Research Article
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A 'one-stop-shop' point-of-care hepatitis C RNA testing intervention to enhance treatment uptake in a reception prison: The PIVOT study

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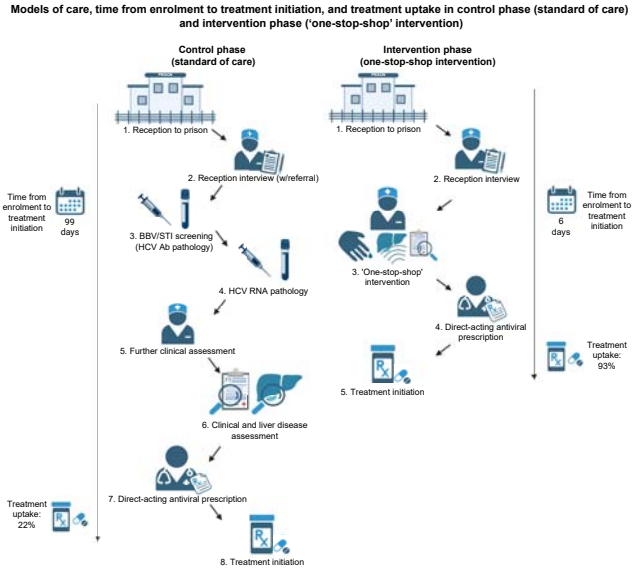
Graphical abstract



Highlights

- The proportion tested for HCV was higher in the intervention (99%) compared with the control phase (26%).
- The proportion treated for HCV was higher in the intervention (93%) compared with the control phase (22%).
- Median time from diagnosis to treatment initiation was shorter in the intervention than in the control phase (6 *vs.* 25 days).
- Combining all key HCV assessments into a single visit improved efficiencies and enhanced testing and treatment uptake.

Impact and implications

This study provides important insights for policymakers regarding optimal HCV testing and treatment pathways for people newly incarcerated in prisons. The findings will improve health outcomes in people in prison with chronic HCV infection by increasing testing and treatment, thereby reducing infections, liver-related morbidity/mortality, and comorbidities. The findings will change clinical practice, clinical guidelines, and international guidance, and will inform future research and national and regional strategies, in particular regarding point-of-care testing, which is being rapidly scaled-up in various settings globally. The economic impact will likely include health budget savings resulting from reduced negative health outcomes relating to HCV, and health system efficiencies resulting from the introduction of simplified models of care.

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A 'one-stop-shop' point-of-care hepatitis C RNA testing intervention to enhance treatment uptake in a reception prison: The PIVOT study

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Background & Aims: Prisons are key venues for scaling-up hepatitis C virus (HCV) testing and treatment. Complex clinical pathways and frequent movements of people in prison remain barriers to HCV care. This study evaluated the impact of a 'one-stop-shop' point-of-care HCV RNA testing intervention on treatment uptake compared with standard of care among people recently incarcerated in Australia.

Methods: PIVOT was a prospective, non-concurrent, controlled study comparing HCV treatment uptake during 'standard of care' (n = 239; November 2019–May 2020) and a 'one-stop-shop' intervention (n = 301; June 2020–April 2021) in one reception prison in Australia. The primary endpoint was uptake of direct-acting antiviral treatment at 12 weeks from enrolment. Secondary outcomes included the time taken from enrolment to each stage in the care cascade.

Results: A total of 540 male participants were enrolled. Median age (29 *vs.* 28 years) and history of injecting drug use (48% *vs.* 42%) were similar between standard of care and intervention phases. Among people diagnosed with current HCV infection (n = 18/63 in the standard of care phase *vs.* n = 30/298 in the intervention phase), the proportion initiating direct-acting antiviral treatment within 12 weeks from enrolment in the intervention phase was higher (93% [95% CI 0.78–0.99] *vs.* 22% [95% CI 0.64–0.48]; p <0.001), and the median time to treatment initiation was shorter (6 days [IQR 5–7] *vs.* 99 days [IQR 57–127]; p <0.001) compared to standard of care.

Conclusions: The 'one-stop-shop' intervention enhanced treatment uptake and reduced time to treatment initiation among people recently incarcerated in Australia, thereby overcoming key barriers to treatment scale-up in the prison sector.

Clinical Trials Registration: This study is registered at Clinicaltrials.gov (NCT04809246).

Introduction

Hepatitis C virus (HCV) infection disproportionately affects people who inject drugs and people in prison (the term 'prisons' is used here to describe correctional facilities, including gaols/jails, prisons, and other custodial settings).[1,2] Scale-up of HCV testing and treatment in prisons is critical for HCV elimination.[3,4] Complex clinical pathways, short stays, and frequent movements are barriers to HCV care in prisons.[5,6] More efficient models of care are required to enhance engagement with HCV testing and treatment in prisons.[3,7]

Few studies have evaluated the effectiveness of interventions to enhance HCV care in prisons.[8,9] In a systematic review, effective interventions to enhance HCV testing in prisons included on-site testing with education and counselling, risk-based screening, and dried blood spot testing.[8] Only one study evaluated an intervention to enhance linkage to HCV care, which assessed facilitated referrals for treatment initiation.[8] Recently, a simplified two-step test and treat strategy was shown to enhance treatment uptake in prison.[10] The World Health Organization has released updated guidelines recommending simplification of service delivery and a move towards a 'one-stop-shop' for prison settings.[11] However, further evaluation of interventions to enhance treatment uptake is required.

