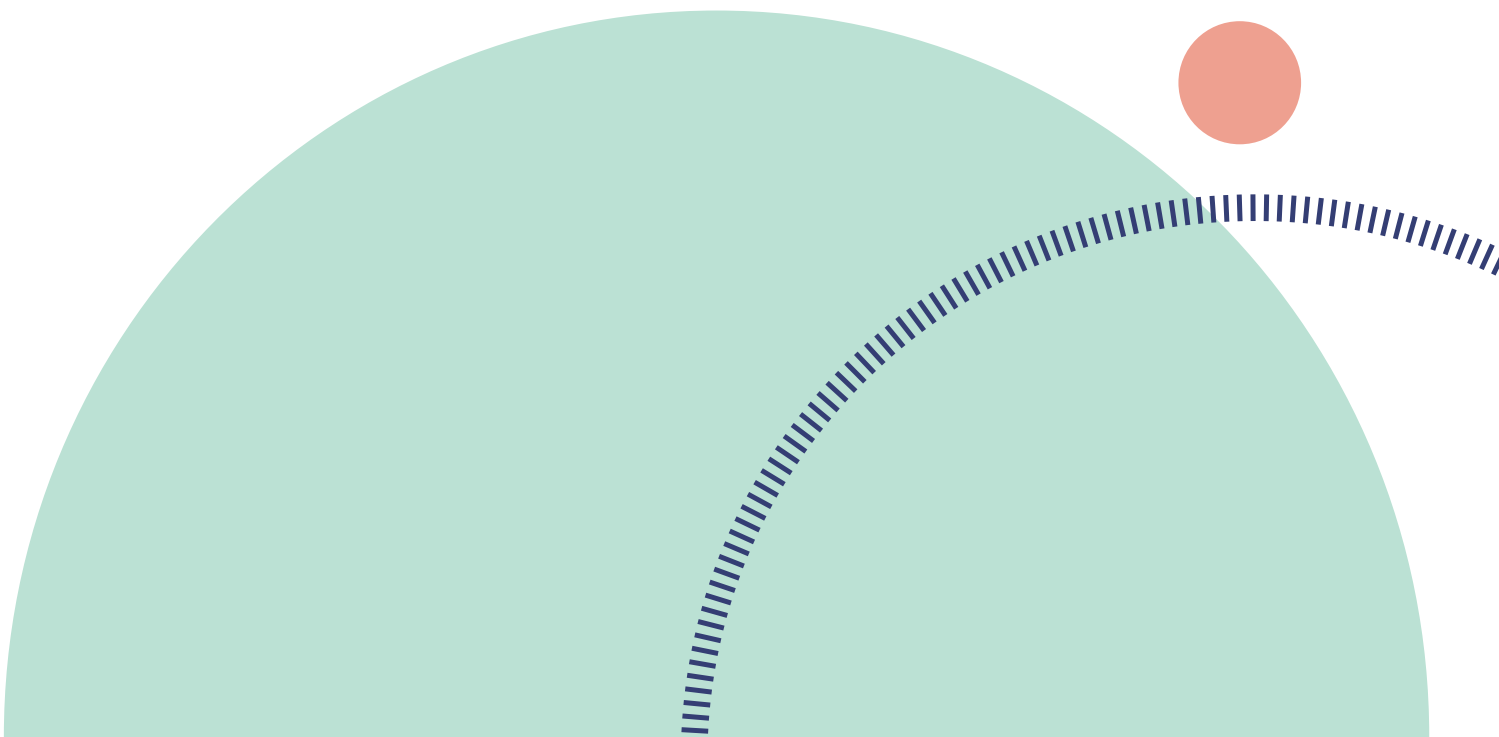


Consensus Statement on the Management of Hepatitis C in Australia's Prisons



NATIONAL PRISONS HEPATITIS NETWORK

MAY 2022



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* These authors contributed equally to the work.



The National Prisons Hepatitis Network acknowledges the traditional custodians of the land on which we live and work and pay our respects to Elders past and present. We also acknowledge the overrepresentation of Aboriginal and Torres Strait Islanders in the criminal justice system and the impact this has on community.

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PREFACE

This statement has been prepared by the [National Prisons Hepatitis Network](#) (NPHN) which includes clinical, consumer, public health and organisational stakeholders with a shared commitment to facilitating best practice in viral hepatitis services for people in Australian prisons.

The need for a national document to articulate best practice in hepatitis C prevention, testing and treatment in prisons was identified and prioritised at the inaugural annual meeting of the NPHN and reiterated in 2019.^{1,2} The aim of the Consensus Statement is to make recommendations for best practice standards in hepatitis C prevention, testing and treatment in the prison sector based on available evidence. The statement is intended to inform policy making by state and territory government departments with responsibility for the provision or oversight of prison health services, including privately and publicly operated prison health services. By setting out recommendations and key performance indicators, the NPHN hopes to promote a coordinated national approach with consistent policy, practice and reporting. The recommendations have been formulated based on a review of local and international literature and apply to adult prisons as well as juvenile detention centres.

The statement is anticipated to be received as a 'living document' and will be periodically revised and updated. Future iterations will be updated based on emerging international literature, incorporating best practice as well as new technologies and strategies to manage hepatitis C within prisons.

While the statement has been reviewed and endorsed by several key stakeholder organisations (Appendix 1) it does not reflect the breadth of all stakeholder perspectives. While aiming to guide standards in hepatitis C prevention, testing and treatment in the prison sector, the statement does not provide specific consideration of many other social and structural factors which contribute to the varied disparities in health status, health-related outcomes, and access to health services by people who are imprisoned in Australia.

Healthcare in prisons should be equivalent to that available in the community.

1.0 BACKGROUND AND PURPOSE

Rule 24 of the United Nations Standard Minimum Rules for the Treatment of Prisoners (the Mandela Rules) defines the equivalence of care principle: healthcare in prisons should be equivalent to that available in the community.³ There are multiple challenges to healthcare implementation in the prison sector, including competing correctional and health priorities, logistical constraints such as frequent prisoner movements and limited clinical space for service provision, as well as knowledge and attitudinal barriers amongst correctional and healthcare providers and those incarcerated.⁴

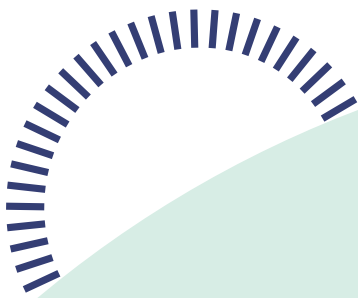
Australia has set the goal of eliminating hepatitis C infection as a public health threat by 2030, in line with targets set by the World Health Organization (WHO).⁵ These targets involve 90% of people living with hepatitis C being diagnosed, with 80% of people treated to achieve a 65% reduction in hepatitis C related mortality, as well as an 80% reduction in new hepatitis C infections, being guided by the principle to 'leave no one behind'. Antiviral treatment and cure of hepatitis C is associated with reduced risk of liver-related morbidity and mortality, as well as reduced risk of transmission.⁶ Most Australians who are living with hepatitis C have been infected through injecting drug use.⁷ However, people who inject drugs are often marginalised and face multiple barriers to engagement with healthcare.⁸ Therefore, a major challenge for Australia in achieving the hepatitis C elimination goals is to increase testing and treatment rates in this socially disadvantaged and underserved population^{9,10} – the prisons offer a key venue for this intervention.¹¹

