Treating Hepatitis C in the Prison Population Is Cost-Saving

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The prevalence of chronic hepatitis C infection in U.S. prisons is 12% to 31%. Treatment of this substantial portion of the population has been subject to much controversy, both medically and legally. Studies have demonstrated that treatment of chronic hepatitis C with pegylated interferon (PEG IFN) and ribavirin is a cost-effective measure in the general population; however, no study has addressed whether the same is true of the prison population. The aim of this study was to determine the cost-effectiveness of hepatitis C treatment with PEG IFN and ribavirin in the U.S. prison population. Cost-effectiveness was determined via a decision analysis model employing Markov simulation. The cohort of prisoners had a distribution of genotypes and stages of fibrosis in accordance with prior studies evaluating inmate populations. The probability of transitioning from one health state to another, reinfection rates, in-prison and out-of-prison mortality rates, sustained viral response rates, costs, and quality of life weights were also obtained from the literature. Sensitivity analysis was performed. In a strategy without a pretreatment liver biopsy, treatment was cost-effective for all ages and genotypes. This model was robust to rates of disease progression, mortality rates, reinfection rates, sustained viral response rates, and costs. In a strategy employing a pretreatment liver biopsy, treatment was also cost-saving for prisoners of all ages and genotypes with portal fibrosis, bridging fibrosis, or compensated cirrhosis. Treatment was not cost-effective in patients between the ages of 40 and 49 with no fibrosis and genotype 1. *Conclusion:* Treatment of chronic hepatitis C with PEG IFN and ribavirin in U.S. prisons results in both improved quality of life and savings in cost for almost all segments of the inmate population. If the decision to treat hepatitis C is based on pharmacoeconomic measures, this significant proportion of infected individuals should not be denied access to therapy. (HEPATOLOGY 2008;48:000-000.)

Hepatitis C infection is an important public health problem in the United States, with 1.3% of the population chronically infected with the virus. An even larger proportion of the U.S. prison population is affected, where the prevalence of chronic infection ranges from 12% to 31%,[1] likely a result of increased rates of injection drug use within this group. Even more striking, approximately 29% to 43% of the total number of persons infected with hepatitis C in the United States pass through a correctional system each year.[3]

As of midyear 2006, the U.S. prison system was continuing to grow in size, housing 2,245,189 inmates per year, or 497 per every 100,000 persons in the United States.[3] The average length of incarceration has been increasing as well, placing a greater burden on prison health care systems to address chronic medical conditions such as hepatitis C. With the predicted cost of medical expenditures related to hepatitis C rising to as high as $10.7 billion from 2010 to 2019,[4] the U.S. prison health care system could see an estimated 15% to 60% increase in its budget in the coming years.[5] Consequently, the cost-effectiveness of hepatitis C treatment in prisons has been a matter of increasing public debate.

Proponents of treatment in prisons argue that we have an ethical duty to provide prisoners with the contemporary best practices in medical care. They suggest that treatment of hepatitis C could be seamlessly integrated into existing programs that successfully manage tuberculosis,

Abbreviations: HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; PEG IFN, pegylated interferon; QALY, quality-adjusted life year; SVR, sustained viral response.