Point-of-care HCV RNA testing to detect current HCV infection within one hour has streamlined HCV care.[12] The Xpert® HCV Viral Load Fingerstick point-of-care test enables diagnosis and treatment in a single visit, increases testing acceptability, and reduces loss to follow-up, thereby enhancing treatment uptake. This assay has good technical accuracy (100% sensitivity/specificity),[13–15] and results in high treatment uptake in needle and syringe programmes (81%),[16] medically supervised injecting sites (89%),[17] and mobile outreach models (74%).[18] The improved timeliness, simplicity, and acceptability

Keywords: HCV; Incarceration; Prisoners; People who inject drugs; DAA treatment.
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of point-of-care HCV RNA testing could overcome barriers to HCV testing and treatment in prison.[14,19] Previous studies evaluating point-of-care HCV RNA testing in prison are limited by a lack of comparator arms and small sample sizes.[9,10]

This study aimed to evaluate the impact of an intervention integrating point-of-care HCV RNA testing, fibro-elastography, nurse-led clinical assessment, and fast-tracked direct-acting antiviral (DAA) prescription ('one-stop-shop' intervention) on HCV treatment uptake compared with standard of care among people recently incarcerated in Australia.

Patients and methods

Study population and design

PIVOT was a prospective, non-concurrent controlled study (clinicaltrials.gov: NCT04809246). Participants were enrolled from one male reception prison (correctional centre for newly incarcerated males) in New South Wales, Australia into a control (October 2019–May 2020) or intervention phase (June 2020–April 2021).

Participants were ≥18 years, male, incarcerated within the previous 6 weeks, and DAA treatment-naïve. People with treatment experience and cirrhosis were excluded and referred to the hepatitis service for more complex clinical assessment. Full eligibility criteria are provided in the study protocol (see supplementary material).

All participants provided written informed consent. The study protocol was approved by the Human Research Ethics Committees of the Justice Health and Forensic Mental Health Network, the Aboriginal Health & Medical Research Council, Corrective Services NSW, and ratified by UNSW Sydney. The study was conducted in accordance with the Declaration of Helsinki and International Conference on Harmonisation Good Clinical Practice (ICH/GCP) guidelines.

Procedures

Control phase – standard of care

Participants completed a nurse-administered survey and received HCV testing and treatment in a protocol-driven, nurse-led model of care with assessments conducted over several separate visits (Fig. 1). A medical chart review was performed by the dedicated study nurse to collect information on HCV testing (antibody and RNA), hepatitis B virus (HBV) testing, fibrosis assessment, and HCV treatment (including response at 12-weeks post-treatment [SVR12]).

Intervention phase – 'one-stop-shop' intervention

Participants completed a nurse-administered survey and received HCV testing and treatment as part of a 'one-stop-shop' intervention which incorporated HCV RNA point-of-care testing and other assessments in a single visit (Fig. 1). Participants initiating DAA treatment had follow-up visits at weeks 8 (treatment completion) and 20 (SVR12), involving point-of-care HCV RNA testing and a nurse-administered survey.

HCV RNA testing was performed using the Xpert® HCV Viral Load Fingerstick Assay (Cepheid, Sunnyvale, CA, USA) and HBsAg testing was performed using the Alere Determine 2 assay (Abbott, USA) – both from a capillary blood sample collected via finger prick. Liver fibrosis assessment was performed using transient fibro-elastography (FibroScan®; Echosens, Paris, France). Results for HCV RNA, HBsAg, and fibrosis status were provided to participants on the same day.

Eligible participants treated through the 'one-stop-shop' intervention were prescribed three fixed-dose combination tablets of glecaprevir (100 mg) and pibrentasvir (40 mg) administered orally once daily for 8 weeks received as monthly bottles for self-administered therapy (if permitted) or supervised daily dosing.

Surveys

The enrolment survey collected self-reported data on demographics, sentence information, injecting drug use and risk behaviours, and HCV testing and treatment history. Follow-up surveys collected self-reported data on injecting drug use and risk behaviours. Survey data were entered on a tablet computer by the study nurse. Participants in both phases were reimbursed AUD$10 per study visit (deposited into their prison bank account).

Study outcomes

The primary endpoint was the proportion of participants with HCV infection who initiated treatment within 12 weeks of enrolment. Secondary outcomes included the proportion of participants with valid HCV testing (antibody and/or RNA) within 12 weeks of enrolment, time from reception and enrolment to each stage in the care cascade, and time from HCV diagnosis to DAA prescription and treatment initiation. Among people who initiated DAA treatment, secondary outcomes included the proportion who completed treatment, treatment adherence, and SVR12.

Statistical analysis

The study planned to recruit 720 participants with an assumed HCV RNA prevalence of 30% and a treatment uptake of 75% in the intervention group, the study had 96% power to detect a difference in the proportion initiating DAA treatment during the control and intervention periods (p <0.05). The study had 82% power to detect an increase in DAA initiation from 50% in the control period to 70% in the intervention period. Because of funding limitations, a decision was made during the study to limit recruitment to 540 participants (75% of those originally planned) and close the study early (protocol revision December 2020).

Proportions were assessed using the Chi square test or Fisher's exact test. Unadjusted and adjusted logistic regression models were used to evaluate the impact of the intervention on treatment uptake within 12 weeks of enrolment in participants with current HCV infection. Adjusted models included key factors hypothesised to be associated with treatment uptake, including recent injecting drug use and receipt of opioid agonist treatment (OAT).