More than 80,000 adults are incarcerated in Australian prisons annually with a large number being for illicit drug offences.¹² Of the 42,970 adults held in Australian prisons in 2021, 92% were male and the median age was 36 years. Aboriginal and Torres Strait Islander people constituted 30% of the imprisoned population, while making up less than 4% of the wider community,^{12,13} reflecting the disproportionate incarceration of Aboriginal and Torres Strait Islander people in every state and territory.¹² Both adults and young people in prison have poor physical and mental health compared with people in the wider community, including a markedly elevated prevalence of communicable and chronic diseases.¹⁴⁻¹⁷ The prevalence of hepatitis C among people in prison is higher than in the general community due to the criminalisation of injecting drug use and barriers to accessing evidence-based prevention measures in prisons. **It is estimated that at least 20% of all people in Australian prisons are seropositive for hepatitis C,**¹⁵ among whom approximately three quarters will have chronic infection. The seroprevalence is greater than 50% among people in prison who report a history of injecting drug use.¹⁵ While there are significant data gaps,¹⁸ the available evidence indicates that Aboriginal and Torres Strait Islander people in prison are disproportionately affected by hepatitis C infection.¹⁹ Prisons are a high-risk environment for hepatitis C transmission, with reduced access to harm reduction strategies such as opioid agonist therapy (OAT) and no regulated access to sterile equipment for injecting, tattooing or body modification practices. The annual incidence of hepatitis C transmissions among people who inject drugs in NSW prisons is approximately 11%.¹⁹⁻²²

The Fifth National Hepatitis C Strategy⁵ and the Fifth National Aboriginal and Torres Strait Islander BBV and STI Strategy¹⁸ both identify people in custodial settings as a priority population for testing and treatment. The Australian government has been a global leader in providing reimbursement for the highly effective DAA treatments of people in prison with chronic hepatitis C since 2016. This has provided the foundation for hepatitis C testing and treatment programs to be offered widely both in the prisons and the community, supporting national elimination goals. Hepatitis C treatment programs in prisons are highly effective^{11,23,24} and have been shown to be cost-effective.^{25,26} Importantly, prison hepatitis programs are now estimated to be responsible for over a third of all hepatitis C treatment prescriptions in Australia.²⁷ Recently, scale-up of hepatitis C treatment was shown to reduce the incidence of hepatitis C infections in Australian prisons.^{28,29} Accordingly, it is evident that as a site for health improvement, prisons can potentially play a key role in the diagnosis of undetected hepatitis C infection, provide treatment, and prevent new infections through integrated harm reduction and treatment-as-prevention programs.

Despite prisons being prioritized in the national strategies, there is a clear gap in the Australian policy landscape without an up-to-date national correctional hepatitis C strategy or framework - the most recent such document pre-dates the widespread availability of DAAs. There is also a lack of policy documents which address hepatitis C services in prisons in many jurisdictions.³⁰ Across Australia, there are both jurisdictional and regional differences in prison operating practices, including the co-existence of private and publicly run prisons, varied budget allocations and contractual arrangements for the provision of health services, the highly varied extent of available services and the state of the prison custodial and health infrastructure.

Mathematical modelling indicates that from 2021 onwards 4,200 – 5,400 people who report injecting drug use need to be treated annually to remain on track to meet Australia’s elimination goals.⁹ With 3,360 and 3,005 treatments dispensed to prisoners in 2019 and 2020 respectively, prison hepatitis services are making a major contribution to annual treatment targets in this key sub-population.²⁷ However, these achievements will be under threat unless there are refocussed efforts on the implementation of in-prison and transitional prevention strategies. With an appropriately resourced strategy and continued commitment and collaboration, Australia’s prison hepatitis programs could further increase their contribution to overall hepatitis C treatment uptake and prevention of infection, reaching those most at risk of transmission and the least likely to access mainstream health services in the community. Prison hepatitis services must continue to play a crucial role in achieving the goal to eliminate hepatitis C as a public health threat in Australia.



THE DEVELOPMENT OF THIS CONSENSUS STATEMENT BY THE NPHN IS A DEMONSTRATION OF THAT COMMITMENT. AS SUCH, THE OBJECTIVES OF THIS STATEMENT ARE:

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

2.0 CONSENSUS RECOMMENDATIONS

Tables:

Recommendations, GRADE, and applicable key performance indicators (KPI) and reporting indices

Principle:

Hepatitis C services should be underpinned by organisational policies, implementation plans and organisational capacity building.

We recommend that jurisdictional authorities:

#	Recommendation	GRADE	KPI	Reporting Indices
1	Maintain an up-to-date policy that addresses hepatitis C prevention, testing and treatment.	A1	Current policy document.	Annual reporting of the existence of a relevant up-to-date policy that addresses viral hepatitis.
2	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	Current implementation plan, including specific actions.	Annual reporting of the progress towards implementation of viral hepatitis actions for each jurisdiction.

Principle:

People in prison should be offered hepatitis C testing, and treatment with direct-acting antiviral (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:

#	Recommendation	GRADE	KPI	Reporting Indices
3	Universal, opt-out testing for hepatitis C infection across all prison locations be adopted for all people newly incarcerated.	A1	At least 75% of all people newly incarcerated tested for hepatitis C within 2 weeks.	Annual reporting of the: <ul style="list-style-type: none"> – number of new receptions and the total (prevalent) prison population; and – number of hepatitis C antibody tests conducted.
4	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	At least 75% of all people newly incarcerated tested for hepatitis C within 2 weeks.	
5	Where screening is performed using venepuncture to test hepatitis C serology, the care provider should ensure reflex testing for hepatitis C RNA is requested for people who screen positive for hepatitis C antibodies.	A1	All positive hepatitis C antibody test results are accompanied by a concurrent RNA test result.	Annual reporting of the proportion of positive hepatitis C antibody tests accompanied by a concurrent RNA test result.
6	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	At least 50% of all people imprisoned for 12 months or longer offered re-testing for hepatitis C.	Annual reporting of the proportion of people imprisoned for 12 months or longer who are offered testing for hepatitis C.
7	All those identified with hepatitis C infection be offered antiviral therapy.	A1	At least 75% of all those identified with hepatitis C initiated on DAA treatment whilst incarcerated.	Annual reporting of the following numbers disaggregated by gender and Aboriginality: <ul style="list-style-type: none"> – number of positive hepatitis C antibody test results; – number of hepatitis C RNA tests conducted; – number of positive hepatitis C RNA results; and – number of DAA treatment initiations.
8	Ensure primary healthcare 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 disease physician support available (including via telehealth where appropriate).	A1	Skilled primary healthcare providers are available to provide hepatitis C services to people in prison.	Annual reporting of the model(s) of viral hepatitis care available in each jurisdiction.

