Kirby Institute

Hepatitis C virus reinfection following direct acting antiviral treatment in the prison setting: the SToP-C study

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Acknowledgements

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Disclosure of interests

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Background

People who inject drugs (PWID) are incarcerated at high rates for drug related crimes

Within prisons, the prevalence and incidence of hepatitis C virus (HCV) infection exceeds that observed in community settings

In Australia, prison based delivery of direct acting antiviral (DAA) therapy for HCV constitutes as increasing proportion of treatment uptake, rising from an estimated 6% in 2016 to 31% in 2019 [1,2]

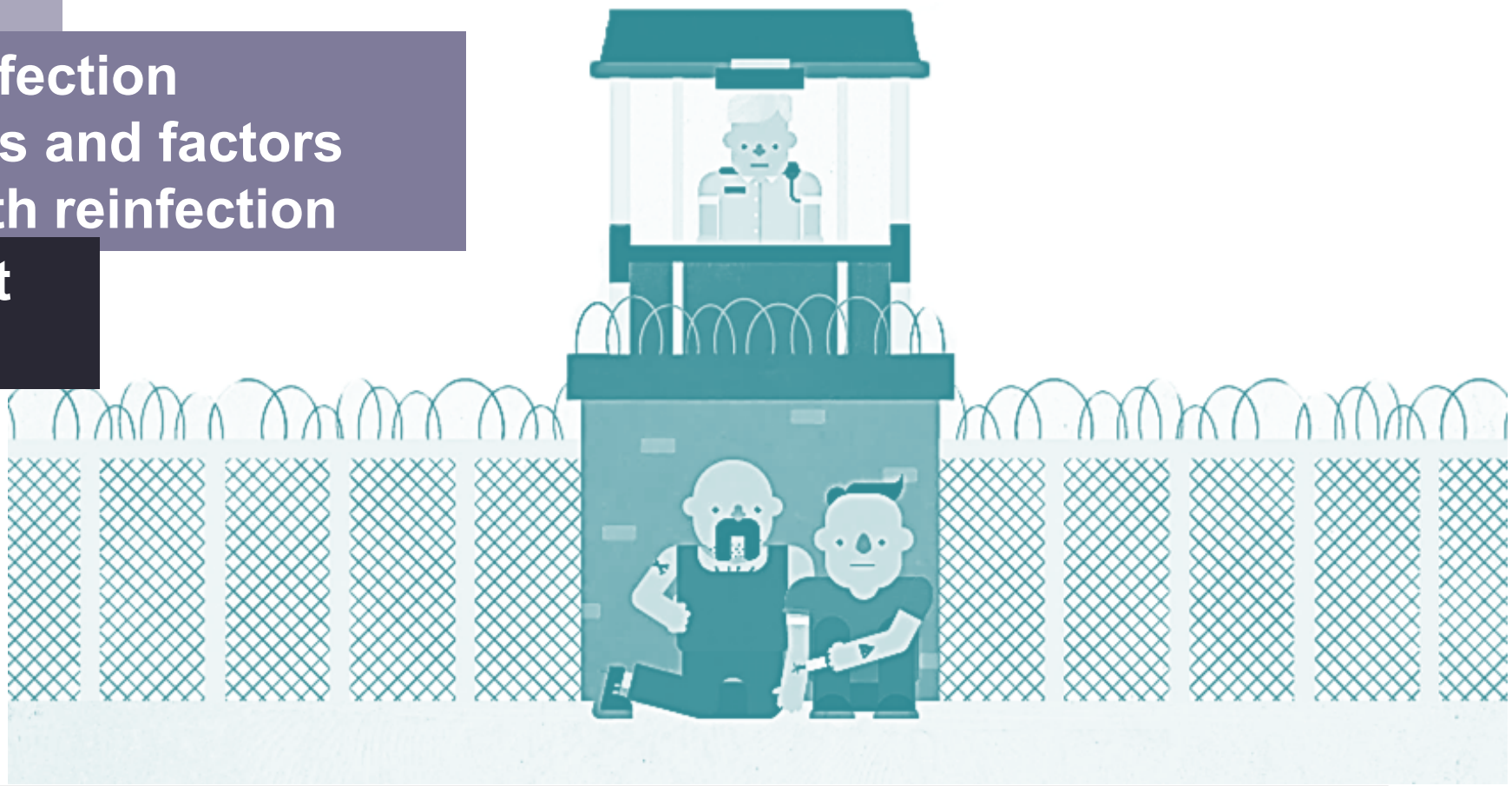
Incarcerated PWID in Australia have access to opioid agonist therapy (OAT) but not access to needle and syringe programs (NSPs)

