Health Education for Liver Providers (H.E.L.P.) Team-based Training Program

presented by the



Updated July 1, 2018



DISCLOSURE

- This curriculum was designed by pro bono physicians and researchers using Centers for Disease Control and Prevention (CDC) guidelines and recommendations. Training materials were not influenced by any pharmaceutical companies.
- The Continuing Education trainings were financially supported by Gilead Sciences, specifically for resources such as: faculty travel, training facilities, printing cost, accreditation fees, logistics, and meals.
- Off-label or investigational use of medications were not discussed in the trainings.
- If you would like to use this training curriculum, please send a courtesy email to <u>hepbtf@gmail.com</u>.



H.E.L.P. Team-based Training Program Background

- In 2017, the National Task Force on Hepatitis B Focus on Asian and Pacific Islander Americans (the Task Force) piloted a team-based continuing medical education (CME) program called "Health Education for Liver Providers" (H.E.L.P.).
 - In-person trainings were provided in 7 regional sites
 - 154 individuals received training; 74 were providers
 - CME credits were provided by the American Academy of Family Physicians (AAFP)
- In 2018, based on feedback provided, the training program was modified to fit a "Train-the-trainer" model to encourage support from local resources.
 - In-person trainings were provided in 6 regional sites.
 - 132 individuals received training; 71 were providers
 - Continuing education credits were extended to nurses / nurse practitioners (by ASPAN) and pharmacists (by ACPE) (in all sites), and social workers (in Hawaii only)



Curriculum Development Team and Faculty (2016-2018)

- Dr. Richard Andrews, M.D., M.PH.
 - Co-Chair, National Task Force on Hepatitis B Focus on APIA (2016-present)
 - Southwestern Regional Director, National Task Force on Hepatitis B Focus on APIA (2015-2016)
 - Director, Research & Viral Hepatitis, HOPE Clinic
- Dr. Moon Chen, Ph.D., M.PH.
 - Co-founder and Advisor, National Task Force on Hepatitis B Focus on APIA
 - Associate Director, Population Research and Cancer Disparities, UC Davis Comprehensive Cancer Center
- Dr. Doan Dao, M.D.
 - Co-Char, National Task Force on Hepatitis B Focus on APIA (2014-2017)
 - Co-founder and President, Vietnam Viral Hepatitis Alliance (2014-present)

- Dr. Robert Gish, M.D., FAASLD
 - Advisor, National Task Force on Hepatitis B Focus on APIA
 - Adjunct Professor of Medicine, Stanford University, CA
 - Clinical Professor, Adjunct, Department of Medicine, University of Nevada in Las Vegas
- Dr. Amy Shen Tang, M.D.
 - Co-Chair, National Task Force on Hepatitis B Focus on APIA (2018-present)
 - Northeastern Regional Director, National Task Force on Hepatitis B Focus on APIA (2016-2017)
 - Hepatitis B Program Director, Charles B Wang Community Health Center
- Dr. Amy Trang, Ph.D., M.Ed.
 - Administrator, National Task Force on Hepatitis B Focus on APIA (2014-present)
 - Adjunct Faculty, University of Virginia Curry School of Education, Social Foundations of Education Program



Health Education for Liver Providers (H.E.L.P.) Team-based Training Program

Description: This training is designed to provide health care providers and their medical team with core medical knowledge of hepatitis B (HBV) and hepatitis C (HCV). Participants will be given an opportunity to collaborate and brainstorm with other health care providers with shared experiences. Additional tools and resources necessary to increase HBV and HCV screenings after the training will be provided on <u>www.hepbtaskforce.org</u>.



Health Education for Liver Providers (H.E.L.P.) Team-based Training Program

Learning Objectives:

By the end of the training, participants will...

- Acquire core medical knowledge of hepatitis B and C
 - Identify those at risk for hepatitis B and C
 - Differentiate between an acute and chronic hepatitis B and C infection
 - Use and interpret appropriate screening methods for hepatitis B and C testing of high risk patients
- Acquire a team-based approach to increasing viral hepatitis screening and linking those infected to care; those who are HBV naïve (negative for HBsAg, anti-HBs and anti-HBc) to vaccination; and education to avoid risks to HCV or HBV

Illustrate team based approaches to hepatitis B and C screening

 Have the tools and resources necessary to increase HBV and HCV screenings after the training

> Apply different treatment modalities for hepatitis B and C



Health Education for Liver Providers (H.E.L.P.) Team-based Training Program

In-person trainings have been provided in:

- Washington, DC metropolitan area (2017)
- Houston, TX (2017)
- Atlanta, GA (2017)
- Seattle, WA (2017)
- New York, NY (2017)
- Chicago, IL (2017)
- San Diego, CA (2017)
- Columbus, OH (2018)
- Minneapolis / St. Paul (Twin Cities), MN (2018)
- Biloxi, MS (2018)
- Philadelphia, PA (2018)
- Kahului, HI (Maui) (2018)
- Honolulu, HI (Oahu) (2018)







Team-based training agenda

Time	Training Topic
20 minutes	Check-in and Pre-test (10 min) Introductions, Overview of training agenda
60 minutes	Core Knowledge training on Hepatitis B and C
60 minutes	Break-out sessions Group 1: Physicians / Providers Group 2: Health-care related professions and support staff
30 minutes	Networking Meal
40 minutes	Team-based model training w/ hands-on activities Participants discuss and design team-based protocol
10 minutes	Post-test and Training evaluations
10 – 20 minutes	Hand-out training Certificates & Group pictures



Activity #1: Introductions

- Please tell us your:
 - Name
 - Job title and/or primary job duty
 - Where you work
- Would you say that you have:
 - No experience working with hepatitis B and/or C patients?
 - **Some experience** working with hepatitis B and/or C patients (1-3 years)?
 - Lots of experience working with hepatitis b and/or C patients (more than 3 years)?



Part 1: Core Knowledge Training

for Hepatitis B and C



https://www.cdc.gov/ hepatitis/HBV/index.h tm

What is hepatitis B and what causes this infection?

- Hepatitis B is a liver infection caused by the hepatitis B virus (HBV) that is also a systemic disease and an infectious disease.
- Hepatitis B is transmitted when blood, semen, or another body fluid from a person infected with the hepatitis B virus enters the body of someone who is not infected.
- This can happen through sexual contact; sharing needles, syringes, or other drug-injection equipment; or from mother to baby at birth.
- For some people, hepatitis B is an acute, or short-term, illness but for others, it can become a long-term, chronic infection.
- Risk for chronic infection is related to age at infection: approximately 90% of infected infants become chronically infected, compared with 2%–6% of adults.
- Chronic Hepatitis B can lead to serious health issues, like cirrhosis or liver cancer. The best way to prevent hepatitis B is by getting vaccinated. HBV has been linked to kidney disease and diabetes.
- Hepatitis B is incurable and may be hidden in many patients



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

How is HBV transmitted?

HBV is transmitted through activities that involve **percutaneous** (i.e., puncture through the skin) **or mucosal contact with infectious blood or body fluids** (e.g., semen, including:

- Sex with an infected partner
- Injection drug use that involves sharing needles, syringes, or drug-preparation equipment
- Birth to an infected mother
- Contact with blood or open sores of an infected person
- Needle sticks or sharp instrument exposures
- Sharing items such as razors or toothbrushes with an infected person

Myths about hepatitis B (i.e. how it cannot be spread):

- Hepatitis B is not spread through sharing meals, bowls or utensils with someone who has the virus.
- It is also not spread by breastfeeding, hugging, kissing, holding hands, coughing, or sneezing.



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

How long does HBV survive outside the body?

- HBV can survive outside the body at least 7 days and still be capable of causing infection.
- Any blood spills including dried blood, which can still be infectious

 should be cleaned using 1:10 dilution of one part household bleach to 10 parts of water for disinfecting the area.
- Gloves should be used when cleaning up any blood spills.
- Hepatitis B virus has been found in frozen cadavers over 500 years old



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

Who is at risk for HBV infection?

The following populations are at increased risk of becoming infected with HBV:

- Infants born to infected mothers
- Sex partners of infected persons
- Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
- Men who have sex with men
- Injection drug users
- Household contacts of persons with chronic HBV infection
- Health care and public safety workers at risk for occupational exposure to blood or blood-contaminated body fluids
- Hemodialysis patients
- Residents and staff of facilities for developmentally disabled persons
- Travelers to countries with intermediate or high prevalence of HBV infection
- Those born in CDC-defined intermediate to high endemic areas for HBV (which corresponds to the green colored areas of the map of the world, which is your next slide).
- Recipients of solid or liquid organ transplants

Global HBV Prevalence



¹ Disease data source: 0tt JJ, Stevens GA, Groeger J, Wiersma ST. Global epidemiology of hepatitis B virus infection: new estimates of age-specific HBsAg seroprevalence and endemicity. Vaccine. 2012; 30(12): 2212-2219.



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

What are the signs and symptoms of HBV infection?