Principle:

Hepatitis C management offered to people in prison should align with the Australian recommendations for the management of hepatitis C virus infection (June 2020).³¹

The assessment of people for treatment and the prescription of DAA regimens should follow accepted best practice in the community. We recommend that:

#	Recommendation	GRADE	KPI	Reporting Indices
9	Treatment work-up include as a minimum: <ol style="list-style-type: none"> testing for serum hepatitis C RNA to confirm active infection; testing for coinfection with HBV and HIV; liver fibrosis assessment in people > 35 years of age using non-invasive markers (e.g. transient fibro-elastography, serum APRI score); chart review for medications with potential for drug-drug interactions with DAA treatments for hepatitis C; review of prior DAA treatment history. 	A1		
10	The following DAA regimens are the first-line treatment for treatment-naïve individuals with compensated liver disease: sofosbuvir/velpatasvir or glecaprevir/pibrentasvir.	A1		
11	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		Annual reporting of the number of DAA retreatments.
12	The following special populations should be linked to gastroenterology/hepatology/infectious diseases services*: <ol style="list-style-type: none"> people living with cirrhosis; people who are predicted to have difficulty managing drug-drug interactions during DAA treatment; people with HIV-HCV or HBV-HCV coinfection; and people who did not respond to second-line treatment. 	A1	All special populations receive annual review overseen by a gastroenterologist/hepatologist/infectious diseases physician.	Annual reporting of the number of people receiving review by a gastroenterologist/hepatologist/infectious diseases physician.
13	Testing [†] for cure of hepatitis C is defined by an undetectable hepatitis C RNA 12 weeks post-treatment, but opportunistic testing after four weeks post-treatment is sufficient ^{32,33} if a week 12 test is not possible or practical.	A1	All patients who have completed DAA therapy and remain in custody are offered SVR testing.	Annual reporting of the number of people tested at least 4 weeks following end of treatment.
14	Vaccination against hepatitis B virus should be universally offered to those susceptible to infection.	A1	At least 90% of all people in prison who are susceptible are offered hepatitis B vaccination.	Annual reporting of the proportion of hepatitis B susceptible people in prison who have received at least one vaccination dose against hepatitis B.
15	All patients with cirrhosis should be offered hepatitis A immunisation if susceptible to infection.	A1	At least 90% of people in prison with cirrhosis and who are susceptible to infection are offered hepatitis A immunisation.	Annual reporting of the proportion of people in prison with cirrhosis who are susceptible to infection have received at least one vaccination dose against hepatitis A.

*Remote consultation is likely to expedite care.

[†]This may be expedited using PoC testing.

Principle:

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 prior to completing a DAA regimen, we recommend that:

#	Recommendation	GRADE	KPI	Reporting Indices
16	Treatment continuation in prison be actively facilitated for people who are incarcerated while taking DAA treatment which was commenced in the community.	A1		
17	People released from prison with incomplete DAA treatment should be provided with their full course of treatment at release (under PBS regulation 49) and linked to community-based primary health care.	A1		
18	People with hepatitis C 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, as well as for ease of reporting against KPIs, we recommend that:

#	Recommendation	GRADE	KPI	Reporting Indices
19	Jurisdiction-wide electronic medical records (eMR) be implemented.	B1	eMR in place	

Principle:

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 hepatitis C transmissions, including new infections and reinfections, in each jurisdiction we recommend that:

#	Recommendation	GRADE	KPI	Reporting Indices
20	Prison needle and syringe programs should be implemented and evaluated.	B1	A prison needle and syringe program is implemented.	
21	Bleach or another disinfectant should be made available and easily accessible to all people in prison.	B1	Bleach or another disinfectant is available and easily accessible at all prisons.	Annual reporting of the number and proportion of prison sites with bleach/disinfectants available to people in prison.
22	All people in prison who are assessed as eligible, and who request access to OAT, receive timely access to OAT.	A1	OAT is available at all prison sites, and accessible to all people in prison who are assessed as eligible and request access to it.	Annual reporting of: <ul style="list-style-type: none"> – the number of people in prison who are prescribed OAT. – the number and proportion of prison sites which have OAT initiation and transition programs available.
23	High coverage DAA treatment be implemented to establish a treatment-as-prevention effect.	A1	At least 75% of all people in prison identified with hepatitis C initiate DAA treatment whilst incarcerated.	Annual reporting of the following numbers disaggregated by gender and Aboriginality: <ul style="list-style-type: none"> – number of positive hepatitis C antibody test results; – number of hepatitis C RNA tests conducted; – number of positive hepatitis C RNA results; and – number of DAA treatment initiations.

Principle:

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:

#	Recommendation	GRADE	KPI	Reporting Indices
24	Viral hepatitis education programs, tailored to people in prison, healthcare 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	Twice-yearly viral hepatitis education sessions provided for correctional and healthcare providers in each prison.	

Imprisonment is an independent risk factor for hepatitis C and so all people in prison should be offered testing.

3.0 HEPATITIS C TESTING IN PRISON POPULATIONS

Given the growing importance of hepatitis C testing and treatment scale-up amongst people in Australian prisons to the national hepatitis C elimination efforts, testing strategies and policies adopted in the prison sector that facilitate timely and efficient case identification are critical.¹¹ In the Australian prison sector, a nurse-led health risk assessment is generally required within 24-48 hours of prisoner incarceration – primarily focusing on identification of the risks of self-harm, drug withdrawal, and significant current health conditions. Screening for hepatitis C infection is offered within several weeks of incarceration in all jurisdictions, most commonly as part of an integrated blood-borne virus (BBV) screening strategy,¹ however data on testing uptake are limited.

Imprisonment is an independent risk factor for hepatitis C and so all people in prison should be offered testing. The potential approaches to hepatitis C testing in the prison sector include ‘targeted screening’, where the person is surveyed for risk factors such as injecting drug use, tattooing, or previous imprisonment, and then offered testing. However, risk-based screening is dependent on people disclosing risk factors such as injecting drug use, and the stigma associated with risk behaviours, as well as the risk of targeted surveillance and imposed restrictions, are well-recognised barriers to hepatitis C testing, both in prison and the

community.³⁴ Targeted screening is therefore not recommended as the sole approach. The second approach is ‘universal screening,’ in which all those newly incarcerated are offered testing.³⁵ The actual offer of testing may be ‘opt-in,’ where the individual requests testing, or ‘opt-out,’ where every person is informed and understands that hepatitis C testing is part of standard care and they will be tested unless they decline. International experts recommend a universal opt-out testing approach for prison settings,³⁶ as it has been found to be both the most effective and cost-effective strategy for maximising testing numbers and case detection.^{34,35} The universal opt-out approach should ensure that every person in prison is fully aware of their choice to opt out of testing. A universal opt-out approach to testing people entering prison should be complemented by repeat annual testing for all prisoners and additional testing offered on any occasion that recent risk factors are disclosed, or on request. Only a few of the smaller jurisdictions report using the best practice approach of universal opt-out screening and the consistency of its application is unknown.¹¹ There are very limited data regarding the actual testing rates in Australian prisons,³⁷ but reports from several jurisdictions suggest that the current testing regime captures only a minority of those at risk.¹

Peer support may promote engagement with testing. Peer-supported models of testing should be further explored in the Australian context, along with the potential role for Aboriginal Community Controlled Health Organisations (ACCHOs) and other in-reach services to provide culturally appropriate care.³⁸ A report from the Irish prison system demonstrated that peer-supported screening, in which prison peer workers promoted testing and accompanied people to the screening visit, improved uptake.³⁹

