U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: *11/18/20*

Title: Integrated Viral Hepatitis Surveillance and Prevention Funding for States

Project Id: 0900f3eb81bf3a1a

Accession #: NCHHSTP-ESB-9/28/20-f3a1a

Project Contact: Cooley_Laura A (whz3)

Organization: NCHHSTP/DVH/ESB

Status: **Project In Progress**

Intended Use: **Project Determination**

Estimated Start Date: 05/01/2021

Estimated Completion Date: 05/01/2026

CDC/ATSDR HRPO/IRB Protocol #:

OMB Control #:

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research - Public Health Surveillance *45 CFR 46.102(l)(2)*	10/26/20	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		10/26/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

ICRO: **Returned with No Decision**		10/26/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	08/01/2021
Determination Start Date:	09/28/20
Description:	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 PWID with opioid use disorder (OUD), MAT reduces the risk of hepatitis C acquisition by 50% and the combination of high coverage needle and syringe exchange and MAT reduces hepatitis C acquisition by 74%. PWID can be treated for hepatitis C with sustained virologic response about 90%. Despite evidence of effectiveness, state policies may limit access to direct acting antiviral treatment and SSPs, and access to MAT 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 41%), are low. Comprehensive SSPs provide syringe exchange and access to other needed services for PWID. 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 states 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.
IMS/CIO/Epi-Aid/Chemical Exposure Submission:	No
IMS Activation Name:	Not selected
Primary Priority of the Project:	Not selected
Secondary Priority(s) of the Project:	Not selected
Task Force Associated with the Response:	Not selected
CIO Emergency Response Name:	Not selected
Epi-Aid Name:	Not selected
Assessment of Chemical Exposure Name:	Not selected

Goals/Purpose	These activities will support integrated viral hepatitis surveillance and prevention programs in states and large cities in the United States. Key strategies include viral hepatitis outbreak planning and response; and surveillance for acute hepatitis A, B and C, and chronic hepatitis C. Participants will develop a jurisdictional viral hepatitis elimination plan, increase comprehensive hepatitis B and C reporting, improve HBV and HCV testing and increase healthcare providers trained to treat hepatitis B and C. The following activities may be supported (contingent on funding): surveillance for chronic hepatitis B and perinatal hepatitis C; increased hepatitis B and C testing and referral to care in high-impact settings (syringe services programs (SSPs), substance use disorder (SUD) treatment centers, correctional facilities, emergency departments and sexually transmitted disease clinics; and increased access to services preventing viral hepatitis and other infections among persons who inject drugs (PWID). 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. Expected outcomes include improved surveillance for viral hepatitis, increased stakeholder engagement in viral hepatitis elimination planning, and improved access to viral hepatitis prevention, diagnosis, and treatment among populations most at risk.
Objective:	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, SSPs and medication assisted treatment (MAT) and 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 SUD treatment.
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	General US Population
Tags/Keywords:	Hepatitis A, Hepatitis B, Hepatitis C, Hepatitis, Drug Users
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided
Method Categories:	Analytic Services (can be data/specimen TA for non-research,research,investigations); Surveillance Support; Technical Assistance
Methods:	Required activities for award recipients include those related to six strategies: 1.1, develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for: hepatitis A, hepatitis B, and hepatitis C; 1.2, systematically 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), systematically 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 viral hepatitis elimination planning and surveillance, and maximize access to testing, treatment, and prevention; 2.2 (contingent upon available funding), increase access to HCV and HBV testing and referral to care in high-impact settings; and 2.3, improve access to services preventing viral hepatitis and other bloodborne infections among PWID.
Collection of Info, Data or Biospecimen:	A standardized Case Report Form will be used for surveillance data collection submitted to the National Notifiable Diseases Surveillance System (NNDSS). Program evaluation will include collection and analysis of program performance data submitted by award recipients which tracks key performance indicators and process indicators and includes required reports. Data collection is used for program accountability, monitoring, evaluation and performance improvement, those data will include, but are not limited to, national viral hepatitis surveillance data submitted to CDC, annual performance reports, and quantitative and qualitative data in a CDC-approved format.
Expected Use of Findings/Results:	This project will enable jurisdictions 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. Data will also be used to produce surveillance reports, reports on project accomplishments, project feedback reports, fact sheets, and other monitoring and evaluation reports.

Could Individuals potentially be identified based on Information Collected? No

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Cooperative Agreement	Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments	PS21-2103	2021	5

HSC Review

Regulation and Policy

Do you anticipate this project will be submitted to the IRB office No

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults No Selection

Children capable of providing assent No Selection

Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested Waivers of Documentation of Informed Consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection

Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
Danae Bixler	10/02/2023				Technical Monitor	nqd0@cdc.gov	404-718-3208	EPIDEMIOLOGY RESEARCH TEAM
David Butterworth	09/17/2022				Technical Monitor	jji7@cdc.gov	404-718-3722	PROGRAM TEAM
Henry Roberts	03/11/2023				Technical Monitor	hdr9@cdc.gov	404-718-8659	SURVEILLANCE TEAM
Laurie Barker	07/23/2022				Technical Monitor	lub2@cdc.gov	404-718-8059	SURVEILLANCE TEAM
Mona Doshani	03/25/2022				Technical Monitor	imf6@cdc.gov	404-718-8854	COMMUNICATIONS AND PROGRAM TEAM

Data

DMP

Proposed Data Collection Start Date:	8/1/21

Proposed Data Collection End Date:	8/1/26
Proposed Public Access Level:	Public
Public Access Justification:	Award recipient surveillance data is submitted to the National Notifiable Diseases Surveillance System (NNDSS) and is made publically accessible by CSELS through CDC Wonder, etc.
How Access Will Be Provided for Data:	WONDER Weekly Tables of Infectious Diseases (1996 to present), CDC WONDER; DATA.CDC.gov Provisional Weekly Infectious Disease Data (2014 to present), Data.cdc.gov; MMWR Weekly Tables of Infectious Diseases (through December 2017), MMWR weekly archive; CDC Stacks Collections of Weekly Infectious Disease Tables (1951 to present), CDC Stacks
Plans for Archival and Long Term Preservation:	Access provided through CDC WONDER, DATA.CDC.gov, MMWR weekly tables, CDC Stacks.

Spatiality

Country	State/Province	County/Region
United States		

Dataset

Dataset Title	Dataset Description	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...									