

## Review

# Impact of New Therapeutics for Hepatitis C Virus Infection in Incarcerated Populations

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*Inmate populations bear a disproportionate share of the burden of hepatitis C virus (HCV) infection. With more than 90% of prisoners released back to their communities within a few years of sentencing, incarceration can be viewed as an opportunity to provide HCV screening and therapeutic interventions to benefit the individual, reduce the costs of HCV management to the health care system from a societal perspective, and improve overall public health. Although optimal medical management of HCV within prison settings would increase the current cost of correctional health care, it could decrease transmission within the community, reduce overall disease burden, and lower the future societal health care costs associated with end-stage liver disease. Nonetheless, most prison systems treat only a small fraction of infected inmates. Current and emerging therapeutic agents will cure HCV infection in the vast majority of patients. Mathematical modeling also shows that expanded HCV screening and treatment are cost-effective from the societal perspective. In this article, we will describe appropriate treatment regimens, propose strategies to lessen the burden of these costly HCV therapies on correctional health care systems, and address the challenges of expanded HCV screening in correctional settings.*

In the late 1990s, it was estimated that 16% to 41% of prisoners in the United States had evidence of exposure to the hepatitis C virus (HCV), compared with 1.6% in the general population.<sup>1</sup> At that time, 1 of every 3 persons with HCV infection in the country passed through a jail or prison over the course of a year.<sup>1,2</sup> Given the overwhelming number of HCV-infected inmate patients seen by correctional health services, protocol-driven strategies for triaging which inmates to treat and how to treat them gained momentum

in the last years of the 20th century.<sup>3</sup> Furthermore, outcomes in correctional systems with standard therapy of peg-interferon alfa plus ribavirin (PEG-IFN/RBV) were comparable to those achieved in the community.<sup>4,5</sup>

Studies have concluded that PEG-IFN/RBV has been cost-effective, with cost per quality-adjusted life-years (QALY) gained less than that of other medical interventions commonly employed in correctional settings, such as hemodialysis.<sup>6</sup> However, only a small percentage of incarcerated individu-

als with chronic HCV infection have been successfully treated owing to numerous barriers, including low rates of HCV screening in correctional settings, poor access to treatment, and high prevalence of conditions among inmates that are contraindications to PEG-IFN/RBV treatment.<sup>3,4,7,8</sup>

The development pipeline is producing a rush of direct-acting antivirals (DAAs) that will reduce treatment duration in most patients and improve sustained virologic response (SVR) rates. The first 2 HCV protease inhibitors, boceprevir and telaprevir, were approved by the US Food and Drug Administration in 2011. Although DAAs are substantially more effective than PEG-IFN/RBV, they also increase costs, from approximately \$25,000 per treatment course for 2 drugs to between \$50,000 and \$75,000 for a 3-drug regimen. In the community, where seroprevalence of HCV is approximately 1.3%, substantially improved efficacy has led third-party payers to embrace DAAs. In correctional systems, however, where HCV seroprevalence has been estimated to be at least 13-fold higher than in the community, costs play a larger role in clinical decision making. Seven years ago, a framework of recommendations for management

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of hepatitis C in correctional care was introduced.<sup>3</sup> The time for revisiting and renovating that framework has come, given the changing epidemiology of the disease, rapid pace of drug development, and high cost of increasingly effective therapies.

### Epidemiology of HCV Infection in Inmate Populations

The epidemiology of HCV disease is dynamic rather than static. Although HCV remains highly prevalent among prisoners, there has been a dearth of recent publications updating estimates of the prevalence of HCV among prisoners. Two years ago, a study in New Mexico reported that prevalence among their state prisoners was 40%.<sup>9</sup> In contrast, during the summer of 2011, routine testing in an Atlanta jail found the seroprevalence among detainees to be 7.5%.<sup>10</sup> These variations likely indicate substantial regional differences in the prevalence of injection drug use, particularly for opiates or methamphetamine.<sup>11</sup>

An online survey among all US state correctional department medical directors and health administrators was conducted between November 2011 and February 2012.<sup>12</sup> Responses were received from individuals from all 50 states. Only 12 state prison systems performed systematic HCV antibody screening during 2001 to 2012 and they provided inmate seroprevalence estimates for that period (range, 9.6%–41.1%). Weighting by the size of the systems, the national inmate HCV prevalence in 2006, the midpoint of the observation period, was estimated to be 17.4%.<sup>12</sup> The 1-day population in prison in 2006 was 1.5 million and approximately 260,000 HCV antibody-positive persons were in prison at that point in time.

