Annual Performance Report—Component 1--Form Instructions
Year 3 Reporting Period (10/1/22-9/30/23)
Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments

Component 1: Core Viral Hepatitis Outbreak Response and Surveillance Activities

The Annual Performance Report (APR) for CDC-RFA-PS21-2103 is required for all award recipients. The instructions in this document are to be used when submitting your APR data through the online form provided by CDC. Data submitted through the online form will be reviewed by CDC and analyzed for future reports (e.g., rapid feedback report).

Recipients must also submit a copy of their APR data via www.Grantsolutions.gov no later than 120 days prior to the end of the budget period (as part of the year 4 continuation application). Please see the Notice of Funding Opportunity (NOFO) document for this cooperative agreement starting on page 68 for additional information.

Evaluation and Performance Measures are listed starting on page 30 of the NOFO. Please review that information, along with Strategies and Activities starting on page 11, before submitting your APR through the online form.

Note: Timelines are provided in the NOFO for each measure, however, in general:

- **Short-term outcomes** should be reached by the end of year 3. Measures associated with these outcomes should be reported annually.
- **Intermediate outcomes** should be reached by the end of year 5. Measures associated with these outcomes should be reported annually. Recipients may define interim goals (for year 3-year 5) that are related to the intermediate outcomes to track progress.
- Outcomes for measures that are “contingent on funding” are not required to be reached unless they are funded during the course of the award. Reporting of these measures is recommended but not required.

1.1—Develop, implement, and maintain plan to rapidly detect and respond to outbreaks of hepatitis A, hepatitis B, and hepatitis C

See NOFO pages 12-13 and 30-32 for more information.

Measure 1.1.1.a

Documented plans for responding to outbreaks of **hepatitis A**, **hepatitis B**, and **hepatitis C** infections

- This is a short-term outcome (years 1–3). For this measure, provide information about the documented plans for responding to outbreaks of hepatitis A, hepatitis B, and hepatitis C infections.
- Jurisdictions will vary when they are able to complete plans for responding to outbreaks of viral hepatitis within years 1–3. After plans are completed, jurisdictions should continue to report on the progress of annual reviews and outbreak response plan updates in subsequent years.
- **Plan status** — Report the status of plan completion as of the close of the reporting period.
- **Topics covered**— Report topics covered by the jurisdictional outbreak response plan. If a topic is not applicable to this outbreak plan at this time, select no and leave 'Year plan was reviewed last' blank.
    - Outbreak response plans may be stand-alone plans or integrated with other jurisdictional health department outbreak response plans. For example, foodborne hepatitis A outbreak investigation and response plans may be integrated with jurisdictional foodborne outbreak plans, and healthcare-associated hepatitis B and C investigation and response plans may be integrated with jurisdictional healthcare-associated outbreak plans. Plans to respond to hepatitis B and C for persons who inject drugs may be integrated with jurisdictional plans to respond to HIV outbreaks or overdose prevention in persons who inject drugs.
    - Community/person-to-person outbreaks may include outbreaks spread by fecal-oral transmission, sexual transmission, transmission in association with injection or non-injection drug use, and other mechanisms.
    - Healthcare-associated investigations encompass a broad range of health care settings, including but not limited to hospitals, ambulatory surgical centers, dialysis centers, dental clinics, complementary and alternative medicine clinics, and long-term care facilities.
- **Year plan was last reviewed**— Enter the year the plan was last reviewed or was completed. If different topics (in the preceding column) were reviewed at different times, please separately report the date each topic was last reviewed in the corresponding space.

Measures 1.1.1.b and 1.1.1.c

CDC is notified of outbreaks within 5 business days of identifying the outbreak
CDC is notified of all cases associated with an outbreak within 30 days of case investigation start date

