Office of the Assistant Secretary for Health

Title of Collection:

Evaluation of Implementation of the Viral Hepatitis Action Plan

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Department of Health and Human Services

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Supporting Statement for Evaluation of Viral Hepatitis

A. Justification

A.1. Circumstances Making the Collection of Information Necessary

Section 301 of the Public Health Service Act (42 U.S.C.241) authorizes this information collection by the Office of the Assistant Secretary for Health.

Viral hepatitis is the most common blood borne infection the United States but public awareness of viral hepatitis remains low. In their 2010 report, the Institute of Medicine found low awareness of hepatitis B and C among health-care providers, social service providers and the general public. Lack of awareness of viral hepatitis in the U.S. contributes to continuing transmission, missed opportunities for prevention and poor health outcomes in infected people (Mitchell et al., 2010). It is estimated that up to 2% of the U.S. population is living with chronic hepatitis B virus (HBV) or hepatitis C virus (HCV) infections, but 65% of those infected with HBV and 75% of those infected with HCV are unaware that they are infected (Lin et al., 2007; Hagan et al., 2006). Viral hepatitis claims the lives of 12,000-15,000 Americans each year and is a leading cause of preventable mortality in the United States. Because of the high disease burden, the low rate of screening, and the fact that most persons infected with viral hepatitis do not have obvious signs of infection for many years, viral hepatitis has been described as a silent epidemic.

Health consequences of these preventable hepatitis infections -- morbidity and mortality -- are severe and treatment costs are high. Chronic HBV infection can lead to cirrhosis, liver failure, or hepatocellular carcinoma in 15-40% of patients and to liver transplantation in roughly 25% of patients (Kanwal et al., 2005.) Liver cancers have a higher mortality than other cancers, and have tripled in the US over the last few decades (ACS, 2010; CDC, 2010; Altekruse, et al., 2009). Many experts estimate this will burgeon with the aging population of individuals chronically infected with viral hepatitis (IOM, 2010; Deuffic-Burban et al., 2007). Infection with HCV begins with an acute phase, when most patients do not have symptoms; thus possibly 65-75% of individuals living with HCV do not know they are infected (IOM, 2010; HHS 2011). Between 15-45% of patients may eliminate HCV after initial infection, but the remainder move on to chronic infection, which can lead to liver dysfunction, cirrhosis, and liver cancer (Ghany, et. al., 2009; Chen & Morgan, 2006).

In response to this silent epidemic of viral hepatitis, the Department of Health and Human Services (HHS) released a comprehensive strategic plan in May 2011 entitled, *The Action Plan for the Prevention, Care and Treatment of Viral Hepatitis.* Implementation of the three year Action Plan requires coordination and communication across participating federal departments and agencies, support for specific actions as needed, and monitoring and reporting of federal viral hepatitis activities.

Another critical component of Action Plan implementation is the evaluation of how viral

hepatitis is being addressed locally. For the action plan to be successful in preventing and treating viral hepatitis, it will be crucial to understand how it is being implemented in the real world. This project will support the goals and strategies of the Action Plan by conducting a formative evaluation of local implementation activities to identify priority areas that need attention, any gaps that exist in implementation, and where additional resources are needed. As part of the evaluation, key informant interviews will be conducted with local stakeholders in four states: Alabama, Massachusetts, New York and Washington. The results of the evaluation will enable HHS to identify potential strategies to strengthen local implementation of the Action Plan, address any barriers that may be ocurring, and inform future implementation efforts to help improve viral hepatitis prevention, care and treatment.

A.2. Purpose and Use of Information Collection

The purpose of the evaluation is to help HHS better understand local implementation of the Action Plan at the state and local level and any barriers or challenges that might be occurring. The results will enable HHS to identify potential strategies to strengthen local implementation of the Action Plan, address barriers, and inform future implementation efforts to help improve viral hepatitis prevention, care and treatment. More specifically, the information collected will provide (1) an assessment at the state and local level of the range of stakeholders currently engaged in viral hepatitis activities; (2) establishment of baseline levels of coordination and activities; 3) engagement of community members; (4) recommendations for a local viral hepatitis implementation report, (5) recommendations for proposed indicators and performance measures for local implementation of Action Plan goals, (6) implementation guidance for stakeholders, and (7) identification of community implementation recommendations for federal agencies. The knowledge gained from the evaluation will support future HHS efforts to address viral hepatitis, realign hepatitis resources, and increase cross-agency and local community collaboration. The evaluation will be implemented by conducting key informant interviews among key local stakeholders in four states: Alabama, Massachusetts, New York and Washington.

