

Hepatitis C in Correctional Settings:

Challenges and Opportunities



Executive Summary

This monograph presents the results of a national survey on hepatitis C virus (HCV) infection in corrections in the U.S. This survey looked at both the current and future management of HCV infected patients in the nation's correctional systems. Participants in the survey consisted of the membership of the Coalition of Correctional Health Authorities (CCHA), which is made up of the health authorities from all 50 states' departments of correction, the country's six large jail systems and the Federal Bureau of Prisons. The data was gathered using an online survey instrument that was distributed to the participants. Participants had two months to gather the necessary information and respond to the 23-question survey. Fifty-three surveys (93%) were returned, forty-nine (86%) of which were fully completed. All completed responses were analyzed, including surveys where questions were skipped.

The survey questions were designed to address six key areas to better understand how HCV infection is managed in corrections. These areas included policy/clinical guidelines, prevalence, current treatment practices, prevention/education strategies, the cost of current treatment and the estimated future cost of treatment using new medications that have recently become available. The findings are presented along with recommendations drawn from those findings that offer guidance to correctional systems as they move forward in treating HCV infection.

Among the more prominent findings in this survey are:

- The prevalence of HCV infection in correctional institutions far exceeds prevalence in the community, although definitive numbers are hard to pinpoint;
- There are differences in approach to identifying the disease, identifying patients for treatment and selecting treatment modalities;
- Most correctional systems are currently treating HCV infection and utilizing treatment algorithms comparable to those utilized in the community;
- There is inconsistency across correctional systems in HCV infection testing practices, as well as in education and treatment involving prevention of HCV infection;
- Approximately half of the correctional facilities combine substance use disorder treatment with HCV infection treatment; and

- Although correctional facilities are regularly treating HCV infection, the expense of new medications may render it difficult for correctional facilities to treat these patients in significant numbers.

Recommendations for Correctional Systems

Based on the findings in this study, a number of recommendations are proposed. These include the following:

- Conduct a comprehensive and statistically sound national correctional prevalence study on HCV infection to refine the data from this survey;
- Develop and implement consistent screening and clinical practices across correctional health services nationwide;
- Develop and implement post-treatment relapse prevention programs;
- Enhance financial support for HCV infection screening and treatment in corrections, including, for example, government funding programs, purchasing agreements and related support mechanisms that are national in scope;
- Support research initiatives that further our understanding of HCV disease in order to more effectively identify appropriate candidates for treatment and protocols for those patients;
- Establish community and correctional linkages, especially in jails, to allow for treatment to easily move from the community to jail and then back to the community, recognizing that partnerships between correctional and community health care are critical to successful management of this and other diseases; and
- Develop and implement comprehensive HCV disease education programs and materials for inmate patients and their family members in our jails and prisons. These should be informative to inmates and written and presented in ways that bridge language, cultural and literacy gaps.

Executive Summary

Continued

Education efforts should include the following components:

- Orientation;
- Peer education;
- Community-based prevention and education;
- Individual prevention and education on request;
- Written and video materials;
- Prevention and education in prerelease, day reporting and pretrial populations;
- Gender-specific programs at facilities;
- Expansion of hepatitis C viral infection curriculum to cover other infectious diseases;
- Programs and materials to be made available in Spanish, English and other languages; and
- Discharge planning.

Introduction

There are more than 2 million Americans incarcerated in the nation's prisons and jails. The U.S. Constitution requires that health care be provided to all offenders.¹ In many patients, treatment of hepatitis C viral infection (HCV) represents a serious medical need, but the treatment of incarcerated individuals who have this infection represents a challenge of considerable proportion for the nation's prison and jail systems. There are several reasons for this, not the least of which are the Food and Drug Administration's (FDA) newly approved medications, which have much improved efficacy and fewer side effects than previously utilized medications. Although clinically more advantageous, these medications are also extraordinarily expensive.

An interesting characteristic of this virus is that HCV infection impacts individuals in different ways; some clear the virus and are unaffected chronically, while others develop slowly smoldering hepatitis C viral infection leading to cirrhotic liver disease and/or hepatocellular carcinoma or liver cancer. These changes typically occur over a course of 25 to 30 years after acquiring the disease. At this time, medical knowledge is not advanced enough to identify those who are likely to progress and those who will not.

The Coalition of Correctional Health Authorities (CCHA) includes the health authorities from all 50 states, the country's six large jails and the Federal Bureau of Prisons. The head of corrections in each jurisdiction appoints his or her CCHA member, and it is typically the person who reports directly to him or her on matters of health care. CCHA was founded on the idea of bringing health authorities together to exchange promising practices in professional health care administration, learn new and improved techniques in quality health care delivery and address critical emerging issues.

CCHA members recognized early on that for the reasons above, treating hepatitis C viral infection in America's criminal justice-involved population would represent challenges of major proportions. In order to better equip its state, county and municipal health authorities to make wise HCV infection management decisions, CCHA developed a survey with the objective of characterizing current correctional practice in the management of hepatitis C viral infection, as well as the cost and other challenges presented by this disease. The remainder of this monograph presents the results of this survey and suggests options to address the key issues of the correctional hepatitis C viral infection treatment challenge.

