

Hepatitis C Testing Toolkit

For Primary Care and Public Health Professionals

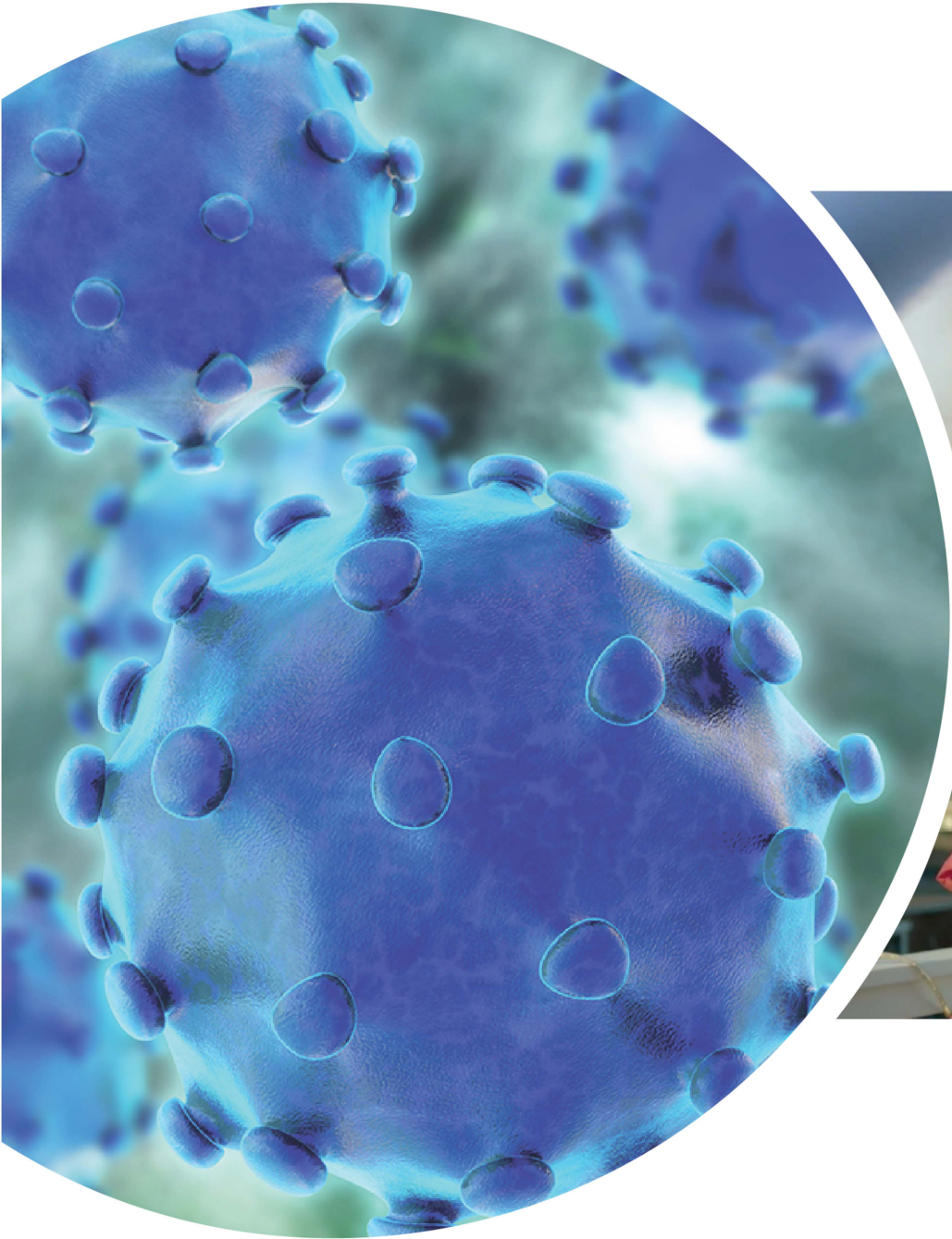




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Introduction

Hepatitis C virus (HCV) infection is a major public health issue, with an estimated 2.4 million Americans living with the infection and an estimated 41,200 new cases in 2016.¹ HCV-related deaths reached nearly 20,000 in 2014, surpassing the combined number of deaths from 60 other infectious diseases, including HIV, pneumococcal disease, and tuberculosis.² Left untreated and undiagnosed, HCV can lead to cirrhosis of the liver, liver cancer, and death. It is the leading cause of liver disease, liver cancer, and liver transplantation in the United States.³ Unfortunately, many persons living with HCV infection are unaware of their infection status because they do not look or feel sick. The only way to know a person has HCV is through a simple blood test. Implementation of current testing recommendations can identify a majority of those infected with HCV.

