Public Policy Statement on the Hepatitis C Virus, Substance Use, and Addiction

Opioid use disorder (OUD) and infectious diseases are intertwined public health crises;[1,2] hepatitis C virus (HCV) is the most prevalent bloodborne infection associated with drug use.[3] Incidence and prevalence of HCV infection have increased significantly as a result of increasing rates of injection drug use, yet the introduction of curative direct acting antiviral (DAA) HCV therapies offer promise in reducing disease burden and transmission.[4]

Most people become infected with HCV by sharing equipment used to prepare and inject drugs.[3] Less common routes of transmission include infection at birth, through health care exposures, or through sex with an infected person.[5] HCV can cause acute and/or chronic infection by attacking the liver, leading to inflammation.[6] An estimated 70 to 80 percent of persons with acute HCV infection develop chronic hepatitis,[6] and about half of persons with chronic hepatitis develop cirrhosis.[3,7]

As a result of increased injection drug use, the incidence of HCV has quadrupled from 2010 to 2017.[8] Estimates show that 3.5 million people are living with HCV.[9] HCV rates are higher among people who inject drugs, people of color,[10] men who have sex with men who are living with HIV or who have injected drugs,[11] and transgender people.[12] HCV antiviral treatment rates are lower for individuals who are racially minoritized,[13–16*] and there are disparities in the quality of care for individuals who are racially minoritized, persons who live in rural areas, and persons who have lower socioeconomic status.[17] Approximately 30% of all individuals living with HCV have spent time in jails or prisons in the first decade of the 21st century.[18,19]

HCV infection is a leading cause of liver-related morbidity, including hepatocellular carcinoma (HCC) and liver transplantation, and mortality.[7,20,21] Direct acting antiviral (DAA) medications have replaced older interferon-based treatments because they have a shorter treatment course, are better tolerated,[22] and are vastly more effective[23] with a cure rate of over 90 percent.[24] The emergence of DAA therapies provides an unprecedented opportunity to address hepatitis C; they are expensive, but the treatment course usually only lasts 8 to 12 weeks. Studies have shown cost-saving benefit post-treatment,[25,26] with a reduction in total medical costs 12 months

* Scholars have advocated for use of the term "minoritized," which is used to refer to the same shared experience of exposure to systemic and individual racism in health and beyond and provides an understanding that people are actively minoritized by others, rather than naturally existing as a minority, as the terms racial or ethnic minorities imply.

after completion of treatment and hepatitis C or liver disease-related costs 30 months after completion of treatment.[27]

More than half of persons living with HCV do not know they have the virus.[28,29] Screening for and diagnosis of HCV infection is low for patients with OUD, even among those in opioid treatment programs (OTPs).[1] Screening rates are also low in jails and prisons.[30] Currently, a low number have universal opt-out screening policies that recognize the need for a standardized protocol that screens everyone, except those who choose not to be tested.[31]

All persons with HCV infection, regardless of their current substance use, are candidates for available, curative treatment, and treatment in the early stages of infection reduces disease burden and has a public health benefit. The American Association for the Study of Liver Disease (AASLD) and the Infectious Disease Society of America (IDSA) recommend treatment for all persons with acute and chronic HCV, including those with active drug and alcohol use. Up-to-date, peer-reviewed, evidence-based recommendations for HCV treatment are available at HCV guidance website (www.HCVGuidelines.org).[8]

The U.S. Constitution requires provision of adequate medical care for those that have been incarcerated by states or the federal government.[32,33†‡] Title II and Title III of the Americans with Disabilities Act (ADA) safeguard a person with a substance use disorder (SUD) that substantially limits a major life activity from discrimination on the basis of such disability, and medical care may not be withheld from such person on the basis of illegal use of drugs, if the individual is otherwise entitled to such services.[33§] In addition, federal Medicaid law requires states to provide Medicaid enrollees with medically necessary treatment in a non-discriminatory manner.[33]

According to available evidence, integrated treatment of SUD and HCV produces the best outcomes.[34,35] Co-administration of addiction medication and DAA treatment increases uptake of DAA and reduces the risk of future transmission of HCV and other infectious diseases.[1] There are a variety of settings in which HCV treatment can be safely delivered, including addiction

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† Estelle v. Gamble, 429 U.S. 97, 103, 97 S. Ct. 285, 290, 50 L. Ed. 2d 251, 256 (1976) (This U.S. Supreme Court case said that a prison's staff "deliberate indifference" to the "serious medical needs" of prisoners is "cruel and unusual punishment." "These elementary principles establish the government's obligation to provide medical care for those whom it is punishing by incarceration.")

‡ In constitutional law, the Eighth Amendment protects prisoners from "cruel and unusual punishment." It is codified in 42 U.S. Code § 250 (1944). Medical care and treatment of Federal prisoners: "The Service shall supervise and furnish medical treatment and other necessary medical, psychiatric, and related technical and scientific services, authorized by section 4005 of title 18, in penal and correctional institutions of the United States."

