Annals of Internal Medicine | Medicine and Public Issues

A Framework for Management of Hepatitis C in Prisons

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The prevalence of chronic hepatitis C virus (HCV) infection in prisons ranges from 12% to 31%. There are generally accepted—albeit still evolving—guidelines for identification and treatment of hepatitis C in the community. However, there is less agreement among health professionals caring for prisoners about best practices for identification, medical management, and treatment of hepatitis C. Inmates often lack health care before incarceration. In prisons, infected persons could be identified and the management of infection initiated; however, the high prevalence of HCV infection among prisoners would impose a disproportionate cost for hepatitis C care on the correctional system. The optimal solution is for prison and public health systems in the United States to jointly provide targeted HCV testing and standard-of-care hepatitis C medical management, treatment, and prevention programs to prison inmate populations. The authors report on a January 2003 meeting of experts in prison health, public health, hepatology, and infectious diseases and explore the clinical care, prevention, and collaboration needed to provide hepatitis C management in prisoners.

Ann Intern Med. 2006;144:762-769. www.annals.org

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Inmates with chronic hepatitis C virus (HCV) infection present a major challenge to prison health systems. In the United States, prisons house approximately 1.4 million adults serving sentences that range from 1 year to life (1). State prisoners serve an average of 30 months, and the average annual population turnover is 33% (2, 3). Sixteen percent to 41% of inmates are positive for antibody to HCV (anti-HCV), and 12% to 31% have chronic infection (4). The primary source of HCV infection in the United States is illegal injection drug use; drug offenders make up 20% of state and 55% of federal prison populations (5).

Although 95% to 99% of prison inmates are eventually released to the community (6, 7), sentences have increased substantially over the past decade (3). Because of longer periods of incarceration, prison health care systems must provide care for chronic medical conditions, including liver disease. Prison health care officials are faced with the question of whether a chronic disease like hepatitis C, which is usually asymptomatic but is responsible for much of the liver disease previously attributed to alcohol abuse (8), is a health condition that merits identification, medical evaluation, and possible treatment.

Prison systems are unlikely to benefit directly from proactive identification of inmates with HCV infection or from treatment of patients whose disease may take years to become symptomatic. In the United States, direct medical expenditures related to chronic hepatitis C are predicted to amount to $10.7 billion from 2010 to 2019 (9). Prison health care budgets could bear a large share of this cost because of the disproportionate number of incarcerated persons with HCV infection. However, current guidelines for identification, counseling, medical evaluation, management, and treatment of persons with chronic hepatitis C specifically recommend offering these services to incarcerated persons (4, 10). To gain insight into the challenges of identifying HCV infection and managing hepatitis C in prisoners, a meeting, funded by the Centers for Disease Control and Prevention and the National Institutes of Health, was held in January 2003. Forty-three state prison systems sent their medical director, a prison administrator, or both to the conference. Experts in prison and public health, hepatology, and infectious diseases (Appendix, available at www.annals.org) gave presentations. The information and viewpoints shared at this meeting were intended to guide development of hepatitis C testing and treatment policies at state departments of corrections.

Background

The high proportion of incarcerated persons with HCV infection or risk factors for infection makes correctional facilities logical venues to implement hepatitis C prevention and medical management programs. The vast majority of incarcerated persons in the United States are short-term detainees. Although time does not permit these individuals to begin hepatitis C treatment before discharge, all inmates can still greatly benefit from hepatitis C education and appropriate referral for testing and, if infected, for disease evaluation in the community. If incarceration extends to months, diagnostic evaluations can begin. Prisons house inmates for longer sentences. This paper will focus on the long-term occupants of prisons.

Many prison systems have established programs to prevent and manage other infectious diseases, such as tuberculosis, HIV/AIDS, and sexually transmitted diseases. Prevention of hepatitis C could feasibly be integrated into such programs (4, 11), which could reduce the incidence of new HCV infections and prevent transmission to others from already infected persons (primary prevention), identify and treat asymptomatic persons with infection to re-

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Appendix

duce chronic liver disease (secondary prevention), and reduce disability among persons with disease (tertiary prevention) (12). Substance abuse treatment and risk reduction counseling provided within prisons to prevent injection drug use can have effects on primary prevention in and outside the prison system. For inmates found to be infected with HCV, prevention services, such as substance abuse treatment and education about risk and harm reduction, could also reduce transmission of HCV to others. Secondary prevention for inmates with HCV infection begins with a medical evaluation to determine the extent of chronic liver disease, to determine the presence of comorbid conditions (for example, HIV infection and substance abuse), to assess the need for antiviral therapy with or without substance abuse (drug and alcohol) treatment, and to provide immunization against hepatitis A and hepatitis B, as needed.

