Hepatitis C Elimination at the Intersection of People Who Use Drugs and the Criminal Justice System

Moving from Hepatitis Discovery to Elimination: NIH Research Advancing Hepatitis Elimination

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Hepatitis C (HCV) infection causes cirrhosis and hepatocellular carcinoma and, until COVID-19, more mortality than the combined total of 60 nationally notifiable infectious conditions. Persons within the criminal legal system are at increased risk for HCV, owing to the intersection of high-risk behaviors, drug-related offenses, and incarceration. While the general US population has an HCV prevalence of approximately 1-2%, in prisons and jails that prevalence stands at 10-40%. The majority of persons with untreated HCV in the United States are associated with the correctional medical system.

Individuals within correctional settings are at elevated risk for the disease not only while incarcerated, but also before they enter the facility and after their release. Limited HCV testing/treatment options are available within jails and prisons, with specific policies and offerings varying state by state. With recidivism high nationwide (approximately 75% of the 10.6 million people admitted to a correctional facility per year are rearrested within five years), the criminal legal system also produces significant churn (rapid turnover), which can make testing and treatment of HCV even more challenging.

In addition, HCV infection disproportionately affects minoritized and marginalized populations, including people of color and persons living in poverty. These populations are already incarcerated at higher rates than other groups owing to systemic racism and other intersectional factors. Eliminating viral hepatitis as a public health threat by 2030 cannot be accomplished without sustained attention and resources directed toward these complex at-risk communities.

Last year, the National Institute on Drug Abuse (NIDA) hosted a webinar presenting research related to HCV testing and treatment among persons who use drugs and/or are incarcerated. This year, NIDA hosted a second webinar outlining collaborative research aimed at expanding access to HCV prevention, testing, and treatment among persons who use drugs within the criminal legal system. Two NIDA grantees delivered presentations: Dr. Matthew Akiyama of Montefiore Medical Center and Albert Einstein College of Medicine spoke about his team's work with the jail populations of New York City, and Dr. Risha Irvin of Johns Hopkins School of Medicine introduced details of the newly launched HCV elimination program in Louisiana's correctional system.

Opening remarks came from Wilson Compton, deputy director of NIDA, and Raul Mandler, senior physician within the Clinical Medical Branch at NIDA’s Division of Therapeutics and Medical Consequences. NIDA is partnering with multiple organizations to support research in the HCV arena, including the National Cancer Institute, the Centers for Disease Control and Prevention, and the Substance Abuse and Mental Health Services Administration. Translational research of the kind presented in this webinar underscores how important such work is for the HCV field: the latest findings need to reach the populations that stand to benefit the most from new discoveries.
Key takeaways:

- Treatment in jails and prisons is feasible and should be prioritized because it allows access to hard-to-reach populations. It also provides important data: jails/prisons serve as sentinels for broader changes in public health in the general population.

- Too often, states don’t test for HCV because they lack the resources to treat. To improve testing, treatment costs and availability must be addressed. Rapid point-of-care (PoC) viral load testing for HCV could be a game changer if/when it becomes available: it will compress the distance between testing, viral load confirmation, and linkage to care.

- The most effective HCV care for this population is the care that takes place while a person is incarcerated. Treat, equip, and prepare the patient while they are in jail or prison, because linkage to care becomes more challenging once a person is released.

- Research that is layered on top of public health implementation work is especially valuable because it advances new knowledge at the same time as providing care and treatment for persons in need. Translating research findings into efficient and effective treatment models is the ideal way forward.

- “Treatment as prevention” in the correctional system has an impact on new transmissions both in jails/prisons and within the community, as shown by the Stop C Study (Australia). The corrections care cascade has an impact well beyond the four walls of a facility.

- Innovative pricing strategies are key to helping states tackle HCV. Costs have improved but still have a long way to go: In terms of access to direct-acting antiviral (DAA) therapy, the costs of these medications previously exceeded the entire correctional healthcare budget. Today, dramatic reductions in cost have eased the burden, thanks to 340B pricing, market competition, generic drugs, and the ‘Netflix’ subscription model. Economies of scale ought to help, but pricing and affordability still remain a challenge.

- Treating HCV in jails and prisons is a global challenge, not just a national one. There are 2.1 million people in US jails and prisons, but 10.7 million people incarcerated worldwide.

