

Comprehensive Understanding of Readiness for Elimination of
Hepatitis C in Corrections (Cure-HepC) Survey

OMB Control Number: 0920-24FU

Supporting Statement A

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Contact Information:
Michtta Jean-Louis, PharmD, MPH, CPH
Division of Viral Hepatitis (DVH)
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
(NCHHSTP)
Centers for Disease Control and Prevention
1600 Clifton Road (MS)
Atlanta, GA 30329
954.232.2801
qdy2@cdc.gov

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Goals of the study: The primary goal(s) of the Comprehensive Understanding of Readiness for Elimination of Hepatitis C in Corrections (Cure-HepC) survey are to: 1) understand practices surrounding hepatitis C virus screening, testing, and treatment practices and the national burden of hepatitis C in carceral settings as well as challenges to testing and treatment of hepatitis C virus, and 2) utilize findings to advance the Division of Viral Hepatitis 2025 Strategic Plan to eliminate viral hepatitis in the nation.

Intended Use: This project aims to improve the ability of CDC to inform program planning and evaluation of carceral programs that aim to reduce new viral hepatitis infections, reduce viral hepatitis-related morbidity and mortality, and reduce viral hepatitis-related disparities in carceral settings. The data collected will establish a system for ongoing program evaluation and improvement and allow for data-driven resource allocation to areas of greatest need.

Methods to be used to collect data: This voluntary survey will be administered annually to state Departments of Correction (DOCs) and the large jails. The goal is to reach 101 state department of corrections (DOCs) and large jails, to include the District of Columbia. Each responding institution will receive a request to complete the web-based survey with advance notification to allow time for record searches. The survey has branching logic to improve efficiency and reduce time burden of survey. Participating institutions will have a set-time period, as determined by the American Correctional Association (ACA), to complete the survey. This survey will be self-administered which we estimate to take between 30 to 80 minutes to complete, with an average time to complete of 55 minutes, to include time for collecting the required data elements into the web-based survey form. If preferred, there will be an option to complete an interviewer-administered survey via telephone or videoconferencing with a member of the ACA survey team.

The subpopulation to be studied: The 101 members of ACA will be surveyed to enable a broad understanding of current hepatitis C testing and treatment practices across the nation, which could not be achieved by surveying a sample of institutions.

Directors/program managers of all state DOCs and large jails in the United States listed as members in the ACA directory (<https://www.aca.org>) will be contacted to complete a survey about their institution.

How data will be analyzed: The data will be deidentified to ensure that responding institutions are not identifiable. The data collected will be used to characterize the distribution of hepatitis C virus prevalence, demographics, clinical management and analyze successes and challenges by state and local department of corrections sites.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Division of Viral Hepatitis (DVH) requests a three-year approval for new data collection. This project aims to improve the ability of CDC to inform program planning and evaluation of carceral programs that aim to reduce new viral hepatitis infections, reduce viral hepatitis-related morbidity and mortality and reduce viral hepatitis-related disparities in carceral settings. The data collected will establish a system for ongoing program evaluation and improvement and allow for data-driven resource allocation to areas of greatest need. The primary goals of this project are to understand practices surrounding hepatitis C virus screening, testing, and treatment practices and the national burden of hepatitis C in carceral settings as well as challenges to testing and treatment of hepatitis C virus, and 2) utilize findings to advance the Division of Viral Hepatitis 2025 Strategic Plan to eliminate viral hepatitis in the nation.

Background, Need and Circumstances Motivating the Request

Hepatitis C virus (HCV) is the most common bloodborne infection in the United States. Approximately 30% of people with HCV infection rotate in and out of the United States carceral system each year¹. The prevalence of HCV is estimated to be 10-20 times higher in carceral settings as compared to the general population². Since 2013, direct acting antivirals (DAAs) have simplified hepatitis C treatment and have cure rates of >95%³. Improving hepatitis C elimination in carceral settings is essential to achieving national hepatitis C elimination targets.

Treating HCV infection is cost saving at both the individual and community levels. Hepatitis C treatment not only prevents further health complications such as liver damage, hepatocellular carcinoma, and cirrhosis, but it also reduces the burden of paying for care as it relates to those complications. Successfully treating individuals for their hepatitis C infection

prevents further transmission during incarceration and after release back into the communities.

Steady progress has been made towards hepatitis C elimination in carceral systems as the costs of DAAs have declined, simplified treatment algorithms have been developed, and lawsuits initiated by incarcerated people have led to rulings or settlements that increased funds allocated for hepatitis C treatment. However, progress towards hepatitis C elimination in carceral settings has been uneven, with many states not adopting best practices and employing strategies to lower DAA costs and implement practices that facilitate broader treatment of their population.

