A Guide to Comprehensive Hepatitis C Counseling and Testing



Preface

The purpose of this CDC Hepatitis C Counseling and Testing manual is to provide guidance for hepatitis C counseling and testing of individuals born during 1945–1965. The guide was used in draft form as part of a field assessment conducted among primary care providers, who field tested the manual and provided recommendations for improving its utility.

The field assessment was conducted under contract with the Battelle Memorial Institute and the American Academy of Family Physicians National Research Network.

This manual is intended for guidance only and may be updated and revised at any time. If you have any questions concerning The *Guide to Comprehensive Hepatitis C Counseling and Testing*, contact: 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 or cdcinfo@cdc.gov.

Preface Page i

Table of Contents

Preface	
Testing Patients for Hepatitis C	1
Counseling Patients for HCV Positive Test Result	8

Table of Contents Page ii

The Need for Hepatitis C Testing in Primary Care

- ◆ The Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF) recommend that adults born during 1945– 1965 should receive one-time testing for hepatitis C virus (HCV) without prior ascertainment of HCV risk (Strong Recommendation, Moderate Quality of Evidence).
- Full implementation of the hepatitis C testing recommendations in primary care would help identify more individuals with hepatitis C, allowing them to get into care and treatment sooner.

Background and Rationale

High Prevalence of HCV Infection in People Born 1945-1965

Of the estimated 3 million people with chronic hepatitis C in the U.S., 75% were born during 1945–1965. National prevalence data show that people born during these years have a five times higher prevalence of hepatitis C than other adults.

Increasing HCV-Associated Morbidity and Mortality

Hepatitis C is a leading cause of liver transplants and liver cancer. Annual HCV-associated mortality in the U.S. increased more than 50% from 1999 to 2007. People born during 1945–1965 account for 73% of all HCV-associated deaths.

Limited Effectiveness of Current Testing Strategies

About 50% of persons with chronic hepatitis C do not know that they are infected. Testing based solely on elevated alanine aminotransferase (ALT) levels is estimated to miss 50% of chronic infections.

Benefits of HCV Testing and Care

Clinical preventive services including regular medical monitoring, hepatitis A and B vaccination, and behavior changes like alcohol reduction/cessation, and achieving and maintaining a healthy BMI can improve health outcomes for persons with HCV infection.

Benefits of HCV Treatment

New therapies, including interferon-free regimens, can halt disease progression and provide a virologic cure in most HCV-infected persons. These treatment options increase the effectiveness and reduce the duration of therapy for many patients.

Resource Implications

Studies of HCV testing of people born from 1945 to 1965, and linking them to care and treatment, have found this strategy to be cost effective. One-time testing is estimated to identify 800,000 infections and, with linkage to care and treatment, to avert more than 120,000 HCV-related deaths and to save \$1.5–\$7.1 billion in liver-disease-related costs.

Source: Centers for Disease Control and Prevention (CDC). <u>Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965</u> (MMWR 2012;61(RR04);1-18).

Testing Recommendations for Hepatitis C Virus Infection

The CDC recommends the following persons be tested for HCV infection:

- ♦ Adults born during 1945 through 1965 (no prior ascertainment of HCV risk needed)
- Anyone who currently injects drugs or who has ever injected drugs, even once or many years ago
- Anyone who has the following medical conditions, including:
 - ♦ received clotting factor concentrates produced before 1987
 - ♦ was ever on long-term hemodialysis
 - ♦ persistently abnormal ALT
 - ♦ HIV infection
- ◆ Anyone who has received a transfusion of blood, blood components, or an organ transplant before July 1992
- ♦ Healthcare, emergency medical, and public safety workers after needlesticks, sharps, or mucosal exposures to HCV-positive blood
- ♦ Children born to HCV-positive women

Testing should be initiated with anti-HCV. A reactive result should be followed by a nucleic acid test (NAT) for HCV ribonucleic acid (RNA).

The tool below can be used to help identify patients who should be tested for HCV.