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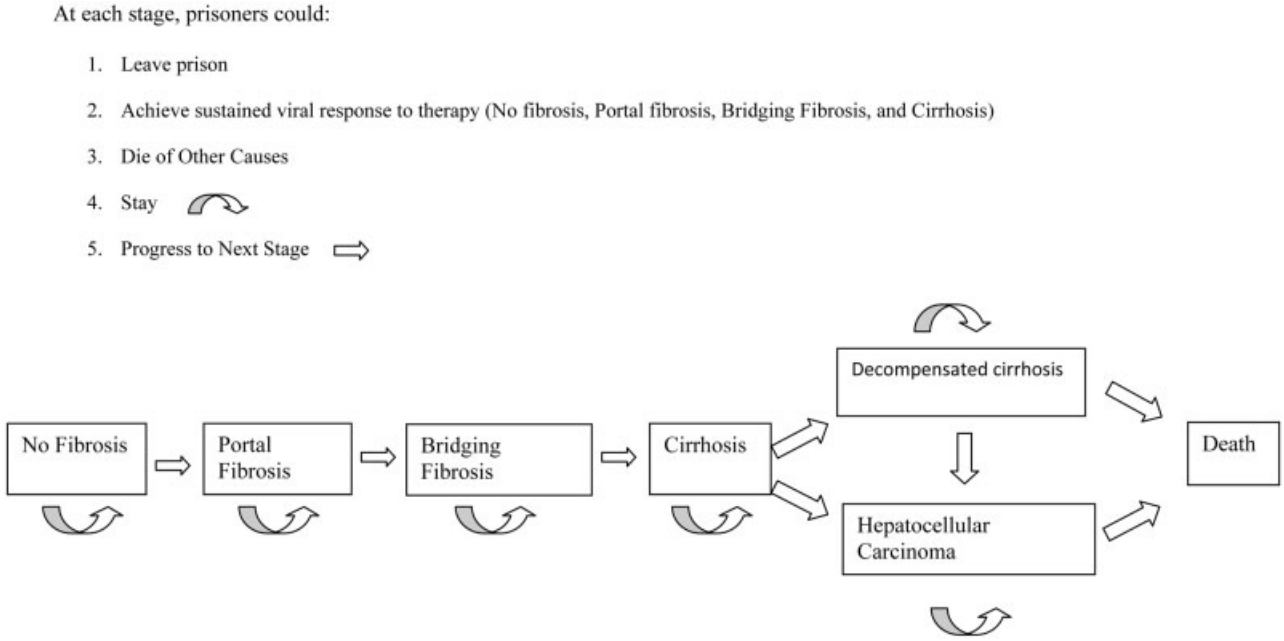

Fig. 1. Schematic of Markov chain

human immunodeficiency virus, and other transmittable diseases. Treatment could feasibly reduce the incidence of new hepatitis C virus (HCV) infections and prevent future complications from liver disease. Substance abuse and risk reduction counseling could be employed simultaneously, resulting in enduring benefits outside of prison.[1,6-10]

Those who oppose treatment note that therapy is often interrupted by prison release or transfer, and that continued care for hepatitis C after release is often unavailable to what is a largely uninsured population. This could promote resistance to therapy or inadequate management of treatment-related adverse events. Furthermore, high rates of relapse to injection drug use or other high-risk activity result in considerable rates of reinfection after prison release, which could be expected to undermine the benefits of treatment.[1,6-10]

Prior studies have demonstrated that treatment of chronic hepatitis C with pegylated interferon (PEG IFN) and ribavirin is a cost-effective measure in the general population.[10-23] However, no study has yet addressed whether combination therapy would be cost-effective in the prison population. This study aims to answer this question in the male prison population, which makes up 87.3% of the inmate population.[7]

Patients and Methods

We conducted a MEDLINE search of the published literature using various combinations of the search terms "hepatitis C," "treatment," "cost-effectiveness," "prisons," "pegylated-interferon and ribavirin," "combination therapy," "jails," and "inmates."

Using data obtained from these articles, we used the software Treeage Pro Health Module (Williamstown, MA) to construct a decision analysis model employing Markov simulation (Fig. 1). This allowed us to estimate the incremental cost-effectiveness ratio (ICER) of combination therapy for hepatitis C in the U.S. prison population and thus compare the strategy of treatment to that of no treatment. The perspective adopted was that of the U.S. prison health care system. We used the generally accepted cost-effectiveness threshold of $50,000 per quality-adjusted life years (QALYs) as the maximum value for determining the preferred treatment option.