The time from reception and enrolment to each step in the care cascade, and time taken from diagnosis of HCV infection to initiation of DAA treatment in the control and intervention phases were compared using the Mann–Whitney U test. The time to treatment initiation in the control and intervention phases was visualised using a Kaplan–Meier curve with groups compared using log rank tests. Stata (version 17.0, StataCorp LLC, College Station, TX, USA) was used for all analyses.

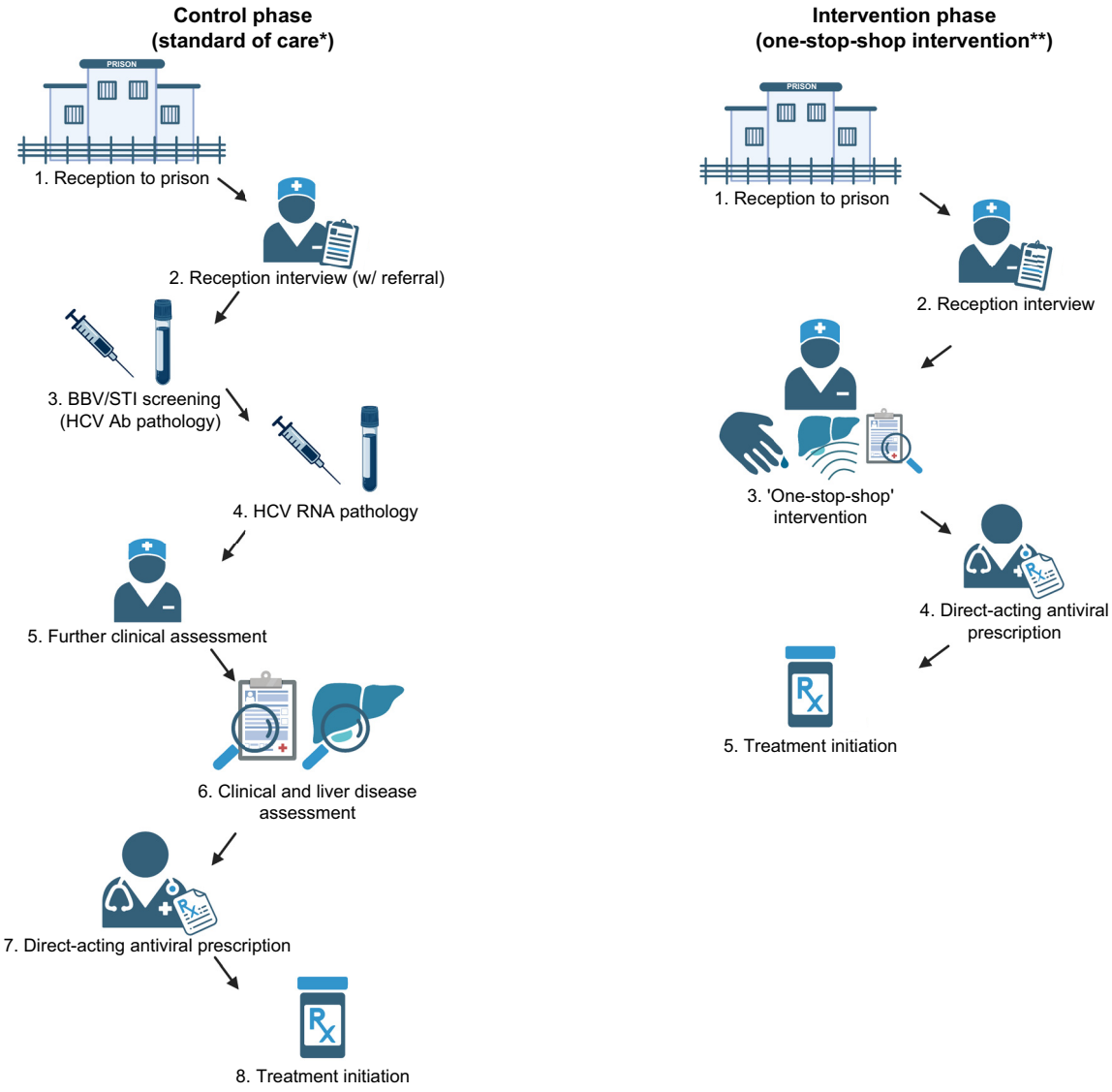

Fig. 1. Models of care in control phase (standard of care) and intervention phase ('one-stop-shop' intervention). *Following reception to prison (1), all newly incarcerated people participated in the standard of care. Standard of care was a protocol-driven, nurse-led model of care involving the following steps: risk screening for BBVs (including HCV) with a primary care nurse on reception to prison (2). People with risk factors for BBV infections were referred for assessment by public health nurses, including opt-out on-site phlebotomy for HCV antibody testing at an off-site laboratory (3), with a second visit for HCV RNA testing in individuals who were antibody positive (4). Those with current HCV infection were assessed for DAA treatment (5), including laboratory investigations, triaged fibrosis assessment using the AST to Platelet Ratio Index (APRI) and/or fibro-elastography, and a clinical assessment by a nurse (including review of comorbidities and potential drug–drug interactions; (6). Nurses then made an electronic referral to an infectious diseases physician for DAA prescription (or for telemedicine consultation for those with prior treatment experience, complex comorbidities, or evidence of decompensated cirrhosis before ultimate DAA prescription); (7) and supervised treatment initiation (8). Numbers in parentheses relate to the numbers in Fig. 1. DAA prescription involved once-weekly scripting and once-weekly medication dispatch from the pharmacy. **Following reception to prison (1) and standard risk screening (2), all newly incarcerated people were offered the 'one-stop-shop' intervention which was a streamlined model of care involving opt-out point-of-care HCV RNA and hepatitis B surface antigen (HBsAg) testing, fibro-elastography to exclude cirrhosis, nurse-led clinical assessment (3), followed by fast-tracked DAA prescription (4) and treatment initiation (5). Numbers in parentheses relate to the numbers in Fig. 1. Fast-tracked DAA prescription involved a dedicated specialist who was available for remote scripting several times per week and a special arrangement with the pharmacy for twice-weekly priority dispatch to the study prison. APRI, AST-to-platelet ratio index; AST, aspartate aminotransferase; BBV, blood-borne virus; DAA, direct-acting antiviral.

