

Co-location and Integration of HIV Prevention and Medical Care into Behavioral Health (Co-located and Integrated Care)

Supporting Statement

B. Statistical Methods

B1. Respondent Universe and Sampling Methods

The respondent universe for each of our data collection instruments is described below:

Combined HIV/Hepatitis Testing Form. It is expected that each grantee will offer a rapid HIV and hepatitis test to all its clients and confirmatory testing to those who screen positive for antibodies to HIV, HBV or HCV. 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.

Grantees will be asked to complete a testing form for each individual who is offered an HIV/hepatitis test.

Co-located and Integrated Care version of TRAC. Individuals who test positive for HIV and receive integrated medical care through this grant program will be required to complete the entire TRAC interview at baseline, at each six-month reassessment, and at discharge

Individuals who only receive prevention services will be required to complete the following sections of TRAC at baseline: Records Management; Demographics; and up to five “pre-test” questions from Section H that focus on HIV knowledge and/or attitudes. At discharge from prevention services, these individuals will be required to respond to the same Section H questions that they answered at baseline.

HIV Indicators. Data will be collected from all individuals who test positive for HIV and receive integrated medical care through this grant program.

Sampling

Sampling procedures will not be used for selecting clients.

B2. Procedures for Collection of Information

Individual grantee sites will be responsible for the collection and submission of all data instruments. SAMHSA will provide or coordinate training on data collection procedures via webinar prior to the collection of any data. Additional trainings will be offered to all grantees as new needs are determined.

Detailed information on the collection of each data instrument is outlined below:

Combined HIV/Hepatitis Testing Form. It is expected that grantee sites will offer an HIV and hepatitis test to each client. Forms will be completed at the time of HIV/hepatitis testing by trained personnel. Questions requiring information from the client (Sections B and C) will be administered in an interview format. Information relating to site characteristics, testing results and services and referrals (Sections A and D-I) will be completed by grantee staff at the time of testing. The completed form is placed in the client's record. At the time the provider receives the results, a decision is made to continue with the vaccination series or refer the patient to follow-up services. Testing forms will be completed at the grantee site and entered into a secure web portal that will be developed and maintained by the evaluation contractor. SAMHSA anticipate that completion and entry of the testing forms will take approximately eight minutes.

Prior to implementation of this collection, SAMHSA will consult with a professional institutional review board and determine whether the collection is exempted from review, informed consent may be waived, or informed consent must be provided.

SAMHSA/CSAT will not make any generalizations or national estimates about these clients who are served or the programs serving them.

Co-located and Integrated Care version of TRAC. The Co-located and Integrated Care version of TRAC will be administered to all clients receiving medical or prevention services covered by grant funds. Some grantees utilize service providers to conduct client-level baseline and follow-up assessments, while others have specially trained evaluators perform this function.

SAMHSA will provide downloadable paper versions of the data collection instruments to facilitate this process. These grantees will then submit their data electronically via a web-based data entry process. The data for those clients with both baseline and periodic reassessment data are matched using a unique encrypted client identifier developed by the grantee. Grantees will be clearly instructed not to use identifying information (i.e., social security number or initials) as the client identifier.

Required data collection points are:

Baseline. HIV positive individuals receiving medical services will complete the entire TRAC instrument during their first appointment with an integrated care team member.

Individuals who only receive prevention services will be required to complete the following sections of TRAC at baseline: Records Management; Demographics; and up to five "pre-test" questions from Section H that focus on HIV knowledge and/or attitudes. These sections will be administered by a provider immediately prior to their first prevention service appointment.

Reassessment: Clients will be required to provide client-level data every six months while the client is receiving funded services. SAMHSA anticipates that the vast majority of prevention services will have a duration of less than six months. Therefore, SAMHSA anticipates that most individuals who are only receiving prevention services will not be eligible for re-assessment interviews, but will only complete a baseline interview and discharge interview at the cessation of prevention services.

Discharge: Grantees must provide information on the type of discharge on all clients who are discharged. When the discharge is a planned event, the client will also be asked the relevant questions on the TRAC client-level data collection instrument. Individuals receiving integrated

medical services will be asked to complete the entire discharge interview at the time of discharge. The one exception to this requirement is when a client had responded to these same questions within the past 30 days as part of a Reassessment.