This Hepatitis C Provider Toolkit was prepared by the Indiana State Department of Health for primary care and public health professionals to use as a guidance for HCV testing and diagnosis.

This toolkit will provide the following information and resources for:

- HCV Testing Recommendations
- Interpretation of Results
- Hepatitis C Screening and Diagnosis Coding
- Treatment Access
- Provider Resources
- Patient Resources

Suggested additions or updates to this guide are welcomed. Please email Sherika Sides at ssides@isdh.in.gov with any questions or comments.

¹ Centers for Disease Control and Prevention <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>

² Centers for Disease Control and Prevention <https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>

³ Centers for Disease Control and Prevention <https://www.cdc.gov/nchhstp/newsroom/docs/factsheets/viral-hep-liver-cancer.pdf>

Hepatitis C: Whom to Test?

Persons born from 1945 through 1965 and people who inject drugs (PWID) remain the priority populations targeted for HCV testing. According to the CDC, persons in the birth cohort 1945 to 1965 account for 75% of persons living with HCV. Most new infections occur among young, white persons who inject drugs.

Most people with hepatitis C do not know they are infected. The only way to know a person has HCV is to test them. Complications from HCV can be prevented if detected early through HCV screening. All person at increased risk for HCV should be screened for the virus. Birth-cohort screening along with risk-based screening can identify a majority of those infected.

Centers for Disease Control and Prevention (CDC)^{4,5}

In 2012, the CDC issued recommendations for one-time hepatitis C screening for all adults born from 1945 through 1965 regardless of risk. This recommendation was an expansion to the existing risk-based guidelines. The recommendations also included referral to care and treatment and a brief screening for alcohol for anyone identified as HCV positive.

U.S. Preventive Services Task Force (USPSTF)^{4,6}

The USPSTF determined that HCV screening among persons of all ages at increased risk and one-time screening for adults born during 1945-1965 as beneficial and gave it a grade of "B". The USPSTF grades recommendations based on the evidence of both the benefits and the harms of the service and an assessment of the balance. Federal law requires that private insurance and Medicaid plans cover USPSTF A or B recommended services without cost-sharing. The final USPSTF recommendations statement can be viewed here:

<https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening>

⁴Hepatitis C Online <https://www.hepatitisc.uw.edu/page/treatment/drugs>

⁵Centers for Disease Control and Prevention <https://www.cdc.gov/hepatitis/hcv/guidelinesc.htm>

⁶U.S. Preventive Service Task Force <https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/hepatitis-c-screening#Pod1>

⁷AASLD <https://www.hcvguidelines.org/evaluate/testing-and-linkage>

Hepatitis C: Whom to Test?

The American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America (IDSA) ^{4,7}

The AASLD/IDSA offers guidance recommendations for the testing, management, and treatment of HCV. Recommendations for testing include one-time screening for adults born from 1945 through 1965 without prior ascertainment of risk, as well as testing based on risk exposures, medical conditions, and risk behaviors, including intranasal drug use and tattoos. See AASLD/IDSA's Recommendations for Testing, Managing, and Treating Hepatitis C here: <https://www.hcvguidelines.org>

| Risk factor/Risk exposure | USPSTF | CDC | AASLD |
|--|--------|-----|-------|
| Born between 1945 and 1965 | • | • | • |
| Current or past injection drug use | • | • | • |
| Intranasal drug use | • | •* | • |
| Other non-injection illegal drug use | | •* | |
| Receipt of tattoo in an unregulated setting | • | •* | • |
| Receipt of blood transfusion and/or organ transplant before 1992 | | • | • |
| Receipt of clotting factor concentrates before 1987 | | • | • |
| Ever been incarcerated | • | | • |
| Children born to HCV-positive infected mothers | • | • | • |
| Persons on long-term hemodialysis | • | • | • |
| Unexplained chronic liver disease and/or chronic hepatitis | | | • |
| Elevated alanine aminotransferase (ALT) levels | | • | • |
| HIV-infected | | • | • |
| Non-HIV infected persons before starting pre-exposure prophylaxis (PreP) | | | • |