- Leadership and governance are key to successfully combating HCV in correctional settings. Having engaged leadership with the political will to address HCV is crucial for these often under-funded facilities—at the state level, at the country level, and globally.
Presentation Highlights

Hepatitis C in the criminal legal system: Using a health systems framework to understand challenges to and opportunities for elimination
Dr. Matthew Akiyama, Montefiore Medical Center and Albert Einstein College of Medicine

Overview:
- Correctional settings are among the lowest resourced in their respective communities, no matter the state or location. They often function outside the healthcare system.
- Understanding and taking seriously the corrections-community cascade using a health systems framework is essential for lowering the rates of HCV in this population.
- As of 2016-2017, the state of New York had an HCV prevalence in its prison population of 11.5%.

Source: Slide 8, Presentation by Matthew Akiyama
Highlights of a case study of HCV elimination efforts within the New York City jail system:

- NYC jails have 35,000 annual admissions. In an overall cohort of 121,371 over three years, 33% were screened for HCV (40,219), and 12% of those screened had detectable HCV RNA. 961 had greater than 10 jail admissions in the three-year study period.
- The team started with phlebotomy but shifted over the study period to rapid point of care antigen testing, reflexed to viral load confirmatory testing.
- This was the same three-year period that transitioned from HCV screening based on risk factors alone to screening universally. Key finding: screening based on risk alone misses cases. In particular, screening based only on birth cohort (1945-1965) missed rising numbers of HCV in the younger prison population (triggered by the shift from opioid to injection drug use during this period).
- Treatment in jail is feasible: 39% of those who tested positive were seen by an HCV clinician (even with many not in jail long enough to be seen). 248 people started on treatment, and 164 remained long enough to have their SVR labs done, with 147 showing undetectable HCV RNA.
- Women were more likely to see a clinician than men, as were those who were frequently incarcerated, had a long stay, or were HIV co-infected.
- The jail system allows clinicians access to hard-to-reach populations. At the same time that medications for community treatments dropped, treatments in NYC jails increased.
**Linkage to care study:**

- Akiyama’s team conducted a single-arm trial in the NYC jail system to assess the impact of a transitional care coordination intervention. Outreach included needs assessment, HCV education, transitional care coordination, and appointment scheduling while in jail, and reminder calls and appointment accompaniment by a community patient navigator in the community.

- Results: Of 100 participants enrolled, 84% were released and 33% were reincarcerated. 31% were linked to care. The reincarceration rate was thus higher than the linkage to care rate – this was not the desired outcome. But the team used those instances of reincarceration to link patients to care whenever possible.

- The release-from-jail period is critical and challenging with many competing priorities. Factors associated with linkage to care included being on methadone treatment and feeling supported socially.

- Reinfection rates for this population overall are high. Even with ready access to opioid therapy and syringe programs, the team has seen high rates of viremic recurrence. These reinfection rates support the call for additional interventions.

**Correctional-community continuum of care**

- 185 Approached for Eligibility, 100 enrolled

Source: Slide 34, Presentation by Matthew Akiyama
The problem:

- If we maintain the status quo, by 2030 only 17% of incarcerated persons with HCV will be cured—a percentage not even close to meeting 2030 elimination goals.

- Barriers to treatment include systemic issues within the criminal legal system and financial considerations: many states do not test in corrections for HCV because they lack the budgets to treat the disease.

Source: Slide 7, Presentation by Risha Irvin
**Louisiana’s response:** HepC Free Louisiana: The Louisiana Hepatitis C Elimination plan, launched in December 2019. Includes seven plan elements:

- A modified HCV medication subscription model for Medicaid and corrections
- Effort to educate the public on the availability of a cure for HCV and to mobilize priority populations for screenings
- Expanded HCV screening and expedited linkage to HCV cure
- Strengthened HCV surveillance to link persons previously diagnosed to treatment
- Expanded provider capacity to treat HCV
- Implementation of harm reduction and complementary treatment strategies
- Extension of elimination efforts to all populations within the state over time.

**Modified Prescription Model details:**

- Allows for capping of costs
- “Treatment as subscription” began with an open call for applications. An agreement was made with a vendor. The state pays the manufacturer for unlimited access to SOF/VEL for a set annual cost over a set contractual period for Medicaid and Corrections populations.
  - Medicaid: uses the negotiated price of federal drug rebates up to the cap. Once that cap is met, costs are effectively $0 regardless of volume.
  - Corrections: uses the 340B Drug Pricing Program.
- Plan works because it aligns incentives (state, manufacturer, local communities).

