Hepatitis C Behind and Beyond Bars: Targeting the US Prison Population and Changing North Carolina Prisoner Health Policy

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Prisoners in the United States are disproportionately affected by hepatitis C. Addressing the disease behind bars is crucial for curtailing the epidemic in the greater population. Effective strategies for testing and treatment are elucidated here. Recommendations for changes in hepatitis C health care policy in North Carolina prisons are also described.

In the United States, hepatitis C virus (HCV) is the most common bloodborne infection, and as of 2012 is the leading cause of death among 60 national reportable infectious diseases [1]. Addressing the HCV epidemic in the general population demands a particular focus on the incarcerated population, which is disproportionately affected due to the presence of risky behaviors and practices such as injection drug use, needle sharing, tattooing, and unprotected high-risk sex [2]. It has been estimated that the seroprevalence of HCV in the US incarcerated population is 17%-33%, but the true prevalence of disease behind bars is likely underestimated due to the lack of widespread screening within the correctional system [3, 4]. Because most prisoners are eventually released back into the community, they also contribute to the spread of HCV beyond bars (see Figure 1). Therefore, targeting the incarcerated population presents a unique opportunity to curtail the spread of disease. These efforts would require expanding testing and treatment for this population.

Direct-acting antiviral (DAA) agents are oral treatments for HCV infection and demonstrate sustained virologic response (SVR) rates (also known as a cure) of greater than 95%. Treatment with DAAs is finite, with current recommended lengths of therapy ranging from eight to 12 weeks [5]. Because prisons house incarcerated people serving sentences of a year or longer, test-and-treat strategies during incarceration would be feasible.

In most states, HCV testing in correctional settings is still largely risk based, which is not aligned with the Federal Bureau of Prisons (BOP) recommendation to provide opt-out screening for all sentenced prisoners and long-term prisoners [6, 7]. Because of the asymptomatic nature of the disease, many people are unaware of their HCV infection, thus expanded screening approaches are critical to identifying those living with the infection. The unwillingness to report risk factors such as injection drug use makes the risk-based screening strategy ineffective in the prison setting. While expansion of HCV screening to include the 1945-1965 birth cohort in the general population has improved identification of HCV infection, the HCV antibody prevalence of 3.25% in this cohort pales in comparison to the prevalence estimated in the incarcerated population [8]. In order to determine the true prevalence of disease in the prison system, screening must be expanded to all incarcerated persons.

Test and Treat Strategies

Opt-out screening is a promising approach for identifying asymptomatic diagnoses and has been shown to increase HCV screening uptake upon entry for prisoners [9]. Currently, the leading obstacle for the implementation of an expanded screening strategy is cost, since it is illegal...
for corrections officials to ignore any prisoner’s illness once it is known. Therefore, new diagnoses would require state and federal systems to financially support efforts to address these illnesses. However, there are cost-effective strategies to address HCV in the correctional setting.

The treatment as prevention (TapHCV) simulation model, which projects the long-term cost and public health benefits of opt-out screening strategies, has demonstrated that opt-out HCV screening would be cost-effective for the correctional system [10]. TapHCV reports that over the course of 30 years, opt-out HCV screening in prisons could prevent up to 900 liver transplantations, 7,300 cases of decompensated cirrhosis, and 11,700 deaths associated with liver disease when compared to no screening [10]. Eighty percent of these averted deaths and 89%-92% of averted HCV infections would be in the general population, thus the taxpayer would benefit from this strategy [10]. Besides the health benefits to the general population, the TapHCV cost analysis reveals that a 12.4% increase to the current state/federal prisons budget would be required in the first year of implementing opt-out screening and DAA treatment, but after 15 years, because HCV prevalence would have dropped in the correctional and general populations, this model would only necessitate a 0.7% increase to the current budget [10]. Because most prisoners are eventually released, much of their disease management will ultimately become a burden to the community when the complications of advanced disease manifest. For this reason, the implementation of one-time opt-out HCV screening for all currently incarcerated individuals along with opt-out screening for those entering the system for one, five, and 10 years would reduce the costs of HCV disease management for prisoners who are eventually released by $510 million, $680 million, and $760 million respectively [10].

