Treatment of HCV in a Correctional Setting

Epidemiology of HCV in Corrections

The burden of hepatitis C virus (HCV) infection is much higher in corrections compared to the general community. In the late 1990's, the Centers for Disease Control and Prevention (CDC) estimated that 16 to 41% of prison inmates had serologic evidence for HCV infection (HCV antibody positive), with extrapolated estimated rates of chronic hepatitis C infection ranging from 12 to 35%. [1] Subsequent estimates based on 12 state prisons in the United States showed an HCV seroprevalence that ranged from 9.6% to 41.1% in 2001 to 2012 (Figure 1). [2] In a review of pooled published studies during 2003-2010, the HCV seroprevalence among incarcerated persons in the United States was 23.3%. [3] In a comprehensive review, investigators estimated an HCV seroprevalence in prisons of 18% in 2015. [4] Regardless of which seroprevalence data is examined, the HCV seroprevalence rate in prisons is clearly markedly higher than in the overall United States population, which has a seroprevalence of approximately 1%. [5] Seroprevalence data only account for the numbers of individuals incarcerated on any given day and do not account for the movement in and out of correctional facilities. Approximately 30% of individuals with hepatitis C infection in the United States pass through the correctional system in a given year. [6,7]
HCV Screening and Testing in Correctional Settings

HCV Screening Policies

In the United States, different HCV screening policies are used in correctional facilities. The following summarizes the various types of HCV screening policies:

- **Upon Request**: HCV testing upon request is offered only to those individuals who ask for testing to be performed.
- **Risk-Based**: Using the risk-based approach, HCV screening is offered only to those individuals who self-identify as belonging to a group considered at risk for acquiring HCV infection.
- **Opt-In**: With an opt-in approach, all individuals are offered HCV testing, but testing is performed only if the person agrees.
- **Opt-Out**: With the opt-out approach, individuals are offered HCV testing and the testing is routinely performed unless the person declines.
- **Mandatory Testing**: For mandatory testing, the test is performed regardless of whether the individual being tested approves of the test.

Rationale for HCV Testing in Corrections

Multiple reasons exist why HCV testing should be emphasized and offered as an opt-out strategy for jails and prisons in the United States. First, the yield of testing is high since the proportion of persons in jails and prisons who have chronic HCV infection is approximately 5-10-fold higher than in the general United States population.[2,3,5,8] Second, performing routine opt-out testing reduces the stigma associated with risk-based screening.[9] Third, using a strategy of only testing persons in corrections who were born between 1945 to 1965 misses approximately 50% of persons with HCV in jails and prisons.[10,11,12,13] Fourth, testing in correctional facilities can lead to earlier identification and treatment of persons with HCV, which results in behavior change related to HCV transmission and liver-associated benefits. Last, testing and treating the large population of persons with HCV in correctional facilities is essential in an overall population strategy to eliminate HCV infection in the United States.[6,14,15]

Recommendations for HCV Testing in Corrections

The United States Preventive Services Task Force (USPSTF) recommends screening for HCV in all persons at risk for infection and all adults born between 1945 and 1965; in these recommendations, incarceration is categorized as a risk factor for HCV acquisition.[16] The 2018 Federal Bureau of Prisons Guidance on the Evaluation and Management of Chronic HCV Infection recommends using an opt-out strategy of voluntary testing for HCV infection at the prevention baseline visit for all people who are sentenced.[17] The American Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD-IDSA) HCV Guidance recommends implementing HCV opt-out testing in jails and in prisons.[18] In addition, multiple experts have also recommended universal opt-out testing in jails and prisons.[6,9,19]
Management of HCV in Jails versus Prisons

Understanding the Difference Between Jails and Prisons

A person is jailed upon arrest for allegedly committing a crime. Jails are confinement facilities typically operated and funded by local cities or counties under the authority of a police chief, sheriff, or city or county administrator. Most individuals placed in jail are awaiting a trial or have received a conviction and are serving a brief sentence.[7] Thus, jails house innocent people as well as people who have committed misdemeanors and felonies. Once sentenced, the length of the sentence is the predominant factor that determines if a person transfers to prison. Most states hold individuals in jail for sentences up to 1 year.[20] Since prisons generally house persons who have received a sentence of at least one year, most people in prison are convicted felons. Prisons are part of either a state or federal system housing people depending on the type of crime committed. A few states have created a unified system that integrates the state correctional system and local jail network.