A previous model estimated that the total number of individuals who spent at least 1 day incarcerated, either in jail or in prison, in 2006 was 10.7 million.<sup>13</sup> The total number of cases of HCV infection represented by all persons who were incarcerated that year was 1.86 million; correctional populations represented approximately a

quarter of the US HCV case burden for the year. This proportion represents a decline from the burden estimated in 1997, which was 29.4% to 43.4%. This decline may be explained, in part, by the evolving distribution of HCV, such that a greater proportion of the epidemic is borne by increasingly older populations. Two-thirds of those living with HCV were born between 1945 and 1965.<sup>14</sup> As this birth cohort ages out of the crime-prone years (approximately 20 years to 45 years of age), prisons would be expected to bear a declining share of the HCV epidemic. Nonetheless, correctional populations continue to represent a substantial proportion of the nation's epidemic, and HCV infection remains a major burden within state correctional systems compared with the general population.

### Outcomes of HCV Infection With or Without Antiviral Treatment

The high prevalence of HCV infection among inmate populations, along with other significant and highly prevalent cofactors (such as HIV coinfection or alcohol use) has led to an increasing number of cases of end-stage liver disease (ESLD) in correctional facilities.<sup>15</sup> Once ESLD develops, liver transplantation often becomes the only chance for extended survival. One study in the Texas prison system showed that over a given 3.5-year period, 484 patients (131 per 100,000 of all prisoners in Texas incarcerated during any point in the study period) reached ESLD; 89% of these patients had HCV infection. Fifty-eight of these patients with ESLD were within 3 months of needing a liver transplant at the time of evaluation.<sup>15</sup>

Prisoners without cirrhosis or ESLD who are not treated with antiviral therapy during incarceration remain at risk for cirrhosis either in prison or in the years following release. If prisoners with advanced fibrosis or cirrhosis receive treatment and viral eradication results, liver decompensation, hepatocellular carcinoma, and liver transplantation can be reduced by approximately 80%.<sup>16</sup> The avoidance of ESLD as a public

health issue for the community as a whole may be the best justification for in-prison HCV treatment.<sup>15</sup>

### Experience With Conventional Treatment Behind Bars

Correctional systems have a constitutional obligation to provide adequate health care to inmates, including HCV management. State prison systems and health care practitioners either have proactively developed treatment guidelines or litigation has forced them to address HCV treatment. The obligation to address health issues stems from the US Supreme Court decision in *Estelle v Gamble*, wherein denial of necessary medical care or deliberate indifference to serious medical needs of inmates was established as a violation of the Eighth Amendment: the right to be free of cruel and unusual punishment.<sup>17,18</sup> Subsequent court decisions have refined the definitions of “serious medical need” and “deliberate indifference.” The definition of serious medical need has varied but has largely been left to the discretion of physicians (eg, “one that has been diagnosed by a physician as mandating treatment”) or in the hands of laypeople (eg, “one that is so obvious that even a layperson would easily recognize the necessity for a doctor’s attention”).<sup>19–21</sup> “Deliberate indifference” requires that the medical practitioner or custody employee knew of the need for medical care and that he or she delayed or refused to provide proper treatment.<sup>20,22,23</sup> Notably, deliberate indifference has been determined in cases in which practitioners chose an “easier and less efficacious treatment.”<sup>17,24–26</sup> A Rhode Island inmate recently received a liver transplant while incarcerated based on the *Estelle v Gamble* decision.<sup>27</sup> Other states may feel obliged to follow the lead of Rhode Island in the future. The Federal Bureau of Prisons, which often leads in the development of clinical policies, has developed guidelines for transplantation services.

Current correctional system guidelines include expected remaining duration of stay as a major factor in treat-

