Hepatitis C Among Offenders– Correctional Challenge and Public Health Opportunity

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CHRONIC INFECTION WITH hepatitis C virus (HCV) is the most common blood-borne illness in the United States, affecting nearly 2 percent of all Americans, or an estimated 4-5 million individuals (Alter et al., 1999). While most individuals with chronic infection are not expected to progress to end-stage liver disease or death, hepatitis C is the most common indication for liver transplantation in the U.S., and it is responsible for 10,000 deaths annually (NIH Consensus Statement on Management of Hepatitis C, 2002). Although HCV can be transmitted through blood and blood product transfusions, hemodialysis and high-risk sexual practices, the leading risk factor for HCV infection is injection drug use (IDU) (Alter, 1997).

While the hepatitis C epidemic is substantial in the country as a whole, it has become a major concern in correctional settings. Prevalence of HCV infection in prisons is 8- to 20-fold higher than in the community, with infection rates between 16-41 percent and evidence of chronic infection in 12-35 percent (Centers for Disease Control and Prevention, 2003). An estimated one out of three Americans with chronic hepatitis C infection rotate through correctional facilities annually (Hammett, et al., 1997). Despite slow progression of most infections, illness and death within correctional systems is already substantial, likely explained by a large number of infections acquired decades ago. Hepatitis C infection is a leading cause of illness and death among in-custody inmates in some correctional facilities (Allen, 2003; D. Reiger, personal communication, 2002) and an emerging cause in others (J. Paris, personal communication, 2003).

Natural History of the Disease and Treatment Options

Hepatitis C virus primarily affects the liver. Over time, the virus can cause inflammation, which can lead to scarring (fibrosis or cirrhosis), and in some cases, liver cancer or end-stage liver failure.

The hepatitis C virus was only identified a little over a decade ago. Consequently, accurate information regarding the natural progression of untreated disease is limited to a number of epidemiologic retrospective analyses. The most widely accepted models state that between 15-20 percent of individuals initially infected will spontaneously clear the virus without any treatment. The majority of those infected, 80-85 percent, will go on to have chronic infection (Alter, 2000).

Fortunately for those with chronic infection, progression occurs slowly over years—typically decades. In a well respected model, in a 25-year period following initial infection, 20 percent of individuals exposed to hepatitis C will develop late-stage scarring of the liver (or cirrhosis) and only 3-5 percent will develop fatal complications such as decompensated liver disease of liver cancer (hepatocellular carcinoma) (Alter, 2000). Co-infection with HIV can cause acceleration of this process, as can regular heavy alcohol use.

While the disease can be staged (determining how advanced the disease is) by means of blood work and a liver biopsy, current experience with the disease does not allow clinicians to accurately predict who will progress to end-stage complications. For that reason, most patients with established disease and evidence of scarring on liver biopsy are potential candidates for anti-viral therapy.

Over the past decade, anti-viral treatments have become available, and have steadily improved. Initially, standard interferon regimens resulted in successful eradication of virus in roughly 20 percent of those treated. With the addition of ribavarin, treatment response increased to roughly 40 percent. With the current therapy, pegylated interferon plus ribavarin has been associated with a response rate in excess of 60 percent, with a response rate as high as 80 percent for some strains of the virus. No effective vaccine is currently available.

Unfortunately, despite improvements in response to therapy, significant side effects limit the utility of treatment. Unlike HIV, where treatment may continue for an indefinite period, current hepatitis C treatments are either 24 or 48 weeks, depending on the strain of the virus and initial response to treatment. Side effects of ribavirin may include significant drops in blood counts, resulting in anemia, fatigue and shortness of breath. In addition, pegylated interferon can cause flu-like symptoms including fever, muscle aches, headache and malaise, plus a host of possible reactions including eye problems, thyroid dysfunction and lung abnormalities. Significant psychiatric adverse effects of the treatment include irritability, depression and suicidality. Therapy for hepatitis C is contraindicated in a number of conditions, including pregnancy, advanced liver disease, autoimmune disease (such as Lupus) and uncontrolled psychiatric illness, among others.

