Hepatitis C elimination among people incarcerated in prisons: challenges and recommendations for action within a health systems framework

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Summary: (150 words)

Hepatitis C virus (HCV) is a global public health problem in correctional settings. The International Network on Hepatitis in Substance Users prisons-focused workgroup (INSHU Prisons) is committed to advancing scientific knowledge exchange and advocacy for HCV prevention and care in correctional settings. In this position paper, we highlight seven priority areas and best practices for improving HCV care in correctional settings: (1) changing political will through stakeholder and community engagement, to support development of national strategies; (2) ensuring access to HCV diagnosis and treatment; (3) promoting alternative models of care and incorporating peer-based services into HCV education and care; (4) improving HCV surveillance to better understand prevalence, incidence and treatment uptake; (5) reducing stigma and tackling the social determinants of health for individuals in correctional settings and upon return to the community; (6) implementing HCV prevention and harm reduction programs; and (7) advancing prison-based research to inform evidence-based interventions.
Introduction

Hepatitis C virus (HCV) is a global public health problem in correctional settings. As HCV is readily transmitted through injection drug use, and individuals with substance use disorders are often heavily incarcerated, there is a disproportionately high HCV prevalence in correctional settings.\(^1\)\(^-\)\(^3\) The incidence of new transmissions is also high as access to effective harm reduction measures is limited.\(^2\)\(^-\)\(^4\) Each year, over 30 million men and women spend time in prisons and other closed settings - the majority of whom will return to the community.\(^5\) Therefore, incorporating correctional settings into HCV elimination plans will reduce the burden of HCV, both in correctional settings as well as surrounding communities.\(^6\)\(^-\)\(^10\)

The ambitious 2030 global HCV elimination goals set by the \(^1\)\(^1\) Organization (WHO) called for a focus of these efforts in correctional populations. In reality, HCV elimination among people who inject drugs (PWID) and in the criminal justice system are inextricably linked due to the overlap of these populations. However, prisons offer a setting with generally lower rates of drug use, and often greater access to healthcare, and improved food and housing security. Therefore, providing care along all steps of the HCV care continuum from HCV prevention, screening, linkage to care, treatment, and prevention of reinfection, can potentially be optimized in correctional settings. Yet, current estimates suggest that of the 124 countries with hepatitis testing and treatment plans, only 51 (63%) have proposed interventions dedicated to people who inject drugs (PWID) and even fewer (28; 23%) have interventions for people in correctional settings.\(^12\)

Methods

The International Network on Hepatitis in Substance Users (INHSU) is an international organization committed to advancing scientific knowledge exchange and advocacy for HCV prevention and care among PWID. To address the problem of HCV in correctional settings, we established a prisons-focused workgroup (INSHU Prisons) in 2019 to improve the care of people living with HCV in correctional settings. All study authors except PT and RL are members of the working group; PT and RL were solicited for their expertise in HCV care in low- and middle-income countries and harm reduction, respectively.

This position paper from INSHU Prisons highlights seven priority areas and best practices for improving HCV care in correctional settings to achieve HCV elimination. The priority areas were discussed and agreed upon by members of the workgroup during the conception of this position paper.

Search strategy and selection criteria
Each study author was responsible for conducting his/her own search strategy for his/her chosen priority area; best practices were agreed upon as a group. The seven priority areas include: (1) changing political will; (2) ensuring access to HCV diagnosis and testing; (3) promoting optimal models of care and treatment; (4) improving surveillance and monitoring of the care cascade; (5) reducing stigma and tackling the social determinants of health inequalities; (6) implementing HCV prevention and harm reduction programs; and (7) advancing prison-based research. This position statement is not intended to be prescriptive, as different correctional healthcare structures have varied priorities, models of care, and implementation plans.13,14

**Changing political will**

Healthcare provision within prisons often varies between countries and may even vary between states, provinces, or territories within a country. This is due to the multiple factors, amongst them the administration of prison health via local, state or federal health authorities, variations in healthcare models between correctional facilities, differences in the financial structure of healthcare provision, and oversight of healthcare provision by relevant government ministries. It is imperative, therefore, that strategies for HCV healthcare delivery take these factors into consideration.15

