

ADVANCES IN HEPATOLOGY

Current Developments in the Treatment of Hepatitis and Hepatobiliary Disease

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Eliminating Hepatitis C Virus Infection in Indigent Patients



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G&H What is the current goal for eliminating hepatitis C virus, and how close is the United States to achieving it?

ET The World Health Organization (WHO) has established the goal of eliminating hepatitis C virus (HCV) globally by 2030. This means minimizing spread of the virus as well as significantly minimizing morbidity and mortality. Elimination differs from eradication, which refers to removing the virus completely from the human population. The WHO is seeking to achieve functional improvement in the current burden of this disease in the global population.

To accomplish its goal of eliminating HCV by 2030, the WHO has established specific targets, including an 80% reduction in new chronic infections and a 65% reduction in mortality from levels based on epidemiologic data from 2015. Since these targets were announced, it has become clear that the United States is lagging behind many other countries in its elimination efforts.

G&H What are the most significant challenges of eliminating HCV?

ET One of the specific challenges that the United States is facing is the opioid epidemic, in which individuals are using injectable opioids and spreading HCV. Research has shown that some injection drug users are superspreaders who can transmit HCV to 20 additional individuals through shared needle use. This is a significant problem that is causing the virus to continue to spread.

Additionally, given that many patients do not experience overt symptoms when they become infected, many

recently infected individuals are not aware that they are infected. This makes it difficult to identify infected individuals to help eliminate the virus.

In general, in the United States, HCV-infected individuals tend to be low income, enrolled in Medicaid, incarcerated, and/or indigent (eg, homeless, jobless, and undocumented), adding other hurdles to elimination.

G&H What proportion of HCV-infected patients are indigent?

ET In the past, HCV was only treated by interferon-containing regimens, which were very long and expensive and caused many side effects. Now, many more patients can be treated with the current HCV therapies, which are oral, extremely effective, and very safe. Given that these therapies have been available for more than 5 years now, many of the patients with HCV who were already in medical care have been treated. The patients who are left are those outside of standard medical care and uninsured, who are unaware that they have HCV and/or who do not have the resources for treatment, or patients who are substance abusers. Thus, a large proportion of the current HCV-infected population is indigent because the patients who had resources have already been identified and treated.

G&H What are the challenges associated with HCV diagnosis and screening?

ET There is still no point-of-care RNA test to diagnose people on site rapidly to facilitate test-and-treat approaches to curing HCV infection. In contrast, tests

are now available that can detect viral antigens or viral nucleic acid for SARS-CoV-2 in patient samples within 20 to 40 minutes. That technology is not yet readily available with approval from the US Food and Drug Administration for HCV. Typically, providers perform an antibody test for HCV first. If that test is positive, providers then have to reflex the patient sample to an RNA test to determine whether the patient currently has an acute or chronic HCV infection. This delay in diagnosis is also contributing to the difficulties of eliminating HCV.

The test-and-treat model has been very effective for HIV, but no good test-and-treat models are yet available for HCV. Unfortunately, HCV treatment is also a little more complicated than HIV treatment. For HCV, it is important to know the patient's stage of liver disease to

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help guide treatment, but evaluation of liver disease takes time. Groups are starting to use new modalities for assessing liver disease, such as portable transient elastography machines. Another challenge involves treating patients who are coinfecting with hepatitis B virus (HBV). It is important that patients be screened for HBV before treatment for HCV can be initiated.

G&H How are individual states trying to treat chronic HCV and limit new infections, particularly in patients who are indigent?

ET The landscape of HCV treatment in each state can be very different. One of the challenges for achieving elimination of HCV is that each state has its own policies that determine how effective an HCV elimination program will be. Nine states account for more than half of HCV infections in the entire country. Thus, focusing on eliminating HCV in those states would have a large impact on the rest of the country.

The states that are able to address HCV effectively have programs that support indigent HCV-infected individuals, who are the most difficult patients to reach. As noted, this population includes people who are homeless, jobless, and undocumented. Each of those categories presents hurdles for the health care system. Effective, all-oral therapies are available for HCV with cure rates of 98% to 99%. However, these drugs can cost tens of thousands of dollars, making treatment challenging to obtain for patients who are indigent, even with the help of patient assistance programs supported by pharmaceutical companies.

Many HCV-infected patients are Medicaid enrollees, but unfortunately, several states still have not expanded Medicaid. Achieving HCV elimination in these states tends to be particularly difficult because of a lack of funds to help treat patients who are indigent. Some states are doing a good job of addressing this problem. Several states have adopted what is often referred to as a Netflix-type treatment model, in which the state buys a bulk quantity of a drug to treat its patient population. That drug is then distributed, but cost is not an issue because the state has already paid for it. This treatment model is being used in Louisiana, Washington, Michigan, and Missouri.

