# Consensus recommendations on the management of hepatitis C in Australia's prisons

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## Abstract

**Introduction:** Prison settings represent the highest concentration of prevalent hepatitis C cases in Australia due to the high rates of incarceration among people who inject drugs. Highly effective direct-acting antiviral (DAA) therapies for hepatitis C virus (HCV) infection are available to people incarcerated in Australian prisons. However, multiple challenges to health care implementation in the prison sector present barriers to people in prison reliably accessing hepatitis C testing, treatment, and prevention measures.

**Main recommendations:** This Consensus statement highlights important considerations for the management of hepatitis C in Australian prisons. High coverage testing, scale-up of streamlined DAA treatment pathways, improved coverage of opioid agonist therapy, and implementation and evaluation of regulated provision of prison needle and syringe programs to reduce HCV infection and reinfection are needed.

**Changes in management as a result of this statement:** The recommendations set current best practice standards in hepatitis C diagnosis, treatment and prevention in the Australian prison sector based on available evidence. Prison-based health services should strive to simplify and improve efficiency in the provision of the hepatitis C care cascade, including strategies such as universal opt-out testing, point-of-care testing, simplified assessment protocols, and earlier confirmation of cure. Optimising hepatitis C management in prisons is essential to prevent long term adverse outcomes for a marginalised population living with HCV. Scale-up of testing and treatment in prisons will make a major contribution towards Australia's efforts to eliminate hepatitis C as a public health threat by 2030.

Australia has set the goal of eliminating hepatitis C as a public health threat by 2030, in line with World Health Organization targets.[1] Most Australians living with hepatitis C virus (HCV) have acquired their infection through injecting drug use.[2] However, people who inject drugs are often marginalised and experience high levels of stigma and other barriers to engagement with health care.[3] Therefore, a major challenge to Australia achieving its hepatitis C elimination goals is to increase health service engagement and HCV testing and treatment in this underserved population.[4]

There were more than 64 000 adult imprisonment episodes in 2021.[5] Australian prison populations have a high HCV seroprevalence (an estimated 20% nationally)[6] due to the criminalisation of injecting drug use. Prison settings themselves also represent high risk settings for HCV acquisition for people who inject drugs. High rates of incident HCV infection (11.4 per 100 person-years) are reported within Australian prisons.[7] Coupled with a lack of evidence-based prevention measures and an increased likelihood of sharing injecting equipment, this infection rate is potentially undermining the health and economic benefits achieved through the investment in community-based harm reduction and the scale-up of HCV direct-acting antiviral (DAA) therapy in both the community and prisons. This underlines the need for both further scale-up of testing and treatment as well as better prevention during incarceration.

Cure of hepatitis C improves quality of life; allows regression of liver fibrosis; reduces the risk of liver failure, liver cancer and liver-related mortality;[8] and prevents onward transmission. In-prison hepatitis C treatment programs are demonstrably effective[9] and cost-effective,[10] and are estimated to account for 40% of all hepatitis C treatment prescriptions in Australia.[11] Recently, scale-up of hepatitis C treatment was shown to reduce the incidence of HCV infections in Australian prisons.[12]

The introduction of DAAs have revolutionised hepatitis C care, but there is a gap in the Australian policy landscape without an up-to-date national correctional hepatitis C strategy or framework that takes this into account.[13] Across Australia, there are both jurisdictional and regional differences in prison-operating practices, including the coexistence of private and publicly run prisons, and varied budget allocations, contractual arrangements for health service provision, health service availability, and prison custodial and health infrastructure. There are also multiple challenges to health care implementation in the prison sector, including competing correctional and health priorities, logistical constraints such as frequent prisoner movements, and limited space for health service provision, as well as knowledge and attitudinal barriers among correctional and health care providers and those incarcerated.[14]

The National Prisons Hepatitis Network (NPHN) has sought to fill this policy gap, producing the first national Consensus statement on the management of hepatitis C in Australia's prisons. The objectives were:

- to present a critical analysis of the evidence supporting the importance of HCV testing, treatment and prevention for people in prison, both for the individual and for national elimination efforts;
- to describe current best practice recommendations for the diagnosis, management, and continuity of care of people in prison living with HCV, as well as policy and practice to support HCV infection prevention; and
- to propose key performance indicators for the testing, treatment and prevention of HCV infection in Australia's prisons.