- <u>Acute infection</u>: Most children under age 5 years and newly infected immunosuppressed adults are asymptomatic. 30%–50% of persons aged ≥5 years have initial signs and symptoms. Signs and symptoms can include
 - Fever, fatigue. Loss of appetite
 - Nausea, vomiting, abdominal pain
 - Dark urine, clay-colored bowel movements
 - Joint pain
 - Jaundice
 - In acute disease: Symptoms begin an average of 90 days (range: 60–150 days) after exposure to HBV.
- <u>Chronic infection</u>: The presence of signs and symptoms varies by age and is associated in most people with end-stage liver disease.
- Persons with chronic HBV infection are mostly asymptomatic, have no evidence of liver disease at diagnosis except for elevated liver tests, or have a spectrum of disease ranging from chronic hepatitis to cirrhosis or hepatocellular carcinoma (the most common type of liver cancer).



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

Acute HBV infection

- Acute infection ranges from asymptomatic or mild disease to rarely — fulminant hepatitis.
- Disease is more severe among adults aged >60 years.
- The fatality rate or need for liver transplant among acute cases reported to CDC is 0.5%–1%.
- About 25% of those who become chronically infected during childhood and 15% of those who become chronically infected after childhood die prematurely from cirrhosis or liver cancer, and the majority remain asymptomatic until onset of cirrhosis or end-stage liver disease.
- In the United States, chronic HBV infection results in an estimated 1,800 deaths per year.
- There are rare patients who need liver transplants for chronic disease but more often it is HBV with liver cancer



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

How likely is HBV infection to become chronic?

- HBV is incurable
- All patients exposed carry some virus in their body for their life time
- The risk for chronic infection (HBsAg+) varies according to the age at infection and is greatest among young children.
- About 90% of infants and 25%–50% of children aged 1–5 years will remain chronically infected with HBV as per the test HBsAg.
- By contrast, about 95% of adults recover from HBV infection and become anti-HBc(+) indicating persistent HBV in the liver in the form of cccDNA.



https://www.cdc.gov/ knowhepatitisb/faqs. htm

Who should get screened / tested for hepatitis B?

- CDC suggests that the following groups may be at-risk:
 - People born in Asia or the Pacific Islands, except Australia and New Zealand
 - People whose parents were born in most parts of Asia or the Pacific Islands
 - People who live with someone who has hepatitis B
- A blood test is the only way for people to know if they are infected. Most people who have hepatitis B don't feel sick, so they don't know they are infected. In fact, nearly 2 out of 3 people with hepatitis B do not know they have it.



https://www.cdc.gov/knowh epatitisb/faqs.htm

Kowdley 2012 Gish 2015 How common is hepatitis B among Asian Americans and Pacific Islanders (AAPIs)?

- In the US, hepatitis B is very common among AAPIs, with 1 in 12 AAPIs living with hepatitis B.
- Even though AAPIs make up less than 5% of the US population, they account for up to 2.2 million of the Americans living with hepatitis B.
- Hepatitis B is very common in many parts of Asia and the Pacific Islands, making it easy for many people born in Asia or the Pacific Islands to come into contact with the Hepatitis B virus.
- Although anyone can get hepatitis B, some people are at greater risk, such as those who live with a person who has hepatitis B or are born to infected mothers.



https://www.cdc.gov /knowhepatitisb/faq s.htm

Why should people get tested for hepatitis B if they don't feel sick?

- Even though most people with hepatitis B don't feel sick, liver damage can still occur.
- Lifesaving treatments are available to slow down or prevent liver damage and liver cancer.
- Getting tested helps people access medical treatments that can save their lives.
- People who get tested for hepatitis B and find out that they are infected can **help protect their family members** by encouraging them to get tested for hepatitis B.
- People who have never been infected with hepatitis B can get a safe, effective vaccine to protect them from getting the infected.
- The vaccine is currently recommended for all children and people at risk, including family members of people with hepatitis B.
- However, adults should get tested first to determine if they have ever had hepatitis B and if they will benefit from getting the vaccine.



Which tests should be ordered?

A 1st level hepatitis B Test panel should include:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B surface antibody (anti-HBs)
- Total hepatitis B core antibody (anti-HBc)

• If the patient presents possible acute HBV disease:

• IgM antibody to hepatitis B core antigen (IgM anti-HBc)

• For patients HBsAg(+):

- Hepatitis B e antigen (HBeAg)
- Hepatitis B e antibody (HBeAb or anti-HBe)
- Quantitative HBV DNA
- Other tests: HAV, HCV antibody and comprehensive metabolic panel (for ALT/AST, bilirubin, albumin), complete blood count (for platelets), and INR
- Optional or for select patients:
 - Quantitative HBsAg
 - HDV antibody
- Costs varies across the country; check with your lab for exact cost



Updated from

Resource: Centers for Disease Control and Prevention

https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

What do all the hepatitis B serologic markers mean?