In order to optimise HCV elimination efforts in correctional settings, key stakeholders need to be engaged.15 Ideally, prior to engaging with policy stakeholders, the prevalence of HCV infection in local correctional centres should be ascertained – or inferred from other regional data. Knowledge of the HCV prevalence helps formulate the scope of the strategy, to define a practice framework for the response, and incorporate financial considerations including drug price negotiations.16-19 For example, Spain’s Strategic Plan for Tackling Hepatitis C in the Spanish National Health System demonstrated the importance of stakeholder engagement by including a detailed budget plan to support treatment allocation including for individuals in the correctional system through funding support from the Ministry of Finance.20 In the United States, drug pricing negotiations have been challenged by prisons and jails being in a pool of payer entities used to calculate “best price,” which determines prices for drugs in state Medicaid programs. Due to constraints in correctional health budgets, many have argued that prisons and jails should be removed from best price calculations to allow them to negotiate better drug prices, or that alternative drug purchasing strategies are needed. However, to date, these strategies have been largely unsuccessful.16-19

With prevalence estimates in hand, multi-stakeholder forums with national or regional politicians, health and correctional services administrators, and primary and secondary healthcare providers from the correctional centres, as well as relevant non-governmental consumer agencies and advocates, should be held to obtain buy-in and to develop a framework for HCV elimination in
correctional settings. Data from existing prison-based treatment programs show that treatment of incarcerated persons is associated with good clinical outcomes and is cost-effective. Such successful programs should be used to guide stakeholder meetings towards incorporating correctional settings into local micro-elimination or national elimination strategies.

Demonstrating the impact of previously successful programs on the affected population, and on national elimination goals, is important to overcome concerns such as logistics, resources, and responsibilities for the various stakeholders, and to define specific goals for the correctional system or facility. Further, modelling of the HCV disease burden and the potential impact of various intervention strategies is helpful in guiding priorities in the implementation of HCV testing and treatment programs, and with health economic assessments, in projecting budget commitments and likely cost benefits of HCV elimination. Overall, incorporating correctional settings into national HCV elimination strategies is a key step towards HCV elimination, recognising that each country and each region will have unique challenges. WHO advocates that health ministries and not justice ministries should provide and be accountable for healthcare services in prisons. An early assessment of the transfer of control of prison health services to the Department of Health in England concluded that benefits include greater transparency, evidence-based assessment of health needs, improved quality of healthcare and greater integration with public health programs.

Ensuring access to HCV diagnosis and testing

While active offer for testing is recommended with individual consent, screening for HCV and other bloodborne viruses in correctional settings is currently undertaken with varied testing strategies. The first is ‘targeted screening,’ where the patient is assessed for risk factors (e.g. injection drug use) or identified as part of a high prevalence epidemiologic group (e.g. membership of the 1945-1965 baby boomer cohort in the United States). The second is ‘universal screening’, where all individuals are eligible for screening. These testing strategies can be administered for those who ‘opt-in’, where the individual has to request testing, or ‘opt-out’, where the individual is told they will be tested unless they refuse. Universal opt-out testing has been found to be the most effective and cost-effective.

Efficient completion of the diagnosis of chronic HCV by testing for HCV RNA, and further assessments with a view to treatment, can be especially challenging in correctional settings, particularly with high turnover rates due to movements between correctional centers or releases to freedom. Therefore, ensuring that screening is performed at the initial health assessment, which is generally conducted within 24 hours of admission, or within a short period thereafter, is critical. Testing strategies should also be quick and accessible. The traditional approach of on-site venipuncture and specimen shipment for diagnostic laboratory testing at a distant site typically has turnaround times of 1-2 weeks. In the latter context, reflex testing offers the
significant advantage of avoiding repeated cycles of testing and results over many weeks. Point-of-care (PoC) tests which offer results in minutes or hours, are not only efficient but also overcome the common difficulty of poor venous access among incarcerated PWID, and have recently been shown to be acceptable among incarcerated individuals. These PoC tests include antibody detection in saliva and RNA detection via finger stick blood sampling. Another option for improved access and efficiency is screening for HCV antibody and RNA via dried blood spot (DBS) testing, which facilitates sample collection as well as the opportunity to simultaneously screen for co-infections such as HIV. Such strategies have been shown to improve screening and treatment uptake.