This article summarises the content of the complete NPHN Consensus statement,[15] which provides a comprehensive overview of the methods, topics, recommendations (Box 1), GRADE (Grading of Recommendations, Assessment, Development and Evaluations) criteria, and applicable key performance indicators and reporting indices.

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## Methods

Evidence was synthesised from the published literature and scientific abstract presentations available in English language at the time of writing to underpin the formulation of draft recommendations. The content, application, wording and feasibility of each recommendation was reviewed by the authors. For each recommendation, the strength of supporting evidence was rated according to the GRADE system.[20] The quality of the evidence supporting the recommendations was classified into one of three levels: high (A), moderate (B) or low (C). The GRADE system also offers two grades of recommendation: strong (1) or weak (2). Consensus between members of the writing group was achieved at the pre-determined level of seven out of nine votes, conducted via live anonymous online polling. Where necessary, the content of recommendations was discussed and revised to achieve consensus. Thirteen key stakeholder organisations provided feedback on the draft.

## Consensus recommendations

### Hepatitis C testing in prison populations (R3–R6)

There are limited data regarding hepatitis C testing rates in Australian prisons,[21] but it is estimated the current testing regimen captures only a minority of individuals at risk.[22] Testing strategies in the prison sector which facilitate timely and efficient case identification are critical, given short stays and the frequent transfers of people in prison.[22] Universal opt-out screening, where all newly incarcerated people are tested for hepatitis C as part of standard care unless they decline,[23] is recommended over targeted screening because of the well recognised barriers associated with risk disclosure, such as the stigma and discrimination that may result from flagging high risk individuals.[24] Universal opt-out testing is the most effective strategy for maximising testing numbers and case detection.[23,24] This should be complemented by repeat annual testing for all people in prison and additional testing offered on any occasion that recent risk factors are disclosed to health workers or on request.

Accessibility is also a key challenge; each health interaction with an individual while incarcerated requires a return custodial escort from the cells to an on-site health clinic. Hepatitis C testing often requires at least two health interactions: one for patient consultation and the second for pathology collection. Clinic space is often limited, creating long wait times for consultations; hence, minimising the number of interactions and time needed to make a chronic hepatitis C diagnosis is a key consideration. Diagnosis usually requires on-site venepuncture, specimen transfer to an off-site laboratory and return of results, and a two-step process of initial antibody testing followed by ribonucleic acid (RNA) testing on confirmation of antibody positivity. Reflex testing, whereby the health care provider draws an extra vial of blood and requests for the laboratory to automatically test the second sample for hepatitis C RNA after detecting hepatitis C antibodies in the first, offers the advantage of avoiding repeated cycles of ordering and completing tests and waiting for results over protracted periods.

Currently, all jurisdictions use venepuncture-based specimen collection. Therapeutic Goods Administration-approved point-of-care testing for HCV RNA offers enhanced timeliness, accessibility, and lower cost.[25] Finger-prick specimen collection for point-of-care testing is also attractive given the frequent difficulty of poor venous access among people who inject drugs as well as the limited clinic space. Evidence supporting the use of point-of-care testing in prisons is promising. In one reception prison in New South Wales, an intervention incorporating HCV RNA point-of-care testing demonstrated an increase in testing (99% *v* 22%; $P < 0.001$) and DAA treatment uptake (93% *v* 26%; $P < 0.001$), as well as reduced time to treatment initiation (6 days *v* 99 days; $P < 0.001$), compared with standard of care (Sheehan Y, Cunningham EB, Cochrane A, et al. Manuscript in preparation.).

### Further assessment of people with chronic hepatitis C in prison (R7–R9, R14, R15)

The clinical assessment before starting treatment for hepatitis C should be brief and targeted to confirm viraemia, test for bloodborne virus co-infection, assess morbidities through liver function tests and full blood examination, assess for cirrhosis, consider potential drug–drug interactions, and determine prior DAA treatment history (Box 2).[16]

Primary care-led prison-based hepatitis C management is effective and can reach people in prison living with HCV in large numbers.[28] Moving away from specialist-led models, primary care-led models, which include clinical nurse consultants, nurse practitioners or general practitioners, should be central to prison-based hepatitis C assessment and management, with support made available from a gastroenterologist, a hepatologist or an infectious diseases physician, which may be delivered via telehealth.