In the practice of hepatitis C testing, there are several logistical challenges. Timeliness is the premier priority, firstly because over 30% of all people in Australian prisons are unsentenced (i.e. on remand) with a median duration of incarceration of only 3.4 months, commonly ending with unsupervised release to the community.¹² In addition, the length of stay in reception prisons (i.e., centres designated to receive those newly incarcerated) in most jurisdictions is weeks only – before transfer to another correctional facility. Secondly, accessibility is a key challenge as each health interaction with an individual whilst incarcerated requires an escorted transfer from the cells to an on-site health ‘clinic’ (and return) by a correctional officer, generally conducted one-on-one. In most prisons, hepatitis C testing requires two health interactions – the consultation to discuss screening and order the test is separate to the consultation for the venepuncture itself. Clinic space is often limited, creating wait times for consultations. Hence, minimising the number of interactions and the time needed to make a diagnosis of chronic hepatitis C infection are key considerations. The diagnostic laboratory tests from correctional centres typically occur at a distant site. Hence, testing usually requires venepuncture on-site followed by specimen transfer and then return of results, leading to a lengthy turnaround time, typically weeks. Testing is still often a two-step process involving an initial antibody test, followed by an RNA test on confirmation of antibody positivity. Reflex testing, whereby the healthcare 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 significant advantage of avoiding repeated cycles of ordering and completing tests and waiting for results over weeks or even months. Such a process maximises the use of scarce clinical space and financial resources and reduces need for repeat consultations.

Given the frequent difficulty of poor venous access among people who inject drugs, as well as the limited clinic space for consultations and pathology collection, point-of-care fingerstick blood sampling is an attractive alternative. The Fifth National Hepatitis C and Aboriginal and Torres Strait Islander BBV/STI Strategies^{5,18} recommend exploring the use of rapid testing and point of care (PoC) technologies to improve access to testing. In high prevalence settings, PoC testing for hepatitis C RNA as a standalone testing

strategy has particular relevance as it offers the key elements of timeliness, accessibility, and lower cost.^{40,41} In Australia, the Therapeutic Goods Administration (TGA) approved the [Cepheid Gene Xpert™](#) hepatitis C viral load fingerstick assay in May 2020, which uses a fingerstick blood sample and returns a result for hepatitis C RNA detection (viral load) within 60 minutes. Local evidence supporting the use of PoC testing in reception prisons for rapid hepatitis C diagnosis and linkage to care is promising.⁴² The prospective historically controlled PIVOT study recorded higher testing uptake during the PoC intervention phase than during the standard of care phase (99% vs 45%; $p < 0.001$) in one reception prison in NSW.⁴³ DAA treatment uptake within 12 weeks of study enrolment was also significantly higher among those who tested positive to hepatitis C on a PoC test (93% vs 26%, $p < 0.001$) and the median time to treatment initiation was shorter (6 days vs 90 days; $p < 0.001$).⁴³ Salivary testing for hepatitis C antibodies may also be considered in the future for rapid PoC screening at reception to triage people to RNA testing, as reliable assays exist, but are not yet approved in Australia.⁴⁴ Both hepatitis C antibody and RNA can be tested on fingerstick blood samples collected via dried blood spot (DBS), which also allows testing for co-infections such as HIV, and hepatitis B.⁴⁵ Although the time to receipt of results from DBS samples is typically longer than standard pathology, it has been shown in some studies to improve testing rates in the prison setting.^{46,47} The rapid PoC testing approach was shown to be superior to DBS testing in a large remand prison in West London.¹⁰ As DBS testing is not currently registered for diagnostic use in Australia it remains a research tool. In practice, currently all jurisdictions predominantly, or exclusively, utilise venepuncture-based specimen collection, with one state increasingly using a state government supported DBS testing strategy.⁴²

In summary, the implementation of rapid testing pathways that minimise delays driven by repeat pathology, the regular movement of people between prison sites, prison operations and infrastructure are necessary to maximise accessibility for people in prison. Rapid testing pathways may include the use of PoC technologies or other strategies depending on the suitability of the context.

4.0 FURTHER ASSESSMENT OF THOSE WITH CHRONIC HEPATITIS C INFECTION

Treatment within prisons has an important role in reducing liver-related morbidity and mortality for those living with hepatitis C, as well as reducing hepatitis C prevalence and risk of transmission.^{28,48,49} Accordingly, all prisoners living with chronic hepatitis C infection should be considered for DAA treatment whilst incarcerated. The accessibility and comprehensibility of information about assessment and DAA treatment for people in prison is an important factor; information about assessment and treatment should be available in commonly used languages and access to an interpreter should be facilitated when required.

Clinical assessment prior to starting treatment for hepatitis C should be efficient and targeted to: i) confirming viraemia; ii) assessing for cirrhosis; iii) testing for BBV coinfection; iv) consideration of potential drug-drug interactions; and v) assessing prior DAA treatment history.³¹

Table 2: Summary of steps in further clinical assessment

#	Step	Description	Clinical notes
i	Confirmation of active viraemia.	Hepatitis C RNA test.	A positive RNA test is sufficient to establish chronic infection.
ii	Assessment for cirrhosis (people > 35 years of age).	Transient elastography OR APRI or FIB-4.	LSM median >12.5kPa threshold. 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. Cirrhosis is very rare in people < 35 years and screening is not recommended.
iii	Testing for BBV coinfection.	Hepatitis B tests (HBsAg, anti-HBs, anti-HBc) HIV antibody test.	Monitor for reactivation of hepatitis B during hepatitis C treatment. Offer hepatitis B vaccination if the individual is not vaccinated or previously infected.
iv	Consideration of potential drug-drug interactions.	Review co-morbidities and current use of prescribed and unprescribed medications/drugs for drug-drug interactions with hepatitis C DAAs.	Potential drug-drug interactions can be checked via https://www.hep-druginteractions.org/checker .
v	Prior DAA treatment history.	Check prior DAA treatment history and outcomes.	Distinguish treatment failure (rare) from reinfection (common) if possible.

Local and international data demonstrate that nurse-led prison-based hepatitis C management is effective and can reach prisoners living with hepatitis C in large numbers, with limited gastroenterologist/hepatologist or infectious diseases physician input.⁵⁰ Primary care-led models of care, which may include hepatitis clinical nurse consultants, nurse practitioners or general practitioners, should therefore be central to prison-based hepatitis C assessment and management, supported by remote telehealth with support available from a gastroenterologist/hepatologist or infectious diseases physician. To address the unique social and medical needs of Aboriginal and Torres Strait Islander people in prison, strong consideration should be given to the inclusion of Aboriginal and Torres Strait Islander health practitioners in primary health care teams. In 2018, 25% of 62 prison health clinics reported receiving visits from an ACCHO or Aboriginal Medical Service and 15% of Aboriginal and Torres Strait Islander people leaving prison reported accessing an Aboriginal and Torres Strait Islander health practitioner during their incarceration.¹⁴ With funding from the ACT government, the Alexander Maconochie Centre has integrated an ACCHO-led model of primary health care, the principles of which were also recently adopted by the South Australian Prison Health Service in their state-wide model of care, which serve as excellent examples of good practice.^{51,52}

Pre-treatment assessments should include a history relevant for hepatitis C treatment initiation as well as factors important for prison-based management specifically, including anticipated incarceration duration and risk factors for transmission and reinfection. Prior treatment experience should be determined, as this may influence the DAA regimen and duration selected. Co-factors for liver disease progression should be assessed including alcohol intake, virological co-factors (hepatitis B and HIV co-infection), and metabolic co-factors (e.g., obesity and diabetes). Vaccination status for hepatitis B should be established. Medical co-morbidities should be noted, and concomitant medications reviewed for potential drug-drug interactions to guide DAA selection. Some illicit drugs and pharmaceutical opioids used in unprescribed dosage can interact with DAAs and their use should be assessed when selecting a DAA regimen.

