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CO-INFECTIONS AND COMORBIDITY (S NAGGIE, SECTION EDITOR)

Addressing Hepatitis C in the American Incarcerated Population: Strategies for Nationwide Elimination

Selin Ocal[1] · Andrew J. Muir[2]

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Abstract

Purpose of Review The prevalence of Hepatitis C virus (HCV) in the US incarcerated population is disproportionately high, and when inmates with infection are released back into the general population, they play a substantial role in the spread of disease. This review provides support for targeting the jail/prison population to eliminate HCV in the general population. It will also summarize various screening/treatment models to curtail the burden of disease behind and beyond bars.

Recent Findings Transitioning from risk-based testing to opt-out testing in prisons/jails would be cost-effective through greater identification of cases and treatment to prevent complications from cirrhosis. Other innovative strategies, such as the nominal pricing mechanism or the "Netflix" DAA subscription model, have the potential to be cost-effective and to increase access to treatment.

Summary Addressing HCV in the incarcerated population is a strategy to bring the US closer to successfully eradicating the epidemic. Such findings should incentivize policymakers to implement care models that target this population.

Keywords Hepatitis C virus · Incarcerated population · Correctional system · HCV testing and treatment · Opt-out testing · HCV elimination

Introduction

Hepatitis C virus (HCV) is the most common blood-borne infection in the United States (US) and a leading cause of cirrhosis, hepatocellular carcinoma (HCC), and liver transplantation [1, 2]. Propelled by increased rates of injection drug use nationally due to the opioid epidemic, the number of cases of acute infection increased almost 3-fold from 2010 through 2015 [3, 4]. Recent national estimates suggest more than 2 million Americans have HCV infection, but these data are most reliable for noninstitutionalized persons [5]. The prevalence of infection in US correctional facilities has been estimated at 23%, but the true incidence and prevalence of HCV infection are unknown due to the lack of widespread screening practices [6••]. The prison population is disproportionately affected by HCV infection and at risk for acquiring HCV while incarcerated due to unsafe practices such as injection drug use, tattooing, and unprotected sex [7]. Opt-out testing and test and treat strategies for incarcerated persons present an opportunity for HCV elimination.

The considerably high burden of disease behind bars is both an obstacle and an opportunity to control the HCV epidemic in the US. Direct-acting antiviral (DAA) agents offer oral treatment of 8 to 12 weeks duration with sustained virologic response (SVR) rates exceeding 90% [8]. The emergence of these therapies led the World Health Organization (WHO) to call for HCV elimination by 2030 [9]. The correctional system should be viewed as an opportunity to identify and cure a key population of Americans with HCV infection. It has been estimated that approximately 30% of Americans who are known to have HCV-infection spend at least part of the year in a jail or prison [10]. Because 95% of prisoners are eventually released, many infected individuals behind bars will contribute to the spread of HCV in the general population following release [11]. There are multiple strategies that could serve as efficient and cost-effective means of addressing the

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✉ Selin Ocal
selin.ocal@duke.edu

Andrew J. Muir
andrew.muir@duke.edu

[1] Duke University, Durham, NC, USA

[2] Division of Gastroenterology, Department of Medicine, Duke University School of Medicine, Durham, NC, USA

epidemic in incarcerated populations including opt-out testing upon entry to prisons and jails and test and treat programs for inmates while incarcerated. When left unaddressed, inmates with infection contribute to onward transmission upon release, and directing efforts towards addressing prevalence in the correctional system is critical to combatting the epidemic.

This review provides support for specifically targeting the incarcerated population for achieving HCV elimination in the general US population. It will outline various models and strategies that would allow for the burden of HCV in prisons to be reduced through opt-out testing and test and treat strategies while incarcerated.