Background

Hepatitis C viral infection is one of the many chronic illnesses that disproportionately impact the correctional population (Tan, 2008). HCV infection is a viral illness transmitted through exposure to infected blood. Risk for infection is especially high among intravenous drug users (Hammett, 2003). Many individuals remain asymptomatic after initial infection for many years. While only between 1 and 2% of the general population is infected by HCV infection, within the U.S. correctional population, the historic literature provides an estimated prevalence rate between 16 and 41% (Allen, 2003). More recent studies suggest that the seroprevalence may be declining, but still estimate the range between 9.6 and 41.1% (Varan, 2014). This is, in part, due to the high prevalence of HCV infection among injection drug users (IDUs), estimated to be between 72 and 86% (Hammett, 2003). Approximately 50% of drug-dependent inmates have previous histories of imprisonment (Dolan, 2015). Inmates also often may bounce between community and correctional settings without knowing they are carriers of HCV infection and may engage in virus-spreading behavior (Fox, 2005). Early on, it became clear that correctional facilities would offer an important place to diagnose, treat and prevent hepatitis C viral infection so that released individuals do not spread the virus to those in the community (Allen, 2003; Hammett, 2003; Spaulding, 2013).

Because injection drug use is a key contributor to HCV infection, several authors have followed treated patients and measured the risk of reinfection. In a noncorrectional environment, one study found that 15 of 50 (30%) treated injection drug users (IDUs) remained alive and free of infection three years after the end of treatment (Backmund, 2004). Relapse to injection drug use remained a risk, and the authors suggest that HCV treatment be started either during detoxification or methadone maintenance and be supervised by physicians trained in treating substance use disorders as well as those treating the HCV disease (Backmund, 2004). Reinfection also may occur within the correctional environment with a prevalence as high as 17%. (Bate, 2010). In a community study of HCV infection among young adult IDUs, Tsui found that maintenance opioid agonist therapy with methadone or buprenorphine reduced the risk for infection for at risk individuals (Tsui, 2014). In a study in Spanish prisons, Marco concluded that HCV reinfection among inmates after successful treatment is high, especially with the population of ongoing IDUs (Marco, 2013). This author recommends implementation of preventive practices.

The management of HCV infection in correctional settings has evolved rapidly in terms of treatment approaches. When examining the history of HCV infection treatment, there are three main therapeutic phases. From the early 1990s until 2011, treatment consisted primarily of combination therapy using pegylated interferon and ribavirin, which achieved a sustained virologic response (SVR)² of 40 to 50% for genotype I patients (Ghany, 2011). Genotype I HCV is the most prevalent genotype in North America (Welsch, 2012). The second phase began in 2011, when treatment was updated by adding direct acting antivirals³ (DAAs), such as telaprevir and boceprevir, which, while more expensive, bumped efficacy rates up to 70% for genotype I patients (Asselah, 2011). The third and current phase, which began after 2013, is characterized by new DAAs, including simeprevir, sofosbuvir, ledipasvir and others, which, while extremely costly, give SVR rates at 90% and above for genotype I patients (Hoofnagle, 2014). Most recently, the combination pill ledipasvir/sofosbuvir offers an oral one-pill-per-day, interferon-free regimen to genotype I patients with a course of therapy of eight, 12 or 24 weeks. These DAAs also have efficacy against a wider range of HCV infection genotypes and appear to have much improved side effect profiles.

Today's management of this disease provides an opportunity to cure a substantial proportion of those infected with hepatitis C viral infection. However, new questions arise because of the costs of the new treatments and whether or how correctional agencies will address the dilemma of already stretched health care budgets. In addition, a recently published article in the *British Medical Journal* raises questions about the advisability of broad-based community screening and treatment without additional research (Koretz, 2015). These authors argue that not enough information is known about the natural history and course of hepatitis C viral infection, especially for those patients in whom the disease does not progress, to justify markedly expanded screening and treatment that might lead to unnecessary risk associated with that treatment. They call for well-designed and well-conducted randomized, placebo-controlled trials to begin to provide answers to these questions (Koretz, 2015). Their article addresses issues involved with screening and treatment of individuals in the community. It does not focus directly on correctional populations and the challenges that these populations represent.

Background

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Studies have shown that providing HCV infection treatment can be cost-effective. In 2003, the Rhode Island Department of Corrections estimated that the treatment cost for 48 weeks of interferon and ribavirin was \$8,000 per patients with lab costs at approximately \$1,500 (Allen, 2003). The total cost for one year of treatment of a select cohort equaled \$622,520. This amounted to about 5% of the annual health care budget for the department (Allen, 2003; Hammett, 2003). Another study using ribavirin and pegylated interferon to treat inmate patients found that when a liver biopsy was not a prerequisite to receive care, treatment was cost-effective for all age ranges and genotypes, decreasing costs and improving the quality of life for inmates, saving up to \$41,321 per inmate (Tan, 2008). More recently, Liu, et.al., used a cost effectiveness model to evaluate several treatment regimens within the unique constraints of the prison environment (Liu, 2014). This analysis showed that treating incarcerated men with genotype I chronic HCV infection for 12 weeks using sofosbuvir as part of a three-drug regimen was comparable in terms of effectiveness and value with other medical interventions considered cost-effective (Liu, 2014). This author concludes that sofosbuvir-based regimens are cost-effective for incarcerated persons, but that affordability could be an issue (Liu, 2014).

One of the more recently FDA-approved treatment regimens utilizing oral medications is the sofosbuvir/ledipasvir combination tablet. This tablet costs \$1,125 per pill, is pre-

scribed daily and totals \$94,500 for the medication alone for a 12-week treatment course. This cost profile places a very heavy financial burden on correctional health budgets across the nation. Nonetheless, recently, Spaulding, et.al., argued that treatment of HCV infection in correctional populations, even with more expensive pharmaceutical regimens, is cost-effective from a societal perspective (Spaulding, 2013).

