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A point-of-care testing intervention to improve hepatitis C diagnosis and treatment uptake among people attending Aboriginal community controlled health services: the SCALE-C study

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Abstract

Background Globally, hepatitis C virus (HCV) elimination is a priority for marginalised communities, including Aboriginal and Torres Strait Islander peoples in Australia. Innovative and equity focused models of care are required to achieve elimination. The aim of this analysis was to evaluate prevalence of, and factors associated with, HCV infection among Aboriginal peoples engaged during implementation of a point-of-care testing and treatment intervention at Aboriginal primary health care services.

Methods The SCALE-C prospective cohort study implemented a decentralised, on-site community-based "test and treat" intervention through four regional Aboriginal Community Controlled Health Organisations (primary care services) in New South Wales and South Australia between May 2019 and July 2022. Following a screening questionnaire (history of HCV infection, injecting drug use, incarceration, opioid agonist therapy use), participants underwent fingerstick point-of-care HCV testing (antibody [no risk] and/or RNA [history of HCV, ever at risk]); those at risk or with current HCV infection were also offered point-of-care HIV and HBV testing, education, and longitudinal follow-up. Participants with current HCV infection were offered DAA treatment. The primary endpoint was current HCV infection, with secondary endpoints including DAA uptake and outcome. Factors associated with current HCV infection were assessed using logistic regression analysis.

Results Of 536 individuals enrolled (median age 39 years, 49% women, 37% injecting drug use ever, 32% incarceration ever), 79% identified as Aboriginal and/or Torres Strait Islander. The proportion with current HCV

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infection was 9%, ranging from 0.5% among people reporting no lifetime risk to 20% among those reporting risk within the past 12 months. Current HCV infection was associated with recent injecting drug use (adjusted OR: 10.43; 95% CI: 1.34–81.01). Among participants with HCV infection, 62% (28/45) received DAA treatment (median time from enrolment to treatment initiation, nine days [range 2, 22]) and 57% (16/28) of those treated had confirmed sustained virological response (SVR); SVR was 100% (16/16) among those retained in follow up.

Conclusion A community-based decentralised on-site "test and treat" intervention integrated within existing Aboriginal community-controlled health organisations was feasible and effective in HCV case detection. While it holds potential for future elimination efforts, health system enhancement will be required (including dedicated staffing and infrastructure) to support broader implementation and improve linkage to care and treatment.

Clinical trial This study was registered with clinicaltrials.gov (NCT03776760) on December 12, 2018.

Keywords Indigenous, First nations, HCV, Direct-acting antiviral, Point-of-care testing

Background

Hepatitis C virus (HCV) infection poses a significant global health challenge and disproportionally affects marginalised communities and population groups where healthcare access is limited [1, 2]. In 2016, the World Health Organisation set the goal of "elimination of viral hepatitis as a public health threat by 2030" [3]. To achieve elimination, high levels of testing, diagnosis and treatment must be achieved among key populations [4].

Indigenous peoples globally require focused attention given the burden of viral hepatitis and inequalities in healthcare access [5–8]. Indigenous peoples of Australia, Aboriginal and Torres Strait Islander peoples (hereafter respectfully referred to as Aboriginal[Δ]), represent 4% of the total Australian population and are a priority population for HCV elimination [9–11]. At the end of 2020, 118,000 Australians were estimated to be living with chronic HCV infection, of whom 18% were Aboriginal people. Intersecting risks for HCV acquisition among Aboriginal people include disproportionate incarceration and injecting drug use, and poorer outcomes in social and economic determinants of health [12–14]. This also occurs on a background of colonisation that failed to assimilate the Aboriginal population, but has disenfranchised communities, resulting in endemic racism, discrimination and intergenerational trauma among the population [15].

Progress towards HCV elimination in Australia has thus far been unequal, increasing the risk of widening health disparities between Aboriginal and non-Aboriginal peoples [16, 17]. In 2016, highly effective direct-acting antiviral (DAA) therapies (sustained virological response, SVR >95%) were made available to all adults living with chronic HCV infection via universal healthcare [1, 18], with Aboriginal people able to access free treatment under the "Closing the Gap" Scheme†. In 2023, seven years after the availability of DAAs within Australia, 20% of all hepatitis C notifications were among Aboriginal people [19], indicating a greater need for equity driven strategies to address ongoing disparities in HCV prevention and care. The Australian Needle Syringe Program Survey has demonstrated lower HCV testing, treatment uptake and harm reduction coverage among Aboriginal people who inject drugs, compared with the general population, but it should be noted that people using these services are often older and accessing pharmacotherapies to manage substance use disorders [17].

[1]Scaling-up DAA treatment among populations with ongoing transmission, can significantly reduce the incidence and prevalence of HCV [20, 21]. However, this requires concurrent strategies at potency to complement the population and setting to prevent incident cases, scale-up testing and diagnosis (especially for those most at risk), and enhance linkage to care, treatment and follow up. Despite the recognized benefits of HCV "test and treat" approaches [22, 23] and integrated models of care [24–26], there remains a critical gap in research evaluating their feasibility and utility among First Nations populations globally. Few studies have assessed the implementation and outcomes of such interventions in these communities, highlighting the need for novel research to address this gap and inform culturally appropriate, evidence-based strategies for HCV elimination.

"Strategies for hepatitis C testing and treatment in Aboriginal communities that Lead to Elimination" (SCALE-C) was an interventional cohort study designed to evaluate a community-based "test and treat" model among people who attended regional Aboriginal

[1] [Δ] Aboriginal and Torres Strait Islander Peoples are collective terms to describe diverse groups of peoples with unique cultures, languages, customs and ways of life. Aboriginal and Torres Strait Islander Peoples are the First Peoples of country now known as Australia and have an ongoing connection to land, skies and waterways. Herein we will be respectfully using the term Aboriginal Peoples to refer to these groups.