- Hepatitis B surface antigen (HBsAg): A protein on the surface of HBV; it can be detected in high levels in serum during acute or chronic HBV infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.
- Hepatitis B surface antibody (anti-HBs): The presence of anti-HBs is generally interpreted as indicating post vaccine immunity from HBV infection if anti-HBc is negative . Anti-HBs alone only develops in a person who has been successfully vaccinated against hepatitis B. There is no such stage or phase of disease as natural immunity.
- Total hepatitis B core antibody (anti-HBc): Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous (occult or "resolved") or ongoing infection with HBV in an undefined time frame. The chance of a false positive anti-HBc(+) is <3/1000 patients. This tests indicates the risk of reactivation of HBV disease in special settings.



Updated from

Resource: Centers for Disease Control and Prevention

https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview What do all the hepatitis B serologic markers mean?

- IgM antibody to hepatitis B core antigen (IgM anti-HBc): Positivity indicates recent infection with HBV (≤6 months). Its presence indicates acute infection.
- Hepatitis B e antigen (HBeAg): another protein produced by the virus that is found in serum during acute and chronic hepatitis B. Its presence indicates that the virus is replicating and the infected person has high levels of HBV and a wild type infection.
- Hepatitis B e antibody (HBeAb or anti-HBe): Produced by the immune system temporarily during acute HBV infection or consistently during or after a burst in viral replication. Spontaneous conversion from e antigen to e antibody (a change known as seroconversion) is a soft predictor of long-term clearance of HBV in patients undergoing antiviral therapy and indicates lower levels of HBV and in patients with HBV DNA, the presence of core and or precore mutations.



What do the HBV test results mean?

Resource: American College of Physicians http://annals.org/aim/fullarticle /2664089/hepatitis-bvaccination-screening-linkagecare-best-practice-advice-from

	Profile 1	Profile 2	Profile 3	Profile 4	Profile 5
1. HBsAg	Negative	Negative	Positive	Negative	Negative
2. Anti-HBc	Negative	Negative	Positive	Positive	Positive
3. Anti HBs	Negative	Positive	Negative	Positive	Negative
Significance	1. No chronic infection; not a hepatitis B carrier.	1. No chronic infection; not a hepatitis B carrier.	 Has acute (if HBc IgM+) or chronic hepatitis B infection. 	1. No hep B infection in the blood if HBV DNA negative	 Subclinical infection at the moment.
	2. Never been infected with hepatitis B virus.	2. Not infected with hep B virus.	2. Has been infected with hep B virus.	2. Has been exposed to hep B	2. Has been exposed to hep B.
	3. No immunity (no protection) against hep B.	3. Has immunity due to vaccination.	3. No immunity or protection against hep B.	3. Has cleared the blood of HBV infection (when combined with negative HBsAg)	3. Clinical meaning at this time is subclinical infection and risk of reactivation.
Action			See Primary care provider for further tests. HBV DNA quant.	Watch for reactivation if becomes immune suppressed	Watch for risks of reactivation
	Get vaccination	No vaccination needed	No vaccination needed	No vaccination needed	No vaccination needed

Table 2: Interpretation HBV serologic test results for HBV infection and Further Actions



How long does it take for blood to test HBsAg-positive after exposure to HBV?

Resource: Centers for Disease Control and Prevention

https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

- HBsAg will be detected in an infected person's blood an average of 4 weeks (range: 1–9 weeks) after exposure to the virus.
- About 1 of 2 patients will no longer be infectious by 7 weeks after onset of symptoms, and all patients who do not remain chronically infected will be HBsAg-negative by 15 weeks after onset of symptoms.



https://www.cdc.gov/ hepatitis/hbv/hbvfaq. htm#overview

How is HBV infection treated?

- For acute infection, HBV medications are available; although most treatment is supportive.
- There are several antiviral medications for persons with chronic infection, but in USA only three are commonly used entecavir, and two different forms of tenofovir.
- Persons with chronic HBV infection require linkage to care with regular monitoring to prevent liver damage and/or hepatocellular carcinoma.
- Lab and imaging surveillance for liver cancer is used for some HBsAg(+) patients and it is imperative to review the AASLD surveillance guidelines (see resource list)



https://www.cdc.gov/ knowhepatitisb/faqs.h tm

How is hepatitis B treated?

- People with hepatitis B should be monitored regularly by a doctor experienced in caring for people with Hepatitis B.
- This can include some NP, PA, pharmacists as well as internists or family medicine practitioners, including specialists such as infectious disease physicians, gastroenterologists, or hepatologists (liver specialists).
- Doctors can monitor for signs of liver disease and prescribe needed treatments.
- Several medications are available for hepatitis B treatment.
- However, not every person with chronic hepatitis B needs to be on medication, and the drugs may cause side effects in some patients.



https://www.cdc.gov/ knowhepatitisb/faqs.h tm

What else can people with hepatitis B do to take care of their liver?