Assessment of liver disease severity is recommended prior to treatment using fibrosis prediction algorithms, such as the APRI (aspartate aminotransferase to platelet ratio index) or FIB-4 (Fibrosis-4), or by transient fibro-elastography (if available). This assessment guides optimal DAA treatment duration, and identifies those with cirrhosis to facilitate advanced liver disease management such as variceal and hepatocellular carcinoma screening.

Promoting optimal models of care and treatment

Models of HCV care in correctional settings vary vastly within and across countries. Traditional hospital-based specialist clinics providing care for people in nearby prisons are still common in many places. This model involves the escort of incarcerated individuals to local hospitals for assessment and treatment; but has been plagued with low rates of treatment initiation. In order to overcome key barriers to linkage to care, notably transfers between correctional settings and short stays, more efficient and targeted models of HCV care must be considered for implementation in correctional settings. Other barriers for consideration include stigma, funding for prison health service infrastructure and for DAA treatments, as well as adequate staffing. The key elements underpinning improved models, include in-reach services in which clinicians visit correctional centers for on-site clinic sessions, potentially incorporating consultations via telemedicine which has been shown to be both acceptable and cost-effective. This service model highlights a move from hospital-based services to the on-site provision of care. Such services are associated with improved completion of the HCV cascade compared to traditional models.

Prison-based services may also employ task transfer in which some or all of the elements of the care cascade are shifted away from specialists to general practitioners or skilled nurses, including DAA prescription in settings where policies allow this. Such task transfer should be underpinned by education of the prison-based health workforce which may be facilitated through tele-mentoring and training such as that used in Project ECHO in the prison system in New Mexico. Direct care by providers to patients can also be provided through telemedicine. While there are no guidelines for integrating telemedicine into the prison health sector, several examples for the
setting and existing telemedicine guidelines can be adapted to provide HCV and other subspeciality care. In prisons, outside internet connections are often not permitted, so specific internal networks need to be used (see box 2). In addition, authorisation for desktop computers to include camera and audio equipment are key.

Combinations of elements from these service models are increasingly common, for instance with nurse-led triage of selected complex patients for specialist consultation. Such decentralized models have resulted in a marked reduction in the time from screening to treatment, a significant increase in retention in care, and successful in-prison treatment initiation. Integration of peers into corrections-based care has been associated with increased knowledge, reduced risk-taking behaviors, and improved engagement with healthcare services by reducing fear, stigma, and encouraging mutual trust. A 2016 systematic review of peer-based health interventions in correctional settings found that peer education interventions are effective at reducing risky behaviors among those in the correctional setting.

Improving surveillance and monitoring of the care cascade

Given the importance of the prison population to national and global HCV elimination efforts, reliable data regarding prevalence and incidence in the prison setting, as well as risk behaviors, prevention measures, and treatment provision, are critical. Further, as individual countries progress towards elimination, such data need to be representative (recognizing the common heterogeneity between individual prisons reflecting differing proportions of PWID, security classifications, representation of ethnic minorities, and gender). In addition, the data collection should be integrated within national surveillance systems to best capture the movements of high risk groups to and from correctional settings, and also ensure integration with surveillance of other blood-borne viruses and health concerns. Surveillance data also need to be made available in a timely fashion and on a regular basis (at least annually). To date, there are no countries that meet these expectations.

From first principles, such public health surveillance systems can be passive (ongoing reporting of the condition by health facilities), or active (where health facilities are visited and representative data obtained). For largely asymptomatic conditions such as HCV infection, passive laboratory-based reporting with individual patient-level identifiers is a cornerstone for optimal surveillance, noting that such laboratory notification systems cannot capture those who are not tested and does not record risk behaviors, or uptake of harm reduction and DAA treatments (termed here bio-behavioral data). In the absence of such comprehensive surveillance, active bio-behavioral sampling of representative sub-populations is commonly undertaken either cross-sectionally for prevalence, or longitudinally for both prevalence (at baseline) and incidence. These latter approaches are far more labour-intensive but offer the potential to concurrently capture bio-behavioral data. For incarcerated populations, unique challenges for surveillance programs
include the high turnover of individuals to and from the community, the concentration of ethnic minorities in prisons (which necessitates adequate sampling), and the custodial barriers to regular surveillance such as reliable access to individuals for testing.