The target population at the beginning of our analysis was a cohort of men, ages 40 to 49 years, who were incarcerated in the U.S. prison system and chronically infected with hepatitis C as evidenced by positive serologic tests and quantitative assays for HCV RNA. Their baseline demographics were assumed to be similar to that of the general U.S. prison population. In a bulletin published by the Bureau of Justice in May 2006,[24] Caucasians comprised the largest proportion of prisoners at 44.3%, followed by African Americans at 38.9% and Latinos at 15%. Men were 7 times more likely to be imprisoned than females, and comprised 87.3% of the prison population.[24] The average age of the prisoners was 41 $\pm$ 7 years.[25] These demographics were consistent with the inmate populations studied in the published literature we used to make baseline assumptions for our model.

Table 1. Clinical Assumptions

Variable	Baseline	Range	References
Prevalence of genotype 1	0.78	0.68-0.80	25,26
Prevalence of genotypes 2 and 3	0.22	0.20-0.32	25,26
SVR for genotype 1	0.42	0.20-0.70	10,25
SVR for genotypes 2 and 3	0.79	0.70-1.00	10,25
Mortality from other causes in prison	0.00201	0-0.0025	3,35
Mortality from other causes outside prison	0.00777	0-0.00777	35
Mortality from decompensated cirrhosis	0.218	0.129-0.315	10,23
Mortality from hepatocellular carcinoma	0.574	0.319-0.99	10,23,41
Mortality from treatment	0.0005	0.00025-0.00075	10
Reinfection rate in prison	0.0071	0.004-0.011	42,43
Reinfection rate outside prison	0.0015	0.001-0.002	44
Distribution of fibrosis			
No fibrosis	0.30	–	25
Portal fibrosis	0.45	–	25
Bridging fibrosis	0.18	–	25
Compensated cirrhosis	0.06	–	25

Data are expressed as rates per year.

We presumed that genotype determination was performed in all prisoners prior to commencement of therapy. The inmates were accorded a distribution of genotypes as reported in the literature specific to the prison population: 78% were assumed to have genotype 1, and 22% were assumed to have genotypes 2 and 3 (Table 1).[25,26]

Two strategies were then analyzed. In the first strategy, prisoners did not undergo a liver biopsy prior to starting treatment. They were assumed to have a distribution of stages of fibrosis in accordance with the literature. Sterling et al.[25] conducted a retrospective study of 302 inmates in Virginia with chronic hepatitis C who had undergone liver biopsy and found that 30% of prisoners had no fibrosis, 45% had portal fibrosis, 18% had bridging fibrosis, and 6% had cirrhosis (Table 1). An ICER was then calculated for these prisoners as a pooled population in various stages of fibrosis.

In the second strategy, all prisoners underwent a liver biopsy prior to beginning therapy in order to determine their stage of fibrosis. A modified METAVIR scoring system was used, and the patients were divided into four groups: (1) no fibrosis, (2) portal fibrosis, (3) bridging fibrosis, and (4) compensated cirrhosis.[27,28] The most cost-effective option was calculated for each group dependent on age and stage of fibrosis.

Treatment was assumed to follow current guidelines, using a combination of weight-based PEG IFN-α2a or -α2b and ribavirin.[29,30] Patients with all disease states except for decompensated cirrhosis and hepatocellular carcinoma were eligible for treatment. Treatment was administered for a total of 48 weeks in patients with genotype 1 and for a total of 24 weeks in patients with genotypes 2 and 3. We assumed that treatment was discontinued after 12 weeks in patients with genotype 1 who did not achieve an early virologic response, defined as a 2-log reduction in their levels of HCV RNA.[29] Antidepressants and growth factors such as erythropoeitin were not used. Sustained viral response (SVR) rates were obtained from the literature and were presumed to be identical to that of the general population—42% for genotype 1 and 79% for genotypes 2 and 3.[31-33] Although adherence would likely approach 100%, given that medication would be administered under the direct supervision of prison health care officials, we nevertheless varied compliance rates to account for patients who might discontinue therapy because of side effects.