† The "Closing the Gap" scheme is an Australian government initiative aimed at reducing health, education, and employment disparities between Aboriginal and Torres Strait Islander peoples and non-Indigenous Australians. In the healthcare sector, Closing the Gap provides better access to essential medical services, including subsidized medications through Pharmaceutical Benefits Scheme (PBS) Co-payment Measure, which reduces or eliminates out-of-pocket costs for eligible Aboriginal and Torres Strait Islander patients.

community controlled primary care and other partnering health services. The aim of this analysis was to evaluate prevalence of, and factors associated with, HCV infection among Aboriginal peoples engaged during implementation of a point-of-care testing and treatment intervention at Aboriginal primary health care services between 2019 and 2022.

Methods

Study design and participants

Participant enrolment took place between May 28, 2019, and July 21, 2022, across four Aboriginal Community Controlled Health Services in regional Australia: two in South Australia and two in New South Wales (population range of included regional urban centres, $n = 14{,}400 - 35{,}400$; estimated Aboriginal populations, $n = 250\text{-}5{,}400$ [3–15%]; Australian Bureau of Statistics 2021 Census; abs.gov.au). Participating sites provided in-(general practice clinics) and outreach primary care for Aboriginal people in their region, including people who use drugs and people in custodial settings. For example, one health service had a focus on engaging people who had previously been in prison or were on probation or parole. Enrolment settings included primary care clinics, needle and syringe programs, community stalls, and home visits. Health workers, both Aboriginal and non-Indigenous, from each service provided local knowledge which informed recruitment processes for each site. Customised recruitment activities occurred at each study site, including dissemination in local media and week-long liver health promotion campaigns co-designed and conducted as a partnership between the health service and the study team.

Eligible participants were adults aged 18 years or older, with the only exclusion criterion being current pregnancy. Written informed consent was obtained from all participants prior to the start of any study procedures. Participants were provided with a voucher (AU$20) at each visit to compensate them for their time.

At inception, the overall objective of the SCALE-C HCV 'treatment as prevention' evaluation was longitudinal assessment of HCV prevalence following implementation of the community-based "test and treat" model. Initial sample size calculations assumed an estimated HCV RNA prevalence of 35% in year one (alpha = 0.05; loss to follow up, 30%). With enrolment of 370 at-risk participants, the study would have had 90% power to detect a relative reduction in HCV RNA prevalence of 50% from the initial to the later study period following scale-up of testing and treatment. However, the study was significantly affected by the COVID-19 pandemic (all sites, March 2020-July 2022) and a natural flooding disaster (one site, February 2022), impacting study conduct. Recruitment and follow up visits were paused in March 2020 because of the Australian public health response to COVID-19, which included primary care services prioritising management of acute respiratory infection, community lockdowns, no or limited face-to-face contact, recommendations to conduct telehealth, and halting non-COVID research. Study activities resumed in July 2022.

Study procedures

Screening and enrolment

The SCALE-C study design is outlined in Fig. 1. Following informed consent, all participants completed a simple standardized questionnaire (Supplementary File 1) to determine the most suitable initial hepatitis C point-of-care test based on self-reported HCV infection history and behaviour. During enrolment, participants were asked, "Which of the following applies to you [1]? I have hepatitis C now [2], I had hepatitis C in the past [3], I have injected drugs [4], I have been to prison [5], I have taken opioid agonist therapy (methadone, buprenorphine) [6], None of the above apply to me [7], Prefer not to answer". Participants who self-reported no lifetime history of HCV infection, no injecting drug use, no opioid agonist therapy and no incarceration (options 6) were categorized as "no or low-risk". These individuals received a finger-stick HCV antibody test (SD Bioline HCV point-of-care assay; Standard Diagnostics Inc, Giheung-gu, Korea), followed by a second finger-stick sample for HCV RNA test (Xpert® HCV Viral Load Fingerstick point-of-care assay; Cepheid, Sunnyvale, USA) if the antibody test was positive. Participants who self-reported current or past HCV infection, or a lifetime history of injecting drug use, incarceration, or opioid agonist therapy (options 1–5) were classified as "at-risk" and received an HCV RNA test. Participants also underwent non-invasive liver disease assessments via transient elastography (FibroScan®) or AST-to-platelet Ratio Index (APRI). Where available, FibroScan® was performed and preferred as the measure of liver disease assessment over APRI. Assessments (including point-of-care testing) were performed on site by health service and/or study staff and results were provided to participants on the same day.

Participants with or at risk of HCV infection

Participants with current HCV infection (HCV RNA detected at enrolment) or who self-identified as belonging to a population at risk of HCV infection also underwent point-of-care HIV (Determine™ HIV-1/2 Combo; Abbott Diagnostics, Scarborough, Canada) and HBV (Determine™ HBsAg2 [formerly known as Alere Determine ™ HBsAg]; Abbott Laboratories, Chiba, Japan) testing, provided a dried blood spot (DBS) sample (for centralised HCV antibody and/or RNA testing in case of missing or invalid point-of-care tests), completed

