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Ohio Disease Reporting System

Data Entry Guide: Hepatitis B & C Reports

Department of Health

Bureau of HIV, STIs, and Viral Hepatitis

Viral Hepatitis Surveillance Program

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Introduction

The Ohio Department of Health (ODH) Viral Hepatitis Surveillance Program is responsible for the on-going and systematic collection, analysis, interpretation, and dissemination of population-based information about persons diagnosed with non-perinatal viral hepatitis B (HBV), viral hepatitis C (HCV), and viral hepatitis D (HDV) in Ohio. The data collected is monitored for trends to evaluate the burden of disease among affected populations and to target and assess hepatitis prevention efforts. In Ohio, HBV and HCV are Class B reportable diseases, which are diseases of significant public health concern that require timely response because of the potential for epidemic spread. Healthcare providers and laboratories are required per Ohio Administrative Code 3701-3-02 to report the

occurrence of cases or suspected cases of HBV or HCV infection under their care and treatment to the public health authority by the end of the next business day in which the positive lab is obtained. Timely and accurate entry of hepatitis reports is critical for both surveillance and prevention of these diseases. *Please note that the other reportable hepatidities, including perinatal HBV, viral hepatitis A (HAV), and viral hepatitis E (HEV), are monitored in separate programs within the ODH*

Bureau of Infectious Diseases (ORBIT@odh.ohio.gov or (614) 995-5599).

This document is a guide to entering HBV non-perinatal and HCV (including perinatal HCV) reports into the Ohio Disease Reporting System (ODRS). ODRS is Ohio's integrated disease surveillance system used by the Viral Hepatitis Surveillance Program and other infectious disease programs for tracking reportable conditions across Ohio and local health jurisdictions. ODRS is a web-based program and is accessed via the ODH Application Gateway (https://odhgateway.odh.ohio.gov/). Questions regarding ODRS, including obtaining access, can be sent to the ODRS administrator at ODRS@odh.ohio.gov.

What is hepatitis?

Hepatitis is characterized by inflammation of the liver. The liver is an organ in the right upper quadrant of the abdomen that processes nutrients, filters the blood, and fights infections. When the liver is inflamed or damaged, its function can be adversely affected. The most frequent cause of hepatitis is a virus, but heavy alcohol use, toxins, some medications, and certain medical conditions may also cause hepatitis. The most common types of viral hepatitis are hepatitis B and hepatitis C. Both HBV and HCV can be acute, chronic, or perinatal, and each has its own case definition. Table 1 shows the name of each disease in the case definition and ODRS. The ODRS name includes "delta," or hepatitis D, as someone cannot be considered a case of hepatitis D unless the case definition for hepatitis B is also met.

Table 1: Names of hepatitis B and hepatitis C in case definitions and ODRS

Case Definition Name	ODRS Names
Hepatitis B, acute	Hepatitis B (including delta) – acute
Hepatitis B, chronic	Hepatitis B (including delta) – chronic
Hepatitis C, acute	Hepatitis C – acute
Hepatitis C, chronic	Hepatitis C – chronic
Hepatitis C, perinatal infection	Hepatitis C - perinatal

When deciding whether to create a new case in ODRS or adding labs to an existing record, case definitions for acute and chronic must be considered. If a person has an existing HBV acute case in ODRS, then add new labs to that record only if the new lab sample collection date is within six months of the initial positive lab in the acute record. Likewise, for HCV-acute, new labs are only to be added to an existing acute HCV record if the new sample collection date is within 12 months of the initial positive labs in the acute HCV record. If sample collection dates are beyond the acute periods of HBV and HCV, then either a new chronic record is to be created or labs are to be added to the existing chronic record in ODRS. Table 2 details when to update an existing record or create a new reportable condition for positive labs.

Table 2: Summary – When to Update Existing Record or Create New Reportable Condition

Disease	Cutoff	Update Record	Create a New Reportable Condition
Hepatitis B – acute	6 months	≤ 6 months from meeting case definition.	If no existing record or no record with any positive labs.
Hepatitis B – chronic	No cutoff	Whenever new labs are reported.	If no existing record or does not meet acute case definition.
Hepatitis C – perinatal	36 months	If < 36 months of age.	If no existing record, or age is >36 months, then create a chronic record.
Hepatitis C – acute	12 months	≤ 12 months from meeting case definition.	If no existing record or no record with any positive labs.
Hepatitis C - chronic	No cutoff	Whenever new labs are reported.	If no existing record or does not meet acute case definition.

Hepatitis B-Acute

HBV-acute is a short-term illness that typically lasts several weeks to six months. Nearly 30-50% of people will experience symptoms between 60-150 days following exposure to HBV. Symptoms are typically mild to severe and may include fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine, clay colored stool and joint pain. Approximately 95% of adults will recover from HBV and will not progress to become chronically infected. The acute period is six months. To meet case definition, the case must have symptoms and either jaundice or alanine transaminase (ALT) >100 IU/L along with a positive hepatitis B surface antigen test (HBsAg). Approximately 90% of infants and 25-50% of children 1 to 5 years of age will remain infected, while 95% of adults recover completely and do not become chronically infected. Hepatitis B is vaccine preventable.

Hepatitis B - chronic

HBV-chronic is an infection that lasts beyond the six-month acute phase. Chronic HBV does not have the clinical requirement of symptoms along with either jaundice or an elevated ALT; positive results for HBsAg, hepatitis B e antigen (HBeAg), or hepatitis B virus deoxyribonucleic acid (HBV DNA) are indicative of an HBV infection.

Hepatitis D

Hepatitis D, or delta hepatitis, is not common in the United States. It is a liver infection caused by the hepatitis D virus (HDV) and only occurs in people who are infected with HBV. HDV is an incomplete virus that requires HBV for replication. HDV is a blood-borne pathogen and is transmitted through percutaneous or mucosal contact with infectious blood. HDV can be an acute (short-term) infection or a chronic (long-term) infection, depending on the type of HBV infection. There is no surveillance case definition for HDV.

Hepatitis C - acute

HCV-acute is an incident case that is over the age of 36 months and has not previously been reported meeting case criteria for chronic hepatitis C or for whom there is laboratory evidence of re-infection. The HCV period lasts 12 months. If the infection is not resolved, it will progress into a chronic case. The HCV acute case definition requires a positive hepatitis C antibody (anti-HCV) or hepatitis C ribonucleic acid (HCV RNA) lab in addition to either jaundice, ALT >200 IU/L or total bilirubin >3.0 mg/dL. Symptoms are not required for HCV acute. Approximately 15-25% of persons with acute HCV will resolve the infection without treatment, while the rest will move into the chronic phase of infection of HCV.

Hepatitis C – chronic

HCV-chronic is a case that is over the age of 36 months and does not meet the acute HCV case definition. People with chronic hepatitis C often have no symptoms and don’t feel sick. When symptoms appear, they often are a sign of advanced liver disease. There is currently no vaccine for hepatitis C.

Hepatitis C - perinatal

HCV-perinatal is a case for infants between the ages of 2 and 36 months, positive for HCV RNA, and is not known to have been exposed to HCV via a mechanism other than perinatal.

Ohio Disease Reporting System

ODRS can be accessed via the ODH Application Gateway (https://odhgateway.odh.ohio.gov/). For HBV and HCV, there should only be one acute case record and/or one chronic record per person in ODRS.

Person Search

Guidelines:

- Always perform a search prior to entering a case or laboratory report to reduce the number of duplicate persons and case records created in ODRS.
- If the person resides in another state, the case or laboratory report should be sent to the appropriate state health department and not entered in ODRS.
- Refer to Table 2 to determine when to update an existing record or create a new reportable condition.
- From the ODRS home page, click *Disease Reporting*, then *Person*, to perform a search.
    - Search by the first three to four letters of the person's First Name and Last Name.
        - Also search for name variations, such as "Thomas/Tom" or "Susan/Sue."
        - For females, it is recommended to search only the first name to account for any maiden name changes.
    - If no match is found searching by Name, search by Date of Birth, if provided. Enter a range from mm/dd/yyyy to mm/dd/yyyy.
    - Other fields that can be used to search include Age, Address, and Phone Number along with reportable condition.
- If a person match is found and the person already has the appropriate reportable condition (acute or chronic), click *Select* for that case report and:
    - Update Person Demographic Information, Laboratory Information, and Clinical Information as needed, following the directions below.
    - The only exception to this is if the existing ODRS case report is for acute HBV or acute HCV and the specimen collect date for the new laboratory result is more than six months for HBV and one year for HCV after the acute report. In this circumstance, click *New Reportable Condition* and create a new chronic report for the person. See Table 2.
- If a person match is found, but the person does not have the appropriate reportable condition in ODRS, click *New Reportable Condition* and:
    - Update Person Demographic Information as needed.
        - Pay particular attention to the address, the address at diagnosis radio button when adding a new address, date of birth, and race.
    - Enter all Laboratory and Clinical information reported, following the directions below:
- If no person match is found:

- Click *New Person*.
- Select the appropriate Reportable Condition.
  - Hepatitis B (including delta)-acute.
  - Hepatitis B (including delta)-chronic.
  - Hepatitis C-acute.
  - Hepatitis C-chronic.
  - Hepatitis C-perinatal.
- Click *Go* to go to the first ODRS module, Person Demographics.

Person Demographics

- Last Name.
  - If unknown, check box for Last Name unknown.
- First Name.
  - If unknown, check box for First Name unknown.
- Middle Name (or initial).
- Suffix.
  - Enter suffix (e.g., Jr. or IV) here rather than in the Last Name field.
- Address.
  - Click *Add* to enter a new Address or click *Edit* to update an existing Address (for example, add an apartment number).
  - Click *Edit* to update an existing address.
  - Country.
    - Defaults to "United States," update as needed.
  - As of Date.
    - mm/dd/yyyy.
    - Change to the earliest date the person was known to reside at the address; defaults to date of entry.
      - The date of specimen collection can be used unless an earlier date is known.
      - If the lab report is entered into ODRS at a later date (weeks or months later) and the *Address As of Date* is not updated to reflect when the person resided at the address, it may be difficult to determine at which address the person resided when each specimen was collected in records where the person has multiple addresses.
  - Type.

- Defaults to Home. Update as needed, particularly for persons reported from local jails, state correctional facilities, drug treatment facilities, long-term care facilities, etc.
  - Select prison **only** for cases incarcerated in state or federal facilities. Prison should not be selected for county jails or institutions.

