



Public Policy Statement on Hepatitis C Infection

Background

Hepatitis C is the most common chronic blood borne infection in the United States. There are currently an estimated 3.5 million persons infected with Hepatitis C virus (HCV) in the United States and almost half are unaware they are infected.¹ Depending on the population, acute Hepatitis C infection becomes chronic in anywhere from 75- 85% of persons. Over the ensuing 20-30 year post-infection, approximately 20% of individuals develop hepatic cirrhosis, and of those, approximately 25% will develop liver failure, liver cancer, or both.² By 2007, HCV had surpassed HIV as a cause of death. A recent analysis by the CDC finds that more Americans now die as a result of HCV infection than from all other reportable infectious diseases combined. In 2014, deaths associated with HCV in the US reached 19,659.² Modeling studies project that without a significant increase in screening, diagnosis and treatment efforts, HCV-related deaths will peak in 2030 to 2035, with approximately 36,000 deaths per year.³

HCV is primarily transmitted through percutaneous exposure to contaminated blood. Since 1992, the US blood supply has been screened for Hepatitis C, making the risk of transfusion-transmitted HCV extremely rare. Injection drug use (IDU) currently accounts for a majority of new infections and is the main driver perpetuating the HCV epidemic.⁴ Approximately 80% of people who inject illicit drugs (PWID) are HCV-infected. Although most new HCV infections are acquired through sharing of contaminated IDU equipment, users of non-injected illicit drugs are at risk as well through shared intranasal apparatuses.

The use of illicit drugs is often accompanied by high-risk and unprotected sexual practices. Though less easily transmitted by sexual contact,² those at highest risk for HCV transmission are men who have sex with men (MSM), particularly those who are co-infected with HIV.^{2,5} Due to shared transmission modes, all persons living with HIV are at high risk of infection with HCV.

Transmission risks for HCV translate into high prevalence of the infection found among people in different settings. For example, an estimated 76% of persons enrolled in opioid treatment programs (OTPs) in the United States have hepatitis C infection, in stark contrast with the estimated prevalence of 1.8% among the US population overall.⁶ An estimated 29% of incarcerated persons in North America have HCV.⁷

With this burden of disease, annual HCV testing is now recommended by the Infectious Disease Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) for persons who are at risk of HCV infection, including PWID or individuals engaging in intranasal illicit drug use. An anti-HCV antibody test is recommended and, if positive, a chronic infection is confirmed with a reflex HCV RNA PCR test. The guidelines recommend linking all persons found to have active HCV infection based on a positive HCV RNA PCR test to a practitioner who can provide comprehensive management that includes assessing for potential

curative antiviral therapies. All patients with chronic HCV are candidates for currently available curative treatment, including those who continue to use alcohol and/or drugs as well as those receiving medication-assisted therapy for opioid use disorder. In fact, the NIH HCV Consensus Conference Statement of 2002 stated that “HCV therapy has been successful even when patients have not abstained from continued drug or alcohol use or are on daily methadone.”⁸

Some practitioners, policy makers, and payers have argued that expensive medication should not be offered to persons who continue to use drugs or alcohol due to the risk of reinfection. However, while more evidence is needed, current data suggest re-infection rates among those with active alcohol and/or drug use is low.⁹ Treatment provides the public health benefit of reducing the number of HCV carriers and transmission to others. Current guidelines, therefore, by the AASLD and IDSA recommend antiviral therapy for “*all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV by transplantation or other directed therapy (Rating Class I, Level A).*”

The goal of antiviral therapy for chronic HCV infection is sustained virological response (SVR), or virological cure, which is defined as the continued absence of detectable virus at least 12-24 weeks after completion of therapy. Current practice standards recommend that patients be treated in the early stages of HCV infection, before the development of severe liver disease and/or extra hepatic manifestations of chronic disease. Initiating therapy in patients with lower stage fibrosis has been shown to augment the benefits of SVR.¹⁰ Recommendations on the specific antiviral treatments are based on a HCV genotype determination and a non-invasive assessment of the degree of liver fibrosis.

As of June 2016, there is no longer any indication for the use interferon in the treatment of HCV disease. Instead, in the United States, all patients may be offered treatment with directly acting antiviral (DAA) medication after they are screened. These medications are associated with high cure rates. DAA regimens have been found to be more efficacious than the older interferon based treatments. In contrast to those interferon containing regimens, treatment with DAA-only regimens has fewer and less severe side effects and is relatively brief, lasting anywhere from 12-24 weeks.

In addition to testing and linkage to care for chronic HCV, there are several important interventions that can maintain or improve the health of HCV-infected substance users. A primary focus is on preventing further liver damage in patients with HCV infection. As alcohol use can accelerate the rate of liver damage, eliminating or significantly reducing alcohol consumption is important. Alcohol-focused screening and brief interventions, such as those outlined by the National Institute of Alcohol Abuse and Alcoholism (NIAAA), have been demonstrated to reduce alcohol consumption and episodes of binge drinking in the general population and among HCV-infected persons. For more individualized approaches, behavioral health interventions and medication assisted treatment (MAT), shown to reduce consumption and support abstinence, can be incorporated into an overall treatment plan.