In combination with the slow smoldering course of disease, the side effect profile of available medications, and the expectation of novel treatment with higher efficacy and improved side

effect profiles in the next 3 to 5 years, patient selection for treatment is highly individualized within treatment guidelines. Treatment recommendations take into consideration a number of factors, including stage of disease (as established by clinical factors such as blood tests and liver biopsy) and co-existing chronic disease such as HIV, diabetes, heart disease and psychiatric illness. Finally, treatment requires fully informed consent of the patient regarding the risks and benefits of treatment.

In the correctional setting, duration of incarceration is often used to determine eligibility for anti-viral therapy (Proceedings of Management of Hepatitis C in Prisons Conference, 2003). As interruption in therapy can adversely affect effectiveness, treatment while incarcerated is typically reserved for those patients who will remain institutionalized for the complete period of anti-viral therapy (24 or 48 weeks depending on genotype). Treatment for patients with shorter sentences is generally safely deferred to the community.

Unfortunately for the large number of inmates being released from correctional facilities with hepatitis C, resources for evaluation and management of this disease are scarce in the community. Public health agencies have generally not been funded to address the high burden of disease in the largely uninsured, post-correctional population.

Response to Hepatitis C in Corrections

Despite the high prevalence of hepatitis C in corrections, response by correctional institutions has been measured. Most facilities have great difficulty in accessing sub-specialty evaluation for the large number of patients who are infected. While some states have developed protocols for evaluation and treatment by general internists (Allen et al., 2003), others have to date failed to offer any treatment at all. States with limited or no access to treatment have been subjected to class action lawsuits seeking access to care for infected inmates. At this time, most states and the Federal Bureau of Prisons are in the process of devising guidelines and protocols for evaluation and management of hepatitis C in the correctional setting (Proceedings of Management of Hepatitis C in Prisons Conference, 2003). In January 2003, the Centers for Disease Control and the National Commission of Correctional Healthcare sponsored a meeting of state and federal correctional healthcare professionals to encourage the sharing of data, treatment experience and strategy for correctional settings (Allen, 2003).

In rare cases, clinically advanced disease can lead to major and potentially fatal complications, with implications for sentencing, classification, probation and parole. In the majority of cases, however, chronic hepatitis C can be safely managed within the prison setting, provided hepatitis C evaluation and treatment are accessible. For inmates undergoing active treatment—typically for 24 or 48 weeks—the significant side effects of therapy can impact on the patient's ability to participate in work and recreational activities. Consequently, timing of therapy and work assignment needs coordination.

Costs of Treatment

In addition to the human cost of treatment-related side effects, the potential financial impact on stressed correctional budgets is a major public policy concern. Funding for medical care of inmates is covered almost entirely by public funds under a constitutional obligation to provide care (Estelle v. Gamble, 1976). Cost for a course of treatment ranges between a low estimate of $7,000 and a high estimate of $20,000 per patient.

Legitimate logistic constraints resulting from short periods of incarceration result in deferral of treatment until after release for the majority of individuals incarcerated with HCV infection (J. Paris, personal communication, 2003; Allen et al., 2003). Other clinical criteria and informed consent resulting in patient decision to defer therapy further reduce the pool of candidates for treatment during the period of incarceration. While correctional facilities have been able to take advantage of reduced cost drugs in some settings, the potential cost impacts are considerable (Spaulding et al., 1999). For the foreseeable future, correctional systems will struggle to provide cost-effective care while not unreasonably limiting access to care. Anticipation of newer therapies with greater effectiveness and improved side-effect profiles can be expected to be more costly than currently available therapies.

