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EDITORIAL

The national hepatitis C elimination program—AASLD's coalition and call to action

A 64-year-old woman presented to the liver clinic. She had known of her diagnosis of chronic hepatitis C for "years" but had not been treated owing to treatment restrictions in the states where she had lived and periods of being uninsured. At evaluation, she had cirrhosis, and unfortunately, imaging showed several liver masses, consistent with multifocal hepatocellular carcinoma (HCC), beyond the criteria eligible for liver transplantation. In the months that followed, she was cured of her hepatitis C virus (HCV) infection with direct-acting antivirals (DAAs). Yet, her life will almost certainly be shortened by having been infected with HCV and we are left knowing that this could have been prevented if only she had been treated years earlier. Her journey highlights the urgent and critical importance of identifying, relinking, and treating those living with HCV.

Global progress to HCV elimination by 2030 is not on track in many countries,[1] including the United States. However, countries with fewer resources (eg, Georgia and Egypt) that have implemented plans for universal HCV screening and treatment are on track, highlighting the importance of national policies in achieving elimination goals. Now, the United States has a bold plan to achieve elimination with a "National HCV Elimination Program" proposed in the fiscal year 2024 White House budget. Finally, the United States, a giant of HCV research and discovery, will step forward with action to prevent any further loss of life due to HCV and to halt the rising health care costs related to HCV and its complications if Congress adopts this plan. In this context, the American Association for the Study of Liver Diseases (AASLD) is reaching out to its members, its collaborators, and its partners in clinical care, public health, research, education, and advocacy to take action and support this transformative initiative.

Thousands of Americans succumb to chronic HCV annually in the United States, and rates of acute HCV are rising coincident with the ongoing opioid epidemic.[2] And yet, an all-oral curative therapy has been available since 2016, is easily tolerated, and cures almost 100% of patients in 8–12 weeks.[3] Treatment with DAAs reduces the risk of transmission to others, a critical component of prevention of new infections. Importantly, HCV cure is associated with improved liver-related outcomes—lower rates of cirrhosis, liver decompensation, liver cancer, and the need for liver transplantation. Less appreciated but relevant is the association of HCV infection with a range of extrahepatic manifestations including mixed cryoglobulinemia, type 2 diabetes mellitus, chronic kidney disease, and others.[4] Cure of HCV is associated with reduced rates of these complications. Finally, DAA treatment is also an effective cancer-prevention strategy. Curing HCV with DAAs can reduce the risk of not only liver cancer but also non-hepatocellular malignancies such as selected types of B-cell non-Hodgkin lymphoma.[4,5] These benefits provide the rationale for identifying and treating every person living with HCV. Modeling of the National Hepatitis C Elimination Program shows that within 5 years of implementation, 92.5% of all persons with HCV will be diagnosed and 89.6% of those with HCV infection will be cured. Over 10 years, compared with the status quo, this initiative will avert 20,000 cases of HCC, 49,100 cases of diabetes, and 25,000 cases of chronic kidney disease. With this disease prevention, the initiative will avert 24,000 deaths adding 220,000 life-years. These benefits in improved health will save $18.1 billion in direct health care spending, of which $13.3 billion would accrue to the federal government. Over 20 years, the health benefits would increase by more than 2-fold and cost savings by 3-fold.[6]

The COVID-19 pandemic significantly disrupted HCV care delivery in the United States, leading to marked reductions in testing and treatment, particularly during the pandemic's early phase.[7] Yet as we recover from these initial setbacks, there is an opportunity to learn from the public health response to the pandemic to reimagine what is possible in addressing HCV with sufficient resources and resolve. The rapidity with which COVID-19 point-of-care tests became available

Abbreviations: AASLD, American Association for the Study of Liver Diseases; APP, advanced practice provider; DAAs, direct acting antivirals; ECHO, extension for community healthcare outcomes; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; PCP, primary care provider.

and widely used, surveillance dashboards were built, and novel therapeutics and vaccines were developed and distributed was unprecedented. We need to leverage the medical innovations and public health infrastructure established to address COVID-19 to assist in HCV elimination. Indeed, the success of the SARS CoV-2 vaccine in addressing the pandemic highlights the critical importance of HCV vaccine development in achieving elimination, with a preventative vaccine being the surest means of reducing new HCV infections.

