

**Integrated Viral Hepatitis Surveillance and Prevention Funding
for Health Departments
CDC-RFA-PS21-2103**

Supporting Statement Part A

July 12, 2021

Contact Information

**Point of Contact: Laura Cooley, MD, MPHTM
Epidemiology and Surveillance Branch
Division of Viral Hepatitis
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop US12-3
Atlanta, GA 30329**

**Voice: (404)639-2096
Email: whz3@cdc.gov**

Table of Contents

Section

A. Justification

1. Circumstances Making the Collection of Information Necessary
2. Purpose and Use of the Information Collection
3. Use of Improved Information Technology and Burden Reduction
4. Efforts to Identify Duplication and Use of Similar Information
5. Impact on Small Businesses or Other Small Entities
6. Consequences of Collecting the Information Less frequently
7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
9. Explanation of Any Payment or Gift to Respondents
10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
11. Institutional Review Board (IRB) and Justification for Sensitive Questions
12. Estimates of Annualized Burden Hours and Costs
13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
14. Annualized Cost to the Government
15. Explanation for Program Changes or Adjustments
16. Plans for Tabulation and Publication and Project Time Schedule
17. Reason(s) Display of OMB Expiration Date is Inappropriate
18. Exceptions to Certification for Paperwork Reduction Act Submissions

B. Collections of Information Employing Statistical Methods

1. Respondent Universe and Sampling Methods
2. Procedures for the Collection of Information
3. Methods to Maximize Response Rates and Deal with Nonresponse
4. Tests of Procedures or Methods to be Undertaken
5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibits

- | | |
|--------------|-----------------------------------|
| Exhibit 12 A | Estimated Annualized Burden Hours |
| Exhibit 12 B | Estimated Annualized Burden Costs |
| Exhibit 14 A | Estimated Cost to the Government |

LIST OF ATTACHMENTS

1. Authorizing Legislation
2. 60 Day Federal Register Notice
- 2a. 60 day Public Comments

- 3. Data collection instruments and data elements**
 - 3(a) Annual Performance Report: Component 1–Core Viral Hepatitis Outbreak Response and Surveillance Activities
 - 3(b) Annual Performance Report: Component 2–Core Viral Hepatitis Prevention Activities
 - 3(c) Annual Performance Report: Component 3–Special Projects – Prevention, Diagnosis, and Treatment Related to the Infectious Disease Consequences of Drug Use
 - 3(d) Initial Outbreak Report Form
 - 3(e) Outbreak Summary Report Form
 - 3(f) Acute Viral Hepatitis Case Reporting

- 4. Form instructions and technical guidance documents**
 - 4(a) Guidance: Component 1 data Annual Performance Report
 - 4(b) Guidance: Component 2 data Annual Performance Report
 - 4(c) Guidance: Component 3 data Annual Performance Report

5. [Viral Hepatitis Case Report Form](#)
6. [Guidelines for Viral Hepatitis Surveillance and Case Management](#)

7. Privacy Impact Assessment (PIA)

8. **Project Determination:** Not Research – Public Health Surveillance 45 CFR 46.102(l)(2)
9. [2019 Viral Hepatitis Surveillance Report](#)
10. [Data Security and Confidentiality Guidelines](#)