Associated Issues: Substance Abuse and Mental Health

The strong association between remote and /or current injection drug use (IDU) and hepatitis C infection has already been described. In prisons, the vast majority of HCV infected patients acquired their infection from drug-related risk behaviors. In addition, alcoholism can have an accelerating effect on the clinical course of the infection (Schiff, 1999) and may help explain some of the more advanced clinical stages of fibrosis and cirrhosis found in some incarcerated patients.

A history of substance abuse had long been considered a relative contraindication to treatment for HCV infection. However, a careful review of published experience has demonstrated little clinical justification for withholding treatment to HCV patients with a history of substance abuse (Edlin, 2001). In 2002, the NIH Consensus Statement on Hepatitis C removed substance abuse from the list of contraindications for anti-viral therapy. The forced sobriety of prison also provides for a window of opportunity for safe and successful treatment (Allen et al., 2003) that, when coupled with substance abuse treatment—including methadone (Tomasino et al.), education, risk reduction counseling and intervention—has the potential to reduce the risk of re-infection. Furthermore, fears about re-infection may be largely theoretical; there are only two confirmed cases of patients re-infecting themselves by drug injection after successful treatment with interferon and ribavirin (Kao et al., 2001; Dalgard et al., 2002).

Still, efforts aimed at addressing HCV in corrections need to be closely coupled with treatment and referral for the health problem of drug dependence. While no longer considered a prerequisite for access to treatment, responsible treatment protocols include counseling, referral and treatment for substance-abuse-related issues as part of their HCV program. Given the persistently high cost of medical anti-viral therapy for HCV for the minority of incarcerated infected patients who will be eligible, broader efforts aimed at dealing with the activity most closely associated with transmission of infection are critical.

Because the side effects of interferon-based anti-viral therapies include significant psychiatric side effects including major depression (Zdilar et al., 2000), caution must be exercised when considering using interferon in patients with a history of psychiatric illness. Evaluation for possible treatment should include screening for history of depression, suicidality and other significant psychiatric illness. Mental illness, including depression, anxiety, and post-traumatic stress disorder, is encountered more commonly in correctional populations than in the general public (Ditton, 1999; Beck and Maruschak, 2000). However, interferon-related depression does respond to anti-depressant medication (Hauser, 2002). Concerns about adverse psychiatric effects in individuals with histories of psychiatric disorders are extrapolated from studies reporting psychiatric side effects in patients without psychiatric diagnoses who were treated for hepatitis C (Schaefer et al., 2003). In fact, a growing body of literature supports the safety of treating hepatitis C in individuals with a history of psychiatric diagnoses (Relault et al., 1987). Hepatitis C treatment can be safely initiated in patients with a history of mental illness provided the illness is stable, a psychiatrist has evaluated and

cleared the patient, and the medical and psychiatric teams collaborate closely during the treatment period. In correctional settings where there are comprehensive mental health services, the controlled and monitored environment of a correctional facility may provide one of the safest settings in which interferon therapies can be undertaken in those with mental illness (Allen et al., 2003).

Have We Been Here Before? The HIV Experience

Corrections has faced the challenge of an epidemic of a chronic blood-borne infectious disease prior to the recognition of the hepatitis C epidemic with HIV, the virus that causes AIDS. There are similarities that may be useful to consider, and factors that make these epidemics quite distinct. The risk factors for HIV and HCV are similar, and in corrections, injection drug use accounts for the majority of both infections (Centers for Disease Control and Prevention, 2003). However, HCV is more effectively transmitted, and is consequently much more common. HIV prevalence among releasees from correctional facilities is estimated to be 2-3 percent, compared to 17-18.6 percent for HCV (National Commission on Correctional Health Care, 2002). While the majority of individuals infected with HCV will not progress to end-stage complications of liver failure, cancer and death even if untreated, the majority of HIV-infected individuals would face fatal outcome from untreated infection.