In all models, the prisoners transitioned in 6 month intervals through a variety of health states until death. An average life expectancy of 75 years was used, as per the average life expectancy of males in the United States.[34] The probability of progression from one health state to another was estimated from published literature looking at the natural history of HCV infection, and assumed to be equivalent for patients both inside and outside prison (Table 2). In addition, prisoners could be released from prison or remain incarcerated at each stage of the model. They could be reinfected with HCV at a rate determined from prior studies, and they could die either from liver disease or other causes. Both reinfection rates and mortal-

Table 2. Transition Probabilities

Variable	Baseline	Range
No fibrosis to portal fibrosis		
Ages 40-49	0.054	0.027-0.095
Ages 50-59	0.125	0.073-0.161
Ages 60-69	0.221	0.125-0.349
Age >70	0.301	0.152-0.478
Portal fibrosis to bridging fibrosis		
Ages 40-49	0.027	0.0135-0.0475
Ages 50-59	0.0625	0.0365-0.0805
Ages 60-69	0.111	0.0625-0.1745
Age >70	0.151	0.076-0.239
Bridging fibrosis to cirrhosis		
Ages 40-49	0.054	0.027-0.095
Ages 50-59	0.125	0.073-0.161
Ages 60-69	0.221	0.125-0.349
Age >70	0.301	0.152-0.478
Compensated cirrhosis to hepatocellular carcinoma	0.017	0.008-0.030
Compensated cirrhosis to decompensated cirrhosis	0.040	0.032-0.0052
Decompensated cirrhosis to hepatocellular carcinoma	0.006	0-0.014

Data are expresses as rates per year and were obtained from references 10, 11, 12, 14, 18, 21, 22, 38, and 44.

Table 3. Costs Per Year

Variable	Baseline	Reference
PEG IFN and ribavirin	$14,861	48,49
Liver biopsy	$1,368	49,51
No fibrosis*	$145	41,49
Portal fibrosis*	$145	41,49
Bridging fibrosis*	$145	41,49
Compensated cirrhosis*	$1,053	41,49
Decompensated cirrhosis†	$13,499	41,49
Hepatocellular carcinoma	$42,255	41,49
End-of-life care	$36,172	49,50

Costs have been adjusted to 2007 U.S. dollars.

*Costs consisted of clinic visits, laboratory tests, and adverse events.

†A composite cost was used for decompensated cirrhosis, taking into account costs related to ascites, variceal bleeding, and hepatic encephalopathy.

ity rates were different in prison and out of prison (Table 1). It was assumed that mortality from liver disease could only occur in patients with decompensated cirrhosis or hepatocellular carcinoma, and that mortality rates from both liver and nonliver causes were similar across age groups. Furthermore, we presumed that disease progression could still occur in patients with compensated cirrhosis even after SVR.

Costs used in our analysis were obtained from the literature and were adjusted to 2007 U.S. dollars (Table 3). We assumed that the absolute and incremental costs of reinfection were identical to those incurred with primary infection. Quality of life weights were similarly obtained and were assumed to be similar to that of the general U.S. population. A discount rate of 3% per year was used.

Sensitivity analysis was performed in order to address our dynamic health care and economic system. Clinical variables, costs, quality of life weights, and discount rate were varied over wide ranges to assess their impact on the calculated ICERs. The ranges used for the clinical variables were based on data from the literature or, in cases where data was limited, were set from zero to the maximum value the model would allow. Costs were halved and doubled to obtain lower and upper limits, and the annual discount rate ranged from 0% to 10%.

Results

Our model found that treatment was cost-effective in prisoners of all age ranges and genotypes when liver biopsy was not a prerequisite to starting antiviral therapy (first strategy). In other words, treatment resulted in both decreased costs and improved quality of life. In prisoners between 40 and 49 years of age, treatment saved $41,321 and increased QALYs by 0.75. For prisoners between 50 and 59 years of age, treatment decreased costs by $33,445 and increased QALYs by 0.69. In prisoners between 60 and 69 years of age, treatment produced $11,637 in savings and a gain of 0.5 in QALYs (Table 4). Sensitivity analysis revealed that the model using this strategy was robust to all variables, including in-prison and out-of-prison mortality rates, rates of disease progression, in-prison and out-of-prison reinfection rates, SVR rates, and costs of treatment.