§ Americans with Disabilities Act, Part 35 Nondiscrimination on the Basis of Disability in State and Local Government Services. (Subpart B, § 35.131 Illegal use of drugs, (b) Health and drug rehabilitation services.
(1) A public entity shall not deny health services, or services provided in connection with drug rehabilitation, to an individual on the basis of that individual's current illegal use of drugs, if the individual is otherwise entitled to such services."). Americans with Disabilities Act, Part 36 Nondiscrimination on the Basis of Disability in Public Accommodations. (Subpart B, § 36.209 Illegal use of drugs, (b) Health and drug rehabilitation services. (1) A public accommodation shall not deny health services, or services provided in connection with drug rehabilitation, to an individual on the basis of that individual´s current illegal use of drugs, if the individual is otherwise entitled to such services.

treatment settings, primary care offices, and jails and prisons. Syringe services programs play a critical role in reducing transmission of HCV and other infectious conditions through delivery of sterile injection equipment, educational information, infectious disease screening, and vaccinations.[1]

Primary care providers (PCPs) can provide safe and effective HCV treatment, including treatment for complex patients with chronic HCV.[20] In addition to providing care for chronic HCV, there are important interventions that can maintain or improve the health of individuals with HCV infections. Targeted strategies such as the screening, brief intervention, and referral to treatment (SBIRT) can reduce alcohol consumption[36] and help prevent further liver damage to persons with SUD and co-occurring HCV infection, such as those outlined by the National Institute of Alcohol Abuse and Alcoholism (NIAAA).[37]

The direct economic burden of HCV-related liver disease in the U.S. was an estimated $6.5 billion in 2011,[38] and today, the economic burden of HCV might exceed $10 billion alone.[39] Direct costs associated with chronic HCV are high and costs are highest with end stage liver disease.[40] The stigma of addiction, the high cost of treatment, and the relatively slow progression of HCV-associated liver disease may have contributed to a lack of urgency to treat HCV.[41] The current structure of healthcare financing systems, including for jails and prisons, creates difficulty for institutions to afford DAA medications.[41] Thus, many state Medicaid programs have limited coverage of DAA medication.[42] However, in 2015, the Centers for Medicare and Medicaid Services (CMS) clarified the extent to which states can restrict DAA use in fee-for service (FFS) and managed care programs,[23] which may have increased access to DAA treatment.[43] Some states have lowered the cost of DAAs by committing to a "subscription fee" to access an unlimited supply per unit of time rather than paying a fixed price per dose.[44,45] Such efforts may increase access to HCV medical treatment at scale. Furthermore, payer coalitions of federal and state agencies and private insurers promote comprehensive care.[41]

Considering these facts, the American Society of Addiction Medicine recommends:

1. State of the art medical care for HCV should be accessible and available to all people who need it, including those who use, or have used, alcohol or other drugs. **Active alcohol or other drug use should not in itself exclude any person from receiving treatment for their HCV infection**. All agencies, third-party payers, and healthcare professionals should align policy and practice accordingly.

    a. The decision to initiate treatment for HCV infection in any patient should be made by the patient and their practitioner following careful consideration of the benefits and risks of therapy in each individual and their circumstances.

2. All healthcare settings, especially addiction treatment programs, should provide or coordinate comprehensive HCV care for their patients. Clinical staff working with people who use, or have used drugs, should be trained in pre- and post-test counseling to

educate patients regarding the prevention, transmission, clinical course, and treatment options for HCV infection.

   a. Payers and policy makers should ensure that medical clinicians are reimbursed for HCV treatment services at OTPs given the unique, high-contact function OTPs serve in communities.[46,47]

   b. Integration of HCV care delivery at nontraditional locations (e.g., harm reduction sites[47–49]) is also strongly encouraged since people with SUD frequently encounter stigma in more traditional healthcare settings and, therefore, may choose not to seek HCV care in such settings.

3. Healthcare systems and clinicians should identify and rectify underlying racial discrimination by adjusting policy and practice accordingly. Research is needed to better delineate what policies and practices are contributing to racial disparities in HCV treatment eligibility and receipt.

4. Screening policies in jails and prisons must be improved to detect HCV infection rates and to communicate those results to those who are screened. Universal "opt-out" testing for HCV, Hepatitis B Virus (HBV), and Human Immunodeficiency Virus (HIV) should be provided to all individuals who are incarcerated.[41]

5. There is a need for increased mutual awareness and collaboration between addiction medicine, infectious disease, and primary care clinicians. Because partnerships between healthcare professionals in infectious disease and addiction medicine are important and synergistic, government agencies should coordinate with organizations from both fields and invest in those fields' evidence-based strategies for reducing HCV infections, including increasing access to addiction medications, DAA treatment, and harm reduction services.[1]

6. Because treating persons with HCV can save future costs[50] and improve health outcomes, third-party payers should cover comprehensive HCV care that is consistent with evidenced-based treatment practices and nationally accepted guidelines, such as those developed by AASLD and IDSA.

   a. Payer restrictions to HCV treatment based on chronicity, fibrosis stage, prescriber specialty, or those with substance abstinence requirements may violate federal law and should be removed.[33]

7. Alternative payment models designed to integrate medical, behavioral, and SUD treatment services should be developed to meet the needs of persons with SUD and co-occurring HCV infection.

   a. Innovative state-based strategies for expanding access to evidence-based pharmaceutical treatments for HCV infection, such as subscription models, should

be considered, their effectiveness should be rigorously evaluated, and successes should be replicated.

b. Governments should invest in local strategies in partnership with community-based organizations to expand HCV screening, diagnosis, linkages to care, and treatment.[51]

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