- These are short-term outcomes (years 1–3). In this section, provide information about notifying CDC of newly reported or identified hepatitis-associated outbreaks during the reporting period. An outbreak is defined as an increase in cases of disease clustered in person, place, and time over and above the expected number of cases.
- As required for PS21-2103, there is a separate process for reporting outbreaks to CDC within 5 days of outbreak confirmation, that includes a follow-up summary form detailing outbreak response activities. This process is described in the guidance document "Identifying *and reporting outbreaks of viral hepatitis, considerations for health departments*" which is available on NPIN. It is not a substitute for responding to the outbreak questions in this APR.
- **Hepatitis-associated outbreaks —** Report the number of hepatitis-associated outbreaks identified in your jurisdiction. A maximum of 6 outbreaks can be reported on the APR form.
- **Jurisdiction-assigned outbreak ID** —A jurisdiction-assigned unique name or identifier for an identified outbreak. For jurisdictions reporting via HL7, this is PHIN variable code=INV151 and data element identifier=77981-9.
- **Outbreak type (select one)**— Report the type of viral hepatitis identified in association with the outbreak at the time of this report. Document if multiple types of viral hepatitis are included in the current outbreak case definition by checking "hepatitis B and hepatitis C" or "other, specify" and providing the hepatitis types.
    - If viral hepatitis coinfection is incidentally noted in association with the outbreak, then do not indicate the coinfection in this field. For example, if hepatitis C coinfection is noted among case-patients in an outbreak of hepatitis A spread person-to-person in association with injection or non-injection drug use or homelessness, but hepatitis C status is not part of the outbreak case definition, then check only "hepatitis A."
- **Date outbreak was confirmed (*MM/DD/YYYY*)** — Report the date that the jurisdiction had accumulated sufficient person, place, and time data during preliminary investigation to reasonably conclude that an outbreak exists.
- **Number of outbreak-associated cases** — This measure is the number of cases that met the current outbreak case definition and the surveillance case definition as of the close of the reporting period.
    - **Surveillance case definitions** are found at: Surveillance Case Definitions for Current and Historical Conditions | NNDSS (cdc.gov)
    - **Outbreak case definitions** are developed by the outbreak investigation team for each outbreak and specify case definition criteria in person, place, and time for cases that are included in the outbreak. Cases meeting the outbreak case definition often also meet the surveillance case definition; however, there are many exceptions. For example, for some outbreaks, asymptomatic cases of hepatitis B or C might be included as outbreak cases based on molecular or epidemiological evidence whereas they might not

meet the surveillance case definition. In some outbreaks of hepatitis B, case patients with isolated positive IgM anti-HBc might be included during the initial phase of the investigation based on a broad outbreak case definition; these patients would not meet a surveillance case definition and might not meet a final and more narrow outbreak case definition.

- **Was the outbreak was reported to CDC** — Report if the outbreak was reported to CDC and the associated time frame.
- **Was the outbreak later determined not to be an outbreak**— Report the outbreak status from the options available. For the purposes of this report, an outbreak is confirmed if the outbreak has been sufficiently investigated by the jurisdiction so that the jurisdiction can confirm that the number of cases meeting the outbreak case definition are in excess of the expected number of cases in person, place, and time. An outbreak might be considered a confirmed outbreak before investigation is completed. Here are two hypothetical examples of situations where an outbreak was initially suspected by the jurisdiction, but was not confirmed to be an outbreak:
    - Example #1- Two dialysis patients in the same unit seroconverted from anti-HCV negative to anti-HCV positive over a three-month period. This was reported to CDC as an outbreak and CDC consultation was requested. HCV quasispecies analysis of RNA from all chronic and acute hepatitis C cases in the unit was performed and quasispecies from both acute cases were unrelated to each other and any other HCV RNA patient specimens from patients in the dialysis unit. On further questioning, one of the patients with acute hepatitis C admitted to sharing injection paraphernalia and heroin with a family member. Investigators concluded that this was not an outbreak.
    - Example #2- A county health department identified a cluster of 9 cases of acute hepatitis B infection in people engaging in male-to-male sexual contact and/or methamphetamine injection during a one-month period and the possible outbreak was reported to CDC. A vaccination campaign was undertaken in collaboration with providers serving the population impacted by the outbreak. On further investigation, two cases were determined to have false-positive anti-HBc IgM because anti-HBc total and anti-HBs were both negative during follow-up, and one case was determined to have chronic HBV infection after old laboratory results were identified in medical records. None of the remaining cases had sexual or needle-sharing partners in common and HBV DNA from four available patient specimens tested in the DVH laboratory were not closely related. By the end of the calendar year, reported cases of HBV were not significantly elevated over reported cases in the county from the previous two years. The health department concluded that the transient rise in HBV incidence did not represent a true outbreak.
- **Out of the number of outbreak-associated cases, how many were reported to CDC within 30 days of case investigation start date (or if unavailable the proxy field being used**) — This measure applies to all cases of disease that met both the outbreak case definition and the surveillance case definition. Of these cases, record the number of cases reported to CDC within 30 days after (investigation start date) or the date the outbreak was reported to CDC, whichever date was later.
    - Viral hepatitis coinfections noted incidentally during outbreak and case investigation (but not included in the outbreak case definition) do not need to be included in this count. For example, in an outbreak of person-to-person