Natural History and Medical Management of Hepatitis C

Most persons, including prisoners, with chronic HCV infection are asymptomatic, although 70% to 85% have histologic evidence of active liver disease, including inflammation, fibrosis, or cirrhosis (13, 14). It is not easy to determine which persons with chronic hepatitis C have infection that will progress to symptomatic liver disease and death. However, several factors speed disease progression, including male sex, becoming infected after 40 years of age, alcohol abuse, and co-infection with other viruses, such as hepatitis B virus and HIV (13).

The efficacy of hepatitis C antiviral treatment has improved substantially over the past decade. Combination therapy with pegylated interferon and ribavirin achieves an overall sustained virologic response (SVR) of 50% to 60% (15). Although long-term data are not available for the effectiveness of antiviral therapy in decreasing hepatitis C–related death, intermediate-term data indicate that persons with SVR have improved liver histologic characteristics and diminished liver disease (16, 17).

Many correctional systems have developed evidence-based protocols for identification, medical evaluation, and antiviral treatment of inmates with HCV infection. Although these protocols vary in their inclusion criteria, they provide a framework for identifying and managing HCV-infected inmates. The use of protocols minimizes interprovider variability in therapeutic decision making, and their guiding principles permit the flexibility required to tailor treatment and medical management to patient needs (18).

Preliminary data indicate that with good adherence to treatment regimens, SVR rates for prison patients treated with combination therapy are comparable to those observed in noninmate patients at similar stages of disease (19–22). However, therapy in prisons can be frequently interrupted (22). Also, in contrast to reports of lower SVR rates among black patients receiving the same therapeutic regimen as white patients in nonprisoner populations, the authors of one small prison study observed that SVR rates were similar among white and black patients with genotype 1 infection treated with interferon and ribavirin under direct observation of correctional nurses (23).

The costs of hepatitis C medical management, including liver biopsy, transportation for specialty care, and medication, vary among correctional systems. Although some systems have negotiated lower prices for antiviral drugs and pay as little as 40% of the retail cost for peginterferon and ribavirin combination therapy (Peterson C, PharmD, Georgia Correctional HealthCare. Personal communication, 8 September 2004), the cost of hepatitis C treatment is still substantial in all systems. Treating eligible patients could represent a 15% to 60% increase in the average state correctional system medical budget (4, 24).

Challenges to Management of Hepatitis C in Prisons

Experts participating in this meeting did not reach consensus about all the issues discussed. However, data and discussion led to the identification of 5 areas in which generalizations could be made about optimal approaches to hepatitis C prevention, identification, and treatment. Participants proposed that consensus in the following areas would support a rational framework for the management of hepatitis C for infected prison inmates.

Testing for HCV Infection in Prisons Would Identify Many Infected Americans

Of all persons infected with HCV, approximately 29% to 43% pass through a correctional system each year (25). It is currently recommended that incarcerated persons with risk factors for HCV infection be screened (4). Although 49 states have at least 1 prison that tests inmates, only 10 states offer routine testing in all facilities. Of 1584 state prison facilities, 4% offer risk-factor–based HCV testing to incoming inmates and 5% offer testing to inmates already in custody (26). Routine HCV testing for all inmates is less common than routine HIV testing, which was performed for inmates at entrance in 19 state prison systems in 2000 (27).

Although court rulings have granted prisoners access to health care, correctional systems are not obligated to seek potential medical problems (28, 29). Medical conditions identified for screening have been selected for the following reasons: 1) They are amenable to treatment; 2) they interfere with activities of daily living; 3) they could progress without treatment during the duration of incarceration; or 4) they pose a risk for infection transmission. Although hepatitis C can be easily identified by testing, it has not been considered a correctional health priority because it does not meet these criteria.