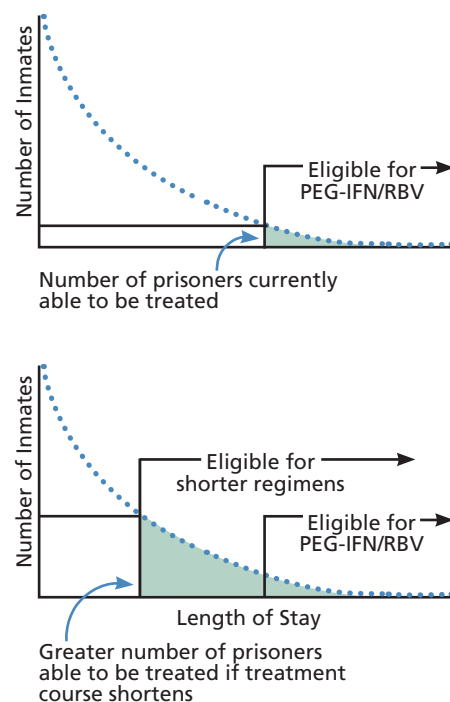
ment decisions for medical problems, including HCV infection. In addition to the expected length of stay, the responsibility for a correctional system to undertake a medical intervention depends on the urgency of existing medical conditions, medical necessity, and the probability of treatment success.<sup>26</sup> For less urgent conditions, the institution's obligation depends on whether addressing them can wait until the inmate returns to the community. In a disease such as HCV, in which pathology may take decades to develop, treatment is not urgent for the short-term inmate.<sup>3</sup> Conversely, with an extended incarceration, correctional systems must address a broader range of medical issues.

Although a short delay in initiating HCV treatment may have no clinical consequences, extended postponement can eventually become clinically significant because earlier stages of infection are more amenable to cure.<sup>28-30</sup> Given that treatment is presently available in the community to well-insured individuals with access to specialists, the specific expected duration of incarceration also plays a role when deciding whom to treat for HCV. The typical individual leaving prison has limited resources and insurance coverage. Thus, if an inmate does not complete his or her course of therapy before release, accessing continued care after release may present a challenge. For this reason, most prison systems want assurance that therapy, if started, will be completed before release. In rare exceptions, a state may have a safety net of practitioners in community health centers across the state who can continue treatment in the case of early release.<sup>31</sup> However, postrelease treatment is typically unavailable to the indigent, thus to attain a cure, the remaining time in the institution must exceed the expected duration of treatment.<sup>32</sup> Because so many inmates do not have a length of stay sufficient for standard evaluation and conventional, year-long therapy, prisons have treated only the small proportion of patients with sufficiently long stays, those with an expected remaining stay of at least 18 months to 24 months.<sup>3</sup> Nonethe-

less, treating even this small proportion of patients has thus far been a major cost driver in prison health care systems.

Most prison systems have developed protocol-driven strategies of treating HCV infection in patients without contraindications to PEG-IFN/RBV.<sup>3</sup> The majority permit therapy for genotype 2 or 3 HCV disease without a prior liver biopsy for staging. Patients with genotype 1 HCV disease typically undergo pretreatment liver biopsy and therapy as appropriate (eg, fibrosis greater than Metavir stage 1).<sup>3</sup> Some systems may employ blood tests to predict the degree of fibrosis (using indices such as aspartate transaminase [AST] to platelet ratio); those individuals with normal values are less likely to have substantial fibrosis and might be considered a lower priority for biopsy and treatment. Protocols vary from state to state and many states base their recommendations on clinical practice guidelines available on the Federal Bureau of Prisons website (<http://www.bop.gov/news/medresources.jsp>). As new therapies emerge, state health care practitioners will have an immediate and ongoing need to update their guidelines.

Newer therapies and evolving standards of care will challenge the exclusion based on length of incarceration. Expected duration of treatment is likely to be reduced with each improvement in therapeutic regimens. Prison systems will remain under no obligation to reverse long-standing, slowly progressive disease in short-term inmates. However, if treatment duration is only a few months, a system that has overlooked an infection for years will have difficulty denying care to the prisoner with sufficient time to complete the new regimen. Anecdotally, jails have also started to consider treatment for inmates with long stays. Depending on how brief the durations of new treatments become, the number of persons who might qualify for treatment could grow substantially, given that length of stay has a negative exponential distribution (Figure); that is, most prisoners have a brief length of stay, and few prisoners have very long



**Figure.** Impact of length of hepatitis C virus (HCV) treatment and remaining duration of incarceration in prison populations, including prisoners with HCV. The duration of incarceration varies by individual. The frequency of various lengths of stay follows a negative exponential distribution. Many persons have short times remaining before prison release. A few have a very long remaining time to serve. (top) Currently, with a year-long peginterferon alfa plus ribavirin (PEG-IFN/RBV) regimen, only a few prisoners with HCV have sufficient time before release to complete therapy—these are represented by the tail end of the distribution of remaining time to be served. (bottom) Shortening the time to complete HCV treatment by using a novel regimen means that there would be an exponentially greater number of prisoners with HCV who could complete therapy before release.

stays.<sup>33</sup> Finally, if regimens continue to decrease in duration and simplify in application so that primary care practitioners seeing releasees could oversee treatment, systems may begin to consider strategies that allow initiation of HCV therapy in correctional settings and continuation of care in the community. Access to community health care, provided for under the Patient Protection and Affordable Care Act (PPACA), would be an essential component of such a strategy.