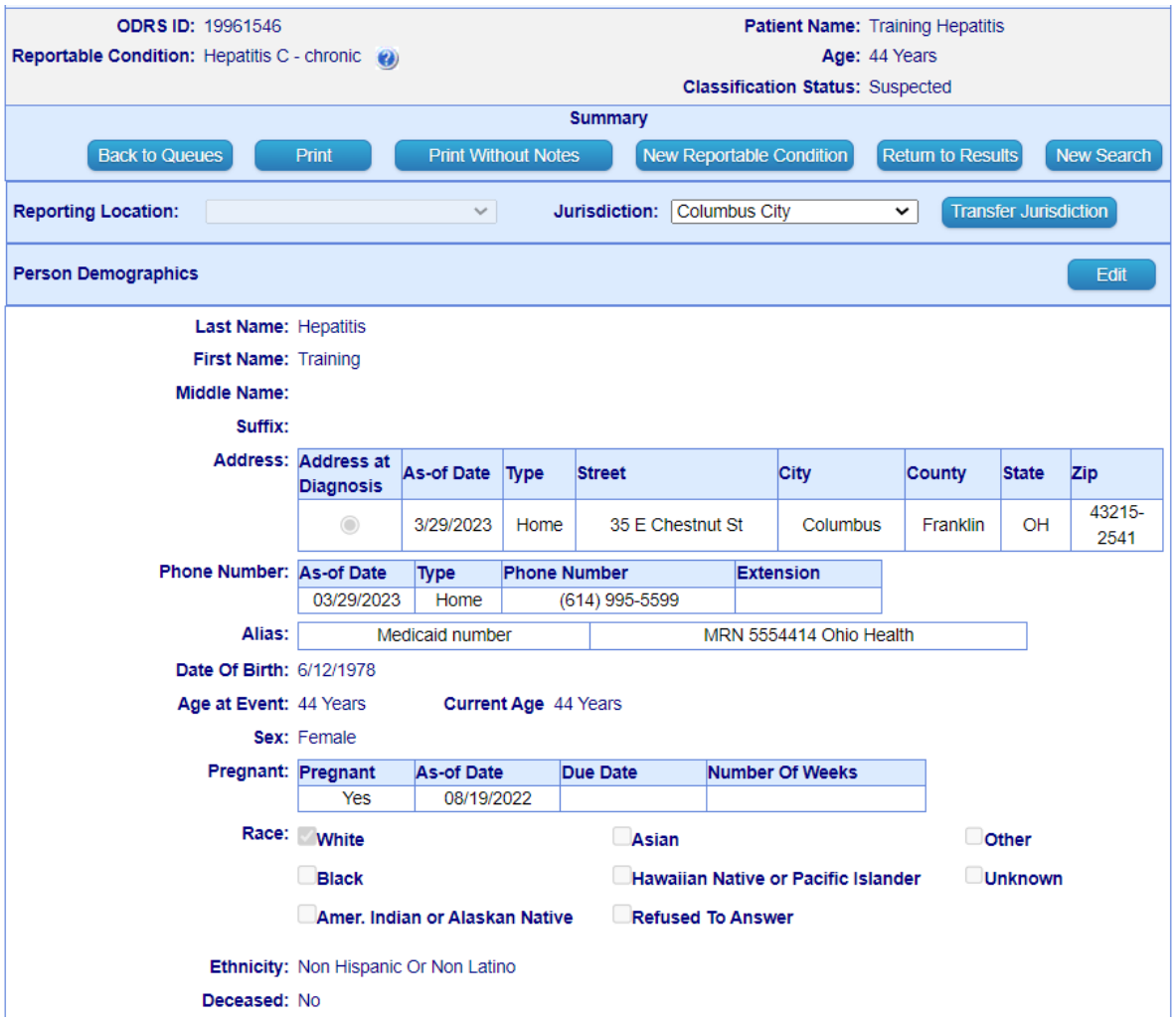
- Street 1, 2.
  - Do not need to use punctuation, such as periods, commas, etc., when entering; capitalization and proper formatting will occur when the address geocodes.
  - Include apartment and suite numbers on the first line with the street address, as Street 2 is not displayed in the Case Summary.
- Zip.
  - Enter a 5-digit ZIP code.
- After entering Street and ZIP code, tab through the State, County, and City fields and they will auto-populate.
  - State.
    - Defaults to OH. Update as needed.
    - Geocoding information is not available for states other than Ohio; all information must be keyed in for addresses in other states or countries for it to display in the case summary.
- Click *Check Address* to geocode the address.
  - If the address is geocoded properly, the ZIP code will change to ZIP code + 4 (#####-####).
    - Click *Accept Validated* to return to the Person Demographics edit screen.
      - A message will appear stating that some fields were changed, such as ZIP Code to ZIP Code + 4, capitalization, etc.
  - If the address does not geocode properly, it means that a match was not found.
    - This may happen because the address is new, the address is incomplete (missing apartment or lot number), or the address is not real.
    - Click *Keep Entered* to retain the information as keyed and return to the Person Demographics edit screen.
- *Address at Diagnosis* Radio Button.

        - If the record has more than one address, the *Address at Diagnosis* radio button should be set to the address where the person initially met the case definition for the reportable condition of the record. The button should not be moved for every new lab added to the record.
- Phone Number.
    - Click *Add* to enter a new Phone Number, click *Edit* to update an existing Phone Number, or *Delete* to remove a Phone Number.
    - As of Date.
        - mm/dd/yyyy.
        - Change to the earliest date the person was known to have this Phone Number. Use the specimen collection date as this field unless an earlier date is known. As of Date defaults to date of entry.
    - Type.
        - Defaults to Home, so update as needed; leave blank if unsure.
    - Phone Number.
    - The Phone Number field contains masking, so there is no need to enter parentheses or dash.
    - Extension.
    - Click *Done* to save and return to the Person Demographics edit screen.
- Alias.
    - Click *Add* to enter a new Alias or click *Edit* to update an existing Alias.
    - Select the appropriate Additional ID type.
        - Example: Medical Record, Social Security Number, Maiden Name, etc.
        - For cases currently residing in a federal correctional facility, look up the person in the Bureau of Federal Prisons website.
            - Add Registration Number as the prisoner ID alias, and the person's race.
        - For cases currently residing in a state correctional facility, look up the person in the ODRC Offender Search website.
            - Add the prisoner ID, along with the date of incarceration. Example: A123456 (as of 3/10/2023)
    - Enter the Additional ID.
        - Example: "MRN 123456 University Hospitals."
    - The alias field can also be used to document name changes for individuals, including maiden names.
    - Click *Done* to save and return to the Person Demographics edit screen.

- Date of Birth.
    - mm/dd/yyyy.
    - Age at Event and Current Age will calculate automatically following entry of the Date of Birth.
    - If date of birth is unknown, but age was reported, enter the age, and select the appropriate age type (e.g., years, months, etc.).
        - Current age will not calculate and display in the search results if the age type is not selected.
- Sex.
    - Sex at birth, not current gender.
- Pregnant.
    - Enables if Sex = Female.
    - Current pregnancy status is needed for all females, 10-50 years of age, with test results indicating a new or continuing HBV infection and for females of childbearing years with test results indicating a new or continuing HBV infection.
    - Click *Add* to enter current pregnancy status.
        - Pregnant.
        - As-of Date.
            - If Pregnant.
                - Due Date.
                - Number of Weeks.
    - Click *Done* to save and return to the Person Demographics edit screen.
- Race.
    - Check all races that may apply.
    - If race is not reported, check *Unknown*.
    - Unknown cannot be checked if another race is checked.
- Ethnicity.
    - Select the appropriate ethnicity.
    - If Ethnicity is not reported, select Unknown.
- Patient Deceased.
    - Select the appropriate answer from the drop-down list.
    - If Yes, enter date of death.
    - Current age will no longer calculate once a date of death is entered.
- Guardian.
    - Should be completed for all children and others with a legal guardian.

- Click *Add* to add a new Guardian, *Edit* to update an existing Guardian, or *Delete* to remove an existing Guardian.
- Type.
  - Select the type of Guardian from the drop-down list.
  - If Other selected, enter the type of Guardian in the Other text box.
- As-of Date.
  - Earliest date the person was known to be a Guardian.
- Last Name.
- First Name.
- Middle Name.
- Select the Country of Birth of the Guardian from the drop-down list.
- Phone Number.
  - Click *Add* to enter a new Phone Number for the Guardian, click *Edit* to update an existing Phone Number, or *Delete* to remove a Phone Number.
  - As of Date.
    - Change to the earliest date the Guardian was known to have this Phone Number. Use the specimen collection date as this field, unless an earlier date is known. As of date defaults to the date of entry.
  - Type.
    - Defaults to Home, so update as needed; leave blank if unsure.
  - Phone Number.
    - The Phone Number field contains masking, so there is no need to enter parentheses or dash.
  - Extension.
  - Click *Done* to save and return to the Guardian edit screen.
- Address.
  - Click *Add – Address Same as Patient* to select the same Address as the person.
    - Update the As-of Date as needed; it should be the earliest date the Guardian was known to reside with the person at this Address.
    - Click *Done* to save and return to the Guardian edit screen.
  - Click *Add* to enter a different address for the Guardian.
    - As-of Date.
      - Change to the earliest date the Guardian was known to reside at this Address; use specimen collection date, unless an earlier date is known. This field defaults to the date of entry.
    - Street.

        - Enter the street address (e.g., 123 W Main St).
        - City.
        - State.
        - Defaults to OH, so update as needed.
        - ZIP Code.
        - Click *Done* to save and return to the Guardian edit screen.
    - Click *Done* to save and return to the Patient Demographics edit screen.
- You may skip Occupation, Sensitive Occupation, and Person Settings.
- Country of Birth.
    - Select the patient's country of birth from the drop-down list.
- To move to the next module, Laboratory Information, do one of the following:
    - Select *Laboratory* from the module menu and Click Go.
    - Click the *Next* button.
    - Select *Alt* + 3.



ODRS ID: 19961546
Reportable Condition: Hepatitis C - chronic
Patient Name: Training Hepatitis
Age: 44 Years
Classification Status: Suspected

Summary

Back to Queues | Print | Print Without Notes | New Reportable Condition | Return to Results | New Search

Reporting Location: **Jurisdiction:** Columbus City | Transfer Jurisdiction

Person Demographics Edit

Last Name: Hepatitis
First Name: Training
Middle Name:
Suffix:

Address:

Address at Diagnosis	As-of Date	Type	Street	City	County	State	Zip
◉	3/29/2023	Home	35 E Chestnut St	Columbus	Franklin	OH	43215-2541

Phone Number:

As-of Date	Type	Phone Number	Extension
03/29/2023	Home	(614) 995-5599	

Alias: Medicaid number | MRN 5554414 Ohio Health

Date Of Birth: 6/12/1978
Age at Event: 44 Years **Current Age** 44 Years
Sex: Female

Pregnant:

Pregnant	As-of Date	Due Date	Number Of Weeks
Yes	08/19/2022		

Race: ☑ White ☐ Asian ☐ Other ☐ Black ☐ Hawaiian Native or Pacific Islander ☐ Unknown ☐ Amer. Indian or Alaskan Native ☐ Refused To Answer

Ethnicity: Non Hispanic Or Non Latino
Deceased: No

Laboratory Information

- The Laboratory Information module is arranged hierarchically in the following order: Laboratory Name, Specimen, then Test.
- If the Laboratory reporting the result(s) is not already listed in the record, click *Add New Lab* to add the Laboratory, followed by the Specimen and Test information to the ODRS record following the directions starting with Laboratory Name below.
- If the Laboratory is already listed in the record, but a new Specimen and Test are being reported, click *Add Specimen* to add the Specimen, followed by Test information, to add the Specimen and Test information to the record following the directions starting with Specimen below.

- If the Laboratory and Specimen are listed in ODRS, but a new Test is being reported, click *Add Test* next to the appropriate specimen to add the Test information to that specimen following the directions starting with Test below.
- If the wrong Laboratory is mistakenly entered, it can be updated by clicking *Change Lab*.
- The *View all laboratory data for patient* link allows the user to view all laboratory results in all the ODRS records for the patient for which the user has access rights, not just the laboratory results for the record that is currently open.
- Laboratory Name.
    - After clicking *Add New Lab*, the system will prompt a search in a popup window, Lab Selection.
    - Enter the laboratory name and click *Search*.
        - Other fields that can be searched include City, Telephone, and Code (ODRS Laboratory ID number).
    - Click *Select* to choose the appropriate laboratory – the one with the most complete and accurate information, including address.
    - If the lab is an out-of-state lab and it is not in ODRS, select *OOJ* (out of jurisdiction) for the lab name and create a note detailing the lab name and contact information.
    - If the laboratory is in Ohio, but is not in ODRS, notify the ODRS administrator at ODRS@odh.ohio.gov to request its addition and be sure to include complete address and phone information in the request.
- Specimen.
    - Click the *Add Specimen* button in the Specimen section to expand the section for entry.
    - Specimen ID.
        - Enter the Specimen ID number, also called the accession number. If reported, this number is useful if the lab needs to be contacted concerning the results.
        - If not reported, ODRS will create a specimen ID number with this format, SYSTEM#########.
    - Specimen Type.
        - Select the appropriate Specimen Type from the drop-down list, generally Blood, Blood/Serum, or Serum are used for HBV and HCV tests. Select *Unknown* if the specimen type is not reported.
    - Date Collected.
        - Date the specimen was collected, mm/dd/yyyy.
    - Invalidated.

- This field is usually not used during routine data entry. This field would be checked if it is discovered during follow-up that this result is not considered valid by the laboratory performing the testing. This could be due to an error in reporting or an error in labeling the specimens.

- Ordering Provider.
  - This is the provider that ordered the test, which may differ from the diagnosing provider and the treatment provider.
  - Click *Add* to begin a search for the Ordering Provider.
  - In the Provider Selection popup, enter the Ordering Provider last name and first name and click *Search*.
    - Other fields that can be searched include City, Telephone, and Code (ODRS Provider ID number).
  - Click *Select* to choose the appropriate Provider – the one with the most complete and accurate information, including the correct address for providers with more than one office.
  - If the Ordering Provider is not found, click the New button to add the Provider to ODRS.
    - In the New Provider pop-up, enter the provider information, including complete address and phone number, and Click *Save* to save the information.
    - The Ordering Provider field will populate with Provider entered and you will return to the Laboratory Specimen screen.
    - If the lab report does not have the complete address and phone number for the provider, the information can usually be found from an internet search.
  - Click *Cancel* to make no selection and return to the Specimen screen.
  - Click *Change* to edit or change the selected Ordering Provider.
- Ordering Facility.
  - Click *Add* to begin a search for the Ordering Facility.
  - In the Facility Selection pop-up, enter the Facility name and click *Search*.
    - Other fields that can be searched include Type, City, Telephone, and Code (ODRS Facility ID number).
  - Click *Select* to choose the appropriate Facility – the one with the most complete and accurate information, including address.