Certainly, corrections environments can provide an opportunity for the nation to develop a meaningful management response to the challenges posed by HCV infection in a population that disproportionately suffers from this disease. New medications available for treating this disease offer much improved efficacy rates, fewer side effects and simpler and shorter treatment courses. To understand best how to utilize these new medications and others to come is the corrections health care challenge of this young century. The first step toward meeting this challenge involves the collection of data to better characterize the behavior of correctional health care systems in the monitoring and management of this disease. The CCHA hepatitis C survey is an important initial component of the broader effort to generate a database that will lead to the development of better policies and practices involving HCV infection treatment in the nation's correctional systems.

The CCHA Hepatitis C Survey

Methodology

During the summer of 2014, the American Correctional Association (ACA) and the CCHA Research and Health Outcomes working group conducted a survey on the changing landscape of HCV infection management in corrections, with an emphasis on the care and management of patients with HCV infection and the financial impact of this treatment in the correctional setting.

The participants in the survey consisted of the membership of CCHA, which is composed of health authorities from all 50 states, the nation's six large jail systems and the Federal Bureau of Prisons. CCHA's membership consists of individuals who manage the health care services for the nation's adult correctional health systems. This group of individuals totals 57 and is composed of physicians and non-physician medical administrators. The survey results represent the experiences of unified systems, as well as large jails and statewide prison systems.

An online survey instrument was developed, beta-tested and distributed to the 57 potential respondents. The participants were given two months to respond to the 23-question survey. The survey addressed six key areas of correctional health care that directly relate to the treatment of HCV infection:

1. Policy and clinical treatment guidance;
2. Prevalence;
3. Current treatment;
4. Prevention and inmate patient education strategies;
5. Cost of current treatment; and
6. Future cost estimates.

Survey Development

As part of ACA's initiative on hepatitis C viral infection, the ACA Office of Correctional Health Care and the CCHA Research and Outcome Measures working group held an initial meeting to discuss the concerns faced by the corrections field in the wake of the new HCV infection drug cost and how these costs might impact the provision of treatment to inmates who are infected with this disease. Once the initial questions were developed, the sample questionnaire was emailed to a focus group of senior health authorities, who have more than 10 years of experience managing HCV infection inmates, to review and determine the appropriateness of the questions and also whether any other pertinent questions should be included. Once the focus group's input and suggestions were received, the questions were edited to reflect these concerns.

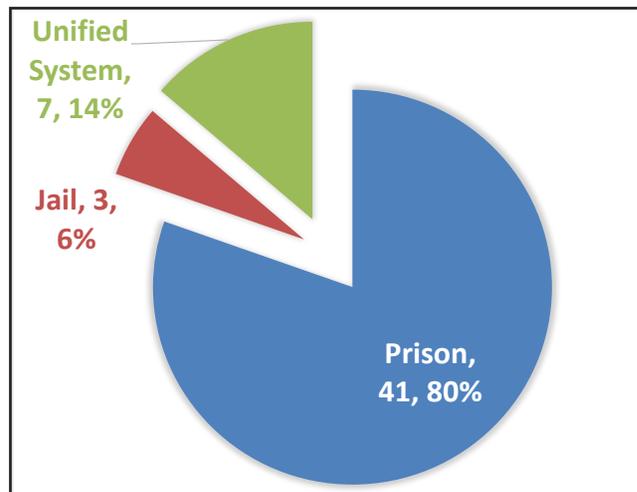
Each participant's email address was entered into the system, and each person had an individualized link only the assigned participants could use. An introductory email was sent to the group, outlining the purpose of the survey and its overall goal. The participants were also informed that their responses were voluntary and confidential and assured their responses would not be identified by individual state during analysis of the results. Reminder emails were sent several times in order to improve response to the survey. Survey Monkey was utilized to distribute the survey tool and collect the responses.

Survey Participation. Fifty-three of the 57 distributed surveys were returned and analyzed. This represents a return rate of 93%. Not all questions in the 53 returned surveys were completed. Forty-nine (86%) of the surveys had responses to every question. All questions with completed responses were included in the analysis, whether or not the entire survey was completed. Of the total of those responding to the correctional agency-type question (51 responses), three (6%) were provided by jails, 41 (80%) represent prisons and seven (14%) came from unified systems (meaning the jails and prisons are managed by one administering agency). Although prisons are overrepresented in this survey, the jails that responded are some of the largest in the country.

The CCHA Hepatitis C Survey *Continued*

Jails and prisons are faced with different challenges as they provide health care and manage disease in their populations. The jailed population tends to be very transient, with offenders coming and going on an almost daily basis. The rapidly changing character of this population renders the care of chronic disease extremely challenging, especially from the perspective of continuity of care. Prisons, on the other hand, have much more stable populations and allow for the effective treatment of chronic disease, such as HCV infection, much more readily than jails.

