

Treatment of HCV in a Correctional Setting

This is a PDF version of the following document:

Module 6: <u>Treatment of Key Populations and Unique Situations</u>

Lesson 4: <u>Treatment of HCV in a Correctional Setting</u>

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Epidemiology of HCV in Corrections

In the United States, the prevalence of hepatitis C virus (HCV) infection is much higher in correctional settings as compared to the general community. Between 2011 and 2012, estimates based on 12 state prisons in the United States showed an HCV seroprevalence of 9.6% to 41.1% (Figure 1).[1] More recent estimates based on surveys of all state prison systems in the United States conducted in 2019-2023, paired with publicly available data, suggest that 15.2% of the United States prison population is HCV antibody-positive and 8.7% viremic.[2] Regardless of which data is examined, the HCV prevalence in prisons is markedly higher than in the overall United States population, which has an estimated prevalence of current HCV infection of 0.9%.[3] In addition, when considering the movement of individuals in and out of the correctional system during a 1-year period, it is estimated that approximately 30% of all individuals living with HCV infection in the United States pass through a correctional system in a given year.[4,5]



HCV Screening in Correctional Settings

Rationale for HCV Screening 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.[1,6,7,8] Second, performing routine opt-out testing reduces the stigma associated with risk-based screening.[9] Third, testing in correctional facilities can lead to earlier identification and treatment of persons with HCV, including the opportunity to provide HCV treatment for persons while they are incarcerated. Finally, testing and treating the large population of persons with HCV in correctional facilities is cost-effective, reduces HCV transmission, and is an essential component of an overall population strategy to eliminate HCV infection in the United States.[4,10,11,12]

Recommendations for HCV Screening in Corrections

In the United States, the Federal Bureau of Prisons recommend an opt-out testing strategy for HCV screening, regardless of sentencing status, unless the persons declines.[13] These recommendations are not strictly followed across facilities in the United States, as there are no requirements to do so. In the past, different correctional facilities have used a variety of screening policies including opt-in screening, opt-out screening, mandatory screening, risk-based screening, and screening only upon request. The Centers for Disease Control and Prevention (CDC) recommends all adults aged 18 years and older should have HCV screening at least once in their lifetime, except in settings where the prevalence of HCV infection is less than 0.1%.[14] In addition, the United States Preventive Services Task Force (USPSTF) recommends screening for HCV in all adults 18 to 79 years of age, regardless of risk factors associated with acquisition of HCV.[15] Further, the AASLD-IDSA HCV Guidance recommends performing one-time opt-out testing for all individuals ages 18 year or older, including those with risk exposures such as incarceration.[16,17]



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 pre-adjudication.[5] 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.[18] Since prisons generally house persons who have received a sentence of at least one year, most people in prison have been convicted of a felony. Prisons are part of either a state or federal system housing people depending on the type of law broken. A few states have created a unified system that integrates the state correctional system and local jail network.

Management of HCV 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 numerous individuals with HCV infection, there has been a reluctance to systematically perform HCV testing if treatment for HCV cannot be accomplished in the jail system. Since the median length of incarceration in a jail is usually only days to weeks, most jail systems currently do not offer treatment for HCV. Given that the HCV treatment duration is now only 8 weeks for most people, it is feasible to treat HCV in a significant number of persons in the jail system. Moreover, given the safety profile of the direct-acting antiviral (DAA) medications used to treat HCV infection, it is reasonable for someone to start HCV treatment in jail prior to release and then complete the remainder of their HCV treatment course while in the community. For these reasons, it is becoming more difficult to justify that not knowing the release date or having inadequate time—due to a short sentence term—should preclude starting HCV treatment. Nevertheless, given the high cost of DAA therapies and the limited budget of most jails, major funding changes or further 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 HCV 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 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 HCV infection have received HCV treatment, often due to time constraints (e.g., inability to complete treatment before release) and individual clinical factors. More recently, with the availability of DAAs, many of the clinical and time-based barriers to treatment have been eliminated, but some significant barriers to care remain, including the 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 Eligibility in Corrections

