Should More People Be Treated for Hepatitis B?

Antiviral treatment for HBV lowers the risk for liver cancer and other complications and can prevent transmission.

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Although current U.S. and global guidelines say that many people with chronic hepatitis B do not need treatment, a growing number of clinicians and advocates are calling for simplified recommendations and expanded eligibility to prevent disease progression and, ultimately, to eliminate hepatitis B as a public health threat.

Around 2 million people in the United States and some 300 million people worldwide are living with chronic hepatitis B. Most people who acquire hepatitis B virus (HBV) as adults naturally clear the infection, but about 10% develop chronic infection; for those infected as infants, these proportions are reversed. Many people with chronic hepatitis B have no symptoms during early stages, but over time, it can lead to serious complications, including cirrhosis and liver cancer.

Hepatitis B can be treated with antivirals, including Viread (tenofovir disoproxil fumarate), Vemlidy (tenofovir alafenamide) and Baraclude (entecavir), sometimes used with pegylated interferon. These medications can suppress viral replication indefinitely, but they seldom lead to a cure. Thus, hepatitis B treatment is more like antiretroviral therapy for HIV, which must be continued for life, rather than direct-acting antivirals for hepatitis C virus (HCV), which usually produce a cure in two or three months.

While treatment is recommended for everyone diagnosed with HIV, and HCV treatment is advised for anyone with active viral replication, hepatitis B treatment guidelines are more complicated. Antiviral therapy can slow or halt disease progression and lower the risk for cirrhosis and liver cancer, but some people with chronic hepatitis B remain healthy for many years—or for a lifetime—without treatment.

The American Association for the Study of Liver Diseases (AASLD) hepatitis B practice guidelines recommend treatment for people with so-called immune-active chronic hepatitis B, meaning they have a viral load above 2,000 if HBeAg negative or above 20,000 if HBeAg positive, an elevated ALT liver enzyme level and at least moderate liver inflammation or fibrosis. People with advanced fibrosis or cirrhosis, older individuals, those with a family history of cirrhosis or liver cancer and others at higher risk for complications should be treated even if HBV DNA or ALT levels

are below these thresholds.

Treatment is generally not recommended for people with inactive chronic hepatitis B, meaning a very low viral load, normal ALT and little or no evidence of liver inflammation or fibrosis. People with so-called immune-tolerant chronic hepatitis B, who have a high viral load but normal ALT and minimal liver inflammation or fibrosis, can also defer treatment. However, both groups should undergo regular monitoring—including blood tests, noninvasive imaging and sometimes liver biopsies—to see whether their condition changes.

But some experts think recommendations should be simplified and more people with chronic hepatitis B should be eligible for treatment. One recent trial found that people with a high HBV viral load but minimally elevated ALT benefitted from antiviral therapy, while other studies have shown that even a low-level viral load raises the risk for liver cancer.

"[E]xisting guidelines are confusing, ambiguous and leave many patients with HBV infection in a 'grey' area where there is no clear guidance on how to manage them," according to Douglas Dieterich, MD, of the Icahn School of Medicine at Mount Sinai, and colleagues. Writing in GastroHep Advances, they proposed an approach that assumes all patients with chronic hepatitis B need to be treated and then exclude those who do not qualify, rather than the reverse. "Recommendations that are difficult to implement or ambiguous recommendations are barriers for treatment," they wrote. "These challenges lead to the exacerbation and perpetuation of health care disparities in populations [that] often already experience societal inequalities. The simplification of guidelines is critical to health equity."

Even many people who do meet current eligibility criteria—including those with cirrhosis—are not getting the treatment they need. Requiring numerous tests reduces treatment accessibility, especially in low-resource settings, and making guidelines simpler would open up treatment to primary care providers and other nonspecialists. The main drawbacks of expanded eligibility are increased cost and overtreatment of people who don't need it, but HBV antivirals are generally safe and well-tolerated, and generic versions are inexpensive.

At IDWeek 2023, Su Wang, MD, MPH, of Cooperman Barnabas Medical Center, called for a "paradigm shift," arguing that offering treatment more broadly would increase patient engagement in decision-making instead of relying on eligibility algorithms. In addition to liver cancer, chronic hepatitis B has been associated with other malignancies, including stomach, colorectal and pancreatic cancer, according to Wang. What's more, persistent HBV infection can lead to T-cell exhaustion and impaired immune response.

Another potential benefit of expanded eligibility is treatment as prevention. Hepatitis B can be prevented with a vaccine, but vaccination coverage is inadequate. Although this has not been studied extensively, as it has been for HIV, people with an undetectable HBV viral load are unlikely to transmit the virus via sex, shared injection equipment or household contact, and antiviral therapy has been shown to prevent mother-to-child transmission. But under existing guidelines, some people with detectable HBV are not considered eligible for treatment.

“Expanding and facilitating treatment indications, including treatment as a public health intervention, could help control the spread of the HBV pandemic,” Jose Perez-Molina, MD, PhD, of Hospital Universitario Ramón y Cajal in Madrid, and colleagues wrote in a recent perspective article in the journal Pathogens.

The AASLD guidelines were last updated in 2018, European Association for the Study of the Liver (EASL) guidelines were updated in 2017 and World Health Organization (WHO) guidelines date back to 2015. The WHO guidelines, which are used in low- and middle-income countries, rely more on simple noninvasive tests to determine treatment eligibility.

AASLD, EASL and WHO are currently working on updates to their guidelines. Chinese experts recently updated their national guidelines to expand treatment coverage, recommending antiviral therapy for more people who do not meet traditional HBV DNA or ALT thresholds.

In a recent commentary in The Lancet Gastroenterology & Hepatology, Wang, Chari Cohen, DrPH, MPH, president of the Hepatitis B Foundation, and colleagues made the case that people living with hepatitis B should have a voice in creating new treatment guidelines.

“Guidelines for treating and managing hepatitis B need to be written with a sensitivity to the practical issues and social-emotional considerations faced by people living with hepatitis B,” Cohen said in a news release. “Additionally, the new guidelines need to be relevant to the real-life conditions that exist in a range of countries around the world, especially those where hepatitis B is most prevalent, such as Africa and Asia.”

HBV DNA testing is a key element of current treatment eligibility assessment, but many people do not have access to viral load tests or to HBeAg testing, liver biopsies or care provided by liver specialists.

“People with HBV know the direct impacts and challenges of accessing care,” the authors wrote. “Many aspects of HBV management require shared decision-making, and both sides of this sharing process must be represented for guidelines to meaningfully reflect optimal care. It is crucial to consider the impacts, and patient preferences, to develop practical treatment guidelines that are relevant, applicable, and realistic to the patient community.”

“HBV is both an infectious and an oncogenic disease and should be framed as such,” they continued. “This would broaden the treatment framework to include treatment as prevention of both virus transmission and liver cancer, addressing the two largest concerns for people with HBV: dying of liver cancer and infecting loved ones. Treatment as prevention can be transformational for people living with HBV, ameliorating these fears, and combating widespread stigma.”

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