Individuals who have ended their participation in prevention services (whether a planned or non-planned event) will be asked to complete a limited number (up to five) of relevant knowledge and attitudes questions contained in Section H. The questions completed in the discharge interview will be the same questions that were administered during the baseline interview.

B3. Methods to Maximize Response

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.

All data collection will occur as part of the normal course of service delivery. Clients are typically quite cooperative with grantee staff because of the relationship established during service provision. However, some clients do not return to services during this timeframe. In these cases, the provider must complete an administrative discharge for the individual. Additional efforts to maximize response rates for each of our data collection instruments are outlined below.

Combined HIV/Hepatitis Testing Form. Grantee staff members will offer clients a rapid HIV and Hepatitis test during the course of normal business. Staff members will note the importance of HIV/hepatitis testing, but will stress that the test is not mandatory, and that their treatment will not be affected if they decline the test. Grantee staff members then briefly explain to clients the reason for the Combined HIV/Hepatitis Testing Form, describe the form length, and explain the process. If clients agree to take a rapid HIV and/or hepatitis test, the grantee staff members administer the rapid tests and complete the Combined HIV/Hepatitis Testing Form while waiting for the test results. Grantees will be required to complete a Combined HIV/Hepatitis Testing Form for each client, whether or not the test was completed. If the client declines the test, only sections A-C are completed. Because this data is only collected at one time-point, attrition is not an issue.

Co-located Care Version of TRAC. Grantees will establish their own procedures to collect baseline, reassessment, and discharge data as part of their own internal protocol.

Baseline data collection will typically take place at the time of each client's first services after testing occurs. For individuals receiving integrated HIV medical services, this baseline data collection will occur during the client's first visit with a medical provider. For individuals receiving only prevention services, baseline data collection will occur at the time

TRAC reassessment interviews will be completed by grantee staff during regularly scheduled appointments with a service provider.

HIV Indicators. Grantees will be required to report information on HIV indicators for clients receiving integrated medical services. Reporting of the HIV indicators will occur as part of client's normally scheduled **Co-located and Integrated Care** interview. Clinical data needed to report the indicators will be obtained by grantee review of each client's medical chart and/or electronic medical record. As providers of HIV medical care, grantee sites will have access to

systems that contain all needed data elements. SAMHSA's personnel and its contractors will work closely with sites in order to ensure that they are able to collect and report all needed data elements.

B4. Tests of Procedures

Combined HIV/Hepatitis Testing Form. The combined HIV/Hepatitis Testing Form is a streamlined version of the MAI-TCE Hepatitis Testing Form (OMB #0930-0300) and the MAI-TCE HIV testing form (OMB # 0930-0295). Both of these forms have been in routine use for several years. No problems related to their implementation or completion have been encountered.

Co-located and Integrated Care Version of TRAC. All the data elements in the TRAC client-level data collection instruments were taken from established data collection instruments that have a history of use in the mental health field and have already been tested for validity and reliability, (i.e., the MHSIP, YSS-F, YSS, K-6). The Co-located and Integrated Care version of TRAC includes several modifications to the existing TRAC instrument. The substance abuse questions included in the current version of TRAC will be replaced with questions utilized in the OMB-approved SAIS tool: (OMB No. 0930-0208; Expiration Date 04/30/2013). The Co-located and Integrated Care version of TRAC will also include program-specific questions related to HIV knowledge and attitudes that are currently OMB approved (OMB No. 0930-0298; Expiration Date: 2/29/2016) or have been OMB-approved in the past (OMB No. 0930-0208; Expiration Date: 4/30/2013).

HIV Indicators. Data elements included in the HIV Indicators includes data needed to calculate the HHS Core HIV Measures as well as the use of several validated and widely used indicators used to provide global assessments of client functioning. The data elements included in this section have been reviewed and approved by SAMHSA's Medical Director, Dr. Elinore McCance-Katz.

B5. Statistical Consultants

The individuals responsible for overseeing instrument design and data collection are the following:

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Attachments

1. Combined HIV/Hepatitis Testing Form
2. Co-located and Integrated Care Version of TRAC
3. HIV Indicators
4. Detailed information regarding the composition of the Co-located and Integrated Care version of TRAC
5. CGI Scales and rating information
6. Karnofsky Scale and detailed rating information