

Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection Among Intravenous Drug Users Hepatitis Test and Vaccine Tracking Form

SUPPORTING STATEMENT

A. Justification

1. Circumstances of Information Collection

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center Substance Abuse Treatment (CSAT), is requesting an OMB review and approval of the Minority AIDS Initiative (MAI) for the Enhancing Substance Abuse Treatment Services to Address Hepatitis Infection among Intravenous Drug Users, Hepatitis Test and Vaccine Tracking Form (see Attachment A). This data form allows the Program to collect essential information that is used for quality assurance and product monitoring on approximately 264 Hepatitis C test kits and 10,628 Hepatitis vaccines that is provided to community-based opioid treatment programs (OTPs) serving predominantly minority communities at no cost to the recipients. These populations include African-American, Hispanic, Asian, Pacific Islander, and Native American ethnic and racial groups.

This data collection is "In Use Without OMB Approval". SAMHSA/CSAT originally thought this data collection fell under the clinical exemption which does not need OMB approval because it is associated with the testing of biological fluids. There is a verified need for Hepatitis vaccines and test kits from OTPs that are depending on these shipments. It has now been determined that the SAMHSA/CSAT SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form requires OMB approval.

This data collection is authorized by Section 505 of the Public Health Service Act (42 USC 290aa-4) – Data Collection.

The intent is to reach the country's most vulnerable population who might otherwise not have adequate access to preventive and treatment services. The target population for the initiative is intravenous drug users at risk for substance use, hepatitis infection, liver disease, and HIV/AIDS. The hope is to build and or strengthen opioid treatment programs' capacity to provide sexually transmitted disease education and prevention services to at-risk populations; increase the awareness of hepatitis screening and vaccination through outreach and education; and increase the number of individuals who know their hepatitis status.

Intervening with intravenous drug users represents a unique opportunity to provide vital healthcare services to a population at risk for and disproportionately affected by hepatitis infection. The program supports SAMHSA goal of providing a comprehensive therapeutic milieu comprising primary medical care, psychosocial counseling, vocational rehabilitation, HIV testing and counseling, HCV education and testing, and other medical and social services to promote recovery from opioid dependence. In a recently published article in the *Public Health Reports*, SAMHSA officials report that demand for hepatitis vaccines by OTPs exceeded the

ability to supply them.

Reducing viral hepatitis is an important public health strategy. Highly efficacious vaccines are available to prevent new hepatitis A virus (HAV) and hepatitis B virus (HBV) infections, but unfortunately, a vaccine for hepatitis C virus (HCV) is not available. Further, a HCV vaccine is difficult to produce because mutations occur during viral replication. Even with effective vaccines, HAV and HBV continue to be among the most commonly reported vaccine-preventable diseases in the United States, and HCV infection is the most common chronic blood-borne infection in the United States. In order to reduce viral hepatitis it is necessary to identify people at risk of infection, educate them about hepatitis, test them for hepatitis exposure, vaccinate those who qualify for it, and treat those with acute infections.

This project focuses on minority intravenous drug users (IDUs) seeking treatment for addiction to opiates. Research has shown a high rate of HCV infection among this population as illustrated in Exhibit 1.3. People are often unaware of an HCV infection because they are not chronically ill. However, about 70% of chronically infected persons develop chronic liver disease with an increased risk for development of cirrhosis and liver cancer. In the United States, HCV is estimated to cause from 40% to 60% of cases of chronic liver disease and 8,000 to 10,000 deaths annually. Intravenous drug use is the chief mode of HCV transmission in the United States, and HCV disproportionately affects people of color: 3.2% of African Americans and 2.1% of Mexican Americans are infected compared to 1.5% of non-Hispanic whites.

IDUs in particular are likely to have undetected HCV infection. The infection is rapidly acquired after drug users first inject drugs and because the majority of acute infections are asymptomatic, it is difficult to diagnose in the acute stage. It is especially important to intervene with this high risk population. If they do not receive treatment and they do not change their behavior, they will likely spread the hepatitis virus to others.

This project is a vital community clinical service involving the use of Federal government purchased, FDA approved Hepatitis C test kits and vaccines; thus, it is critical to get these test kits and vaccines into the community as soon as possible. It is also important for SAMHSA/CSAT to know that the test kits and vaccines are reaching their intended audience. Furthermore, since State jurisdictions often require associated pre- and post-counseling and referral strategies, it is important for us to know whether compliance with these expectations are occurring.