- Purpose: Tools exist to prevent new cases of hepatitis A, B, and C, to treat people living with hepatitis B, and to cure people living with hepatitis C. Yet new cases of viral hepatitis (VH) continue to rise, many people infected with VH remain undiagnosed, and far too many VH-related deaths occur in the US each year. This project will enable states to collect data to evaluate disease burden and trends and to analyze and disseminate that data to develop or refine recommendations, policies, and practices that will ultimately reduce the burden of VH in their jurisdictions.
- Goals: To reduce new VH infections, reduce VH-related morbidity and mortality, and reduce VH-related disparities and to establish comprehensive national VH surveillance
- Intended Use: Performance measures will be monitored to assess the performance of the overall project (i.e., all recipients combined) and each individual recipient (jurisdiction), including quality of data, effective program implementation, and accountability of funds. Data collection is used for program accountability and to inform performance improvement. Surveillance data specifically plays an important role in outbreak detection and response, characterizing disease burden, and monitoring progress in achieving public health goals.
- Methods: A standardized Case Report Form is used for surveillance data collection submitted to the National Notifiable Diseases Surveillance System (NNDSS). De-identified data including national VH surveillance data will be submitted to CDC electronically per each jurisdiction's usual mechanism. Recipients will submit other required quantitative and qualitative data in formats and at frequencies specified in Attachment 3, related to activities associated with six strategies: six strategies: 1.1, develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for hepatitis A, B, and C; 1.2, collect, analyze, interpret, and disseminate data to characterize trends, and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C; 1.3 (contingent on available funding), collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C; 2.1, support VH elimination planning and surveillance, and maximize access to testing, treatment, and prevention; 2.2 (contingent), increase access to HCV and HBV testing and referral to care in high-impact settings; and 2.3 (contingent), improve access to services preventing VH among persons who inject drugs.
- Target Population: Among recipients, VH surveillance data will be collected (per each jurisdiction's usual mechanism) on all adults/adolescents and children who meet the case definition for acute hepatitis A, B, and C; perinatal hepatitis C, and chronic hepatitis B and C. Additional data will be collected as specified in Attachment 3. Contingent on funding, the following activities can be supported: increased hepatitis B and C testing and referral to care in high-impact settings (syringe services programs, substance use disorder treatment centers, correctional facilities, emergency departments, and sexually transmitted disease clinics); and increased access to services preventing VH among persons who inject drugs. Contingent on funding, an optional component will support improved access to prevention, diagnosis, and treatment of viral, bacterial and fungal infections related to drug use in settings disproportionately affected by drug use.
- Analysis Plan: Health departments routinely review and analyze their data to monitor VH trends, evaluate program success, and assist in focusing resources to reduce the burden of VH. CDC publishes annual surveillance reports summarizing national VH statistics and also conducts special analyses for publication in peer-reviewed scientific journals to further describe and interpret national viral hepatitis data. Special analyses describe key trends, identify high risk groups, and assist in developing new prevention and treatment strategies.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a 3-year approval for data collection instruments associated with the Notice of Funding Opportunity entitled "Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments" (CDC-RFA-PS21-2103).

An estimated 2.4 million people are infected with hepatitis C virus in the United States, and an estimated 50,000 people are newly infected every year. Hepatitis C is curable, yet only about 56% of adults living with hepatitis C know they are infected, and about 1 out of every 14 new cases is reported to public health. An estimated 862,000 people are living with hepatitis B virus in the United States, and an estimated 22,000 people are newly infected every year. Hepatitis B is vaccine preventable and treatable, yet only about 32% of adults living with HBV know they are infected, and about 1 out of every 7 new cases are reported to public health. The most common risk factor for acute hepatitis B and C is injection drug use. Further, the United States continues to experience an unprecedented multi-state outbreak of acute hepatitis A, with over 30,000 reported cases between July 2016 and January 2020, primarily affecting people who use drugs and people experiencing homelessness.

National surveillance data has been critical for identifying injection drug use as the primary risk factor for ongoing transmission of hepatitis B and C. For persons who inject drugs with opioid use disorder, medication assisted treatment reduces the risk of hepatitis C acquisition by 50% and the combination of high coverage needle and syringe exchange and medication assisted treatment reduces hepatitis C acquisition by 74%. Persons who use drugs can be treated for hepatitis C with sustained viral response about 90%. Despite evidence of effectiveness, state policies may limit access to direct acting antiviral treatment and SSPs, and access to medication assisted treatment remains suboptimal. In addition, hepatitis A and B are vaccine preventable, yet vaccination rates among adults (hepatitis A: 9%, hepatitis B: 24.5%), including adults at increased risk (hepatitis B estimated 17 - 41%), are low. Comprehensive syringe services programs (<https://www.cdc.gov/hiv/pdf/risk/cdc-hiv-syringe-exchange-services.pdf>) provide syringe exchange and access to other needed services for persons who inject drugs.

National surveillance data can be leveraged for rapidly detecting outbreaks, accurately assessing burden of disease, and monitoring elimination efforts for hepatitis B and C at the jurisdictional level. This project will enable recipients to collect data to evaluate disease burden and trends and analyze and disseminate that data to develop or refine recommendations, policies, and practices that will

ultimately reduce the burden of viral hepatitis in their jurisdictions.

Priorities for this project are: Component 1, improve surveillance for viral hepatitis A, B and C in states and large cities, including outbreak detection, investigation, and control; Component 2, facilitate state and large city viral hepatitis elimination planning, and increase access to hepatitis B and C testing and prevention, including hepatitis A and B vaccination, syringe services programs, and medication assisted treatment services. An additional optional Component 3 funds comprehensive, outcome-focused approaches to preventing infections associated with injection drug use, reducing overdose deaths, and linking people to substance use disorder treatment.