Assessment of current injecting drug use is also important to integrate harm reduction measures with DAA treatment - those disclosing injecting drug use during incarceration should be prioritised for treatment to prevent onward transmission and this should be facilitated by prison health staff with an emphasis on non-disclosure beyond the health setting.²¹ Referral for harm reduction should be offered as appropriate, including OAT to reduce opioid use, and supported access to bleach where possible.

A targeted physical examination should be performed to identify the key stigmata of chronic liver disease including spider naevi, and signs of clinical decompensation including ascites, jaundice and encephalopathy, noting that most patients with cirrhosis will have no symptoms or signs.⁵³ Nevertheless, these features may influence treatment selection, decision-making regarding fibrosis determination, the need for review from a gastroenterologist/hepatologist or 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.⁵⁴ Treatment could therefore be considered with more limited test results, where this can be prescribed safely.

The minimum laboratory investigations currently recommended prior to hepatitis C treatment include: hepatitis C RNA, liver enzyme tests (including serum ALT and AST), a full blood examination and testing for hepatitis B and HIV (Table 2). Hepatitis C RNA testing confirms active hepatitis C infection, and in a prisoner with a history of injecting drug use, is sufficient to establish chronic infection. Hepatitis C genotyping is

no longer required by the Australian Pharmaceutical Benefits Scheme (PBS) for DAA prescription, but may be useful in the prison context to help differentiate between relapse and reinfection in the small number of prisoners who remain HCV RNA positive after treatment. Hepatitis C genotype may also influence DAA selection in those who are treatment experienced or with cirrhosis.³¹ Genotype testing should not delay treatment initiation however. Liver enzymes including serum AST and full blood count are performed to allow screening for patients with cirrhosis using the APRI or FIB-4 scores (Table 2), as well as to assess for portal hypertension and hepatic decompensation in patients with cirrhosis. Hepatitis B testing should include HBsAg, anti-HBc and anti-HBs serology to identify current or previous infection, or prior immunisation, as this infection is increased in prevalence amongst people who inject drugs, and there is a small risk of hepatitis B reactivation amongst HBsAg positive individuals during DAA treatment for hepatitis C.⁵⁵ Where active hepatitis B coinfection is identified, antiviral therapy for hepatitis B should be considered prior to DAA initiation in patients with cirrhosis, and all co-infected patients should be monitored for reactivation of hepatitis B. Vaccination should be arranged for those who are non-immune.

All prisoners should be evaluated for cirrhosis prior to hepatitis C treatment to identify those requiring ongoing management, including to initiate surveillance for complications of advanced liver disease or hepatocellular carcinoma (HCC). We recommend a practical approach to cirrhosis evaluation based on age, clinical assessment, serum biomarker scores and/or transient elastography (Table 2):

- i) Cirrhosis is very rare in prisoners < 35 years of age,⁵⁶ and so no further assessment is necessary for this group unless co-factors are present such as alcohol excess or hepatitis B.
- ii) Among prisoners > 35 years, assessment for cirrhosis is recommended.

Transient elastography measurement of liver stiffness remains the most accurate non-invasive method of fibrosis determination and Fibroscan®, which has been extensively validated in people with chronic hepatitis C infection, is available as a portable device suitable for outreach. Other methods of ultrasound-based elastography, such as acoustic radiation force impulse (ARFI), available as an add-on to diagnostic ultrasound, are also becoming available but generally require patients to be sent off-site.^{57,58} We recommend that transient elastography be used routinely in the prison sector as the first-line method of fibrosis determination.⁵⁹ A liver stiffness measure (LSM) ≤ 12.5 kPa can be used to exclude cirrhosis (Table 2). If transient elastography is not available in a timely fashion, we recommend the use of serum biomarker scores (e.g. APRI, FIB-4; Table 2) to triage cirrhosis risk. For example, an APRI score < 1.0 has a 94-96% negative predictive value for cirrhosis.^{56,60} People with APRI > 1.0 should be referred for elastography prior to starting treatment; however, referral for elastography should not delay hepatitis C treatment. If cirrhosis assessment cannot be organised in a timely fashion, we recommend that people should proceed immediately to start hepatitis C treatment, especially where release from prison is imminent.

Individuals identified as being at risk of having cirrhosis (LSM >12.5kPa) should be prioritised to start treatment as soon as practical. People with confirmed cirrhosis should enter surveillance programs for HCC and oesophageal varices whilst incarcerated, as recommended by existing guidelines,³¹ and incorporated into discharge planning. When cirrhosis is detected, hepatitis A virus serology should be performed and people who are seronegative should be offered vaccination.⁶¹⁻⁶³

All people in prison living with hepatitis C should be offered antiviral treatment.

5.0 DAA TREATMENT

5.1 Treatment regimens for hepatitis C infection

The goal of treatment is to cure hepatitis C as cure is associated with multiple clinical benefits, including improvement in quality of life, regression of liver fibrosis and cirrhosis, and a reduction in the risk of liver failure, liver cancer and liver-related mortality.^{64,65} Cure also prevents transmission of infection, particularly important in prisons where there is no access to sterile injecting equipment.

All people in prison living with hepatitis C should be offered antiviral treatment. There are now three pan-genotypic DAA regimens for the treatment of hepatitis C listed on the PBS: i) sofosbuvir plus velpatasvir, ii) glecaprevir plus pibrentasvir, and iii) sofosbuvir plus velpatasvir plus voxilaprevir. The first-line treatment regimens for treatment-naïve people living with hepatitis C are sofosbuvir plus velpatasvir, and glecaprevir plus pibrentasvir (Table 3).³¹ The combination of sofosbuvir plus velpatasvir plus voxilaprevir was specifically developed as a salvage regimen for people who did not respond to previous treatment with a first-line treatment regimen (Table 3).³¹ These simple oral treatment regimens are highly effective and well tolerated. In clinical trials, these regimens were associated with cure rates greater than 95%.⁶⁶ Treatment duration is 8 to 12 weeks.³¹ Treatment for hepatitis C can be prescribed locally by any medical practitioner or nurse practitioner experienced in the treatment of chronic hepatitis C infection, or in (remote) consultation with a gastroenterologist, hepatologist or infectious diseases physician experienced in treating chronic hepatitis C infection.

Consultation with a gastroenterologist/hepatologist or infectious diseases physician is recommended for the following special populations: people with cirrhosis, decompensated liver disease, hepatitis B or HIV co-infection, people with concomitant medications that are associated with problematic drug-drug interactions; or non-response to the second-line treatment regimen. More information about the treatment of hepatitis C is available in the [Australian recommendations for the management of hepatitis C virus infection: a consensus statement](#).³¹

Table 3: Recommended pan-genotypic treatment protocols for people in prison with hepatitis C virus infection and compensated liver disease, including people with HIV coinfection.