Treatment was also cost-effective for most situations employing pretreatment liver biopsy (second strategy). In our base case population with portal fibrosis, treatment resulted in $18,516 in saved costs and an increase in QALYs of 0.58 (Table 5). It was also cost-effective in the base case populations with bridging fibrosis and compensated cirrhosis. In prisoners with portal fibrosis and bridging fibrosis, the model was sensitive to life expectancy, with treatment no longer cost-effective if lifespan after the initiation of therapy was less than 10 years. For these populations, the model was robust to all other clinical variables and to costs.

In the subset of patients who had no fibrosis on pretreatment liver biopsy, treatment was not cost-effective in those between ages 40-49 who had genotype 1, incurring $3,367 in increased costs and a decrease in QALYs of 0.01 (Table 5). For patients in the same age group with genotypes 2 or 3, however, treatment resulted in $10,844 in saved costs and a gain in QALYs of 0.11. For this cohort, the model was sensitive to in-prison reinfection rates and nonliver mortality rates, with treatment no longer pre-

Table 4. Summary of Costs, Efficacy, and ICERs for Strategy 1 (No Pretreatment Liver Biopsy)

	Cost ($)		Efficacy (QALY)		
	Treatment	No Treatment	Treatment	No Treatment	ICER, U.S. $
Ages 40–49 years	179,484	220,715	18.25	17.50	No treatment dominated
Genotype 1	189,598	220,834	18.09	17.4	No treatment dominated
Genotype 2/3	141,820	219,750	18.82	17.50	No treatment dominated
Ages 50–59 years	113,485	146,930	15.00	14.31	No treatment dominated
Genotype 1	122,294	146,847	14.86	14.31	No treatment dominated
Genotype 2/3	82,252	147,223	15.52	14.30	No treatment dominated
Ages 60–69 years	52,667	64,304	10.48	9.98	No treatment dominated
Genotype 1	57,697	65,395	10.37	9.98	No treatment dominated
Genotype 2/3	34,833	64,697	10.87	9.99	No treatment dominated

Table 5. Summary of Costs, Efficacy, and ICERs for Strategy 2 (Pretreatment Liver Biopsy)