This Notice of Funding Opportunity builds on CDC-RFA PS17-1703 which funded 14 states to build registries of hepatitis B and hepatitis C cases and improve completeness of case reports; and CDC-RFA-PS17-1702 which funded 50 jurisdictions to identify high burden areas for hepatitis B and/or hepatitis C and improve prevention and treatment in those areas. Both awards have been in place since fiscal year 2017.

Viral hepatitis surveillance data collection by CDC is authorized under Sections 317(k) (2) and 318(c) of the Public Health Service Act [42 U.S.C. Sections 247b (k) (2) and 247c(c)], as amended and Sections 304 and 306 of the Public Health Service Act (42 USC 242b and 242k) (**Attachment 1**).

2. Purpose of Use of the Information Collection

The goals of this project are to reduce new viral hepatitis infections, viral hepatitis-related morbidity and mortality, and viral hepatitis-related disparities and to establish comprehensive national viral hepatitis surveillance. Data are needed to confirm progress towards achieving these goals. This project seeks to enable recipients to collect data to evaluate disease burden and trends and to analyze and disseminate that data to develop or refine recommendations, policies, and practices that will ultimately reduce the burden of viral hepatitis in their jurisdictions. Viral hepatitis case surveillance data will be collected per each jurisdiction's usual mechanism using variables that have been approved by OMB separately (OMB No. 0920-0728). Performance measure data will be collected as specified in **Attachment 3**.

By building capacity to collect and report consistent, standardized, comprehensive viral hepatitis surveillance data, this project strengthens the ability of recipients to review their data critically to effect change. This project endeavors to expand jurisdictional surveillance for acute hepatitis A, hepatitis B, and hepatitis C, perinatal hepatitis C, and chronic hepatitis B and C as part of the

effort to establish comprehensive national viral hepatitis surveillance.

Cluster and outbreak data, which complement case data as another key component of national viral hepatitis surveillance, are critical to determining both the level of viral hepatitis activity within a jurisdiction as well as the effectiveness of each jurisdiction's approach to cluster and outbreak response. Required activities of this project include developing, implementing, and maintaining a plan to rapidly detect and respond to outbreaks for hepatitis A, B, and C, and to report and notifying CDC of outbreaks within 5 business days of identifying the outbreak (**Attachments 3a, 3d, 3e**).

Monitoring of performance measure data (**Attachments 3a-3c**) allows for the assessment of the performance of the overall project (i.e., all recipients combined) and each individual recipient (jurisdiction), including quality of data, effective program implementation, and accountability of funds. Data collection is used for program accountability and to inform performance improvement.

Health department processes to identify and report acute cases of viral hepatitis depend on various factors, including reportable labs in their jurisdiction, human resources, and local processes to conduct case investigations. Understanding these factors at the jurisdiction-level are important to interpreting the surveillance data they submit to CDC. Answers from these questions (**Attachment 3f**) will be used to inform a mathematical model that will be used to generate annual estimates of acute infections based on the number of acute cases reported to CDC.

3. Use of Improved Information Technology and Burden Reduction

For performance measure and cluster/ outbreak data, intuitive, standardized, user-friendly data collection instruments have been developed in an effort to reduce burden for respondents (**Attachments 3a-3f**).

Information on cases of viral hepatitis reported nationally is received and maintained through a single unified electronic reporting system using the variables included on the OMB-approved (OMB No. 0920-0728) [Viral Hepatitis Case Report Form](#) (**Attachment 5**), which includes diagnosis, event dates (e.g., illness onset), basic demographic data (e.g., state, county, age, race, ethnicity), clinical features, serologic test results, and risk factors for infection. This information is needed to confirm the diagnosis, determine a source of infection, and identify others at risk of infection that would benefit from preventive intervention.

[Guidelines for Viral Hepatitis Surveillance and Case Management](#)

(Attachment 6) describe the essential elements and best practices for conducting surveillance for viral hepatitis, and were developed based on consultation with representatives from state and local health departments.

Previously, this information was maintained in two surveillance systems: NNDSS and the Viral Hepatitis Surveillance Program (VHSP). In 1989, a consolidation of NNDSS and VHSP was initiated with efforts to have all acute viral hepatitis surveillance data reported electronically to a single system, the National Electronic Telecommunications System for Surveillance (NETSS). Data entry screens are available in NETSS that include all of the information requested for both NNDSS and the VHSP. Paper reporting via VHSP was discontinued as of January 2002. Thus, all information on reported cases of acute viral hepatitis are now received and maintained through a single unified electronic reporting system. Improving the completeness of case reports made through this system will require further efforts by CDC and state health departments.