CDC seeks to expand hepatitis C testing and treatment in carceral settings but requires a better understanding of which facilities have high numbers of people with hepatitis C that pass through their systems and which carceral facilities have implemented best practices to eliminate hepatitis C. This includes both state Departments of Correction (DOCs) prisons as well as large jails which may have the capacity to diagnose and treat hepatitis C while an individual is incarcerated or detained. To increase CDC's effectiveness in advancing hepatitis C elimination in carceral settings, CDC aims to characterize hepatitis C burden of disease as well as prevention, testing, and treatment policies at carceral facilities nationally.

This proposed information collection is authorized under Section 301(a) of the Public Health Services Act (42.U.S.C.241) **(Attachment 1)**.

2. Purpose and Use of Information Collection

The purpose of the Comprehensive Understanding of Readiness for Elimination of Hepatitis C in Corrections (Cure-HepC) Survey is to quantify the burden of hepatitis C virus in carceral settings to guide provision of appropriate technical assistance and support. The data collected will provide some foundational knowledge to guide programmatic planning to support the scale up of hepatitis C virus screening, testing, and treatment in these settings. Carceral settings house individuals with the greatest health needs and various competing priorities.

3. Use of Improved Information Technology and Burden Reduction

Data will be collected electronically to minimize burden to respondents via a survey. The survey will be offered online using

a secure web-based application (e.g., REDCap, Survey Monkey). This self-administered survey modality will include programmed required data elements, logic checks, skip patterns, and range values, thereby improving the quality of the data and reducing burden for respondents. Respondents who do not wish to complete the survey online via secure web-based application will be given other options including to schedule a telephone or videoconference interview with a member of the study administration team. All data, regardless of survey modality used, will be entered into a secure web-based application (e.g., REDCap, Survey Monkey). The burden to respondents will remain the same regardless of mode of administration.

4. Efforts to Identify Duplication and Use of Similar Information

CDC does not have a repository of data specifically directed towards hepatitis C testing and treatment within state DOCs or large jails. We do not currently possess data that will allow continuous program planning and evaluation of programs that aim to reduce new viral hepatitis infections, reduce viral hepatitis-related morbidity and mortality, and reduce viral hepatitis-related disparities in carceral settings. This survey will provide CDC the information it needs to advance the DVH strategic plan to eliminate viral hepatitis in the nation.

5. Impact on Small Businesses or Other Small Entities

Data will be collected from state DOCs and large jails, which are not-for-profit entities. The survey has been held to the absolute minimum required for the intended use of the data. Program directors or designated staff will be able to complete the survey at a time that is convenient for them through the method of their choosing (e.g., online or by scheduling a telephone or videoconferencing interview).

6. Consequences of Collecting the Information Less Frequently

Data collection activities under the current funding period are expected to occur annually, as funding and timelines allow. It is expected that if successful, these activities will continue beyond this initial funding period to establish a routine activity to support continuous program monitoring and improvement. Data for resource planning need to be collected on an annual basis to inform programming and funding.

Carceral settings are an important component of community-level public health interventions addressing hepatitis C virus which is a curable disease. There is a lack of standardized and systematic information on hepatitis C virus screening and testing practices, hepatitis C point prevalence, treatment rates, access to substance use disorder treatment including medications for opioid use disorder (MOUD), and challenges in scaling hepatitis C testing and treatment programming. The consequences of not routinely collecting this information include:

- inadequate program monitoring and evaluation,
- limited visibility on impact of carceral health on community health,
- lack of understanding of national program gaps and needs, and
- inability to properly support programs to address these gaps and better serve their clients.

There are no legal obstacles to reduce the burden.

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

We are aware of the sexual orientation and gender identity (SOGI) requirement to include inclusive language to capture gender identity and sexual orientation questions on survey instruments. Unfortunately, due to the limited IT infrastructure of carceral settings which are designed to capture the most basic information to identify and track individuals under their care, we are only able to capture the designation of sex assigned at birth. Race and ethnicity might also be a challenge due to the same limitations. However, for race and ethnicity we did ensure our answer choices aligned with the 7 minimum categories as outlined by SPD-15. We also included an answer choice of "other/missing/unknown" to account for the variability across state department of corrections prisons and large jails in how they can capture race/ethnicity. When we piloted the survey with 7 correctional systems, we identified unique challenges to answering the questions: inadequate data collection systems, challenges with calculating proportions, unanswered survey questions, confusion with some of the wording and flow of the survey. With this feedback, we've refined our survey to improve response rate and reduce the number of unanswered questions. The public reporting burden of this collection of information varies from 30 to 80 minutes with an estimated average of 55 minutes per response. This is outside of the scope of this survey, but it is our hope that through the

administration of this survey this might spark internal discussions among state department of corrections prisons and large jails on the type of data being captured and how it is being stored. The scope of this survey is to understand the burden of hepatitis C in carceral settings and to understand screening, testing, and treatment practices.

