Hepatitis C Virus Prevention, Care, and Treatment: From Policy to Practice

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The prevention of hepatitis C virus (HCV) infection and associated health conditions (eg, cirrhosis and hepatocellular carcinoma) is a public health priority in the United States. Hepatitis C virus–related morbidity and mortality is increasing at a time when the advent of highly effective therapies greatly increases opportunities to prevent HCV transmission and disease. In 2010, the Institute of Medicine recommended that national action be taken to address this “underappreciated health concern for the nation.” In response, in 2011, the US Department of Health and Human Services (HHS) published a viral hepatitis action plan that guides response to the viral hepatitis epidemic by providing explicit steps to be undertaken by specific HHS agencies to improve provider training and community education; expand access to testing, care, and treatment; strengthen public health surveillance; improve HCV preventive services for injection drug users; develop a hepatitis C vaccine; and prevent HCV transmission in healthcare settings. For all aspects of the action plan, infectious disease specialists and other clinicians assume a key role in efforts to reduce HCV-related morbidity and mortality. With successful collaboration of the public and private sectors, the hepatitis C epidemic can be forever silenced.

Recently, the US Department of Health and Human Services (HHS) unveiled a new strategic plan to align with and recognize the rising public health priority of hepatitis C virus (HCV), the changing epidemiology of this infectious disease, and steady advances in prevention, care, and treatment. In an era of improved therapy, publication of this plan has created a unique opportunity to rally the nation to advance clinical and public health practices and decrease HCV-related suffering and disease.

The changing epidemiology of HCV is reflected in the rising morbidity and mortality among the 2.7–3.9 million persons living with the virus [1]. Hepatitis C virus greatly raises risk for hepatocellular carcinoma (HCC) and cirrhosis, and HCV-associated disease is the leading indication for liver transplantation [2–5]. In contrast to most other forms of cancer, rates of HCC are increasing [6], with at least 50% of the increase attributable to HCV [7]. The high rates of HCV-related morbidity and mortality are expected to continue for several decades. Without access to therapy, an estimated 1.76 million persons (61% of HCV-infected persons) will develop cirrhosis, 418,000 persons (14% of HCV-infected persons) will develop liver cancer, and 1,071,000 persons (37% of HCV-infected persons) will die from HCV-related diseases over the next 50 years [8]. Indeed, from 1999 to 2007, HCV-associated deaths increased 50%, superseding deaths associated with human immunodeficiency virus (HIV) [9]. The burden of HCV-related morbidity and mortality disproportionately impacts baby boomers (persons born during 1945–1965), most of whom have been infected for several decades and are at increased risk for HCV-associated cirrhosis and HCC as they age. This large population currently accounts for 81% of all HCV infection in the United States [10].
Annual declines in new HCV infections over the last several decades reflect improvements in blood safety and infection control. Nevertheless, an estimated 16,000 persons were infected with HCV in 2009. Approximately half of these cases occurred among persons with a history of injection drug use; in some states, HCV has increased among adolescents and young adults, many of whom reported engaging in this behavior [11].

Although recent advances have been made in preventing and treating HCV, as many as 75% of persons living with HCV have not been tested [12] and remain unaware of their infection status. Fortunately, a new point-of-care test is available that can increase access to testing, presenting an opportunity for improved HCV prevention, particularly for marginalized populations with limited access to routine clinical care. To be effective, this intervention must be followed by receipt of care and treatment, as appropriate; however, of persons who are tested and found to be infected with HCV, many never receive appropriate therapy.

To ensure that more persons are tested and linked to care and treatment, the Centers for Disease Control and Prevention (CDC) is considering expanding current HCV screening guidelines to include a birth-cohort approach to testing [10]. Identifying baby boomers and other HCV-infected persons is the first step to receiving new medications that can improve treatment response and shorten the duration of therapy for infected patients. In May 2011, the first generation of HCV NS3/4A protease inhibitors, telaprevir and boceprevir, were licensed for clinical use in the United States. Compared with peginterferon/ribavirin therapy alone, the addition of boceprevir or telaprevir to this standard regimen increased sustained virologic response rates from 38% to 63% and 46% to 79%, respectively [13, 14]. The pipeline of promising HCV therapies is robust, making an all-oral regimen to eradicate HCV after a short course (ie, 12 weeks) of therapy an achievable goal in the coming years [15].