Regimen	Dosage	Treatment duration	
		No cirrhosis	Cirrhosis
First-line treatment: people who are treatment naïve			
Sofosbuvir 400 mg, orally, daily + Velpatasvir 100 mg, orally, daily	1 pill daily	12 weeks	12 weeks
Glecaprevir 300 mg, orally, daily + Pibrentasvir 120 mg, orally, daily	3 pills once daily	8 weeks	8 weeks
Second-line treatment: people who did not respond to a first-line treatment regimen			
Sofosbuvir 400 mg, orally, daily + Velpatasvir 100 mg, orally, daily + Voxilaprevir 100mg, orally, daily	1 pill daily	12 weeks	12 weeks

5.2 Models of care for the treatment of hepatitis C

In the context of short prison sentences, models of care for the management of hepatitis C should promote a streamlined cascade of care to maximise testing uptake and minimise the time taken for diagnosis and treatment initiation. Testing and DAA assessment strategies that can reduce delays to hepatitis C treatment have been discussed in Sections 3.0 and 4.0. In addition, **care should be provided locally to people in prison without the need for transfer between prisons, or between prison and hospital clinics. Locally provided treatment can be led by primary care providers, including nurses, nurse practitioners or general practitioners**, as detailed above. Holistic care for people being treated for hepatitis C should include harm reduction strategies to reduce the risk of transmission or reinfection (see Section 6.0).

Telemedicine for remote consultations can be key to ensuring access to high quality prison-based care, and provides opportunities for engagement and mentoring with external healthcare providers such as gastroenterologists/hepatologists/infectious diseases physicians and ACCHOs.^{67,68} The use of regimens with shorter treatment duration can promote completion of treatment within the period of a prison sentence. Where possible, the entire treatment course should be dispensed to people in prison by endorsing the PBS prescription with [Regulation 49](#) (previously regulation 24) to avoid the risk of release without medications; and people should be released with their full treatment course to complete in the community. Linkage to care following release from prison for people living with hepatitis C who have incomplete DAA therapy or not yet started treatment can be challenging. Release planning including direct referral to community hepatitis C care navigators has been shown to increase treatment uptake in the community following release.⁶⁹

5.3 Monitoring of patients and defining cure of hepatitis C

As DAA therapies for hepatitis C are very safe and effective, on-treatment monitoring with laboratory tests is not routinely required.³¹ **We recommend testing to confirm cure following treatment, which is currently defined as undetectable plasma hepatitis C RNA at least 12 weeks after treatment, also known as a sustained virological response (SVR12). Recent data has shown that an undetectable hepatitis C RNA four weeks after treatment (SVR4) also strongly predicts the SVR12 result.^{33,70} Therefore, opportunistic testing of hepatitis C RNA at any time beyond four weeks after treatment completion is adequate, especially where release to the community may be imminent.**

Earlier confirmation of cure (SVR4) may also aid in differentiating reinfections versus treatment failures. The uptake of the SVR12 or SVR4 test by people in prison may be maximised by using less invasive testing procedures such as PoC tests. Liver enzyme testing may be performed at the same time to document return to normal once hepatitis C has been cured. In patients with persistently abnormal liver enzymes post cure, clinicians should consider a second liver disease such as metabolic-dysfunction associated fatty liver disease (MAFLD), or unrecognised cirrhosis and consider a referral to a gastroenterologist/hepatologist.³¹

5.4 Treatment non-response versus hepatitis C reinfection

In people with detectable hepatitis C RNA post-treatment, it is important to try and distinguish treatment non-response from hepatitis C reinfection as this distinction influences the DAA re-treatment plan. Clinicians should consider treatment adherence as well as ongoing risk behaviours for hepatitis C reinfection.^{28,71} If the previous hepatitis C genotype is available, repeated genotype testing is potentially useful, as a genotype “switch” indicates reinfection.⁷² However the same genotype as the initial infection does not rule out reinfection, underscoring the importance of testing for SVR12. Reinfection should not be a barrier to retreatment.

Those who are confirmed or suspected to be non-responders should be re-treated with the combination of sofosbuvir plus velpatasvir plus voxilaprevir, whereas those with confirmed reinfection can be re-treated with the same DAA regimens used for initial treatment (Table 3). More information about the assessment and management of non-response versus reinfection is available in the [Australian recommendations for the management of HCV virus infection: a consensus statement](#).³¹



Reinfection should not be a barrier to retreatment.

6.0 PREVENTION STRATEGIES

Prevention of hepatitis C transmission within prisons remains a key component of prison healthcare and national elimination goals. **The prison environment is associated with an increased risk for hepatitis C transmissions due to the relative lack of access to the harm reduction interventions that have demonstrated efficacy in community settings – primarily regulated needle and syringe programs - and ongoing injecting drug use in prison.** Nationally there is inconsistent in-prison access to opioid agonist therapy (OAT), which offers benefits including a reduction in risk factors for hepatitis C transmission.²¹ People who inject drugs report a lower frequency of injecting drug use while in prison, but an increased likelihood of sharing injecting equipment.^{73,74} Approximately one-third of recently released people who inject drugs report having continued injecting while in prison,^{74,75} and some inject in prison for the first time.⁷⁶ High rates of incident hepatitis C infection (11.4 per 100 person years) are reported within Australian prisons,¹⁹⁻²² undermining the health and economic benefits achieved through the investment in community-based harm reduction and the scale up of DAA therapy in both the community and prisons. This underlines the need for both scale-up of treatment and better prevention during incarceration.

6.1 Harm and demand reduction

6.1.1 Opioid agonist treatment

Benefits from the provision of OAT in prisons include reducing the frequency of injection episodes and needle/syringe sharing among people who inject drugs.⁷⁷⁻⁷⁹ There is varied evidence regarding the effectiveness of prison OAT programs to reduce hepatitis C incidence, with factors such as higher risk behaviours among OAT recipients, timeliness of access and sub-therapeutic doses having a confounding influence on research findings. OAT was not available in prisons across all jurisdictions in Australia until 2018. Methadone has traditionally been the most commonly prescribed OAT,^{80,81} but sublingual or depot buprenorphine have been introduced in some jurisdictions. OAT coverage is estimated to be well below the WHO coverage indicator of >40 per 100 people who have injected drugs in the last 12 months and who are opioid dependent.⁸² Only 28% of participants in the recently completed Surveillance and Treatment of Prisoners with hepatitis C (SToP-C) study who reported injecting drug use during the current imprisonment were enrolled on OAT during their incarceration.²⁸ Better coverage (51%) was found in the PATH Study, a Victorian sample of 400 men leaving prison with recent pre-imprisonment injecting drug use.⁸³ There are also logistical challenges with ensuring continuity of OAT for people moving between custodial settings and the community, with over a third of PATH participants who transitioned from a prison to a community OAT program reporting either interrupted, or discontinued, OAT three months following their release from prison.⁸³ In some jurisdictions measures such as actively facilitated linkage to community prescribers and dispensers, and short-term treatment cost reimbursements, may help to mitigate the risk of treatment interruptions.

A trial of long-acting subcutaneous depot-buprenorphine in Australian prisons has recently demonstrated a comparable safety and efficacy profile to other OAT formulations,⁸⁴ and has become widely used in some jurisdictions.⁸¹ The depot-buprenorphine formulation is attractive for the prison setting due to the reduced potential for diversion and the reduced frequency of patient dosing requirements

(weekly or monthly versus daily or every two to three days). This decreases the administrative and clinical burden and can provide more secure treatment continuity for patients who may be released or transferred at short notice.⁸⁵ A range of OAT options, with treatment matching where possible, should be made available to people in prison.