	Cost ($)		Efficacy (QALY)		
	Treatment	No Treatment	Treatment	No Treatment	ICER, US $
No fibrosis					
Men, age 40–49	126,200	125,900	19.18	19.16	$15,000/QALY
Genotype 1	129,459	126,092	19.15	19.16	Treatment dominated
Genotype 2/3	114,640	125,524	19.28	19.17	No treatment dominated
Men, age 50–59	78,735	84,672	15.60	15.38	No treatment dominated
Genotype 1	82,755	84,762	15.53	15.38	No treatment dominated
Genotype 2/3	64,483	84,855	15.82	15.39	No treatment dominated
Men, age 60–69	34,663	33,641	10.91	10.76	$6,813/QALY
Genotype 1	37,140	33,696	10.86	10.76	$34,440/QALY
Genotype 2/3	25,880	33,444	11.07	10.76	No treatment dominated
Portal fibrosis					
Men, age 40–49	143,750	162,266	18.67	18.09	No treatment dominated
Genotype 1	151,960	162,387	18.50	18.09	No treatment dominated
Genotype 2/3	114,640	161,837	19.28	18.12	No treatment dominated
Men, age 50–59	96,901	122,162	15.15	14.45	No treatment dominated
Genotype 1	106,044	122,248	14.97	14.45	No treatment dominated
Genotype 2/3	64,483	121,858	15.82	14.45	No treatment dominated
Men, age 60–69	43,226	50,940	10.64	10.19	No treatment dominated
Genotype 1	48,118	50,993	10.52	10.19	No treatment dominated
Genotype 2/3	25,880	50,750	11.07	10.20	No treatment dominated
Bridging fibrosis					
Men, age 40–49	248,129	350,642	17.30	15.70	No treatment dominated
Genotype 1	269,660	350,511	17.00	15.71	No treatment dominated
Genotype 2/3	175,114	350,051	18.39	15.73	No treatment dominated
Men, age 50–59	174,120	259,574	13.91	12.27	No treatment dominated
Genotype 1	192,053	259,645	13.49	12.27	No treatment dominated
Genotype 2/3	110,539	259,321	15.05	12.28	No treatment dominated
Men, age 60–69	78,456	113,229	9.94	8.98	No treatment dominated
Genotype 1	87,562	113,276	9.74	8.98	No treatment dominated
Genotype 2/3	46,579	113,062	10.64	8.98	No treatment dominated
Compensated cirrhosis					
Men, age 40–49	491,126	753,439	13.65	9.58	No treatment dominated
Genotype 1	541,519	754,660	12.88	9.57	No treatment dominated
Genotype 2/3	312,756	750,025	16.40	9.64	No treatment dominated
Men, age 50–59	292,311	448,285	11.87	8.96	No treatment dominated
Genotype 1	323,990	449,193	11.30	8.95	No treatment dominated
Genotype 2/3	179,994	445,063	13.89	9.02	No treatment dominated
Men, age 60–69	131,307	192,849	8.92	7.38	No treatment dominated
Genotype 1	146,054	193,545	8.60	7.36	No treatment dominated
Genotype 2/3	79,023	190,381	10.05	7.43	No treatment dominated

ferred if these rates increased to more than twice their baseline values. Cost-effectiveness was also affected by SVR rate, with a rate of less than 72.6% resulting in no treatment being favored, and by costs, with sums greater than $15,712 (baseline value $14,680) making treatment cost-effective no longer.

Treatment was cost-effective in patients with no fibrosis between 50 and 59 years of age and cost-effective but not dominant in patients between 60 and 69 years of age, with an ICER of $6,813/QALY (Table 5). The model was robust to all variables for patients in these age groups with no fibrosis.

Discussion

Our results demonstrate that PEG IFN and ribavirin combination therapy is cost-effective in the prison population, both in strategies with and without biopsy. Incorporating a pretreatment liver biopsy may be the most cost-effective approach, however, as one could potentially exclude certain patients with no fibrosis from therapy. Although we had not expected treatment to be cost-effective because of the high reinfection rates and nonliver mortality rates both inside and outside prison, treatment remained cost-effective despite varying these factors over wide ranges.

The only segment of the prison population in which treatment was not cost-effective was incarcerated individuals between the ages of 40 and 49 with genotype 1 and no fibrosis. Given their age and lack of liver damage, they have a lower probability than other groups of developing cirrhosis and hepatic decompensation. Their disease process is largely silent, their quality of life is relatively unaf-

fected, and they are more likely to die from non–liver-related causes. SVR rates are low, and the benefits of treatment are outweighed by the costs and morbidity of treatment. On the other hand, although the risk of developing liver-related complications remains small in similarly aged patients with genotypes 2 and 3, higher SVR rates make treatment more likely to result in benefits that outweigh other factors. The ICER for this group with no fibrosis between 40 and 49 years of age was particularly sensitive to rates of SVR and costs of treatment, emphasizing that treatment in these patients is only worthwhile if it is highly effective or relatively inexpensive.