Viral hepatitis and HIV infections are intersecting epidemics among injection drug users and possess many shared public health and treatment concerns.¹ In 2000, there was an estimated 240,000 persons co-infected with HCV and HIV, which was approximately 30 percent of the estimated 800,000 individuals with HIV infection.² Because HCV and HIV are both transmitted by percutaneous exposure to blood, coinfection is common in IDUs. The U.S. Public Health

1 Peters M. Managing hepatitis B coinfection in HIV-infected patients. *Curr HIV/AIDS Report* 2005; 2:122-6.

2 Sulkowski MS, Mast EE, Seef LB, Thomas DL. Hepatitis C virus infection as an opportunistic disease in persons infected with human immunodeficiency virus. *Clinical Infectious Diseases*. 2000 April; 30 Supplement 1: S77-S84.

Service/Infectious Diseases Society of America (USPHS/IDSA) guidelines recommend that all HIV-infected persons should be screened for HCV infection.³ SAMHSA/CSAT understands that the prevention of HCV infection for those not already infected and reducing chronic liver disease in those who are infected are important components of public health, especially for HIV-infected individuals.

2. Purpose and Use of Information

The data on the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form will be used to collect information that will be used for quality assurance, quality performance, and product monitoring. The form does not require patient specific information to be collected from parties participating in the MAI program. The form is designed to inform SAMHSA that the hepatitis tests/vaccines are reaching their intended audience, as many communities have expressed an interest in acquiring these no cost test kits to assist them in informing and protecting their citizens. The information that we require, will also serve to justify the use of Federal funds to benefit these communities.

The SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is one-page, and it takes approximately 3 minutes to complete.

The information collected on the Form will solicit and reflect the following information:

- Demographics (age, gender, ethnicity) of designated OTP site
- History (Screening) of Hepatitis C exposure
- Results of Rapid Hepatitis C Testing (Kit) and Follow-up information
- Service Provided (type of vaccine given) Divalent vaccine (Twinrix- combination HAV and HBV) or Monovalent vaccine (HAV or/and HBV)
- Substance Abuse Treatment Outcomes (Information regarding the beginning, continuing or completion of vaccination series)
- Type of Referral Services Indicated (ie; Gastroenterology, TB; Mental Health, Counseling, Reproductive/Prenatal, etc.)

The form does not contain patient specific identifiers, however it does contain space for lot number identification in the event that the FDA determines that problems exist with a specific lot; such problems have already occurred in several areas of the United States, making this information of critical importance to providers and to patients.

3. Use of Information Technology

The design of the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form encourages the use of automation to reduce burden on participating opioid treatment programs. The form can be completed within Microsoft Word and then emailed; it can be completed by hand and faxed or

³ CDC, 2002 USPHS/IDSA Guidelines for the Prevention of Opportunistic Infections in HIV Infected Persons. U.S. Public Health Service (USPHS) and Infectious Diseases Society of America (IDSA). MMWR 2002; 51(No. RR-8).

mailed in pre-paid envelopes. Additionally, if the program previously collects the information needed on the form, they can send the information in the format they use. The use of information technology and the methods for transmitting the form will be determined by program based on the least burden for the opioid treatment program staff.

It is estimated that 80 percent of the responses will be submitted electronically. For the programs where electronic submission increases burden, paper forms will be preprinted and provided at no cost to the opioid treatment programs as needed.

4. Efforts to Identify Duplication

The information is collected only for the purposes of this program and is not available elsewhere. It is possible that the information requested by the SAMHSA/CSAT Hepatitis Test and Vaccine Tracking Form is already being collected by the participating opioid treatment programs. In the cases where the opioid treatment program has a hepatitis protocols in place, the information can be sent without reliance on the form.

5. Involvement of Small Entities

The participating opioid treatment programs are usually small not-for-profit organizations, not dominant in the field. They are considered “small entities” but they do not have a significant impact on these organizations.

6. Consequences If Information Is Collected Less Frequently

Each respondent is asked to respond three times annually. The first time the respondent is asked to provide demographic information, vaccination history, and hepatitis testing information. The second and third times the respondent is asked to provide the date and lot number for subsequent vaccinations and/or HCV test. One month after intake, the programs are asked to send the Hepatitis Test and Vaccine Tracking Form. This timeframe captures all of the information except for the date and lot number of the third dose. Consequently, after the third dose is administered (approximately six months after intake), the programs are asked to send the third dose’s date and lot number.

