HCV CAN BE CURED

RETHINK HCV

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Today’s Meeting Goals

- Discover the increasing burden of HCV
- Understand that HCV is a curable disease
- Consider your role in screening, diagnosing, and referring patients

Keypad Instructions

- To use the keypad, simply press the button that corresponds with the option that you wish to choose.
- There is no Enter button; simply press the voting button.
- If you make a mistake, you can correct it by pressing the button that correlates with your response before polling ends.
- Your last selection is the one that counts.
In the past month, how many patients did you screen for HCV using an HCV antibody test?

1. 0
2. 1-5
3. 6-10
4. 11-19
5. 20+

In the past month, for how many patients did you order an HCV RNA test to confirm diagnosis?

1. 0
2. 1-5
3. 6-10
4. 11-19
5. 20+
What percentage of your HCV-diagnosed patients are currently under the care of a specialist?

1. 0%
2. ~25%
3. ~50%
4. ~75%
5. 100%

Do you currently prescribe therapy for HCV?

1. Yes
2. No
What is HCV?
HCV History

- An RNA virus that used to be known as non-A, non-B hepatitis until it was discovered in 1988\(^1\)
- No vaccine available
- First therapy approved in 1991\(^2\)
- Before 2011, HCV treatment could last as long as a year, with cure* (SVR) rates of 40%-50% for the most common genotype in the US\(^3\)
- Since that time, scientific advances have made HCV treatment shorter and more effective
- There are interferon-free treatment options available that have shown cure (SVR) rates of 90% and greater in clinical studies\(^4\)

*Cure, also known as sustained virologic response (SVR), is defined as no detectable HCV in the blood at 12 or more weeks after therapy is complete\(^4,5\)

HCV Treatment Advances Through the Years

- 1991: Interferon approved
- 1998: Ribavirin approved
- 2001: Pegylated interferon approved
- 2011-Present: Direct-acting antiviral agents approved

HCV Genotypes

- 6 HCV genotypes
- Genotypic prevalence varies by geography
- Genotype 1 is the most common in the US and accounts for approximately 79% of HCV infections

Impact of HCV
HCV Is Underdiagnosed and Undertreated

An estimated 3.5 million Americans have chronic HCV.

- It is estimated that 3.5 million Americans have chronic hepatitis C.
- Approximately 9% of infected individuals successfully treated.

Increase in Liver Complications Projected to Continue

- In a study, approximately 45% of untreated HCV patients were projected to develop cirrhosis by 2030.
- HCV is a progressive disease. Patients who develop cirrhosis are at greater risk for developing liver cancer and other liver-related complications.

References:
Liver Complications in HCV Patients Contribute to a Shorter Lifespan

In the US, HCV is the Leading Cause of Liver Transplantation and Liver Cancer

HCV Has a Mortality Rate That Exceeds HIV

**OVERVIEW**

**HCV is a systemic disease that may affect organs other than the liver**

**Extrahepatic Manifestations**

1. Mixed cryoglobulinemia vasculitis
2. Lymphoproliferative disorders
3. Peripheral neuropathy
4. Membranoproliferative glomerulonephritis
5. Insulin resistance
6. Cutaneous manifestations (e.g., lichen planus, porphyria cutanea tarda, palpable purpura)

*Secondary to mixed cryoglobulinemia vasculitis

**associated extrahepatic conditions**

**INCREASED RISK FOR:**

1. Depression
2. Carotid atherosclerosis/atherothrombosis
3. Type 2 diabetes mellitus
4. Hypertension
5. Congestive heart failure
6. Chronic kidney disease
7. End-stage renal disease
8. Kidney cancer
9. Other renal manifestations (e.g., glomerulonephritis, proteinuria)
10. Low bone mineral density (BMD)
11. Rheumatologic manifestations (e.g., polyarthritis, polyarthralgia)
12. Fatigue

**POSSIBLE INCREASED RISK FOR:***

1. Neurologic impairment/disorders
2. Stroke
3. Coronary artery disease/atherosclerotic heart disease

*Secondary to mixed cryoglobulinemia vasculitis

*Conflicting or equivocal data from studies
HCV Can Be Cured

Unlike Some Chronic Conditions, HCV Can Be Cured

MANAGEABLE

Diabetes
Hypertension

CURABLE

HCV
HCV does not integrate into the nuclei of infected cells, while HBV and HIV DNA are incorporated into the nucleus of the cell.

Why Is Cure Possible?


*HBV cccDNA (covalently closed DNA) accumulates in hepatocyte nuclei, acting as a template for viral messenger RNA transcription.
†HIV proviral DNA: integrates into the chromatin of infected cells, acting as the template for the transcription of viral genes.

Cure, also known as sustained virologic response (SVR), is defined as no detectable HCV in the blood at 12 or more weeks after therapy is complete.

What Defines HCV Cure?