As an element of the planned National Electronic Data Surveillance Systems (NEDSS), substantial changes in the structure and function of NETSS are expected. The development of a person-based system that collects and stores public health information according to widely used, standardized definitions and formats and that uses unique identifiers to link information from different disease reports and other health data sources will significantly enhance the capacity to conduct surveillance for viral hepatitis.

As part of a large data modernization effort, CDC is in the process of developing new HL7 Message Mapping Guides to improve collection, transmission, and analysis of data needed at the national level for public health surveillance. In doing so, CDC is implementing messaging standards and vocabulary standards in case notifications.

4. Efforts to Identify Duplication and Use of Similar Information

Through literature searches, attendance at national hepatitis meetings/conferences, and ongoing consultations with viral hepatitis experts and partners nationwide, CDC has determined that the data collected by NNDSS provide the sole source of comprehensive national statistics and are not available from any other source within the federal government or from non-federal sources.

Likewise, performance measure and cluster/ outbreak data (**Attachments 3a-3f**) are not collected systematically at a national level via any other mechanism.

5. Impact on Small Business or Other Small Entities

Data collection and electronic submissions to CDC from the reporting areas are performed by viral hepatitis programs in state and local health departments funded by CDC to conduct these activities. Health departments compile reported information and are the respondents for this surveillance system. No small businesses or small entities are involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

Timely reporting of clusters and outbreaks (**Attachment 3d**) is essential to ensuring that recipients have the assistance they need to implement a prompt and effective response. To reduce illness and save lives, it is important that recipients identify contacts and additional cases, investigate the underlying cause(s) of the cluster or outbreak, and recommend appropriate interventions to prevent additional cases. To provide meaningful technical support, it is necessary for program staff within the Division of Viral Hepatitis to have knowledge of clusters and outbreaks as they occur.

Annual performance measure data (**Attachments 3a-3c**) will be monitored to assess the performance of the overall project, including quality of data, effective program implementation, and accountability of funds. Data collection is used for program accountability and to inform performance improvement. It is necessary to review these data annually to ensure that necessary improvements and modifications can be implemented during subsequent years.

Surveillance staff within the Division of Viral Hepatitis receive viral hepatitis case surveillance data in real time through the usual, established mechanism and review case reports at least weekly. Less frequent reporting may delay detection of increases and changes in case numbers and trends, thereby delaying CDC's ability to assist jurisdictions in their response. Less frequent reporting may also delay detection of data entry errors, for which correction may become more challenging as time passes.

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

Collection of data is conducted in a manner consistent with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

The 60-Day FRN was published in the *Federal Register* on April 16, 2021, Volume 86, Number 72, Pages 20161-20163 (**Attachment 2**). Two non-substantive public comments were received (**Attachment 2a**). No information permitting a CDC response was provided. Therefore, no CDC response was sent.

9. Explanation of Any Payment or Gift to Respondents

The respondents for this ICR are health departments that are funded through CDC cooperative agreements to collect data. There are no other provisions for payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC NCHHSTP Privacy and Confidentiality Review Officer has assessed this package for applicability of 5 U.S.C. § 552a, and has determined that the Privacy Act does not apply to the information collection (**Attachment 7: Privacy Impact Assessment**). Although, names, email addresses and phone numbers are collected by the health departments as part of their normal course of business, no personally identifiable information (PII) will be forwarded to the CDC. No sensitive information will be collected on individuals and no personal contact patient information, electronic or otherwise, will be asked of respondents.

As part of this cooperative agreement, performance measure data will be collected from recipients. Reporting information will be used to guide the provision of technical assistance to recipients for program improvement.

All data will be maintained in a database by the CDC project officers in a secure fashion. Files will be available to authorized Division of Viral Hepatitis staff by invitation only and may also be password protected.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

Viral hepatitis surveillance data including data collected for adult/adolescent and pediatric case reporting, surveillance evaluations, outbreaks, cluster detection and response, and perinatal exposure reporting have been determined to be non-research, routine disease surveillance and epidemiologic activities/public health program activities by NCHHSTP/CDC and IRB approval is not required (see **Attachment 8**). For the gender identity variable (**Attachments 3d and 3e**), a small cell problem is not expected, but to avoid this issue, all response options other than female, male, and unknown/missing, have been collapsed into "other gender identity."