In the past decade, injection of methamphetamines has become increasingly common, and recent data highlights the high prevalence of pre- and during- imprisonment injection of methamphetamines among people in Australian prisons.^{73,74} There is no substitution therapy currently available for people who use amphetamines, underscoring the urgent need for the development of evidence-based programs to reduce the demand for and harms associated with the use of methamphetamines.

6.1.2 Regulated needle and syringe programs

In community settings, needle and syringe programs (NSP) have been shown to reduce BBV spread, and are particularly effective when implemented in combination with OAT for people who are opioid dependent.⁸⁶ Despite the prevailing equivalence of care principle for people in prison, and specific recommendations related to prison NSP in the National Hepatitis C Strategy 2018-2022 as well as the BBV strategies of South Australia and Western Australia,³⁰ to date no Australian jurisdiction has trialled a regulated NSP in a correctional setting.⁸⁷

Globally, there are 10 countries which currently operate at least one prison-based NSP.⁸⁷ Evaluation of these programs supports their feasibility and a reduction in needle/syringe sharing or reuse, with no increase in occupational risk for staff.^{88,89} A recent systematic review found that prison-based NSP may contribute to the prevention of BBV transmission among people in prison, but the literature is limited with only a small number of studies having been conducted.⁹⁰ Models of prison NSP vary considerably - to be effective they need to be accessible, confidential, trusted by people in prison and available in prisons across the whole jurisdiction as inter-prison transfer is common.^{91,92} The implementation of prison-based NSPs requires careful coordination and planning, with the engagement of a broad range of stakeholders, to ensure the best possible design for the local context and widespread engagement. The implementation of prison based NSPs should also be accompanied by rigorous process and outcome evaluations to contribute both to the international evidence base and to support the refinement, maintenance and expansion of local programs.

6.1.3 Disinfectants

Some Australian jurisdictions currently provide people in prison access to a quaternary amine disinfectant or bleach, for general cleaning purposes, which may include use in cleaning used needles/syringes, and tattooing/body piercing implements. As a hepatitis C prevention strategy in prison conditions, the evidence for such disinfectants is weak^{79,93} as efforts to clean used needles/syringes can be hampered by accessibility to bleach/disinfectant supplies, the time and environment to use it appropriately,⁹⁴ and the risk to the integrity and function of needles/syringes.^{79,95} In the absence of prison NSPs, the availability of disinfectants/bleach may be considered a suitable, although sub-efficacious, harm reduction strategy.

6.2 Treatment as prevention

The hepatitis C
incidence declined by

48%



Initially used in the context of HIV combination antiretroviral therapy,⁹⁶ treatment-as-prevention (TasP) utilises population-wide scale-up of effective DAA treatment as a tool for limiting transmissions in epidemics in a particular setting.⁶² **Recent data has established the efficacy of TasP for hepatitis C in Australian prisons.** The SToP-C study assessed hepatitis C TasP in four Australian prisons enrolling a total of 3,691 participants (approximately 70% of all people incarcerated in the centres), of whom 2,965 were at-risk of primary infection (n=2,240) or re-infection (n=725). DAA treatment was conducted in a 'business-as-usual' phase for all those with chronic hepatitis C before scale-up, in which 80% of those diagnosed received DAA treatment with sofosbuvir/velpatasvir. Among the at-risk population with longitudinal follow-up, 31% reported injecting drugs during their current imprisonment. **The hepatitis C incidence declined by 48%, from 8.31 to 4.35 per 100 person-years between pre- and post-treatment scale-up periods.**⁹⁷ This landmark study has established TasP as an effective prevention tool in the prison setting.

However, there are valid concerns about the potential futility of DAA treatment in a context of high rates of risk behaviour and ongoing transmissions, as well limited access to harm reduction.⁷¹ In the SToP-C study, the TasP effect on the incidence of re-infection (after spontaneous or treatment-associated clearance) declined from 12.36 to 7.27 per 100 person-years.²⁸ Whilst TasP is effective, modelling studies, including those based on data from SToP-C, clearly indicate that combined implementation of sterile needle/syringe provision, OAT, as well as scale up of hepatitis C treatment is the most effective means of mitigating hepatitis C transmissions in prisons.⁹⁸

Accordingly, it is evident a holistic approach to hepatitis C management is necessary; an approach that recognises the complexity of drug use trajectories, combined with frequent incarceration episodes, and includes tailored education for people in prison, correctional officers and healthcare workers, improved coverage of OAT, as well as DAA treatment, and regulated provision of sterile needles and syringes.⁹⁸

The Fifth National Hepatitis C Strategy⁵ and Fifth National Aboriginal and Torres Strait Islander Blood Borne Virus and Sexually Transmitted Infections Strategy¹⁸ highlight the importance of increasing awareness and provision of hepatitis C education tailored specifically to people in custodial settings. Knowledge of hepatitis C transmission risk is particularly poor among youth in detention.⁹⁹ The goal of hepatitis C education must go beyond a focus on improving knowledge to changing attitudes and risk behaviours.^{100,101} A systematic review of hepatitis C education interventions revealed consistent supporting evidence for improvements in patients' hepatitis C knowledge, reported testing behaviours, as well as willingness to commence treatment, both among people living with hepatitis C and high-risk groups (people with current and recent injecting drug use), in non-custodial settings (AOD facilities, specialist clinics).¹⁰² An 'educate, test, and treat' program designed around enhancing knowledge, shifting attitudes, and changing health-seeking behaviours (i.e. health literacy concepts) amongst a community population in rural Egypt was shown to underpin dramatically enhanced engagement with hepatitis C services.^{103,104} Prison-based hepatitis C education programs that address key barriers in custodial settings (lack of awareness of hepatitis C and of DAA treatment efficacy, harm reduction strategies, and stigma)^{73,105-107} have the potential to similarly achieve positive outcomes and enhance testing and treatment rates amongst prison populations.^{11,105} Use of peer-educators may be an attractive and cost-effective strategy for the custodial setting.^{105,108,109} Correctional officers involved with supporting prison-based drug treatment programs in Nordic countries reported that an increased awareness of the benefits of engaging people in prison with treatment positively influenced their own behaviours regarding how to engage with, better support, and ultimately, help rehabilitate people in prison.¹¹⁰ Thus, in addition to educating the imprisoned population, there is clear potential to upskill correctional officers and healthcare providers regarding the benefits of enhanced hepatitis C testing, treatment and prevention in the prisons to similarly overcome stigma and raise awareness of the benefits of DAAs and harm reduction, both for the prison sector and the wider community.^{11,106,107}

Addressing stigma requires cultural change, innovation in education and service delivery, committed leadership, operational investment and engagement with people imprisoned.