If this information is not collected, there will be no opportunity for HHS and other federal agencies to understand how the Action Plan is being implemented in the real world, or learn about the barriers and challenges that might be occurring on a state and local level. Without this information it would be extremely difficult to understand how federal agencies can best support local implementation of the Action Plan.

A.3. Use of Improved Information Technology and Burden Reduction

Consideration was given to using technology to collect information; however, the use of technology is unlikely to achieve the research objectives or to reduce the burden. The evaluation will be collecting formative data and thus the most effective data collection method will involve using qualitative data collection such as key informant interviews. Since qualitative methods are useful for gaining an in-depth understanding of issues

related to a "real word" setting, this approach was well suited for this study. The interview method will allow specific issues to be addressed, yet still remain open and receptive to unexpected information from the interviewees. Since collecting qualitative data is an iterative process, this flexibility will be very important for conducting the interviews and capturing issues relevant to stakeholders. The interviews will further be conducted by staff that are knowledgeable about viral hepatitis in order to have the most meaningful discussions with stakeholders.

To reduce burden on the respondent, data collection staff will travel to the site to meet with select participants and/or schedule a telephone interview at a time that is convenient for the respondent. Additionally, interviews will be audio-taped so that they can be easily transcribed rather than relying on hand-written field notes. Interviews will additionally be analyzed through the use of QSR 9, a software program specifically designed for analyzing qualitative data.

A.4. Efforts to Identify Duplication and Use of Similar Information

Since the Action Plan was released by HHS in 2011, there has been no information collected on how the plan has been received locally and how its strategies are being implemented in real world settings. Due to this lack of data, there is no information available on the barriers and challenges that local communities might be facing with regards to the strategies in the Action Plan or the additional resources that might be needed by local communities to prevent and treat viral hepatitis.

Information about state and local viral hepatitis activities has also not been collected in any systematic way and has not been identified via literature searches or in consultation with the interdepartmental Viral Hepatitis Implementation Group- a group of federal partners that are implementing the Viral Hepatitis Action Plan and comprised of leadership from each agency within HHS, the Veteran's Administration, and the Federal Bureau of Prisons.

A.5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection. We will be conducting interviews with state and local health departments, correctional facilities, healthcare provider organizations, and community-based organizations. In some cases, the community-based organizations may be smaller entities. In all cases, the information being being requested has been held to the absolute minimum required.

A.6. Consequences of Collecting the Information Less Frequent Collection

This data collection is anticipated to be a one-time activity. The consequences of not collecting this information would be to limit HHS's ability to assess local implementation of the Action Plan and direct any future efforts to improve the Plan's ability to meet local community needs and improve the prevention and treatment of viral hepatitis on a local level.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published in the Federal Register as required by 5 CFR 1320.8 was published on January 18, 2013, Vol. 78 No. 13 pp. 4146-4147 (see attachment). There were/were no public comments.

A.9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any monetary payment or incentive for participating in the study.

A.10. Assurance of Confidentiality Provided to Respondents

The proposed data collection activities will have no effect on the respondents' privacy. Participants will not be identified by name or description in any reports. The data collection instruments and protocols will be reviewed by the contractor's Institutional Review Board.

A.11. Justification for Sensitive Questions

Topics typically considered to be of a sensitive nature include sexual practices, alcohol or drug use, religious beliefs or affiliations, immigration status and employment history. No questions regarding these topics or any other topic of a sensitive nature will be asked in these data collection activities.

A.12. Estimates of Annualized Hour and Cost Burden

This section summarizes the total burden hours for this information collection in addition to the cost associated with those hours. Estimated burden to respondents is based on the

estimated time it will take to schedule and conduct key informant interviews and the number of respondents who are expected to complete interviews in each stakeholder group as follows:

Adult Viral Hepatitis Prevention Coordinators. Four Coordinators will be asked to participate in an in-person interview. The estimated length of the interview is anticipated to be 90 minutes. The total estimated burden for all respondents is 6 hours.

State and local health departments: Up to sixteen stakeholders will be asked to participate in a 45 minute telephone interview. The total estimated burden for all respondents is 12 hours.

Community-based organizations: Up to twelve stakeholders will be asked to participate in a 30 minute telephone interview. The total estimated burden for all respondents is 6 hours.

Healthcare providers: Up to twelve stakeholders will be asked to participate in a 30 minute telephone interview. The total estimated burden for all respondents is 6 hours.

Correctional facilities: Up to twelve stakeholders will be asked to participate in a 30 minute telephone interview. The total estimated burden for all respondents is 6 hours.

