Public Policy Statement on Hepatitis C: Supplemental Information for Physicians

Background

Epidemiology and Transmission

Of the nearly 4 million people in the United States infected with the hepatitis C virus (HCV), approximately 60% acquired their infection from injection drug use (IDU). Most new HCV infections are acquired through sharing of injection equipment (needles, syringes, “cookers”, cotton swabs and rinse water). Approximately 80% of IDUs (injection drug users) have become infected with HCV. Non-parenteral users of illicit drugs are at risk as well: 20-30% of persons in drug treatment services who are listed as “non-IDU drug users” have HCV. Such persons a) may not have disclosed a history of injection drug use, b) may have acquired HCV through sexual transmission, or c) may have become infected with HCV by sharing intranasal drug sniffing apparatus (e.g., straws).(1) Of the 205,000 persons enrolled in methadone maintenance treatment in the United States, an estimated 155,000 (76%) have hepatitis C infection, in stark contrast with the estimated prevalence of 1.8% among the US population overall.

Natural History

The majority of cases of acute hepatitis C are asymptomatic. All patients with a history of injection drug use should be tested. Once infection occurs, approximately 15% of persons spontaneously clear the virus (remaining antibody-positive but negative by the polymerase chain reaction, or PCR, which measures HCV RNA in the blood), and 85% develop chronic hepatitis C infection. Of those with chronic infection, approximately 20% develop hepatic cirrhosis over the ensuing 20-30 years, and of those, approximately 25% will develop liver failure, hepatoma, or both. In the US, 10,000-20,000 deaths per year are presently attributed to HCV infection, and a 3-4 fold increase in HCV-related deaths is anticipated over the next 20 years.(2)(3)

Treatment

The decision to treat is based on the degree of biochemical and histologic liver disease, whether there is active virus detectable in the bloodstream, whether there is concurrent disease—and the choice of the patient. As of 2003, the most effective treatment is
combination therapy with pegylated interferon (via a weekly subcutaneous injection) and ribavirin (via pills taken orally twice daily), and results in an overall sustained viral response (SVR) of up to 56%. The SVR connotes the proportion of people treated who not only clear HCV RNA from their blood during therapy, but who also demonstrate no evidence of viral RNA 6 months following treatment completion. Some investigators believe that most if not all persons with SVR may actually be cured of their HCV infection.

Some genotypic strains of HCV are more responsive than others to treatment. SVRs of 42-46% are achieved after 48 weeks of treatment among persons infected with genotype 1, while those infected with genotypes 2 or 3 achieve SVRs of 76-82% after 24 weeks of treatment. In 2003, the standard duration of treatment is thus forty-eight weeks for persons with genotype 1 and 24 weeks for persons with genotypes 2 and 3. (1)

Common side effects associated with initiation of combination therapy include chills, myalgias, nausea, insomnia, and irritability. Some of these symptoms are similar to those of opiate withdrawal. In a recent study, 42% of methadone-maintained persons with HCV infection received methadone dose increases after initiation of combination therapy, presumably in response to opiate withdrawal-like symptoms. (4) Depression, which is associated with both substance use and with HCV infection, is also associated with interferon treatment and occurs in more than 20% of persons receiving interferon treatment for their HCV infection. A recent study showed that IDUs with preexisting psychiatric conditions could successfully complete a course of combination therapy if psychiatric symptoms were aggressively managed with antidepressant treatment. (5) Screening for depression before and during combination treatment for HCV infection, and access to psychiatric backup services, are important elements of treating drug users with HCV.

Since pegylated interferon is self-administered as a subcutaneous injection, physicians should be aware of and discuss with patients the possible trigger effect of self-injection with interferon as a risk for resumption of illicit drug injection. In some cases, directly observed therapy of at least the SQ injection may be an option. An important issue clinically is how to assess the risk for reinfection (following new exposure) with HCV following successful completion of HCV therapy. In a study that examined this issue, after 5 years of follow-up, exogenous reinfection with HCV occurred in only 1 of 27 IDUs who had achieved SVR with HCV treatment, although a return to injecting drug use occurred in 9 out of 27 participants. (6)

In short, it is critical to explore a range of issues (e.g., potential rates of response to treatment, anticipated side effects, coping with injecting the medication) with the patient prior to taking the decision to initiate treatment. Addressing these concerns in the context of the patient’s motivation for treatment maximizes the chances for successful completion of therapy.
Access to Treatment

The NIH HCV Consensus Conference Statement of 2002 represents a significant breakthrough with respect to access to care for HCV-infected injection drug users. As stated in the Consensus Statement:

“HCV therapy has been successful even when patients have not abstained from continued drug or alcohol use or are on daily methadone. Methadone treatment has been shown to reduce risky behaviors that can spread HCV infection, and it is not a contraindication to HCV treatment. Thus, it is recommended that treatment of active injection drug use be considered on a case-by-case basis, and that active injection drug use in and of itself not be used to exclude such patients from antiviral therapy.”(1)

These recommendations depart significantly from 1997 NIH guidelines, which cautioned against treating drug users. Another important barrier to care is the lack of coverage of HCV PCR and genotype tests by many state Medicaid programs, even though state-of-the-art medications (pegylated interferon and ribavirin) are covered. Finally, the medications themselves are expensive: the cost of a 48-week course of combination therapy with pegylated interferon and ribavirin was over $25,000 in 2002.

Several important interventions should be offered to all HCV-infected drug users. Alcohol use has been demonstrated to accelerate development of hepatic fibrosis among persons with HCV infection.(7) Counseling regarding alcohol abuse and dependence, and access to treatment for these conditions, must be provided to all patients. Although HCV treatment may be considered in patients who continue to drink modest amounts of alcohol, abstinence is clearly preferable, as alcohol appears to reduce the likelihood of achieving SVR. All drug users, but particularly those with HCV infection, should also be tested for hepatitis A and B infection, and immunized if not immune.

Approximately 30% of the 800,000 HIV-infected individuals in the United States are co-infected with HCV. Among HIV-infected injection drug users, the prevalence of co-infection with HCV is as high as 70-90%. Testing for HCV infection should thus routinely be offered to HIV-infected persons. HIV co-infection accelerates the progression of HCV-related liver disease. Indeed, HCV-related liver disease has become a leading cause of morbidity and mortality among dually infected persons. Treatment for HCV with pegylated interferon and ribavirin can achieve sustained virologic responses and prevent progression of liver disease in co-infected patients.

A recent study showed that the majority of IDUs infected with HCV continue to share needles and other drug paraphernalia after learning of their diagnosis.(8) Behavioral interventions to decrease the frequency of high-risk behaviors, and ready access to addiction treatment services, as well as to HCV education, counseling and testing, are essential elements of the public health response to the epidemic of HCV infection among drug users. Widespread access to sterile injection equipment needle is an
important objective in this regard. Drug users both in and out of formal treatment programs must be engaged in such efforts.


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