In the prison setting, the most commonly utilised surveillance strategy is prevalence surveys amongst recent prison entrants with screening via HCV antibody testing and brief behavioural questionnaires, noting that such screening is rarely universal or opt-out, and therefore of uncertain representativeness. The most recent systematic review of such prevalence data for the period 2005-2015 revealed that only 46 of 196 countries had HCV antibody prevalence data, with regional pooled estimates amongst all prisoners ranging from 20% in eastern Europe and central Asia, to 16% in western Europe and 15% in North America, and 5% in Latin America. Only 19 countries had prison data for PWID, with far higher prevalence rates (ranging from 8% to 95%). There were substantial data gaps, particularly for female inmates and ethnic minorities. In addition, data regarding temporal trends in prevalence are scarce, but there is evidence of reductions in correctional centres in Spain and in Australia.

Only three incidence estimates were reported during the same period from Australia, Scotland, and Spain with widely varied rates ranging from 0.9% per annum in Scotland to 14.1% in Australia. The follow-up estimate from the Australian prospective cohort revealed a sustained annual incidence of 11.4%, over a decade of surveillance. A more recent cross-sectional survey of Danish prisoners conducted in eight correctional centers using a dried blood spot method revealed the HCV antibody prevalence was 7.4% (59 of 801 tested) and the HCV RNA prevalence was 4.2% (34/801). The analysis also included an estimate of incidence based on RNA positive/antibody negative status of 0.7-1.0% overall, and 18-24% among PWID. In combination, these data highlight wide variation in HCV prevalence and incidence in prisoner populations, and the need for improved surveillance in the prison sector including concurrent data collection regarding risk factors, prevention, and engagement with the HCV care cascade. The recently launched WHO Health in Prisons European Database (HIPED) is an important surveillance initiative highlighting the existing data (and the many gaps) in national prison health services and health surveillance among people who are incarcerated in Europe, including testing and treatment of HCV.

Reducing stigma and tackling the social determinants of health inequalities

Key contributors to the low uptake of HCV-related services in correctional settings are perceived stigma toward incarcerated individuals and limited awareness of both HCV and advances in HCV treatment. People who are incarcerated often fear being stigmatized by both correctional staff, healthcare workers, and their peers, leading many to forgo uptake of existing testing and treatment services. Moreover, many incarcerated individuals have misconceptions about their diagnosis and are unaware of the newer DAA therapies that are well-tolerated and have fewer
side effects than interferon-based therapies.\textsuperscript{70} It is clear that offering education to individuals who are living with HCV may alleviate the stigma that some individuals experience while seeking HCV care in correctional settings.\textsuperscript{55,56,70,72,73} As noted above, peer mentorship may be particularly effective in increasing uptake of screening and treatment, as this approach has been associated with improved engagement with healthcare services by reducing stigma.\textsuperscript{55,56}

Uptake of HCV care in correctional settings also requires addressing the social determinants of health that many in the criminal justice system face prior to, during, and after incarceration. This includes a lack of social support, but extends to homelessness, food and housing insecurity, and mistrust in the health system.\textsuperscript{74-77} Some of these factors can serve as barriers to HCV treatment uptake whilst in prison, but they tend to have far more impact once the incarcerated individual returns to the community.\textsuperscript{72,78} The majority of people who are on remand (or those incarcerated in jails in the United States) are incarcerated for only days to weeks,\textsuperscript{79} which is less than the standard length of DAA treatment. While HCV treatment is feasible even in short term correctional settings for those with lengths of stay that permit it,\textsuperscript{27,80} incarceration is often too short to complete or even initiate treatment for many individuals. If HCV treatment cannot be initiated in corrections, connecting individuals living with HCV to care after incarceration requires mitigation of the social determinants of health in the transition to the community. Discharge planners or patient navigators have been used with some success to connect individuals to local partners for treatment initiation upon their release back into the community. Such programs tend to be more effective when discharge plans also include linkage to mental health, substance use, and housing services to address behavioral and structural determinants of health. These programs have been more widely implemented among people living with HIV and have been shown to improve linkage and retention in HIV care.\textsuperscript{81} Leveraging existing discharge planning programs is a promising way to address linkage to HCV care after incarceration.\textsuperscript{82} Complimentary strategies to engage people in post-release care also include decentralised services outside of traditional medical clinics, such as mobile clinics, needle exchange centres, and drug rehabilitation centres.\textsuperscript{83} Engaging incarcerated individuals in co-located, integrated care including harm reduction and treatment of substance use disorders prior to release may be a way to improve engagement in care. Connecting those with chronic HCV with a community partner upon release not only maintains continuity of care, but is an effective and necessary solution to curtail HCV among transmission networks of PWID who are involved with the criminal justice system.

