

What Stands in the Way of Making Hepatitis B and C Rare Diseases in the United States?

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Hepatitis B virus (HBV) and hepatitis C virus (HCV) account for most of the world's chronic viral hepatitis, killing more people every year than road traffic injuries, HIV/AIDS, or diabetes (1). Despite accounting for massive suffering and early death, viral hepatitis garners relatively little national or international attention. Whereas deaths from malaria, tuberculosis, and HIV/AIDS have decreased since the early 2000s, deaths attributable to viral hepatitis continue to rise (1). Hepatitis B and C kill about 20 000 people every year in the United States and more than 1 million worldwide (2, 3).

These deaths could be averted. The world has the tools to prevent hepatitis B and cure hepatitis C. Hepatitis B vaccine conveys 95% immunity; new direct-acting antiviral drugs can eliminate HCV infection in more than 90% of chronically infected patients (4, 5). Taken together, these advances have encouraged global momentum for action against viral hepatitis. In May 2016, the World Health Assembly will consider a resolution setting a broad target of 90% reduction in incidence of viral hepatitis and 65% reduction in its mortality by 2030. These are global targets, however. The disease burden and epidemiologic features of hepatitis B and C in individual countries should determine the national elimination strategy.

The United States has both an opportunity and a responsibility to be part of the global action against viral hepatitis. Toward that end, the Centers for Disease Control and Prevention (CDC), with support from the Department of Health and Human Services, commissioned 2 reports on elimination of hepatitis B and C from the National Academies of Sciences, Engineering, and Medicine. The first report, released in April 2016, considered the feasibility of eliminating the public health problems of hepatitis B and C (6). (In the past, the term *disease elimination* has been used to mean complete termination of incident infections in a population. *Elimination of a public health problem* can be a less absolute goal. The Academies' committee defined a *public health problem* as a disease that, by virtue of transmission, morbidity, or mortality, commands attention as a major threat to the health of the community.) The committee concluded that eliminating the public health problem of both diseases is feasible in the United States, but there are significant barriers to meeting this goal.

The HBV vaccine makes it possible to interrupt horizontal transmission of the virus, but ending transmission would require immunization of every susceptible person in a population. Vertical transmission can be prevented with proper prenatal screening to identify

pregnant women with hepatitis B and plan for prompt vaccination and immune prophylaxis of their newborns. The risk for prophylaxis failure increases among babies born to highly viremic women, however, and it is unclear what measures might prevent such cases (7, 8). The medical management of chronic hepatitis B has advanced to the point that no one in the United States should die of it, but there is no cure and better therapies are needed. The virus is also endemic abroad; U.S. support for HBV vaccination in hepatitis B–endemic countries in Asia and sub-Saharan Africa, especially the birth-dose coverage crucial for prevention of perinatal transmission, would be a wise investment in reducing the future burden of hepatitis B in the United States.

Although there is no vaccine for HCV, new direct-acting antiviral treatments can cure the infection in most chronically infected patients. This development makes a strategy of treating infected persons as a way to prevent transmission an option, but the costs of curative hepatitis C drugs have made this strategy impractical. Despite their high prices, direct-acting agents are still cost-effective, especially for patients with genotype 1 HCV. That is, even at their high prices, the treatments' likely benefits to society outweigh the costs. However, given the high cost and anticipated demand for these drugs, many private insurers and three quarters of states' Medicaid programs limit access to direct-acting antivirals to patients whose advanced liver disease puts them at imminent risk for death (9). So despite the impressive effectiveness of direct-acting agents, only about 1 in 10 chronically infected people receives them. Because eliminating hepatitis C would require near universal treatment, current drug pricing and policies present major barriers.

Even if universal treatment were possible, most people chronically infected with HBV and HCV are unaware of their condition. Reducing transmission and increasing treatment require both better screening and public health surveillance systems that can identify and control potential outbreaks early. The CDC currently funds comprehensive viral hepatitis surveillance in only 7 jurisdictions, 5 states, and 2 cities (10). In most of the country, limited surveillance systems impede understanding of the true scope of the epidemic and make it impossible to design effective disease control strategies.

Limitations with disease surveillance, like all barriers to elimination of hepatitis B and C, are consequences of a more basic problem—that viral hepatitis is simply not a public priority in the United States. This could change. Attitudes toward disease can shift rapidly, and there is room for creative solutions to the

problems discussed in the recent Academies' report. Still, although hepatitis B and C may be entirely tractable targets, elimination in the United States is not likely to occur without changes to policy and directed research. The committee's next report will outline how such change might work and what actions might hasten the elimination of hepatitis B and C as major threats to the health of the nation, a goal that—while ambitious and immensely challenging—is within reach.

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