In January 2010, the Institute of Medicine (IOM) summarized these new developments and recommended national action in its report “Hepatitis and Liver Cancer: a National Strategy for Prevention and Control of Hepatitis B and C” (http://www.iom.edu/viralhepatitis) [12]. In its report, the IOM identified viral hepatitis as an “underappreciated health concern for the nation” and recommended ways for the federal government to improve prevention of HCV transmission and disease, prompting HHS to develop a new strategic plan and strengthen HCV-related policies.

**VIRAL HEPATITIS ACTION PLAN: A ROADMAP FOR IMPROVING HCV PREVENTION, CARE, AND TREATMENT**

In 2011, HHS published “Combating the Silent Epidemic of Viral Hepatitis: US Department of Health and Human Services Action Plan for the Prevention and Treatment of Viral Hepatitis” (the action plan) [16]. The action plan provides a roadmap for guiding the nation’s public health response to viral hepatitis, presenting explicit steps for improving prevention and enhancing the care and treatment provided to infected persons. When fully implemented, the action plan can increase the proportion of persons who are aware of their HCV from 45% to 66% and reduce the number of new HCV infections by 25%.

Reducing HCV transmission and improving health outcomes for persons living with hepatitis C infection requires three things: (1) recognizing existing barriers to HCV testing and referral to care, (2) identifying strategies for overcoming these barriers, and (3) creating public policies, guidance, and resources to support implementation of these strategies. In order to achieve these goals, it will be necessary to

- improve community awareness and provider education;
- improve testing, care, and treatment;
- strengthen public health surveillance;
- improve HCV preventive services for injection drug users (IDUs);
- develop a hepatitis C vaccine; and
- prevent HCV transmission in healthcare settings.

To reach these goals, the action plan assigns specific actions to the appropriate HHS agencies. Further, the action plan highlights opportunities for the coordination of viral hepatitis activities across HHS operating divisions, sets priorities for developing an effective public health and primary care infrastructure, and provides a framework for engaging other governmental and nongovernmental partners (eg, medical specialty associations) in efforts to improve viral hepatitis prevention and care.

**Improving Community Awareness and Provider Education**

Along with the general public, many hard-to-reach communities and populations remain uninformed about viral hepatitis and the benefits of prevention and treatment. Providers also have inadequate knowledge about viral hepatitis [17], often failing to provide at-risk patients with viral hepatitis–related services [18–21]. Because the opinion of a medical provider is one of the strongest motivators for a patient to accept an intervention or change behaviors [21], increasing provider awareness of viral hepatitis is pivotal.

The action plan activities for improving education include:

- creating an educational curriculum for HCV prevention, care, and treatment to be used by multiple disciplines of health professionals;
- integrating viral hepatitis into the curricula of all HHS healthcare provider training programs; and
collaborating with professional, medical, and other organizations to build a workforce capable of providing HCV-related prevention, care, and treatment.

Many of these actions are already underway. The CDC is developing a medical school curriculum and a national education campaign to increase public awareness called “Know More Hepatitis,” and the Federal Bureau of Prisons (BOP) is training regional hepatitis pharmacists on new direct acting antivirals (DAAs). Both the Veterans Health Administration and the American Association for the Study of Liver Diseases are developing national treatment guidelines and criteria for use of DAAs [22].

Improving Testing, Care, and Treatment
Identifying persons infected with HCV and referring them to appropriate care and treatment can greatly reduce the public health and economic consequences of HCV. Increasing the number of patients who know their infection status can lead to better health outcomes by providing opportunities to prevent cirrhosis, HCC, and mortality from undetected liver disease and other causes [23–25]. Rates of viral hepatitis testing also can be improved by eliminating existing barriers (eg, testing policies that inadvertently pose impediments to the timely diagnosis of HIV and cost-related deterrents to screening for both providers and patients).

Once tested, persons found to be infected with HCV must receive ongoing care (eg, alcohol counseling, hepatitis A and hepatitis B vaccination, assessment of liver disease, management of comorbidities) and treatment services (eg, antiviral therapy, monitoring of therapeutic response) to improve health outcomes. Care coordination is critical to linking infected persons to these needed services after diagnosis.