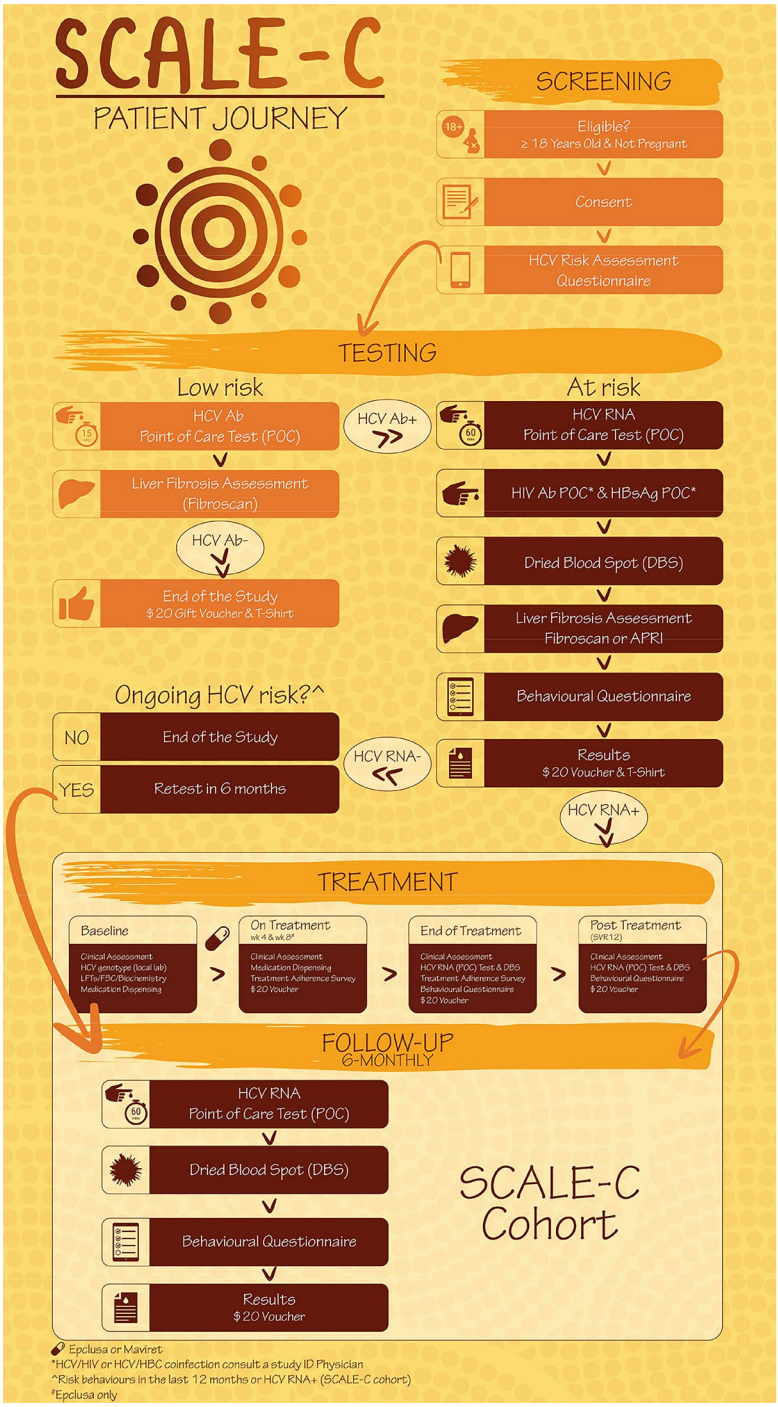

Fig. 1 SCALE-C study design and participant recruitment material

a behavioural screening questionnaire (Supplementary File 2), and received education on HCV transmission and risk reduction. The behavioural questionnaire, which was administered via electronic tablet with assistance from study staff as needed, gathered information on demographics, HCV and drug treatment history, drug and alcohol use, and injecting risk behaviours; the questionnaire has been used previously among people who inject drugs, including Aboriginal and Torres Strait Islander peoples, and incorporated validated tools [27, 28]. For example, alcohol consumption was measured using AUDIT-C [29], a 3-item alcohol screening tool that identifies hazardous drinking or alcohol use disorder. The AUDIT-C score ranges from 0 to 12, with 0–3 indicating low-risk drinking, 4–5 suggesting hazardous or risky alcohol use, and scores of 6 or higher indicating potential

alcohol dependence or use disorder. Participants with current HCV infection (HCV RNA detected) at enrolment or who self-reported risk behaviours or belonging to a risk population within the past 12 months (i.e., injecting drugs, incarceration, or receiving opioid agonist therapy) were scheduled for follow-up visits every six months throughout the study for up to three years.

HCV treatment

Participants with current HCV infection (HCV RNA detected) were offered DAA therapy. The prescribed treatment regimen was at the discretion of the site investigators and consistent with local standard clinical practice and availability on the Pharmaceutical Benefits Scheme, glecaprevir-pibrentasvir for eight weeks or sofosbuvir-velpatasvir for 12 weeks. Clinicians (general practitioners) were available to prescribe DAA therapy at all sites. Participants could start DAA treatment at any point during the study. For those receiving treatment, additional follow-up visits were scheduled at the end of treatment and 12 weeks post-treatment; these visits included point-of-care HCV RNA testing, nurse-led clinical assessment, and a self-reported treatment adherence questionnaire (end of treatment). An abbreviated behavioural questionnaire was administered at the end of treatment, 12 weeks post-treatment, and during routine follow-up visits (FU1-6).

Outcomes

The primary objective of this analysis was to evaluate HCV infection status among the SCALE-C study population, overall and stratified by demographic and risk categories, with the primary endpoint being proportion with current HCV infection (HCV RNA detected). Among people with current HCV infection, secondary objectives included DAA treatment uptake, DAA treatment completion, and outcome (SVR12).

Statistical analysis

The proportion with current HCV infection was described overall and stratified by key variables. Variables of interest included age (median), gender (men, women, transgender), Indigenous identification (Aboriginal and/or Torres Strait Islander, non-Indigenous, other), level of education (primary school or less, high school and higher education), homelessness (in the last month), history of incarceration (never, more than 12 months ago, within last 12 months), history of injecting drug use (never, ever but not in the last month, last month), alcohol consumption (no or low risk drinking, hazardous drinking/risky alcohol use, alcohol dependence/alcohol use disorder), history of opioid agonist therapy (never, ever but not currently, currently), and history of HCV testing (never tested, tested in the last year, tested more than a year ago, unknown).

Factors associated with current HCV infection were analysed using logistic regression and reported as odds ratios (OR). The populations for analysis included: (1) individuals who reported ever being at risk (lifetime risk), (2) individuals who reported risk in the last 12 months, and (3) individuals who reported risk in the last 12 months and/or had current HCV infection (HCV RNA detected on any testing modality – fingerstick point-of-care, venepuncture, dried blood spot). Variables were selected for inclusion in the adjusted model based on known clinical relevance and/or with a significance level of $p \leq 0.20$ in univariate analysis.

Among people with current HCV infection, DAA treatment commencement, DAA treatment completion and outcome were summarised. For DAA treatment outcome, the proportion who achieved SVR12 was calculated, defined as HCV RNA below the lower limit of quantitation at 12 weeks post-treatment.