Recommended screening strategies maximize identification of individuals infected with HCV while avoiding the cost of universal testing (4). In Wisconsin, 91% of

anti-HCV–positive inmates were identified through testing the 27% of the population with a history of injection drug use, serologic evidence or a history of hepatitis B virus infection, or elevated alanine aminotransferase (ALT) levels (30, 31). Risk-based screening programs in the Federal Bureau of Prisons and Washington State prisons identified 6% and 15% of their populations, respectively, as anti-HCV–positive. However, the percentage of the entire inmate population that was anti-HCV–positive was not determined (22, 32). Correctional health authorities in other states have found testing based on predictors of risk insufficient to identify infected inmates. In Indiana, because only two thirds of the expected numbers of HIV-positive inmates were identified when testing was done on inmate request or by identified clinical indication, subsequent legislation required universal, mandatory HIV and HCV testing (33). Universal testing found that 13% of inmates were anti-HCV–positive (34).

Determination of inmates' infection status benefits the individual, the prison system, and the public's health. Inmates who are HCV-negative but have risk factors for infection are candidates for primary prevention interventions both inside and outside of the prison. Inmates positive for HCV can be provided prevention services to minimize HCV transmission and further liver damage. Although prison health systems would bear the greater initial costs, over time they may benefit from the decreased infection prevalence and lower rates of chronic liver disease.

Providing In-Prison Treatment for Substance Abuse Would Prevent Hepatitis C and Future Prison Costs

Treatment of substance abuse is an essential element of hepatitis C prevention. In 2002, 69% of jail inmates reported regular drug use before incarceration (35), and in 1997, 70% of state prison inmates reported regular preincarceration drug use. Among state prisoners, 15% used opiates, 34% used cocaine, and 58% used marijuana (36). Substance use is associated with incarceration and recidivism. In state prisons, 41% of first-time offenders used drugs regularly compared with 63% of second-time offenders and 81% of those who had 5 or more previous convictions (37).

Incarceration can provide an opportunity to treat drug-using offenders. However, programs addressing substance abuse are limited in prisons. In 1997, although an estimated 70% of inmates needed some substance abuse treatment, only 10% received treatment, which could consist of residential programs, professional counseling, detoxification units, and opiate replacement programs. An additional 20% of inmates participated in less effective interventions, including self-help, peer counseling, and educational and awareness programs (36). Opiate replacement therapy is effective in reducing drug use but is unavailable in most prison systems (37).

Substance abuse treatment in prison reduces drug use in the community (37) and should reduce HCV transmission. In 1 prison, 30% of inmates who completed treatment in a therapeutic community while incarcerated were drug-free in the community 3 years later, compared with 5% who had not been treated ($P < 0.05$) (38). Recidivism decreased among those released inmates who received effective drug treatment, and 88% of treatment costs were recovered from the reduced number of prison days during the first year after treatment, with higher savings if the costs of averted crimes were considered (39).

Educational programs have increased inmate and staff understanding of transmission and prevention of bloodborne viral infections (40, 41). For injection drug users, harm reduction education, such as teaching the use of clean syringes, needles, and bleach solutions, may help reduce HCV transmission (42). Although injecting drugs is prohibited in prisons, safer techniques can be used after discharge if a drug user relapses. In addition, community follow-up, including ongoing substance abuse treatment, life-skills support, and health education, is needed for drug treatment and harm reduction to be most effective.

Selecting Patients To Treat Can Be Done by Using Published Guidelines

In 2002, the National Institutes of Health published a consensus statement on management of hepatitis C (10). Medical management and adherence to antiviral therapy require lifestyle stability that can be provided by incarceration, particularly for offenders with a history of mental illness or substance abuse (43). However, careful patient selection to maximize treatment adherence is as important in prison as it is outside prison, although considerations differ for each setting. With few exceptions, continued hepatitis C care for inmates after prison release is not available in most communities because of lack of medical providers qualified or willing to treat the disease in this largely uninsured population. This reality has forced prison health administrators to make the expected duration of incarceration an important selection factor and to exclude inmates with insufficient time to complete evaluation and treatment. In addition, medical evaluation to identify existing comorbid conditions and to stage the extent of liver disease (10) excludes many inmate-patients because of contraindications to treatment, including unstable psychiatric disease, decompensated cirrhosis, and cytopenias.

Among patients with chronic HCV infection and no medical or psychiatric contraindications, ALT levels are often used to decide who should be considered for antiviral therapy (44). Although no specific guidelines were given by the National Institutes of Health consensus statement, some correctional health protocols have considered an ALT level abnormal only if it is more than twice the upper limit of normal, recommending that treatment decisions be made on a case-by-case basis below this threshold (45). These protocols may exclude inmate-patients who should be considered for treatment. One study found that treating only inmates with an elevated ALT level measured on a

single occasion failed to detect 45% with fibrosis and 21% of those with cirrhosis (14). These findings emphasize the need for complete medical evaluations and individualized treatment decisions. Regardless of ALT level, antiviral treatment should be considered in HCV-infected patients with increased fibrosis, HIV co-infection, or HCV-induced cryoglobulinemia (44).