- People with hepatitis B should avoid (or minimize) alcohol in their diet because it can cause additional liver damage.
- They also should check with a health professional before taking any prescription pills, supplements, or over-the-counter medications, as these can potentially damage the liver.
- Work actively on achieving or maintaining a healthy weight, BMI= 22-24, since extra weight can also irritate the liver and markedly increase the risk of cirrhosis and or liver cancer.



Other things to consider when testing for hepatitis B:

- Test HBV + patients for Delta (HDV) infection in at-risk patients:
 - 1) Cirrhosis
 - 2) From endemic regions: Mongolia, Africa, Middle East, Eastern Europe, Central Asia
 - 3) Active liver disease (high ALT) when an HBV patient is fully suppressed on an oral HBV medication
 - 4) HBV in PWID/IVDU or people who have paid for sex
- Vaccinate all susceptible individuals for HBV if the triple HBV panel is negative
- For even more questions and answers on Hepatitis B, please visit: <u>http://www.cdc.gov/hepatitis/B/bFAQ.htm</u>
- Online and other resources about hepatitis B, include AASLD Practice guidelines are available for the treatment of chronic hepatitis B and can be found on this site: http://www.aasld.org/publications/practice-guidelines-0



https://www.cdc.gov/hepa titis/hcv/index.htm

NOTE: In some populations, hepatitis C was spread from mother to child at birth or because of poor medical conditions in other countries.

What is hepatitis C and what causes it?

- Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV).
- Hepatitis C is a blood-borne virus.
- Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs.
- For some people, hepatitis C is a short-term illness but for 70%– 85% of people who become infected with hepatitis C, it becomes a long-term, chronic infection.
- Chronic hepatitis C is a serious disease than can result in long-term health problems, even death.
- The majority of infected persons might not be aware of their infection because they are not clinically ill.
- There is no vaccine for hepatitis C.
- The best way to prevent Hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs.



https://www.cdc. gov/hepatitis/hcv /hcvfaq.htm#secti on1

How is HCV transmitted?

- HCV is transmitted primarily through large or repeated percutaneous (i.e., passage through the skin) exposures to infectious blood, such as
- Injection drug use (currently the most common means of HCV transmission in the United States)
- Receipt of donated blood, blood products, and organs (once a common means of transmission but now rare in the United States since blood screening became available in 1992)
- Needle stick injuries in health care settings
- Birth to an HCV-infected mother
- HCV can also be spread infrequently through sex with an HCV-infected person (an inefficient means of transmission)
- Sharing personal items contaminated with infectious blood, such as razors or toothbrushes (also inefficient vectors of transmission)
- Other health care procedures that involve invasive procedures, such as injections (usually recognized in the context of outbreaks)



https://www.cdc. gov/hepatitis/hcv /hcvfaq.htm#secti on1

What are the signs and symptoms of the rare event of acute symptomatic HCV infection?

- Persons with newly acquired HCV infection usually are asymptomatic or have mild symptoms that are unlikely to prompt a visit to a health care professional. When symptoms occur, they can include:
 - Fever
 - Fatigue
 - Dark urine
 - Clay-colored stool
 - Abdominal pain
 - Loss of appetite
 - Nausea
 - Vomiting
 - Joint pain
 - Jaundice
- Approximately 20%–30% of those newly infected with HCV experience fatigue, abdominal pain, poor appetite, or jaundice.
- In those persons who do develop symptoms, the average time period from exposure to symptom onset is 4–12 weeks (range: 2–24 weeks).



https://www.cdc. gov/hepatitis/hcv /hcvfaq.htm#secti on1

What are the signs and symptoms of chronic HCV infection?

- Most persons with chronic HCV infection have vague symptoms such as fatigue and mental fog. However, many have chronic liver disease, which can range from mild to severe, including cirrhosis and liver cancer.
- Chronic liver disease in HCV-infected persons is usually insidious, progressing slowly without specific symptoms for several decades. The major sign of HCV infection is an ALT > 20 in women and 30 IU/mL in men
- In fact, HCV infection is often not recognized until asymptomatic persons are identified as HCV-positive when screened for blood donation or when elevated ALT, a liver enzyme, levels are detected during routine examinations or are tested as part of the birth cohort.



https://www.cd c.gov/hepatitis/ hcv/hcvfaq.htm #section1

Who should get screened / tested for HCV?