Otherwise, this request fully complies with the guidelines of 5 CFR 1320.5.

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

A 60-day Federal Register Notice to solicit public comments was published in the *Federal Register* on 05/28/2024, Volume 89, Page 46120 (**Attachment 2a**). There were 2 non-substantive comments.

9. Explanation of any Payment or Gift to Respondents

No payment will be given to respondents.

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

The information collection pertains to institutions (e.g., state DOCs and large jails), not individuals or households. No individual-level information or potentially identifying information about incarcerated persons or any other individuals will be collected. Designated staff member(s) serving as the representative for the institution can complete the survey. Data collected from responding institutions will be stored by ACA and CDC will receive a deidentified data set for analysis. CDC will not directly know the identity of each institution but can indicate institutions it wishes to contact for technical assistance or support. ACA will then ask the institution for permission to reveal their identity to CDC and connect them. The responding institution retains the option to decline identification and remain anonymous to CDC.

Participation in the survey is optional. State DOCs and large jails can abstain from participating by not accessing the web-based survey, not submitting survey responses, or not scheduling a telephone or videoconferencing interview. All respondents will

be informed that data about their programs will be kept secure and that the data will be reported to CDC without the name of the institution and the location reported as region for state DOCs and state for jails. Interviewer-administered surveys over the telephone or a videoconferencing platform will be conducted by trained ACA project staff in a private location where the survey responses cannot be overheard by others.

Data for this project will be collected using a secure web-based application (e.g., REDCap, Survey Monkey). For respondents who choose to complete the web-based survey, data entered by respondents will be transmitted directly to the secure web-based application server rather than stored locally. Respondents who choose to complete the survey for example, via telephone or videoconferencing, will provide verbal responses to be entered into the web-based application by the survey interviewer at the time of interview. ACA will routinely download and clean the data files and will provide routine recruitment monitoring reports to CDC. At the conclusion of data collection, the ACA will process all data collected and produce a clean, final deidentified data set for use by CDC. This dataset will be sent via a secure network to CDC.

Encryption security for all data must meet the current National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES). Data will be kept private to the extent allowed by law.

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

The approved Project Determination Form (**Attachment 5**) indicates that because the project is a program evaluation activity, the protocol will not be reviewed by CDC's IRB.

12. Estimates of Annualized Burden Hours and Costs

This voluntary survey will be administered annually to state DOCs and the large jails that are listed as members of ACA (<https://www.aca.org/>). The goal is to reach 101 state DOCs and large jails, to include the District of Columbia. Each responding institution will receive a request to complete the web-based survey with advance notification to allow time for record searches (**Attachment 3b**). The survey has branching logic to improve efficiency and reduce time burden of survey.

Participating institutions will have a set-time period, as determined by ACA, to complete the survey. This survey will be self-administered which we estimate to take between 30 to 80 minutes to complete, with an average time to complete of 55 minutes, to include time for collecting the required data elements and entering the data elements into the web-based survey form. If preferred, there will be an option to complete an interviewer-administered survey via telephone or videoconferencing with a member of the ACA survey team.

State DOCs and large jails can agree or decline to participate in the survey. We are aiming for 100% response rate. We anticipate that approximately 20% of invited institutions will decline to complete the survey, yielding approximately 80% completed surveys per year. However, given that this is the first survey of all state DOCs and large jails funded by CDC, we are requesting enough burden hours to allow 100% of institutions to respond to the survey.

Institutions that do not respond to the initial survey invitation will be given set reminders (**Attachment 3c**) to complete the survey over the duration of the survey implementation period. The final reminder (**Attachment 3d**) will include a link to a single question for institutions that choose not to complete the survey about why they declined to complete the survey. Given the uncertainties in response rates described above, we are requesting enough burden hours to allow 100% of institutions to respond to this question. We estimate that it will take approximately two minutes to respond to the non-response survey item (**Attachment 3e**).

Burden estimates were informed by previously piloting the CURE-HepC Survey with ACA project staff and seven total institutions.

The estimates in the table below cover the time that each respondent will spend communicating with the ACA project staff to answer survey questions.