Liver biopsy is currently the most accurate way to stage liver disease and to predict disease progression. The degree of fibrosis (for example, METAVIR stages 0 to 4+) best predicts whether a patient would benefit from treatment. Those with stage 2, 3, or 4 liver disease might benefit from treatment, and therapy may be deferred in patients with METAVIR stage 0 or stage 1 disease long after the onset of infection (10, 15). Use of biopsy to stage liver disease is cost-saving compared with treating all eligible inmate-patients (13, 46). However, some prison facilities, because of geographic location and security challenges, do not perform biopsies routinely and may initiate treatment on the basis of ALT levels (47, 48).

Prison health systems are often forced to prioritize inmate-patients for treatment because of limited resources. Inmate-patients at highest risk for cirrhosis benefit most from treatment. However, fibrosis does not develop at the same rate in all patients (49). Although this method was not evaluated with respect to sensitivity and specificity, one prison system has estimated the rate of fibrosis development to identify "rapid fibrosis progressors." Risk-factor history is used to estimate the timing of HCV infection and is combined with biopsy results to identify those infected with METAVIR stage 1 disease for less than 10 years. These patients are offered antiviral therapy, as are patients with METAVIR fibrosis in stages greater than 2 (50, 51).

Hepatitis C virus genotype is not included in selection criteria for antiviral treatment in the general population (10). However, shorter therapeutic courses are used to treat genotypes 2 and 3. Because of the importance in most states of inmate-patients completing therapy before release, patients with genotypes 2 and 3 and a shorter duration of incarceration may be considered for treatment.

In the past, alcohol or injection drug abuse without treatment was considered a relative contraindication to treatment (52). However, injection drug users taking methadone and abstaining from injecting drugs have hepatitis C treatment outcomes similar to those of noninjection drug users, and occasional drug users have only slightly lower SVR rates (53, 54). Although relapse of injection drug use has the potential to cause HCV re-infection or infection with another bloodborne virus, it should not contraindicate antiviral treatment (55, 56). In prisons, drug use is usually sporadic and the environment ensures relative sobriety, which presumably is conducive to successful antiviral treatment (57). Some prisons treat alcohol and drug addictions concurrently with hepatitis C, although outcomes of concurrent treatment have not been evaluated. Despite the damage that alcohol can cause to the liver, correctional physicians managing patients with liver disease may not identify substance abuse as a health issue. Integration of drug and alcohol treatment with hepatitis C management is essential for optimal outcome.

Some inmate-patients for whom monotherapy or combination therapy with nonpegylated interferon has failed may benefit from retreatment. Retreatment with peginterferon and ribavirin for nonresponders has resulted in low SVR rates (58). Strategies for retreatment with other interferon products are under investigation. Inmates identified as having infections that previously did not respond to less effective treatment should receive the same medical evaluation and treatment assessment as other HCV-positive inmates.

Treatment in Prisons Reflects Community Standards and Requires Sufficient Medical Workforce Resources

Prisons strive to follow community standards for treating chronic hepatitis C. At the time of the meeting, a 48-week course of pegylated interferon-α2a or interferon-α2b and weight-based ribavirin (with early discontinuation of treatment if HCV RNA levels do not decrease because SVR is unlikely) was optimal treatment for patients infected with genotype 1 (10, 15). Hepatitis C virus genotypes 2 and 3 require a shorter course of peginterferon with a lower dose of ribavirin (10, 15, 59). Although monotherapy or combination therapy with nonpegylated interferon may be less expensive, patients treated with these regimens have statistically significantly lower SVRs, making the treatments unacceptable options, except in special circumstances.

In community-based clinical trials, severe adverse events during hepatitis C treatment resulted in discontinuation of therapy in 10% to 20% of patients (60). Depression and psychosis, common in prison settings, occur with interferon treatment, and it is essential to provide psychiatric evaluation of patients during treatment. Suicide concomitant with interferon use has occurred in a prison setting. However, discontinuation of therapy due to psychiatric and other adverse events appears to be infrequent among prisoner-patients. In 1 case series, only 3 of 93 (3%) patients were denied therapy because of psychiatric reasons, although 41 (44%) had a history of depression and 4 (4%) had a history of attempted suicide. Of those who underwent therapy, none subsequently stopped because of psychiatric reasons (61). In another case series, only 20 of 674 (3%) patients treated over 2 years discontinued therapy because of adverse events, 3 of which were related to severe psychiatric symptoms (47).