The action plan strategies for improving HCV testing, care, and treatment include:

- creating standard recommendations to guide HCV testing and referral to care;
- implementing routine HCV testing and linkage to care as standard practice in healthcare systems;
- promoting health information technology to improve testing and enhance referral to viral hepatitis care; and
- developing care models to optimize management of the diverse populations living with HCV.

Several HHS agencies have already begun implementing these strategies. The Health Resources and Services Administration (HRSA) is funding 29 demonstration projects to integrate HCV care into HIV primary care, the Agency for Healthcare Research and Quality is reviewing the comparative effectiveness of HCV treatment in adults, and the National Institutes of Health (NIH) is conducting research on HCV therapy. In addition, the US Preventive Services Task Force, an independent group of national experts, is in the process of updating its previous recommendations on HCV screening [26]. Finally, because approximately 3 of every 4 HCV-infected persons in the United States were born during 1945–1965, the CDC is reviewing evidence for recommending HCV testing as a cost-effective preventive service for this population [10].

Strengthening Public Health Surveillance
National surveillance for viral hepatitis is underresourced, resulting in vast underreporting. The CDC estimates that only 10% of new cases of viral hepatitis are reported through the National Notifiable Diseases Surveillance System; further, only two-thirds of states report cases of chronic HCV, and among those that do, substantial backlogs of cases exist because capacity issues make it difficult for states to enter relevant information into surveillance systems in a timely manner. Surveys may also underrepresent priority populations (eg, Asian Pacific Islanders) and lack the key data needed for state and local planning.

The action plan proposes to improve surveillance through strategies that include, but are not limited to:

- integrating electronic laboratory and medical records as components of HCV surveillance;
- collecting data at the community level to help state and local programs identify and address HCV-related health disparities; and
- documenting and monitoring provision and impact of testing, care, and treatment services.

Activities to improve public health surveillance capacity in the United States have already begun. For instance, the CDC has funded 5 health departments to begin integration of electronic lab reporting as a component of viral hepatitis case surveillance, and the HRSA is reporting on HCV testing and prevalence in community health centers.

Improving HCV Services for IDUs
In the United States, injection drug use is the most common mode of transmission among persons with acute HCV infection. IDUs are more likely to have adverse hepatitis-related health outcomes than other infected populations, primarily because of comorbidities and inadequate access to and receipt of needed health services [27, 28]. Still, it has been shown that IDUs can successfully adhere to a full course of HCV therapy [29], reducing their risk for chronic infection and possibly lowering the risk of transmission to partners; new HCV treatments can serve as valuable prevention tools for reducing HCV transmission in this population. According to one modeling study, treating 10 HCV infections per 1000 IDUs per year could result in a relative decrease in HCV prevalence over 10 years of 7%–31% [30]. Because HCV prevalence among incarcerated
persons is high (23.1%–39.4%), representing an estimated 373,000–665,000 infected persons [31], prevention and treatment is particularly needed for current inmates. Further, continued prevention and care services are needed for HCV-infected persons after they return to their communities because these persons have been shown to reengage in risk behaviors following incarceration [32].

The action plan identifies the following strategies for preventing HCV among IDUs and improving health outcomes among those already infected:

- integrating viral hepatitis prevention and care services as standard components of substance abuse and treatment programs;
- integrating HCV prevention services with HIV prevention programs;
- enhancing substance abuse treatment;
- increasing access to state and local syringe service programs as part of a comprehensive approach that includes access to substance abuse prevention and treatment services; and
- promoting integrated approaches for managing HCV-infected patients who have comorbid health conditions.

Many of these actions are underway. The Substance Abuse and Mental Health Services Administration is not only updating its Opioid Treatment Program accreditation guidelines to include a hepatitis testing standard but is developing curricula on integrating drug treatment and hepatitis treatment and care. The Veterans Administration is educating providers caring for persons with substance-use disorders about the risk of viral hepatitis in these populations, and the BOP has incorporated information on viral hepatitis prevention, care, and treatment into the drug education program they provide to inmates.

**Developing a Hepatitis C Vaccine**

Vaccines to prevent infection with hepatitis A virus and hepatitis B virus have been available in the United States since 1995 and 1981, respectively. Although effective treatment options exist for HCV-infected persons, no effective vaccines have been developed; hence, without antiviral treatment, >75% of acute HCV infections will become chronic, often leading to serious, progressive, and fatal liver disease.