The Hepatitis C Cost-Effectiveness (HEP-CE) simulation model also analyzed the cost-effectiveness of HCV testing and treatment for prisoners in the United States. The findings from this model are evaluated based on forecasted QALYs, or quality adjusted life years, resulting from these interventions. QALYs are often used in health economics evaluations to quantify the efficacy and value of different medical interventions. Incremental cost-effectiveness ratios (ICER), or cost per QALY, are used to represent the average return on QALY expected. In the United States, the willingness-to-pay threshold is typically considered to be $50,000 or $100,000/QALY gained. The HEP-CE model predicts that testing prisoners at intake, treating all those diagnosed, and then linking them to care upon release would lead to an additional 0.1374 discounted QALY and an ICER of $19,000/QALY gained when compared to no testing at intake, no treatment, and no linkage to care [11]. Another cost-effectiveness analysis performed in England demonstrated that doubling HCV testing through opt-out screening and providing DAA treatment to prisoners would lead to a mean incremental gain of 171.25 QALYs and an average ICER of £15,090/QALY (US $19,608/QALY) gained [12].

The projected outcomes of these simulation models show the economic feasibility and cost-effectiveness of an opt-out testing approach within the prison system, as well as the greater public health benefits that expanded access to DAA therapies could pose for the general population. Though offering opt-out screening and DAA treatment could be financially favorable, there are also other novel strategies that could further reduce the costs associated with DAA treatments.

**Novel Strategies to Lower Cost**

A subscription-based model, known as “the Netflix model,” is a novel drug acquisition alternative that would make DAA access more affordable [13]. This has been tested on the country (Australia [14]) and US state level. In January 2019, Louisiana announced that Gilead, manufacturer of HCV drugs such as ledipasvir/sofosbuvir, velpatasvir/sofosbuvir, and sofosbuvir/velpatasvir/voxilaprevir, will supply the state with unrestricted access to DAAs for five years at a flat rate [15]. This strategy will allow more Louisiana citizens with HCV who are on Medicaid or in prisons to gain access to treatment [15, 16]. Following this, the state of Washington also adopted the so-called Netflix model in April 2019 and will receive unrestricted access to DAAs from Abbvie, which manufactures glecaprevir/pibrentasvir [17]. Implementation of these statewide policies shows a state-level commitment to HCV elimination and should incentivize other states, like North Carolina, to adopt similar models and to set similar goals of elimination.

This model was first tested at the national level in 2015 in Australia, where the government chose to pay a flat rate for unrestricted access to DAAs for five years [14]. One cost analysis of their program reports that the government will have saved AU$6.42 billion (US $4.92 billion) by the end of the fifth year when compared to traditional DAA pricing [14]. These findings not only show the economic favorability of such a model, but also demonstrate the logistical viability of its implementation at the national scale. After two years of a country-wide effort to eliminate HCV infection, 82% of the people in Australia with HCV infection have been diagnosed and 26% of those identified were treated with DAA in the first year of universal treatment access [18]. Those treated in the first year included 70% of HCV patients with cirrhosis, 22% of those who inject drugs, and >60% of those with HIV co-infection [18].

Another strategy for reducing the cost of DAAs and opening up the correctional setting to test-and-treat efforts is to extend nominal pricing to state prisons [19]. Currently, prisons purchase medications from wholesalers at premium rates because federal laws prohibit prisons from negotiating for lower prices with drug manufacturers. Safety net providers—federally designated institutions that offer considerable health care services to vulnerable populations, Medicaid users, and the uninsured—pay nominal prices...
for medications. These nominal rates are 10% less than the average manufacturer prices offered to other federal organizations. Because prisoners constitute a vulnerable population, the argument could be made that the penal system meets the safety net characterization. With this federal designation, prisons would be able to negotiate lower drug costs, similar to those available to the US Department of Veterans Affairs, which has the goal of HCV elimination in all veterans who want treatment. If state prisons and local jails could acquire DAAs at nominal prices, the cost to treat the population of HCV-infected prisoners would drop from $3.3 billion to $337.5 million [19].

Beyond the economic feasibility of these large-scale strategies to expand HCV test-and-treat programs in the correctional setting, the greatest impact will be the potential for substantially reduced burden and spread of disease. In 2016, Iceland launched a program providing universal access to DAAs for all those infected with HCV. Within 15 months of initiating the program, 557 people (representing 56-70% of the estimated national HCV-infected population) had been evaluated and 526 of them had started a course of treatment [20]. This treatment-as-prevention model in Iceland demonstrates that such a strategy could quickly and effectively curtail the spread of HCV at a national level.