Results

Participant characteristics

There were 541 participants enrolled, including 240 in the control phase (November 2019–May 2020) and 301 in the intervention phase (June 2020–April 2021; Fig. 2). One ineligible participant (protocol violation) was excluded (control phase), leaving 540 participants.

At enrolment, participant characteristics were similar between control and intervention phases (Table 1), including mean age (29 *vs.* 28 years), Aboriginal and/or Torres Strait Islander descent (54% *vs.* 49%), history of incarceration (80% *vs.* 80%),

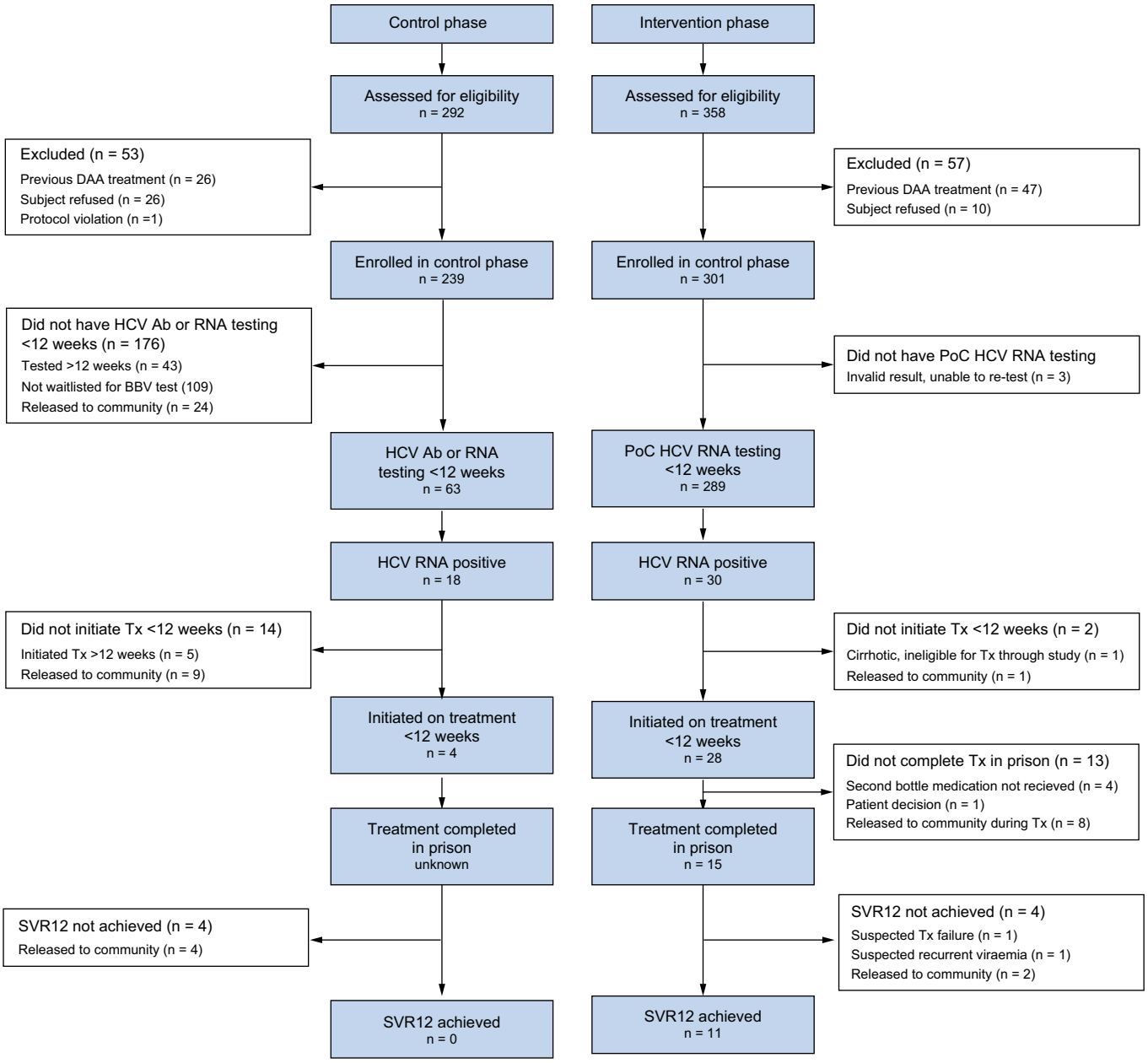

Fig. 2. Participant disposition comparing control and intervention phases among enrolled population. BBV, blood-borne virus; DAA, direct-acting antiviral; PoC, point-of-care; SVR12, sustained virological response at 12 weeks post-treatment; Tx, treatment.

history of injecting drug use (48% *vs.* 42%), recent injecting drug use (35% *vs.* 32%), and current OAT (8% *vs.* 4%).