- HCV testing is recommended for anyone at increased risk for HCV infection, including:
- Persons born from 1945 through 1965
- Persons who have ever injected illegal drugs, including those who injected only once many years ago
- Recipients of clotting factor concentrates made before 1987; Recipients of blood transfusions or solid organ transplants before July 1992
- Patients who have ever received long-term hemodialysis treatment
- Persons with known exposures to HCV, such as
 - health care workers after needle sticks involving HCV-positive blood
 - recipients of blood or organs from a donor who later tested HCV-positive
- All persons with HIV infection
- Patients with signs or symptoms of liver disease (e.g., abnormal liver enzyme tests)
- Children born to HCV-positive mothers (to avoid detecting maternal antibody, these children should not be tested before age 18 months)
- Persons born in high or intermediate prevalence countries, or born to mothers from these countries



https://www.cd c.gov/hepatitis/ hcv/hcvfaq.htm #section1 What blood tests are used to detect HCV infection?

Several blood tests are performed to test for HCV infection, including:

- Screening tests for antibody to HCV (anti-HCV)
 - enzyme immunoassay (EIA)
 - enhanced chemiluminescence immunoassay (CIA)
- If anti-HCV test is positive: order quantitative tests to detect amount (titer) of virus (HCV RNA PCR)

What do the test results mean?

Print this and provide as handout: https://www.cdc.gov/hepatitis/hcv/pdfs/hcv_graph.pdf

Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions



TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS		
HCV antibody nonreactive	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required.		
		If recent exposure in person tested is suspected, test for HCV RNA.*		
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.		
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.*		
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations, ⁶ follow up with HCV RNA testing and appropriate counseling.		

* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

⁺ It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

⁶ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

HCV Testing FAQ

How soon after exposure to HCV can anti-HCV be detected?

- HCV infection can be detected by anti-HCV screening tests (enzyme immunoassay) 4–10 weeks after infection.
- Anti-HCV can be detected in >97% of persons by 6 months after exposure.

How soon after exposure to HCV can HCV RNA be detected by PCR?

• HCV RNA appears in blood and can be detected as early as 2–3 weeks after infection.

Under what circumstances is a false-positive anti-HCV test result likely?

- False-positive anti-HCV tests appear more often when persons at low risk for HCV infection (e.g., blood donors) are tested.
- Therefore, it is important to follow-up all positive anti-HCV tests with an RNA test to establish current infection.

Under what circumstances might a false-negative anti-HCV test happen?

- Persons with early HCV infection might not yet have developed antibody levels high enough that the test can measure.
- In addition, some persons might lack the (immune) response necessary for the test to work well.
- In these persons, further testing such as PCR for HCV RNA may be considered.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

HCV Testing FAQ (cont.)

Can a patient have a normal liver enzyme (e.g.. ALT) level and still have chronic hepatitis C?

- Yes. It is common for patients with chronic hepatitis C to have liver enzyme levels that go up and down, with periodic returns to normal or near normal levels.
- Liver enzyme levels can remain normal for over a year despite chronic liver disease.

What should be done for a patient with confirmed HCV infection?

• HCV-positive persons should be evaluated (by referral or consultation, if appropriate) for presence of chronic liver disease, including assessment of liver function tests, evaluation for severity of liver disease and possible treatment, and determination of the need for Hepatitis A and Hepatitis B vaccination.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1 When might a specialist be consulted in the management of HCV-infected persons?

 CDC suggests that any provider who manages a person with hepatitis C should be knowledgeable and current on all aspects of the care of a person with hepatitis C; this can include some internal medicine and family practice physicians as well as specialists such as infectious disease physicians, gastroenterologists, NP, PA or pharmacists or hepatologists.

The Task Force is suggesting that Midlevel providers (NP/PA) can also serve as appropriate clinicians for this care when they have been trained in the use of a suitable protocol, and have access to physician input.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

What is the treatment for acute hepatitis C?

- Treatment for acute hepatitis C is similar to treatment for chronic hepatitis C. This issue was addressed in the 2009 AASLD Practice Guidance, the response rate to treatment in acute infection is very high. However, the optimal treatment regimen and when it should be initiated remains uncertain.
- 2009 AASLD Practice Guidelines can be found at: http://www.aasld.org/publications/practiceguidelines-0



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

What is the treatment for chronic hepatitis C?

- The treatment for hepatitis C virus (HCV) infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. Since that time new drugs with different mechanisms of action have become and continue to become available. For a complete list of currently approved FDA therapies to treat hepatitis C, please visit <u>http://www.hepatitisc.uw.edu/page/treatment/drugs</u>.
- To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD), in collaboration with the International Antiviral Society–USA (IAS– USA), developed evidence-based, expert-developed recommendations for hepatitis C management: <u>http://www.hcvguidelines.org</u>.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

What topics should be discussed with patients who have HCV infection?