Other side effects and underlying comorbid conditions common in prisoner-patients can also complicate hepatitis C treatment and require changes in drug doses or specific treatment. Cytopenia requires dose reductions, and ribavirin-induced anemia has unmasked coronary artery disease. Researchers in small studies have suggested that adjunctive

therapy with erythropoietin (to raise hemoglobin levels) and granulocyte colony-stimulating factor (to raise neutrophil counts) can allow patients with anemia and neutropenia to continue therapy (60).

Management and treatment of hepatitis C requires health care providers to deliver an often complex therapeutic regimen, to closely monitor patients for a wide range of adverse events, and to anticipate potential treatment complications. Many prison systems do not have specialists with experience in hepatitis C treatment. However, hepatitis C can be successfully managed by general internists or other primary care physicians who have access to appropriate specialists (19–21, 47). Some prison health care systems use telemedicine consultations to review cases (47).

Collaboration between Correctional and Public Health Systems Is Needed

Because inmates become wards of state, federal, or tribal governments upon incarceration, private and public health insurance cannot be used to provide health care services in most correctional systems. All health care and preventive services, including those provided by the public health system in the outside community, become the responsibility of the correctional system. Currently, few prison medical systems are organizationally or fiscally linked to their respective state or local public health system (29), making postrelease follow-up challenging. Follow-up is essential for individuals with or at risk for HCV infection, and initiating contacts with community agencies during incarceration improves follow-up and health outcomes for released inmates (37, 62–64).

Many inmates enter prison with social, medical, and mental health conditions and reenter the community with few of these conditions addressed. Hepatitis C is one such condition, and its management challenges both the correctional and public health systems. Many incarcerated persons have not previously sought preventive health care, and the correctional system is their first opportunity to access these services (4, 65). Currently, there are limited examples of correctional and public health systems jointly addressing the needs of current and former inmates with hepatitis C. Widespread collaborations could effect noticeable improvements in care and prevention of hepatitis C and its associated conditions, such as injection drug use.

To best reach persons at risk for HCV infection and other diseases, such as HIV/AIDS, prevention services should be integrated into all health care venues that serve populations with high-risk behaviors. Clearly, this includes both correctional and public health systems. Both systems should question patients about risk behaviors, such as injection drug use; offer prevention services at each patient encounter; and share information with each other. There are many examples of health departments and community-based organizations assisting correctional facilities in implementing prevention activities (63). Health departments have provided prisons with health educational materials, testing for HCV and other infectious diseases, and care and treatment for inmates; they have also conducted blinded seroprevalence studies and ensured continuity of care upon inmate release (66, 67).

Medical care in the community after release of inmates with hepatitis C would allow for completion of their hepatitis A and hepatitis B vaccination series and hepatitis C medical management. It would also provide them with continued substance abuse treatment, harm reduction education, and social support. Some offenders may be able to link with community health clinics and Veterans Administration programs for hepatitis C treatment and substance abuse services (Miles J, MPA, Centers for Disease Control and Prevention. Personal communication, 13 December 2004). One recent initiative permits inmates with HCV infection in New York to start treatment in prison and continue in designated clinics once released, allowing treatment for patients anticipating short incarcerations (Wright L, MD, MPH, New York Department of Corrections, and Beck J, JD, Correctional Association of New York. Personal communication, 21 November 2005). However, in many states, transitional medical care programs are categorically directed to HIV/AIDS and only serve inmates with HCV infection who are co-infected with HIV.

Federally funded hepatitis C coordinators, whose role is to facilitate collaboration and integration of services among programs serving persons at risk for hepatitis C, exist in health departments in 48 states and the District of Columbia, 4 large metropolitan cities, and the Indian Health Service (68). In some jurisdictions, hepatitis C coordinators have facilitated links between correctional facilities and communities to improve hepatitis C aftercare.

The correctional and public health systems have created case-management systems to enable continuous medical care for inmates and released inmates with AIDS. Resources for this continuity of care came primarily from the Ryan White Comprehensive Care Act (69) and should serve as a model for hepatitis C care. Currently, patients leaving prison while receiving HCV treatment can access programs sponsored by 2 pharmaceutical manufacturers, which provide peginterferon at no cost (70, 71). However, finding a community physician who will oversee management may be more difficult. Stakeholders can motivate communities to address hepatitis C in prisons: Family members have become advocates for offenders' needs, and communities with many released inmates have worked with elected representatives for development and improvement of aftercare systems (72).