*Mentioned but described as uncertain need

Assessing Patient Risk

Sex practices and drug use are difficult topics to discuss — especially with youth. It is important to provide everyone with information on how to protect themselves. Here are some tips to keep in mind when talking with patients/clients about practicing safe sex and reducing or stopping substance use.

- Assure patient confidentiality
- Listen to your patient
- Accept that your patient/client's values may be different from your own
- Avoid judging a patient/client's personal behaviors
- Be sensitive to expressions and gestures (both yours and your patient/client's)
- Help your patients explore their options for reducing or stopping unsafe sexual or substance-using behaviors

To identify patients at risk for HCV infection, ask the following questions:

1. Were you born between 1945 and 1965?
2. Do you inject drugs?
3. Have you ever injected, even if just once?
4. Have you ever received a blood transfusion or organ transplant before July 1992?
5. Have you ever inhaled (snorted) drugs?
6. Have you ever gotten a tattoo or piercing from anyone other than a licensed professional?
7. Have you ever been to jail or prison?
8. Have you ever received blood clotting factor concentrate before 1987?
9. Are you HIV-positive?
10. Have you had sex with someone who you know has hepatitis C?
11. Have you been exposed to blood or had an accidental needle stick on the job?
12. Was your mother infected with hepatitis C when you were born?

Patient who answer yes to any of these questions should be educated on HCV and other infections for which they may be at risk. Once the patient has been identified as at risk, he or she should be tested.

Hepatitis C Screening and Diagnosis

Once an individual is identified as someone who may be at risk for hepatitis C infection, testing should be considered. Hepatitis C testing is a two-step process, including a hepatitis C screening test that detects hepatitis C antibodies, followed by a confirmatory RNA test.

Hepatitis C Screening Test

Testing for hepatitis C starts with a hepatitis C screening test that detects the HCV antibody. This test can be either a rapid test or a laboratory conducted assay for HCV antibody. The test detects hepatitis C antibodies (anti-HCV) in the blood. It is used to determine if someone has ever been infected with HCV. HCV can be detected by anti-HCV screening tests 4-10 weeks after exposure to the infection. Anti-HCV can be detected in more than 97% of persons six months after exposure. Test results are reported as non-reactive or reactive.

- A **non-reactive** or negative antibody test means that the patient does not have hepatitis C. No further testing is needed, unless the patient has been recently exposed. If exposure to HCV was in the last 6 months, they will need to be tested again.
- A **reactive** or positive antibody test mean that the patient has been infected with HCV at some point in time. A reactive antibody test does not indicate current infection. Further testing is required to diagnose HCV infection.

Hepatitis C Diagnostic Test

If the anti-HCV result is reactive, it should be followed by a test to detect HCV RNA. Another name used for this test is polymerase chain reaction or PCR. HCV RNA can be detected as early as two-to-three weeks after exposure to HCV infection.

- If HCV RNA is **not detected**, the patient does not have HCV infection.
- If HCV RNA is **detected**, the patient is infected with HCV. The presence of HCV in the blood indicates HCV infection.

If a patient was exposed in the last six months, testing for HCV RNA or follow-up testing for HCV antibody is recommended.

Please refer to [Recommended Testing Sequence for Identifying Current Hepatitis C Virus Infection](#) and [Interpretation of Results of Test for Hepatitis C Virus Infection and Further Action](#), for additional information.

Actions for Healthcare Providers to Identify and Test for HCV

Implement systems to promote screening and referral for care. These systems can include standing orders for nurses and medical assistants to screen for HCV, electronic medical record (EMR) prompts and reminders, and clinical decision support tools in your EMR to track and follow up with patients with HCV.

Consult the most up-to-date HCV prevention and treatment guidelines at www.hcvguidelines.org.