spread of hepatitis A, report time for chronic hepatitis C among case-patients with chronic hepatitis C coinfection should not be included in this measure because chronic hepatitis C is not part of the outbreak case definition.

- For city and county health departments that do not report their data to CDC, use the number of cases reported to your state health department (instead of "reported to CDC").

Additional information (challenges and successes)

Recipients must describe challenges and successes experienced when implementing Strategy 1.1 activities.

- This information should be reported in the APR form. Please do not develop a separate document to submit with your jurisdiction's non-competing continuation application.
- When describing challenges, please indicate how CDC could provide support to your jurisdiction to complete activities in the work plan and achieve the short and intermediate outcomes.
- Also include any contextual information that would help us interpret your annual performance data for any activities in progress or not started.
- See NOFO page 68 for more information.

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

See NOFO pages 12-13 and 30-32 for more information.

Measure 1.2.1.a

Are negative/undetectable results for [**hepatitis B surface antigen (sAg), HBV DNA, hepatitis C antibody (anti-HCV), and HCV RNA]** currently reportable by law in your jurisdiction?

If "Yes, some…" explain the context for which some negative lab results are reportable in your jurisdiction. If either "Yes, all…" or "Yes, some…" what was the first year that negative/undetectable results were reportable in your jurisdiction?

Are negative/undetectable results for [**hepatitis B surface antigen (sAg), HBV DNA, hepatitis C antibody (anti-HCV), and HCV RNA]** currently received by your health department?

If "Yes", Explain the context for which negative lab results are received in your jurisdiction. Include the following information:

1. Estimate the proportion of all negative lab results received by your health department
2. Provide reporting sources (laboratories, hospitals, other)
3. Provide reporting mechanisms (ELR, fax, other, received with positives/panel/reflex testing, and/or as part of an investigation, etc.)

- These are short-term outcomes (years 1–3). The goal is to have reporting of and receive negative HBV DNA and negative HCV RNA results by year 3.
- Reportable is defined as being mandated by law or regulation at the local and/or state level.
- Please provide an estimate of the proportion of all negative lab results that you believe are received by your health department. The estimate does not need to be exact.

Measure 1.2.2.a and 1.2.2.b

Measure 1.2.2.a

Have you identified all of the laboratories that perform viral hepatitis-related testing for your jurisdiction?
If "Completed," then enter

- Total number of laboratories that perform viral hepatitis testing
- Number of these laboratories that report test results

Measure 1.2.2.b

Total number of test results entered into database during the reporting period
Number of test results entered into database within 60 days of specimen collection date

- These are short-term outcomes (years 1–3). The goal is for at least 95% of laboratories that perform viral hepatitis-related testing for the jurisdiction to report viral hepatitis-related test results to the health department and at least 85% of viral hepatitis lab results to be entered into jurisdiction's viral hepatitis surveillance database within 60 days of specimen collection date by year 3.
    - Viral hepatitis-related test results include positive and negative hepatitis A, B, and C results as well as results received as part of a hepatitis panel, and ALT and total bilirubin that are associated with a positive marker.
- For each viral hepatitis lab result entered into the viral hepatitis surveillance database, calculate the number of days between specimen collection date and the date the lab test result was entered into the database. Then, categorize the lab results by those

entered into the surveillance database more than 60 days from the specimen collection date and those entered on or before the 60th day.
    - For example, a lab result entered into the surveillance database on May 30, 2022, for a specimen collected on March 31, 2022, would be counted as having been entered within 60 days of the specimen collection date. If the same lab result had been entered into the database on May 31, 2022, it would not be considered to have been entered within 60 days of the specimen collection date.
- Percentages will be automatically calculated by REDCap. Percentage calculations:
    - Number of laboratories from which viral hepatitis-related test results were received by your health department divided by the total number laboratories that perform viral hepatitis-related testing for your jurisdiction
    - Number of lab results entered into the database within 60 days of the specimen date within the reporting period divided by the total number of lab results entered into the database within the reporting period

