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Quest Diagnostics™

Spotlight on Health

Hepatitis C Virus

Hepatitis C virus (HCV) infection can now be cured in >90% of people.[1] Identifying and treating those with HCV infection can greatly reduce the need for liver transplantation. It could also reduce the number of deaths from liver failure and liver cancer.

Unfortunately, many people born during 1945 to 1965 (baby boomers) still have not been screened for HCV, though the Centers for Disease Control and Prevention (CDC) has recommended it for several years now. This population accounts for about 75% of HCV-related deaths each year.[2] Thus the low rate of screening in this group reflects a missed opportunity to reduce morbidity and mortality from HCV.

Screening younger people who are at high risk is also important. The CDC has shown that the number of new HCV infections has increased 20% from 2012 to 2013 and 2.5-fold from 2010 to 2013.[1] The largest increase occurred primarily among those aged 20 to 39 years.[1]

In this newsletter, we'll review the new therapies which are accounting for the high cure rate. We'll also look more at screening people who are at high risk for HCV infection.

New Therapies Lead to Higher Cure Rates

Over the last 5 years, targeted therapies called direct-acting antiviral agents (DAAs) have been developed. DAAs interrupt HCV replication by targeting the HCV NS3/4A protease or the NS5A or NS5B genomic regions. DAAs are more specific in their action, more effective, and better tolerated than older therapies. Cure rates have increased from around 45% to >90%.[3] Furthermore, a cure can often be achieved in 12 weeks or less vs the 6 to 12 months that were required with older, interferon-based regimens.[3] For these reasons, DAAs are now the standard of care for treatment of HCV infection.

The higher cure rates have also led to a change in the way patients are selected for treatment. Guidelines now recommend treating everyone with chronic HCV.[4] The only exceptions are people who have a short life expectancy that can't be increased by HCV treatment or liver transplantation. Guidelines no longer support prioritizing patients for treatment based on "greatest need."

The good news is that HCV can be cured. The challenge is that before people infected with HCV can be treated, they must be identified and diagnosed. This is a particularly urgent need in populations at increased risk.

HCV Treatment Selection

Selection of an HCV treatment regimen begins with determination of the patient's viral genotype. Current guidelines from the American Association for the Study of Liver Diseases outline DAA-based combinations for the various genotypes (1a, 1b, 2, 3, 4, and 5 or 6).[4] Other variables that may be considered include previous treatment, presence or absence of cirrhosis, presence or absence of the *NS3* Q80K polymorphism, and presence or absence of *NS5A* or *NS5B* resistance-associated variants. Co-infection with HIV, renal disease, and previous liver transplantation are also factors to be considered.

Two Populations at Increased Risk

Baby Boomers

More than 75% of Americans infected with HCV were born between 1945 and 1965.[2] Most were infected decades ago before HCV was even identified and the dangers of HCV were well known. Most don't know they are infected and about 35% of them already have advanced liver disease.[2]

As baby boomers age, the incidence of liver disease and deaths from HCV infection is expected to rise rapidly. Therefore in 2012, the CDC recommended that all baby boomers be tested once for HCV. This initiative is predicted to detect about 800,000 infected people. Getting them into DAA treatment could save about 120,000 lives and prevent many cases of liver cancer and liver transplantation.[5] The United States Preventive Services Task Force and the American Association for the Study of Liver Diseases also recommend screening people in this group. Medicare and Medicaid cover one-time HCV screening for baby boomers.

Injection Drug Users

Acute HCV infection most commonly occurs in young people who have a history of injection drug use and use of opioid drugs such as oxycodone. These people are predominantly white and live in nonurban areas.

About one-third of injection drug users aged 18 to 30 years are infected with HCV.[6] Older and previous users have an even higher prevalence: 70% to 90%.[6] Injection drug use is now the most common mode of HCV transmission in the United States and thus the most important risk factor.

Recommendations for HCV Screening

In addition to baby boomers and injection drug users, other groups of people at increased risk of HCV should be screened. This includes those who[4]:

- Have a history of using illegal drugs intranasally
- Are or were ever on long-term hemodialysis
- Got a tattoo in an unregulated setting
- Are healthcare workers who were accidentally exposed to HCV-infected blood via needlestick, etc.
- Were born to an HCV-infected mother
- Received blood transfusions or organ transplants before 1992
- Received clotting factor concentrates made before 1987
- Received blood or organs from a donor who later tested positive for HCV
- Were ever in jail or prison
- Are infected with HIV
- Have unexplained chronic liver disease and/or chronic hepatitis including elevated alanine aminotransferase levels

Additional Information

You can find more information about HCV at these Web sites:

- Centers for Disease Control and Prevention: cdc.gov/hepatitis/hcv/
- American Association for the Study of Liver Diseases: hcvguidelines.org/full-report-view
- National Viral Hepatitis Roundtable: nvhr.org/

How the Laboratory Can Help

The laboratory plays a critical role in screening and diagnosis, guiding treatment selection, and monitoring response to treatment.

- HCV antibody tests are used to screen for infection. All positive tests need to be confirmed by a viral RNA testing.
- RNA tests are used to confirm active infection, measure viral load, and assess treatment response.
- Genotyping tests are necessary to help guide choice of treatment and to predict likelihood of therapeutic response.
- Tests for drug resistance-associated variants in the *NS3*, *NS5A*, and *NS5B* genes are used in people with HCV genotype 1 or 3. Detection of these variants can help with treatment selection.
- Routine blood tests are used to assess liver damage and to monitor response to therapy.

You can find more information about these tests and their use for diagnosis and management of HCV infection here. You can also visit the Quest Diagnostics Test Center for more information.

References

1. Centers for Disease Control and Prevention. Surveillance for Viral Hepatitis – United States, 2013. cdc.gov/hepatitis/statistics/2013surveillance/commentary.htm. Updated October 19, 2015. Accessed March 15, 2016.
2. National Viral Hepatitis Roundtable. The urgency of hepatitis C screening for baby boomers. nvhr.org/sites/default/files/.users/u27/NVHR%20Urgency%20Fact%20Sheet_One%20Pager%20Final.pdf. Accessed March 15, 2016.
3. Lam BP, Jeffers T, Younoszai Z, Fazel Y, Younossi ZM. The changing landscape of hepatitis C virus therapy: focus on interferon-free treatment. *Therap Adv Gastroenterol*. 2015;8:298-312.
4. American Association for the Study of Liver Disease. HCV guidance: recommendations for testing, managing, and treating hepatitis C. hcvguidelines.org/full-report-view. Published March 2016. Accessed March 15, 2016.
5. Centers for Disease Control and Prevention. Viral hepatitis–CDC recommendations for specific populations and settings. cdc.gov/hepatitis/populations/1945-1965.htm. Updated May 31, 2015. Accessed March 15, 2016.
6. Centers for Disease Control and Prevention. Hepatitis C FAQs for health professionals. cdc.gov/hepatitis/hcv/hcvfaq.htm. Updated March 11, 2016. Accessed March 15, 2016.