## Considerations for Protease Inhibitor Therapies in Prisons

Adding the first DAAs available, boceprevir and telaprevir, to PEG-IFN/RBV has resulted in dramatically improved outcomes. Nonetheless, the prison environment is not well suited for these agents, because of their unforgiving dosing schedule of every 7 hours to 9 hours and the need for coconsumption of a meal or snack. In prisons, inmates are usually fed en masse and at variable times. Prison nurses usually directly supervise each dose of medication. Groups of inmates queue in “pill lines” on a schedule that is often not coordinated with mealtimes. Protocols have been developed to manage the challenges of synchronizing food intake and medication administration.<sup>34</sup> A favorable consequence of direct observed therapy in prisons is that the regimented system of medication administration may actually lead to greater adherence to treatment in a correctional setting than in the community, which is important when adherence is clearly a substantial factor in successful treatment with triple-drug regimens, or “triple therapy.”

Treatment that includes boceprevir or telaprevir, although clearly more effective than dual therapy, adds to cost. A course of therapy with a protease inhibitor added to PEG-IFN/RBV can cost up to \$75,000.<sup>35,36</sup> The addition of boceprevir or telaprevir also potentiates cytopenias (particularly anemia), which occur with PEG-IFN/RBV therapy, thus expanding costs to correctional systems via additional laboratory testing and the potential addition of hematopoietic growth factor treatment.

Because of their markedly improved efficacy, however, these agents are cost-effective compared with dual therapy, with an incremental cost-effectiveness ratio of approximately \$70,000 per QALY gained.<sup>35</sup> Thus, compared with many other health care interventions commonly provided in the prison setting, triple therapy for HCV provides good value for the money invested.

Advantages and disadvantages of instituting these novel HCV protease

**Table.** Advantages and Disadvantages of Integrating Hepatitis C Virus (HCV) Direct-Acting Antivirals Into Therapy for Inmate Patients With HCV Genotype 1 Infection

Potential Advantages to Adopting Triple-Drug Therapy	Potential Disadvantages of Triple-Drug Therapy
Increased efficacy	Cost
Reduced treatment duration for a subset of patients	Effective, less toxic, and perhaps less expensive therapies may be available in the near future
Standard of care in the community	Additive toxic effects
Opportunity to decrease the epidemic of projected deaths from liver disease	Drug–drug interactions <sup>a</sup>
Avoid overall high costs of advanced liver disease, cancers, and transplants paid for by other publicly funded programs postrelease	Administration schedule: dosing 3 times/day, every 7-9 hours to avoid resistance emergence
Once litigated, prisons will likely be required to provide treatment with triple-drug therapy	

<sup>a</sup>An example of an important drug–drug interaction is off-label use of telaprevir as part of a regimen to treat HIV-infected patients who are taking the antiretroviral drug efavirenz. Telaprevir has been studied at a 50% higher dose in phase II trials to compensate for expected drug interactions, thus increasing the cost of this regimen. Strategies that compare increased telaprevir dose while maintaining efavirenz or that compare standard telaprevir dose while switching antiretroviral drugs may be considered.

inhibitors in correctional settings are summarized in the Table. Potential strategies have been proposed for minimizing costs while preserving efficacy, such as (a) pretreatment testing for a genetic polymorphism (interleukin-28 beta subunit [IL-28B]) that predicts response to PEG-IFN/RBV therapy or (b) assessment of initial virologic responses with conventional therapy; if a rapid response is achieved, dual therapy may be sufficient. In contrast, if a rapid viral response is not achieved by week 4, then adding a protease inhibitor may improve the chance of viral clearance. Such strategies could allow the use of the less costly dual regimen for persons highly likely to respond to conventional therapy, reserving the more expensive regimens for those who would benefit.<sup>36</sup> On the other hand, proposed strategies that initiate PEG-IFN/RBV only for all patients for the complete course and offer triple therapy to nonresponders are not recommended, because this approach would result in long periods of drug exposure and increase overall

costs. These initial DAAs have numerous drug–drug interactions, especially with antiretroviral medications used in the treatment of HIV. Prescribing boceprevir and telaprevir often requires input from a specialist.