**Implementation of HCV prevention and harm reduction programs**

Harm reduction measures, including needle syringe exchange programmes (NSP) and opioid agonist therapy (OAT), have been a central pillar of the global prevention strategy for HIV, along with condom use, and more recently antiviral treatment-as-prevention (TasP). NSP and OAT programmes, which are also the cornerstone of HCV prevention amongst PWID, are now available in at least 86 countries.\textsuperscript{84} However, the acceptance of such harm reduction programmes in the community has rarely followed their implementation in prisons, despite evidence demonstrating that these programs in the correctional setting reduce engagement in risky behaviors like illicit
drug use and sharing of drug paraphernalia and likely contribute to a reduction in the spread of infection blood-borne viruses.\textsuperscript{34} Currently, only eight countries provide NSP in at least one prison, while 54 offer some level of OAT.\textsuperscript{84} These harm reduction measures are denied to the vast majority of people in detention worldwide, largely due to lack of political will for implementation, suggesting that the success of community-based NSP and OAT programs could be bolstered through partnerships with nearby correctional settings to encourage service utilization among those re-entering the community. The gap between the levels of access in the community and prisons exists despite the fact that providing harm reduction measures in places of detention is acknowledged as best practice by the WHO, the United Nations Office on Drugs and Crime and UNAIDS, among other expert bodies.\textsuperscript{85} The provision of harm reduction measures is also supported by European bodies, including the European Centre for Disease Prevention and Control and the European Monitoring Centre for Drugs and Drug Addiction.\textsuperscript{86} In addition, although tattooing has been significantly associated with HCV transmission,\textsuperscript{87} in most jurisdictions, tattooing in prisons is illegal and safe tattooing initiatives are rare, with only one prison–based programme ever evaluated.\textsuperscript{88}

While the effectiveness of harm reduction programmes in prisons and their successful implementation in many different countries and custody settings is well evidenced,\textsuperscript{88} opposition remains common in many countries. This is primarily based on the belief that the provision of harm reduction runs counter to the ‘drug free’ ethos of prison systems, and that providing sterile injecting equipment represents an admission of failure by the prison service. NSPs are often opposed on the belief that syringes may be used as weapons, thereby compromising the safety of staff and prisoners.\textsuperscript{89} However, international experience demonstrates that NSPs and OAT can be safely and effectively implemented in closed custody settings,\textsuperscript{89–91} and that these interventions contribute to decreased levels of syringe sharing, and thereby likely reduced risk of transmission of blood borne viruses.\textsuperscript{88}

With regard to TasP, the Surveillance and Treatment of prisoners with hepatitis C (SToP-C) study evaluated the reduction in HCV incidence associated with scale-up of HCV testing and DAA treatment in four prisons in Australia (Hajarizadeh, B et al, manuscript submitted). This five-year study enrolled approximately 70\% of all prisoners in the centers where OAT but no NSP was available, and demonstrated a significant decline in incidence. This outcome was consistent with the effect predicted by a modelling study of the same setting, which also argued for scale-up of both DAAs and harm reduction as being critical to achieving prison-based elimination.\textsuperscript{92}