The action plan stresses the urgency of developing such a vaccine. The NIH, the CDC, and the US Food and Drug Administration (FDA) are tasked to facilitate development of candidate hepatitis C vaccines designed to induce protective immune responses and to evaluate indications for hepatitis C vaccination in the United States and globally. The NIH has begun to implement these activities by supporting a portfolio of HCV vaccine research.

**Preventing HCV Transmission in Healthcare Settings**

Reports of healthcare-associated outbreaks of HCV infection attributed to unsafe injection practices and inadequate infection control are unacceptably high [33], compromising patient safety and requiring local health departments, many of which already face substantial resource constraints, to investigate incidents and offer testing to possibly exposed patients. Several actions can further protect patients and providers, including increased infection control education for all healthcare providers, enhanced professional and institutional accountability, and improved practice oversight. Also needed are efforts to better protect patients receiving blood, tissue, and organs.

The action plan strategies for protecting patients and workers from healthcare-associated HCV include efforts to

- improve surveillance and detection of outbreaks in healthcare settings;
- lower the risk of HCV transmission associated with improper handling and use of point-of-care devices, reusable equipment, and syringes;
- improve provider education regarding basic infection control and improve infection control oversight at long-term care and outpatient facilities;
- reduce device-related percutaneous exposures; and
- update existing guidelines for management of HCV exposures in healthcare settings.

Progress toward preventing healthcare-associated infection is being made. For instance, the CDC is expanding participation of healthcare facilities in the National Healthcare Safety Network (http://www.cdc.gov/nhsn/) and responding to healthcare-associated outbreaks of HCV [34]. The NIH is conducting research on tests to improve detection of transfusion-transmissible infections, and the FDA has issued draft guidance for industry on the reprocessing of reusable medical devices in healthcare settings that addresses the validation of device cleaning, disinfection, and sterilization.

**CONCLUSION**

The 2011 HHS report “Combating the Silent Epidemic of Viral Hepatitis: US Department of Health and Human Services Action Plan for the Prevention and Treatment of Viral Hepatitis” can help strengthen public and provider awareness of HCV as a significant public health problem, identify unmet needs, spur the development of partnerships and collaborative initiatives, and provide a framework and impetus for action. Further, these directives can be integrated with other HHS health initiatives (e.g., Healthy People 2020, the National HIV/AIDS Strategy, the National Prevention Strategy, and the HHS Action Plan to Reduce Racial and Ethnic Health Disparities) to leverage existing efforts to improve the health of the nation.
For all aspects of the action plan, infectious disease specialists and other clinicians assume a key role in efforts to reduce HCV-related morbidity and mortality. Infectious disease clinicians must remain knowledgeable about how HCV is transmitted, understand which populations are at risk for transmission and disease, and be prepared to offer HCV testing and to counsel patients regarding their test results. For patients found to be infected with HCV, clinicians should provide care to help patients protect their liver (eg, vaccination for hepatitis A and hepatitis B and counseling about alcohol use) and evaluate and manage comorbidities (eg, HIV) and risk behaviors that can result in exposure or transmission (eg, injection drug use). To increase access to therapy, a greater number of clinicians must become HCV treatment providers, staying abreast of changes in the field to incorporate new therapies and new treatment recommendations into their practices. Beyond providing HCV services to their patients, clinicians play a critical role in disease surveillance, helping public health entities identify outbreaks, emerging modes of transmission, and the sequelae of chronic liver disease. They can also reduce healthcare-associated infection by implementing practices to protect their patients from HCV infection in the healthcare setting.

Public health authorities have an equally important obligation to help clinicians by developing and promoting evidence-based policies for HCV testing that are readily implemented at the provider level, providing public education to help patients and communities understand the value of preventive services, developing models of care that improve the effectiveness and efficiency of medical management, and providing surveillance and program evaluation data to policy makers to build support for a comprehensive continuum of HCV-related preventive and clinical services. Furthermore, the success of HCV prevention hinges on a fully functional health infrastructure. The HHS is committed to promoting changes in the health system that will help clinicians better deliver needed services to their patients. With successful collaboration of the public and private sectors, the hepatitis C epidemic can be forever silenced.

Notes

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