Still, there is much to learn about the current HCV epidemic from the HIV experience in corrections. First, HIV treatment programs have shown that inmates who are engaged in well-designed longitudinal treatment programs have lower recidivism rates and are more likely to practice health-conscious behaviors (Conklin et al., 1998). Second, in the early days of antiretroviral therapy for HIV, providers were often reluctant to prescribe these life-saving medications to drug users and persons with mental illness because of fears of non-adherence and potential drug interactions (Clarke and Mulcahy, 2000). However, in the context of programs that specifically address the unique needs of these populations (Mitty et al., 2002), including adherence programs for incarcerated persons (Kirkland et al., 2002), drug users and persons with psychiatric illness are consistently safely and successfully treated for HIV.

A Public Health Opportunity

Many observers understandably look at the large concentration of chronic hepatitis C within prisons as a daunting medical and fiscal challenge to state and federal correctional systems, which indeed it is. At the same time, it is also a significant public health opportunity. One-third of Americans with a clinically silent and often undiagnosed transmissible infectious disease are congregating in jails and prisons. The majority of these individuals will return to the community. The Centers for Disease Control and Prevention estimate that 1.3 million individuals with hepatitis C, or 39 percent of all Americans with this disease, are released from correctional facilities each year. Once back in the community, infected individuals may continue to transmit the infection, particularly if they remain undiagnosed and untreated. This situation presents a rare opportunity for targeted interventions aimed at reducing spread of the virus. Including the incarcerated population in efforts to impact the burden of infectious disease is a valid and effective approach, and is now recognized as an important strategy by those in corrections and public health agencies (Glaser and Greifinger, 1993; Association of State and Territorial Health Officials, 2002).

While medical treatment of HCV has the theoretical effect of reducing the size of the infectious pool for those returning to the community, other preventive interventions, such as diagnosis of the disease, education and counseling about transmission, education about harm reduction through clean needle access, and referral and treatment for substance abuse make sense from a public health and safety perspective. Related cost-effective interventions, such as vaccination of HCV-infected inmates against hepatitis B (whose co-infection could accelerate liver failure) would also save money and lives for states and localities (Rich et al., 2003).

Conclusions

Hepatitis C is a significant problem for individuals involved with the correctional justice system nationally. This epidemic has significant policy and fiscal implications, and correctional institutions are in the early stages of developing systematic responses to the epidemic. A significant minority (39 percent) of Americans infected with the virus congregates in correctional institutions. This situation provides a unique opportunity to diagnose, educate and treat appropriate individuals, and to reduce transmission in the community upon the inmate's release.

While diagnosis, evaluation and treatment has significant medical implications for individual patients, access to proper medical care after prison also has the potential to influence future criminal behavior. Linkage of incarcerated HIV-seropositive patients to medical care upon prison release has been associated with improved access to health services and reduced recidivism (Flanigan et al., 1996; Kim et al., 1997). Addressing the factors that influence the ability to tolerate HCV treatment (substance abuse, stable mental health, social support) will likely also reduce recidivism. In substance abuse treatment settings, linkage to medical care is associated with improved addiction-related outcomes (Friedmann et al., 2003). The same positive effect on recidivism and addiction outcomes will likely accrue to drug-involved prison releasees who become motivated to address their HCV infection. Continuity of care will help the drug-involved offender develop "trust in the system," work toward rehabilitative goals and community readjustment (Mitty et al., 1998), and address mental health and substance abuse issues as part of community management of HCV.

Systematic approaches to the hepatitis C epidemic in corrections are needed. Unlike the early days of the HIV epidemic, which spawned a highly organized, politically influential constituency, incarcerated individuals with substance abuse histories have few advocates. As a result, the public and legislative response to hepatitis C in corrections has been muted. The public health and fiscal implication of this epidemic, however, warrant a more proactive response. Cost-effective interventions, such as targeted screening, health education and individual counseling, clean needle access, immunization against hepatitis B and substance abuse treatment, should form the foundation of that response.

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