Epidemiology

Due to high rates of incarceration among people who inject drugs (PWID) and the risk of acquiring HCV infection while injecting drugs, rates of HCV infection among people who are incarcerated are 18–20 times greater than those never incarcerated [12]. People who are incarcerated are more likely to have risk factors for HCV acquisition including history of injection drug use (IDU) and limited access to harm reduction interventions [13]. In addition, for PWID, recent incarceration is a risk factor for HCV acquisition; suggesting an association with acquisition and incarceration [12]. Once incarcerated, many of these high-risk practices remain prevalent, including IDU, high-risk sexual practices, multiple sex partners, and non-sterile tattooing [14–17]. Also, the period following release is a high-risk period for acquisition with increased risk behaviors and social determinants of risk such as homelessness. These factors are likely why the estimated prevalence of HCV is disproportionately higher in correctional settings when compared to the general population [7].

Most of these estimates for prevalence of disease in carceral settings are based on known infections, and due to the lack of widespread screening practices and comprehensive statewide studies, it is likely that the prevalence of disease in prisons is much higher than anticipated. Only 13 US states have data with good reliability on the current prevalence of disease in their state prison system [18]. For these states, HCV antibody prevalence ranges from 9.7% in Georgia to 39.7% in New Mexico [18, 19]. This wide range indicates that there is likely a substantial number of cases that remain undiagnosed behind bars in other states, and that the true magnitude of national prevalence is likely being underestimated given the lack of reliable HCV data in state prisons.

Testing

HCV infection is largely an asymptomatic infection, going unnoticed by patients and often resulting in delayed diagnosis for decades. In addition, those who have been diagnosed often do not understand the potential consequences of chronic liver disease, and do not seek medical attention until liver-related complications manifest [20, 21]. Until updates to recommendations for screening in 2012, the approach to screening implementation for HCV was largely risk-based. The risk-based strategy was ineffective, including for inmates, due to lack of awareness of risk factors, and also the unwillingness to disclose risk behaviors such as injection drug use due to stigma and/or potential legal consequences [19]. A series of prevalence studies revealed that people born between 1945 and 1965 accounted for about three-fourths of the total burden of HCV infection in the US [22]. In 2012, the Centers for Disease Control and Prevention (CDC) recommended one-time testing for individuals born between 1945 and 1965, and the U.S. Preventative Services Task Force followed with the same recommendation in 2013 [23, 24]. These recommendations prompted increased screening of this cohort, and as a result, it is estimated that 118,000 additional cases of HCV were identified by the end of 2014 [25]. The observed decrease in undiagnosed HCV from 70 to 50% in the past 5 years is likely also attributable to these testing recommendations [25, 26]. Directing efforts towards detecting disease in this group with disproportionately high prevalence proved to be effective, but there remains a need to reach the remaining 50%. One strategy that is likely to be high yield is expanding testing to other groups with high prevalence, such as the prison population. Screening is the first step of the care cascade (Fig. 1) [27], and is therefore mandatory before the additional steps in care can be achieved, including linkage to care, access to treatment, and ultimately access to HCV cure. Thus, under-diagnosis serves as an early hurdle for elimination, while prioritizing testing for prisoners is a promising strategy for progress.

In order to minimize the discrepancy between known and unknown infections, screening practices should be expanded to focus on settings where there is high prevalence for HCV, such as in correctional facilities. The U.S. Preventative Services Task Force (USPSTF) has recently drafted a proposal to replace their 2013 HCV screening recommendation, which was to screen high-risk persons for infection and to implement one-time screening in individuals born between 1945 and 1965. The updated statement recommends universal screening for HCV infection for all adults from age 18 to 79 [28••]. The American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD/IDSA) also updated their HCV testing recommendations in November 2019, and advise that all individuals aged 18 years and older should be offered one-time, routine, opt-out HCV testing [29]. Opt-out screening, where the default protocol is testing upon entry unless the individual declines, is purported to be a potent strategy in uncovering diagnoses [30]. These universal screening recommendations should similarly be applied to targeting and screening all adults in the correctional system.

