

Hepatitis Testing and Linkage to Care Monitoring and Evaluation
System (HEPTLC)

Supporting Statement B

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Contact Information:

Jianglan White, M.D., M.P.H.
National Center for HIV, STD, and TB Prevention
Division of Viral Hepatitis/Prevention Branch
Centers for Disease Control and Prevention
1600 Clifton Rd, NE, MS G-37
Atlanta, Georgia 30333
Voice: (404) 718-8551
Fax: (404) 718-8595
E-mail: vyg1@cdc.gov

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B. Statistical Methods

This collection does not employ statistical methods.

1. Respondent Universe.

Agencies and organizations funded to conduct hepatitis testing and linkage to care activities to increase early identification and linkage to care and treatment of persons with undiagnosed chronic Hepatitis C and/or B infection, with a focus on populations who are disproportionately affected by these infections in multiple settings. Data will be collected from all of these awardees via a web-based Hepatitis Testing and Linkage to Care Monitoring and Evaluation System (HEPTLC).

The target populations and risk factors are identified through surveillance data. The testing participants will be recruited at testing sites. Teams of trained hepatitis counseling and testing staff will provide testing and associated counseling and linkage to care and preventive services to participants at implementation sites. Data will be collected in the process of planning and delivering the testing, counseling and linkage to care services. Data will be collected for every client in every session of testing event, including prevision of testing, counseling and linkage to care. Since all awardees are reporting on all participants, no sampling or respondent selection will be

employed in data collection process. Awardees will include approximately 40 sites at multiple settings, such as state and local health departments, community based organizations, community health centers, PWID treatment centers and other settings, including STD, HIV clinics, FQHCs, etc. Test-level data will be submitted to CDC monthly, and aggregated programmatic data will be submitted to CDC quarterly.

The HEPTLC data are used to monitor and evaluate hepatitis testing and linkage to care activities undertaken by funded sites, including novel implementation efforts and numbers of persons reached through the PPHF testing and linkage to care activities. In particular:

CDC will use HEPTLC data for the following purposes:

- Monitor the implementation activities of HEPTLC initiative, as well as evaluate the progress and performance made by the awardees in meeting with goals and measurable objectives outlined in the cooperative agreements (Attachment 3: Goals/Objectives Table). Findings will further inform strategic planning and program improvement;
- Inform recommendations and strategies to increase early identification of infected persons and linkage to care, based on the information of client characteristics and linkage to care. Data collected via the HEPTLC system will

inform whether the target populations have been reached under the hepatitis control and prevention recommendations and strategies, which calling for prevision of testing and linkage to care services to control and prevention of chronic hepatitis B among foreign born populations, and of chronic hepatitis C among baby boomers and injection drug users, based on demographic information, risk factors, vaccination history...etc. (**Attachment 4 & 5**);

- Based on data collected via HEPTLC (**Attachment 4 & 5**), CDC will be able to determine the progress of awardees in achieving the goals and measurable objectives outlined in the cooperative agreement (**Attachment 3**), identify best practices (effective targeting strategies, implementation models, collaborative partnerships)and gaps in implementation of hepatitis testing & linkage to care , and guide CDC in the provision of technical assistance to grantees;
- Produce standardized and specialized reports with process and outcome measures that will inform awardees, CDC Project Officers, HHS, Congress and other stakeholders of project accountability and transparency. The HEPTLC data are also used to inform stakeholders, including federal and state executive offices and legislative bodies, based on specific information regarding how public health resources are used

programmatically, for what purpose, to whom and to what effect;

- Assess Prevention Public Health Funds (PPHF) budget allocation with respect to prioritized risk populations;
- Advocate the needs for priority setting and budget allocation for hepatitis prevention.

Funded sites will use HEPTLC data for the following purposes:

- Understand targeted populations (demographics, risk behaviors, vaccination histories, etc.) and assess the extent to which the targeted populations have been reached;
- Document how well the project is progressing in meeting goals/objectives set forth by CDC (e.g. who delivered what to whom, how many, where, when, and how well);
- as well as performance indicators related to testing, counseling and linkage to care;
- Highlight opportunities for local program collaboration and service integration (PCSI) to prevent viral hepatitis and other infectious diseases, including HIV, STD and TB;
- Fulfill data collection and reporting requirements outlined in the cooperative agreements.

The approaches or methods associated with the monitoring and evaluation include:

- 1) Monthly testing and linkage to care activity reporting via HEPTLC System on data variables set in the system, consisting of Section A: Agency and Site Information; Section B: Client Demographic Information; Section C: Hep B and C Test Laboratory Information and Test Result; Section D: Client Vaccination History; Section E: Post Test Follow up (providing test results, post-test counseling and linkage to care, reporting to surveillance); Section F: Risk Factors (**Attachment 4.1 & 4.2: HEPTLC Data Collection Templates**);
- 2) Quarterly programmatic reporting via HEPTLC system with aggregated programmatic activities across testing, counseling and linkage to care treatment and preventive services (**Attachment 5: HEPTLC Programmatic Reporting Templates**);
- 3) The collection of data via HEPTLC will also contribute to two major reporting documents throughout project period, including Interim Progress Reporting (IPR), Annual Progress Reporting (APR).

2. Procedures for the Collection of Information

Although data elements that will be entered in the HEPTLC system in this ICR are standardized, data collection procedures across

grantee's sites may vary. Awardees will collect both test-level and programmatic data information from test sites. They will then either enter it directly into the HEPTLC system by using HEPTLC system form or by using their own data collection instruments at multiple test sites. Data in HEPTLC will be encrypted and transmitted via the CDC FTP or SDN to CDC. CDC will not have access to Information in Identifiable Form (IIF), as it will be stripped out before reaching by CDC. All grantees are required to use a secure application, for collecting and reporting standardized, sensitive hepatitis testing data.

3. Methods to Maximize Response Rates and Deal with Nonresponse
Not applicable.

4. Tests of Procedures or Methods to be Undertaken.

As part of the HEPTLC development and dissemination, there will be test runs conducted to ensure the functionality and security of the system. The testing procedure will ensure that CDC does not receive IIF and that encryption is sound.

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

The Hepatitis Testing and Linkage to Care (HEPTLC) variables and values have been developed over the past six month by Prevention

Branch under the direction of the Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD, and TB Prevention. The Director of the Division of Viral Hepatitis is Dr. John Ward (404-718-8513). Data will be analyzed by the Prevention Branch staff, to monitor and evaluate the progress and performance undertaken by the grantees in meeting objectives outlined in the cooperative agreements.