Exhibit 12 A: Estimates of Annualized Burden Hours

Respondent	Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (hours)	Total Burden (in hours)
Participating State Department of Corrections Prisons and large jails, to include District of Columbia	Comprehensive Understanding of Readiness for Elimination of Hepatitis C in Corrections (Cure-HepC) survey (Attachment 3a)	101	1	55/60	93
Non-responding State Department of Corrections Prisons and large jails, to include District of Columbia	Non-Response Survey Item (Attachment 3e)	101	1	2/60	3
Total Annualized Burden					96

B. Estimated Annualized Burden Costs

Note: The hourly rate was determined by using data obtained from the U.S. Department of Labor, Bureau of Labor Statistics (<http://www.bls.gov/cps/cpsaat39.htm>). The 2019 rate for “social and community service managers” was used.

Type of Respondent	No. of Participants	No. of Responses per Respondent	Total Burden Hours	Hourly wage rate	Total Respondent Cost
All participating State Department of Corrections Prisons and large jails, to include District of Columbia	101	1	93	\$36.00	\$3,348
Non-responding State Department of Corrections Prisons and large jails, to include District of Columbia	101	1	3	\$36.08	\$108
Total Annualized Cost					\$3,456

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

There are no other costs to participants associated with this proposed collection of information.

14. Annualized Cost to the Federal Government

The annualized cost to the government for one year is \$279,624 and for the three years is estimated to be \$838,872. The annualized cost is summarized in Exhibit 14.A.

Exhibit 14.A. Annualized Cost to the Federal Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	Personnel Health Scientist - GS-14 1 10% \$9,298.00	\$29,624
	Epidemiologist - GS-13 1 25% \$20,326	
	Cooperative agreement funds	\$250,000
	TOTAL COST TO THE GOVERNMENT	\$279,624

*Salary estimates were obtained from the U.S. Office of Personnel Management salary scale at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/>.

15. Explanation for Program Changes or Adjustments

This is a new data/information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The survey will be administered up to three times during this approval period; approval is requested for three total years. The following is a brief overview of the project timeline.

Annual Survey Activities	Estimated Time Schedule Based on Expected OMB Approval
Pre-survey activities (e.g., socialization of survey among potential respondents via a webinar and preparing database to receive survey responses, recruitment of respondents)	1-2 months prior to OMB approval
Begin Data Collection: Year 1	Immediately after OMB approval
End Data Collection and Clean Data: Year 1	Seven months after OMB approval
Contractor submits cleaned and validated data to CDC: Year 1	Nine months after OMB approval
Complete Analysis of Data,	Ten months after OMB approval

draft report, and review with CDC: Year 1	
Publication of Data: Year 1	No more than 16 months after OMB approval
Begin Data Collection: Year 2	Ten months after OMB approval
End Data Collection and Clean Data: Year 2	17 months after OMB approval
Contractor submits cleaned and validated data to CDC: Year 2	19 months after OMB approval
Complete Analysis of Data: Year 2	20 months after OMB approval
Publication of Data: Year 2	No more than 26 months after OMB approval
Begin Data Collection: Year 3	20 months after OMB approval
End Data Collection and Clean Data: Year 3	27 months after OMB approval
Contractor submits cleaned and validated data to CDC: Year 3	29 months after OMB approval
Complete Analysis of Data: Year 3	30 months after OMB approval
Publication of Data: Year 3	No more than 36 months after OMB approval

Data from the CURE-HepC survey will increase existing knowledge on hepatitis C point prevalence in carceral settings and successes and challenges to scaling up hepatitis C screening, testing, and treatment. See **Attachment 4** for sample analysis tables.

For anonymity of institutions to CDC, institution name will be withheld, and location reported as region for state DOCs and state for large jails. ACA will be responsible for the release of de-identified data to CDC from all participating institutions. Data may be further distributed in a report, abstract, publication in peer reviewed journal, presentation at different forums such as continuing medical education courses and seminars, or national conference.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

- 1) Varan, A. K., Mercer, D. W., Stein, M. S., & Spaulding, A. C. (2014). Hepatitis C seroprevalence among prison inmates since 2001: Still high but declining. *Public Health Reports*, 129(2), 187-195. <https://doi.org/10.1177/003335491412900213>
- 2) Akiyama M.J., Kaba F., Rosner Z. (2017). Correlates of Hepatitis C Virus Infection in the Targeted Testing Program of the New York City Jail System. *Public Health Reports*, 132(1), 41-47. <https://doi.org/10.1177/0033354916679367>
- 3) Afdahl N., Zeuzem S., Chojkier P.K., et al (2014) Ledipasvir and sofosbuvir for untreated HCV genotype 1 infection. *N Engl J Med*, 370(20), 1889-98. <https://doi.org/10.1056/NEJMoa1402454>