8.0 THE PERSPECTIVES OF PEOPLE IN PRISON AND THE EXPERIENCE OF STIGMA

Prison is a unique environment and presents distinct organisational and policy challenges in relation to the provision of health services, including the inherent power imbalance between people incarcerated and health and correctional workers. At the same time, the prison setting may facilitate uptake of hepatitis C treatment among people who have encountered barriers to access in the community including competing priorities, geography, transport, cost of appointments, and multiple visits for pathology, assessment and prescription dispensing.¹¹¹ Imprisonment may also be a self-motivating factor by providing structured routine, an opportunity for self-improvement, and removing the distraction of the competing priorities of everyday life.^{105,111}

Australian and international research on the perspectives of people in prison highlights several structural/environmental, social, and individual barriers and enablers impacting the uptake of prison-based hepatitis C testing and treatment. People in prison have described apprehension regarding invasive tests, treatment side effects, reinfection risk, lack of social support and physical vulnerability in prison.^{105,111,112} Stigma and discrimination, lack of confidentiality and unintended disclosure are universal themes and carry potential consequences such as social isolation, additional disciplinary attention and targeted drug screening.^{105,107,111-114} Addressing stigma requires cultural change, innovation in education and service delivery, committed leadership, operational investment and engagement with people imprisoned.^{107,115} Assessments of social impacts, including stigma, should feature in the development of any policy or intervention. In particular, the avoidance of attributing blame is paramount.¹¹¹ Both the process of imprisonment and the barriers to accessing prison health services are commonly associated with and mediated by structural, institutional, and individual racism.

9.0 CONCLUSION

The prison sector is increasingly recognised as a key venue for scale-up of services for the prevention, diagnosis and treatment of people with hepatitis C infection, thereby supporting Australia's elimination efforts. Crucially, scaling up hepatitis services in prisons confers both individual and public health benefits. In addition, the prison setting is also recognised to be an important venue for ongoing transmissions which may undermine the elimination efforts, and so should be a priority setting for harm reduction and educational interventions. Nevertheless, the prison environment is uniquely challenging for health service delivery. Accordingly, the best practice recommendations outlined in this statement recognise these challenges and set minimum standards in the form of key performance indicators for the sector.

Each of the recommendations is supported by the cited evidence and the quality evaluated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach¹¹⁶ which is considered best practice by many international organisations that develop policy and practice recommendations. The key performance indicators seek to establish measures for quantification of successful implementation of the best practice recommendations for regular reporting to jurisdictional and Commonwealth agencies. Regular reporting of the key performance indicators will provide data to underpin implementation of the National Hepatitis C Strategy at both the jurisdictional and national levels. These data will also inform continued Australian efforts to achieve the WHO elimination goals.

METHODOLOGY

This consensus statement was prepared by an NPHN writing group consisting of clinicians, specialist nurses, and public health researchers. The process of development was led by the NPHN Chair and co-Vice Chairs, the NPHN Coordinator, and an appointed statement Coordinator ('statement sub-committee') (Appendix 1). The development of the statement was undertaken in a phased process.

Phase i: planning

The writing group was identified by the statement sub-committee according to expertise and with a view to varied jurisdictional representation; members of the writing group are listed in Appendix 1. Key stakeholder groups and representatives were also identified.

Phase ii: literature review, writing and peer review

Members of the writing group were invited to research and write topic sections in groups of two or three according to their specific expertise. The writing group synthesised evidence from the published literature and scientific abstract presentations available in English language at the time of writing. Draft sections were reviewed by at least two other members of the writing group and then collated and edited by the statement sub-committee.

Phase iii: development of recommendations and KPIs

The writing group (including the statement sub-committee) formulated draft recommendations based on the evidence synthesis conducted in Phase ii. The content, application, wording and feasibility of each of the recommendations was discussed in detail at a special meeting of the writing group. For each recommendation, the strength of supporting evidence was rated according to the GRADE system.¹⁰¹ 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 offers two grades of recommendation: strong (1) or weak (2) (see Table 4). Consensus between members of the writing group was achieved at the pre-determined level of 7 of 9 anonymous votes, conducted via live online polling. Where necessary, the content of recommendations was discussed and revised to achieve consensus.

Phase iv: stakeholder feedback and consolidation

Key stakeholder groups identified in Phase i were invited to comment on the draft statement, with a view to formal endorsement in the final stage. Twelve organisations (listed in Appendix 1) were invited to comment on the draft and all of them provided feedback.

Phase v: stakeholder endorsement

The statement was endorsed by the NPHN Executive at the March 2022 meeting (with one member abstaining from voting). Professional associations and peak consumer organisations were also invited to formally endorse the statement (Appendix 1).

Table 4: GRADE system classification of recommendations

Evidence quality	Notes	Grade
High	Further research is very unlikely to change our confidence in the estimate of the effect.	A
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	B
Low	Further research is very likely to have an important impact on our confidence in the estimate and is likely to change the estimate. Any change of estimate is uncertain.	C
Recommendation	Notes	Grade
Strong	Factors influencing the strength of the recommendation included the quality of the evidence, presumed patient-important outcomes and cost.	1
Weak	Variability in preferences and values, or more uncertainty. Recommendation is made with less certainty, higher cost or higher resource consumption.	2

GLOSSARY

ACCHO	Aboriginal Community-Controlled Health Organisation
ARFI	acoustic radiation force impulse
APRI	AST-to-platelet ratio index
BBV	Blood-borne virus
anti-HBc	Hepatitis B core antibody
anti-HBs	Hepatitis B surface antibody
DAA	Direct-acting antiviral
DBS	Dried blood spot
FBE	Full blood examination
HCC	Hepatocellular carcinoma
HIV	Human immunodeficiency virus
HBsAg	Hepatitis B surface antigen
INR	International normalised ratio (of prothrombin time)
MAFLD	metabolic-dysfunction associated fatty liver disease
NPHN	National Prisons Hepatitis Network
NSP	Needle and syringe program
OAT	Opioid agonist therapy
PBS	Pharmaceutical Benefits Scheme
PoC	Point of care
RNA	Ribonucleic acid
SVR12	Sustained virological response
TasP	Treatment as Prevention
TGA	Therapeutic Goods Administration
WHO	World Health Organization

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APPENDIX 1

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A2. Members of the NPHN Executive Committee

Name	Role(s)	Years of membership
Alexander Thompson	Author, statement sub-committee	2017 - current
Andrew Lloyd	Author, statement sub-committee	2017 - current
Yumi Sheehan	Author, statement sub-committee	2018 - current
Mark Stoové	Author, statement sub-committee	2020 - current
Anton Colman	Author	2018 - current
Joy Rowland	Author	2018 - current
Graeme Macdonald	Author	2018 - current
Colette McGrath	Service Director Population Health, Justice Health and Forensic Mental Health Network, NSW	2018 - current
Carrie Fowlie	Chief Executive Officer, Hepatitis Australia, ACT	2021 - current
Catherine Marshall	Infectious Diseases Physician, Royal Darwin Hospital, NT	2018 - current
Chris Wake	Clinical Director, Correctional Health Services, TAS	2018 - current
Katerina Lagios	Clinical Director, Justice Health Services, ACT	2018 - 2021
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The following organisations and collectives provided valuable feedback on an early draft of the Statement:

AbbVie, Australasian Hepatology Association, Australian Illicit and Injecting Drug Users League, Australian Professional Society on Alcohol and other Drugs, Australian Society for Infectious Diseases, Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, Commonwealth Department of Health, Gastroenterology Society of Australia, Gilead Sciences, the Harm Reduction in Prisons Reference Group, Hepatitis Australia, National Aboriginal Community Controlled Health Organisation, Society of Hospital Pharmacists of Australia. The statement has been endorsed by the Australasian Hepatology Association, Australian Professional Society on Alcohol and other Drugs, Australian Society for Infectious Diseases, Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine, Gastroenterology Society of Australia, Society of Hospital Pharmacists of Australia.



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