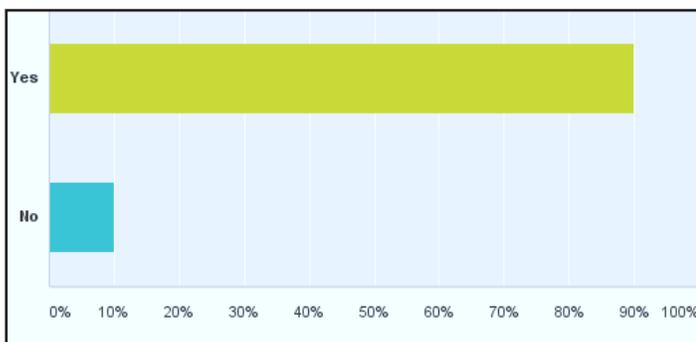
Figure 1-1: Types of Correctional Agencies Represented in the Survey



Burden of Hepatitis C Viral Infection in Prisons and Jails

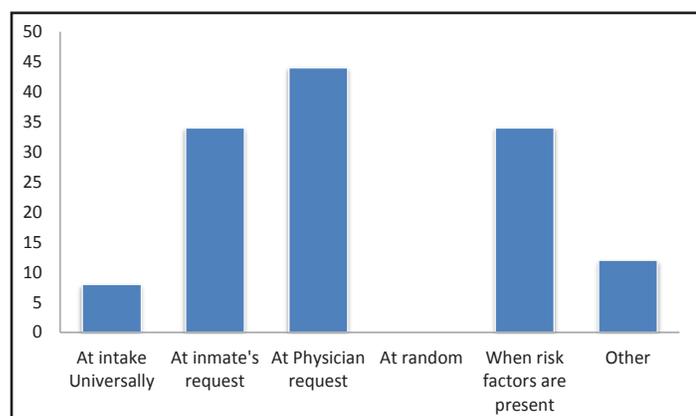
Screening. The survey asked a number of questions aimed at understanding the methods and extent of medical screening for HCV infection in prisons and jails. Respondents were asked about what triggered screening for HCV infection in their facilities. Ten percent (representing five respondents) do not test for hepatitis C. The remaining 90% or 45 systems test based on a variety of criteria.

Figure 2-1: Systems That Test for Hepatitis C Viral Infection



Of the remaining 90% who do test, the three most common triggers for HCV infection screening were physician request (44 or 90%), identified risk factors (34 or 69%) and inmate request (34 or 69%). Eight facilities or 16% screen all offenders at intake, and none screen randomly.

Figure 2-2: When Hepatitis C Viral Infection Testing Occurs



To better understand diagnostic practices related to HCV infection in the correctional setting, the survey requested information on the case definition for chronic hepatitis C viral in-

fection that each jurisdiction utilized. Of the 49 respondents to this question, 23 or 47% utilize hepatitis C infection antibody positivity to identify cases of disease. Thirty-four or 70% utilize both antibody positivity and evidence of viremia (virus present in the blood) to confirm a case of chronic HCV infection. Because up to 20% of individuals who are affected with HCV infection may clear the disease and thus are not susceptible to the development of chronic disease, follow up of a positive HCV infection antibody with a measure of viremia will lead to a more accurate measure of prevalence.

Prevalence. One of the primary goals of this survey was to provide a measure of the true population prevalence of chronic HCV infection in the nation's correctional systems. This is a complex task in part because different systems measure prevalence differently. Also, only a limited number of systems screen all inmates for hepatitis C viral infection. In addition, a large number consider HCV infection antibody positivity without a measure of viremia as evidence for the disease. Since the approach to screening varies across the spectrum of facilities, getting accurate data on prevalence is very difficult. Because of this, the prevalence data from the survey is presented in two formats. The first separates the data from the relatively few systems (seven responding correctional systems) that test every inmate for hepatitis C viral infection on intake and compares this to average daily census. This generates a true prevalence of HCV infection. This is the most accurate true prevalence data that we have since all inmates have been tested and all known cases have been identified. The second source of data is called diagnosed prevalence. Rather than knowing the HCV infection status of all the inmate population, diagnosed prevalence only accounts for those whose HCV infection status is known, and since these systems do not test their entire populations, it is not true prevalence. Diagnosed prevalence data is generated by taking only known cases that have been identified as a percentage of average daily population. In addition to these two prevalence measures, there is additional information provided by several systems that, while not representing true or diagnosed prevalence data, does offer additional insights into the burden of HCV infection in corrections in the U.S.

Measures of True Prevalence. Seven of the surveyed systems measure the prevalence of HCV infection in inmates entering their systems. Some have been doing this for a number of years. For those who test everyone, prevalence was defined by the number of HCV infection cases divided by the average daily population. The true prevalence data presented here were generated within the past 12 months, largely at intake. Of these systems, the prevalence ranges from 8 to 10% on the low end and 17% on the higher end. The average of this group

Results

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is 11.6%, as shown below. The systems that have provided this information range from small to large — their average daily population ranges from 5,200 to 49,000 offenders. The following chart describes the population utilized to determine true prevalence. The calculated true prevalence for this population group is 11.6%. There are 22,907 cases represented in this group.

Figure 3-1: True Prevalence of Hepatitis C Viral Infection in Correctional Facilities

True Prevalence Measures	# of Facilities	# of Infected Individuals	Total Offender Population Represented
< 10%	2	4,486	53,200
10% - 20%	5	18,421	144,520
>20%	0	0	0
TOTAL	7	22,907	197,720

Diagnosed Prevalence. Thirty-one correctional systems provided diagnosed prevalence data in response to the survey question regarding prevalence. Diagnosed prevalence in this study was calculated by comparing known HCV infection cases by average daily population. Diagnosed prevalence provides information on known cases of the disease, but because not all of the population is tested, it is very likely that diagnosed prevalence underestimates the true prevalence of disease. The chart below summarizes the data provided by 31 systems on diagnosed prevalence. Almost two-thirds of the systems (19 out of 31, or 61%) report diagnosed prevalence of less than 10%, representing 26,230 cases and an offender population of 527,746. Only one facility has diagnosed prevalence of more than 20%, and the remainder lie between 10 and 20%. The known number of HCV infection cases in these 31 correctional systems is 86,647. The average daily population of these 31 systems is 996,634. The number of cases not yet identified within these systems is unknown.