        - If the ordering facility is an out-of-state facility and it is not in ODRS, select *OOJ* (out of jurisdiction) for the facility name and create a note detailing the facility name and contact information.
            - If the Ordering Facility is one that will be used frequently, notify the ODRS administrator at ODRS@odh.ohio.gov to request its addition and be sure to include complete address and phone number information in the request.
            - The Ordering Facility, Diagnosing Facility, and Treatment Facility fields use the same Facility master list, so the addition of a facility only needs to be requested one time.
        - Click *Cancel* to make no selection and return to the Specimen screen.
        - Click *Change* to edit or change the selected Ordering Facility.
    - Click *Done* to save the Specimen information and return to the Laboratory screen.
- Test.
    - Click the *Add Test* button in the Test section to expand the section for entry.
    - Each test result should be entered separately (in its own row); multiple test results should not be combined into one entry.
        - The only exception is the qualitative result and one quantitative result for the same test on the same specimen; these may be entered together; multiple numeric results need to be entered separately.
            - HBV DNA detected + one numeric result.
            - Anti-HCV (antibody test) positive + signal to cutoff ratio.
            - HCV RNA detected + one numeric result.
    - Specimen ID.
        - The Specimen ID number will auto-populate with the specimen ID from the specimen section.
        - Check the number to make sure the test information is being entered for the correct specimen.
    - Reason for Test.
        - Usually not reported; if not reported, leave blank.
    - Test Name.
        - Select the appropriate Test Name from the drop-down list, which is disease specific.
        - If unsure of which test name to select, click on *Equivalent Test Names* for guidance, also refer to Appendix A or the ODH Viral Hepatitis Program webpage.

- Both acute and chronic HBV use the following Test Names:
    - ALT (alanine aminotransferase).
    - anti-HBe (antibody to hepatitis B e antigen).
    - anti-HBs (antibody to hepatitis B surface antigen).
    - anti-HDV (antibody to hepatitis D).
    - AST (aspartate aminotransferase).
    - HBeAg (hepatitis B e antigen).
    - HBsAg (hepatitis B surface antigen).
    - HBsAg confirmatory (hepatitis B surface antigen).
    - HBV DNA (hepatitis B virus deoxyribonucleic acid).
    - Hep A IgM (immunoglobulin M antibody to hepatitis A).
    - IgM anti-HBc (immunoglobulin M antibody to hepatitis B core antigen).
    - total anti-HBc (immunoglobulin G and Immunoglobulin M antibodies to hepatitis B core antigen).
    - Total Bilirubin.
    - Other (specify the Test Name in the text box).
- This option should rarely need to be used, as the test name drop-down list has been customized for HBV. If you have any questions about which test name to select, click the *Equivalent Test Names* hyperlink or refer to Appendix A or the ODH Viral Hepatitis Program webpage.
- Acute, chronic, and perinatal HCV use the following Test Names:
    - ALT (alanine aminotransferase).
    - Anti-HCV (antibody to hepatitis C).
    - Anti-HDV (antibody to hepatitis D).
    - AST (aspartate aminotransferase).
    - HBsAg (hepatitis B surface antigen).
    - HCV RNA (hepatitis C virus deoxyribonucleic acid).
    - Hep A IgM (immunoglobulin M antibody to hepatitis A).
    - IgM anti-HBc (immunoglobulin M antibody to hepatitis B core antigen).
    - RIBA (recombinant immunoblot assay; this test is no longer available in the United States and should not selected).
    - Total Bilirubin.
    - Other (specify the Test Name in the text box).
- This option should rarely need to be used, as the test name drop-down list has been customized for HCV; if you have any questions about which test name to

select, click the Equivalent Test Names hyperlink or refer to Appendix A or the ODH Viral Hepatitis Program webpage.

- Test Method.
  - Report the type of assay used in this field (e.g., EIA, PCR, etc.).
  - Frequently not reported; if not reported, leave blank.
- Result.
  - Select the appropriate qualitative Result from the drop-down list; results vary according to the test selected.
    - For case definition purposes, Positive, Reactive, and Detected are equivalent results.
  - For anti-HCV, HBsAg, HBsAg confirmatory, or IgM anti-HBc, select one of the following results:
    - Positive.
    - Reactive.
    - Negative.
    - Indeterminate.
    - Invalidated. This field is not used during routine data entry; if needed, one of the ODH Epidemiologists will update this field.
    - Other. Should rarely be used; enter the Result in the Other text box; this field should not be used for numeric or quantitative results, only qualitative results.
    - Unknown.
  - For ALT, anti-HDV, AST, anti-HBs, anti-HDV, Hep A IgM, Other, Total anti-HBc, select one of the following results:
    - Positive.
    - Negative.
    - Indeterminate.
    - Invalidated. This field is not used during routine data entry; if needed, one of the ODH Epidemiologists will update this field.
    - Other. Should rarely be used; enter the Result in the Other text box; this field should not be used for numeric or quantitative results, only for qualitative results.
    - Unknown.
  - For HBV DNA or HCV RNA, select one of the following results:
    - Positive.
    - Detected.

- Negative.
- Indeterminate.
- Undetectable.
- Invalidated. This field is not used during routine data entry; if needed, one of the ODH Epidemiologists will update this field.
- Other. Should rarely be used; enter the Result in the Other text box; this field should not be used for numeric or quantitative results, only for qualitative results.
- Unknown.

▪ For anti-HBe or HBeAg, select one of the following:

- Positive.
- Negative.
- Indeterminate.
- Undetectable.
- Invalidated. This field is not used during routine data entry; if needed, one of the ODH Epidemiologists will update this field.
- Other. Should rarely be used; enter the Result in the Other text box; this field should not be used for numeric or quantitative results, only for qualitative results.
- Unknown.

o Numeric Result.

▪ Used for anti-HCV, HBV DNA, HCV RNA, and ALT tests to indicate numeric or quantitative results that may be needed to determine if the report meets the case definition.

▪ Enter the numeric result, as indicated below, when reported.

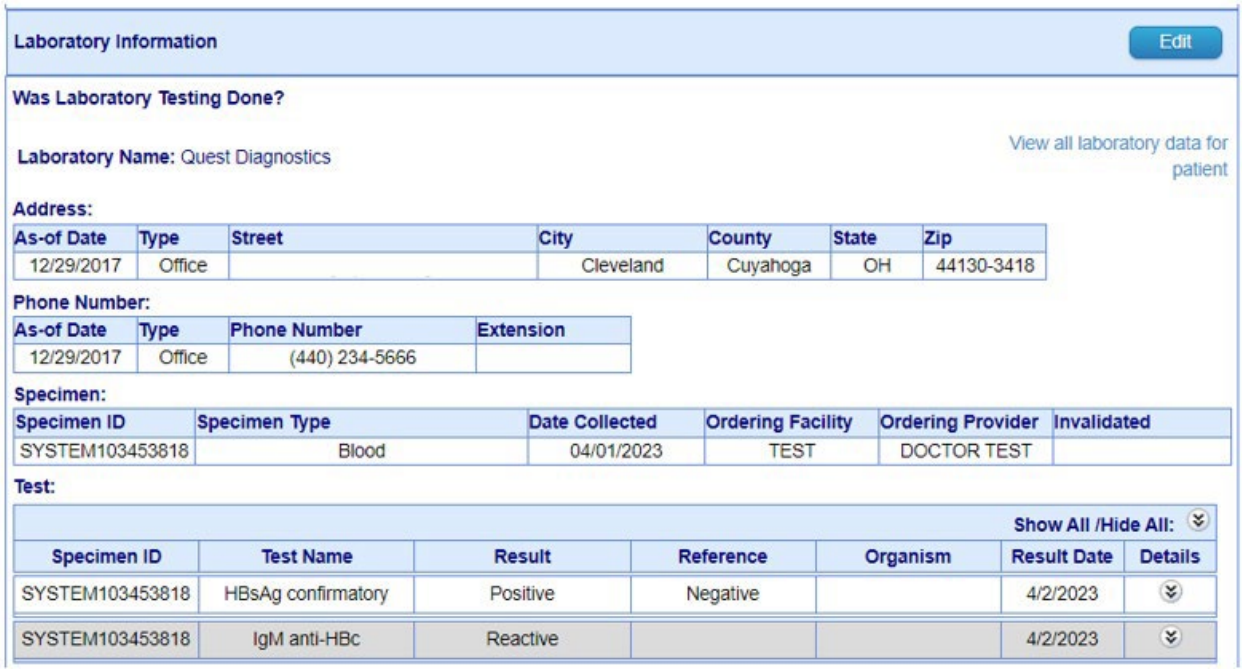
- HBV DNA. Has three types of numeric results.
  - XXXX IU/mL or copies/mL.
  - X.X log IU or log copies.
  - Genotype results – A, B, C, D, E, F, G, H, I, J.
- Anti-HCV.
  - 32.1 or >11.0.
  - The words, Signal to cutoff, sco, s/co, or other variations are not needed as they are self-evident from the test name of Anti-HCV.
- HCV RNA. Has three types of numeric results.
  - XXXXXXX IU/mL or copies/mL.

- X.X log IU or log copies.
- Genotype results - 1a, 1b, 2a, 2b, etc.

- ALT.
  - 405

- Once the Test section is saved by clicking *Done*, the Result and the Numeric Result will display together in the Result field in the Case Summary.

- Reference. Needed for numeric results to determine if they are elevated or meet case definition criteria.
- Result Date. Should be entered if reported.
- Organism. As neither the hepatitis tests nor the liver function tests (ALT or AST) identify organism, the organism field may be left blank.
- Earliest known positive HBsAg Test Date (for HBV only).
- Enter the date of the earliest known positive HBsAg test for the person.
- Anti-HCV signal to cut-off ratio.
- The anti-HCV signal to cut-off ratio should be entered in the Numeric Result field so that it is visible in the case summary screen; information entered in this field will not be visible in the case summary.
- Electronic Laboratory Reporting (ELR) Test Data.
- This section provides test information for test results that were received electronically.
- Click *Done* to save the Test information and return to the Laboratory edit screen.



Laboratory Information Edit

Was Laboratory Testing Done?

Laboratory Name: Quest Diagnostics

View all laboratory data for patient

Address:

As-of Date	Type	Street	City	County	State	Zip
12/29/2017	Office		Cleveland	Cuyahoga	OH	44130-3418

Phone Number:

As-of Date	Type	Phone Number	Extension
12/29/2017	Office	(440) 234-5666	

Specimen:

Specimen ID	Specimen Type	Date Collected	Ordering Facility	Ordering Provider	Invalidated
SYSTEM103453818	Blood	04/01/2023	TEST	DOCTOR TEST	

Test:

Show All /Hide All:

Specimen ID	Test Name	Result	Reference	Organism	Result Date	Details
SYSTEM103453818	HBsAg confirmatory	Positive	Negative		4/2/2023	
SYSTEM103453818	IgM anti-HBc	Reactive			4/2/2023	

- To move to the next module, Clinical Information, do one of the following:
    - Select *Laboratory* from the module menu and Click Go.
    - Click the *Next* button.
    - Select *Alt* + 3.

Clinical Information – the following fields should be entered as reported:

- Reportable Condition.
    - Populates with the condition selected at the beginning of data entry.
    - Review to ensure it is accurate and update as needed.
        - Please note that changing the reportable condition will result in the loss of some risk-behavior information in the Epidemiology Information module, as *acute* and *chronic* have different time periods for the risk; print case report before changing reportable condition so risk information can be re-entered.
- Date Reported to Ohio Dept of Health.
    - The date ODH first received notification.
    - Defaults to date of entry of the record in ODRS and should be updated by ODH staff as needed.
- Date Reported to Local Health Dept.
    - The date the LHD first received notification.
    - Defaults to date of entry of the record in ODRS and should be updated by LHD staff as needed.
- Date of Illness Onset.
    - If known, enter the date the patient became ill with HBV or HCV. This may be the day that symptoms were noted.
- Date of Diagnosis.
    - Enter the date the patient was diagnosed with HBV or HCV by a medical care provider.
- Diagnosing Provider.
    - Click *Add* to begin a search for the Ordering Provider
    - If the Diagnosing Provider is the same as the Ordering Provider, click *Select Ordering Provider for Newest Specimen* in the Provider Selection pop-up.
        - The Diagnosing Provider field will populate with the Ordering Provider, and you will return to the Clinical Information screen.
    - If the Diagnosing Provider is not the same as the Ordering Provider, search for the Diagnosing Provider by entering the provider's last name and first name and clicking *Search*.

