

ABSTRACT

The approval of an oral, short-course, curative therapy for chronic hepatitis C (HCV) infection presents a public health opportunity to reduce morbidity and mortality. However, a fragmented U.S. healthcare delivery system may limit its public health benefit. Patients with chronic HCV have predictable medical and social comorbidities that reduce access to care. The Affordable Care Act presents an opportunity to focus on the benefits of insurance expansions and the medical home model for integrated chronic disease management. New, highly effective HCV treatment regimens in combination with the medical home model for chronic disease management could reduce disease prevalence. This article describes the challenges posed by comorbidities in patients with chronic HCV and limitations within our current healthcare system, and recommends specific solutions to maximize the public benefit from health reform and this pharmacological innovation.

BACKGROUND

Over 180 million people worldwide have chronic HCV with an estimated yearly incidence of 17,000 and prevalence of 3.2 million people in the United States alone.^{1,2} Years of undetected infection and untreated disease can culminate in hepatic fibrosis, cirrhosis, hepatocellular carcinoma, and liver transplantation, accompanied by increased rates of morbidity and mortality. Approximately 20% of chronically infected adults develop cirrhosis within 20 years.^{3,4}

Each stage of HCV disease incurs increasing human and economic costs, with medical treatment of infected patients in the United States estimated as high as \$9 billion in 2012.⁵⁻⁷ Curing HCV infection, measured by a sustained virological response (negative HCV-RNA PCR) 24 weeks after the end of therapy (SVR 24), reduces morbidity and mortality.^{8,9} Regrettably, the reach of curative therapy has been limited by the efficacy and tolerability of past treatment regimens.

Even as improved HCV treatment regimens might stimulate physicians to offer and patients to seek HCV treatment, the long-term success of treatment will depend on a sustained campaign to align the medical care and SUD treatment systems.¹⁰ Furthermore, new HCV treatment regimens underscore the need for a coordinated public health response that should include prevention of new infections, screening, social support and medical management for those infected.¹¹

OPPORTUNITY

An important shift in standard therapy for HCV infection is underway in which new regimens exceed 90% cure rates, eliminate injectable interferon, reduce dosing frequency and pill burden potentially to one pill once per day, and reduce treatment duration to as short as 3 months.^{12,13}

This dramatic improvement in HCV treatment has the potential to substantially reduce the public health burden of chronic liver disease as prior therapy yielded low efficacy, was long in duration, and had challenging side effects which deterred both physicians and patients. Better treatment regimens could lead to more screening, diagnoses, stronger adherence, more cures, and ultimately reduce HCV-associated morbidity and mortality.

Moreover, reduced treatment duration, elimination of side effects associated with interferon-based regimens, and reduction in pill burden may encourage more patients to seek testing and treatment. However, as demand increases, other challenges, such as workforce capacity and training, the cost of new regimens, and the costs associated with effective delivery of care will mount. These challenges are considerable.¹⁴

POTENTIAL BARRIERS

Maximizing the public health benefit from this therapeutic innovation will require addressing the barriers that US patients with chronic hepatitis C face when attempting to access treatment. Most people in the United States with chronic HCV infection live in areas of high poverty, lack health insurance or rely on public insurance¹⁵ and have a history of injection drug use.¹⁶ In sum, they face a fragmented healthcare delivery system with multiple medical comorbidities. Barriers include:

- **Untreated Medical and Mental Health Conditions**

The treatment of patients with chronic hepatitis C in the United States will continue to be complicated by significant medical comorbidities¹⁷ including mental illness,¹⁸ hepatitis B, and HIV.^{19,20}

- **System Readiness and Untreated Substance Use Disorders**

Historically, the substance abuse specialty care treatment system has been segregated from its medical counterpart.²¹ Not surprisingly, intervention rates for SUD in primary care have been lower than for other behavioral health issues, including physician recommendations for patients to exercise (35%),²² lose weight (42%),²³ and quit smoking (37%).²⁴ In fact, fewer than 11% of all patients diagnosed with alcohol dependence (DSM-IV)²⁵ or alcohol use disorder (DSM-V)²⁶ in primary care received an indicated treatment referral.²⁷

Intravenous drug use is the most common risk factor for acquiring HCV infection.²⁸ Untreated SUD compromise treatment adherence, predispose patients to reinfection, and might exacerbate the potential development of antiviral resistance.^{29,30}

Both buprenorphine/naloxone and methadone medical maintenance can be successfully administered by physicians in office-based settings.^{30,31} However, office-based buprenorphine/naloxone and methadone maintenance treatment in primary care remain limited.^{32,33} Historically, weak counselor retention, inadequate professional development, limited Medicaid billing³⁴ and a dearth of electronic health record systems,³⁶ constrained integration with primary care.³⁰ There is ongoing concern regarding primary care workforce shortages and a lack of provider education.^{37,38}

Though guidelines encourage HCV treatment in drug users,^{39,40} several studies have indicated that only 1% to 6% of drug users receive antiviral therapy.^{41,42} Despite evidence that HCV treatment among patients engaged in opioid treatment is similar to those without a history of substance abuse, physicians appear reluctant to prescribe therapy to intravenous drug users.^{43,44}

- **Lack of Health Coverage/Cost of Treatment**

Many states are not expanding health coverage under the ACA, making a coordinated effort to reduce hepatitis C among high risk populations particularly challenging. As of May 26, 2015, for example, 29 States plus the District of Columbia adopted the Medicaid expansion to meet ACA standards, 18 have not and 3 states have it under discussion.⁴⁵ Even among those states that have expanded access, the cost of new treatment regimens may prove prohibitive for many public systems.

- **Lack of Surveillance**

Most states do not submit reports of hepatitis C seroprevalence to the CDC.⁴⁶ Without accurate surveillance, the success of a population based screening and treatment approach to reduce incidence and prevalence will be difficult to measure.

AFFORDABLE CARE ACT

The ACA expands Medicaid eligibility, offers healthcare consumers premium subsidies through state health insurance exchanges, defines substance abuse treatment as an essential benefit, and in so doing confers parity between SUD and medical care treatment.⁴⁷ The law will extend medical and behavioral health care⁴⁸ insurance coverage for up to an additional 14 million people.⁴⁹ Given that at least half of infected HCV patients do not know that they are infected,⁵⁰ expanded insurance coverage and new pharmacotherapy could increase screening and treatment rates to reduce disease prevalence.

RECOMMENDATIONS

(1) Develop and maintain a national surveillance system. As recommended by the Institute of Medicine (IOM), a national surveillance system is needed, including a thorough surveillance evaluation by the Centers for Disease Control and Prevention (CDC) and the development of collaborative agreements with States and territories to support core HCV surveillance.¹¹

(2) Enhance primary care providers' capacity to screen and treat HCV. As recommended by the IOM, CMS should adopt guidelines for HCV screening and assure that infected patients receive appropriate medical management. Similarly, the Health Resources and Services Administration (HRSA) should provide resources to federally qualified health centers in high prevalence areas for viral-hepatitis services.¹¹

(3) Improve primary care and substance abuse treatment integration. Greater buprenorphine/naloxone or methadone maintenance treatment availability in primary care,²⁹ colocation of substance abuse treatment and stronger referral practices⁵¹ are needed to curb new HCV infections.

(4) Expand local and national primary and secondary HCV prevention efforts. Increase prevention efforts at opioid treatment programs, correctional facilities and community based organizations, including needle exchange programs as recommended by the IOM.¹¹

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The list of citations is available upon request.