One study done at the Dallas County jail demonstrated that changing testing during intake from opt-in to opt-out

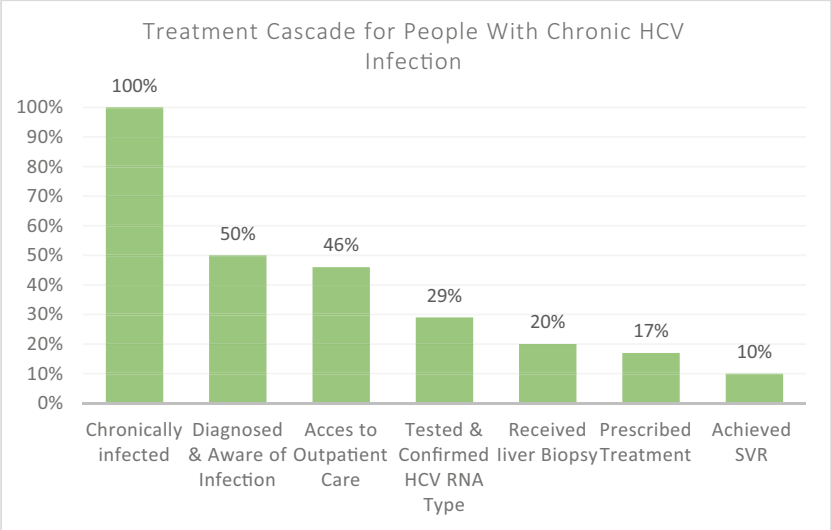

Fig. 1 Percentages based on the estimated 3,500,000 people in the US with chronic HCV infection. Source: Adapted from Yehia et al. (2014)

prompted an increase in uptake in HCV screening from 13 to 81% in less than 1 year; of those tested, 17% were HCV antibody-positive [31]. Implementing opt-out screening could significantly increase new diagnoses and provide more reliable data on the true prevalence of infection among those imprisoned, a population otherwise poorly represented in national level surveys.

The costs associated with expanding testing and identifying new diagnoses serve as a prominent barrier for changing screening practices since US correctional officials are legally prohibited from ignoring a prisoner's health care once an illness becomes known. New diagnoses would need to be addressed and financially supported by state and federal institutions. While it has been demonstrated that opt-out HCV screening would be cost-effective for the penal system, these data have not translated to implementation of broad screening programs of incarcerated persons [8]. The TapHCV (Treatment as prevention) simulation model, which forecasted the long-term costs and advantages of various HCV screening and testing approaches in US prisons, evaluated the impact of this strategy on the general population. By identifying and treating HCV among prisoners, onward transmission of HCV was prevented in the general population after release. This study revealed that over the next 30 years, prison screening would have the potential to prevent up to 900 liver transplantations, 7300 cases of decompensated cirrhosis, and 11,700 liver-related deaths (80% of which would have occurred in the general population) when compared to no screening [8]. Among the number of infections that would be averted by such prison screening programs, 89–92% of these cases would otherwise occur in the general US population (Fig. 2b).

The cost analysis of this model indicates that the implementation of opt-out screening followed by DAA treatment would require a 12.4% increase to the current health care budget of federal and state prisons during the first year. But after 15 years, correctional facilities would only require an 0.7% increase of the current budget due to the fact that HCV prevalence would have been reduced in both the incarcerated setting and the greater US population [8]. This model also demonstrates that if one-time opt-out screening for HCV was implemented for all currently incarcerated inmates followed by opt-out screening for all incoming individuals for 1, 5, and 10 years, the costs for HCV disease management for released inmates would be reduced by $510 million, $680 million, and $760 million respectively (Fig. 2b) [8].

The Hepatitis C Cost-Effectiveness (HEP-CE) simulation model was also used to understand the clinical outcomes and cost-effectiveness of HCV testing and treatment in US prisons. Compared to no testing at intake, no treatment, and no linkage to care following release, the strategy of routinely testing all prisoners at intake, treating all prisoners with HCV, and linking them to care upon release demonstrated an increased proportion of lifetime SVR (60% vs 37%) and a 54% decrease in the lifetime cumulative prevalence of cirrhosis [32]. This transition to the practice of testing all, treating all, and linking to care would also provide an additional 0.1374 discounted QALY, leading to an ICER of $19,000/QALY gained.