Figure 3-2: Diagnosed Prevalence of Hepatitis C Viral Infection in Correctional Facilities

Diagnosed Prevalence Measures	# of Facilities	# of Infected Individuals	Total Offender Population Represented
< 10%	19	26,230	527,746
10% - 20%	11	59,517	464,688
>20%	1	900	4,200
TOTAL	31	86,647	996,634

The total number of cases represented by the above diagnosed prevalence data is 86,647. The total number of inmates represented by the data is 996,634. The calculated diagnostic prevalence of this correctional population is 8.7%. Again, this number represents only those cases that are diagnosed, not the true prevalence in these 31 correctional systems.

Other Prevalence Information. Several other systems have provided information relevant to this question, but the data was collected during a previous time period or in a more limited way. One large system measured prevalence several years ago and identified 30% of the incoming population as positive for HCV infection. A second system provided data from a random test that showed a prevalence of 26%. Similarly, a smaller system that measured a small cohort of prison inmates identified a prevalence of 24%.

Case Burden. From the survey data, it is possible to calculate the number of known cases in these systems. Combining the number of cases from the true prevalence group with those in the diagnosed prevalence group, the total is 109,554 cases of known HCV infection.

Hepatitis C Treatment Guidelines. In response to a question regarding a clinical practice guideline on the evaluation and treatment of chronic HCV infection, more than half (57%) of the correctional systems responded that they did have this

type of guideline. Twelve percent did not have a clinical practice guideline regarding HCV infection, and 31% selected the “other” option.

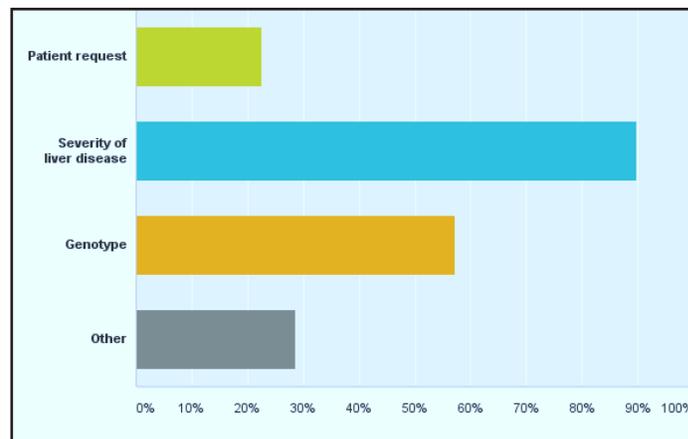
Approximately 90% of the systems that responded have methods in place to allow for selecting candidates for treatment. Only 6% or three correctional systems responded that they were not treating HCV infection patients with antiviral medications. It is very likely that these three represent jails as long-term chronic disease treatment, as required by HCV infection, is difficult in the relatively chaotic and ever-changing jail environment. The survey also requested information on the numbers of patients treated by the respondents. Over 40% are treating more than 20 patients each year. The next highest treatment number is zero to five patients for 21% of the respondents. It is very likely that this variation is, in part, based on facility and system size.

Figure 3-3: Average Number of Patients Treated Per Year

# of Treated Patients	% of Correctional Systems	# of Correctional Systems
0-5	21%	10
5-10	17%	8
10-15	13%	6
15-20	6%	3
More than 20	44%	21
Total		48

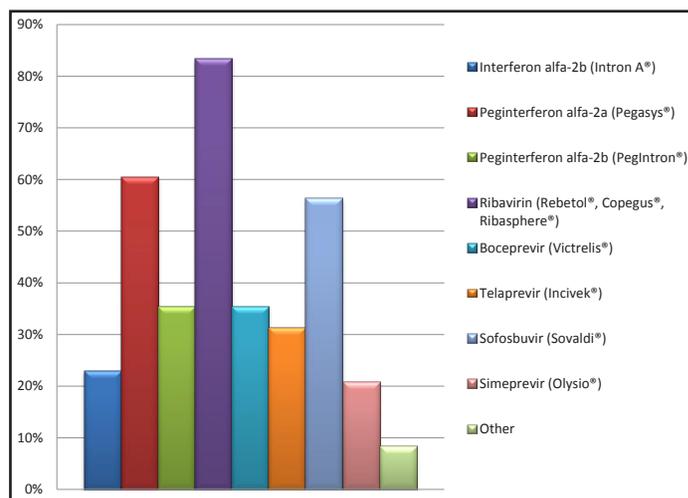
Patient Selection Criteria. In terms of treatment decision-making, most of the respondents (90%) select patients for treatment based on severity of their liver disease. Other treatment factors include genotype (57%) and patient request for treatment (22%). Although not included as a response option in this question, length of stay may also enter into this decision-making process.

Figure 3-4: Hepatitis C Viral Infection Treatment Decision Factors



The range of medications utilized by corrections organizations to treat HCV infection patients is broad. At the time of this survey (summer 2014), the most commonly used medications were pegylated interferon (96% of respondents), ribavirin (83% of respondents) and sofosbuvir (56% of respondents). Boceprevir (35%) and telaprevir (31%) were used by only approximately a third of systems. Telaprevir is no longer available on the market in the U.S., and boceprevir will soon be no longer available in this country.