The AASLD-IDSA HCV Guidance recommends treating all individuals with acute and chronic HCV, except for those with limited life expectancy that cannot be remedied by HCV treatment, liver transplantation, or another directed therapy.[16] The Bureau of Prisons issued similar guidance on HCV treatment for individuals in the correctional system, and the 2021 Bureau of Prisons HCV clinical guidance states that all individuals with a detectable HCV RNA are eligible for consideration of HCV treatment.[13] There are, however, some limitations in the Bureau of Prisons guidance that still exist based on sentence length, which are no longer clinically necessary with current treatment regimens, and there is room to expand treatment eligibility in Bureau of Prisons guidance to further align with the AASLD-IDSA HCV Guidance.[13,16] Further, the Bureau of Prisons guidance specifically states that ongoing injection drug use or other behaviors placing incarcerated persons at increased risk for HCV transmission and reinfection, should not automatically exclude them from treatment.[13] In these settings, treatment decisions should be individualized, and ideally treatment for HCV is provided within an integrated care model that also includes treatment for substance use disorder(s),[13] Further, for pregnant women, the Bureau of Prisons guidance states that treatment could be considered "on a case-by-case basis using a shared decision-making model."[13] And, for inmates with insufficient time remaining in their sentence or for long-term, pre-sentence detainees, treatment can be considered for those at high risk for disease progression and complications.[13]

Identifying and Prioritizing Persons at Higher risk for Complications and Disease Progression

Although treatment should ideally be considered for all inmates with HCV, in the correctional setting, medical necessity often dictates whom to treat first, with medical necessity usually determined by the degree of liver fibrosis or by the presence of significant HCV-related extrahepatic manifestations. Many state prison systems have used the Bureau of Prisons 2021 HCV Clinical Guidance or a similar protocol to guide prioritization for HCV treatment.[13] This guidance specifically lists the following conditions to be high risk for disease progression and complications, thus requiring more urgent consideration for treatment:

- Advanced hepatic fibrosis or known cirrhosis
- Liver transplant recipients
- Hepatocellular carcinoma (HCC)
- Comorbid conditions associated with HCV, including cryoglobulinemia, certain lymphomas or hematologic malignancies, or porphyria cutanea tarda
- Immunosuppressant medications
- Evidence for progressive fibrosis, including stage 2 fibrosis on liver biopsy
- Select comorbid conditions associated with faster progression of fibrosis, including HIV, HBV, other comorbid liver diseases, diabetes mellitus
- · Chronic kidney disease
- Persons born between 1945 and 1965
- · Persons already on HCV treatment, including those newly incarcerated

Impact of Cost of Therapy

Given the high prevalence of HCV in corrections, the cumulative cost of HCV treatment can be extremely high for correctional systems, even with the decreasing cost of DAAs. Although HCV treatment should be provided for all HCV RNA-positive individuals, the expense of HCV therapy continues to force some facilities to prioritize treatment for those individuals for whom it is most medically necessary. The prioritization of treatment for individuals 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.[5,19,20,21] Despite the high cost of therapy, correctional systems have a constitutional obligation to provide access to medical care.[22,23] Nevertheless, it has been difficult to precisely define what this means with regard to treatment of HCV infection. Regardless of the prioritized 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.



Providing HCV Treatment in Correctional Settings

Treatment Models

In the correctional setting, a variety of treatment models have been utilized to provide HCV treatment.[13] With the simplicity of current DAA treatment options that are appropriate for most persons with HCV, many correctional systems have on-site primary medical providers who can provide HCV treatment.[16] Additional support and care models, as well as input from an HCV specialist, may be required to effectively treat persons with more complex HCV treatment needs, such as those with prior treatment failure or coinfection with HIV.

- On-Site Correctional HCV Specialist: For example, some 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.
- On-Site Community HCV Specialist: Some systems may 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. In addition, some systems provide their own HCV evaluation and treatment on-site with the assistance of off-site consultation and mentoring, such as that provided by the Project ECHO (Extension of Community Health Outcomes) model.[24]
- **Project ECHO Support**: Project ECHO utilizes regular teleconferencing sessions to link medical care providers on-site at a correctional facility with an off-site HCV specialist panel, with the goal that the specialists will help co-manage HCV evaluation and treatment with the on-site medical provider.[24] Excellent sustained virologic response rates at 12 weeks posttreatment (SVR12) with DAA therapy have been documented in the corrections setting with the assistance of telemedicine.[25]
- **Community Referral**: If on-site treatment is not offered, individuals are sent to a community HCV provider for treatment recommendations.