**Changing HCV Care in North Carolina Prisons**

Many of these strategies could be applied to reduce the burden of disease in the state of North Carolina. On behalf of three North Carolina prisoners with hepatitis C, civil rights groups filed a class action lawsuit against the NC Department of Public Safety (NC DPS) in March 2019, arguing that the state was restricting access to DAA treatment for prisoners with known HCV infection. Court documents from the case allege that the NC DPS has identified 1,543 prisoners with known chronic HCV, only 589 of whom had completed treatment and 72 of whom had been approved for DAA treatment as of April 2018 [21]. The complaint alleged that NC DPS utilized a prioritization schema based on stage of fibrosis that denied access to prisoners with minimal fibrosis as well as using other criteria that are not consistent with the recommendations of the BOP, including not providing treatment for those with a sentence of less than a year remaining, a life expectancy below 10 years, or with a disciplinary infraction for drugs/alcohol in the past year [21, 22]. According to the complaint, the NC DPS HCV Clinical Practice Guideline has multiple deviations from the guidelines of the American Association for the Study of the Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) as well as those of the BOP and appears to reflect an outdated approach to HCV treatment that is no longer considered standard of care [5, 6, 22]. For example, the North Carolina prison system allegedly still uses a risk-based screening approach and does not include the expanded testing of the birth cohort born between 1945 and 1965, which has been recommended by the CDC and US Preventive Services Task Force since 2012 [8, 21]. Thus, the plaintiffs, a group of three prisoners with HCV, argued that testing efforts have been ineffective at identifying the true burden of HCV infection. Far from the -1,500 HCV infections identified to date, NC DPS officials have estimated that the actual number of infected prisoners is likely between 6,559 and 12,553 [21]. In March 2019, US District Judge William Osteen, Jr. issued a ruling that ordered NC DPS to provide DAAs to the plaintiffs, and to stop denying DAAs to any prisoners based on fibrosis level [23]. However, though the request for the NC DPS to expand access to DAAs was granted, the request to implement opt-out screening was denied.

**Conclusion**

The AASLD, the IDSA, the World Health Organization, and the BOP all recommend that prisons should instate universal opt-out testing, and it is time for North Carolina policy makers to prioritize the implementation of this screening strategy, given its cost-effectiveness and its potential to improve the health of North Carolina communities (see Table 1) [6, 5, 24]. There are multiple economically favorable strategies, like the “Netflix model,” that are already being implemented in other states. As more states work to create novel solutions to address their local HCV epidemics, North Carolina will fall further behind in nationwide elimination efforts. We would encourage our state leaders and NC DPS to develop a statewide strategy for HCV elimination, which should include a test-and-treat model in the North Carolina correctional setting. The way has been paved by other states and countries; all we have to do is follow.

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### TABLE 1. Comparison of Recommended Screening and Treatment Strategies

| Screening Criteria | NC DPS | Federal BOP | AASLD-IDSA |
|-------------------|--------|-------------|------------|
| Recommends opt-out HCV screening for all sentenced prisoners | Recommends opt-out HCV screening for all sentenced prisoners | Recommends opt-out HCV screening for all sentenced prisoners |

| Treatment Criteria | NC DPS | Federal BOP | AASLD-IDSA |
|-------------------|--------|-------------|------------|
| HCV treatment will be provided unless: 1. Prisoner will be incarcerated for less than 12 months 2. Prisoner has medical/mental health condition that would prohibit him/her from undergoing DA therapy 3. Treatment is refused by prisoner 4. Prisoner has a life expectancy that is less than 10 years 5. Prisoner has any alcohol/drug violations in the last 12 months 6. Prisoner undergoes Fibrosure testing for liver scarring and receives a score that is less than 0.48 (Stage 2) | Recommends that HCV treatment be provided unless: 1. Prisoner has a life expectancy of less than 18 months 2. Prisoner has contraindications to, or drug interactions with, any part of the treatment regimen 3. Prisoner does not have sufficient time remaining on sentence to complete a course of therapy (6) | Recommends that HCV treatment be provided to all prisoners who are chronically infected and have sufficient time left in sentence to complete course of therapy. Recommends that patients should be provided linkage to community health care resources upon release for surveillance of HCV-associated complications [5] |

Note: The screening and treatment guidelines of the North Carolina Department of Public Safety (NC DPS) are outlined alongside the recommendations of the Federal Bureau of Prisons (BOP) and the American Association for the Study of Liver Diseases-Infectious Diseases Society of America (AASLD-IDSA).

Source: Ocal, et al.