What is the contribution of the AASLD and specialists in the National Hepatitis C Elimination Program? Multiple opportunities are available—as capacity builders, educators, treatment givers, advocacy champions, and researchers (Figure 1). Specialists will need to be engaged in each pillar in the National Hepatitis C Elimination Program for success to be achieved. Elimination of this lethal disease in the United States is within reach, but a concerted response from specialists, primary care providers, and public health workers will be required to achieve elimination.

As proposed by the White House, the first pillar of the national program is to accelerate the availability of point-of-care HCV diagnostic tests, as they are widely available in other countries, with the goal of creating a "test and treat" program, particularly in communities of high HCV burden including justice-involved populations, individuals using injection drugs, and those using emergency department services. Our community of HCV experts can perform validation studies on these new diagnostics overseeing the broad implementation of testing programs. Further, as the US Preventive Services Task Force recommends testing of all adults at least once, we can advocate for the designation of HCV testing as a metric through the Centers for Medicare & Medicaid Services. Indeed, given the recent Centers for Disease Control and Prevention recommendation to test all adults for hepatitis B virus (HBV), it is time to make one-time

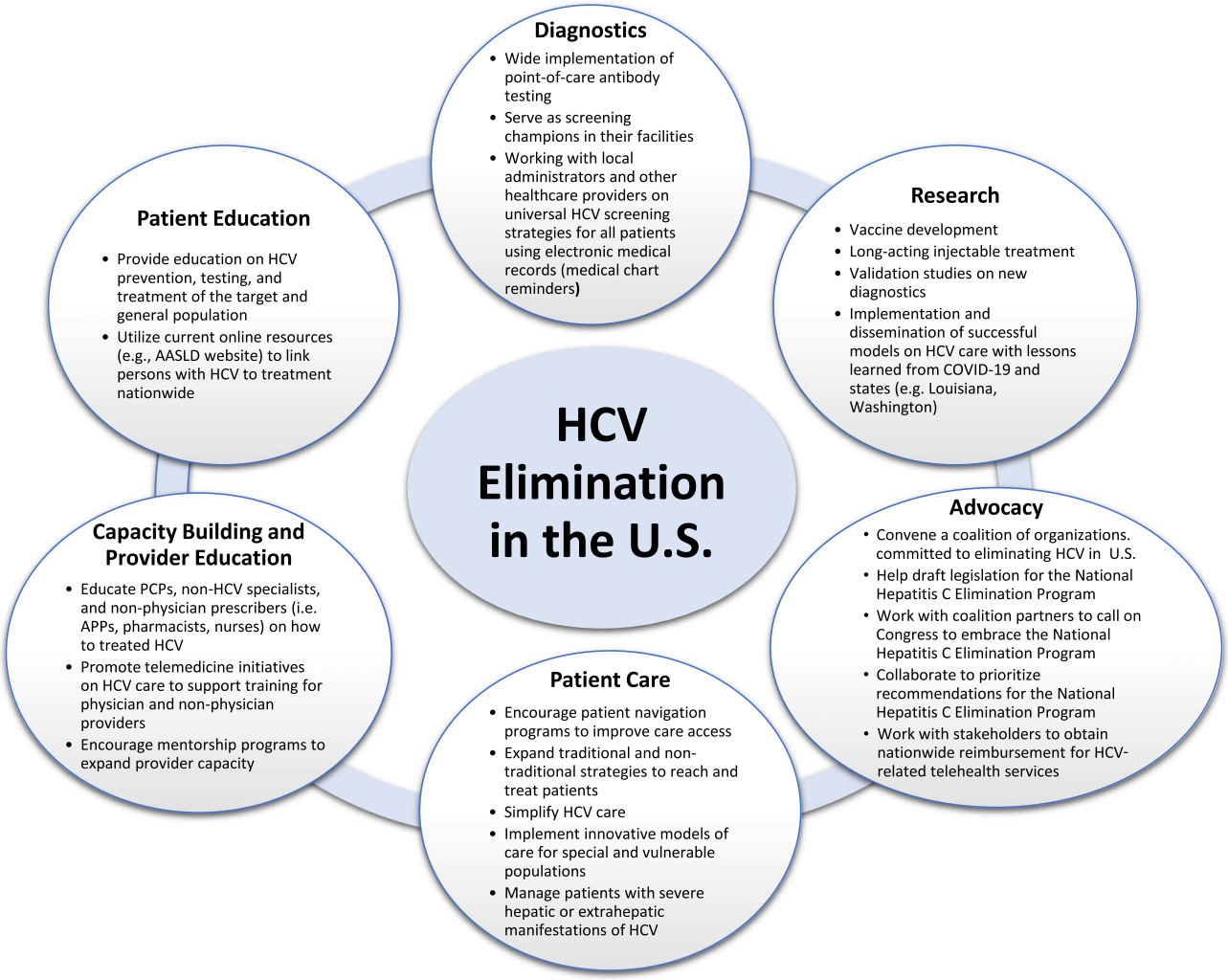

FIGURE 1 Role of hepatologists and other HCV providers in the National HCV Elimination Plan in the United States. Abbreviations: AASLD, American Association for the Study of Liver Diseases; APP, advanced practice provider; PCPs, primary care providers.

testing for hepatitis B virus and HCV among adults a practice norm.

The second pillar of the national program is to make DAA treatment available to all in the United States. An important impediment to the universal treatment of patients with chronic HCV infection is the cost of DAA therapies. We agree with the strategy proposed in the HCV Elimination Program of creating a national subscription model,[8] providing copay assistance to Medicare beneficiaries, and strongly encouraging private insurers to increase coverage and limit out-of-pocket costs. AASLD can support the federal government in the negotiation with manufacturers to purchase DAA therapy at the lowest per-patient cost possible. Removal of all DAA restrictions (eg, prior authorizations, genotype or fibrosis requirements, confirmation of patient adherence, and documentation of substance or alcohol abstinence) should be removed. Our HCV specialists can share their local experiences with other health care professionals in the implementation of treatment programs, including the development of simplified treatment protocols, and management support for difficult-to-treat patients like those with multiple HCV treatment failures, decompensated cirrhosis, liver or solid organ transplant, cancer, severe comorbidities, or extrahepatic manifestations of HCV. Our specialists will continue to manage those for whom DAA therapy is not recommended and provide management of chronic liver disease and surveillance for HCC before and after cure.