National-level organizations: Up to twelve stakeholders will be asked to participate in a 30 minute telephone interview. The total estimated burden for all respondents is 6 hours.

The total estimated response burden in hours is 42 hours as summarized in Table 1.

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Table 1. Estimated response burden in hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Burden Hours
Adult Viral Hepatitis Prevention Coordinators	AVHPC Interview Guide	4	1	1.5	6
State and Local health department officials	State Interview Guide	16	1	45/60	12
Community-based organizations	CBO Interview Guide	12	1	30/60	6
National Organizations	National Interview Guide	12	1	30/60	6
Correctional facilities	Correctional Interview Guide	12	1	30/60	6

Healthcare providers	Provider Interview Guide	12	1	30/60	6
				Total	**42**

The annualized cost to respondents is $1,689.80 as summarized in table 2. The United States Department of Labor Statistics May, 2011. http://www.bls.gov/oes/current/oes_nat.htm was used to estimate the hourly wage rate for all respondents with the exception of the Adult Viral Hepatitis Coordinators. The categories that were consulted included substance abuse counselors, health educators, managers of social service/community organizations, correctional treatment specialist, and general practitioners. The hourly wage rate for the Adult Coordinators was calculated based on the amount that CDC allocates for this CDC-funded position.

Table 2. Estimated cost to respondents

Type of Respondent (Form Name)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Adult Viral Hepatitis Coordinators (Interview Guide)	6	$43.27	$260.00
State and local health department officials (Interview Guide)	12	$27.22	$326.64
Community-based organizations (Interview guide)	6	$36.82	$220.92
National organizations (Interview Guide)	6	$55.55	$333.30
Correctional facilities (Interview guide)	6	$42.55	$255.30
Healthcare providers (Interview guide)	6	$48.94	293.64
Total	42	$--	$1,689.80

A.13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no costs to respondents associated with either capital or startup efforts or operations and maintenance of services for this project.

A.14 Annualized Cost to Federal Government

The total one-time cost to the Federal Government for this information collection is anticipated to be $300,000 inclusive of the cost of the project as well as the personnel costs of federal employees involved in oversight and analysis. Costs were estimated based on quantification of hours.

Table 3. Annualized costs to the federal government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	Staff FTE on project	71,500
	Any HHS travel costs for project	???
Cooperative Agreement or Contract Costs		199,948
	TOTAL COST TO THE GOVERNMENT	$271,448

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

Plan for tabulation

The evaluation will be conducted over a 5-month period. Since this is a qualitative evaluation, no quantitative statistical analyses will be conducted. The data from the key informant interviews and discussion groups will be examined using qualitative content analysis methods. Battelle analysts will examine the interview data and assign the responses to a set of codes or themes that are contained in a project specific codebook. The codebook will be based on both anticipated themes and those that emerge from the data. As new themes and codes are identified and defined, they will be incorporated into the codebook. This approach will allow us to identify themes that are anticipated as well as emergent topics, thus accounting for all of the relevant response categories found in the interview data.

Battelle will take steps to ensure that coding of the interview data is consistent. First, analysts will be trained by the study leader on the analytical procedures, including a thorough review of an initial codebook to ensure a common understanding of the codes and their definitions. Second, prior to conducting the analyses of the interview data, analysts will code the same small set of interview data (2-3) for a comparison of coding differences or inconsistencies. Analysts will jointly review the coding results, discuss and reconcile any differences/inconsistencies, and clarify code definitions to ensure consensus on their meanings for moving on to the complete analyses. If necessary, this double-coding review process will continue until an adequate level of consensus between analysts is reached. Third, as new codes are identified, the analysts will add those codes and their definitions (with examples) to the master codebook and will share them with the other analysts (and the study leader) to ensure that all valid response categories are used consistently. This qualitative coding technique will allow us to draw conclusions from

the data. All interviews will be analyzed with the assistance of QSR NVivo 9, a qualitative software program used for the systematic management and analysis of qualitative data.

Plan for Publication and Dissemination

As part of the evaluation results, the contractor, Battelle, will develop a final report that describes the evaluation activities and results. The final report will include appendices for all study materials such as protocols and data collection instruments.

Other dissemination activities may also be pursued given available time and resources. These activities may include developing a manuscript of results or sharing results through conference presentations such as at the American Public Health Association annual meeting.

Project Time Schedule

Activity	Time Schedule
Conduct key informant interviews	1-5 months after OMB approval
Analyze interview data	6-7 months after OMB approval
Final report and presentation of data	8-9 months after OMB approval

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

Not seeking approval to not show expiration date.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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