Infection with HIV can also accelerate the progression of HCV-related liver disease. Public education on the risks of HCV and HIV co-infection is an essential primary public health prevention response to the epidemic of HCV infection among drug users. Other public health interventions, such as syringe exchange programs and free condom distribution, can decrease the frequency of IDU injection and associated high-risk, unprotected sex. Access to free testing and counseling for exposure to both HIV and HCV is important to identify infected individuals.

As of 2014, the Centers for Disease Control (CDC) recommends pre-exposure prophylaxis (PrEP) treatment for patients with chronic HCV who have not been exposed to HIV. The CDC also believes it is critical that patients with chronic HCV are placed on antiretroviral therapy to treat co-infection with HIV.

Other helpful interventions to prevent further liver damage include screening for and vaccination against infection with other hepatitis viruses (hepatitis A and B). Vaccinations for pneumococcal infections and influenza infections are also important interventions for HCV-infected drug users.

Recommendations:

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

1. Screening/Prevention/Education
 - a. Voluntary serologic testing for hepatitis C antibody along with reflex HCV RNA PCR testing in those with a positive HCV antibody screen should be offered to:
 - i. All persons with a history of drug use (current and past, including one time use via non-oral routes of drug administration), particularly those with a history of injection drug use and intranasal drug use
 - ii. All persons living with HIV infection
 - b. All patients with HCV infection should be offered testing for immunity to hepatitis A and hepatitis B virus infection. Those testing negative should be advised of the benefits of vaccination against hepatitis A and hepatitis B infection and, upon the person's consent, administered the necessary vaccinations. The testing includes:
 - i. Hepatitis A testing for IgG (Hep A IgG) only, not IgM
 - ii. Hepatitis B testing for Hepatitis Surface Antibody (HBsAb), Hepatitis B Surface Antigen (HBsAg) and Hepatitis Core Antibody (HBcAb)
 - c. Patients with chronic HCV infection should be offered pneumovax and influenza vaccines, consistent with current guidelines.
 - d. Clinical staff working with current or former drug users should be trained in pre- and post-test counseling to effectively educate patients regarding the prevention, transmission, clinical course and treatment options for HCV infection.
2. Treatment
 - a. State of the art medical treatment for HCV should be accessible and available to all current and former drug users with chronic HCV infection. **Active alcohol and/or drug use should not in itself exclude any person from receiving treatment for their HCV infection.** The outcomes for patients who continue to use alcohol and/or drugs are comparable to those who do not. The decision to initiate treatment for HCV infection in any patient should be made by the patient and his/her practitioner following careful consideration of the benefits and risks of therapy.
 - b. All persons found to have chronic HCV infection based upon detectable HCV viral load should be linked to a provider who can provide comprehensive HCV assessment and treatment.
 - c. All patients with HCV infection who fulfill diagnostic criteria for substance use disorders involving alcohol and/or other drugs should receive treatment for these disorders.
 - i. Persons with chronic HCV infection with active opioid use disorders should be offered access to addiction treatment services, including

pharmacological treatment such as methadone, buprenorphine, and extended-release naltrexone.

- ii. Patients with drug addiction with chronic HCV infection should be counseled to reduce or eliminate alcohol use. Those with alcohol use disorders should also be considered for psychosocial treatments as well as pharmacological therapies for alcohol use disorder, consistent with the recommendations of NIAAA.
- d. Addiction treatment programs can be well situated to provide or coordinate HCV counseling, screening, and treatment for their patients; innovative interventions such as supervised therapy to enhance adherence to HCV treatment may be integrated effectively with addiction treatment services. Physical co-location or remote electronic support of general medical, psychiatric and addiction treatment services fosters integration of elements of a patient's treatment, optimizing communication and minimizing fragmentation of care. A well-established practitioner-patient relationship is crucial for optimal outcomes with the new direct-acting antiviral regimens. Patients who seek addiction treatment are frequently marginalized and stigmatized by the health care system, and therefore many choose not to seek HCV treatment at primary health care or specialty clinics. Thus, integration of service delivery, addressing the unique needs of addiction patients including HCV treatment, is strongly encouraged.

3. Benefit Coverage and Reimbursement

- a. Commercial and public sector third-party payers should cover medically necessary HCV treatment, including infectious disease and hepatology consults, recommended medication regimens, and genotype testing consistent with evidenced-based treatment and accepted national guidelines.
- b. There is no clinical evidence to support HCV benefit denial for patients with an active alcohol and/or drug use disorder.
- c. Payers and providers should collaborate to develop alternative payment models designed to integrate medical, behavioral and substance use disorder treatment services to meet the needs of patients with co-occurring HCV infection

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