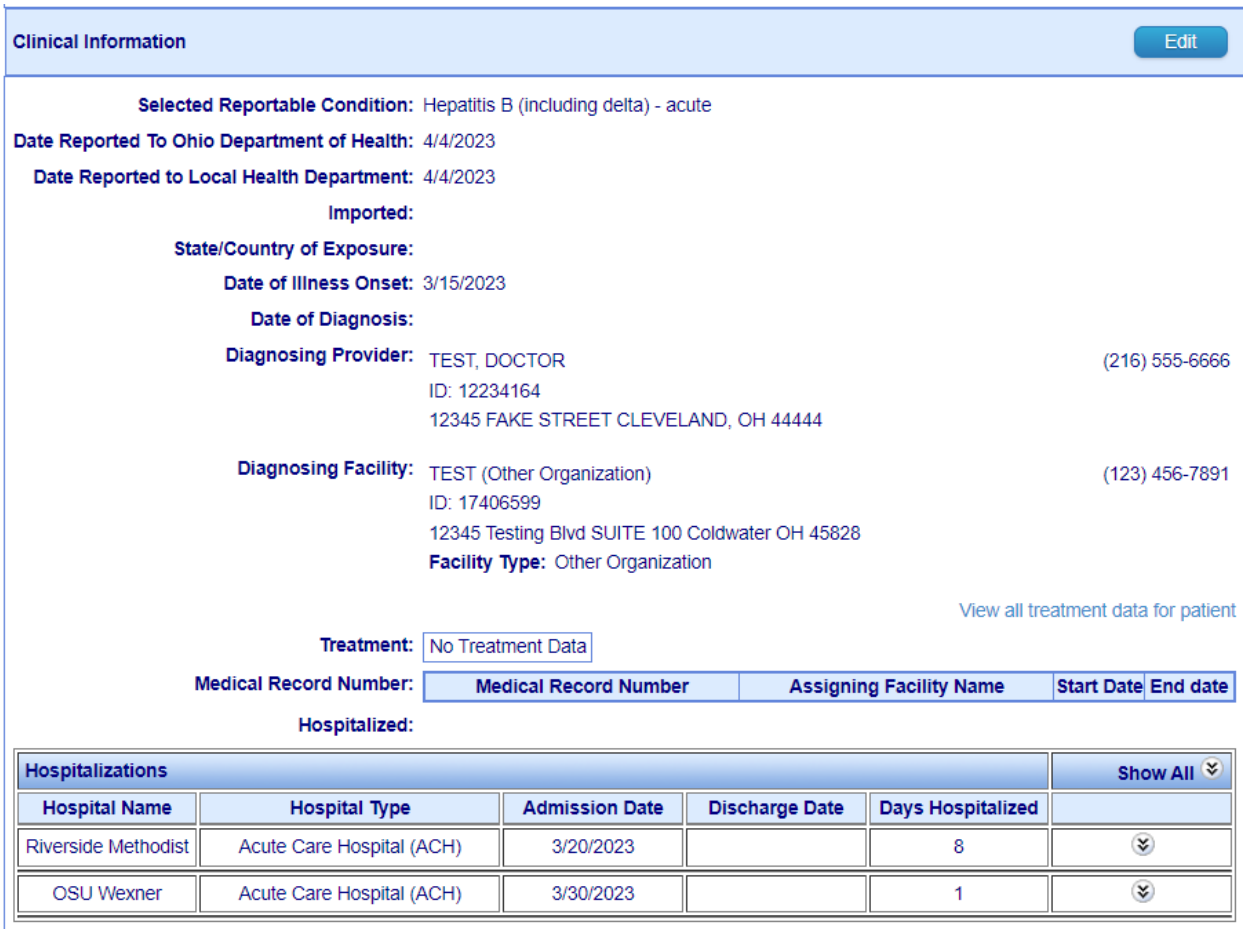
        - Other fields that can be searched include City, Telephone, and Code (ODRS Provider ID number).
    - Click *Select* to choose the appropriate Provider – the one with the most complete and accurate information, including address.
    - If the Diagnosing Provider is not found, click the *New* button to add the Provider to ODRS.
        - In the New Provider popup, enter the Provider information and click *Save*.
        - The Diagnosing Provider field will populate with Provider entered and you will return to the Clinical Information screen.
        - If the lab report does not have the complete address and phone number for the provider, the information can usually be found in an internet search.
    - Click *Cancel* to make no selection and return to the Clinical Information screen.
    - Click *Change* to edit or change the selected Diagnosing Provider.
- Diagnosing Facility.
    - Click *Add* to begin a search for the Diagnosing Facility.
    - If the Diagnosing Facility is the same as the Ordering Facility, Click *Select Ordering Facility for the Newest Specimen* in the Facility Selection popup.
        - The Diagnosing Facility field will populate with the Ordering Facility, and you will return to the Clinical Information Screen.
    - If the Diagnosing Facility is not the same as the Ordering Facility, search for the Diagnosing Facility by entering the Facility name and clicking *Search*.
        - Other fields that can be searched include Type, City, Telephone, and Code (ODRS Facility ID number).
    - Click *Select* to choose the appropriate Facility – the one with the most complete and accurate information, including address.
    - If the ordering facility is an out-of-state facility or it is not in ODRS, select OOJ (out of jurisdiction) for the facility name and create a note detailing the facility name and contact information.
        - If the Ordering Facility is one that will be used frequently, notify the ODRS administrator at ODRS@odh.ohio.gov to request its addition and be sure to include complete address and phone number information in the request.
        - The Ordering Facility, Diagnosing Facility, and Treatment Facility fields use the same Facility master list, so the addition of a facility only needs to be requested one time.
    - Click *Cancel* to make no selection and return to the Clinical Information screen.
    - Click *Change* to edit or change the selected Diagnosing Facility.

- Treatment.
    - Click *Add* to add a new Treatment, *Edit* to update an existing Treatment, or *Delete* to remove a Treatment.
    - Enter treatment, if reported, entering each medication separately.
    - Treatment Name – enter generic name of medication.
    - Dose – enter dose, selecting appropriate units from the drop down to the right.
    - Frequency – enter how often the medication was taken.
    - Duration – enter how long the medication was taken, selecting the appropriate units from the drop down to the right.
    - Start Date – enter the date (mm/dd/yyyy) the patient ingested the first dose; if unknown, check the box to the right.
    - End Date – enter the date (mm/dd/yyyy) the patient ingested the last dose; if unknown, check the box to the right.
    - Treatment Provider
        - This is the provider that prescribed treatment, which may differ from the ordering provider and the diagnosing provider.
        - Click *Add* to begin a search for the Treatment Provider.
        - In the Provider Selection popup, enter the Treatment Provider last name and first name and click *Search*.
            - Other fields that can be searched include City, Telephone, and Code (ODRS Provider ID number).
        - Click *Select* to choose the appropriate Provider – the one with the most complete and accurate information, including the correct address for providers with more than one office.
        - If the Treatment Provider is not found, click the *New* button to add the Provider to ODRS.
            - In the New Provider popup, enter the provider information, including complete address and phone number, and Click *Save* to save the information.
            - The Treatment Provider field will populate with Provider entered and you will return to the Clinical Information screen.
            - If the lab report does not have the complete address and phone number for the provider, the information can usually be found in an internet search.
        - Click *Cancel* to make no selection and return to the Clinical Information screen.

        - Click *Change* to edit or change the selected Treatment Provider.
    - Treatment Facility.
        - Click *Add* to begin a search for the Treatment Facility.
        - In the Facility Selection popup, enter the Facility name and click *Search*.
            - Other fields that can be searched include Type, City, Telephone, and Code (ODRS Facility ID number).
        - Click *Select* to choose the appropriate Facility – the one with the most complete and accurate information, including address.
        - If the Treatment Facility is an out-of-state facility and it is not in ODRS, select *OOJ* (out of jurisdiction) for the facility name and create a note detailing the facility name and contact information.
            - If the Treatment Facility is one that will be used frequently, notify the ODRS administrator at ODRS@odh.ohio.gov, to request its addition and be sure to include complete address and phone number information in the request.
            - The Ordering Facility, Diagnosing Facility, and Treatment Facility fields use the same Facility master list, so the addition of a facility only needs to be requested one time.
        - Click *Cancel* to make no selection and return to the Clinical Information screen.
        - Click *Change* to edit or change the selected Treatment Facility.
    - Click *Done* to save treatment information and return to the Clinical Information edit screen.
- Click *View all treatment data for patient* to view all reported treatment for the patient.
- Medical Record Number.
    - Click *Add* to add a new Medical Record Number, click *Edit* to update an existing Medical Record Number, or *Delete* to remove a Medical Record Number.
    - The Medical Record Number should also be added in the Alias section in the Person Demographics module.
    - Assigning Facility Name.
        - Needed to know which facility to contact.
    - Start Date.
        - Date Medical Record Number assigned; if admitted to Assigning Facility, date of admission.
    - End Date.
        - Discharge date.

- Click *Done* to save the Medical Record Number information and Return to the Clinical Information edit screen.

- Hospitalized.
- Was the patient hospitalized?
  - If Yes, enter the Facility Admit and Facility Discharge dates.
- Facility Admit Date (mm/dd/yyyy).
- Facility Discharge Date (mm/dd/yyyy).
- Days Hospitalized.
  - Enter the number of days the patient was hospitalized.
- Does Patient have drug allergies?
  - If Yes, enter the drugs to which the patient is allergic in the 'If yes, specify' text box.



Clinical Information Edit

Selected Reportable Condition: Hepatitis B (including delta) - acute
Date Reported To Ohio Department of Health: 4/4/2023
Date Reported to Local Health Department: 4/4/2023
Imported:
State/Country of Exposure:
Date of Illness Onset: 3/15/2023
Date of Diagnosis:
Diagnosing Provider: TEST, DOCTOR (216) 555-6666
ID: 12234164
12345 FAKE STREET CLEVELAND, OH 44444
Diagnosing Facility: TEST (Other Organization) (123) 456-7891
ID: 17406599
12345 Testing Blvd SUITE 100 Coldwater OH 45828
Facility Type: Other Organization

View all treatment data for patient

Treatment: No Treatment Data
Medical Record Number:

Medical Record Number	Assigning Facility Name	Start Date	End date

Hospitalized:

Hospitalizations Show All

Hospital Name	Hospital Type	Admission Date	Discharge Date	Days Hospitalized	
Riverside Methodist	Acute Care Hospital (ACH)	3/20/2023		8	
OSU Wexner	Acute Care Hospital (ACH)	3/30/2023		1	

- Does the patient have a provider of care for hepatitis?
- Has the patient received medication for the type of hepatitis being reported?

- Did the patient have a negative HBsAG (or HCV antibody) test within 6 months prior to positive test?
- Last known negative HBsAG (or HCV antibody) test (mm/dd/yyyy).
- Was the patient aware that they had viral hepatitis prior to lab testing?
- Does the patient have diabetes?
- Diabetes diagnosis date.
- Reasons for Testing (Check Multiple).
    - Select the reason or reasons the patient was tested for HBV or HCV; check all that apply.
        - Symptoms of Acute Hepatitis.
        - Screening of Asymptomatic Patient with Reported Risk Factors.
        - Evaluation of elevated liver enzymes.
        - Blood/organ donor screening.
        - Screening of asymptomatic patient with no risk factors.
        - Follow-up testing for previous marker of viral hepatitis.
        - Post Vaccine Serology.
        - Prenatal screening.
        - Other.
            - Specify the reason in the *Reason for Testing: Specify Other* text box, which will appear below Unknown.
        - Unknown.
- Is patient symptomatic?
    - Select the appropriate answer from the drop-down list.
    - Acute HBV must have symptoms to meet the acute case definition. However, if symptoms are known for HCV, it can be noted here.
    - If Yes, enter the Symptom Onset Date.
- Was the patient jaundiced?
    - If Yes, enter jaundice as of date.
- Was the patient Hospitalized for hepatitis?
    - This question is concerned with hospitalization specifically for hepatitis; the Hospitalized question above is concerned with hospitalization for any reason.
- Did the patient die from Hepatitis?
- Did Condition resolve?
    - For acute HBV only.
    - If Yes, enter the As of Date.
    - Do not change classification status to Resolved.

- To move to the next module, Epidemiology Information, do one of the following:
  - Select *Epidemiology* from the module menu and Click *Go*.
  - Click the *Next* button.
  - Select *Alt* + 3.