Figure 3-5: Medications Used in Treating HCV Infection Patients



Results

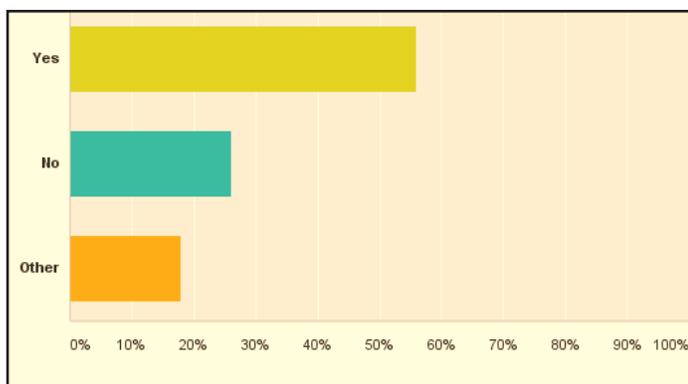
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Medication side effects are a concern in the treatment of HCV infection, especially with the medication regimens that were available at the time that this survey was undertaken. The survey requested information regarding the numbers of patients for whom treatment was discontinued due to medication side effects. The number of cases where treatment was stopped due to medication side effects varied widely by system (probably due largely to the medications used). The survey responses provided estimates that an average of about 30% of HCV infection patients discontinue treatment due to side effects under the existing treatment regimens.

Patient Education and Substance Use Disorder Treatment. Patient education is an important component of medical care, whether in the correctional system or the community. Individual patient counseling and written educational information are provided by more than 90% of jurisdictions. Group counseling is provided by slightly less than half. Peer education, where former inmates are utilized to provide education to current inmates, is used by approximately 40% of correctional systems.

Substance use disorder treatment takes on special importance in this population since injection drug use is an important cause of HCV infection. Over half of the jurisdictions (56%) provide substance use disorder treatment for patients with HCV infection. Slightly more than one-quarter (26%) do not. Eighteen percent selected the “other” option in response to this question.

Figure 3-6: Do Systems Provide Substance Use Disorder Treatment?



Current Treatment Costs. The survey asked respondents to provide data on five separate categories of HCV infection management costs:

1. Costs of testing;
2. Costs of pretreatment evaluation, separate from testing;
3. Costs of treatment medications;
4. Costs of side effect management; and
5. Administrative costs.

Three-quarters of respondents (75%) spent \$100,000 or less for testing. One jurisdiction spent over \$2 million. Approximately 75% of respondents spent \$250,000 or less for pretreatment evaluation (the five respondents who answered “less than \$1,000” were left out of this analysis). Finally, in terms of cost of treatment medications, 24% of the jurisdictions spent over \$2 million. Seventy percent of the jurisdictions spent more than \$250,000. Side effect management was relatively less costly, as 14 systems spent between \$10,000 and \$50,000, with approximately 90% spending less than \$100,000. Administrative costs varied from less than \$1,000 to a maximum of \$250,000. Over half of the correctional jurisdictions paid less than \$50,000 for annual administrative costs. These differences are almost certainly a result of differences in facility functions (jails versus prisons) and size.

Estimated Future Costs. One survey question asked the health authorities to estimate the cost of HCV infection treatment and management in their systems for the next year. Cost estimates were provided in two formats: cost per patient and the total cost per year. Twenty-seven jurisdictions estimated that the total cost per patient would be approximately \$110,000. The range of these estimates was between \$10,000 to \$250,000. In terms of total cost per jurisdiction, the other group (the systems that estimated total rather than per patient costs) estimated a total average cost of \$5 million, with the range between \$500,000 and \$25 million.

Prevalence data generated by this survey continues to support the importance of the role that America's correctional facilities should and do play in the treatment of HCV infection. This HCV survey is the first such survey to characterize the management of HCV infection patients in the nation's correctional facilities since the new and expensive generations of medications were approved by the FDA for use in treating HCV viral infection. The results of this inquiry illustrate a number of important characteristics about the approach of correctional health care to HCV infection treatment.

It is not surprising that almost all of the nation's correctional systems are currently treating HCV infection patients. The level of national interest in this disease, its prevalence in the U.S. and the development of new and very effective medications that, for the first time, can effectively eradicate this viral disease has challenged the medical community at large and correctional providers, specifically regarding the most cost-effective way to manage and treat patients with HCV infection. Although many correctional systems are treating HCV infection patients, there is wide variation in the approach to diagnosing those that may be at risk and in determining which patients to target for treatment. For example, major differences appear in screening practices, patient selection strategies, treatment protocols and modalities and estimates of treatment cost. Further, the review of data from the survey suggests correctional facilities might benefit from a nationally coordinated HCV infection treatment program specifically geared to the correctional population that provides evidence-based clinical guidelines, as well as financial support for treatment.

Prevalence of Hepatitis C Viral Infection in Corrections. Although this survey was designed to generate definitive data on several key characteristics of HCV infection treatment in correctional facilities in the U.S., this data revealed the wide variability in the practice of HCV infection treatment across

the country. Due to great variability in the screening practices across the various correctional jurisdictions, it is difficult to accurately assess prevalence. It follows that without accurate prevalence information, it is very challenging to estimate costs of treating this population group.