Screen all persons born 1945-1965 (Baby Boomers) once in their lifetime without attaining past risk and all persons with risk factors for HCV. People at-risk can include persons who are currently or who have ever injected drugs in the past (even one time), and HIV-positive persons at their first medical visit, annually for all HIV-positive men who have sex with men (MSM). For complete risk factor information, visit www.cdc.gov/hepatitis/hcv/guidelinesc.htm

Confirm HCV infections by performing HCV RNA tests on all patients who screen antibody-positive.

Refer and link for confirmatory testing if HCV RNA testing is not conducted within your healthcare setting. If already RNA-confirmed, patients should be referred and linked to a medical provider to be assessed for treatment.

Counsel HCV-positive persons on adherence to treatment, transmission, prevention, and liver health. Counsel HCV-negative persons on harm reduction information.

Follow up with antibody-positive patients in your practice to ensure they receive a confirmatory RNA test and are linked to care for treatment.

Important: Positive hepatitis B and hepatitis C labs should be reported to the local health department or the Indiana State Department of Health (ISDH), as detailed in the Communicable Disease Reporting Rule, Title 410, Article 1, Rule 2.5 of the Indiana Administrative Code. ISDH requires that hospitals, healthcare providers and laboratories report positive hepatitis B labs immediately if the patient is pregnant. All other positive hepatitis B labs must be reported within 72 hours. Positive hepatitis C results must be reported within five business day, **this includes HCV rapid antibody test results**. The Communicable Disease Reporting Rule and the Confidential Report of Communicable Diseases Form can be found at: <https://www.in.gov/isdh/25366.htm>.

Hepatitis C Billing Codes

| CPT® Code | Description |
|--------------------------------------|--|
| Hepatitis C Screening Tests | |
| 86803 | Hepatitis C antibody |
| 86804 | Hepatitis C antibody, confirmatory test (with reflex) |
| G0472 | Hepatitis C screening, for an individual at high risk and other covered indication |
| Hepatitis C Diagnostic Tests | |
| 87520 | Hepatitis C RNA; direct probe technique |
| 87521 | Hepatitis C RNA; amplified probe technique |
| 87522 | Hepatitis C RNA; quantification |
| 87902 | Hepatitis C Virus genotype analysis |
| Other Hepatitis-related Tests | |
| 86708 | Hepatitis A antibody (HAAb); total |
| 86709 | Hepatitis A antibody (HAAb), IgM antibody |
| 86704 | Hepatitis B core antibody (HBcAb); total |
| 86705 | Hepatitis B core antibody (HbcAb); IgM |
| 86706 | Hepatitis B surface antibody (HbsAb) |
| 87340 | Hepatitis B surface antigen (HBsAg) detection |
| 80074 | Acute hepatitis panel This panel must include the following: Hepatitis A antibody, IgM antibody (86709) Hepatitis B core antibody (HBcAb), IgM antibody (86705) Hepatitis B surface antigen (HBsAg) (87340) Hepatitis C antibody (86803) |

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Hepatitis C: Diagnosis Codes

| ICD-10 Diagnosis Codes | Description |
|---|---|
| HCV Codes | |
| B17.10 | Acute hepatitis C without hepatic coma |
| B18.20 | Chronic hepatitis C without hepatitis coma |
| B19.20 | Unspecified viral hepatitis C without hepatic coma |
| B19.21 | Unspecified viral hepatitis C with hepatic coma |
| B17. 8 | Other specified acute viral hepatitis |
| Z22.50 | Carrier of unspecified viral hepatitis |
| Z22.52 | Carrier of viral hepatitis C |
| Z22.59 | Carrier of other viral hepatitis |
| Other hepatitis-related ICD-10 codes | |
| B15.9 | Acute hepatitis A without hepatic coma |
| B18.0 | Chronic hepatitis B with delta-agent |
| B18.1 | Chronic viral hepatitis B without delta-agent |
| Z20.5 | Contact with and (suspected) exposure to viral hepatitis |
| B18.8 | Other chronic viral hepatitis |
| B19.9 | Chronic viral hepatitis unspecified |
| B19.0 | Unspecified viral hepatitis with hepatic coma |
| B19.9 | Unspecified viral hepatitis without hepatic coma |
| Z86.19 | Personal history of other infectious diseases |
| Other ICD-10 codes | |
| Z72.51 | High-risk sexual behavior, heterosexual |
| Z72.52 | High-risk sexual behavior, homosexual |
| Z72.53 | High-risk sexual behavior, bisexual |
| Z00.00 | Routine medical examination of adult; Encounter for laboratory as part of general medical examination |
| Z00.01 | Encounter for general medical examination of adult with abnormal finding |
| Z11.59 | Encounter for screening for other viral disease |
| O98.41 | Pregnancy complicated by care of/management affected by viral hepatitis |
| F19.20 | Other psychoactive substance abuse, uncomplicated |
| Z72.89 | Other problems related to lifestyle |