The third and final pillar of the national program involves building the public health capacity to reach and treat all people living with HCV. To reach patients where they are, the program will support the decentralization of HCV testing and treatment. Thus, front-line providers and community-based organizations, particularly those that serve vulnerable populations, will be essential to the program's success. Hepatologists and other HCV specialists are critical to training and supporting these clinicians and community partners. This role as educators and capacity builders is not new to us. The AASLD-IDSA Hepatitis C Guidance[3] has provided simplified models of HCV treatment to make prescribing DAAs more accessible to nonspecialists, HCV experts throughout the United States have started HCV Extension for Community Healthcare Outcomes (ECHO) or similar programs aimed at building front-line provider capacity to treat HCV,[9] and specialists have contributed to a variety of successful innovative models of HCV microelimination.[10] However, the national program will require us to scale up our education aimed at clinicians of all types who are new to HCV management, establish new multidisciplinary partnerships, and think creatively to facilitate innovative elimination strategies. This is a challenge that we embrace with enthusiasm. We bring decades of experience managing the devastating complications of HCV and treating patients with suboptimal and poorly tolerated medications before the advent of all oral DAAs, and we have long anticipated this opportunity to eliminate HCV as a public health threat. Yet, we also need to bring humility —we have much to learn from our colleagues who regularly provide medical care to individuals who are uninsured, justice-involved, and using illicit drugs, our patients who have experienced medical stigma in our health care facilities, and the organizations with long-standing experience building community trust. It is in this spirit that we will seek to foster collaborative partnerships with HCV champions in these communities.

In summary, while specialists have been at the forefront of HCV management for decades, the future of HCV elimination lies in a broad coalition of specialists, primary care providers, community workers, and public health experts. As we look to bring diagnosis and treatment to every person affected by HCV in the United States, the AASLD is leading a broad coalition with the goals of heightening awareness, building capacity for care, and advocating for Congress to authorize and fund the plan. The diversity of this coalition reflects the recognized importance of HCV in both liver-related and nonliver-related morbidity and mortality as well as the urgency of undertaking HCV elimination to prevent the future burden of disease and health care costs.

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