## Emerging and Future Therapies

Although boceprevir- and telaprevir-containing triple-drug therapy represent the standard of care as of early 2013 and pose a substantial challenge for correctional systems, evolving antiviral regimens in development will eventually supplant the current paradigm. The next paradigm may involve regimens of only oral DAAs, for which pilot studies have demonstrated that SVR can be achieved without PEG-IFN.<sup>37</sup> The first of these emerging therapies may be more complicated and have more adverse effects than previous standards of care. They will likely, in the immediate future, require practitioner expertise and intensive management. As clinical outcomes and medication tolerability improve,

paradigms will be far simpler to apply, thereby broadening the potential pool of practitioners able to treat HCV infection and reducing the costs of patient monitoring. As efficacy improves, the rationale for liver biopsies may lessen as it did in the past for patients with a favorable HCV genotype (ie, genotypes 2 or 3).<sup>38</sup>

The rapid evolution of community-standard HCV care and potential expansion of the pool of individuals eligible for treatment will need to be met by nimble approaches in order to provide care within prison walls. Such approaches will necessitate expansion of HCV-specific knowledge among practitioners, systems to integrate rapidly changing community standards, and the expertise to choose among a rapidly growing arsenal of antiviral drugs with close monitoring to avoid futile therapies. An innovative model known as Project ECHO (Extension of Community Health Outcomes) has resulted in primary care practitioners being informed by specialists through so-called knowledge networks (eg, via teleconferences) and having advice in state-of-the-art HCV therapy delivered. In a setting where access to specialists had been a major barrier, the efforts of Project ECHO resulted in equivalent SVR rates and lower adverse event rates compared with a central specialty clinic.<sup>9,39</sup> Similar systems could be implemented in prison health care settings to allow wider application of the expertise offered by community specialists.

### Screening Practices in Correctional Settings

The rationale for screening is to increase access to therapy and thereby reduce future complications of disease. To borrow a concept from HIV epidemiology, eradication of infection can also lead to a reduction of community viral load, meaning individuals engaging in high-risk behavior are less likely to be exposed to HCV. Treatment can thus result in primary prevention.<sup>40</sup>

Historically, practitioners in the community and in prison systems have been advised to perform HCV

screening for individuals at high risk, including injection drug users. However, this risk-targeted approach has proved inadequate, as it depends on ascertainment of illegal behavior<sup>41</sup> that prisoners may be unwilling to admit for fear of additional criminal charges. The recently published recommendations from the Centers for Disease Control and Prevention (CDC) to screen all those born between 1945 and 1965, the age group with the highest prevalence of HCV, if followed in correctional settings, may increase the number of persons who are aware of their infection.<sup>42</sup> A recent cost-effectiveness analysis compared survival, quality-adjusted survival, lifetime medical costs, and the incremental cost-effectiveness ratio of birth-cohort screening for HCV and application of the risk-targeted approach for the United States. Compared with risk-targeted screening, birth-cohort screening with linkage to HCV triple therapy has the potential to identify more than 800,000 additional cases of HCV infection and prevent 121,000 HCV-related deaths at an incremental cost-effectiveness ratio of \$35,700 per QALY gained.<sup>43</sup> The authors conclude that birth-cohort screening for HCV in primary care settings is cost-effective.

Although these findings inform policy for community-based settings, their implications for prison health care are not clear. Because incarceration is so closely correlated with drug use, routine universal screening in correctional settings may be the most efficient and cost-effective approach for HCV screening. However, if screening is not coupled with either widely available prison-based HCV treatment or excellent care coordination with community-based treatment systems to ensure postrelease linkage to HCV care, screening in prisons may be ineffectual. Further, because the demographics, comorbidities, and social history of incarcerated individuals differs substantially from those of the cohorts modeled in analyses of community-based HCV screening, published cost-effectiveness estimates may not be generalizable for policy making in prisons.