All analyses were conducted using Stata version 14.2 (College Station, TX, USA).

Study oversight

All participants provided written informed consent prior to any study procedures. Ethics approvals were obtained from three human research ethics committees: the Aboriginal Health & Medical Research Council of NSW (1474/18), the Aboriginal Health Research Ethics Committee (04-18-797), and St Vincent's Hospital Sydney (2019/ETHO3406). The study was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice (ICH/GCP) guidelines.

Results

Participant characteristics

Between 28 May 2019 and 21 July 2022, 536 individuals were screened. Of those, 79% ($n = 425$) identified as Aboriginal and/or Torres Strait Islander, 49% ($n = 262$) were women, and the median age of the screened population was 39 years (range 28, 51; Table 1). A history of ever injecting drugs, incarceration, and receiving opioid agonist therapy were reported by 37%, 32%, and 11%, of participants respectively. Recent injecting drug use (within the last month) was reported by 18% ($n = 95$). Among people who injected drugs in the last month, 61% reported injecting daily or more, 58% reported injecting methamphetamine, 39% reported injecting opioids, 65% reported use of unsterile needles and syringes, and 46% reported receptive sharing of other injecting equipment (Supplementary Table 1). 12% ($n = 67$) reported a history of previous HCV diagnosis, and 4% ($n = 24$) had previously received HCV treatment.

Table 1 Characteristics of screened participants

Characteristic		Total population (*N* = 536)	Lifetime risk + known HCV status (*N* = 253)	Risk last 12 months + known HCV status (*N* = 193)
Age, median (IQR)		39 (28, 51)	38 (29, 46)	37 (27, 44)
Gender, n (%)	Men	273 (51)	180 (71)	143 (74)
	Women	262 (49)	72 (28)	49 (25)
	Transgender	1 (< 0.5)	1 (< 0.5)	1 (0.5)
Indigenous identity, n (%)	Aboriginal and/or Torres Strait Islander	425 (79)	195 (77)	149 (77)
	Non-Indigenous	106 (20)	54 (21)	41 (21)
	Other*	5 (1)	4 (1)	3 (1)
Lifetime history of injecting drug use, n (%)		197 (37)	196 (77)	170 (88)
Lifetime history of incarceration, n (%)		172 (32)	170 (67)	148 (77)
Lifetime history of opioid agonist therapy, n (%)		58 (11)	58 (23)	56 (29)
Self-reported history of HCV diagnosis, n (%)		67 (12)	65 (26)	56 (29)
Self-reported history of HCV treatment, n (%)		24 (4)	24 (9)	21 (11)

*Other = Asian (*n* = 1), Indian (*n* = 1), Māori (*n* = 2), Sudanese (*n* = 1)

At enrolment, 47% (*n* = 252) reported no history of HCV infection or lifetime risk of exposure, 49% (*n* = 260) reported a history of HCV infection and/or lifetime risk of exposure, and 4% (*n* = 24) had unknown lifetime risk (non-response to risk assessment questionnaire and/or behavioral survey). Further details are available in Fig. 2.

Point-of-care testing

HCV testing at enrolment was performed in 99% (*n* = 531), which included 278 fingerstick point-of-care HCV antibody tests, 257 fingerstick point-of-care HCV RNA tests, and seven standard-of-care venepuncture HCV RNA tests (more than one test could have been performed on a participant). Supplementary testing on dried blood spot samples (which was not available to sites in real time) included 247 HCV antibody and five HCV RNA tests. A detailed breakdown of HCV testing and results by self-reported risk categories is shown in Supplementary Fig. 1. HCV status was determined in 98% (*n* = 527); HCV status could not be determined in 2% (*n* = 9) due to no or insufficient testing.

In addition, 238 and 232 participants underwent HIV and HBV point-of-care testing, respectively. HIV Ag/Ab testing was positive in 0.4% (*n* = 1), negative in 98% (*n* = 234), and invalid in 1% (*n* = 3). HBV surface antigen testing was negative in 99% (*n* = 230) and invalid in 1% (*n* = 2).

HCV infection status

Among 536 individuals screened in the SCALE-C study, 9% had current HCV infection(*n* = 47), 14% had evidence of prior HCV infection (*n* = 74), 76% had never been infected (*n* = 406), and 2% were unknown (*n* = 9; no or inadequate testing to determine status). Figure 3 presents the distribution of HCV infection status overall and stratified by key demographic and risk characteristics.

Among individuals who reported ever being at risk (lifetime risk; *n* = 253), the proportion with current HCV infection was 17% (*n* = 44). Characteristics of this population are summarised in Tables 2 and 77% identified as Aboriginal and/or Torres Strait Islander peoples, 28% were women, median age was 38 years (range 29, 46), 77% had ever injected drugs (37% in the last month), 23% had ever received opioid agonist therapy, and 67% had