Management of Hepatitis C in Jails

Some jails screen incoming newly arrested persons for HCV infection and then ideally attempt to link individuals with diagnosed HCV infection to care upon release. Although jails can be a place to identify a large number of individuals with HCV infection, there has been a reluctance to systematically perform HCV testing if treatment for HCV cannot be offered in the jail system. Since the average length of incarceration in a jail is usually only days to weeks, most jail systems currently do not offer treatment for HCV. As treatment options for HCV expand and include shorter courses with newer combinations of direct-acting antiviral (DAA) medications, it will likely become more feasible to treat some individuals in the jail system, especially if they have advanced liver disease and/or they have an expected jail stay of at least 3 to 4 months. Given the high cost of DAA therapies and the limited budget of most jails, either major funding changes or significant price reductions for HCV DAA-based therapies would need to occur before HCV treatment can be made widely available in the jail setting.

Management of Hepatitis C in Prisons

In contrast with the situation in jails, the average prison sentence is usually a couple of years, and treatment for HCV can easily be completed during incarceration for many individuals. In addition, prison systems are larger in size than most jails and usually have larger budgets to provide health services. Most prisons offer HCV treatment, but historically only a small fraction of patients with chronic HCV infection have received the treatment. In a study performed at the Connecticut Department of Corrections during 2002 to 2006 (in the interferon era), investigators characterized major reasons for deferral of therapy, and inability to complete therapy before a person is released was the most common reason for deferral; other major reasons included lack of indication for treatment, patient refusal, and unstable clinical conditions (Figure 2).[21] With the advent of DAAs, many of the clinical barriers to treatment have been eliminated, but some significant barriers to care remain, including cost of therapy, limited clinician capacity, and lack of perceived expertise among clinicians. These barriers are magnified by the size of the population living with HCV infection in the prison setting.
HCV Treatment Prioritization in Corrections

Impact of Cost of Therapy

Given the high prevalence of HCV in corrections, even with the decreasing cost of DAAs, cumulative cost of HCV treatment can be astronomical for correctional systems. The expense of HCV therapy continues to force many facilities to prioritize treatment for those individuals in whom it is most medically necessary. The prioritization of treatment for the patients with advanced liver disease has been ongoing for years in the correctional systems, but the issue was amplified with the availability of expensive DAA medications as more patients desired and had fewer contraindications for treatment.[7,22,23,24] Despite the high cost of therapy, correctional systems have a constitutional obligation to provide adequate healthcare based on a United States Supreme Court decision [Estelle v Gamble].[25,26] It has been difficult to precisely define what this means in regards to HCV infection. Regardless of the order in which persons in correctional facilities are treated, there are several class action lawsuits currently challenging the blanket restriction of treatment of persons with little to no fibrosis in whom treatment is deemed not medically necessary.

Prioritization Based on Medical Necessity

Different correctional systems vary in how they decide who and when to treat for hepatitis C infection. Similar to the decision-making process for persons living with HCV in the community, medical necessity typically dictates whom to treat first in the correctional setting, with medical necessity usually determined by the degree of liver fibrosis or by the presence of significant HCV-related extrahepatic manifestations. Methods used to estimate the degree of liver fibrosis, whether by aspartate aminotransferase (AST) to platelet ratio index (APRI) score, FibroSure, transient elastography (FibroScan), liver biopsy, or a combination of these tests, are highly variable as are the cutoffs used for determining treatment eligibility. Many state prison systems have used the Federal Bureau of Prison Clinical Guidance on the Evaluation and Management of Chronic Hepatitis C Virus Infection or a similar protocol to guide prioritization for HCV treatment.[17]