Our study results apply only to prisoners in the United States and are not meant to be applicable to the general population. Nevertheless, prior cost-effective analyses performed on nonprison cohorts show results similar to ours, with most studies demonstrating that treatment with PEG IFN and ribavirin is a cost-effective measure regardless of stage of fibrosis.[10-23] Although our analysis differed from that of Salomon et al.,[10] who reported that treatment of men with no fibrosis was cost-effective in patients with genotype 1 as well as patients with genotypes 2 and 3, the Salomon et al. study compared treatment with PEG IFN and ribavirin to treatment with standard interferon and ribavirin, while our analysis compared treatment based on PEG IFN with no treatment. Comparison to no treatment results in a substantially greater incremental difference in cost, which likely accounts for these varying results.

This study is in large part limited by its reliance on data obtained from prior literature rather than data gathered prospectively. The natural history of hepatitis C and its response to treatment has not been studied extensively in the prison population, and we assumed for many aspects of our model that the prison population would behave similarly to the general U.S. population.

One such variable was rates of SVR, because only limited data exist on treatment response in prisoners. For instance, one published study assessed the efficacy of standard rather than PEG IFN in prisoners in Rhode Island but did not stratify outcomes according to genotype.[26] One might expect SVR rates to be lower in the prison population, because prior studies have shown SVR rates to be significantly lower in African Americans than in non–African Americans,[52] and this group comprises a larger proportion of the inmate population than the populations studied in registry trials. However, a retrospective study comparing response rates to standard interferon between African Americans and Caucasians in the Virginia correctional system found no significant difference in SVR between the two groups, perhaps a result of increased compliance with directly observed therapy.[53] Furthermore, our model was robust to SVR rates varied over wide ranges in all cohorts except prisoners between 40-49 years of age with no fibrosis. Therefore, even if SVR was as low as 28% in African American inmates,[52] treatment would still be at least cost-effective for almost all prison cohorts.

Similarly, rates of fibrosis and disease progression in prisoners were assumed to be comparable to those of nonprisoners. Although there are no studies evaluating whether the natural history of hepatitis C is identical in this population, we accounted for possible differences by varying rates of fibrosis and disease progression over wide ranges. Because our model was robust to these variations, this assumption is unlikely to be a source of bias.

Costs and quality of life weights were also obtained from studies of nonprison populations.[39,49-51] Despite the increasing use of growth factors and antidepressants as adjuncts to treatment, we elected not to include these as potential costs. This is consistent with prior cost-effective analyses of hepatitis C treatment in the general population.[10-23] Most pivotal trials of hepatitis C treatment, from which we estimated the SVRs for our model, did not allow for growth factors, and their use may not be consistently available at all prison settings.[31-33]

Although the incidence of depression during hepatitis C treatment is not trivial (20%–30%),[54] this additional cost would be unlikely to impact our analysis, because it remains small relative to the total cost of therapy. The average wholesale cost of 12 months of the antidepressant oral medication citalopram, for instance,[54] is approximately $972.[48] Assuming that 30% of the inmates would require citalopram during treatment, this would represent less than 2% of the total cost of therapy.

Moreover, the high background rate of depression in the prison population (an estimated 23.5% in state prisons and 16% in federal prisons)[56] makes it difficult to distinguish which patients would require antidepressants as a complication of therapy and which patients would already require antidepressants regardless of antiviral therapy. In contrast, the baseline rate of depression in registry trials was 1% to 5%[32] and in the general U.S. population is reported to be approximately 10.6%.[56] Potential treatment candidates in the prison setting would also need to be carefully screened for other mental illnesses, because they can be found in up to 50% of state and federal inmates.[56]

Although quality of life in prisoners is lower than that of the general population, hepatitis C infection has not been shown to make a significant impact.[57] This is likely because non-HCV factors override HCV-specific quality of life impairment. Furthermore, nonviral HCV-specific quality of life impairments are likely to be equally distrib-

uted between prisoners who are and who are not treated for hepatitis C infection.