The anticipated duration of the incarceration should be considered. Confidential assessment of current injecting drug use is also important to integrate harm reduction measures with DAA treatment and guide conversations about post-cure testing and opportunities for re-treatment. Individuals disclosing injecting drug use during incarceration should be prioritised for treatment to prevent onward transmission[7] and offered opioid agonist therapy (OAT) referral where appropriate.

A targeted physical examination should identify key stigmata of chronic liver disease and signs of clinical decompensation,[29] as these features may influence treatment selection; decision making regarding fibrosis determination; the need for review from a gastroenterologist, a hepatologist or an infectious diseases physician; and post-treatment management. The requirement for extensive pre-treatment blood tests, and repeated venepuncture, can present a significant barrier to efficient and timely prison-based care.[30] Treatment should be considered with more limited test results, where this can be prescribed safely. The minimum recommended laboratory investigations are outlined in Box 2.

A triaged approach to the evaluation for cirrhosis is recommended. People diagnosed with cirrhosis should have a specialist consultation, which may be performed remotely. They should be enrolled in a surveillance program for hepatocellular carcinoma and should be assessed for clinically significant portal hypertension and osteoporosis (Box 2).[16] People with cirrhosis should be screened for hepatitis A and vaccination should be offered to those who are seronegative. Release to community should involve linkage to ongoing care for cirrhosis.

### Direct-acting antiviral treatment (R10–R13, R16–R18)

#### Treatment regimens for hepatitis C

Three pan-genotypic DAA regimens for the treatment of hepatitis C are available on the Pharmaceutical Benefits Scheme (PBS): sofosbuvir plus velpatasvir, glecaprevir plus pibrentasvir, and sofosbuvir plus velpatasvir plus voxilaprevir.[16] These oral treatment regimens are highly effective, well tolerated,

**1 Recommendations and GRADE (Grading of Recommendations, Assessment, Development and Evaluations) criteria***

| Principle | Number | Recommendation | GRADE |
|---|---|---|---|
| **Hepatitis C services should be underpinned by organisational policies, implementation plans and organisational capacity building** | | We recommend that jurisdictional authorities: | |
| | R1 | • Maintain an up-to-date policy that addresses hepatitis C prevention, testing and treatment | A1 |
| | R2 | • Enact an up-to-date implementation plan that addresses access to hepatitis C prevention, testing and treatment, stigma and discrimination, and specifies strategies to address the needs of diverse groups including Aboriginal and Torres Strait Islander people | B1 |
| **People in prison should be offered hepatitis C testing, and treatment with DAA therapy, equivalent to that available in the community** | | To increase testing in prisons, reduce delays between diagnosis and treatment, and ensure continuity in the care cascade for hepatitis C in Australian prisons, we recommend to corrections health services that: | |
| | R3 | • Universal, opt-out testing for HCV infection across all prison locations be adopted for all newly incarcerated people | A1 |
| | R4 | • Rapid testing pathways, including point-of-care where possible, be adopted for all newly incarcerated people, with a maximum turnaround time to provision of results of two weeks | A1 |
| | R5 | • Where screening is performed using venepuncture to test HCV serology, the care provider should ensure reflex testing† for HCV RNA is requested for people who screen positive for HCV antibodies | A1 |
| | R6 | • Re-testing be offered at least annually for all those incarcerated and offered at any time for people who disclose risk factors or request testing | B1 |
| | R7 | • All those identified with HCV infection be offered antiviral therapy | A1 |
| | R8 | • Ensure primary health care providers with experience in hepatitis C care — such as hepatitis nurses, nurse practitioners and general practitioners — are the preferred providers of in-prison hepatitis C care, with appropriate gastroenterologist, hepatologist or infectious diseases physician support available (including via telehealth where appropriate) | A1 |
| **Hepatitis C management offered to people in prison should align with the Australian recommendations for the management of HCV infection (June 2020)[16]** | | The assessment of people for treatment and the prescription of DAA regimens should follow accepted best practice in the community. We recommend that: | |
| | R9 | • Treatment work-up includes as a minimum:<br>▸ testing for serum HCV RNA to confirm active infection;<br>▸ testing for co-infection with HBV and HIV;<br>▸ liver fibrosis assessment in people > 35 years of age using non-invasive markers (eg, transient fibro-elastography, serum APRI score);<br>▸ chart review for medications with potential for drug–drug interactions with DAA treatments for hepatitis C;<br>▸ review of prior DAA treatment history | A1 |
| | R10 | • The following DAA regimens are the first line treatment for treatment-naïve individuals with compensated liver disease: sofosbuvir/velpatasvir or glecaprevir/pibrentasvir | A1 |
| | R11 | • People who do not respond to first line DAA treatment due to proven or suspected virological relapse should be treated with the second line regimen sofosbuvir/velpatasvir/voxilaprevir | A1 |
| | R12 | • The following special populations should be linked to gastroenterology, hepatology or infectious diseases services:‡<br>▸ people living with cirrhosis;<br>▸ people who are predicted to have difficulty managing drug–drug interactions during DAA treatment;<br>▸ people with HIV–HCV or HBV–HCV co-infection; and<br>▸ people who did not respond to second line treatment | A1 |
| | R13 | • Testing§ for cure of hepatitis C is defined by an undetectable HCV RNA 12 weeks after treatment, but opportunistic testing after four weeks after treatment is sufficient[17,18] if a week 12 test is not possible or practical | A1 |
| | R14 | • Vaccination against HBV should be universally offered to those susceptible to infection | A1 |
| | R15 | • All patients with cirrhosis should be offered hepatitis A immunisation if susceptible to infection | A1 |