12. Estimates of Annualized Burden Hours and Costs

A. Estimate of annualized burden hours

59 recipients will report using the 'Annual Performance Report: Component 1–Core Viral Hepatitis Outbreak Response and Surveillance Activities' form (**Attachment 3a**) with 1 annual response for a total of 59 responses. We estimate an average of 1 hour per response for a total of 59 annual burden hours. Similarly, 59 recipients will report using the 'Annual Performance Report: Component 2–Core Viral Hepatitis Prevention Activities' form (**Attachment 3b**) with 1 annual response for a total of 59 responses. We estimate an average of 1 hour per response for a total of 59 annual burden hours. 14 recipients will report using the 'Annual Performance Report: Component 3–Special Projects – Prevention, Diagnosis, and Treatment Related to the Infectious Disease Consequences of Drug Use' form (**Attachment 3c**) with 1 annual response for a total of 14 responses. We estimate an average of 1 hour per response for a total of 14 annual burden hours. 59 recipients will report using the 'Initial Outbreak Report Form' (**Attachment 3d**) for each outbreak, an average of two annually. We estimate an average of 20 minutes per response for a total of 39 annual burden hours. 59 recipients will report using the 'Outbreak Summary Report Form' (**Attachment 3e**) for each outbreak, an average of two annually. We estimate an average of 20 minutes per response for a total of 39 annual burden hours. Finally, 59 recipients will report using the 'Acute Viral Hepatitis Case Reporting' form (**Attachment 3f**) with 1 annual response for a total of 59 responses. We estimate an average of 1/2 hour per response for a total of 29 annual burden hours. The total estimated burden in hours for this ICR is 239 annual burden hours.

Exhibit 12 A. Estimates of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Total Annual Burden (in hours)
Health Departments	51 (att 3a)	59	1	59	1	59
Health Departments	APR: Component 2 (att 3b)	59	1	59	1	59
Health Departments	APR: Component 3 (att 3c)	14	1	14	1	14
Health Departments	Initial Outbreak Report Form (att 3d)	59	2	118	20/60	39
Health Departments	Outbreak Summary	59	2	118	20/60	39

	Report Form (att 3e)					
Health Departments	Acute Viral Hepatitis Case Reporting (att 3f)	59	1	59	30/60	29
Total						239

B. Estimates of Annualized Cost

The estimated total cost to respondents is \$6,725. This is based on an estimated hourly wage of \$28/hour for each health department. Since typically the data collection is a collaborative effort, we used an average of an estimated salary of one data entry person at \$17/hour and one epidemiologist at \$38/hour for an estimated \$28/hour. The salary estimates were based on [U.S. Department of Labor estimated mean hourly rates](#) in the United States in 2019 for one data entry person (data entry keyer) at \$17/hour and one epidemiologist at \$38/hour. Note this estimated cost is subsumed in the cooperative agreement costs outlined in section 14 below and should not be considered as additional costs.

Exhibit 12 B. Estimates of Annualized Burden Cost

Type of Respondent	Form Name	No. of Respondents	Total No. of Annual Responses	Avg. Burden per Response (in hours)	Hourly Wage Rate	Total Respondent Costs
Health Departments	APR: Component 1(att 3a)	59	59	1	\$28	\$1,652
Health Departments	APR: Component 2(att 3b)	59	59	1	\$28	\$1,652
Health Departments	APR: Component 3(att 3c)	14	14	1	\$28	\$392
Health Departments	Initial Outbreak Report Form (att 3d)	59	118	20/60	\$28	\$1,101.33
Health Departments	Outbreak Summary Report	59	118	20/60	\$28	\$1,101.33

	Form (att 3e)					
Health Departments	Acute Viral Hepatitis Case Reporting (att 3f)	59	59	30/60	\$28	\$826
Total						\$6,725

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital or maintenance costs to the respondent resulting from the collection of the information, other than their time.

14. Annualized Cost to the Federal Government

Exhibit 14 A. Estimates of Annualized Costs to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
CDC Costs	7 program staff 0.20 x \$103,309	\$144,633
	Subtotal	\$144,633
Cooperative Agreements with Recipients	Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments	\$22,301,157
	Total	\$22,445,790

15. Explanation for Program Changes or Adjustments

N/A

16. Plans for Tabulation and Publication and Project Time Schedule

Timeline for reporting of case surveillance data will follow the [usual NNDSS timelines](#), with publication of [annual Viral Hepatitis Surveillance Reports](#) as determined by the Division of Viral Hepatitis Surveillance Team (**Attachment 9**).

Other reports and peer-reviewed manuscripts will be prepared in collaboration with health departments on an ad hoc basis.

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

The Division of Viral Hepatitis/CDC is not seeking an exception to the required display of the expiration date for the forms.

18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions [5CFR 1320.3\(h\) \(1\)-\(10\)](#)[5CFR 1320.3\(h\) \(1\)-\(10\)](#)

There are no exceptions to the certification.