Reinfection following successful treatment may compromise the individual and population level benefits of cure.

[1]Papaluca et al (2019), Scale-up of hepatitis C treatment in prisons Scale-up of hepatitis C treatment in prisons is key to national elimination. Med J Aust.
[2]Burnet Institute (2020). Australia's progress towards hepatitis C elimination: annual report 2020.

AIMS

1. Describe population at risk of reinfection
2. Assess reinfection incidence rates and factors associated with reinfection
3. Evaluate retreatment uptake and outcomes



The SToP-C study design

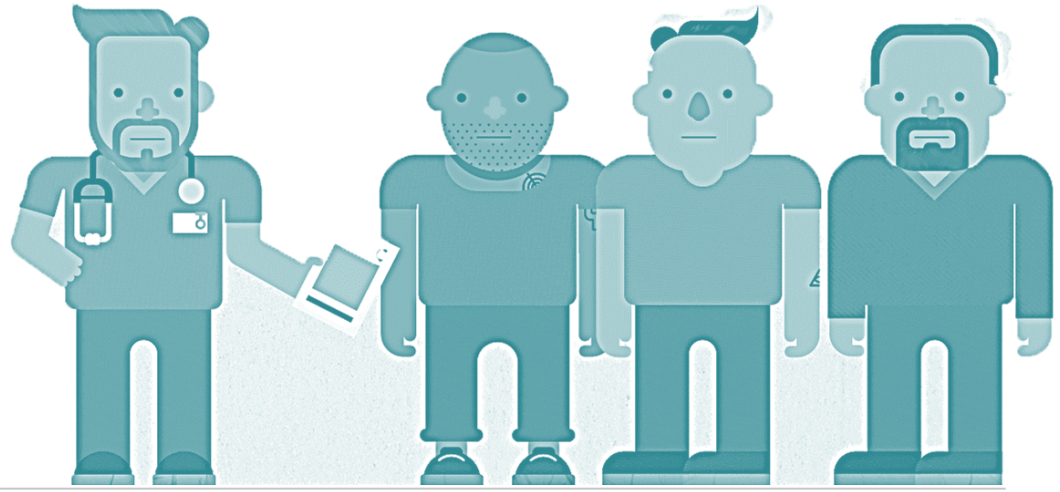
Surveillance and treatment of prisoners with hepatitis C (SToP-C) was a non-randomized clinical trial running from 2014-2019[1]

Four prison sites in New South Wales (NSW), Australia
- 2 x maximum security (male)
- 2 x medium security (male + female)

Participants were screened for HCV at enrolment then every 3-6 months. Those that were HCV RNA+ were referred for treatment.
- Treatment was through prison health services before mid-2017 (pre-treatment scale up phase)
- Treatment was through SToP-C after mid-2017 (rapid treatment scale up phase)

Participants that received treatment were followed up for post-treatment reinfection every 3-6 months while incarcerated

- Reinfection was identified by sequencing
- Injecting drug use risk was assessed by behavioural survey



[1]Hajarizadeh B, et al (2021). Evaluation of hepatitis C treatment-as-prevention within Australian prisons (SToP-C): a prospective cohort study. Lancet Gastroenterol Hepatol.