Patient born between 1945 and 1965:				
Yes. Test for HCV infection. No further risk assessment needed.				
No. Ascertain HCV risk as indicated below. If any of the questions are answered 'yes', then the patient should be tested for HCV infection.				
Patient had a blood transfusion or organ transplant before 1992:				
Yes				
□ No				
Patient currently uses (or previously used, even once) intravenous drugs:				
□ Yes				
□ No				
Patient received clotting factor concentrates produced before 1987:				
□ Yes				
□ No				
Patient has ever been on long-term hemodialysis:				
□ Yes				
□ No				
Patient has persistently abnormal alanine aminotransferase levels (ALT):				
□ Yes				
□ No				
Patient has HIV infection:				
□ Yes				
□ No				
Patient works in healthcare, emergency medical, or public safety and has been exposed to HCV-positive blood due to needlestick, sharps, or mucosal exposure:				
Yes				
□ No				
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Hepatitis C Overview

- ◆ Hepatitis C virus (HCV) infection is the most common chronic blood-borne infection in the United States; approximately 3 million people in the U.S. are living with chronic hepatitis C.
- ◆ Chronic HCV infection develops in 75%—85% of HCV-infected persons; about 15%—25% of people will clear the virus from their bodies without treatment.
- ◆ The majority of infected persons might not be aware of their infection because they are not clinically ill. However, infected persons serve as a source of transmission to others and are at risk for chronic liver disease or other HCV-related chronic diseases decades after infection.
- ♦ Over time, approximately 60%-70% of people with chronic hepatitis C develop liver disease and 1%-5% will get liver cancer and die.
- ♦ HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected blood (e.g., through injecting drugs). Although much less frequent, occupational, perinatal, and sexual exposures can also result in transmission of HCV.
- ♦ Before improved screening of the blood supply began in 1992, hepatitis C was also spread through blood transfusions and organ transplants.
- ◆ There is no vaccine available for hepatitis C.

Talking to Patients about Hepatitis C Testing

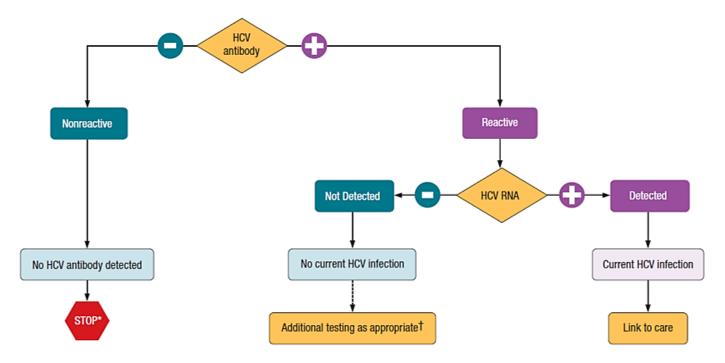
You may wish to present the hepatitis C test as simply one in a set of routine tests conducted to assess general health. The following script was designed to help facilitate a discussion about hepatitis C testing.

sample conversation



Indicate the rationale for the test	The Centers for Disease Control and Prevention (CDC) now recommends that people your age be tested for hepatitis C.
	OR
	Hepatitis C is a virus that can cause gradual, progressive liver damage. People can have the infection for many years — even decades — without knowing it. Many people have no symptoms, so getting a blood test is the only way to know if you have hepatitis C.
Reassure patient about the value of the HCV test	The antibody test will help you find out if you have been exposed to the virus at any time in your life.
Obtain consent	If it is all right with you, I would like to test you for hepatitis C today.

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



^{*} For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

[†] To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had 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.

Interpretation of Results of Tests for 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, 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.

⁵ 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.

Providing a Positive Hepatitis C Test Result

A positive hepatitis C test result should be communicated confidentially through personal contact by a clinician or trained health professional. When first hearing the test result, the patient may have a strong emotional reaction. The patient may want additional information immediately or may need some time to process what he/she has just heard. Take a cue from his or her reaction. It is important not to rush the patient after this initial disclosure.

sample conversation

Provide results

I have your test result.



If antibody test result and HCV RNA tests are both positive

Your hepatitis C test results were positive. You have hepatitis C.

If the patient is upset or scared about the test result, you may want to convey a positive message of hope about hepatitis C.

sample conversation



Convey a positive message

- Many people with hepatitis C remain healthy throughout their lives
- ♦ There are treatments available that can cure hepatitis C for many people.
- There is a lot you can do to keep yourself healthy.
- You can find out if you have liver damage.
- You can start doing things to take care of your liver and prevent more damage.
- ♦ You can prevent transmitting the virus to others.