If the information is not collected, the program will be contacted by phone in order to determine the problem. For those cases, when the third dose information is not received, the program will be contacted to verify that the patient did not return for the service.

7. Consistency With the Guidelines in 5 CFR 1320.5 (d) (2)

This information collection fully complies with 5 CFR 1320.5 (d) (2).

8. Consultation Outside the Agency

The notice required in 5 CPR 1320.8 (d) was published on November 6, 2008. No comments were received.

CSAT e-mailed the following potential respondents draft copies of the form on August 19, 2008 to solicit views on whether the information requested was reasonable and whether the form was written in plain, unambiguous language.

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9. Payment to Respondents

Respondents will not be paid.

10. Assurance of Confidentiality

This form will be stored and compiled by a contractor which has experience in securing the information collected during the collection processing (electronically via unique secured password). The contractor also recognizes the importance of restricting access to data of this nature. The form itself is provider specific and not client specific. Nevertheless, the provider information will be restricted to only those with a need to know. The information shared will be in aggregated form only.

11. Questions of a Sensitive Nature

The information collection does not include questions concerning sensitive information such as the patient's risk factors, and no patient identifier information is collected. The information collected relates the normal use of hepatitis vaccination and testing in the community. The opioid treatment program retains all patient specific information and the code by which a specific patient can be identified. The Federal government receives only a coded patient identifier which can only be used to determine that a specific unknown patient received the test kit and that certain demographic and referral information.

12. Estimates of Project Hour Burden

Form	Number of Screened Respondents	Responses/ Respondents	Hours/Response	Total Hour Burden	Hourly Wage Cost	Total Hour Cost
Hepatitis Test and Vaccine Tracking Form	50,000	1	0.05	2,500	\$38.15	\$250,500

13. Estimates of Annualized Cost Burden to Respondents

This information is routinely collected and stored as a part of customary and usual business practices. There are no system, technology acquisition, capital, or start-up costs associated with its collection.

14. Estimates of the Annualized Cost to the Government

The annualized cost to the government is approximately \$93,000 which will be expended to cover distribution and collection of the tracking form. This cost includes a 5% time commitment of Federal FTE at GS- 14 level at an estimated cost of \$5,500 annually.

15. Changes in Burden

This is a new project.

16. Time Schedule, Publication, and Analysis Plans

The interpretation or publication of this information maybe used at SAMHSA sponsored conferences, reports to Secretary of Health or Congressional.

Activity and time schedule

The information is collected on a continuous basis by the grantee. The information will be compiled and sent to SAMHSA quarterly.

17. Display of Expiration Date

The expiration date for OMB approval will be displayed.

18. Exceptions to Certification Statement

This collection of information involves no exceptions to the Certification for Paperwork Reduction Act Submissions. The certifications are included in this submission.

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods

To minimize response burden, SAMHSA will allow the designated Opioid Treatment Programs to self-select.

The OTPs reside in California, New Mexico, New York, Ohio, Hawaii, Minnesota, Connecticut, Massachusetts, and Pennsylvania. (States Identified with High OTP Substance Abuse associated Morbidity)

Table 1: Providers within the 13 MAI States.

State	OTPs	Total Providers
Ohio	2	2
New Mexico	1	1
California	2	2
New York	2	2
Hawaii	1	1
Minnesota	1	1
Connecticut	1	1
Massachusetts	1	1
Pennsylvania	1	1
Total	12	12

Sample Size: 264 Test Kits and 10, 628 Vaccines

2. Information Collection Procedures

When a client comes into the provider organization to request to be screened for hepatitis; the provider will select a no cost hepatitis test along with the corresponding Hepatitis Test and Vaccine Tracking Form. The provider will complete the form at the time the test is performed. After the completion of the form, it 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. Approximately one month after the initial intake, the forms are sent to the contractor.

3. Methods to Maximize Response Rates

SAMHSA/CSAT anticipates that they will receive near 80% response rate because the form would be completed whenever a no cost test kit or vaccine is administered by the provider. The test kits and vaccines will have a unique number as well as a lot number.

4. Test of Procedures

This Project is a follow-up from a previous CSAT demonstration hepatitis vaccination Study done in FY 2006 under a clinical exemption.

5. Statistical Consultants

This material has been reviewed by:

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List of Attachments

Attachment A: SAMHSA/CSAT Hepatitis Tracking Form