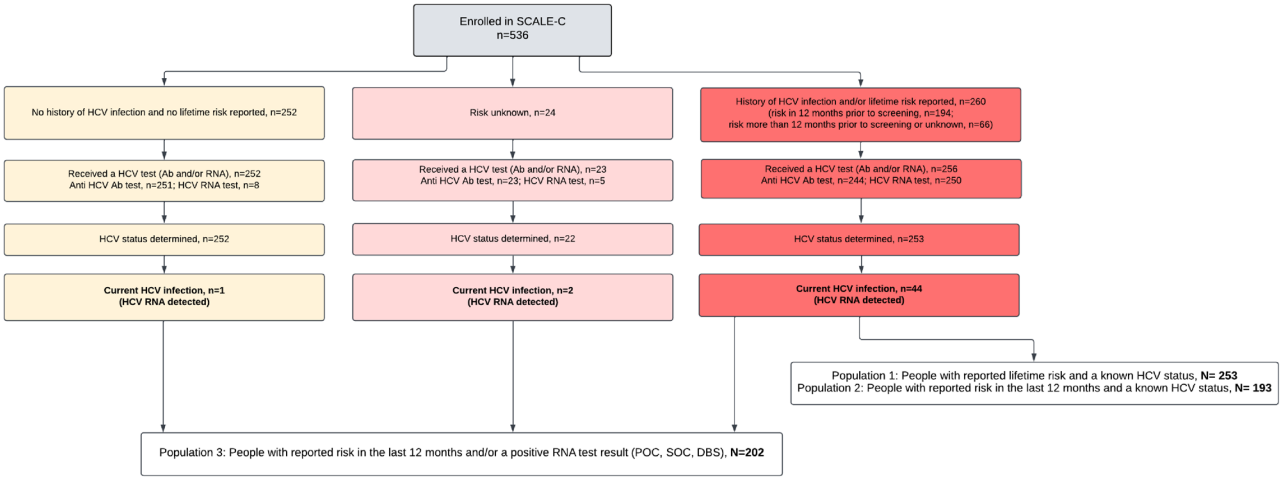

Fig. 2 SCALE-C participant flowchart. Abbreviations: SCALE-C, Strategies for hepatitis C testing and treatment in Aboriginal communities that Lead to Elimination; HCV, hepatitis C virus; Ab, antibody; RNA, Ribonucleic acid

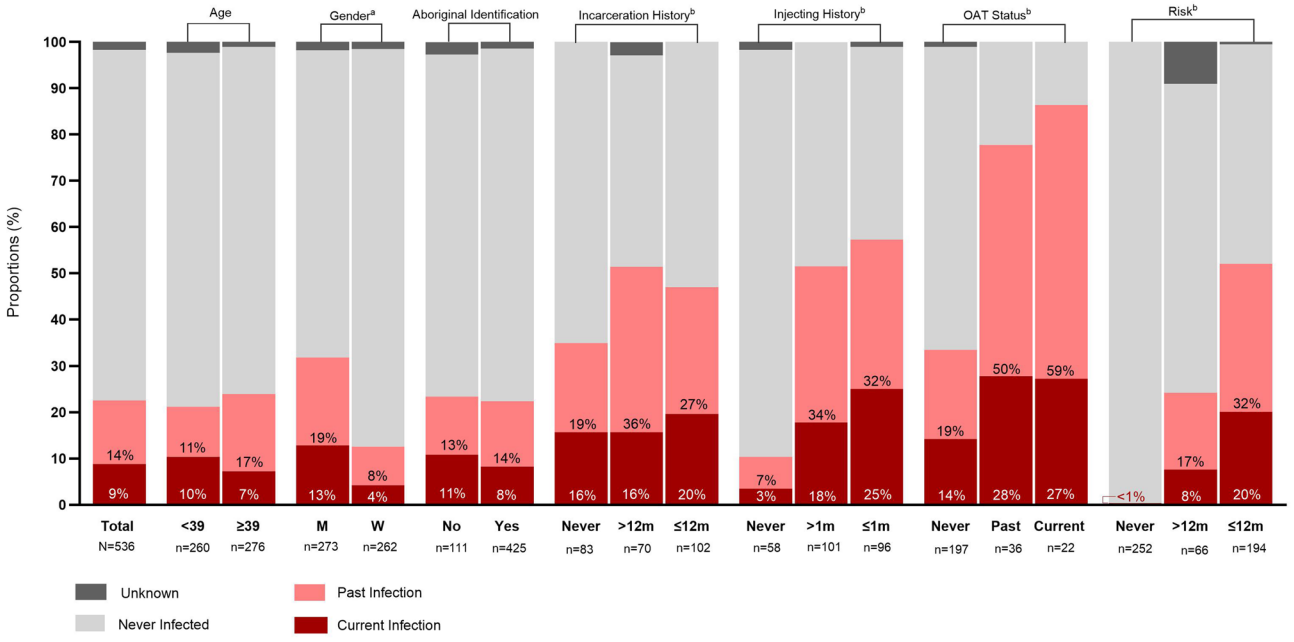

Fig. 3 HCV infection status among SCALE-C participants, overall and stratified by key demographic and risk characteristics. Infection status was categorised as: *never infected* (no self-reported history of HCV infection or treatment and anti-HCV Ab negative [*n* = 400] OR no self-reported history of HCV infection or treatment and anti-HCV Ab unknown + HCV RNA negative [*n* = 6]), *past infection* (anti-HCV Ab positive, HCV RNA negative [*n* = 50] or self-reported history of HCV infection or treatment and anti-HCV Ab negative [*n* = 21] or self-reported history of HCV infection or treatment and anti-HCV Ab unknown + HCV RNA negative [*n* = 3]), *current infection* (HCV RNA detected [*n* = 47]), and *unknown* (no or inadequate testing to determine status [*n* = 9]). (a) 1 transgender person was not included; (b) among those with available data. Abbreviations: Ab, antibody; F, female; HCV, hepatitis C virus; M, male; m, month(s); OAT, opioid agonist therapy; RNA, ribonucleic acid

ever been incarcerated; 60% self-reported a history of HCV testing (34% last 12 months).

Among those who reported risk within the past 12 months (*n* = 193), the proportion with current HCV infection was 20% (*n* = 39). Characteristics of this population are summarised in Supplementary Table 2; 77% identified as Aboriginal and/or Torres Strait Islander peoples, 25% were women, median age was 37 years (range 27, 44), 88% had ever injected drugs (49% in the last month), 29% had ever received opioid agonist therapy and 77% had ever been incarcerated; 65% self-reported a history of HCV testing (39% last 12 months).

Factors associated with current HCV infection

In univariate analysis among individuals with lifetime risk (*n* = 253), current HCV infection (*n* = 45) was associated with injecting drugs ever (OR 8.89, 95% CI 1.14–69.02) and in the past month (OR 13.76, 95% CI: 1.79–105.72). In the adjusted model, current HCV infection was significantly associated with injecting drug use in the past month (adjusted OR [aOR]: 10.43; 95% CI: 1.34–81.01, *p* = 0.025; Table 1).