- Patients should be informed about the low, but present risk for transmission with sex partners.
- Sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others.
- Cuts and sores on the skin should be covered to keep from spreading infectious blood or secretions.
- Donating blood, organs, tissue, or semen can spread HCV to others.
- HCV is not spread by sneezing, hugging, holding hands, coughing, sharing eating utensils or drinking glasses, or through food or water.
- Patients may benefit from joining a support group.
- HCV-positive persons should be advised to stop all alcohol intake because it can accelerate cirrhosis and end-stage liver disease.
- Viral hepatitis patients should also check with a health professional before taking any new prescription pills, over-the counter drugs (such as non-aspirin pain relievers), or supplements, as these can potentially damage the liver.
- Patients who have or used to have HCV should seek to achieve and maintain a healthy weight BMI of 24.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

Should HCV-infected persons be restricted from working in certain occupations or settings?

 CDC's recommendations for prevention and control of HCV infection specify that persons should not be excluded from work, school, play, child care, or other settings on the basis of their HCV infection status.

(https://www.cdc.gov/mmwr/preview/mmwrhtml/0005515 4.htm)

 There is no evidence of HCV transmission from food handlers, teachers, or other service providers in the absence of blood-to-blood contact.



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1 What is the risk of HCV infection from a needle stick exposure to HCV-contaminated blood?

- After a needle stick or sharps exposure to HCV-positive blood, the risk of HCV infection is approximately 1.8% (range: 0%–10%).
- Although a few cases of HCV transmission via blood splash to the eye have been reported, the risk for such transmission is expected to be very low. Avoiding occupational exposure to blood is the primary way to prevent transmission of blood borne illnesses among health care personnel. All health care personnel should adhere to Standard Precautions.

(https://www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm)

• Depending on the medical procedure involved, Standard Precautions may include the appropriate use of personal protective equipment (e.g., gloves, masks, and protective eyewear).

Information for Healthcare Personnel Potentially Exposed to Hepatitis C Virus (HCV)

Recommended Testing and Follow-up

Exposure to viral hepatitis has long been recognized as an occupational risk for healthcare personnel, with recommendations previously established for the management of occupational exposures to hepatitis C virus (HCV). This notice, which is based on current laboratory guidance¹, updates the 2001 HCV testing algorithm for healthcare personnel².

Test the source for HCV RNA'. If the source is HCV RNA positive, or if HCV infection status unknown, follow the algorithm below:



'If it is not possible to test source for HCV RNA, then test for antibodies to HCV (antI-HCV) and screen HCW exposed to antI-HCV positive source. Note that persons with acute infection may test HCV RNA positive but anti-HCV negative.

'In a nationally representative population sample with low (1%) HCV infection prevalence, 22% of anti-HCV positive results were determined to be false-positive. An additional 10% had indeterminate results in a confirmatory assay; most were likely to be false-positive. Among the subset of persons testing anti-HCV screening reactive and subsequently HCV RNA negative, 50% of the anti-HCV tests were false-positive.3

*Anti-HCV testing at >= 6 months with reflex to HCV RNA test, if positive, could also be done.

 5 A single negative HCV RNA test using currently available FDA-approved tests in the US is considered sufficient to rule out chronic HCV infection when screening an HCV antibody-positive individual with no known ongoing risk of exposure. HCV RNA becomes detectable within 3 weeks after exposure even when the antibody is still undetectable. Persons who develop symptoms of acute HCV infection such as jaundice may be tested earlier than 3 weeks, but if negative would require re-testing at \ge 3 weeks. Spontaneous clearance of acute infection may occur up to six months after exposure, hould PCV RNA positive < 6 months after exposure should be tested again at \ge 6 months to determine infection status.

¹All patients with current HCV infection as evidenced by a positive HCV RNA test result should be evaluated by a practitioner with expertise in assessment of liver disease severity and HCV treatment. Guidance for hepatitis C treatment may be found at www.hcvguidelines.org and is changing rapidly with the advent of new therapies.

 1 Spontaneous clearance of infection may occur up to six months after exposure; persons testing HCV RNA positive < 6 months after exposure should be tested again at \geq 6 months after exposure to determine infection status.

References

CDC. Testing for HCV Infection: An Update of Guidance for Clinicians and Laboratorians. MMWR 2013; 62(18): 362-5.

²Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis. MMWR 2001; 50 (RR11): 1-42.

³CDC Division of Viral Hepatitis, manuscript in preparation, *Prevalence of false-positive hepatitis C antibody results, NHANES* 2007-2012.

Print this and provide as handout: https://www.cdc.gov/hepatitis/pdfs/tes ting-followup-exposed-hc-personnel-3d.pdf

November 2016

www.cdc.gov/hepatitis



https://www.cdc.gov/ hepatitis/hcv/hcvfaq.h tm#section1

What is the risk that an HCV-infected mother will spread HCV to her infant during birth?