Louisiana was the first state that implemented this model. It partnered with Gilead Sciences and found a pricing scheme that worked for both the state and the pharmaceutical company. When the program started in 2018, it moved quickly and was effective. However, the diversion of resources to address the COVID-19 pandemic significantly halted the ability to successfully employ such a program. As we move through the pandemic, these types of treatment models are starting up again and demonstrating success.

Interestingly, Texas recently put out a call for pharmaceutical makers of HCV drugs to provide the state with a Netflix-type payer model. However, Texas is not a Medicaid expansion state. Thus, it appears that Medicaid expansion is not necessary to establish a Netflix-type model as a treatment approach, which is exciting news.

G&H How are states attempting to address the opioid epidemic to help eliminate HCV?

ET One of the most effective interventions involves syringe services programs, which provide clean needles to injection drug users, thereby limiting the spread of HCV through used, dirty needles. States that have these programs are more likely to achieve elimination of HCV because they can minimize spread of the virus. Some states have hundreds of syringe services programs, whereas other states only have a handful. Many states, including Florida, do not have enough funding earmarked to support these

programs. Departments of health may have viral hepatitis programs, but they typically are not well funded or are overburdened with other outbreaks, including those involving hepatitis A virus.

G&H How is elimination of HCV being targeted in incarcerated individuals?

ET A large proportion of individuals in jails and prisons are infected with HCV, and the virus spreads in these settings because of tattooing practices and other behaviors. Appropriate resources and programs are needed to treat these patients successfully. An example is state-specific legislative policies that support opt-out HCV testing. Most states did this for HIV, meaning that patients were tested for HIV unless they opted out; thus, testing could be implemented effectively. However, many states do not currently have HCV opt-out testing policies. One of the considerations is that if a state enacts this policy, it will have to test all of its prisoners and will likely find that many are infected with HCV. Unfortunately, there may not be enough money in the budget of the state's department of health to treat all of those prisoners. This is where a Netflix-type model would support effective interventions.

G&H What other measures are being used to try to facilitate elimination of HCV?

ET Through patient assistance programs, some pharmaceutical companies are offering free HCV drugs to certain patients if they meet the criteria for financial eligibility. However, those programs have other criteria as well. For instance, patient assistance programs are not used for

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undocumented individuals, and there are a significant number of undocumented individuals in the United States who have HCV. Thus, indigent patients are not always able to leverage this type of support.

Other state services require individuals to have an address. For example, many hospitals that care for indigent patients require them to have a physical address.

Therefore, if an individual is homeless, it can be difficult for him or her to obtain assistance from indigent care facilities. That can be addressed by living in a shelter, but some infected individuals do not want to live in shelters. Thus, there are populations of HCV-infected people who do not receive any help in obtaining treatment even if they have advanced liver disease.

G&H What have studies found regarding the treatment of HCV in patients who are indigent?

ET Several studies have demonstrated successful treatment of indigent patients, including active drug users and homeless individuals. All of the HCV treatment regimens, whether for 8 or 12 weeks, are equally effective in patients who are indigent; however, efforts are still being undertaken to further shorten treatment duration, which would be especially beneficial to indigent populations. A new treatment model, MINMON, features minimal monitoring of treatment. Patients are given the drug when appropriate and are tested at the end of treatment to make sure that they are cured of the disease with minimal additional monitoring required during therapy. This model has been demonstrated to be very effective.

G&H What else can help facilitate elimination of HCV, particularly in indigent patients?

ET It should be noted that some patients can be successfully treated for HCV by nonspecialists such as nurse practitioners, physician assistants, and family physicians. The safety profiles of the current HCV drugs and their simple treatment regimens allow for nonspecialists to treat HCV-infected patients who are relatively healthy and have no signs of liver disease, especially coinfection with HBV. The medical community should increase efforts to support those providers in being able to successfully treat these HCV-infected patients. Specialists will still be needed for patients who have documented advanced liver disease and/or HBV coinfection.

G&H Are there any special considerations that should be kept in mind when managing HCV-infected patients who are indigent?

ET For individuals who are homeless, it is important to make sure that they have a secure place to store their medication so that they can have continued access to the medication over the treatment period. Some facilities offer secure lockers for patients to store their medication as opposed to carrying it around with them on the streets.

Patients who are undocumented tend to be the most difficult to treat because they receive essentially no state or

federal support. These patients will need additional assistance for HCV treatment either by moving into a shelter or receiving some type of income or support that allows them to access resources from the health care system.

Disclosures

Dr Thomas receives grant funding from Gilead Sciences and is on advisory boards for AbbVie and Gilead Sciences.

Suggested Reading

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