- In some instances, HCV treatment does not result in cure, or SVR, because the virus does not reach undetectable levels or because it does not stay undetectable after therapy completion.
- In one study, of those patients who reached SVR, 99% had undetectable levels of HCV RNA more than 4 years after treatment end.
- These patients do not experience viral recurrence and may be considered to be cured.

Cure, or SVR, is associated with improvements in disease complications, such as rates of hepatocellular carcinoma, ascites, hepatic encephalopathy, and variceal bleeding.

SVR is also associated with reduced risk of all-cause mortality.

Give your HCV patients access to treatment and a potential cure.
Currently, what is your primary HCV screening criterion?

1. Elevated liver enzymes
2. Symptoms
3. Behavioral risk factors
4. HIV infection
5. Age cohort
6. I currently do not screen
Limited Success With Risk-Based Screening

- Since 1998, the CDC has recommended screening individuals largely based on behavioral risk factors (e.g., IV drug use, tattoos from unregulated environments)\(^1\)
- Risk-based screening has had limited success, as shown by the large number of undiagnosed individuals\(^1\)
- HCV is also much more prevalent among baby boomers, persons born between 1945–1965, than other age cohorts\(^1\)
- HCV screening guidelines include both risk-based and age-based factors
  - Expand screening to all baby boomers regardless of the presence of risk factors

Baby boomers account for 73% of HCV-related mortality and are at greatest risk for liver cancer and other liver-related complications\(^1\)

CDC, USPSTF, and AASLD Recommend the One-Time Screening of All Baby Boomers, Regardless of Risk Factors\(^1-3\)

Baby boomers: born between 1945 and 1965

~75% OF ALL HCV PATIENTS ARE BABY BOOMERS\(^4\)

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Regardless of Any Symptoms, Screen Patients Who Have Any of These Risk Factors


Screen Whether or Not Symptoms Are Present

• HCV is often asymptomatic
• Elevated liver enzymes are not present in all infected individuals
• USPSTF granted a grade B recommendation for HCV screening
  – Benefits of HCV screening outweigh the risks for appropriate individuals
Which test do you typically use to screen for HCV?

1. Liver enzyme panel
2. Acute hepatitis panel
3. HCV antibody test
4. Liver biopsy
5. Abdominal ultrasound
6. HCV RNA test
7. I currently do not screen for HCV

HCV is screened using a simple blood test to detect the presence of antibodies against HCV.

- A positive antibody test is an indicator of exposure to HCV.
  - Elevated liver enzymes are not present in all infected individuals.

Talk with the patient before screening:

- Explain why he/she should be screened.
- Tell the patient that HCV is a progressive disease.
- Describe the screening process.

Consider selecting a lab’s “reflex-testing” option at the screening step so an HCV RNA test will be run automatically if the antibody test is positive. (CPT CODE 86804)

Enable an EHR flag or standing order as a reminder to screen, diagnose, and refer patients. Such reminders have proven helpful in improving outcomes.

Next Steps After HCV Antibody Test Results

**Antibody Negative**
- Patient not exposed to HCV
- No further action needed, unless exposure suspected in past 6 months
  - If suspected, consider re-testing for HCV antibodies or running an HCV RNA test

**Antibody Positive**
- Patient exposed to HCV
- An HCV RNA test is needed to confirm the chronic HCV diagnosis
  - If the reflex option was ordered for the screening test, the antibody and HCV RNA results will be returned at the same time

**DIAGNOSE**

The next crucial step toward potential cure
Diagnosis Must Be Confirmed

Not everyone exposed to HCV becomes chronically infected
- Approximately 20%-50% of patients clear HCV spontaneously and do not develop a chronic HCV infection.

Only by confirming the diagnosis can you be sure the patient has a chronic infection.

How to Diagnose

To test for a chronic HCV infection, an HCV RNA test is used to detect HCV RNA in the blood.

Talk with your patients before diagnosis:
- Explain to the patient why an HCV RNA test is necessary.
- Describe how the diagnostic test is performed.

Consider selecting a lab’s "reflex-testing" option at the screening step so an HCV RNA test will be run automatically if the antibody test is positive.

(CPT CODE 86804)
**What to Do If HCV RNA Is Not Detected**

- Patient is not chronically infected with HCV
- No further medical evaluation for HCV infection is required
- **Discuss** the results with the patient
  - Tell patient that he/she is not chronically infected, and no further testing or treatment is needed
  - Confirm he/she understands how the virus is spread and the situations in which he/she could be exposed
  - Explain that he/she will always test positive for HCV antibodies

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**What to Do If HCV RNA Is Detected**

- Patient is infected with HCV
- Consider ordering an HCV genotype test (optional)
- Refer patient to an HCV specialist for additional tests and treatment evaluation
- **Discuss** the diagnosis with the patient
  - Tell your patient that he/she is infected with HCV and will be referred to a specialist for more tests and possible treatment
  - Explain that HCV is a progressive disease that can lead to serious complications
  - Emphasize that HCV can be curable, and treatment options are available

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Select billing codes for HCV-related tests

This is a select list of CPT®, HCPCS, and ICD-10 codes that may be used for ordering tests related to screening and diagnosing potential patients with HCV.