- Approximately 6 of every 100 infants born to HCV-infected mothers become infected with the virus.
- Transmission occurs at the time of birth, and no prophylaxis is available to prevent it.
- The risk is increased by the presence of maternal HCV viremia at delivery and also is 2–3 times greater if the woman is co-infected with HIV.
- Most infants infected with HCV at birth have no symptoms and do well during childhood.
- More research is needed to find out the long-term effects of perinatal HCV infection.
- Children should be tested for anti-HCV no sooner than age 18 months because anti-HCV from the mother might last until this age.
- If diagnosis is desired before the child turns 18 months, testing for HCV RNA could be performed at or after the infant's first well-child visit at age 1–2 months.
- HCV RNA testing should then be repeated at a subsequent visit, independent of the initial HCV RNA test result.



Other things to consider when testing for hepatitis C:

 CDC offers an online training that covers the serology of acute and chronic hepatitis C and other types of viral hepatitis, available at <u>http://www.cdc.gov/hepatitis/resources/professionals/training/serology/training.htm(https://www.cdc.gov/hepatitis/resources/professionals/training/serology/training.htm).</u>



This is something else to consider to help patients reduce their chances of liver cancer, i.e. reduce risks for fatty liver.



Part 2: Break-out Sessions

- Group 1: Physician/Provider specific training
- Group 2: Health care related professionals training



Note: Case scenarios will be shared during this session. Break-out Session Discussion: Physicians/Providers Group

- What is the appropriate follow-up for each case scenario?
- Who should be consulted in this area if one has questions on what to do?

This session will be focused on providing patient care and treatment services for populations that may be culturally sensitive to seeking health care services.



Note: Case scenarios will be shared during this session. Break-out Session Discussion: Health Care Related Professionals

- What do you do and why do you do what you do?
- What are cultural factors that team members need to be aware when interacting with the at-risk population?

This session will be focused on how to deliver culturally appropriate outreach and public health education messages to the target population.



Part 3: Team-based Plan

for addressing HBV and HCV



Team-based Screening & Linkage to Care Protocol Discussion

- Objective: To share information and local resources for hepatitis B and C, including free services for patients.
- Materials: Post-It notes in multi-colors
- Directions:
 - Each person will be given different color Post-It notes.
 - The instructor will call out a color and ask each person to write down a name of a
 person or organization that provides "Outreach" services for hepatitis B and/or C in
 the local area.
 - After you write down your answer, you may begin to discuss with other members of your table what you have written and how to access services or resources. (~5 min)
 - The instructor will then convene a large group discussion and ask each table to share their answers until there are no duplicate answers. (~5 min)
 - The same will be done for "Education," "Screening," "Vaccination," and "Linkage to Care / Treatment Services."



Training Evaluation

- Review: <u>Video: https://www.cancer.gov/types/liver/dyk-hepatitis-liver-cancer-video?cid=eb_govdel</u>
- Evaluation measures:
 - Core knowledge assessment (pre- and post-test evaluation)
 - Training satisfaction
 - Were you able to learn skills that would help improve your service delivery?
 - Did you and your team members acquire new resources for patient care, i.e. outreach, education, screening, vaccination, and linkage to care and/or treatment services?
- Follow-up evaluation (longitudinal?)
 - How will what has been taught in this CME/CE training improve screening efforts and linkage to care?
 - Email us your progress at <u>hepbtf@gmail.com</u>.

Attendees as well as other Task Force members will provide links and resources to share that could be posted on <u>www.hepbtaskforce.org</u>.



About Hep B Task Force

• The National Task Force on Hepatitis B Focus on Asian Pacific Islander Americans (Hep B Task Force) is a volunteer-based national coalition that brings together scientists, health professionals, not-for-profit organizations, and concerned citizens in a concerted effort to eliminate the transmission of hepatitis B and decrease health disparities among those chronically infected. The Task Force was founded in 1997 and was funded by CDC until 2002. During that time, members of the Task Force contributed articles to the AAPI Journal of Health and presented position papers to the American Cancer Society. Following those years, the Task Force became involved with advocacy and screening recommendations for HBV infections. The Task Force has traditionally been physician-led. The Task Force currently focuses on providing educational resources for providers.

Our Vision

• A United States free of hepatitis B.

Our Mission

 Eliminate hepatitis B, hepatitis B related liver disease, and liver cancer in the United States by empowering and mobilizing communities; enabling national networking and policy development; and advocating for education, access to comprehensive care, and affordable treatment for all Asian and Pacific Islander Americans.