Participant characteristics and factors associated with current HCV infection among people who reported risk within the past 12 months (*n* = 193) and people who reported risk in the last 12 months and/or had current HCV infection (*n* = 202) are presented in Supplementary Tables 2 and 3, respectively. Among individuals who reported injecting drug use in the past month (*n* = 95), injecting behaviours (including frequency, and receptive needle and syringe sharing) were not associated with current HCV infection (Supplementary Table 1).

HCV treatment uptake and outcome

Among participants with HCV infection at enrolment (*n* = 45; excluding two participants diagnosed on supplementary dried blood spot testing), 62% (*n* = 28) received treatment (sofosbuvir-velpatasvir, *n* = 11; glecaprevir-pibrentasvir, *n* = 17). One participant was on treatment at enrolment (commenced seven days prior). Excluding this participant, median time from enrolment to treatment initiation was nine days [range 2, 22]), with 81% of those initiating treatment doing so within 30 days (same day, *n* = 6; day 2–14, *n* = 9). Eight (18%) participants with HCV infection were provided with prescriptions for DAA therapy on the day of enrolment.

Of the 28 people treated, 57% (*n* = 16) completed DAA therapy. All individuals who completed treatment underwent post-treatment HCV RNA testing at or after 12 weeks (Fig. 4). Sustained virological response was confirmed in 57% (16/28); sustained virological response was 100% (16/16) among those who completed treatment and

Table 2 Baseline characteristics and factors associated with current HCV infection among people with self-reported lifetime risk*

Characteristics		Total, *n* (col%)	Current HCV infection, *n* (row%)	Unadjusted analysis		Adjusted analysis**	
				OR (95% CI)	*P*	aOR (95% CI)	*P*
Total		253	44 (17)	-	-		
Median age	< 38	116 (46)	22 (19)	-ref-	-ref-		
	>=38	137 (54)	22 (16)	0.79 (0.41, 1.52)	0.478		
Gender	Men	180 (71)	32 (18)	-ref-	-ref-		
	Women	72 (28)	11 (15)	0.79 (0.37, 1.68)	0.543		
	Transgender	1 (< 0.5)	1 (100)	omitted	-		
Indigenous identify	Aboriginal and/or Torres Strait Islander	195 (77)	33 (17)	-ref-	-ref-		
	Non-Indigenous	54 (21)	10 (18)	1.05 (0.48, 2.30)	0.903		
	Other***	4 (2)	1 (25)	1.50 (0.15, 14.93)	0.727		
Education****	Primary school or less	120 (47)	24 (20)	-ref-	-ref-		
	High school and higher education	120 (47)	19 (16)	0 0.77 (0.40, 1.51)	0.453		
	Missing	13 (5)	1 (8)	0.42 (0.05, 3.53)	0.429		
Unstable housing in last month	No	209 (83)	39 (19)	-ref-	-ref-		
	Yes	25 (10)	4 (16)	0.82 (0.26, 2.54)	0.731		
	Not stated/Missing	19 (7)	1 (5)	0.27 (0.03, 2.13)	0.216		
History of incarceration	Never	70 (28)	12 (17)	-ref-	-ref-		
	> 12 months ago	68 (27)	11 (16)	0.95 (0.9, 2.34)	0.913		
	Within last 12 months	102 (40)	20 (20)	1.17 (0.53, 2.60)	0.690		
	Missing	13 (5)	1 (8)	0.51 (0.06, 4.41)	0.540		
Injecting drug use	Never	44 (17)	1 (2)	-ref-	-ref-	-ref-	-ref-
	Ever but not in the last month	101 (40)	18 (18)	8.89 (1.14, 69.02)	**0.037**	5.16 (0.64, 41.70)	0.123
	Last 1 month	95 (37)	24 (25)	13.76 (1.79, 105.72)	**0.012**	10.43 (1.34, 81.01)	**0.025**
	Missing	13 (5)	1 (8)	4.33 (0.25, 76.04)	0.316	4.81 (0.27, 84.74)	0.283
Alcohol consumption	Low risk drinking	143 (56)	26 (18)	-ref-	-ref-		
	Hazardous drinking/risky alcohol use	24 (9)	5 (21)	1.20 (0.41, 3.52)	0.744		
	Alcohol dependence/use disorder	73 (29)	12 (16)	0.92 (0.43, 1.96)	0.835		
	Missing	13 (5)	1 (8)	0.48 (0.06, 3.95)	0.494		
Opioid agonist therapy	Never	182 (72)	27 (15)	-ref-	-ref-	-ref-	-ref-
	Ever but not current	36 (14)	10 (28)	2.25 (0.97, 5.24)	0.059	1.56 (0.57, 4.21)	0.383
	Current	22 (9)	6 (27)	2.03 (0.73, 5.65)	0.176	1.68 (0.53, 5.25)	0.375
	Missing	13 (5)	1 (8)	0.60 (0.07, 4.93)	0.635	omitted	-
Ever tested for HCV	Never tested	45 (18)	9 (20)	-ref-	-ref-		
	Yes, in the last year	87 (34)	17 (19)	0.93 (0.37, 2.31)	0.876		
	Yes, more than a year ago	65 (26)	10 (15)	0.69 (0.25, 1.88)	0.470		
	Don't know	43 (17)	7 (16)	0.78 (0.26, 2.33)	0.654		
	Missing	13 (5)	1 (8)	0.41 (0.04, 3.65)	0.422		

* Analysis population: People self-reporting lifetime time of HCV infection; 3 people with detectable HCV RNA have been removed from this analysis as they had no or unknown lifetime risk

** Model has been adjusted for history of HCV treatment ($N = 24$ reported a history of treatment)

*** Other = Asian ($n = 1$), Indian ($n = 1$), Māori ($n = 1$), Sudanese ($n = 1$)

**** Education: Primary school or less – 0 to 10 years of formal schooling; high school or higher education - >10 years of formal schooling and/or university, college, further education and training

attended for post-treatment testing. Additionally, one participant who did not have HCV infection at enrolment (HCV RNA not detected) was diagnosed with HCV infection (HCV RNA detected) during follow-up. This participant also completed treatment (glecaprevir-pibrentasvir, 8 weeks) and achieved sustained virological response. There was no difference in baseline characteristics between participants with current HCV infection who did and did not initiate treatment (Supplementary Table 4).