Release Date

Correctional systems have historically taken a patient’s release date into account when deciding whether to treat them for HCV while they are incarcerated. The slow progression of disease that occurs with chronic HCV infection has allowed for the deferral of treatment for many patients until they are released to the community. In the states that have expanded Medicaid programs, individuals who are incarcerated will have good access to HCV care and treatment in the community through their medical insurance plan upon release. Although a short delay in initiating HCV treatment (until a patient is released) will likely have no significant clinical consequences, prolonged treatment postponement can eventually lead to worse outcomes, especially if the patient has already developed cirrhosis. With current 8- to 12-week DAA treatment courses, most patients can start and complete an HCV treatment course prior to release from prison and for those who are unable to complete the course, it will become increasingly important to establish linkages to care for treatment completion. Some systems have managed to establish relationships with community providers to allow smooth transitions while on treatment and avoiding any gaps in care. The New York State Hepatitis C Continuity Program is an important model to assist with the transition of patients with HCV upon release to the community: patients who have initiated HCV treatment are transitioned to a community-based provider for completion of treatment and patients who have not yet been started on treatment are given a referral to a community-based provider in order to be evaluated in a timely manner upon release.
Providing HCV Treatment in Corrections

Treatment Models

In the correctional setting, a variety of different types of treatment models have been utilized to provide specialty care for HCV treatment.[17] Some systems evaluate the patient for HCV treatment eligibility based on local protocols or guidelines, with those patients considered appropriate treatment candidates then sent to a community HCV specialist for treatment. Other systems contract with a community HCV specialist to provide consultation at the corrections facility and the HCV specialist participates in the entire evaluation and treatment process. Some systems provide their own HCV evaluation and treatment on-site with the assistance of consultation and mentoring, such as that provided by the Project ECHO (Extension of Community Health Outcomes) model.[27] Project ECHO utilizes regular teleconferencing sessions to link medical care providers on-site at a correctional facility with an HCV specialist panel, with the goal that the specialists will help co-manage HCV evaluation and treatment with the on-site medical provider.[27] In some instances, correctional facilities have a medical provider working within the system who has HCV expertise and this individual can supervise evaluation and treatment plans carried out by primary medical providers within the correctional system. In addition, excellent sustained virologic response (SVR12) rates with DAA therapy have been documented in the corrections setting with the assistance of telemedicine.[28]

Treatment Outcomes

The correctional setting can be the ideal environment to provide hepatitis C treatment. Medication adherence levels within corrections can usually exceed those in the community for several reasons. First, incarcerated persons have limited access to drugs and alcohol that could diminish adherence or treatment follow-up. Second, nurses working together with medical practitioners are able to frequently monitor patients during treatment for side effects and support patients throughout the treatment course. Third, the structure of the daily routine in corrections usually leads to improved adherence. Whether medications are dispensed for patient self-administration or by staff-distributed individual doses, it is easier to monitor adherence to the treatment protocol and quickly address issues that arise in a timely manner.

Treatment Regimens

The Federal Bureau of Prisons Clinical Guidance recommends using the AASLD-IDSA Hepatitis C Treatment Guidance for initial treatment options.[17,29] Since multiple options typically exist, factors such as cost often determine the choice of regimen.
Ongoing Care after HCV Treatment

Preventing Reinfection

Patients who achieve an SVR with HCV therapy can potentially become reinfected with HCV. The following summarizes some of the key issues related to HCV reinfection on persons successfully treated for HCV in a correctional setting.

- **Risk of Reinfection**: Persons achieving an SVR12 with treatment for HCV while incarcerated remain at risk for reinfection, particularly upon release when there is higher risk for relapse of intravenous drug use.[30,31,32] Some correctional systems deny patients treatment based on their drug use history or risk of future relapse, which is contrary to the goal from a public health perspective as these individuals are the most likely to transmit HCV to others. In general, limited data exist regarding hepatitis C reinfection rates and these data are often biased as surveys and studies frequently only follow those individuals who become reincarcerated, which often serves as a marker for ongoing high-risk behaviors and inherent higher risk for reinfection. Although the risk for HCV reinfection clearly exists, the actual risk of reinfection will vary depending on the prevalence of HCV in the community of release, the injecting behavior after release, the availability of needle exchange programs in the community, and sexual practices.