**Advancing prison-based research**

The fundamental principle of equity of healthcare for prisoners is stipulated in the Mandela rules “...the same standards of healthcare that are available in the community and providing access to necessary healthcare services to prisoners free of charge without discrimination.”\textsuperscript{5} Best practice
health services in the prison setting are not only underpinned by this principle but also by research.\textsuperscript{93,94} However, prison-based research faces numerous challenges and obstacles beyond health research in other settings. This is primarily due to troubled history of forced exploitation of incarcerated populations for health research during the second half of the 20\textsuperscript{th} century, such as the infamous Tuskegee syphilis study.\textsuperscript{95} Indispensable federal and institutional regulations were introduced to promote the “safety and security” of people in prison;\textsuperscript{96} however, a perhaps unintended consequence was that correctional settings became far more challenging environments for research. Common challenges in prison-based research include gaining access to the research setting, obtaining research review and approval, navigating the research settings’ policies and procedures, and managing interruptions and delays due to the research setting.\textsuperscript{97} Another commonly cited barrier includes the recruitment of participants, hampered by unanticipated logistical delays related to lockdowns and/or the inability to move without supervision, a lack of private interview areas, and the unavailability of participants due to court dates, meal-times, etc.\textsuperscript{97} Studies that seek to follow released inmates also report high levels of attrition despite post-release monetary incentives due primarily to incorrect contact information, recidivism, and the presence of competing priorities at the time of release.\textsuperscript{97,98} These challenges have likely contributed to the modest number of HCV studies conducted in prison settings to date.

There are also unique ethical challenges that exist in conducting prison-based research. Firstly, as correctional settings were not designed to promote privacy, ensuring confidentiality – often cited as the most significant ethical challenge facing prison-based researchers – can be particularly difficult.\textsuperscript{99} This is of utmost importance with HCV given its stigmatization and the potential for harm through disclosure of an individual’s status. Secondly, as autonomy is sacrificed with incarceration, the ability to decide freely to participate or not in research (i.e. autonomy), particularly in the context of financial incentives that can result in undue influence, is compromised.\textsuperscript{99} Thirdly, obtaining consent among people in prison can be threatened as a result of lower educational and literacy levels and higher rates of mental illness and substance abuse compared to the general population.\textsuperscript{100,101} Finally, ensuring that people in prison are not coerced into participation as a result of power imbalances, incentives, or to access better medical services or care is another important ethical dilemma.\textsuperscript{102}

Despite the numerous challenges that exist, advancing prison-based HCV research is an essential step towards HCV elimination. This cannot be done without the recognition of the justice-involved individuals as a key population for inclusion in global HCV research.\textsuperscript{94} Ensuring open and honest dialogue among all involved stakeholders should be promoted to facilitate the process, manage the challenges encountered in a timely fashion, and to ensure the maintenance of a high ethical code for health research in prison settings.\textsuperscript{96,103} This may be achieved by incorporating a “governance and stakeholder engagement strategy” within the research study with the goal of active partner engagement. This proactive process could seek to involve various stakeholders (from study investigators to correctional staff and people with lived experience of incarceration) to identify possible concerns for study participants, address potential risks that study participants might encounter, maximize safety, and ascertain the implications for those involved in the study.
and for the community at large. An additional goal may be to infuse partners’ experiences and preferences into the study design, such that the methods used and the data captured are person-centric and meet the needs of all partners. It is important to emphasize that efforts should be made to involve community members (currently or previously incarcerated individuals) during this process to ensure that research is conducted in a culturally-sensitive and ethically-sound manner.

Conclusions

In conclusion, HCV is a global health problem that is deeply intertwined with criminal justice systems internationally. The priority areas outlined here are not only supported by the Mandela Rules - ensuring that prisoner healthcare be consistent with community standards, but also by state obligations under international and regional human rights law. Prisons and prisoners are also increasingly important for national and global HCV elimination efforts. Optimizing both in-prison testing and treatment strategies and connections to care in the community are critical for this endeavor. Not only are correctional facilities ideal settings to engage individuals in care while they are incarcerated, but they also provide an opportunity to address the social determinants of health that may benefit overall health outcomes of those who have been incarcerated as they return to their communities.

Contributors

MJA, NK, JC, YS, and AL for conceptualization, writing, review, and editing; PHT and RL for writing and review. All authors approved the final version of the manuscript.

Declaration of interests

The authors declare no competing interests.

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