Another assumption made in our model was that patients with cirrhosis who achieved SVR could still develop decompensated cirrhosis and hepatocellular carcinoma at rates similar to those who did not achieve SVR. This is a bias against treatment. Recent studies have demonstrated that cirrhotic patients who have achieved SVR actually have lower rates of hepatic decompensation and hepatocellular carcinoma than those who do not achieve SVR.[36,37]

Finally, the cohort we used for our model consisted of only male prisoners. We felt this nevertheless resulted in an adequate representation of the prison population, because men are 7 times more likely to be imprisoned than females and make up 87.3% of the U.S. prison population.[7] Furthermore, there have been no studies published in the literature thus far showing significant sex differences in regard to both the natural history of hepatitis C infection or response rates to treatment.

Currently, we are not aware of a standard policy on the treatment of U.S. prisoners with chronic hepatitis C. Even screening for hepatitis C infection remains controversial and is not universally performed.[9] As of 2000, 1,209 of 1,584 state public and private adult correctional facilities, housing 94% of all state prisoners, reported that they tested inmates for hepatitis C; 1,104 (70%) state correctional facilities reported that they had some type of policy for treating hepatitis C in their inmates. Between July 1, 1999, and June 30, 2000, 4,750 inmates were treated for hepatitis C.[58]

Policies vary widely from state to state, however. In some states, written protocols exist for the treatment of prisoners, and in others, selection for treatment is performed on a case-by-case basis. In certain states, liver biopsy is mandatory prior to treatment, and in others, the decision to biopsy is left to health care providers. A minimum prison sentence of 15 to 18 months is required by many states in order to assure completion of treatment and adequate follow-up prior to release. A minority of states do not have any established programs for hepatitis C treatment.[38]

In order to address this issue, the Federal Bureau of Prisons put forth a set of clinical practice guidelines in 2005. They recommend that treatment be continued in prisoners who are already on therapy and that therapy be initiated in prisoners who meet criteria published by the American Association for the Study of Liver Diseases, provided that they do not have contraindications such as severe psychiatric or medical illness. Prisoners must also demonstrate a commitment to abstinence from alcohol and other substances. Genotyping is suggested for all patients, and liver biopsy is suggested for patients with elevated alanine aminotransferase levels, genotype 1, or suspected compensated cirrhosis. The Bureau recommends that treatment not be initiated in short-term inmates, given the high likelihood that therapy will not be completed.[39] Enforcement of such a national guideline is problematic, however, because there is currently no centrally funded or administered program to employ hepatitis C treatment. Each state manages its own budget and therefore adopts its own set of treatment guidelines.

Ethical considerations also play a large role in this matter of public controversy, and the cost-effectiveness of treatment must be weighed against these other concerns. As with liver transplantation, proponents of treatment argue that it is unconstitutional to deny inmates access to treatment that is considered standard care. In 2003, Oregon inmates filed a class-action lawsuit against the state prison system, alleging cruel and unusual punishment, and sought $17.5 million in medical expenses, drug therapy, and potential liver transplantations (Anstett et al. v. State of Oregon). A settlement was reached in 2004, resulting in liberalization of the state's hepatitis C treatment guidelines,[59,60] and was considered by many to be a victory in favor of treatment.

Those who oppose therapy for prisoners, however, maintain that incarcerated individuals, by virtue of their offenses, have forfeited their right to receive these resources,[40] particularly as treatment would be administered at the expense of taxpayers, while a large proportion of uninsured patients continue to be denied access to therapy.

If the decision to treat is based on pharmaco-economic measures, however, the results of our analysis suggest that treatment is cost-saving and should not be withheld in U.S. prisoners with hepatitis C. Because the efficacy of treatment is diminished by relapse of injection drug use and reinfection, this treatment strategy must be coupled with educational and substance abuse programs. Furthermore, because mental illness is widespread in the prison population and can often be exacerbated by treatment, careful mental health screening and follow-up would be required.

In conclusion, although the ethical debate regarding the implementation of treatment for hepatitis C in prisons is not likely to be settled soon, we can assert that from a pharmaco-economic standpoint, treatment of hepatitis C in the prison population is cost-effective.

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