Continues

**1 Continued**

| Principle | Number | Recommendation | GRADE |
|---|---|---|---|
| **Continuity of care when moving between prison and community settings** | | To minimise treatment interruptions and linkage to primary health care, especially where people are released from prison before completing a DAA regimen, we recommend that: | |
| | R16 | • Treatment continuation in prison be actively facilitated for people who are incarcerated while taking DAA treatment that was commenced in the community | A1 |
| | R17 | • People released from prison with incomplete DAA treatment should be provided with their full course of treatment at release (under PBS Regulation 49[19]) and linked to community-based primary health care | A1 |
| | R18 | • People with HCV who remain untreated during their incarceration should be actively linked to community-based primary health care | A1 |
| | | To support the ready availability of medical records for people moving between prisons and from prison into the community, we recommend that: | |
| | R19 | • Jurisdiction-wide electronic medical records be implemented | B1 |
| **People in prison should have access to evidence-based hepatitis C prevention strategies equivalent to those available in the community** | | To support the prevention of in-prison HCV transmissions, including new infections and reinfections, in each jurisdiction we recommend that: | |
| | R20 | • Prison needle and syringe programs should be implemented and evaluated | B1 |
| | R21 | • Bleach or another disinfectant should be made available and easily accessible to all people in prison | B1 |
| | R22 | • All people in prison who are assessed as eligible, and who request access to OAT, receive timely access to OAT | A1 |
| | R23 | • High coverage DAA treatment be implemented to establish a treatment-as-prevention effect | A1 |
| **People in prison, as well as clinical and custodial staff and prison management should be supported to engage with relevant, up-to-date, and accessible information regarding viral hepatitis** | | To support knowledge improvement, as well as the reduction of stigma and discrimination, we recommend that: | |
| | R24 | • Viral hepatitis education programs, tailored to people in prison, health care providers, and correctional staff be implemented in each prison. Curricula should be culturally appropriate, inclusive and accessible to people with varying levels of health literacy and include harm reduction and the effects of stigma | B1 |

APRI = Aspartate Transaminase to Platelet Ratio Index; DAA = direct-acting antiviral; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; OAT = opioid agonist therapy; PBS = Pharmaceutical Benefits Scheme; RNA = ribonucleic acid. * See the full NPHN Consensus statement[15] for applicable key performance indicators and reporting indices. † Reflex testing involves the health care provider drawing an extra vial of blood and requesting for the laboratory to automatically test the second sample for HCV RNA after detecting HCV antibodies in the first. ‡ Remote consultation is likely to expedite care. § This may be expedited using point-of-care testing. ◆

and achieve cure rates greater than 95%.[31] Consultation with a gastroenterologist, a hepatologist or an infectious diseases physician is recommended for special populations, such as those with prior DAA treatment failure.[16]

