAs) and Metropolitan Divisions (MDs) most impacted by HIV/AIDS. It is expected that the additional grantees would increase the burden on grantees by an annual average of 6,384 hours.

Funded grantees include substance abuse treatment clinics, federally qualified health centers, community-based organizations, local health departments, AIDS service organizations, and States receiving block grants.

2. Information Collection Procedures

The RHT form is available to all grantees for completion through the online data collection system. Grantees also have the option to print a blank copy of the RHT form from the online system, mark data on the paper form, and enter the data in the online system at a later time. Each RHT form has the client's unique GPRA identification number. Grantee staff offers each client a rapid HIV test and completes the RHT form during the in-person encounter. If a client refuses a rapid HIV test or has already been confirmed HIV-positive, then only Sections A to D of the RHT form are completed. RHT form data are entered at the grantee site on the password-protected online system. Each person using the online data collection system has a unique username and password. In the event that a rapid HIV test is positive, grantee staff conducts a

confirmatory test and records the results in the online data collection system, which can be edited up to 30 days before the data are exported.

3. Methods to Maximize Response Rates

SAMHSA anticipates that a 100 percent response rate will be achieved because the RHT form is completed for all clients regardless of whether they take a rapid HIV test. If the respondent refuses to take a rapid HIV test, only Sections A to D of the RHT form are completed.

Traditionally a non-response rate refers to the calculation of rates of refusal to be surveyed or to answer a particular question on a survey or form. High non-response rates jeopardize the utility of the data received and introduce an unknown source of bias in the results. In this case, non-response can be seen as either 1) the absence of the RHT form (missing data), and 2) presence of the form but refusal to take the RHT. Both sources of error are important to address.

Absence of the form. Each grantee is required by SAMSHA to use the RHT form for *all* clients in the MAI-TCE program, regardless of whether they are actually tested. For all clients there should be a RHT form and data in the TRAC-NOMS data system which has been mandated for each grantee. In developing the client level analysis file for this evaluation, programmers will merge the RHT form with data on each client recorded by the program in the SAMHSA TRAC-NOMS system. If there is not a RHT form for an identified client, Abt staff will notify the program and request that a form be submitted for that client, thus addressing non-response related to missing test form data. In this case analysts have to assume that the absence of the form does not represent a systematic bias, but an administrative failure on the part of the grantee program.

Presence of the form but refusal to take the test. The case of large numbers of clients refusing to take the RHT is an operational issue for each of the grantee programs to address, as one of the goals of the program is to test as many at risk individuals as possible. Part of the evaluation of program implementation and process is to examine each grantee's success in reaching that goal and to identify those grantees that have lower than anticipated numbers of clients being tested; those grantee sites may require technical assistance from SAMHSA in that regard.

But there will still be clients who refuse to be tested. Given that all clients should have a RHT form regardless of whether he/she was tested, considerable data are available to examine both the proportion of the grantee's population who are tested and those who refuse. Refusal is indicated in Section C on the form. Clients may refuse to take the test and the reasons for refusal are recorded in an open text field. Even if they refuse, the questions in Sections A, B, C and D are asked.

However, non-response in the case of a refusal to be tested is likely not just based on operational issues; that is, there is likely some relationship between refusal to take the HIV test and some characteristic of the respondent (gender, use of drugs) or the circumstances of the survey (fear of disclosure). We plan to address the issue of refusal to take the rapid test (non-response) in the

following ways. The first step in examining biases in refusals is to examine the answers recorded in Section C. The text field ("Reason for client refusal") will be coded into logical categories and examined in descriptive statistics. If there are reasons that can be addressed through program operations (language barrier, time it is offered) these will be transmitted to the grantee periodically to improve response rates.

But there are also likely observable factors that influence an individual's reason for refusing the test, and these factors may also have an impact on outcomes. In the most direct sense, knowledge of HIV status is an important independent variable in examining the effectiveness of programming, making a client's refusal to be tested for that information a critical piece of data. Fortunately, the RHT form provides considerable data with which to predict refusal to be tested (i.e., demographics, risk behaviors, drug use, and prior treatment). Using refusal/no refusal as the dependent variable, analysts can use regression to assess the relative contribution of factors to that refusal. If the decision to refuse testing is random, none of these factors will be significant and we can assume no clear pattern of bias. If however there are significant differences in terms of who agrees to testing, we would adjust the analysis to control for those biasing characteristics in analysis of outcomes. A multivariate analysis such as logistic regression of possible relationships between the refusal and some of the outcomes of interest can help identify those variables with the potential for producing the greatest bias in results.

One method to make that adjustment is to develop case weights through creating propensity scores for those cases based on regressions. Propensity scores are usually used to help compare two or more groups where there is a bias or confounding effect in the characteristics of the groups that will affect the analysis of outcomes. Since in this case we have a large amount of data on both those who refuse testing and those who don't, we can summarize that data into a single score and use that score as a weight or as a covariate in the analysis.

The propensity scores come from a series of logistic regressions where the explanatory variables are those variables that may affect the probability that an individual will refuse; again, these factors could be could be age, gender, risk factors, etc. While the selection of variables to enter into the analysis can be theory or research driven (risk behaviors, gender), they can also be identified or reduced in number in the initial cross tabulations of characteristics of individuals and whether they refused the test or not. For weighting purposes, the inverse of the joint probability scores derived from the regression can then be used sampling weights in analyses. The score itself can also be used as a covariate in the analysis of outcomes.

4. Test of Procedures

The RHT form has been in use since the fall of 2009, and no problems related to either its implementation or completion have been encountered.

Instruments and Consent Forms

Although no directly identifiable information is collected for each respondent, a small possibility exists of connecting the information contained on a form to the tested individual. This possibility only exists if the client ID can be linked to a specific individual. With the grantees using federally approved measures for securing sensitive information the chance connecting such information to an individual is very remote.

Benefits

The benefit to the client in taking the RHT is awareness of their HIV status and the possible need for services.

5. Statistical Consultants

This material has been reviewed by:

Robert Atanda, Ph.D.	Chief, Performance Measurement Branch CSAT, SAMHSA	240-276-1621
Wilson Washington, Ph.D.	Public Health Advisor, Performance Measurement Branch CSAT, SAMHSA	240-276-2973
Darren Fulmore, Ph.D.	Public Health Advisor, Performance Measurement Branch CSAT, SAMHSA	240-276-2824
Resa Matthew, Ph.D.	Senior Researcher, JBS International, Inc.	240-645-4608
Nancy Silva, Ph.D.	Program Manager, JBS International, Inc.	240-645-4301
Jaslean La Taillade, Ph.D.	Data Manager, JBS International, Inc.	240-645-4803

Additional consultation outside of SAMHSA Center's team (comprised of CSAT, CMHS and CSAP representatives) was not utilized. This request, essentially, is for the continued use of an approved form.

REFERENCES

Latkin, C. and Vlahov, D. (1998) Socially desirable response tendency as a correlat4 of accuracy of self-reported HIV serostatus for HIV injection drug users. *Addiction* 93:1191-7.

Strauss, S., Rindskopf, D., Deren, S., and Falkin, G (2001). Concurrence of drug users' self-reports of current HIV status and serotest results, *Journal of Acquired Immune Deficiency*

Syndrome, 27:301-307.

List of Attachments

Attachment A: Minority AIDS Initiative (MAI) Rapid HIV Testing Clinical Information Form

Attachment B: List of RHT Grantees

Attachment C: List of MAI-TCE Grantees

Attachment D: Consent Form