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 use of 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. Although limited information exists on outcomes of HCV treatment within the United States correctional system, available data suggest SVR12 rates are high in this setting.[26]

Treatment Regimens

Selected treatment regimens should ideally follow the AASLD-IDSA HCV Guidance, recommendations that list glecaprevir-pibrentasvir or sofosbuvir-velpatasvir as preferred options for most treatment-naïve persons, given the pan-genotypic activity and very high cure rates with these drug regimens.[16,17] In the correctional system, however, the preferred treatment choice is often driven by negotiated pricing with drug companies, and as such the Bureau of Prisons Guidance for HCV Infection lists all available DAAs, including elbasvir-grazoprevir, glecaprevir-pibrentasvir, ledipasvir-sofosbuvir, sofosbuvir-velpatasvir, and sofosbuvir-velpatasvir-voxilaprevir as options for HCV treatment, with a preference for the 8-week course of glecaprevir-pibrentasvir.[13] Although cost may affect DAA availability within the correctional system, to the extent possible, the treatment recommendations in the AASLD-IDSA HCV Guidance should be followed. For more information on guideline-recommended treatments for HCV, please see Module 5 on this website for additional information.





Ongoing Care after HCV Treatment

Preventing Reinfection

Patients who achieve an SVR with HCV therapy can potentially become reinfected with HCV. The following summarizes several key issues related to HCV reinfection of persons who have previously been 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 a higher risk for relapse of intravenous drug use.[27,28,29] In general, limited data exist regarding HCV reinfection rates among people who are in prison. These data are often biased as surveys and studies frequently follow only individuals who become reincarcerated, often serving as a marker for ongoing activities associated with risk for HCV 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, particularly given limited access to safe injection equipment. A cohort of 119 adults in Spain were followed for an average of 1.4 years after successful HCV 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.[30] Among 53 persons with chronic HCV who achieved an SVR while in an Australian prison, 5 had HCV reinfection and 5 had late virologic relapse.[31] 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.
- 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 implementation of substance use treatment and harm reduction strategies. Several correctional facilities have implemented effective peer-led programs. Education and prevention services should ideally be part of any HCV treatment program and should continue long after achieving an SVR. Unfortunately, most correctional systems in the United States have chosen not to adopt effective harm reduction strategies that have been utilized in some other countries during incarceration and upon release, such as mechanisms for safe tattooing, needle exchange programs, medications for substance use disorders, and access to condoms.

Management of Persons with Cirrhosis

Although the risk of developing complications of end-stage liver disease and hepatocellular carcinoma decreases after successful HCV treatment, these risks are not eliminated. Unfortunately, clearance of HCV does not always reverse the amount of preexisting scarring present in the liver. Accordingly, all patients with HCV-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 recommend that cirrhotic patients successfully treated for HCV continue regular surveillance (every 6 months) for hepatocellular carcinoma using hepatic ultrasound, with or without alfa-fetoprotein levels.[32] 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 their 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 are released back into the community. Due to a number of factors, these individuals often do not engage in medical care following release from incarceration.[20] Effectively screening and treating patients with HCV infection during incarceration has individual benefit and societal advantages.[4] 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.[33] To achieve the goal of HCV eradication in the United States, prison and jail populations will need to be included as a primary target group for treatment.[4,10,11] Therefore, it will become increasingly important for correctional systems to partner with public health systems to achieve HCV elimination.



Summary Points

- The prevalence of HCV infection is much higher in corrections than in the general community.
- Screening for HCV in jails plays an important role in identifying individuals with HCV infection.
- Incarceration can be an ideal time to treat HCV infection, given the high level of structure and oversight that enhances high treatment completion and SVR rates.
- The high cost of HCV therapy and limited workforce capacity has forced most correctional facilities to prioritize treatment based on disease severity, but many facilities are 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 HCV treatment program and should continue long after a sustained virologic response has been achieved. Services should include effective harm reduction strategies, such as mechanisms for safe tattooing, needle exchange programs, medications for substance use disorder, and access to condoms.
- All persons with HCV-related cirrhosis, even those successfully treated for HCV, need ongoing medical surveillance and care.
- To achieve the goal of HCV eradication in the United States, jail and prison populations will need to be included as a high-priority group for treatment; as such, it will become increasingly important for correctional systems to partner with public health systems.



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Figures

Figure 1 Hepatitis C Prevalence among Persons in Prison, 2001-2012

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

Source: Varan AK, Mercer DW, Stein MS, Spaulding AC. Hepatitis C seroprevalence among prison inmates since 2001: still high but declining. Public Health Rep. 2014;129:187-95.

Hepatitis C Seroprevalence Among Persons in Prison in 12 States, 2001-2012		
State Correctional Department	Year of Estimate	HCV Antibody Positive (%)
Indiana	2003	15.2
Iowa	2001	23.6
Maryland	2002	29.7
Michigan	2004	13.7
Montana	2012	13.9
Nebraska	2011	9.6
New Mexico	2010	41.1
New York	2005	11.1
North Dakota	2008	13.0
Oregon	2005	23.3
Pennsylvania	2006	18.9
Washington	2008	20.9