<table>
<thead>
<tr>
<th>CPT/HCPCS Codes</th>
<th>ICD-10 Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis C antibody screening, for individual at high risk and other covered indication(s)</td>
<td>Z22.52</td>
</tr>
<tr>
<td>Hepatitis C antibody</td>
<td>Z22.59</td>
</tr>
<tr>
<td>Hepatitis C antibody, confirmatory test (with reflex)</td>
<td>Z22.6</td>
</tr>
<tr>
<td>Collection of venous blood by venipuncture</td>
<td>Z22.6</td>
</tr>
<tr>
<td>Hepatitis C, RNA, direct probe technique (qualitative)</td>
<td>Z22.73</td>
</tr>
<tr>
<td>Hepatitis C, RNA, amplified probe technique (quantitative)</td>
<td>Z22.74</td>
</tr>
<tr>
<td>Hepatitis C, RNA, quantification with reflex to genotype</td>
<td>Z22.75</td>
</tr>
<tr>
<td>HCV genotype test</td>
<td>Z22.76</td>
</tr>
</tbody>
</table>

Use these codes to order the appropriate screening or diagnostic test for your patient.

Use these codes to indicate why you are ordering the HCV test.

Refer to the CPT® Code/Relative Value Search and HCPCS HCV Codes for more information.

FOR SCREENING
FOR DIAGNOSIS
OTHER HCV TESTS
OTHER HCV TESTS ONCE CHRONIC INFECTION IS CONFIRMED

Other HCV tests

Other problems related to lifestyle

Use these codes to indicate why you are ordering the HCV test.

The final link toward a possible cure

Sources:

Use these codes to indicate why you are ordering the HCV test.
When do you typically refer a patient with HCV to a specialist?

1. At the point of diagnosis
2. When the patient starts experiencing symptoms
3. When liver enzymes become elevated
4. When fibrosis is detected
5. I do not currently refer

Historically, treatment has been prioritized for patients with advanced liver disease or those at high risk for disease progression in part because of the benefit versus risk profile of therapies.

However, treatment has been shown to be most effective at early-stage disease. Patients with cirrhosis show a lower response to treatment.

Progression of fibrosis is unpredictable.

A prompt referral is important to ensure the patient is evaluated for treatment by a specialist. Treatment decisions may be made based on several factors including:

- The risks and benefits of treatment
- Patient's disease status compared with treatment tolerability
- Patient motivation

Prompt, Quality Referral Is Crucial

Refer HCV Patients to an HCV Specialist for Treatment Evaluation

- Refer patients immediately, regardless of viral load or liver enzyme levels.\(^1\)
  - Liver damage is possible in the presence of low viral loads and normal ALT or AST levels.\(^1,2\)
  - Disease progression may not be reliably assessed by liver function tests.\(^2\)

Refer HCV Patients to an HCV Specialist for Treatment Evaluation

Patient Follow-Up After Referral

- Between 25% and 50% of referred HCV patients miss their first specialist appointment.\(^3\)
- Many HCV patients do not follow up on their HCV referral for a variety of reasons, such as:
  - Patients’ unwillingness to treat a largely asymptomatic disease
  - Lack of insurance coverage
  - Social rejection and stigmatization

A Quality Referral Can Help Overcome Barriers

What Makes a Quality Referral?

• Confirmed diagnosis with an HCV RNA test
• Referring to a specialist with experience treating HCV
• Arranging the appointment for the patient
• Following up with the patient to ensure he/she attended the appointment

Discuss Referral With Your Patient

• **Explain** why referral is necessary
• **Describe** the liver complications that can arise from delaying treatment
• **Tell** your patient what to expect
• **Make it clear** that therapy may lead to cure
• **Let your patient know** that you are available for questions
HCV Management Has Evolved, Making Cure More Possible for Patients

• HCV screening criteria have been expanded to include screening of all baby boomers, those born between 1945 and 19651-3
• Treatment options have evolved
  • Before 2011, HCV treatment could last as long as a year, with cure rates of 40%-50% for the most common genotype in the US4
  • Since that time, scientific advances have made HCV treatment shorter and more effective
  • There are interferon-free treatment options that have shown cure rates of 90% or greater in clinical studies3
• Rethink HCV: Screen, Diagnose, and Refer


For more HCV resources, register on HCVcanbecured.com to receive:
• Your complete HCV Toolkit
• Educational videos
• Patient discussion guides
• Select CPT®, HCPCS, and ICD-10 codes

Visit HCVcanbecured.com
Prompt, Quality Referral Is Crucial

- Treatment is most effective before the onset of fibrosis.
- Progression of fibrosis is unpredictable, so all patients should be evaluated by a treating specialist.
- Patients with advanced liver damage show a lower response to treatment.
- Referral can lead to cure, reducing the risk of HCV-related morbidity and mortality.