Administration

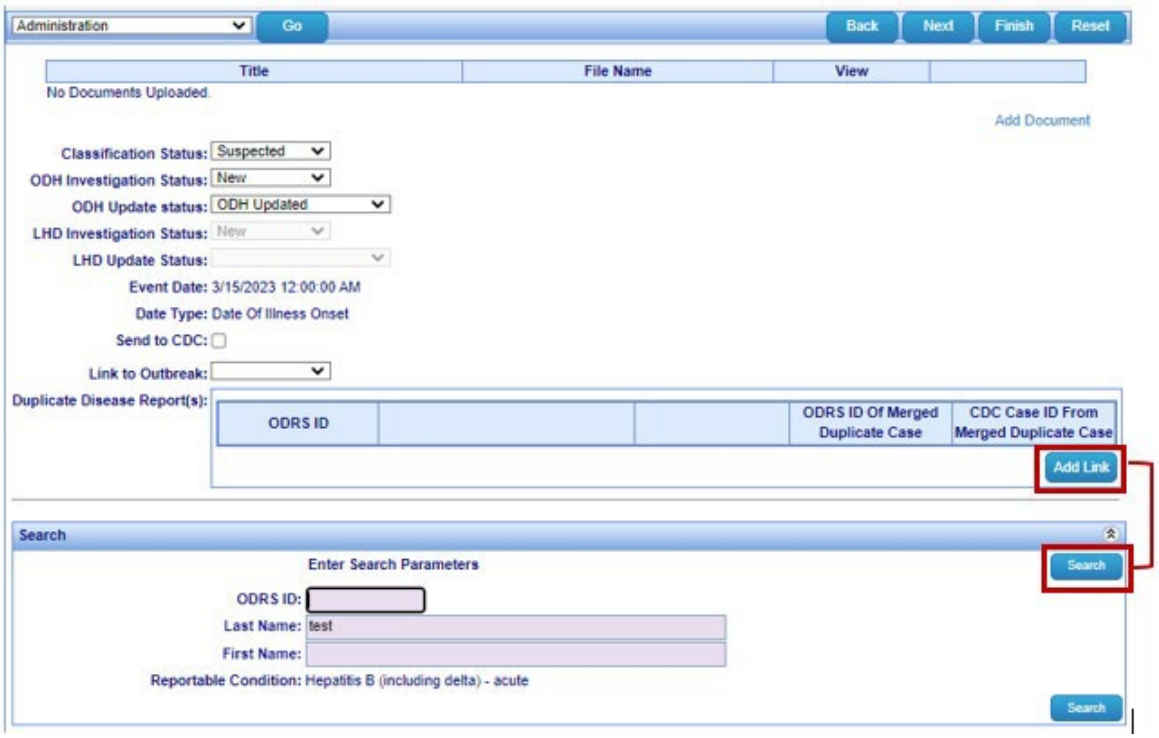
This module is usually not accessed during initial data entry but may be accessed to update information or upload documents.

- Documents Uploaded.
  - Laboratory results and other information that have fields in ODRS need to be entered in those fields and not uploaded in lieu of entry.
    - If information is uploaded rather than entered, it may delay or impede the determination of appropriate case status (e.g., Confirmed, Not a Case, etc.).

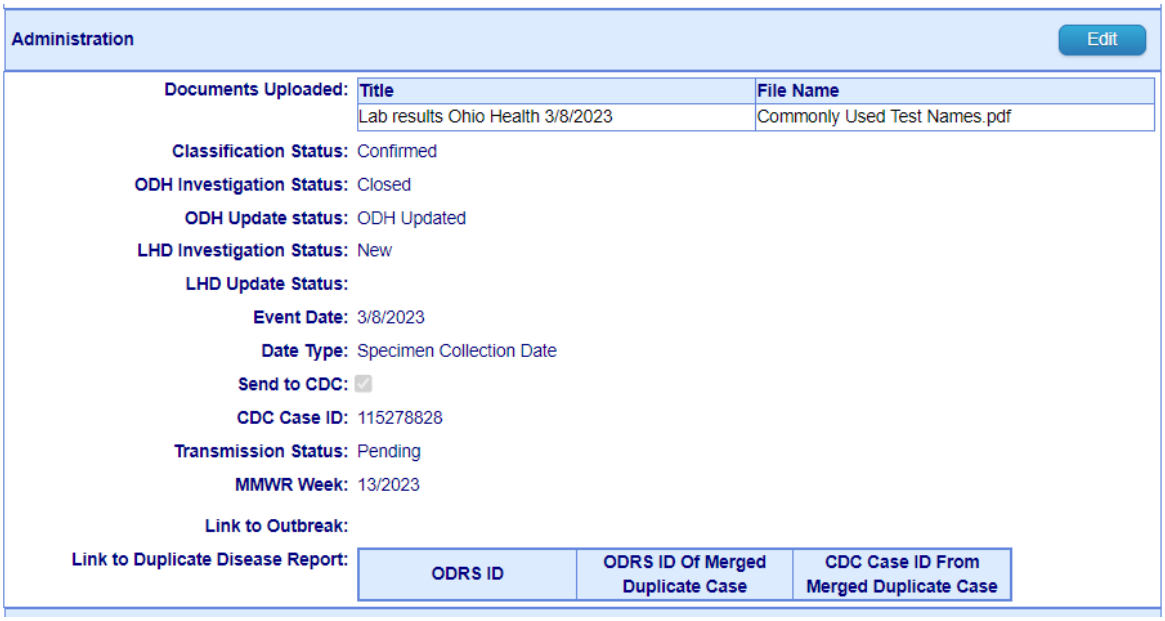
  - The document must be in electronic format.
  - Click *Add Document* to select a document to upload, click *Edit* to update an existing uploaded document, or click *Delete* to remove an uploaded document.
  - Enter a title for the document to display in ODRS.
  - Click *Browse* to search for the document to upload.
    - Select the document to upload.
  - Click *Save* to upload the document.
  - ODRS displays the document title, the file name, and the user who added the document to the record.
  - Click the *Document Icon* under View to review any uploaded documents.
- Classification Status.
  - Defaults to Suspected for newly entered records.
  - This field should accurately reflect the status as it relates to the case definition.
    - It may be updated as needed when certain new test results and other information are reported.
    - If someone later resolves the infection or is cured by treatment, the Classification Status should remain as it was when the case definition was met and not changed to Not a Case.
  - Change the status to Duplicate if the record is a duplicate of another record in ODRS.
    - Email the Viral Hepatitis Surveillance Program staff at Hepatitis@odh.ohio.gov along with ODRS case IDs for any cases that may need merged.
  - An HBV record that is checked Send to CDC should not have the status of Resolved.
- ODH Investigation Status.
  - This field defaults to New for newly created records.
  - This field is for use by ODH staff only; certain changes to the record by local health department staff or addition of new ELR results will cause this field to change to New.
  - ODH staff will change this field to Closed once Classification Status is determined.
    - This does not affect LHD staff ability to keep the record open for their follow-up (see LHD Investigation Status below).
- ODH Update Status.
  - This field is for use by ODH staff only.
  - LHD staff may create a queue to monitor this field to see when ODH staff have either updated (e.g., checked Send to CDC, merged duplicate records, etc.) or reviewed the record.
- LHD Investigation Status.
  - This field defaults to New for newly created records.

  - This field is for use by LHD staff only; select ODH staff can update this field; certain changes to the record by ODH staff or addition of new ELR results will also cause this field to change to New.
  - LHD staff can use this field in queues to assist with managing hepatitis records.
  - "Open" can be used to distinguish new records from records that have been reviewed and are being followed up on to obtain additional information (e.g., symptoms, risk, etc.).
  - "Closed" is used to indicate that the LHD has ended all follow-up activities.
- LHD Update Status.
  - This field automatically changes to LHD Updated when LHD staff update the record. LHD staff can also manually change this field to LHD Reviewed and use this field in queues.
  - ODH staff use this field to review records that LHD staff have updated.
- Event Date.
  - A read-only field that is calculated from the earliest of the following dates:
    - Date of Illness Onset.
    - Date of Diagnosis.
    - Specimen Collection Date.
    - Date Reported to Local Health Department.
    - Date Reported to Ohio Department of Health.
- Date Type.
  - A read-only field that indicates which date was used to populate Event Date.
- Send to CDC.
  - Access to this field is limited to ODH staff.
  - When checked, indicates the record meets the case definition and will be sent to CDC as a case.
  - Also indicates the record is included in morbidity statistics.
  - Send to CDC, along with Morbidity and Mortality Weekly Report (MMWR) Week and Year should be used when extracting HBV and HCV case data from ODRS for analysis.
    - In queries, use Send to CDC is equal to (or contains) "True" to select cases meeting the case definition; use "False" to select records not meeting the case definition.
- CDC Case ID.
  - Number automatically assigned to the record when the field Send to CDC is checked.
  - If the record is unchecked Send to CDC, the CDC Case ID is retained by ODRS.
- Transmission Status.

  - Name changes to CDC Submission Status when the Administration module is opened for editing.
  - Defaults to Pending when Send to CDC is initially checked; when the next CDC submission occurs, the status changes to Sent.
  - If an update is made to any field in a case that has already been submitted to CDC, the status changes to Resend Pending; when the next CDC submission occurs, the status changes back to Sent.
  - If Send to CDC is unchecked, the status changes to Retracted.
- MMWR (Morbidity and Mortality Weekly Report) Week.
  - Indicates the MMWR Week and Year the record was checked Send to CDC.
  - If the record is unchecked Send to CDC, then rechecked, the initial MMWR Week and Year are retained.
  - If the record is unchecked Send to CDC, the MMWR Week and Year is retained by ODRS; therefore, MMWR Year must be used in conjunction with Send to CDC checked (True) to pull cases for analysis.
- Link to Outbreak.
  - Select the Outbreak number from the drop-down list.
- Duplicate Disease Report(s).
  - This section is used to link and merge duplicate disease or reports.
  - Click *Add Link* to link the current record (record that is open) with a duplicate disease report.
  - A search screen opens where the user can enter the ODRS ID number of the duplicate report (if known) or search by the First and Last Name of the person.
    - This search selects records with the same reportable condition; to link an acute and chronic record, you must first change the reportable condition of one record so that both records have the same condition.
  - Click *View* to review the record(s) returned by the search to make sure the correct duplicate record is selected to link.
  - Click *Select* to select a duplicate record to link to the open record.
    - The search results will collapse and the ODRS ID of the record selected will display under ODRS ID.
  - Click *View* to open the linked record for viewing in a pop-up window.
  - Click *Edit* to close the current record and open the linked record for editing.
  - Click *Remove Link* to remove the linkage between the two records.
  - Only ODH staff can merge linked duplicate case reports.



- Email the Viral Hepatitis Surveillance Program staff at Hepatitis@odh.ohio.gov along with ODRS case IDs for any cases that may need merged.
- Once the duplicate is merged with the index case the ODRS ID number of the index case displays under ODRS ID and the ODRS ID number of the duplicate case displays under ODRS ID of Merged Duplicate Case.
- If the Duplicate Case record was sent to CDC as a case prior to merging, the CDC Case ID number will display under CDC Case ID from Merged Duplicate Case.



Epidemiology Information

The Epidemiology Information module collects information concerning the patient's risk for disease, so the questions vary depending on whether the patient has HBV or HCV and whether the disease is acute or chronic.

Epidemiology Information - Acute HBV

- Select the appropriate answer from the drop-down list, enter the number requested, or enter the date requested for the following risk behavior questions for persons reported with acute HBV:
    - Was the Patient EVER treated for a sexually transmitted Disease?
        - If the user has access to STD records in ODRS, this field can be answered if there is a positive STD case prior to the HBV positive test.
    - Year of Most Recent Treatment.

    IN THE 6 MONTHS BEFORE SYMPTOM ONSET
    - Ask both of the following questions regardless of the Patient's Gender:
        - How many Male Sex Partners did the Person have?
        - How many Female Sex Partners did the Person have?

    DURING THE 6 WEEKS - 6 MONTHS PRIOR TO ONSET OF SYMPTOMS
    - Was the Patient a contact of a Person with Confirmed or Suspected Acute or Chronic Hepatitis B Virus Infection?
        - If Yes, enter:
            - Type of Contact: Sexual.
            - Type of Contact: Household [Non-sexual].
            - Type of Contact: Other.
                - If Yes, Specify Other Contact in text field.
    - Did the Patient use Street Drugs but not inject?
    - Did the Patient Inject Drugs not prescribed by a doctor?
    - Did the Patient undergo Hemodialysis?
    - Did the Patient have an Accidental Stick or Puncture with a needle or other object Contaminated with Blood?
    - Did the Patient receive Blood or Blood Products [Transfusion]?
        - If Yes, enter Date of Transfusion in date field.
    - Did the Patient have Other Exposure to someone else's Blood?
        - If Yes, Specify Other Exposure in text field.
    - Was the Patient Employed in a Medical or Dental field involving direct contact with Human Blood?