HCV screening practices in prison settings, as well as their sensitivity and cost-effectiveness have not been well studied. A 2000 survey of state prisons at a facility level found most prison facilities (69% of facilities, holding 88% of US state prisoners) targeted screening based on risk, patient request, or clinical indication and that few (9% of facilities, holding 6% of US state prisoners) had routine screening. Of note, 33% of tests returned positive results with risk-targeted screening, whereas 27% of tests were positive under routine screening.<sup>44</sup> Risk-targeted screening strategies may be missing a substantial number of cases, and the CDC recommends periodic reassessment of the efficacy of risk-based screening.<sup>1</sup> There may be resistance, however, to deploying broader, routine HCV screening in prison systems, because increased case identification would also increase pharmaceutical expenditures in prison health care systems that are already financially strained.<sup>3</sup>

When HCV infection is detected among state prisoners, health service administrators might ask why detection did not occur prior to imprisonment. Earlier detection may have permitted treatment in the community, where federal funding (eg, Medicaid) and private insurance can supplement state resources. When the burden of treatment falls to prisons, the state alone bears the cost of treatment. One possible approach to reduce the burden of treatment costs to prisons may be for public health agencies to partner with jails to institute screening in short-term facilities.<sup>45</sup> Jail and prison populations have similar risk factors for HCV infection. Most jail admissions do not lead to long-term imprisonment and treatment has rarely been considered feasible for short-term inmates. However, testing in jail settings with appropriate links to community settings for evaluation will allow important preventive interventions and treatment at an earlier stage of HCV infection. For the younger populations passing through jail settings, there may be substantial personal and public health benefits, short of the provision of treatment with antiviral drugs when time is

insufficient, by immunizing against hepatitis A and hepatitis B viruses, determining viremic status, and providing harm reduction. Together, these interventions may prevent new infections in individuals testing negative or in those with cleared infections (spontaneous clearance) or may reduce secondary transmission (by narrowing the pool of HCV-infected persons). Thus, from a societal perspective, coordinated HCV screening and treatment among jails, prisons, and the community may enhance the overall integration of care.

### Policy Implications of New Therapies for HCV Infection

The structured prison environment may facilitate excellent adherence to demanding therapeutic protocols and administration schedules. As such, the correctional institution can be an effective site to treat and cure HCV-infected patients in a controlled setting, potentially reducing the burden of ESLD—for patients and for health care payers (both public and private)—upon release to the community.<sup>4,5</sup>

Whereas triple therapy has become the standard of care in the community for individuals with genotype 1 HCV infection, the legal obligations of state correctional health care systems will also shift. As described above, Eighth Amendment principles, and interpretations thereof by the federal courts, prohibit deliberate indifference to serious medical need and delay in providing known, effective treatments. It is likely that the judicial system will ultimately require that state correctional health care systems provide HCV treatment that is consistent with current standards of care in the community (except perhaps in cases in which the length of incarceration is so short that delay in treatment until release would not have adverse clinical impact). Because these therapeutic developments directly impact the legal and fiscal obligations of correctional health administration and the public health, prison systems need to create a strategy to deal with a future in which a higher percentage of inmates can tolerate

medications and complete treatment prior to release.

The primary strategic challenge, given the limitations of correctional health care and pharmacy budgets, is the high cost of these new drug regimens. Discounted pricing for pharmaceutical drugs is available to other entities caring for low-income populations under federal provisions (Section 340B) of the Public Health Service Act but is not directly available to prisons by regulations of the Health Resources and Services Administration. Long-standing federal statutory exclusions of inmates from Medicaid and Medicare benefits also leave state and local governments without federal funding support. But well-settled law providing a constitutional right to adequate health care for inmates means that with the exception of federal prisoners, the costs of correctional health care fall entirely on local, county, and state budgets. Given the recent estimate that 9.6% to 41.4% of inmates are seropositive for HCV<sup>12</sup> and that approximately 75% of those with a reactive HCV antibody test are viremic, many of these prisoners may be candidates for DAA treatment. Several authors of this paper estimate that if prices are not lowered, expanded HCV screening and access to treatment in their state's prison system could lead to HCV-related medical costs consuming 10% to 40% of prison system pharmacy budgets. This is an enormous strain on a budget that is already burdened by medications required for a host of other comorbidities, such as serious mental illness, heart disease, kidney disease, and HIV infection.

One important consideration crucial to formulating rational policy for HCV treatment in prisons is the external nature of the benefits gained from HCV cure. Viral eradication stops liver fibrosis progression, but the complications of cirrhosis that would have occurred in the absence of HCV treatment may take decades.<sup>39</sup> As a result, correctional systems are asked to pay for HCV therapy, but they likely will not accrue the future benefits of preventing complications of liver disease. Similarly, when prisons do not have adequate resources to provide

treatment, the eventual costs of ESLD will fall on Medicaid, Medicare, and private insurers.