In England, a 2014 study showed that the implementation of opt-out testing in select prisons doubled the number of HCV tests performed when compared to voluntary risk-based testing [33•]. Based on these findings, a cost-effectiveness analysis was performed for increased HCV testing and DAA treatments. Results indicate that the doubling of HCV testing in prisons (due to opt-out method) combined with non-DAA treatments would induce a mean incremental gain of 421.27 QALYs, with a mean ICER of £19,851 per QALY gained. Meanwhile, doubling HCV testing in prisons combined with 8- to 12-week DAA treatments would induce a mean incremental gain of 171.25 QALYs, with a mean ICER of £15,090 per QALY gained [34].

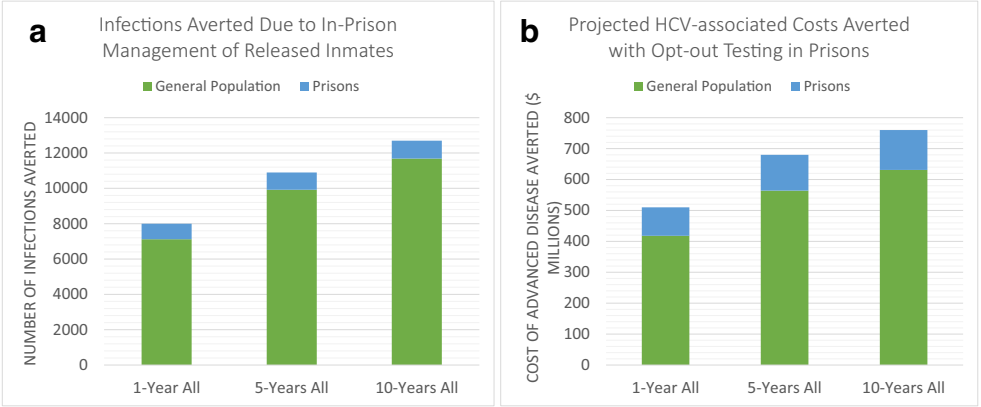

Fig. 2 **a** 1-Year All represents the number of infections averted if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 1 year. 5-Years All reflects the number of infections averted if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 5 years. 10-Years All reflects the number of infections averted if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 10 years. Projected costs and number of averted infections determined by TapHCV simulation model(Source: Adapted from He et al. (2016)). **b** 1-Year All represents the cost of advanced disease averted if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 1 year. 5-Years All reflects the cost if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 5 years. 10-Years All reflects the cost if 1-time opt-out testing was done on all currently incarcerated individuals and those newly entering for 10 years. Projected costs and number of averted infections determined by TapHCV simulation model (Source: Adapted from He et al. (2016))

These findings highlight the economic viability and health benefits of opt-out testing strategies, which would reduce the wide gap between the number of individuals infected and those aware of their condition in the care cascade.

Treatment

Care While Incarcerated

In the HCV treatment cascade, there remain multiple barriers after diagnosis including access and linkage to care and access to treatment. Outside of the correctional setting, various barriers can inhibit progression through the care cascade, including lack of insurance coverage, lack of transportation to prescribers/pharmacies, appointment-work conflicts, long wait times, and stigma within the health system [35]. However, many of these obstacles would not apply in closed, controlled settings like correctional facilities. For Americans in prison, the median time served is 1.3 years, which is sufficient time to initiate and complete a course of DAA therapy [36]. This was not true in the interferon era, when treatments were 12 months in duration. Providing treatment in-house would help to ensure that patients have access to treatment and cure, removing common barriers that impact adherence or treatment interruption. Onsite treatment is achievable both fiscally and logistically.