Centers for Medicare & Medicaid Services, <https://www.cms.gov/medicare-coverage-database/staticpages/icd-10-code-lookup.aspx>

Treatment Access

There are several highly effective treatments that can cure greater than 90% of persons infected with hepatitis C. Prior to 2013, HCV infection was treated with a combination of pegylated interferon and ribavirin for a duration of up to 48 weeks. The introduction of direct-acting antivirals improved HCV treatment dramatically, resulting in higher treatment success rates. Treatment success is measured by a sustained virologic response (SVR), which is a lower-than-detectable viral load 12 weeks after finishing treatment. Despite there being simpler, shorter and more effective treatment options available for hepatitis C, few patients have been treated due to barriers, including access to medical care, cost, insurance restrictions, and stigma.

Patients who have been diagnosed with HCV should be evaluated to determine the best treatment option. Specialists who work with patients with HCV include hepatologists, gastroenterologists, and infectious disease physicians. Most often, specialists care for and treat patients with HCV, but new therapy options are allowing primary care providers to become the main source of care for patients with HCV.

For a full list of FDA approved treatments, please visit <https://www.fda.gov/forpatients/illness/hepatitisbc/ucm408658.htm>.

Co-pay and Patient Assistance Programs

Patient assistance programs provide free or discounted medications to people who cannot afford to buy their prescription. Pharmaceutical companies have a long-standing tradition of providing prescription medications free of charge to physicians whose patients might not otherwise have access to necessary medicines. Pharmaceutical companies operate these programs, voluntarily. Many drug manufacturers offer patient assistance programs, which can greatly decrease or entirely eliminate the costs of many medications. Each pharmaceutical company has their own eligibility criteria. For a list of pharmaceutical companies that offer patient assistance, please visit https://www.nastad.org/sites/default/files/hepatitis-and-paps-caps-resource-document-080917_0.pdf.

Treatment Access

Indiana Medicaid

In 2016, all covered hepatitis C drugs stopped being reimbursed through managed care programs and began reimbursement through fee-for-service (FFS) pharmacy benefit manager OptumRX. This change was referred to as a “carve out” of the hepatitis C pharmacy benefit from managed care.

Prior Authorization (PA) Requirements for Approval of Initial HCV Treatment:

- Must be ≥ 18 years of age (≥ 12 years of age for Harvoni and Sovaldi)
- For women of childbearing age, must confirm negative pregnancy test prior to therapy
- Prescription must be written by or in consultation with an Infectious Disease or GI specialist (including hepatitis C Project ECHO participants)
- $>$ stage 1 fibrosis, co-infection with HIV or AIDs, post liver transplant, or other comorbidity associated with rapid progression

PA Requirements for Approval of Treatment for Relapse or Re-infection:

- Must be ≥ 18 years of age
- For women of childbearing age, must confirm negative pregnancy test prior to therapy
- Prescription must be written by or in consultation with an infectious disease or gastrointestinal specialist
- Duration of approval will be up to 24 weeks
- Must confirm member was previously compliant with therapy
- In the case of previous non-compliance due to intolerance of drug therapy will be approved if the new regimen does not contain the compound that produced intolerance
- Non-compliance will be further reviewed through medical review
- Must have a diagnosis of chronic hepatitis C with $>$ stage 3 fibrosis (regimen approved will be dependent on genotype per initial treatment criteria)
- Must be first request for re-treatment
- Prescriber and member must provide documentation regarding rationale and methodology to ensure compliance with therapy

Policies around hepatitis C medication access are continuously changing. For the most up to date information on Indiana Medicaid’s hepatitis C criteria visit the following link and click on “Preferred Drug List” under “Quick Links.”