### Models of care for the treatment of hepatitis C

In the context of short prison sentences, streamlined models of care provided locally should be supported and regimens with shorter treatment duration promoted. Where possible, the entire treatment course should be dispensed in prison by endorsing the PBS prescription with Regulation 49[19] to avoid the risk of release or transfer without medications. Direct referral to community hepatitis C care navigators following release has been shown to increase treatment uptake in the community and should be facilitated for individuals continuing, or planning to commence, therapy after release.[32]

### Monitoring of patients and defining cure of hepatitis C

On-treatment monitoring with laboratory tests is not routinely required.[16] Testing to confirm cure (sustained virological response; SVR12), which is currently defined as undetectable plasma HCV RNA at least 12 weeks after treatment, is recommended. Recent data show that undetectable HCV RNA four weeks after treatment (SVR4) strongly predicts the SVR12 result.[17,18] Therefore, opportunistic testing of HCV RNA, potentially via point of care, at any time from four weeks (SVR4) after treatment completion is adequate, especially where release to the community may be imminent. Earlier confirmation of cure may also aid in differentiating reinfections versus treatment failures.

### Treatment non-response versus HCV reinfection

In people with detectable HCV RNA after treatment, it is important to try and distinguish treatment non-response from HCV reinfection, as this distinction influences the DAA re-treatment plan. Clinicians should consider treatment adherence as well as ongoing risk behaviour for HCV reinfection.[33,34] Reinfection should not be a barrier to re-treatment — see the full NPHN Consensus statement for further detail.[15] More information about the assessment and management of non-response versus reinfection is available in the Australian HCV infection management consensus statement.[16]

**2 Summary of steps in further clinical assessment**

| Number | Step | Description | Clinical notes |
|---|---|---|---|
| 1 | Confirmation of active viraemia | • HCV RNA test | • A positive RNA test is sufficient to establish chronic infection |
| 2 | Testing for BBV co-infection | • Hepatitis B tests (HBsAg, anti-HBs, anti-HBc)<br>• HIV antibody test | • Monitor for reactivation of hepatitis B during hepatitis C treatment<br>• Offer hepatitis B vaccination if the individual is not vaccinated or previously infected |
| 3 | Liver function tests and full blood examination | • Including serum ALT and AST | • To allow screening for patients with cirrhosis using the APRI or FIB-4 scores and to assess for portal hypertension and hepatic decompensation in patients with cirrhosis |
| 4 | Assessment for cirrhosis (people > 35 years of age) | • Transient elastography; or<br>• APRI or FIB-4 | • LSM median > 12.5 kPa threshold for diagnosis of cirrhosis<br>• If transient elastography is not available or would delay treatment initiation, calculation of APRI* or FIB-4† using serum biomarkers (AST and FBE) is recommended<br>• Cirrhosis is very rare in people aged < 35 years[26] and screening is not recommended |
| | Additional measures in people with cirrhosis | • Specialist consultation<br>• Screening for complications of cirrhosis<br>• HAV serology | • Surveillance for liver cancer<br>• Assessment and management for clinically significant portal hypertension<br>• Screen for osteoporosis<br>• If cirrhosis is detected, HAV serology should be performed and vaccination offered for those who are seronegative[27] |
| 5 | Consideration of potential drug–drug interactions | • Review comorbid conditions and current use of prescribed and unprescribed medications/drugs for drug–drug interactions with HCV DAAs | • Check potential drug–drug interactions‡ |
| 6 | Prior DAA treatment history | • Check prior DAA treatment history and outcomes | • Distinguish treatment failure (rare) from reinfection (common) if possible |

ALT = alanine aminotransferase; anti-HBc = hepatitis B core antibody; anti-HBS = hepatitis B surface antibody; APRI = Aspartate Transaminase to Platelet Ratio Index; AST = aspartate transaminase; BBV = bloodborne virus; DAA = direct-acting antiviral; FBE = full blood examination; FIB-4 = Fibrosis-4 score; HAV = hepatitis A virus; HBsAg = hepatitis B virus surface antigen; HBV = hepatitis B virus; HCV = hepatitis C virus; HIV = human immunodeficiency virus; LSM = liver stiffness measure; RNA = ribonucleic acid. * APRI calculator: https://www.hepatitisc.uw.edu/page/clinical-calculators/apri. † FIB-4 calculator: https://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4. ‡ Interaction checker: www.hep-druginteractions.org/checker. ◆