Current health care policy reform provides an opportunity to expand access to HCV treatment, but it could also create additional incentives to postpone HCV therapy in prisons and exacerbate the inefficiencies generated by external benefits. Under a key component of the PPACA, nearly all formerly incarcerated adults (aged 19 years to 64 years) could become eligible for Medicaid (or insurance tax credits) at the time of release. States that elect to opt in to this expanded Medicaid eligibility will qualify for generous federal funding, including funds to initially cover 100% and then 90% of all medical costs for these newly eligible enrollees. As a result, the federal government, rather than the state, will pay the majority of HCV treatment and care costs for former inmates who subsequently live in the community. In contrast, inmates who remain incarcerated will not be eligible for Medicaid or Medicare. As a result, their HCV treatment costs will fall entirely within the state department of corrections health care budget.

For some HCV-infected inmates with short sentences and minimal liver fibrosis, deferring treatment to postrelease may be effective and, from the perspective of the state department of corrections, could contain costs. To the extent that those savings are applied to expanding HCV treatment for those with long sentences or advanced liver disease, the PPACA funding could indirectly result in improved HCV outcomes among current and former inmates. If, however, states pursue an overly aggressive strategy of deferring HCV therapy until postrelease to leverage PPACA Medicaid funding and minimize HCV treatment costs in the correctional setting, increased morbidity and mortality could result. Further, the challenges of postrelease linkage are substantial. Without interventions to ensure postrelease follow-up of HCV infection,<sup>31</sup> deferring treatment may result in maintenance of the status quo, in which as few as 6% of HCV-infected persons initiate HCV therapy.<sup>46</sup>

The cost-benefit analysis of providing HCV therapy to inmates, therefore, must take a societal perspective rather than compartmentalize the state department of corrections, state Medicaid program, and federal Medicaid and Medicare budgets. Policy made purely from the perspective of the state department of corrections, or even of the entire state health care budget, will tend to favor deferring HCV therapy until after release, as doing so will shift costs to the federal government. Similarly, policy made entirely from the perspective of the federal Medicaid and Medicare budget will favor immediate HCV treatment, even for patients who have no immediate need for treatment and who could be treated safely and effectively in a community setting. The societal perspective, which recognizes all costs and benefits related to HCV treatment and complications of HCV infection, regardless of where or when they occur, treats HCV disease in a holistic manner and is likely the only perspective from which to formulate efficient HCV policy that minimizes costs and maximizes public health.

Action items for stakeholders in prisoner health care to address the HCV epidemic as novel therapeutics emerge are summarized below.

**1. Develop and implement policies that provide for the clinical care of HCV-infected individuals in prisons that parallels the community and that are adaptable to future needs.**

When treating HCV infection, appropriate treatment, ie, the community standard of care, can be implemented in correctional settings, rather than less efficacious treatment. Resources should be used wisely; if treatment is futile, eg, when a patient has inadequate response to therapy, having systems in place to stop therapy promptly is important. Information on changing aspects of HCV care should be regularly disseminated (eg, via teleconferencing) among correctional practitioners. Expansion of the pool of practitioners with specific knowledge and skills to provide HCV-related care is also needed, and some of this can be accomplished with models like

Project ECHO.<sup>9</sup> The design of treatment protocols and delivery systems nimble and flexible enough to be updated to keep pace with the development of new paradigms and inclusive of special populations such as HIV coinfection is another goal. Finally, it will be important to integrate screening for HCV in both jails and prisons, with appropriate systems for follow-up and treatment in the community once inmates are released.

**2. Close knowledge gaps.** Correctional health officials can help close knowledge gaps among public policy makers by educating them about the availability and efficacy of new HCV treatments, the short-term increased cost burden on correctional health care systems, and the long-term benefits of these treatments in lowering future health care costs and avoiding much more expensive ESLD and liver transplants in the future.

**3. Fully ascertain the impact of the PPACA and expansion of Medicaid in the community on prisoner health.**

Decision making by policy makers about financing the health care costs of HCV-infected inmates and releasees can be planned and aligned with the benefit of a full understanding of the fiscal impact before and after incarceration, as well as new sources of financing under the federal Medicaid expansion option that becomes available to states in January 2014. Today, most affected inmates cannot qualify for Medicaid coverage upon release, even if they have little or no income. Although most releasees may qualify for care at community health centers, the costs of these health center systems fall mainly to practitioners and state-funded safety net programs. Under the PPACA, however, generous federal matching funds will become available to state Medicaid programs that opt in to expanding Medicaid coverage to all adults with low income (ie, income at or below 133% of the federal poverty level after income “disregards” are applied). Because almost all releasees would meet the low-income eligibility criteria, the

PPACA Medicaid expansion presents a compelling opportunity for states to substantially improve the coordination of effective postrelease treatment and to provide continuity of care for releasees.