Similar to testing, the financial burden of obtaining DAA treatment for patients in prisons is a chief deterrent for implementation of this practice, but these fiscal implications also have feasible and economically-favorable solutions. The projected costs of the TapHCV simulation model, which emphasizes the cost-effectiveness of opt-out testing, incorporates DAA treatment expenses in their estimates [8]. Another novel and favorable strategy by which fiscal strain could be reduced would be to extend nominal pricing to state prisons and local jails [37]. Federal laws currently bar prisons from negotiating with manufacturers for lower prices, and so medications are usually purchased through wholesalers who charge these facilities at premium rates. However, federally determined "safety net providers" pay the "nominal" prices for drugs, which are defined as being less than 10% of the average manufacturer prices offered to other federal entities, such as the Department of Veterans Affairs and Coast Guard [37]. These "safety net providers" are designated as those that deliver a substantial degree of health care services to those who are uninsured, on Medicaid, or other vulnerable populations [38]. Based on these standards, the vulnerable prison population would fit these criteria, thus making the safety net designation a realistic mechanism through which correctional facilities could gain access to lower costs. Taking advantage of a policy like this would increase access to treatment 17-fold when compared to drugs bought at the average wholesale or "sticker" price [37]. Estimates indicate that if manufacturers sold DAAs to correctional facilities at a nominal price, the total cost to treat the large proportion of infected inmates can be reduced from $3.3 billion to $337.5 million [37]. Providing treatment in-house is particularly crucial for hindering onward transmission and for preventing the increased financial burden due to disease progression and ultimately shifting the burden to Medicaid or Medicare following release.

Another promising alternative to gaining more affordable access to DAAs at the state level is a subscription-based model, referred to as the "Netflix Model" [39]. Louisiana officials declared in January 2019 that they would be the first to launch this program, in which the state will pay a recurring

subscription fee to a pharmaceutical company in exchange for unlimited access to DAA therapy. The proposal surfaced after the state announced its priority to treat the substantial number of people with HCV in prison and on Medicaid [39]. The state of Washington also adopted this model in April 2019 [40]. This could incentivize other states to follow suit in implementing this model, and therefore reduce the strain of cost and maximize treatment access for all patients. Outside of the US, the "Netflix model" had also been adopted nationally by authorities in Australia in 2015, where the government agreed to pay a lump sum over 5 years for an unlimited number of DAA therapeutic courses. One recent cost analysis of this elimination effort reported that by the end of the fifth year, the government will have saved AU$6.42 billion (US $4.92 billion) when compared to the projected cost of treating the same number of people with traditional pricing [41].

Strategies for treatment as prevention have been heeded as having the potential to markedly reduce the burden and spread of disease [42, 43]. This approach was adopted in Iceland in 2016, when a nationwide program providing universal access to DAAs was launched in order to treat all domestic patients infected with HCV [44]. Goals include decreasing the incidence of HCV in Iceland by 80% before the WHO elimination target for 2030 [9]. As a part of this project, all prison inmates are offered HCV testing and treatment. Within 15 months, 557 individuals were evaluated (accounting for 56–70% of the estimated viremic population) and 526 initiated treatment. This effort, involving collaboration between the government, health services, community organizations, and the correctional system of Iceland, has further illustrated the efficacy of scaling up testing and treatment to curtail the HCV epidemic [44]. Similarly, treatment as prevention could be an effective strategy for addressing the disease in the US incarcerated population, and consequently reducing the rate of dissemination into the general population.

Access to Health Professionals and Task-Shifting

In addition to cost, another barrier to HCV test and treat strategies in prisons is the limited access to specialists, since correctional facilities are often located in rural areas far from large cities where most tertiary care providers reside [45]. However, approaches such as the use of telemedicine or task-shifting could help to alleviate this burden. The Extension for Community Healthcare Outcomes (ECHO) model, where providers in prisons have the ability to collaborate and consult with specialist via video and teleconferencing, successfully demonstrated that the use of this kind of technology can be used to overcome the relative absence of specialists in the prison setting [46]. In two adolescent prisons, one study showed a substantial drop in overall wait time for referrals, and a decrease in the time between referral and treatment initiation after implementing a telemedicine program. In addition, outpatient visits went up by 40% and the number of ER visits was significantly reduced by the second year of the program [46]. Bridging prisoners to specialist care through these practices has the potential to both facilitate and accelerate access to care. Furthermore, it would curtail the costs and lengths of time associated with mobilizing security/correctional staff to safely transport detainees to tertiary care centers.