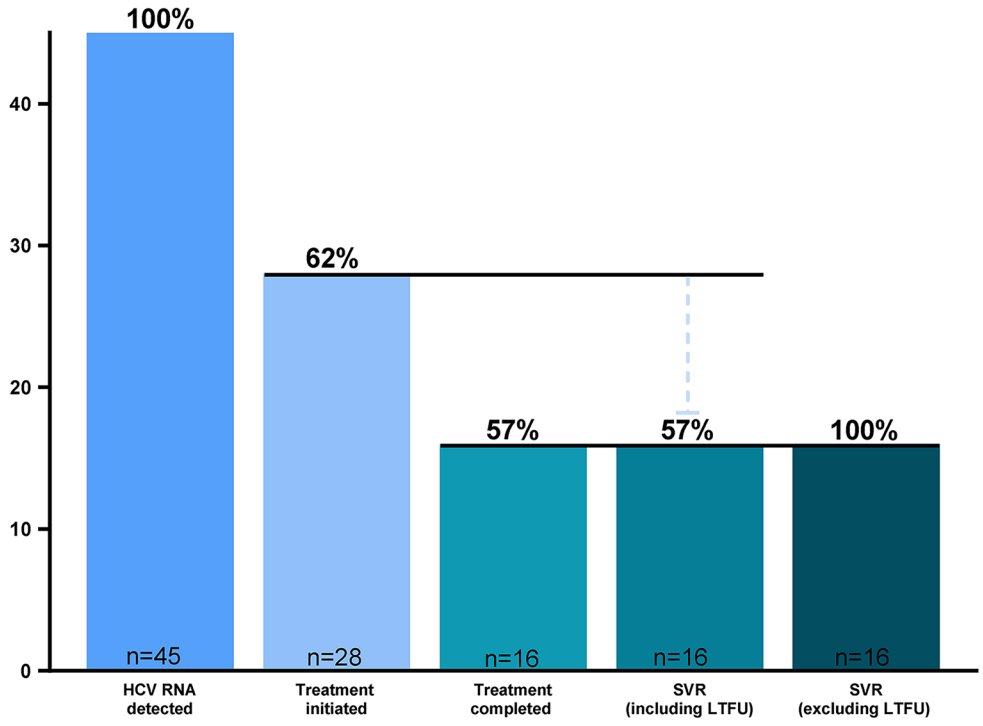

Fig. 4 SCALE-C HCV treatment cascade. Abbreviations: LTFU, loss to follow up; RNA, ribonucleic acid; SVR, sustained virological response

Follow up

Among individuals who reported risk within the past 12 months and were scheduled for study follow-up ($n = 193$), 32% attended at least one post-enrolment visit ($n = 62$). One participant (mentioned above) was diagnosed with incident HCV infection during follow up. Participants concluded their involvement in the study for various reasons, including completion of scheduled study visits or study close ($n = 48$), loss to follow-up ($n = 134$), incarceration ($n = 3$), death ($n = 1$), and other (COVID restrictions [$n = 2$], change of address [$n = 4$], and mental health [$n = 1$]).

Discussion

A community-based HCV "test and treat" intervention (including on-site point-of-care diagnostics) implemented in Aboriginal primary health services enabled risk-based screening and diagnosis, identification of Aboriginal people deemed to be at low or high risk of HCV infection, and highlighted social, structural and health system issues that need to be addressed in the move towards elimination. Overall, 9% of the SCALE-C population had current HCV infection, with the burden predominately among people who inject drugs. Among those with HCV infection, DAA treatment uptake was 62%, with most commencing within 30 days of diagnosis; sustained virological response was achieved in all participants with confirmed DAA treatment completion who attended follow-up, however many were lost after initiation of treatment. Decentralised point-of-care testing facilitated diagnosis of HCV infection, however elimination success will require additional strategies, including resources to improve follow up and linkage to care.

Aboriginal people who inject drugs continue to be disproportionately impacted by HCV infection [12, 16], consistent with other Indigenous and tribal populations globally [8]. Higher HCV infection prevalence was documented among participants who reported characteristics associated with greater marginalisation, including recent injecting drug use (25%), receipt of opioid agonist therapy (27%), and incarceration (20%). Only two cases of current HCV infection were identified among those considered at low or unknown risk highlighting the validity of self-reported history of infection or risk behaviour. Identifying those most at-risk and working with affected communities will be critical in coordinating culturally safe clinical and public health responses. However, shame and stigma associated with injecting drug use and HCV may hinder disclosure to health services [30, 31], and limit access to or engagement with health care and harm reduction services [15, 32–34]. This highlights the importance of integrating hepatitis C care into existing healthcare services used by Aboriginal peoples and other Indigenous and First Nations people globally; low levels of testing have been seen Leveraging trusted healthcare relationships and existing infrastructure, integrated care has been shown to enhance HCV linkage to care

and treatment initiation [24–26]. Ensuring health care is accessible, culturally safe, and free from stigma that creates shame is essential to achieving HCV elimination and improving health equity.

While most (62%) people with HCV infection in the SCALE-C study received treatment, DAA uptake was challenging even in a research environment. In a global systematic review and meta-analysis, HCV treatment uptake was seen to be higher with models of care including on-site (77%) or mobile (81%) point-of-care testing as compared with standard of care laboratory testing (53%); importantly, none of the included studies focused on Indigenous or First Nations peoples. Bespoke community-led models of HCV care have shown promise among Indigenous peoples; in an Indigenous community in Saskatchewan, Canada, 189 received HCV testing and 51 (27%) had current HCV infection, of whom 45 (88%) were linked to care (HCV treatment uptake was not reported) [35]. SCALE-C confirmed the feasibility of a "test and treat" model of care in this population and setting, permitting expedited DAA initiation (with the option for same site, same day diagnosis and treatment). Median time from diagnosis to treatment in SCALE-C was nine days, shorter than published pooled estimates for on-site point-of-care testing models (19 days [95% CI 14–53]) and standard-of-care testing approaches (67 days [95% CI 50–67]) [22]. However, additional health care resourcing will be required, alongside point of care technology, to enable follow up and ongoing management for those who chose not to receive results on the same day or who chose to defer treatment [36].