- **Reinfection during Incarceration**: The risk of reinfection also exists during incarceration. A cohort of 119 patients in Spain were followed for an average of 1.4 years after successful treatment while they remained in prisons that had needle exchange and/or methadone programs and found an overall reinfection rate of 5.27 cases per 100 person-years.[33] Among 53 patients with chronic HCV who achieved an SVR while in an Australian prison, 5 were reinfected and 5 had late relapse.[34] Comparable data from the United States do not exist, but presumably some risk for reinfection during incarceration exists after successful treatment, especially considering the high prevalence of HCV in correctional facilities. Between 1998 and 2000 at the Rhode Island Adult Correctional Institute, the incidence of HCV among 446 treatment-naïve persons incarcerated for a year or more was 0.4 per 100 person-years.[35] The prevalence of hepatitis C was 23.1% at the time.[35]

- **Patient Education Related to Reinfection**: The risk for reinfection, even if low, highlights the importance of providing hepatitis education and prevention services during and after incarceration, including adequate chemical dependency treatment and harm reduction strategies. Several correctional facilities have implemented effective peer-led programs. Education and prevention services should ideally be part of any hepatitis C treatment program and should continue long after an SVR has been achieved. Unfortunately, most correctional systems in the United States have chosen not to adopt effective harm reduction strategies that have been utilized in other countries during incarceration and upon release, such as mechanisms for safe tattooing, needle exchange programs, medication-assisted therapy, and access to condoms. These recommendations would equally apply to cirrhotic patients who are incarcerated as to those in the community, highlighting the advantages of treating patients earlier in the course of disease.

Management of Persons with Cirrhosis

Although the risk of developing complications of end-stage liver disease and hepatocellular carcinoma decrease after successful HCV treatment, these risks are not eliminated. Unfortunately, clearance of the hepatitis C virus does not always reverse the amount of preexisting scarring present in the liver. Accordingly, all patients with hepatitis C-related cirrhosis, even those who have successful treatment for HCV, need ongoing medical care. Specifically, those patients who have cirrhosis at the time of HCV treatment should have routine medical follow-up every 6 months for evaluation of symptoms and to monitor laboratory values. In addition, the AASLD guidelines for the Treatment of Hepatocellular Carcinoma recommends that cirrhotic patients successfully treated for
hepatitis C continue regular surveillance (every 6 months) for hepatocellular carcinoma using hepatic ultrasound, with or without alfa-fetoprotein levels.[36] These recommendations would apply equally to cirrhotic patients who are incarcerated as to those in the community, highlighting the advantages of treating patients earlier in the course of disease.
Public Health Opportunity

Given the high prevalence of HCV in correctional settings, a public health opportunity exists in corrections to combat HCV infection and its complications. More than 90% of persons who are incarcerated release back out into the community and these individuals often do not engage in medical care following release from incarceration, due to a number of factors.[23] Effectively screening and treating patients with HCV infection during incarceration has individual benefit, but it also has societal advantages.[6] One modeling study demonstrated that (1) incarceration and the elevated transmission risk following prison release can contribute significantly to ongoing HCV transmission and (2) scaling up DAA treatment in these settings can have a major impact on reducing HCV incidence and prevalence in communities.[37] To achieve a goal of HCV eradication in the United States, prison and jail populations will need to be included as a primary target group for treatment.[6,14,15] Therefore, it will become increasingly important for correctional systems to partner with public health systems when determining standards of medical treatment and prevention of HCV.
Summary Points