        - If Yes, select Frequency of Direct Blood Contact in Medical Field from the drop-down list.
    - Was the Patient Employed as a Public Safety Worker (Fire Fighter, Law Enforcement, or Correctional Officer) having direct contact with Human Blood?
        - If Yes, select Frequency of Direct Blood Contact as a Public Safety Worker from the drop-down list.
    - Did the Patient Receive a Tattoo?
        - If Yes, check Where was the Tattooing Performed?
            - Check all that apply.
            - If Other checked, Specify other in the text field.
    - Did the Patient have any part of their body pierced (other than ear)?
        - If Yes, check Where was the Piercing Performed?
            - Check all that apply.
            - If Other checked, Specify other in the text field.
    - Did the Patient have Dental Work or Oral Surgery?
    - Did the Patient have Surgery (Other than Oral Surgery)?
    - Was the Patient Hospitalized?
    - Was the Patient a Resident of Long-Term Care Facility?
    - Was the Patient Incarcerated for longer than 24 hours?
        - If Yes, check the Type of Facility.
            - Jail.
            - Prison.
            - Juvenile.

    <u>EVER INCARCERATED</u>

    - During his/her lifetime, was the Patient EVER incarcerated for longer than six months?
        - If Yes, enter:
        - Year of most recent incarceration (YYYY).
        - Length of most recent incarceration in Months.

Epidemiology Information – Chronic HBV

- Select the appropriate answer from the drop-down list or enter the number requested for the following risk behavior questions for person reported with chronic HBV.
    - Was the Patient ever on Long Term Hemodialysis?
    - Has the Patient ever injected drugs not prescribed by a doctor even if only once or a few times?
    - How many Sex Partners has Patient had (Approximate Lifetime)?

- Was the Patient ever incarcerated?
- Was the Patient EVER treated for a Sexually Transmitted Disease (STD)?
- Was the Patient ever a Contact of a Person who had Hepatitis?
  - If Yes, enter:
    - Type of Contact: Sexual.
    - Type of Contact: Household [Non-sexual].
    - Type of Contact: Other.
      - If Yes, Specify Other Contact in text field.

- Was the Patient ever employed in a Medical or Dental Field involving direct contact with Human Blood?

Epidemiology Information – Acute HCV

- Select the appropriate answer from the drop-down list, enter the number requested, or enter the date requested for the following risk behavior questions for persons reported with acute HCV.
  - Was the Patient EVER treated for a Sexually Transmitted Disease (STD)?
    - If the user has access to STD records in ODRS, this field can be answered if there is a positive STD case prior to the HBV positive test.
  - Year of Most Recent Treatment (YYYY).

<u>IN THE 6 MONTHS BEFORE SYMPTOM ONSET.</u>

- Ask both of the following questions regardless of the Patient's Gender:
  - How many Male Sex Partners did the Person have?
  - How many Female Sex Partners did the Person have?

<u>DURING THE 2 WEEKS – 6 MONTHS PRIOR TO ONSET OF SYMPTOMS</u>

- Was the Patient a contact of a Person with Confirmed or Suspected Acute or Chronic Hepatitis C Virus Infection?
- Type of Contact: Sexual.
- Type of Contact: Household [Non-Sexual].
- Type of Contact: Other.
  - If Yes, Specify Other Contact in text field.
- Did the Patient use Street Drugs but not inject?
- Did the Patient Inject Drugs not prescribed by a doctor?
- Did the Patient undergo Hemodialysis?
- Did the Patient have an Accidental Stick or Puncture with a needle or other object Contaminated with Blood?
- Did the Patient receive Blood or Blood Products [Transfusion]?

        - If Yes, enter Date of Transfusion (mm/dd/yyyy).
    - Did the Patient have Other Exposure to someone else's Blood?
        - If Yes, Specify Other Exposure in text field.
    - Was the Patient Employed in a Medical or Dental field involving direct contact with Human Blood?
        - If Yes, indicate the Frequency of Direct Blood Contact in Medical Field by selecting the appropriate response from the drop-down list.
    - Was the Patient Employed as a Public Safety Worker (Fire Fighter, Law Enforcement, or Correctional Officer) having direct contact with Human Blood?
        - If Yes, indicate the Frequency of Direct Blood Contact as a Public Safety Worker by selecting the appropriate response from the drop-down list.
    - Did the Patient Receive a Tattoo?
        - If Yes, check Where was the Tattooing Performed?
            - Check all that apply.
            - If Other checked, Specify other in the text field.
    - Did the Patient have any part of their body pierced (other than ear)?
        - If Yes, check Where was the Piercing performed?
            - Check all that apply.
            - If Other checked, Specify other in the text field.
    - Did the Patient have Dental Work or Oral Surgery?
    - Did the Patient have Surgery? (Other than Oral Surgery)
    - Was the Patient Hospitalized?
    - Was the Patient a Resident of Long-Term Care Facility?
    - Was the Patient Incarcerated for longer than 24 hours?
        - If Yes, check the Type of Facility.
        - Check all that apply.

EVER INCARCERATED

- During his/her lifetime, was the Patient EVER incarcerated for longer than 6 months?
    - If Yes, enter:
        - Year of most recent incarceration (YYYY).
        - Length of most recent Incarceration in Months.

Epidemiology Information – Chronic HCV

- Select the appropriate answer from the drop-down list or enter the appropriate number for the following risk behavior questions for persons reported with chronic HCV:
    - Did the Patient receive a Blood Transfusion prior to 1992?

- Did the Patient receive an Organ Transplant prior to 1992?
- Did the Patient receive Clotting Factor Concentrates produced prior to 1987?
- Was the Patient ever on Long Term Hemodialysis?
- Has the Patient ever injected drugs not prescribed by a doctor even if only once or a few times?
- How many Sex Partners has Patient had (Approximate Lifetime)?
- Was the Patient ever incarcerated?
- Was the Patient EVER treated for a Sexually transmitted Disease (STD)?
- Was the Patient ever a Contact of a Person who had Hepatitis?
    - If Yes, enter:
        - Type of Contact: Sexual.
        - Type of Contact: Household [Non-sexual].
        - Type of Contact: Other.
            - If Yes, Specify Other Contact in text field.
- Was the Patient ever employed in a Medical or Dental Field involving direct contact with Human Blood?

- To move to the next module, Vaccination History, do one of the following:
    - Select *Contacts* from the module menu and Click *Go*.
    - Click the *Next* button.
    - Select *Alt* + 3.

Epidemiology Information Edit

Was the Patient EVER treated for a Sexually-transmitted Disease?	Yes
Year of Most Recent Treatment	2015

IN THE 6 MONTHS BEFORE SYMPTOM ONSET

Ask both of the following questions regardless of the Patient's Gender:	
How many Male Sex Partners did the Person have?	One
How many Female Sex Partners did the Person have?	

DURING THE 2 WEEKS - 6 MONTHS PRIOR TO ONSET OF SYMPTOMS

Was the Patient a contact of a Person with Confirmed or Suspected Acute or Chronic Hepatitis C Virus Infection?	Unknown
Type of Contact: Sexual	
Type of Contact: Household [Non-Sexual]	Unknown
Type of Contact: Other	
Specify Other Contact	
Did the Patient use Street Drugs but not inject?	Yes
Did the Patient Inject Drugs not prescribed by a doctor?	No
Did the Patient undergo Hemodialysis?	No
Did the Patient have an Accidental Stick or Puncture with a needle or other object Contaminated with Blood?	No
Did the Patient receive Blood or Blood Products [Transfusion]?	No
Date of Transfusion	
Did the Patient have Other Exposure to someone else's Blood?	No
Specify Other Exposure	
Was the Patient Employed in a Medical or Dental field involving direct contact with Human Blood?	No
Frequency of Direct Blood Contact in Medical Field:	
Was the Patient Employed as a Public Safety Worker (Fire Fighter, Law Enforcement, or Correctional Officer) having direct contact with Human Blood?	No
Frequency of Direct Blood Contact as a Public Safety Worker:	
Did the Patient Receive a Tattoo?	No
Where was the Tattooing Performed?	☐ Commercial parlor/shop
	☐ Correctional facility
	☐ Other
Specify other	
Did the Patient have any part of their body pierced (other than ear)?	No
Where was the Piercing performed?	☐ Commercial parlor/shop

Did the Patient have Dental Work or Oral Surgery?	
Did the Patient have Surgery? (Other than Oral Surgery)	
Was the Patient Hospitalized?	
Was the Patient a Resident of Long Term Care Facility?	
Was the Patient Incarcerated for longer than 24 hours?	
Type of Facility	☐ Jail
	☐ Prison
	☐ Juvenile

EVER INCARCERATED

During his/her lifetime, was the Patient EVER Incarcerated for longer than 6 months?	
Year of most recent Incarceration	
Length of most recent Incarceration in Months	

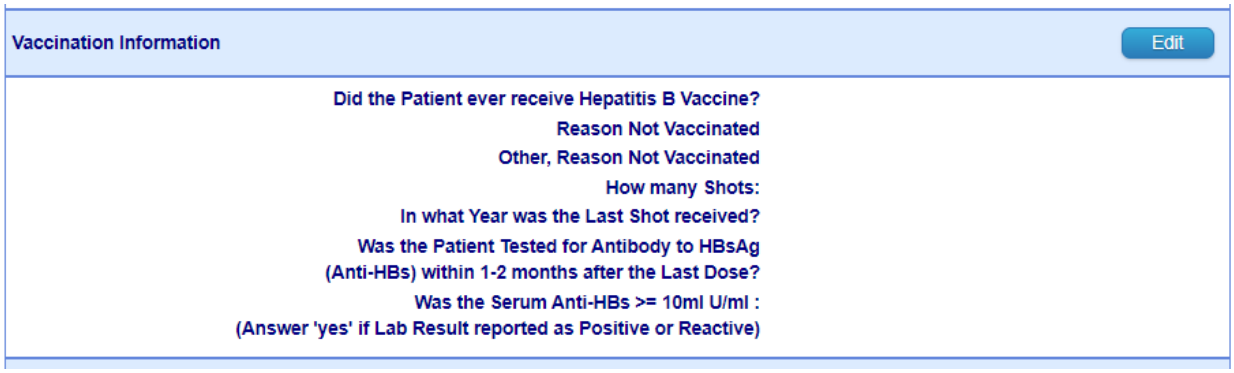
Vaccination History

This section is for persons with acute HBV or chronic HBV.

- Did the Patient ever receive Hepatitis B Vaccine?
    - If Yes, enter:
        - How many Shots – select correct number from drop down list.
        - In what Year was the Last Shot received? (YYYY).
        - Was the Patient Tested for Antibody to HBsAg (Anti-HBs) within 1-2 months after the Last Dose?
        - Was the Serum Anti-HBs >=10ml U/ml (Answer 'yes' if Lab Result reported as Positive or Reactive).
    - If No, select Reason Not Vaccinated:
        - Religious Exemption.
        - Medical Contraindication.
        - Philosophical Objection.
        - Lab Evidence of Previous Disease.
        - Physician Diagnosis of Previous Disease.
        - Underage for Vaccination.
        - Parental Refusal.
        - Other (specify Reason Not Vaccinated in the text box).
        - Unknown.
- Click *Add* to add information about the vaccination.
    - Vaccination Date (mm/dd/yyyy) If date unknown, enter 01/01/YYYY.
        - If a vaccination date is entered, enter the vaccination time, if known.
            - Military Time: (HH:MM:SS)
        - Vaccination Type.
            - Comvax.
            - Engerix-B.
            - HBIG.
            - Pediarix.
            - Recombivax HB.
            - Twinrix.
            - Other (specify Vaccination Type in the text box).
            - Unknown.
        - Vaccine Manufacturer.
            - GlaxoSmithKine.

- Merck.
- Talecris.
- Other (specify Vaccine Manufacturer in the text box).

- Vaccine Lot Number.
- Dose Number.
- Facility Administering Vaccine.
  - Text Box, 50-character limit.