Care cascade

In the control phase, 239 participants were enrolled, of whom 63 (26%) received HCV antibody and/or RNA testing within 12 weeks (Figs 2 and 3 and Table 2). Among those tested, 18 (29%) participants had current HCV infection, of whom 12 (67%) underwent a clinical assessment, and four (22%) initiated treatment within 12 weeks of enrolment (glecaprevir/pibrentasvir, n = 3; sofosbuvir/velpatasvir, n = 1). All four participants initiating treatment were released to the community during treatment and lost to follow-up before SVR12.

In the intervention phase, 301 participants were enrolled, of whom 298 (99%) had a valid point-of-care HCV RNA test result (three invalid results could not be re-tested; Fig. 2). The proportion of participants with a valid test for HCV (HCV Ab and/or RNA) within 12 weeks from enrolment was higher in the 'one-stop-shop' intervention than in the standard of care phase (99% *vs.* 26%; p <0.001; Table 2).

Among those tested in the intervention phase (n = 298), 30 (10%) were found to have current HCV infection, of whom 29 (97%) underwent further clinical assessment, and 28 (93%) initiated treatment within 12 weeks. Among those not initiating treatment (n = 2), one had evidence of cirrhosis (ineligible for treatment through the study), and one was released to the community shortly after testing. Among people with current

Table 1. Participant characteristics among enrolled and HCV RNA population, stratified by group.

	Overall (n = 540)		HCV RNA positive (n = 48)	
Variable	**Control**	**Intervention**	**Control**	**Intervention**
Male, n (%)	239 (100)	301 (100)	18 (100)	30 (100)
Age, median (IQR)	29 (22–34)	28 (20–34)	24 (20–33)	27 (20–31)
Aboriginal and/or Torres Strait Islander, n (%)	130 (54)	148 (49)	13 (72)	16 (53)
Previous incarceration, n (%)	191 (80)	242 (80)	18 (100)	29 (97)
Sentenced, n (%)	41 (17)	43 (14)	5 (28)	5 (17)
Injecting drug use ever, n (%)	115 (48)	125 (45)	18 (100)	28 (93)
Injecting drug use in past 6 months, n (%)	84 (35)	95 (32)	16 (89)	23 (77)
History of OAT				
Never, n (%)	190 (79)	264 (88)	10 (56)	22 (73)
Yes, but not currently receiving OAT, n (%)	30 (13)	25 (8)	6 (33)	5 (17)
Currently receiving OAT, n (%)	19 (8)	12 (4)	2 (11)	3 (1)

IQR, interquartile range; OAT, opioid agonist treatment.

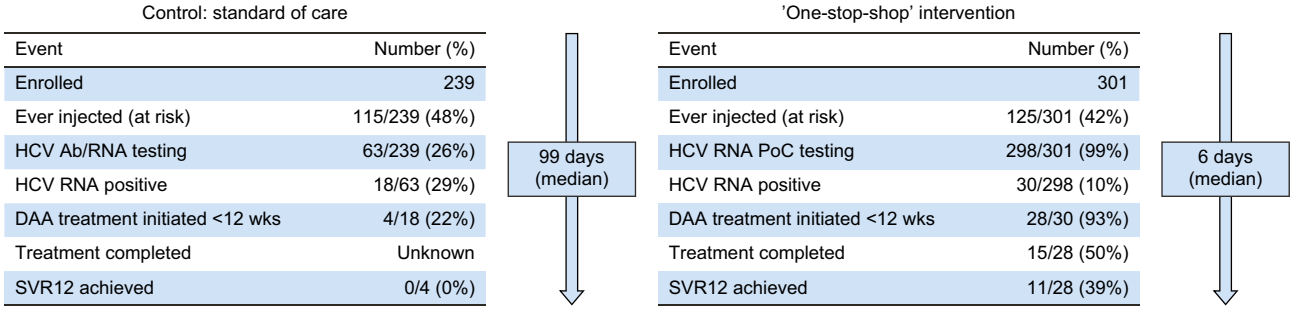

Fig. 3. HCV care cascade comparing control and intervention phases among enrolled and population initiating DAA treatment within 12 weeks. *Using the entire enrolled population as the denominator, the HCV RNA positivity rate in the control phase was 8% which was comparable to the 10% positivity rate in the intervention phase. Ab, antibody; DAA, direct-acting antiviral; PoC, point-of-care; SVR12, sustained virological response at 12 weeks post-treatment.

Table 2. Comparison of study endpoints among enrolled population stratified by group.