Treatment of Hepatitis C Viral Infection in Corrections. Similarly, there is wide variety in treatment practices for HCV infection among the nation's correctional facilities responding to this survey. At the time of this survey, only approximately half of responding systems said they had clinical practice guidelines that determined their care or policy guidance regarding treatment of HCV infection. Several features of the treatment of HCV infection may contribute to this. First, the practice guidelines for HCV infection are rapidly changing as new medications receive FDA approval and reach the treatment market. Second, these new pharmaceuticals are extremely expensive, and many systems may not be financially able to adjust their practice patterns to the reality of these new costs. The challenge for correctional systems will be to effectively triage who to treat to make sure that the sicker individuals are prioritized and treated.

Substance Use and Other Prevention. Treating HCV infection, whether in the community or correctional environments, requires a huge financial investment. Because many initial HCV infections are a result of intravenous drug use, treating substance use disorders is of major significance in this population. Slightly more than half of correctional systems treat the fundamental substance use disorders in the patients they treat for HCV infection. This is a treatment gap that should be addressed with appropriate treatment methodologies, such as opioid substitution therapies that are evidence-based and shown to reduce relapse in this population.

Recommendations

Recommendations flowing from this survey of the nation's correctional facilities involve the following key areas:

1. **Determine the true prevalence of hepatitis C viral infection in U.S. correctional settings.** There is a great need for a comprehensive and statistically based national prevalence study that focuses upon determining the burden of HCV disease in the nation's correctional systems. Knowing the true prevalence of this disease will be the first and essential step toward establishing a systematic national approach to HCV disease care in corrections. This would include both the development of national standards for the treatment of HCV infection, as well as strategies for financing this care. Although there is some debate at this time regarding the specific details of treatment indications, there is no doubt that correctional systems across the country have a major responsibility to treat HCV-infected patients and that patients with chronic HCV disease are overrepresented in our correctional systems. The cost of addressing this disease will fall disproportionately upon these systems, and having accurate knowledge about this burden, both in terms of dollars and numbers of patients, will provide for much more responsible decision-making about management of this disease.
2. **Practice consistency in screening and clinical practice across the nation.** The 53 correctional systems that responded to the CCHA survey represent many of the most medically sophisticated systems in the country. Even among the group of more medically advanced systems, there is a great deal of variation in screening and clinical management of hepatitis C viral infection. Correctional systems would be greatly aided by national recommendations on screening and treatment of this disease. One option for providing this leadership would be to establish a national correctional advisory group on hepatitis C viral infection made up of correctional medical leaders, governmental officials, such as those from the Centers for Disease Control and Prevention, and one or more members from the group that generates hepatitis C viral infection treatment guidelines (hcvguidelines.org). This group is composed of three separate scholarly organizations, including the Infectious Diseases Society of America, the American Association for the Study of Liver Diseases and a collaborating partner, the International Antiviral Society — USA. This membership mix would contribute greatly to developing medically appropriate hepatitis C management guidelines that would be designed with support from correctional environments across the nation.
3. **Practice post-treatment relapse prevention.** A large percentage of HCV infection in correctional environments is thought to be related to intravenous drug use. Once patients are successfully treated, or in conjunction with treatment, it makes medical and financial sense to treat the underlying substance use disorders along with the HCV infection in patients who have a history of substance use disorders. There should be a strong emphasis placed on substance use treatment, including possible use of a variety of opioid substitution therapies if they are indicated. For years, the nation's correctional systems have lagged far behind those in other countries in the utilization of medication-assisted therapies, even though these are evidence-based and have been used in some U.S. systems for years. This not only supports sound financial management, but also represents strong public health policy.
4. **Support financial needs for hepatitis C viral infection research and treatment.** The responsibility for paying for the cost of correctional system health care falls upon either the budgets of various states or municipalities or, in the case of the Federal Bureau of Prisons, the federal budget. Because of the extraordinary expense of the new medications, the cost of expanded treatment for HCV infection will be extremely difficult for most jurisdictions to support. There is a great need for the development of creative financing mechanisms to enable local and state governments and the federal government to effectively bear the cost of these new treatments. For example, there are already special arrangements for certain national prescription drug management companies, as well as large government

agencies, to purchase these medications at reduced prices. All responsible correctional jurisdictions should be allowed to participate in a nationwide purchasing agreement at reduced cost or in other means to reduce the costs of the new medications.

5. **Support research to identify appropriate candidates for treatment and treatment protocols for those patients.** The development and availability of medications to treat HCV infection is moving forward more rapidly than the understanding of the natural history of the disease. Because of this, although there are a growing range of medications, there is still a great deal of uncertainty about which patients are likely to progress toward end-stage liver disease and/or hepatocellular carcinoma, and therefore, which patients should be treated and when. For correctional systems and the community in general, improved understanding of the natural history and individual risk of this disease is critical as we move forward to address this challenge.

Develop targeted community and correctional linkages to improve continuity of care and patient outcomes.

For jails, treating HCV infection patients is exceptionally complex, largely because the patients' time of residence in the jail is often unknown and unpredictable. Yet, this population remains one of the most critical from the perspective of the public health interest in corrections because members of this group frequently cycle between the jail and community environments. As a result, there are many opportunities to expose others to HCV infection while in the community. Because of this, we recommend the development of targeted jail-community care linkages that would support a multifaceted, integrated approach to care for this population of patients. This model would support HCV infection screening in jails and, when appropriate, be followed by immediate and direct referral to community providers such as federally qualified health centers prior to release for those who are found to be positive.