Shifting the responsibility away from specialists also poses a promising alternative to overcoming the reliance on access to specialists. A study performed in three Australian correctional facilities examined and elucidated the efficacy of nurse-led treatment models for prisoners with chronic HCV; through this paradigm, protocol-directed assessment, triage, and therapy management was conducted by specially-trained nurses, and this care model resulted in an increase in HCV treatment uptake and reduction in burden of liver disease [47].

HCV care can also be shifted to clinical pharmacy specialists (CPS). In 2016, the Department of Veterans Affairs (VA) hired 47 CPS providers and 5 clinical pharmacy technicians in order to expand HCV treatment services for veterans; data from this program show that the VA had treated almost two-thirds of its viremic population by June 2017 [48]. The CPS providers had prescribed almost 30% of all the HCV-related prescriptions at the VA in 2017. Compared to CPS provider services, it was estimated that the same services offered by nonpharmacist specialists would have costed an additional $930,000 annually, a 48% increase in costs. Similarly, recruiting CPS providers to oversee HCV treatment for the prison population could expedite and expand treatment access for inmates, and save money for the correctional health system. Thus, the various logistical barriers to HCV treatment in correctional facilities can be addressed and overcome using strategies already implemented by other US institutions, states, and countries.

Ensuring Continuity and Linking to Care

Treating incarcerated patients in-house provides a means to combat disease transmission and ensure high treatment uptake, which is expected to translate to high SVR. These closed settings can eliminate the barriers faced by these patients when they transition to the general population. In one recent study, HCV cure rates among people in prison are higher (74%) when treated in-house than when transferred (59%) or released during their course of therapy (45%) [49]. These numbers emphasize the risk of interrupting treatment for those who may be released or transferred to another facility before therapy completion. In order to optimize the number of persons continuing along the treatment cascade, early access to DAA therapy during incarceration removes major hurdles that impede a person's ability to obtain DAAs following release.

Various interventions can be implemented to support linkage to care for prisoners who are released. In the case of HIV

infection, released patients were found to be more likely to complete a post-release follow-up if the appointment with an HIV provider was made for them prior to release [50]. In addition, carrying out discharge planning while incarcerated, attending an HIV education session following release, and being offered transportation assistance were also associated with increased likelihood of follow-up [50]. Similar interventions could and should be applied to HCV care.

The aforementioned HEP-CE simulation model and cost-effectiveness analysis also establishes the added benefit of linking infected prisoners to care following release; if all prisoners are routinely tested at intake and if all of those diagnosed with HCV are treated, then providing linkage to care results in an additional 0.0673 QALY and an ICER of $24,000/QALY when compared to no linkage to care [32].

Whereas prison inmates typically serve sentences lasting more than 1 year, the average length of stay in jail is 25 days [51]. Because this is not sufficient time to undergo treatment, different strategies are needed for this group. Some have argued that screening patients who will not be offered treatment is futile. However, prior studies have shown that for people who inject drugs with HCV and HIV coinfection, those who are tested for HCV and find out that they are positive tend to reduce risk behaviors by over 50% [52]. For this reason, although treatment services in prisons/jails are crucial for elimination in the general population, even if individuals are not offered DAAs, being screened and made aware of their condition at the very minimum could still prompt individuals to seek treatment later in life or reduce risk behaviors to prevent further transmission.

Conclusion

The high prevalence of HCV infection in the incarcerated population serves as both a challenge and an opportunity. Screening and treating infected inmates would help to reduce the burden and dissemination of HCV in the general population. Transitioning from risk-based screening to opt-out screening would be cost-effective and would uncover many unknown diagnoses. Treating inmates in-house and linking patients to care upon release would promote completion of DAA therapy and reduce the prevalence of infection and associated liver disease. Various models support that these strategies, if implemented, would be cost-effective. These findings call for the cooperation and action of policymakers, health professionals, and correctional authorities in order to reduce the adverse effects of HCV on inmates and society.

Compliance with Ethical Standards

Conflict of Interest Selin Ocal and Andrew J. Muir declare that they have no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance

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