Participant disposition	**Control**	**Intervention**	***p* value***
Overall (n = 540)			
Participants tested for HCV antibody, n (%)			
Within 12 weeks following enrolment	41 (17)	—	—
Any testing	81 (34)	—	—
Participants tested for HCV antibody and/or HCV RNA, n (%)			
Within 12 weeks following enrolment	63 (26)	298 (99)	<0.001
Any testing	106 (44)	298 (99)	<0.001
Participants tested for HBV, n (%)			
Within 12 weeks following enrolment	55 (23)	300 (100)	<0.001
Any testing	91 (38)	300 (100)	<0.001
HCV RNA detectable (n = 48)			
Participants who initiated treatment, n (%)			
Within 12 weeks following enrolment	4 (22)	28 (93)	<0.001
Any treatment	9 (50)	28 (93)	<0.001
Initiated HCV treatment within 12 weeks (n = 32)			
Participants who completed treatment (ETR), n (%)			
Completed full treatment course	—	15 (54)	—
Discontinued treatment	—	5 (18)	—
Lost to study follow-up	—	8 (29)	—
Study follow-up (SVR12), n (%)			
Completed study follow-up	0 (0)	13 (46)	0.13
Did not complete study follow-up	4 (100)	15 (54)	
Participants tested for HCV RNA at SVR12, n (%)			—
Study site	0 (0)	6 (46)	—
Non-study site	0 (0)	7 (54)	—
Participants who were HCV RNA positive at SVR12, n (%)	—	2 (9)	—

*The *p* value is the result of X^2 or Fisher's exact tests, as appropriate. Mann-Whitney *U* tests were used to compare time to events in both control and intervention phases. Dashes included in the control column indicate 'not offered as part of standard of care' or 'not applicable'. Dashes included in the Intervention column indicate 'not offered as part of the 'one-stop-shop' intervention'. ETR, end-of treatment response; HBV, hepatitis B virus; SVR12, sustained virological response at 12 weeks post-treatment.

Table 3. Time to events among the enrolled population stratified by group.

	Control	Intervention
Care cascade (days from reception), median (IQR)		
HCV antibody testing	33 (3–94)	–
HCV RNA testing	49 (22–83)	12 (5–17)
Provision of HCV RNA results	91 (63–125)*	12 (5–17)
Clinical assessment for DAA suitability	88 (55–137)*	14 (5–16)
Liver fibrosis assessment (APRI/FibroScan®)	88 (37–137)*	12 (5–17)
DAA prescription	98 (47–130)	15 (7–18)
Treatment initiation	100 (62–141)	18 (13–22)
Care cascade (days from enrolment), median (IQR or range)		
HCV antibody testing	26 (0–83)	–
HCV RNA testing	47 (16–74)	0 (0–0)
Provision of HCV RNA results	84 (57–111)	0 (0–41)
Clinical assessment for DAA suitability	85 (50–130)	0 (0–0)
Liver fibrosis assessment (APRI/FibroScan®)	85 (28–130)	0 (0–0)
DAA prescription	91 (42–119)	1 (1–3)
Treatment initiation	99 (57–127)	6 (5–7)
Care cascade (days from HCV diagnosis), median (IQR)		
Clinical assessment for DAA suitability	0 (0–7)	0 (0–0)
Liver fibrosis assessment (APRI/FibroScan®)	0 (0–15)	0 (0–0)
DAA prescription	15 (1–28)	1 (1–3)
Treatment initiation	25 (18–62)	6 (5–7)

APRI, AST-to-platelet ratio index; AST, aspartate aminotransferase; DAA, direct-acting antiviral.
*Each individual received an RNA test followed by clinical/liver fibrosis assessment and then received RNA results. The differences in time to event are a result of reporting in the population-level *vs*. individual-level data (median days to event is reported). Mann-Whitney *U* tests were used to compare time to events in both control and intervention phases.

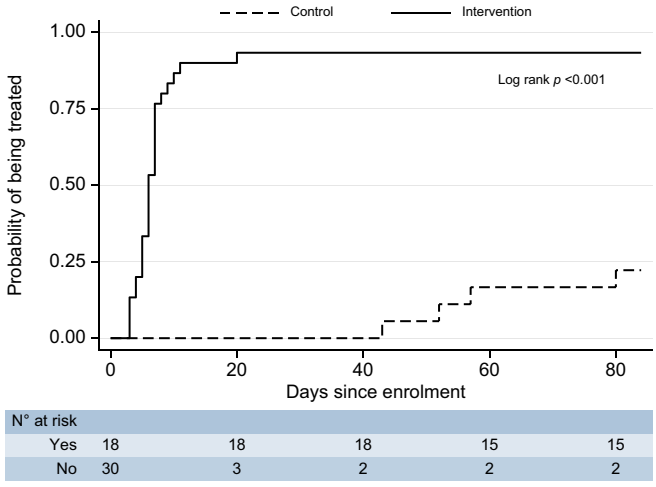

Fig. 4. Kaplan–Meier curve for probability of being treated among population initiating DAA treatment within 12 weeks. DAA, direct-acting antiviral.

HCV infection, the proportion initiating DAA treatment within 12 weeks was significantly higher (93% [95% CI 0.78–0.99] *vs.* 22% [95% CI 0.64–0.48]; *p* <0.001) in the 'one-stop-shop' intervention compared with standard of care (Fig. 4). In unadjusted analysis, the intervention was associated with increased HCV treatment initiation (odds ratio 49.00, 95% CI 7.99–300.79; *p* <0.001; Table 4). In analyses adjusting for recent injection drug use and current opioid agonist therapy, the intervention was associated with increased HCV treatment initiation (adjusted OR 82.35, 95% CI 7.93–855.52; *p* <0.001; Table 4).

Among participants initiating treatment in the intervention phase (n = 28), 15 (54%) completed treatment in prison. Among 13 people who did not complete treatment in prison, four did not receive their second (last) bottle of medication but remained in prison, one decided not to continue treatment, and eight were released to the community while on treatment. Overall, 13/28 were tested for SVR12 and 11 achieved SVR12. Among the four people who completed treatment while in prison but did not achieve SVR12, two were HCV positive at SVR12 (one suspected treatment failure as a result of incomplete treatment and one recurrent viraemia) and two were released to the community before SVR12 testing. In a modified intent-to-treat analysis (excluding those with missing HCV RNA testing at SVR12), 11 of 13 (85%) achieved SVR12.