## Prevention strategies (R20–R22)

### Opioid agonist therapy

Benefits of OAT in prisons include reducing the frequency of injection episodes and needle/syringe sharing among people who inject drugs.[35-37] There is varied evidence regarding the effectiveness of prison OAT programs in reducing hepatitis C incidence, with factors such as higher risk behaviour among OAT recipients, timeliness of access, and subtherapeutic doses confounding research findings. OAT coverage in Australian prisons is estimated to be below the WHO coverage indicator of more than 40 per 100 people who have injected drugs in the past 12 months and who are opioid dependent.[38]

### Regulated needle and syringe programs

In community settings, needle and syringe programs reduce bloodborne virus spread and are particularly effective when implemented in combination with OAT for people who are opioid dependent.[39] No Australian jurisdiction has trialled a regulated prison needle and syringe program (PNSP) in a correctional setting. Well used PNSPs will contribute to the prevention of bloodborne virus transmission among people in prison, but the literature is limited.[40] Evaluations of PNSPs internationally support their feasibility and a reduction in needle/syringe sharing or reuse, with no increase in occupational risk for staff.[41,42]

### Disinfectants

Some jurisdictions provide in-prison access to a quaternary amine disinfectant or bleach. As a hepatitis C prevention strategy, the evidence for such disinfectants is weak,[37] and the cleaning of used needles and syringes is hampered by accessibility to bleach or disinfectant, the time and environment to use it appropriately,[43] and the risk to the integrity and function of needles and syringes.[37] In the absence of PNSPs, the availability of disinfectants or bleach may be considered a suitable, although subefficacious, harm reduction strategy.

### Treatment as prevention

Treatment as prevention uses population-wide scale-up of effective DAA treatment to reduce population-level HCV viraemia (chronic hepatitis C prevalence) and reduce the risk of new incident infections.[44] The efficacy of hepatitis C

treatment as prevention has been established in Australian prisons,[12] where DAA treatment scale-up resulted in reduced hepatitis C incidence by 48% between pre- and post-treatment scale-up periods. Modelling studies indicate that combined implementation of OAT and sterile needle and syringe provision, alongside hepatitis C treatment scale-up, is the most effective means of mitigating HCV transmissions in prisons.[45]

### Education strategies (R24)

Hepatitis C education interventions have been shown to improve patients' hepatitis C knowledge, testing behaviour, and willingness to commence treatment, both among people living with HCV and high risk groups in non-custodial settings,[46,47] and have the potential to achieve similar positive outcomes among prison populations.[22,48] Use of peer educators may be an attractive and cost-effective strategy for the custodial setting.[48,49] In addition, whole-of-sector education that includes correctional officers and health care providers is likely to help overcome stigma and raise awareness of patient and occupational-level benefits of testing and treatment of people in prison.[22]

### The perspectives of people in prison and the experience of stigma

Imprisonment may facilitate the uptake of hepatitis C treatment among people who have encountered barriers to accessing treatment in the community.[50] Imprisonment may also motivate health-seeking behaviour by providing secure accommodation, structured routine including regular meals, removing the distraction of the competing priorities of everyday life, and opportunities for self-improvement.[48,50] However, people in prison also describe apprehension regarding invasive tests, treatment side effects, reinfection risk, lack of social support, and physical vulnerability in prison. Power imbalances, stigma and discrimination, lack of confidentiality, and unintended disclosure of injecting or HCV infection status are universal themes and carry potential consequences such as social isolation, additional disciplinary attention, and targeted drug screening.[48,50] Addressing stigma requires cultural change, innovation in education and service delivery, committed leadership, operational investment, and engagement with people who are imprisoned.[51]

## Conclusion

The prison sector is increasingly recognised as a key venue for scale-up of services for hepatitis C diagnosis, treatment and prevention to support Australia's elimination efforts.[11] Scale-up of hepatitis services in prisons confers both individual and public health benefits. Prison settings are also recognised as important risk environments for ongoing transmissions, which may undermine hepatitis C elimination efforts, and so should be a priority setting for harm reduction and clinical and educational interventions.

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