Measure 1.2.2.c & 1.2.3.a (Only for city or county health departments)

Measure 1.2.2.c
Number of **hepatitis A, acute hepatitis B, or acute hepatitis C)** case reports submitted to state health departments within 90 days of case investigation start date
Measure 1.2.3.a
Number of **chronic hepatitis C** case reports submitted to state health departments within 90 days of case investigation start date

- These are short-term outcomes (years 1–3). The goal is for at least 90% of hepatitis A, acute hepatitis B, acute hepatitis C, and chronic hepatitis C case reports to be submitted to State Health Departments (SHDs) within 90 days of case investigation start date by year 3.
- For a hepatitis A (or acute hepatitis B, or acute hepatitis C, or chronic hepatitis C) case for which the investigation start date was May 4, 2023, and the jurisdiction submitted the case to the state health department on August 2, 2023 — this would be counted as having been submitted to the state health department within 90 days of case investigation start date.
- Percentages will be automatically calculated by REDCap. Percentage calculation:
    - Number of cases submitted to SHDs within 90 days of case investigation start date during the reporting period divided by the total number of cases submitted to SHDs within the reporting period (for hepatitis A, acute hepatitis B, acute hepatitis C, and chronic hepatitis C).

Measure 1.2.2.d & 1.2.3.c (Only for city or county health departments)

Measure 1.2.2.d
Number of **(hepatitis A, acute hepatitis B, or hepatitis C)** case reports submitted to state health departments that are complete for demographic categories (age, gender, race/ethnicity, county of residence, and outbreak)
Measure 1.2.3.b
Number of **chronic hepatitis C** case reports submitted to state health departments that are complete for demographic categories (age, gender, race/ethnicity, and county of residence)

- These are short-term outcomes (years 1–3). The goal is for hepatitis A, acute hepatitis B, and acute hepatitis C case reports to be at least 90% complete for age, gender, race/ethnicity, county of residence, and outbreak status by year 3. Year 2 goal should be determined based on interim activities.

- Race and ethnicity information should be entered as one combined data element. If any of the following conditions are present, this information is considered '**complete'**:
    - Ethnicity and race data are both known,
    - Ethnicity equals Hispanic* and race data is missing, or
    - Ethnicity equals non-Hispanic* and race is known.

  If any of the following conditions are present, this information is considered '**incomplete'**:
    - Ethnicity and race are both missing,
    - Ethnicity equals non-Hispanic* and race is missing, or
    - Ethnicity is missing and race is known.

  *Hispanic or Latino/a/x
- Percentage will be automatically calculated by REDCap. Completeness for demographic categories is defined as the number of cases with age, gender, race/ethnicity, county of residence, and outbreak status reported (Yes and No) divided by the total number of cases reported (Yes and No and Unknown/Missing).

Measure 1.2.2.e (Only for city or county health departments)

Number of **(hepatitis A, acute hepatitis B, or hepatitis C)** case reports submitted to state health departments that are complete for risk behaviors and exposures

- These are short-term outcomes (years 1–3). The goal is for hepatitis A, acute hepatitis B, and acute hepatitis C case reports to be at least 70% complete (reported as Yes or No) for each of the risk behaviors or exposures questions by year 3.
- Completeness information for the highlighted risk behaviors and exposures in the table below is requested in the REDCap APR form.
- Percentage will be automatically calculated by REDCap. Completeness for each risk behavior or exposure is defined as the number of cases with the risk behavior or exposure reported (Yes and No) divided by the total number of cases reported (Yes and No and Unknown/Missing).