References

- Allen, SA, Spaulding, AC, Osei, AM, Taylor, LE, Cabral, AM, and Rich, JD. Brief Communication. Treatment of Chronic Hepatitis C in a State Correctional Facility. *Ann Intern Med.* 2003. 138: 187-190.
- Asselah, T and Marcellin, P. New direct-acting antivirals' combination for the treatment of chronic hepatitis C. *Liver International* (2011), 68-77.
- Backmund, M, Meyer, K, Edlin, BR. Infrequent Reinfection after Successful Treatment for Hepatitis C Virus Infection in Injection Drug Users. *Clinical Infectious Diseases.* 2004; 39(10): 1540-1543.
- Bate, JP, Colman, AJ, Frost, PJ, Shaw, DR, Harley, HA. High prevalence of late relapse and reinfection in prisoners treated for chronic hepatitis C. *J Gastroenterol Hepatol.* 2010 July;25(7): 1276-80.
- Dolan, K, Moazen, B, Noori, A, Rahimzadeh, S, Farzadfar, F and Hariga, F. People who inject drugs in prison: HIV prevalence, transmission and prevention. *International Journal of Drug Policy.* 26 (2015) 512-515.
- Fox, RK, Currie, SL, Evans, J, Wright, RL, Tobler, L, Phelps, B, Busch, MP, Page-Shafer, KA. Hepatitis C Virus Infection among Prisoners in the California State Correctional System. *Clinical Infectious Diseases.* 2005; 41:177-86.
- Ghany, MG, Nelson, DR, Strader, DB, Thomas, DL, Seeff, LB. AASLD Practice Guideline. An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection: 2011 Practice Guideline by the American Association for the Study of Liver diseases. *Hepatology*, October 2011, 1433 – 1444.
- Hammett, TM. Editorial. Adopting More Systematic Approaches to Hepatitis C Treatment in Correctional Facilities. *Ann Intern Med.* 2003. 138: 235-236.
- Hoofnagle, JH, and Sherker, AH. Editorials. Therapy for Hepatitis C—the Costs of Success. *N Engl J Med* 370; 16, April 17, 2014.
- Jazwinski, AB, and Muir, AJ. Direct-acting antiviral medications for chronic hepatitis C virus infection. *Gastroenterol Hepatol (NY)*, 2011 Mar; 7(3): 154-162.
- Koretz, RL, Lin, KW, Ioannidis, JPA, Lenzer, J. *BMJ* 2015; 350:g7809.
- Liu, S, Watcha, D, Holodniy, M and Goldhaber-Fiebert, JD. Sofosbuvir-Based Treatment Regimens for Chronic, Genotype 1 Hepatitis C Virus Infection in US Incarcerated Populations: A Cost-Effectiveness Analysis. *Ann Intern Med.* 2014; 161(8): 546-553.
- Marco, A, Esteban, JI, Sole, C, da Silva, A, Ortiz, J, Roget, M, Sarriera, C, Teixido, N, Guerrero, RA, Cayla, JA. Hepatitis C virus reinfection among prisoners with sustained virological response after treatment for chronic hepatitis. *Journal of Hepatology* 2013. 59: 45-51.
- Pearlman, BL and Traub, N. Sustained virologic response to antiviral therapy for chronic hepatitis C virus infection: a cure and so much more. *Clin Infect Dis* 2011;52 (1 April): 889-900.
- Spaulding, AC, Kim, AY, Harzka, AJ, Sullivan, JC, Linas, BP, Brewer, A, Dickert, J, McGovern, BH, Strick, LB, Trestman, R, and Ferguson, WJ. Review: Impact of New Therapeutics for Hepatitis C Virus Infection in Incarcerated Populations. *IAS-USA Topics in Antiviral Medicine.* Vol 21, No. 1, February/March 2013, 27-35.
- Tan, JA, Joseph, TA, and Saab, S. Treating Hepatitis C in the Prison Population is Cost-Saving. *Hepatology* 2008; 48:1387-1395.
- Tsui, JI, Evans, JL, Lum, PJ, Hahn, JA, Page, K. *JMA Intern Med.* 2014; 174(12): 1974-1981.
- Varan, AK, Mercer, DW, Stein, MS, and Spaulding, AC. Hepatitis C seroprevalence among prison inmates since 2001: Still high but declining. *Public Health Rep.* 2014 Mar-Apr, 129(2), 187-195.
- Welsch, C, Jesudian, A, Zeuzem, S, Jacobson, I. New direct-acting antiviral agents for the treatment of hepatitis C virus infection and perspectives. *Gut* 2012;61 (Suppl 1):i36 –i46.

Endnotes

¹ Estelle v. Gamble, 429 US 97 (1976).

² Sustained Virological Response or SVR is a term used to measure treatment success for hepatitis C. SVR is defined as the absence of detectable levels of viral RNA in the blood 24 weeks after completion of therapy (Jazwinski, 2011). It is measured by a blood test at the end of 24 weeks following completion of antiviral therapy for chronic hepatitis C infection. Once a patient has achieved SVR the patient may be considered cured. Achieving SVR is associated with resolution of many of the signs and symptoms, and fewer of the long-term complications associated with HCV. (Pearlman, 2011)

³ Direct Acting Antiviral Agents or DAA agents refers to a new class of medications utilized to treat chronic hepatitis C disease that directly target the hepatitis C virus life cycle and directly impact the virus (Jazwinski, 2011) This is in contrast to earlier medications such as interferon and ribavirin whose antiviral impact is indirect, acting through non-specific pathways that potentiate the immune system generally. (Jazwinski, 2011; Welsch, 2012).

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