Treatment of HCV in a Correctional Setting

This is a PDF version of the following document:
Module 6: Treatment of Key Populations and Unique Situations
Lesson 4: Treatment of HCV in a Correctional Setting

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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 1990s, 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] Pooling published studies from 2003-2010, the HCV seroprevalence among incarcerated persons in the United States was 23.3%.[3] In a subsequent 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 markedly higher than in the overall United States population, which has a seroprevalence of approximately 1%. [5] 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.[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. A correctional facility may choose to implement only one of these strategies or a combination of strategies at different time points during incarceration. For example, upon entry to a facility testing could be based on self-identified risk (risk-based), then throughout the time of incarceration, testing is done upon request, and lastly, testing may be opt-out or mandatory prior to release back into the community. 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, 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. 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.[6,10,11]

Recommendations for HCV Testing in Corrections

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%.[12] 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.[13] 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.[14,15] 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 in federal prisons,[16] but multiple experts have also recommended universal opt-out testing for all persons who are incarcerated in jails and prisons, regardless of whether they are pre- or post-sentencing.[6,9,17]

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 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.[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. Now that the HCV treatment duration is only 8 weeks for most people it has become 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, either 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 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).[19] With the availability 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 extremely high 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.[7,20,21,22] 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*].[23,24] It has been difficult to precisely define what this means with regard to 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.

Prioritization Based on Medical Necessity

Different correctional systems vary in how they decide who and when to treat HCV infection. 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. 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 Prisons Clinical Guidance on the Evaluation and Management of Chronic Hepatitis C Virus Infection or a similar protocol to guide prioritization for HCV treatment.[16]

Release Date

Correctional systems have historically taken an individual’s release date into account when deciding whether to treat someone for HCV while incarcerated. The slow progression of disease that occurs with chronic HCV infection has led to the rationale to defer treatment until release to the community. The HCV treatment options for persons after release from a correctional facility depends on a number of factors, including whether the individual subsequently engages in medical care for HCV treatment and if a mechanism exists to fund the HCV treatment. Although a short delay in initiating HCV treatment (until an individual 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 persons in prison can start and complete an HCV treatment course prior to release. In addition, when considering the short duration and safety profile of the DAAs, it is reasonable for someone to start HCV treatment in prison prior to release and then complete the HCV treatment course in the community after their release. In addition, some systems have managed to establish relationships with community providers to allow smooth transitions while on treatment and avoid gaps in care. Thus, it is difficult to justify using release data as a barrier to starting HCV treatment.

Providing HCV Treatment in Correctional Settings

Treatment Models

In the correctional setting, a variety of treatment models have been utilized to provide HCV treatment.[16] 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.[14] 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 consultation and mentoring, such as that provided by the Project ECHO (Extension of Community Health Outcomes) model.[25]
- **Project ECHO Support**: 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.[25] Excellent sustained virologic response at 12 weeks posttreatment (SVR12) rates with DAA therapy have been documented in the corrections setting with the assistance of telemedicine.[26]
- **Community Referral**: If on-site treatment is not offered, individuals are sent to a community HCV provider for treatment.

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. 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.[27]

Treatment Regimens

The Federal Bureau of Prisons Clinical Guidance recommends using the AASLD-IDSA Hepatitis C Treatment Guidance for initial treatment options.[14,16] 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 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 higher risk for relapse of intravenous drug use.[28,29,30] 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 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. 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.[31] 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.[32] 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.[33] The prevalence of HCV infection was 23.1% at the time.[33]
- **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 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 HCV 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 some other countries during incarceration and upon release, such as mechanisms for safe tattooing, needle exchange programs, medication-assisted therapy, and access to condoms.

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 recommend 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.[34] 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 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.[21] 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.[35] 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.[6,10,11] 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 HCV infection is much higher in corrections than in the general community.
- Jails are an ideal setting for identifying individuals with HCV infection.
- 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 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, medication-assisted therapy, and access to condoms.
- All persons with HCV-related cirrhosis, even those who have successful treatment for HCV, need ongoing medical care.
- To achieve the goal of HCV 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.

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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.

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 Prison Inmates 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

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.

Source: Maru DS, Bruce RD, Basu S, Altice FL. Clinical outcomes of hepatitis C treatment in a prison setting: feasibility and effectiveness for challenging treatment populations. Clin Infect Dis. 2008;47:952–61.

Reasons for HCV Treatment Deferral in a Prison Setting, 2002-2006	
Reason for Deferral	**No. (%) of Patients**
Patient's release was too soon	40 (57.1)
Normal liver function test results	8 (11.4)
Normal biopsy findings	7 (10.0)
Patient refused consent/change of facilities	2 (2.9)
Patient refused consent/other	5 (7.1)
Hepatic decompensation	2 (2.9)
Patient deemed to be noncompliant	1 (1.4)
Patient had uncontrolled HIV disease	3 (4.3)
Patient had uncontrolled diabetes	1 (1.4)
Unclear	1 (1.4)