**Implementation highlights:**

- Launched in 8 state facilities with a plan to expand to a portion of jails. Department of Public Health and Department of Corrections co-launched the effort. They also added hepatitis A, B, and C serologies.
- The plan includes a cohort treatment model: persons across the 8 facilities can start treatment at the same time. This alignment makes it easier for coordinators to track people along the care cascade (though the COVID19 pandemic has affected the program).
- Public health research has been layered on top of the implementation project:
  - Aim 1 (just completed): To characterize the dynamics of HCV infection in the correctional system among HIV/HCV coinfected and HCV mono-infected incarcerated persons.
- Aim 2 (will launch this summer): To assess treatment impact as the trajectory of decline in HCV viremia among HCV antibody-positive incarcerated persons, and to explore whether this trajectory differs between those with and without HIV.
- Aim 3 (will use data from aim 1 and aim 2): To disentangle the impact of the correctional HCV treatment program on HCV viremic decline, and to assess the impact of scaling-up correctional treatment programs on HCV incidence and mortality in Louisiana and elsewhere.

**HCV Treatment in Louisiana (Medicaid and Corrections)**

*For persons on Medicaid, treatment is calculated using DAA claims data. Due to delays in reporting of claims data, numbers from recent months, are preliminary and are an undercount.*

Source: Slide 21, Presentation by Risha Irvin

**Key research findings to date:**

- Out of approximately 13,000 people in the 8 state facilities, 10,000 have been tested for HCV. (The last two sites are actively testing in the north of the state after pandemic-related delays.)
- Significant variation among sites: HCV prevalence ranges from a high of 22% (with 14.4% HCV RNA confirmed) to lower rates.
- There is a 7% refusal rate for testing to date.
• From Jan 2020 to August 2021: Of 1,108 confirmed HCV RNA cases, 100% were prescribed treatment; 91% completed treatment; and 87% were cured (though some were lost to follow up or are lacking data because of release timing). If the results are limited to those who have data available, the cure rate rises to 91%.

Lessons learned from Louisiana’s effort:
• There is high HCV testing and treatment uptake in corrections: the desire for HCV treatment exists among this population.
• Cohort treatment has been manageable for the corrections system and offers a model for others to consider.
• HCV screening on facility entry/exit is crucial.
• More resources should be applied to correctional facility exit planning—to follow up on HCV linkage to care in the community and to track cure rates.
• This is a public health implementation strategy, not just a research project. The team has layered research on top of the implementation to gain information on best practices.
• The team is showing what a relatively poorly financed state can do with resources when interested parties mobilize and align incentives toward a goal.
Highlights from round-table discussion

Dr. Frederick Altice, Yale School of Medicine and Public Health
Dr. David Thomas, Johns Hopkins School of Medicine and Bloomberg School of Public Health

- Adherence to treatment after release from incarceration is an ongoing challenge. This transitional phase for individuals returning to their communities is critically important and difficult to manage owing to multiple factors (family duties, other medical needs, job searches, potential reengagement in substance-abusing behavior). Data also indicates that people accelerate their risk taking four times the usual rate after release from prison.

- More active linkages to harm reduction offerings are needed during this transitional period. This population needs a combination of treatment as prevention plus drug treatment, along with harm reduction for those who are unable to change their behavior.

- Would individuals fare just as well if prescribed HCV medication alone with no follow-up or coordinating care as they reenter the community? More data are needed, but lessons with HIV patients regarding ART adherence suggest that sustained engagement is needed. A pilot study in Rhode Island is testing what happens when individuals are discharged from correctional facilities with a full course of medications in hand and then followed up with (or attempted to follow up with) in the community.

- Is HCV treatment in the criminal justice system going to continue to be a state-by-state process, or is there a strategy underway for a comprehensive solution? This is a political question as well as a public health one, and the requirements to provide equivalence of care increase the stakes for decision makers and state leaders. Many states don’t test for the disease because if there’s a diagnosis and they don’t treat (owing to lack of funds), the state can potentially be legally vulnerable.

- Long-acting buprenorphine could support this high-risk population in important ways, but there needs to be education and awareness in order for these treatments to be utilized by communities in conjunction with other interventions.

- In the United States and globally, HCV will not be eliminated as a public health threat by 2030 without sustained engagement in the corrections medical arena.