Table 4. Multivariate logistic regression of HCV treatment uptake within 12 weeks.

Variable	Treated	Not treated	Odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Phase, n (%)				
Control	4 (22)	14 (78)	–	–
Intervention	28 (93)	2 (7)	49.00 (7.99–300.79)	82.35 (7.93–855.52)
Recent injecting drug use, n (%)*				
No	8 (89)	1 (11)	–	–
Yes	24 (62)	15 (38)	0.20 (0.02–1.76)	0.23 (0.01–4.47)
History of OAT, n (%)				
Never	24 (75)	8 (25)	–	–
Yes, but not currently on OAT	6 (55)	5 (45)	0.40 (0.10–1.67)	0.93 (0.09–9.48)
Currently on OAT	2 (40)	3 (60)	0.22 (0.03–1.56)	0.09 (0.00–1.79)

*Injecting drug use within past 6 months. OAT, opioid agonist treatment.

Among intervention phase participants, seven (47%) had at least one adverse event. No serious adverse events were reported. The most common adverse event was early discontinuation of therapy as a result of failure of the health service to provide the medication (n = 4), followed by mild headache (n = 2), and aggressive behaviour (n = 1).

The median time from enrolment to HCV RNA testing (0 days [IQR: 0–0] *vs.* 47 days [IQR: 16–74]; p <0.001) and treatment initiation (6 days [IQR: 5–7] *vs.* 99 days [IQR: 57–127]; p <0.001) and median time from current HCV diagnosis to DAA prescription (1 day [IQR: 1–3] *vs.* 15 days [IQR: 1–28]; p <0.001) and to treatment initiation (6 days [IQR: 5–7] *vs.* 25 days [IQR: 18–62] (p <0.001) was shorter in the intervention compared to the control phase (Table 3).

Discussion

A 'one-stop-shop' intervention incorporating point-of-care HCV RNA and HBsAg testing, fibro-elastography, nurse-led clinical assessment, and fast-tracked DAA prescription within a single visit was associated with increased HCV testing (99% *vs.* 26%) and treatment uptake (93% *vs.* 22%) compared with standard of care at a reception prison in Australia. This intervention improved efficiency of the care cascade by markedly reducing the time to treatment initiation. This study provides important insights for health service and policy makers regarding optimal HCV testing and treatment pathways for people in prisons.

These findings extend other prison and community-based studies involving point-of-care testing.[8,10,20,21] This study addressed gaps in the HCV care cascade by combining key assessments into a single visit and incorporating on-site, nurse-led point-of-care HCV RNA testing and further clinical assessment, fast-tracked prescription, and medication dispatch from the pharmacy. The dedicated study nurse and correctional officer likely facilitated throughput and retention in the care cascade. However, rather than any standalone element, the combined package of all 'one-stop-shop' elements was the likely contributor to facilitating enhanced treatment uptake. Unbundling the key elements will likely lead to delays unless all assessments happen on-site and on the same day. The most impactful elements were the fast time to result which facilitated fast-tracked prescription and medication dispatch from the pharmacy. Although the shorter course glecapbrevir/pibrentasvir regimen was more widely used in the intervention phase compared with the control phase, this regimen is most commonly prescribed in the prisons because of short incarceration periods (averaging approximately 36 and 9 weeks for sentenced and unsentenced individuals).[22]

The intervention reduced the time to treatment initiation from several months to a few days. The current standard of care in the prison setting imposes barriers to both patient engagement and retention along the HCV care cascade,[3,4] with people transferred or released at critical time points.[23,24] Major delays occurred at the beginning of the care cascade with respect to testing and provision of results, highlighting the potential benefits of a universal opt-out point-of-care approach to testing. Simplification and streamlining care in prisons is critical given the short stays and frequent movements people in prison experience.[5,6,23]

The challenging environment for prison-based health care can also impact on adherence and continuity of treatment (*e.g.* custodial priorities such as parole hearings), hence treatment outcomes reported in this study with a 10% treatment failure rate, should be considered in this context. Long-acting DAAs could potentially further simplify the care cascade, however research is needed to establish safety and efficacy.[25]

Testing uptake was higher in the 'one-stop-shop' intervention compared with standard of care, consistent with other studies.[10,20] People entering prison prefer fingerstick point-of-care testing over venepuncture[26] because of its simplicity and quicker provision of results.[23] Point-of-care testing overcame barriers such as the extended time to provision of laboratory results (several weeks with standard of care),[27] and poor venous access common among people who inject drugs.[23,28] Testing on reception to prison results in higher testing than delayed testing,[29] and knowing one's HCV status upon entry to prison alleviates psychological burden, allows confidence in health-seeking behaviours during incarceration,[23] and is perceived as having potential to improve public health benefits and linkage to treatment.[24] The hepatitis service at the study prison was well-established, however, the control phase results demonstrated how the relatively complex model of care led to sub-optimal engagement and a high loss to follow-up at each stage of the care cascade, contrasting with the higher retention demonstrated in the streamlined model in the intervention phase.