Risk behaviors and exposures		
Hepatitis A	**Acute hepatitis B**	**Acute hepatitis C**
Injection drug use	Injection drug use	Injection drug use
Sexual contact	Sexual contact	Sexual contact
Household contact (non-sexual)	Household contact (non-sexual)	Household contact (non-sexual)
Other contact	Multiple sex partners	Multiple sex partners
Men who have sex with men^{+}	Men who have sex with men^{+}	Men who have sex with men^{+}
International travel	Surgery	Surgery
Homelessness/unstable housing*	Dialysis patient	Dialysis patient
Incarceration*	Transplant (tissue or organ*)	Transplant (tissue or organ*)
Non-injection drug use*	Needlestick	Needlestick
Drug sharing partner*	Occupational exposure to blood	Occupational exposure to blood
	Drug sharing partner*	Drug sharing partner*
	Homelessness/unstable housing*	Homelessness/unstable housing*
	Incarceration*	Incarceration*
	Non-injection drug use*	Non-injection drug use*
	Tattoo receipt	Tattoo receipt

	International travel	
[+]Percentage is calculated using the denominator of case reports for males only (birth sex). * Risk behaviors and exposures may not be available to report on until the hepatitis Message Mapping Guide (MMG) 2.0 is in use. For risk factors not collected by your jurisdiction or reported to CDC, enter "-888."		

Measure 1.2.3.c

Have you developed a longitudinal surveillance registry for **chronic hepatitis C**?

If "Completed or In-progress," then enter

- Total number of chronic hepatitis C case reports received
- Number of chronic hepatitis C cases reports in the registry
- Indicate if your longitudinal surveillance registry includes each of the following attributes: longitudinal detectable (positive) HCV RNA test results, longitudinal undetectable/negative HCV RNA test results, person-based, deduplicating of cases, update (or append) case investigations when new laboratory results are received, and captures laboratory results that allow for tracking each patient along the hepatitis C viral clearance cascade from current infection through viral clearance
- Are case statuses (e.g., probable to confirmed) updated as indicated when additional test results are received?
  - If "No" provide additional details:
- Is a chronic HCV case investigation created if additional positive laboratory results are received 12+ months after the acute HCV investigation?
  - If "No" provide additional details:

- These are short-term outcomes (years 1–3). The goal is for at least 90% of chronic hepatitis C case reports to be included in a longitudinal surveillance registry, including longitudinal detectable and undetectable HCV RNA test results, by year 3.
- Percentage will be automatically calculated by REDCap. Percentage calculation:
  - Number of chronic hepatitis C case reports received from October 1, 2022, to September 30, 2023, and included in the registry as of the end of the reporting period divided by the total number of chronic hepatitis C case reports received during the reporting period.
- Resources below provide information about defining a longitudinal surveillance registry for viral hepatitis.
  - Monitoring Infection Trends and Disease Outcomes Using a Person-Level Database and Supplemental Data Sources
  - Surveillance Activities for Chronic Hepatitis C

Measure 1.2.4.a

Have you developed a **hepatitis C** viral clearance cascade?

If "Yes," when was the most recent cascade completed? (MM/DD/YYYY)

- This is an intermediate outcome (years 4–5). Use jurisdiction-specific data, including undetectable HCV RNA, mortality data, and other data as available to monitor the hepatitis C viral clearance cascade.
- **URL** — Please provide the URL for the **most recent hepatitis C viral clearance cascade**, if available. If no URL is available, please submit a copy of the cascade with the APR.
- *The 2021 Laboratory-based Hepatitis C Virus Clearance Cascade Program Guidance for Local and State Health Departments is available on NPIN.*

Measure 1.2.5.a

Have you developed a viral hepatitis surveillance report?

If "Yes," when was the most recent report completed? (MM/DD/YYYY)

- This is an intermediate outcome (years 4–5). Produce and disseminate an annual surveillance report that includes hepatitis A, acute hepatitis B, and acute and chronic hepatitis C surveillance data, as well as hepatitis C viral clearance cascade data.
- **URL** — Please provide the URL for the **most recent surveillance report**, if available. If no URL is available, please submit a copy of the report with the APR.

Additional information (challenges and successes)

Recipients must describe challenges and successes experienced when implementing Strategy 1.2 activities.

- This information should be reported in the APR form. Please do not develop a separate document to submit with your jurisdiction's non-competing continuation application.
- When describing challenges, please indicate how CDC could provide support to your jurisdiction to complete activities in the work plan and achieve the short and intermediate outcomes.
- Also include any contextual information that would help us interpret your annual performance data for any activities in progress or not started.
- See NOFO page 68 for more information.