- To move to the next module, Pregnancy Information (for females only), do one of the following:
- Select *Pregnancy* Information from the module menu and Click Go.
- Click the *Next* Button.
- Select *Alt* + 3

Pregnancy Information

To be completed for females 10-50 years of age reported with acute HBV or chronic HBV. Current pregnancy status is needed for all females, 10-50 years of age, with test results indicating continuing HBV infection. **Contact the Hepatitis B Perinatal program for assistance with HBV pregnancies at ORBIT@odh.ohio.gov or (614) 995-5599.**

- Click *Remove* to delete existing pregnancy information.
- Click *Edit* Record to edit existing pregnancy information.
- Click *Add* New Pregnancy to add pregnancy information.
- A select box, Existing Pregnancies, will display with pregnancy information entered in Person Demographics; click *Select* to select the pregnancy to update.
  - Prenatal Notification.
  - Reporting Source.
    - Family.

        - Hospital.
        - Immunization Registry.
        - Impact SIIS.
        - Lab.
        - Pediatrician.
        - Prenatal Provider.
        - Vital Statistics.
        - Other.
    - Date Identified (mm/dd/yyyy).
    - Date LHD Started Investigation (mm/dd/yyyy).
    - Is the Mother HBsAg Positive?
    - When was the Mother Confirmed HBsAg Positive?
        - Prior to delivery.
        - At the time of delivery.
        - After delivery.
    - Date of HBsAg Positive Test Result (mm/dd/yyyy)?
    - Expected Delivery Date.
        - Will populate with date entered in Person Demographics.
    - Pregnancy Number.
    - Birth Order.
    - Insurance Type.
        - Public.
        - Private.
        - Uninsured.
        - Status.
        - Active follow-up.
        - Active follow-up transferred from another state.
        - Closed by false positive/resolved mom.
        - Closed by Infant Completion.
        - Closed by Infant Death.
        - Closed by miscarriage/termination.
        - Closed by noncompliance.
        - Closed by other.
        - Lost to follow-up.
        - Moved out of Country.
        - Moved out of State.

- Closed by contact completion.
- Closed by contact death.
- Closed by provider refusal.
- Closed by contact refusal.

- Delivered.
  - If Yes, the search screen Search Infant will appear.
  - Enter ODRS ID, Last Name, First Name, Guardian Last Name, Guardian First Name, or Date of Birth to search for an existing infant record.
    - Select the appropriate infant from the search results.
    - If no results are returned or the needed infant is not listed, click New to create a new infant record in ODRS and enter as much of the demographic information that is known.

Prenatal Care Information

- Prenatal Facility.
  - Click *Add* to begin a search for the Prenatal Facility.
  - Search for the Prenatal Facility by entering the facility name and clicking *Search*.
    - Other fields that can be searched include Type, City, Telephone, and Code (ODRS Facility ID number).
  - Click *Select* to choose the appropriate facility – the one with the most complete and accurate information, including address.
  - If the Prenatal Facility is an out-of-state facility or it is not in ODRS, select *OOJ* (out of jurisdiction) for the facility name and create a note detailing the facility name and contact information.
    - If the Prenatal Facility is one that will be used frequently, notify the ODRS administrator at ODRS@odh.ohio.gov, to request its addition and be sure to include complete address and phone number information in the request.
    - The Prenatal Facility, Ordering Facility, Diagnosing Facility, and Treatment Facility fields use the same facility master list, so the addition of a facility only needs to be requested one time.
  - Click *Cancel* to make no selection and return to the Pregnancy screen.
  - Click *Change* to edit or change the selected Prenatal Facility.
- Prenatal Provider
  - Click *Add* to begin a search for the Prenatal Provider.

- Search for the Prenatal Provider by entering the provider's last name and first name and clicking *Search*.
  - Other fields that can be searched include City, Telephone, and Code (ODRS Provider ID number).
- Click *Select* to choose the appropriate Provider – the one with the most complete and accurate information, including address.
- If the Prenatal Provider is not found, click the New button to add the Provider to ODRS.
  - In the New Provider popup, enter the Provider information and click *Save*.
  - The Prenatal Provider field will populate with Provider entered and you will return to the Pregnancy Information screen.
  - If the complete address and phone number are not available for the provider, the information can usually be found in an internet search.
- Click *Cancel* to make no selection and return to the Pregnancy Information screen.
- Click *Change* to edit or change the selected Prenatal Provider.

o Provider Contact (text box).
- Enter the name of the primary contact person for the provider's office.

o Prenatal Chart Number (text box).
- Enter the prenatal chart number given by the provider.

<u>Delivery Hospital Information</u>

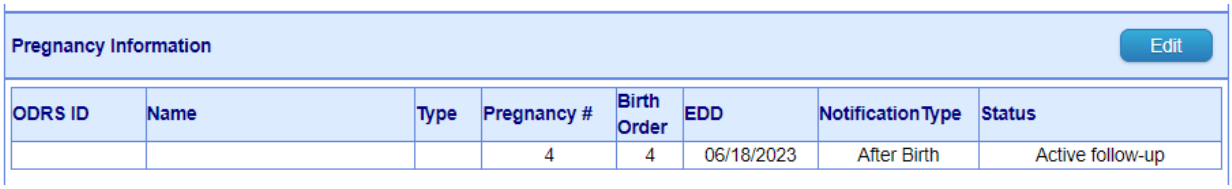
o Delivery Facility.
- Click *Add* to begin a search for the Delivery Facility.
- Search for the Delivery Facility by entering the facility name and clicking *Search*.
  - Other fields that can be searched include Type, City, Telephone, and Code (ODRS Facility ID number).
- Click *Select* to choose the appropriate facility – the one with the most complete and accurate information, including address.
- If the Delivery Facility is an out-of-state facility or it is not in ODRS, select *OOJ* (out of jurisdiction) for the facility name and create a note detailing the facility name and contact information.
  - If the Delivery Facility is one that will be used frequently, notify the ODRS administrator at ODRS@odh.ohio.gov, to request its addition

and be sure to include complete address and phone number information in the request.

- The Delivery Facility, Prenatal Facility, Ordering Facility, Diagnosing Facility, and Treatment Facility fields use the same facility master list, so the addition of a facility only needs to be requested one time.

- Click *Cancel* to make no selection and return to the Pregnancy screen.
- Click *Change* to edit or change the selected Delivery Facility.

- Nursery Contact (text box).
  - Enter the name of the primary contact person for the Delivery Facility.
- Nursery Phone (XXX) XXX-XXXX.
  - Enter the phone number of the primary contact person for the Delivery Facility.



HepB Letters

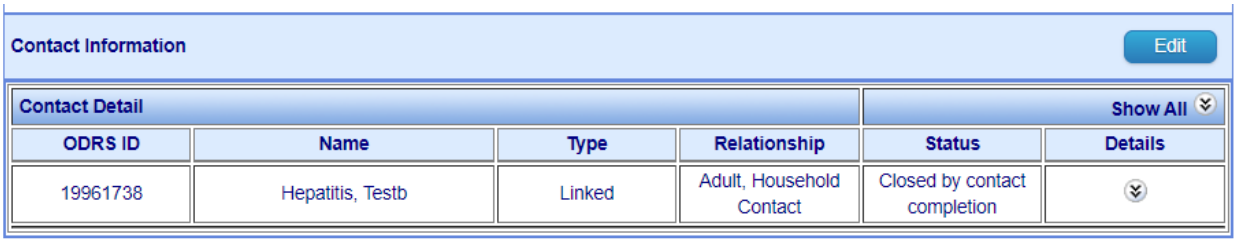
To be completed for pregnant females with acute HBV or chronic HBV to select follow-up letters to print. For more information, please contact the ODH Perinatal Hepatitis B Coordinator at ORBIT@odh.ohio.gov or (614) 995-5599.

Contact Information.

- Click *Add New Contact* to begin a search for the contact.
  - As in the search for the index case, search by the first three to four letters of the contact's First Name and Last Name.
    - Also search for name variations, such as Nicholas/Nick or Alexandra/Alex.
  - If no match is found searching by Name, search by the Date of Birth, if reported, from mm/dd/yyyy to mm/dd/yyyy.
  - Other fields that can be used to search are Age, Address, and Phone Number.
- If a match is found, click *Select Person* to import the information into the contact record.
  - Review the information imported and update as needed, including entry of missing information, following the direction below for New contact.
  - Click *Save Contact* to save the contact information.
- If no match if found, click *New* to enter a new contact.

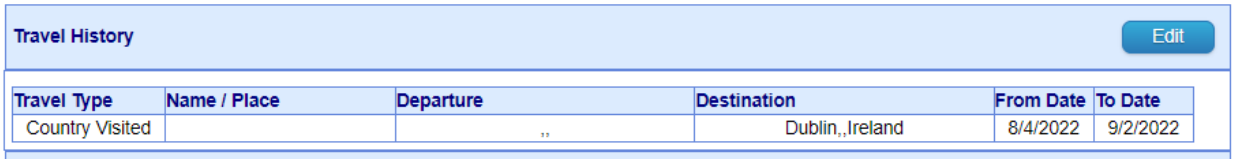
- Last Name.
  - If unknown, check box for *Last Name Unknown*.
- First Name.
  - If unknown, check box for *First Name Unknown*.
- Middle Name (or Initial).
- Suffix.
- Sex.
  - Sex at birth, not current gender.
- Date of Birth.
  - mm/dd/yyyy.
  - Age at Event will calculate automatically following entry of the date of birth.
  - If date of birth is unknown, but age was reported, enter the age.
    - Age type will default to years, update as needed.
- Ethnicity.
- Address.
  - If the contact resides with the index case, click the *Same Address as Index* button and the address fields will populate with the index case address information.
  - To enter a different address, click *Add*.
    - Follow the instructions for adding a new address.
- Phone Number.
  - To enter a phone number, click *Add*.
  - Follow the instructions for adding a new phone number.
- Alias.
  - To enter an alias, click *Add*.
  - Follow the instructions for adding a new alias.
- Race.
  - Check all that apply.
  - If race is not reported, check *Unknown*.
- Relationship to Patient.
  - Select the relationship from the drop-down list.
  - If Other selected, specify the type of relationship in the text box.
- Transmission Setting.
  - Home.
  - Work.
  - Day Care.

        - School.
        - College.
        - Doctor Office.
        - Hospital.
        - Travel.
        - Military.
        - Correctional Facility.
        - Place of Worship.
        - Restaurant.
        - Other
        - Unknown
    - Contact Ill.
        - If Yes, enter the Date Illness Began (mm/dd/yyyy).
    - Status of Contact.
        - Active follow-up.
        - Active follow-up transferred from another state.
        - Closed by contact completion.
        - Closed by contact death.
        - Closed by contact refusal.
        - Closed by false positive/resolved.
        - Closed by noncompliance.
        - Closed by other.
        - Closed by provider refusal.
        - Lost to follow-up.
        - Moved out of country.
        - Moved out of state.
    - Date entered (mm/dd/yyyy).
    - Vaccination Status for This Condition (*Acute HBV and Chronic HBV only*).
- To save the contact record, click *Save Contact*.



Travel History

This section is used to record travel history for patients where knowledge of recent travel history is needed for disease control. Entry of information in this section is optional.

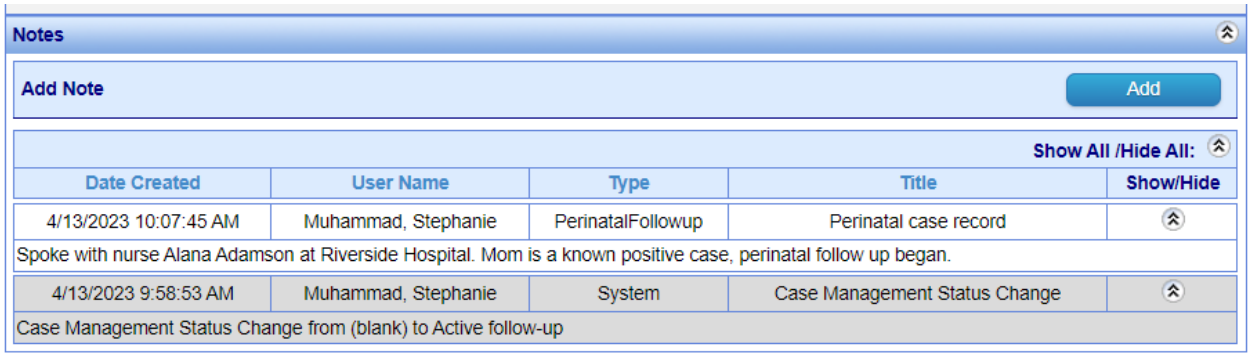


Saving the Record

- To save the record, do one of the following:
  - Click the *Finish* button.
  - Select *Alt* + 4.