- The prevalence of hepatitis C is much higher in corrections than in the general community.
- Jails are an ideal setting for identifying individuals with HCV infection, but not generally well-suited for DAA treatment of persons with HCV.
- Incarceration can be an ideal time to treat HCV infection, given the high level of structure and oversight that enhance high treatment completion and SVR rates.
- The high cost of HCV therapy and limited capacity of the workforce has forced most correctional facilities to prioritize treatment based on disease severity, but many facilities are quickly expanding the population receiving treatment based on changing standards and external pressures.
- Because the risk for reinfection exists, education and prevention services should be part of any hepatitis C treatment program and should continue long after a sustained virologic response has been achieved. The services should include effective harm reduction strategies, such as mechanisms for safe tattooing, needle exchange programs, medication-assisted therapy, and access to condoms.
- All patient with hepatitis C-related cirrhosis, even those who have successful treatment for HCV, need ongoing medical care.
- To achieve a goal of hepatitis C eradication in the United States, jail and prison populations will need to be included as a primary target group for treatment and as such it will become increasingly important for correctional systems to partner with public health systems.
Citations


18. AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. Key populations: HCV testing and treatment in correctional settings. [AASLD/IDSA Hepatitis C Guidance]


29. AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. Initial treatment of HCV infection. [AASLD-IDSA Hepatitis C Guidance]


References

- AASLD-IDSA. Recommendations for testing, management, and treating hepatitis C. Monitoring patients who are starting HCV treatment, are on treatment, or have completed therapy. [AASLD-IDSA HCV Guidance] -


- Coalition of Correctional Health Authorities American Correctional Association. Hepatitis C in Correctional Settings: Challenges and Opportunities [ACA] -


• Tan JA, Joseph TA, Saab S. Treating hepatitis C in the prison population is cost-saving.
Figures

Figure 1 Hepatitis C Prevalence among Prison Inmates, 2001-2012

This table shows HCV-antibody positive rates among inmates from State Correctional Departments in 12 states.


<table>
<thead>
<tr>
<th>State Correctional Department</th>
<th>Year of Estimate</th>
<th>HCV Antibody Positive (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indiana</td>
<td>2003</td>
<td>15.2</td>
</tr>
<tr>
<td>Iowa</td>
<td>2001</td>
<td>23.6</td>
</tr>
<tr>
<td>Maryland</td>
<td>2002</td>
<td>29.7</td>
</tr>
<tr>
<td>Michigan</td>
<td>2004</td>
<td>13.7</td>
</tr>
<tr>
<td>Montana</td>
<td>2012</td>
<td>13.9</td>
</tr>
<tr>
<td>Nebraska</td>
<td>2011</td>
<td>9.6</td>
</tr>
<tr>
<td>New Mexico</td>
<td>2010</td>
<td>41.1</td>
</tr>
<tr>
<td>New York</td>
<td>2005</td>
<td>11.1</td>
</tr>
<tr>
<td>North Dakota</td>
<td>2008</td>
<td>13.0</td>
</tr>
<tr>
<td>Oregon</td>
<td>2005</td>
<td>23.3</td>
</tr>
<tr>
<td>Pennsylvania</td>
<td>2006</td>
<td>18.9</td>
</tr>
<tr>
<td>Washington</td>
<td>2008</td>
<td>20.9</td>
</tr>
</tbody>
</table>
### Figure 2 Reasons for Deferring HCV Treatment in Corrections Setting, 2002-2006

This table shows the major reasons for deferring hepatitis C treatment at the Connecticut Department of Corrections during the years 2002 to 2006.


<table>
<thead>
<tr>
<th>Reason for Deferral</th>
<th>No. (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient's release was too soon</td>
<td>40 (57.1)</td>
</tr>
<tr>
<td>Normal liver function test results</td>
<td>8 (11.4)</td>
</tr>
<tr>
<td>Normal biopsy findings</td>
<td>7 (10.0)</td>
</tr>
<tr>
<td>Patient refused consent/change of facilities</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td>Patient refused consent/other</td>
<td>5 (7.1)</td>
</tr>
<tr>
<td>Hepatic decompensation</td>
<td>2 (2.9)</td>
</tr>
<tr>
<td>Patient deemed to be noncompliant</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Patient had uncontrolled HIV disease</td>
<td>3 (4.3)</td>
</tr>
<tr>
<td>Patient had uncontrolled diabetes</td>
<td>1 (1.4)</td>
</tr>
<tr>
<td>Unclear</td>
<td>1 (1.4)</td>
</tr>
</tbody>
</table>