<https://inm-providerportal.optum.com/providerportal/faces/PreLogin.jsp>

Treatment Access

Project ECHO

Access to hepatitis C care can be difficult for patients living in underserved and rural areas. Project ECHO (Extension for Community Healthcare Outcomes) is a telehealth model that provides specialty education and training from expert specialists to primary care clinicians. It allows physicians, nurse practitioners and other clinicians to care for and treat patients with HCV or other complex illnesses in their community. This program is offered in Indiana through the Richard M. Fairbanks School of Public Health. To learn more information and to sign up to become a participant, please visit <https://fsph.iupui.edu/research-centers/centers/public-health-practice/ECHO/index.html>.

Clinical Trials

The American Liver Foundation has partnered with Antidote to provide a tool to help patients find clinical trials. Patients can find a list of clinical trials in the area where they live after answering a few questions. Antidote uses publicly-available data from [Clinicaltrials.gov](https://clinicaltrials.gov), so all trials are verified by the National Institutes of Health. Click here to find a clinical trial: <https://liverfoundation.org/for-patients/resources/clinical-trials/>

Viral Hepatitis Immunizations

Hepatitis A and Hepatitis B Vaccines

Hepatitis A and hepatitis B immunizations are recommended for all who are at risk. People infected with hepatitis C should receive hepatitis A and hepatitis B immunizations to prevent co-infection and further liver damage. There is no immunization available for hepatitis C.

The Hepatitis A vaccine series is a two-dose series, with the second dose administered at least six months after the first. This vaccine is available to anyone ages 12 months and older. The hepatitis B vaccine series is a three-dose series with the first dose routinely given at birth. Both the hepatitis A and hepatitis B vaccines are included in the Centers for Disease Control and Prevention's recommended childhood immunization schedule so many children will have already received these vaccines. In addition, both the hepatitis A and hepatitis B vaccines are included in the Indiana school immunization requirements. The current Indiana school immunization requirements are available in English and Spanish on the [ISDH Immunization Division website](#).

We strongly recommend these vaccines for both children and adults and encourage healthcare providers to check a patient's immunization status at every visit.

Cost and availability

The Indiana Adult Vaccine Program offers vaccines to uninsured and underinsured adults in a number of sites across Indiana, including STD clinics, Federally Qualified Health Centers and local health departments.

For more information on immunizations and where you can find Adult Vaccine Providers in your area, please visit the Indiana State Department of Health's immunization website at <https://secure.in.gov/isdh/17094.htm>.

Resources

Provider Resources

[A Guide to Comprehensive Hepatitis C Counseling and Testing](#)

[Recommended Testing Sequence for Identifying Current Hepatitis C Virus Infection](#)

[Interpretation of Results of Test for Hepatitis C Virus Infection and Further Action](#)

[CenterWatch provides state by state listings of clinical trials for viral hepatitis](#)

[Hepatitis C Clinical Support Tools](#)

[University of Washington Hepatitis C Online](#)

[Hepatitis Web Study \(Opportunity for CE Credits\)](#)

[HepCure Live Webinars Tuesdays 4:30-5:30pm EST \(Opportunity of CE Credits\)](#)

[PRIME CME \(Opportunities for CE Credits\)](#)

[NASTAD's Science over Stigma: The Public Health Case against HCV Treatment Sobriety Restrictions](#)

[Hepatitis C: State of Medicaid Access](#)

[AASLD/IDSA HCV Guidance: Recommendations for Testing, Managing, and Treating](#)

[Hepatitis C](#)

[CDC Viral Hepatitis Serology Training](#)

[National Viral Hepatitis Action Plan 2017-2020](#)

[National Strategy to Eliminate Hepatitis B and C](#)

[Indiana State Department of Health Viral Hepatitis Page](#)

Patient Resources

[Help-4-Hep National Hepatitis C Support Line](#)

[Clinical Trials](#)

[Find free HIV, STD and Viral Hepatitis Testing and Vaccinations](#)

[Caring Ambassadors](#)

[CDC Know More Hepatitis Campaign and Educational Materials](#)