Daily Living with Hepatitis C

Once your patient has had the opportunity to express his/her feelings, you may want to provide information about the meaning of the test results and some basic information about hepatitis C.

You may choose to review the key messages below with your patient.

sample conversation

Talk about daily living

Let's talk about what it means for your day-to-day life now that you have hepatitis C.

You may have some questions about how hepatitis C can be transmitted. Since this is a blood-borne infection,

- Hepatitis C is not spread by sneezing, hugging, holding hands, coughing, sharing eating utensils or drinking glasses, or through food or water.
- ♦ You can cook and eat together with your family.
- However, sharing personal items that might have blood on them, such as toothbrushes or razors, can pose a risk to others.
- Cover any wounds or open sores that cause you to bleed so that no one can come in contact with your blood.

Discuss contact with blood

Discuss sexual

transmission

Be careful about preventing exposure to others, especially any friends or family with whom you live – keep items to yourself that might have your blood on them, like toothbrushes or razors.

If you get a cut or sore that causes you to bleed, be sure to keep it covered with a bandage so no one can come in contact with your blood.

While the hepatitis C virus can be passed during sex, it is uncommon. If you have one, long-term, steady sexual partner, the chance is very low that you will give hepatitis C to that person through sexual activity.

However, having multiple sex partners, or HIV, or engaging in rough or anal sex have been shown to increase the risk of transmitting the virus.

Although there are no research studies showing that condoms are effective in preventing sexual transmission of hepatitis C, anyone with multiple sex partners should use condoms to protect against other STDs and HIV.

Fact sheets can also be given to your patients. Centers for Disease Control and Prevention (CDC) patient education resources can be found here: http://www.cdc.gov/hepatitis/C/PatientEduC.htm

Alcohol Education

The CDC recommends that all persons identified with HCV infection should receive a brief alcohol screening and intervention as clinically indicated, followed by referral to appropriate care and treatment services for HCV infection and related conditions (Strong Recommendation, Moderate Quality of Evidence).

The American Association for the Study of Liver Diseases (AASLD) and the National Institutes of Health (NIH) Consensus statement recommend that all patients with hepatitis C **avoid alcohol**.

Alcohol screening and brief interventions (SBI) can reduce the number of drinks consumed per week and episodes of binge drinking. SBI includes screening patients for excessive alcohol consumption, brief counseling for those who screen positive, and referral to specialized alcohol treatment for patients with possible alcohol dependence. The brief intervention is also an opportunity to communicate the HCV-associated risks posed by alcohol consumption and provide options for behavioral change. To reduce alcohol misuse, the U.S. Preventive Services Task Force (USPSTF) recommends screening and behavioral counseling interventions to be used in primary-care settings. Screening tools shown to be effective in eliciting a history of alcohol use from patients include the <u>Alcohol Use Disorders Identification Test (AUDIT)</u> and <u>AUDIT-C</u> (3-item modified version of the 10-item AUDIT).

The following resources from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the National Institutes of Health (NIH) provide more information on alcohol screening and counseling:

SAMHSA: Older Adults and Alcohol Use: Pocket Screening Tools http://store.samhsa.gov/shin/content//SMA02-3621/SMA02-3621.pdf

NIH: Helping Patients Who Drink Too Much: A Clinician's Guide http://pubs.niaaa.nih.gov/publications/Practitioner/CliniciansGuide2005/clinicians guide.htm

SAMHSA: Screening, Brief Intervention, and Referral to Treatment (SBIRT) http://www.integration.samhsa.gov/clinical-practice/SBIRT

NIH: Alcohol and Health: Support and Treatment http://www.niaaa.nih.gov/alcohol-health/support-treatment

Treating Hepatitis C

After providing the patient with an initial diagnosis, you may wish to refer him or her to a specialist. Decisions about starting treatment are based on many factors, such as the genotype of the virus, the condition of the liver, and other health factors. Appropriate medical monitoring and evaluation are very important, as not everyone needs or can benefit from treatment.

Advances in treatment and new medications are being developed for hepatitis C that will increase the number of people who are cured and reduce the length of treatment. For up-to-date information on hepatitis C treatment, please visit:

American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) – Recommendations for Testing, Managing, and Treating Hepatitis C

http://hcvguidelines.org/

Food and Drug Administration (FDA)

http://www.fda.gov/