**4. Plan now to deliver state-of-the-art HCV care, before litigation.**

Jurisdictions that have not already done so can engage in strategic planning now for the new resources and funding needed to appropriately screen, treat, and coordinate postrelease community care for inmates with HCV infection. Because the new treatment protocols are now recognized as the community standard of care for affected individuals, well-settled constitutional requirements to provide timely medical treatments to inmates will apply to these new HCV therapies. It may only be a matter of time before lawsuits will result in court decisions ordering provision of these treatments to inmates with and without HIV and HBV coinfection whenever they are clinically indicated and delay would have adverse clinical outcomes.

**5. Negotiate discounted pharmacy pricing for novel therapeutics.**

In light of the known long-term public health benefits and substantial cost savings in the long-term costs of liver disease for the entire health care system, it is important for federal policy makers to reevaluate exclusionary policies relative to discounted pharmacy pricing for state correctional health systems. Current federal regulations governing the pharmacy discount pricing program known as 340B severely limit the capacity to obtain discounted pricing for medications used in correctional health systems, leaving state prison systems to bear the full cost of very expensive therapies. Even if society as a whole would benefit from avoiding treatment of ESLD, currently, there is no incentive for prisons to avert future, society-wide health care costs. Changing federal policy to make 340B discounted pricing available to state correctional facilities would give financial incentives for states to treat early-stage disease.

**6. Approach all of HCV management from a societal perspective.** Public health policy making can address HCV treatment decisions in a holistic manner, rather than compartmentalizing in-prison and community-based costs of funding the current community standard of care for HCV treatment. It is important that cost-benefit analysis of providing triple-drug therapy to inmates take into account the substantial but downstream long-term benefits gained from HCV cure. Viral eradication stops liver fibrosis progression and the complications of cirrhosis, ESLD, and the need for liver transplants that otherwise would have occurred decades later. When the public health benefits for society and the lower lifetime costs for the whole health care system of appropriate HCV screening and treatment are taken into consideration, the short-term costs to state correctional facilities are more than offset.

**7. Determine an agenda for future research.** Better data collection is needed to measure disease burden and project costs to both correctional and community health care systems. Only 12 states have recently surveyed their prison system for current seroprevalence. States should consider surveying all state-funded health care populations, including prison populations, to determine prevalence across state-funded programs and to assess downstream fiscal impacts of providing or delaying treatment. Design and funding of interventions that determine the best approaches to integrate HCV care for inmates across the jail, prison, and community settings are necessary. Similarly, the efficacy of newer treatment regimens and unique strategies for addressing HCV infection within prison walls can be studied to understand barriers to care within prison systems and compared with community-based outcomes. Finally, mathematical modeling can effectively describe the specific impact of screening and treatment of HCV-infected individuals in prisons on societal disease burden and costs, including lowering liver disease burden and the community viral load of HCV.

New therapeutics for HCV are expected to become available at a quickened pace. Incarcerated individuals infected with HCV stand to benefit from treatments with better efficacy. These developments can be an opportunity to rethink the financing of correctional health care. ☒

## Acknowledgements

Drs Kim and Spaulding contributed equally as authors to this review article.

*Financial Affiliations: Dr Spaulding has received research grants paid to her institution from Bristol-Myers Squibb and Gilead Sciences, Inc (Updated 3/25/13). Dr Kim has received consulting or advising fees or honoraria from Vertex Pharmaceuticals, Inc (Updated 3/25/13). Dr Harzke has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Sullivan has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Linas has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Brewer has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Dickert has no relevant financial affiliations to disclose (Updated 3/25/13). At the time of her contribution, Dr McGovern had no relevant financial affiliations to disclose; she is currently an employee of Abbott Laboratories (Updated 3/25/13). Dr Strick has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Trestman has no relevant financial affiliations to disclose (Updated 3/25/13). Dr Ferguson has no relevant financial affiliations to disclose (Updated 3/25/13).*

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*Top Antivir Med*. 2013;21(1): 27-35

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