The proportion with SVR12 in this study was comparable to other prison-based studies,[5,30] with no SVR12 outcome data for control phase participants and for the majority of intervention phase participants loss to follow-up upon release to the community. Confirmation of cure is important for patient awareness of infection status and improved linkage to care with community-based services following release from prison important, such as via active patient navigator programmes both for those who are continuing treatment and those who are yet to commence treatment.[31,32] SVR testing at week 4 following treatment completion and point-of-care testing at SVR12 may improve ascertainment of cure.[33]

Prisons have been listed as a priority setting for testing and treatment in national strategies.[34–36] Prison-based hepatitis programmes are effective[3,5,37] and cost-effective.[38,39] In Australia, greater than a third of all HCV treatment initiations occur in prisons.[3,40] highlighting the critical role of this setting for elimination.[41] However, only a minority of those with current HCV in prison actually receive treatment,[42] further emphasising the importance of strategies to engage the remaining population in prison with testing and treatment.[36] Whole-of-prison, high intensity point-of-care testing campaigns', currently being implemented in Australian prisons,[43] may be an efficient testing and treatment model, particularly in prisons with high HCV prevalence. Point-of-care HCV antibody testing (with reflex point-of-care HCV RNA testing) should also be explored in lower prevalence prisons, given the shorter time to results and enhanced cost-effectiveness.[44,45]

Scale-up of DAA treatment alone in prisons will be insufficient to reach national elimination targets, given high rates of reinfection occurring in prisons.[46] Treatment scale-up should be combined with enhanced provision of harm reduction strategies such as OAT and/or prison-based needle syringe programmes.[46] Initiatives are needed to address barriers for scale-up of HCV testing and treatment in prisons, including provision of education to improve awareness and reduce stigma towards people who inject drugs and have HCV infection.

The PIVOT study was conducted at a single prison site in Australia (where universal healthcare and DAA treatment accessibility extend to people incarcerated in prisons). The study enrolled newly incarcerated males only, hence the applicability of the findings to females and to prison settings nationally and internationally is unknown. The study was well-resourced, with a dedicated study nurse and correctional officer for the enrolment visits in both phases as well as for on-treatment visits in the intervention phase – these dedicated staff are a likely contributor to the success of the model. Adequate resourcing needs to be considered for real-world implementation of a similar model. It would have been preferable to randomise participants to either the standard of care or 'one-stop-shop' intervention phases, however this was not considered acceptable or feasible in this setting. There was high comparability in participant demographics and clinical characteristics between phases attributable to the stable reception population (primarily from the local community) and reception practices which were not impacted by COVID-19. A large proportion of participants were released to the community at various stages in the care cascade resulting in gaps in outcome data. Although the study was powered to detect a difference in outcomes between the control and intervention phases, the small sample size was a limitation of this study (particularly those with current HCV and those initiating treatment). The small sample size resulted in wide confidence intervals for the estimate of the impact of this intervention on HCV treatment uptake in unadjusted and adjusted analyses. As such, considerable caution should be taken in the interpretation of the effect size estimates and consideration of the wide confidence intervals is critical. However, given the study was not randomised, it was considered important to adjust for key variables that may have differed between the study phases (*e.g.* recent injecting drug use and OAT). It is encouraging that following adjustment of key variables, this intervention was still associated with increased treatment uptake.

Conclusions

The PIVOT study demonstrated that a 'one-stop-shop' intervention integrating point-of-care HCV RNA testing, fibroelastography, and fast-tracked DAA prescription enhanced testing and treatment uptake, and reduced time to treatment initiation among people recently incarcerated, thereby overcoming key barriers to treatment scale-up in prison. Further work is needed to understand how to best optimise HCV prevention, testing, and treatment interventions in prisons, given the critical role that this setting will play in achieving global HCV elimination efforts.

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Abbreviations

APRI, AST to Platelet Ratio Index; AST, aspartate aminotransferase; BBV, bloodborne virus; DAA, direct-acting antiviral; ETR, end-of treatment response; HBV, hepatitis B virus; HBsAg, hepatitis B surface antigen; IQR, interquartile range; OAT, opioid agonist treatment; OR, odds ratio; PoC, point-of-care; RNA, ribonucleic acid; SVR, sustained virological response; SVR12, sustained virological response at 12 weeks post-treatment; Tx, treatment.

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Conflicts of interest

YS is a co-investigator on investigator-initiated research grants from AbbVie and Gilead Sciences. LL and AC have received speaker fees from AbbVie. GJD has received research grants from AbbVie, Gilead Sciences, and Merck, and is supported by an NHRMC Investigator Grant (2008276). ARL has received investigator-initiated research grants from AbbVie, Gilead Sciences, and Sequiris, and is supported by an NHMRC Practitioner Fellowship (1137587). JG is a consultant/advisor and has received research grants from Abbott, AbbVie, bioLytical, Cepheid, Gilead Sciences, Hologic, Indivior, and Merck/MSD, and is supported by an NHMRC Investigator Grant (1176131). All other authors declare no competing interests.

Please refer to the accompanying ICMJE disclosure forms for further details.

Authors' contributions

Study concept and design: ARL, JG. Data curation and formal analysis: YS, EBC, ARL, JG. Investigation and data interpretation: YS, ARL, JG, with input from all authors. Manuscript preparation (drafting/review and revision): YS, ARL, JG, with input from all authors. Approved the final manuscript: all authors.

Data availability statement

Data used for this research cannot be deposited on servers other than those approved by ethics committees. This publication has used highly sensitive health information through prospectively collected samples and information from people in prison, as well as chart review of justice health medical records. This information has been provided to the research team under strict privacy regulations. Except in the form of conclusions drawn from the data, researchers do not have permission to disclose any data to any person other than those authorised for the research project.

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Supplementary data

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