Notes

There are two types of notes in ODRS. Auto generated by ODRS are notes that are created when certain actions occur or are taken by users. Examples include changing jurisdiction, changing classification status, and when new electronic laboratory reporting (ELR) results are added. ODRS users can also create notes. ODRS is a disease reporting system, so only notes that pertain to the case, case status, or investigation should be added. ODRS should not be treated as a medical record for the patient.



Additional ODRS Shortcuts.

Within case record (opened for editing).

TAB – to move forward to the next field.

Shift + Tab – to move backward to the previous field.

From Case Summary Screen.

Alt + 1 - Back to Queues.

Alt + 2 - Print.

Alt + 3 - Print without Notes.

Alt + 4 - New Reportable Condition.

Alt + 5 - Return to Results.

Alt + 6 - New Search.

Appendix A

Hepatitis B Test Names

Test Name	ODRS Test Name
Hep Be Ab	Anti-HBe
Hep Be antibody	Anti-HBe
Hepatitis B surface Abs	Anti-HBs
Surface Ab	Anti-HBs
Hep Be antigen	HBeAg
Hep B Surf Ag QL	HBeAg
Hepatitis B AG	HBeAg
Surface antigen	HBeAg
HBsAg confirmatory	HBeAg confirmatory
dHBV	HBV DNA
HBV NAT	HBV DNA
HBV Nucleic Acid Test	HBV DNA
HBV PCR	HBV DNA
Ab IgM	IgM anti-HBc
HBc Ab IgM	IgM anti-HBc
Hep B Core IgM	IgM anti-HBc
IgM Ab core	IgM anti-HBc
Hep B core Ab	Total anti-HBc
Hep B total core	Total anti-HBc
Total Ab, total anitbodies	Total anti-HBc

Hepatitis C Test Names

Test Name	ODRS Test Name
Chemiluminescence	Anti-HCV
CIA	Anti-HCV
EIA	Anti-HCV
Elisa	Anti-HCV
HCV Ab	Anti-HCV
HCV antibody	Anti-HCV
HCV EIA	Anti-HCV
Hep C Virus Ab	Anti-HCV
Hepatitis C antibody	Anti-HCV
s/co	Anti-HCV
Signal to cutoff ratio	Anti-HCV
Genotype	HCV RNA
HCV amplification	HCV RNA
HCV Genotype	HCV RNA
HCV NAT	HCV RNA
HCV PCR	HCV RNA
HCV Quant	HCV RNA
Hep C log	HCV RNA
Hep C RNA	HCV RNA
Viral load	HCV RNA

Appendix B

Hepatitis B-Acute

2012 Case Definition

CSTE Position Statement(s)

11-ID-03

Clinical Description

An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either a) jaundice, or b) elevated serum alanine aminotransferase (ALT) levels >100 IU/L.

A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.

Laboratory Criteria for Diagnosis

- HBsAg positive, AND
- Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

Case Classification

Confirmed

A case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic hepatitis B.

https://ndc.services.cdc.gov/case-definitions/hepatitis-b-acute-2012/

Hepatitis B-Chronic

2012 Case Definition

CSTE Position Statement(s)

11-ID-04

Clinical Description

No symptoms are required. Persons with chronic hepatitis B virus (HBV) infection may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer.

Laboratory Criteria for Diagnosis

- Immunoglobulin M (IgM) antibodies to hepatitis B core antigen (IgM anti-HBc) negative AND a positive result on one of the following tests: hepatitis B surface antigen (HBsAg), hepatitis Be antigen (HBeAg), or nucleic acid test for hepatitis B virus DNA (including qualitative, quantitative and genotype testing), OR
- HBsAg positive or nucleic acid test for HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Case Classification

Probable

A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Confirmed

A person who meets either of the above laboratory criteria for diagnosis.

Comments

Multiple laboratory tests indicative of chronic HBV infection may be performed simultaneously on the same patient specimen as part of a "hepatitis panel." Testing performed in this manner may lead to seemingly discordant results, e.g., HBsAg-negative AND HBV DNA-positive. For the purposes of this case definition, any positive result among the three laboratory tests mentioned above is acceptable, regardless of other testing results. Negative HBeAg results and HBV DNA levels below positive cutoff level do not confirm the absence of HBV infection.

https://ndc.services.cdc.gov/case-definitions/hepatitis-b-chronic-2012/

Hepatitis C-Acute

2020 Case Definition

CSTE Position Statement(s)

19-ID-06

Clinical Criteria

All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:

- Jaundice, OR
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL, OR
- Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L,

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria

- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing), OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV)

Epidemiologic Linkage

No epidemiologic linkage is required for case classification.

Criteria to Distinguish a New Case from an Existing Case

A new acute case is an incident case that is over the age of 36 months and has not previously been reported meeting case criteria for chronic hepatitis C or for whom there is laboratory evidence of re-infection. Cases under the age of 36 months should be classified under the Perinatal HCV Position Statement (17-ID-08) unless the exposure mode is not perinatal (e.g., healthcare acquired).

All jurisdictions are encouraged to track negative HCV viral detection tests to document both spontaneous clearance of infection or sustained viral response to HCV treatment. Cases that have

evidence of having cleared the infection at time of initial report or are considered false positive should not be reported to CDC.

Acute cases determined via anti-HCV test conversion do not need to have a positive HCV viral detection test reported to be considered confirmed acute cases.

A new probable acute case may be reclassified as confirmed acute if a positive HCV viral detection test is reported in the same reporting year (e.g., prior to CDC closing reporting for the calendar year).

Collection of risk history data is recommended for probable and confirmed acute HCV cases. Timing of risk history data to collect ranges from 2 weeks to 12 months prior to symptom onset or diagnosis. The time frame to employ depends on the method of classification (e.g. if a case meets clinical criteria and has a positive HCV detection test, a risk history time frame of 2 weeks to 6 months prior to onset should be used; for a case classified via anti-HCV test conversion or HCV RNA test conversion, 2 weeks to12 months prior to onset should be considered).

If evidence indicating resolution of infection is received after a confirmed acute case has been reported to CDC, the case report does not need to be modified as it was a confirmed case at the time of initial report. However, negative HCV viral detection test results received on confirmed acute case, subsequent to an initial positive result, should be appended to case reports, as feasible, and considered for the purpose of data analysis by each jurisdiction.

For probable acute cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable acute and should not be reported to CDC. A confirmed acute case may be classified as a confirmed chronic case if a positive HCV viral detection test is reported one year or longer after acute case onset. A confirmed acute case may not be reported as a probable chronic case (i.e., HCV antibody positive, but with an unknown HCV viral detection test). For purposes of incidence and prevalence calculations, confirmed acute and chronic HCV cases should be counted.

Case Classification

Probable

- A case that meets clinical criteria and has presumptive laboratory evidence, AND
- Does not have a hepatitis C virus detection test reported, AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months.

Confirmed

- A case that meets clinical criteria and has confirmatory laboratory evidence, OR

- A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis, OR
- A documented negative HCV antibody OR negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis.

https://ndc.services.cdc.gov/case-definitions/hepatitis-c-acute-2020/

Hepatitis C-Chronic

2020 Case Definitions

CSTE Position Statement(s)

19-ID-06

Clinical Criteria

All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:

- Jaundice, OR
- Peak elevated total bilirubin levels ≥ 3.0 mg/dL, OR
- Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L,

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria

Confirmatory laboratory evidence:

- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing), OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen),

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV).

Epidemiologic Linkage

No epidemiologic linkage is required for case classification.

Criteria to Distinguish a New Case from an Existing Case

All jurisdictions are encouraged to track negative HCV viral detection tests to document both spontaneous clearance of infection or sustained viral response to HCV treatment. Cases that have evidence of having cleared the infection at time of initial report or are considered false positive should not be reported to CDC.

If evidence indicating resolution of infection is received after a confirmed chronic case has been reported to CDC, the case report does not need to be modified as it was a confirmed case at the time of initial report. However, negative HCV viral detection test results received on confirmed chronic cases, subsequent to an initial positive result, should be appended to case reports, as feasible, and considered for the purpose of data analysis by each jurisdiction.

Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least two sequential negative HCV viral detection tests reported, indicative of treatment initiation and sustained virologic response, followed by a positive HCV viral detection test. Under current treatment recommendations, those two negative tests should be at least three months apart, however, the timing may change as standard of care for HCV treatment evolves. Other evidence of reinfection should be considered, including a report of a new genotype on a case that has previously cleared a different genotype. Jurisdictions are encouraged to ensure that cases of HCV treatment failure are not classified as new cases of HCV infection to the extent that it can be determined. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.

For probable chronic cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable chronic and should not be reported to CDC.

A new chronic case is a newly reported case that does not have evidence of being an acute case of HCV infection. A confirmed acute case may be classified as a confirmed chronic case if a positive HCV viral detection test is reported one year or longer after acute case onset. A confirmed acute case may not be reported as a probable chronic case (i.e., HCV antibody positive, but with an unknown HCV viral detection test). For purposes of incidence and prevalence calculations, confirmed chronic HCV cases should be counted.

Jurisdictions are also encouraged to track and classify possible re-infection cases that may have been previously submitted to CDC as a confirmed or probable chronic HCV infection case. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.

Case Classification

Suspect

NUL

Probable

- A case that does not meet OR has no report of clinical criteria, AND
- Has presumptive laboratory evidence, AND
- Has no documentation of anti-HCV or RNA test conversion within 12 months, AND
- Does not have an HCV RNA detection test reported.

Confirmed

- A case that does not meet OR has no report of clinical criteria, AND
- Has confirmatory laboratory evidence, AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months.

https://ndc.services.cdc.gov/case-definitions/hepatitis-c-chronic-2020/

Hepatitis C, Perinatal Infection

2018 Case Definition

CSTE Position Statement(s)

17-ID-08

Background

Screening recommendations and interpretation of perinatal hepatitis C virus

(HCV) laboratory test results for infants born to HCV-infected mothers differ from those for adolescents and adults (1, 2). There has been a reported increase of HCV infection among women of childbearing age in numerous jurisdictions in the United States (3-5), and there would be an expected rise in perinatal transmission as a result. While there are no measures currently recommended for prevention of HCV transmission by pregnant women to their infants, HCV in pediatric populations can lead to significant illness (6) and it is important for those children to be appropriately assessed and in clinical care for HCV infection. Available curative HCV therapies are not currently recommended for pediatric patients under the age of 12, but that may change as data become available on the use of recently approved medications in younger pediatric populations.

There is no one standard HCV screening recommendation for infants born to HCV infected mothers. Available guidelines consistently recommend against antibody testing for children under 18 months of age due to transient maternal HCV antibody that may not reflect actual infection status of the child. However, there are multiple recommended timelines for HCV ribonucleic acid (RNA) screening of infants born to HCV-infected mothers. These include not testing until at least 1-2 months of age and, in some cases, recommending repeat serial testing of infants if an infant tests positive on one test, if done before 12 months of age. There is concern that testing outside of recommended parameters may identify transient HCV RNA in infants that may spontaneously clear the infection following perinatal exposure. Inappropriate testing and loss of follow-up of infants born to HCV-infected mothers has been reported (7).

There is currently no recommendation for universal HCV screening among pregnant women. Testing is only recommended for women of childbearing age if they are known to be at-risk for HCV infection, regardless of pregnancy status.

Clinical Criteria

Perinatal hepatitis C in pediatric patients may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Diagnosis

- HCV RNA positive test results for infants between 2 to 36 months of age; OR
- HCV genotype test results for infants between 2 to 36 months of age or greater; OR
- HCV antigen test results for infants between 2 to 36 months of age or greater.

Epidemiologic Linkage

Maternal infection with HCV of any duration, if known. Not known to have been exposed to HCV via a mechanism other than perinatal (e.g., not acquired via healthcare).

Criteria to Distinguish a New Case from an Existing Case

Test results prior to 2 months of age should not be used for classification. Test results after 36 months of age should be reported under the 2015 Acute and Chronic HCV Infection case classification and not as perinatal HCV infection. Cases in the specified age range that are known to have been exposed to HCV via healthcare and not perinatally should be reported under the 2015 position statement. Event date should be based on earliest relevant laboratory test date within the 2–36-month window.

Case Classification

Confirmed

Infant who has a positive test for HCV RNA nucleic acid amplification test

(NAAT), HCV antigen, or detectable HCV genotype at ≥2 months and ≤36 months of age and is not known to have been exposed to HCV via a mechanism other than perinatal.

https://ndc.services.cdc.gov/case-definitions/hepatitis-c-perinatal-infection-2018/