FUTURE DIRECTIONS AND UNANSWERED QUESTIONS

Prevention and management of hepatitis C in prison inmates continue to be evolving practices, limited by scarce resources and by gaps in knowledge both in prisons and in the community. Research and further consensus-building is needed before optimal prevention and health care ser-

vices will be given to inmates. Some important questions remain.

1. Is there an overall reduction in the incidence of HCV infection and chronic liver disease by identifying inmates with HCV infection? Long-term population-based studies could improve HCV testing strategies for inmates, determine whether former inmates require retesting upon prison reentry, and determine whether identification of infected inmates affects the clinical outcome of hepatitis C.

2. Can simple and widely accepted testing and treatment algorithms for prisons be developed and evaluated? Economic analyses of hepatitis C medical management in prisons could provide important evidence on the effectiveness of prison-based hepatitis C testing, prevention, and treatment programs. Population-based studies could determine how treating eligible patients with hepatitis C in prisons could contribute to the nation's health. Conversely, we need to know the effects of continually returning inmates with untreated HCV infection to the community.

3. Do prison-based educational programs, often modeled after HIV prevention programs, affect inmates' knowledge of, attitudes about, and practice related to prevention of HCV transmission? Evaluations of existing curricula and development of effective educational interventions are needed to justify and guide the development of successful educational programs.

4. After release, what is the rate of HCV re-infection among inmates with SVR after therapy? Many drug-injecting inmates will return to parenteral drug use after release. Research is needed to determine the rate of re-infection among this group and the effect of prevention services on stopping both injection drug use and re-infection.

5. Does community aftercare for released inmates prevent relapse of injection drug use and HCV infection? Follow-up studies of prisoners returning to communities are needed to determine what types of resources are most effective to maintain optimal health among former inmate-patients with hepatitis C and would provide a basis for designing successful aftercare interventions.

CONCLUSIONS

Hepatitis C viral infections are highly prevalent in prison populations. Although the overall rate of progression to cirrhosis or liver cancer is relatively low, the high prevalence of infection results in a large burden of disease from hepatitis C. Indeed, the national incidence of hepatocellular carcinoma has begun to increase, and this is partly attributable to chronic HCV infection (73).

For the management of hepatitis C in prisons, there are many short-term concerns, but there are reasons for long-term optimism, despite questions about the best practices for prevention, identification, and treatment of hepatitis C in this setting. Most prison health practitioners agree on the need to 1) identify individuals infected with HCV in incarcerated populations; 2) provide these individuals with substance abuse treatment; 3) select HCV inmate-patients who may benefit from treatment; 4) use treatment regimens that follow published guidelines; and 5) improve collaboration between correctional and public health systems.

Cost is the major barrier to implementation of comprehensive hepatitis C prevention programs in every prison system. Future therapies promise to be more efficacious and less costly. As treatment evolves, there will be a greater impetus to treat a broader range of patients. Prison health directors currently have to choose among competing health care priorities, including hepatitis C antiviral therapy and HIV and hepatitis B management. However, prisoners should be provided contemporary best practices in hepatitis C medical and preventive care.

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Acknowledgments: The authors thank the following people for providing the planning group with the correctional professional viewpoint: James Gondles, American Correctional Association; Edward Harrison, National Commission on Correctional Health Care; Timothy Ryan, American Jail Association; and Richard Stalder, Association of State Correctional Administrators. The authors also thank Keith Bordelon, Centers for Disease Control and Prevention, and Samantha McCready and Carol Schagunn, University of Minnesota, for contributions to the coordination and planning of the January 2003 meeting in San Antonio, Texas.

Potential Financial Conflicts of Interest: *Consultancies:* D.T.-Y. Lau (Roche, GlaxoSmithKline, Bristol-Myers Squibb); *Expert testimony:* A.C. Spaulding (Dr. Spaulding has given expert testimony on prisoners' right to receive medical management of hepatitis C); *Honoraria:* D.T.-Y. Lau (Bristol-Myers Squibb, Roche, GlaxoSmithKline); *Grants received:* D.T.-Y. Lau (GlaxoSmithKline, Bristol-Myers Squibb, Roche), R. Sterling (Schering-Plough, Roche); *Grants pending:* R. Sterling (Roche, Schering-Plough).

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