While case detection using point of care testing is an effective tool in the path to HCV elimination [22], additional efforts will be required to reach those that may benefit most. SCALE-C offered staffing, infrastructure and funding support to the primary care sites to implement HCV point-of-care testing and assisted in engaging participants who may not have been retained in mainstream health care. Without these intense efforts, we speculate that participant recruitment would have been more difficult. Another consideration for health care services considering point of care testing, particularly molecular (nucleic acid) testing, is the ongoing operator training required for providers, especially in the context of high staff turnover. These two factors should be a primary consideration when offering point of care technology to health services.

Systems and procedures to support treatment completion and post-treatment follow-up are also required on the road to HCV elimination in the Aboriginal population. Among those who completed DAA therapy, high effectiveness (sustained virological response) was observed, consistent with clinical trials and other real-world cohorts [37–39]. However, additional strategies will be required to address retention in care, assist with treatment completion and follow up, permit confirmation of cure, monitor for reinfection, and manage ongoing liver disease, given the proportion lost to follow up. Health systems must adapt to provide support for Aboriginal people most at risk for greatest individual and population-level benefit; among people who reported recent injecting drug use in SCALE-C, 46% reported sharing injecting equipment and 65% reported using unsterile needles or syringes. Additionally, fewer than 20% of the SCALE-C population reported HCV testing in the past year. An integrated approach which includes HCV treatment, peer navigation and support, education, harm reduction, and social support within health services may help achieve parity in health outcomes [40–43].

The model of care implemented in SCALE-C demonstrated the scale of efforts required to improve access to care beyond normal practice for populations at greatest risk of HCV. Globally, viral hepatitis elimination strategies must involve Indigenous and First Nations peoples and people who inject drugs in decision making, policy development, care delivery and research to ensure impact and appropriateness. In Australia, this requires partnerships with Aboriginal communities and meaningful involvement of Aboriginal people in the design and implementation of programs, ensuring services are tailored to community needs. Many of the SCALE-C population were recruited through specific study measures, such as liver health promotion campaigns, peers, and word of mouth. Many also reported characteristics known to impact health care access such as injecting drug use, incarceration, and hazardous alcohol use. Moving forward a multifaceted approach involving community leadership, integration of HCV testing, treatment, prevention and education (including peer-to-peer knowledge exchange and peer support), and social support within services frequented by Aboriginal peoples is recommended to improve health outcomes [40–43]. More broadly, to "close the gap", multisectoral collaboration is required to reduce disparities in health outcomes between Aboriginal peoples and other Australians, including ensuring access to culturally appropriate healthcare (Aboriginal Community Controlled Health Services), addressing social determinants of health (housing, employment), and preventing infection and chronic disease. Working to ensure health equity should be a priority for Indigenous and First Nations people globally.

Limitation of this analysis should be noted. SCALE-C was undertaken in four regional centres in two states and may not be generalisable to other primary healthcare settings or represent the diversity of Aboriginal and Torres Strait Islander peoples and communities in Australia. Participants were opportunistically recruited in healthcare settings and affiliated services. To reduce selection

bias, affiliated services included community outreach to non-traditional healthcare settings (including needle and syringe programs, home visits, community fairs and halls) to engage with the broader Aboriginal population, particularly people who inject drugs. Data obtained through questionnaires relied on participant self-report and recall; self-report is considered a reliable source of data collection, including among people who inject drugs. However, recall bias could not be systematically alleviated. Social-desirability bias was reduced through provision of self-administered questionnaires. Further, study conduct was significantly disrupted by the COVID-19 pandemic and Australia's associated public health response. These unprecedented events redirected health services and impacted research participation, having a particular impact on follow-up.

Conclusions

Australia has made significant progress towards national hepatitis C elimination targets, however progress among Aboriginal people, including people who inject drugs, has been less impactful. To achieve equity, integrated models of care that are community-led and culturally safe should be optimised to facilitate ongoing healthcare engagement among Aboriginal peoples living with and at risk of HCV. Evidence from the SCALE-C study will help strengthen targeted HCV testing and treatment strategies for Aboriginal and Torres Strait Islander communities and ensure they are not left behind in Australia's pursuit of HCV elimination as a public health threat by 2030. More broadly, ensuring equitable access to HCV testing, treatment, and prevention among Aboriginal and other Indigenous peoples is essential to ensure greatest individual and population-level benefit.

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

Supplementary Material 3

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Author contributions

MM, JW, GJD, JG, GVM, MB, CT, MB, KP conceived and designed the study. SA, LDK, DS, NW, EF, HV, SHH were involved in participant recruitment and data collection. EF and SHH coordinated the study. SHH undertook the analysis and interpretation of the results. SHH wrote the first draft of the manuscript under the supervision of MM. All authors contributed to the critical review and development of this final manuscript for publication.

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Data availability

This publication involved information collected from consenting individuals. 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 the collection of survey data. All identifying information, including full name, has been anonymized 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 authorized for the research project.

Declarations

Ethics approval and consent to participate

All participants provided written informed consent prior to any study procedures. Ethics approvals were obtained from three human research ethics committees: the Aboriginal Health & Medical Research Council of NSW (1474/18), the Aboriginal Health Research Ethics Committee (04-18-797), and St Vincent's Hospital Sydney (2019/ETHO3406). The study was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice (ICH/GCP) guidelines.

Consent for publication
Participant informed consent included acknowledgement of future publication and/or presentation of aggregated, de-identified data.

Inclusion and diversity
One or more of the authors identifies as Indigenous or First Nations. One or more of the authors of this paper self-identifies as an underrepresented ethnic minority in science. One or more of the authors of this paper self-identifies as a member of the LGBTQI + community.

Competing interests
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