Participant flow

Screened for HCV
n=3691

HCV RNA positive
n=803

HCV RNA+ at enrolment (n=719)
HCV RNA+ during follow up (n=106)

HCV RNA positive
with treatment data
n=388

Through SToP-C (n=324)
Through prison health service or in the community (n=64)

No post-treatment
HCV RNA negative visit
n=227*

Transfer to non-SToP-C prison (n=116)
Release from prison (n=93)
Treatment failure (n=2)
Other (n=16)

HCV RNA negative at
ETR/SVR12 with
post-treatment
follow up visit
n=161

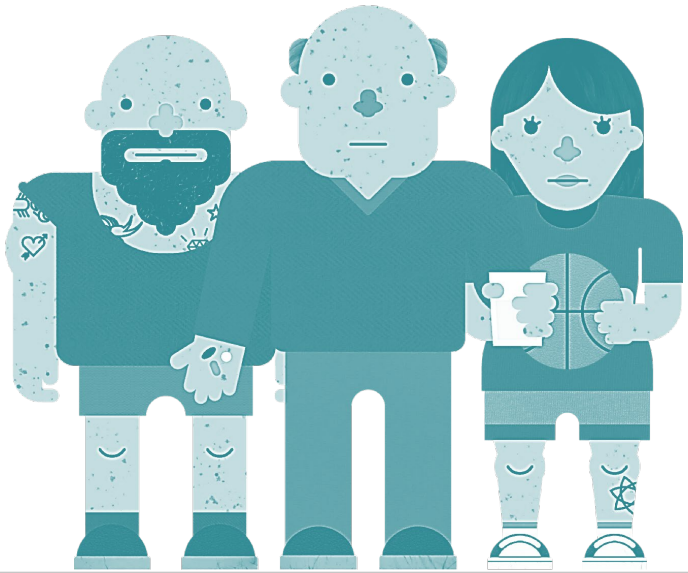
No post-treatment
reinfection
n=143

Post treatment
reinfection
n=18

Abbreviations: ETR, end of treatment response; SVR, sustained virological response 12 weeks post-treatment

Characteristics at enrolment

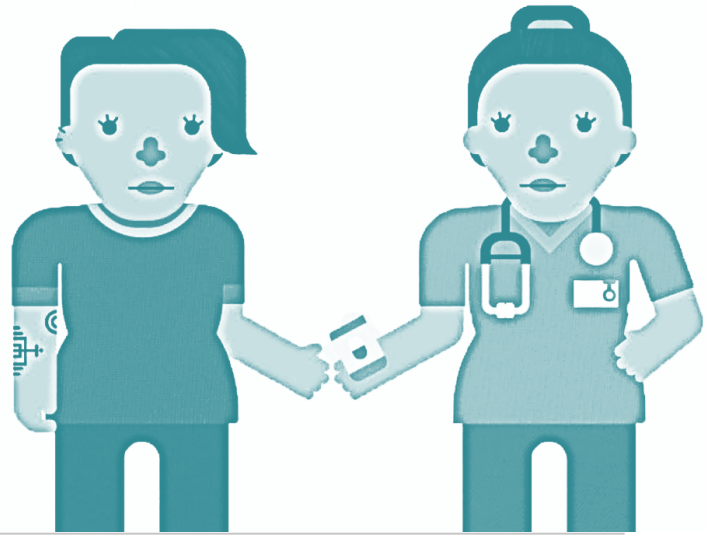
	FU available *included in analysis* (n=161)	No FU available *not included in analysis* (n=227)
Male	92%	91%
Median age (IQR)	33 (27-40)	31 (25-36)
Indigenous	36%	35%
Max security	76%	72%
Previous incarceration	88%	93%
Median prison stay (IQR)	17 (7-44)	6 (2-17)
Pyschiatric medication	33%	26%
History of IDU	94%	91%
OAT among those with history of IDU	33%	26%
IDU during current incarceration	67%	63%
IDU within the last month	44%	55%
Among those with IDU last month	(n=71)	(n=119)
Daily or more IDU	59%	55%
Needle/syringe sharing	90%	89%
Methadone/bupenorphine used most	79%	86%
Methamphetamine used most	20%	7%
Heroin used most	1%	6%



Abbreviations: IDU, injecting drug use; OAT; opioid agonist therapy; FU, follow up

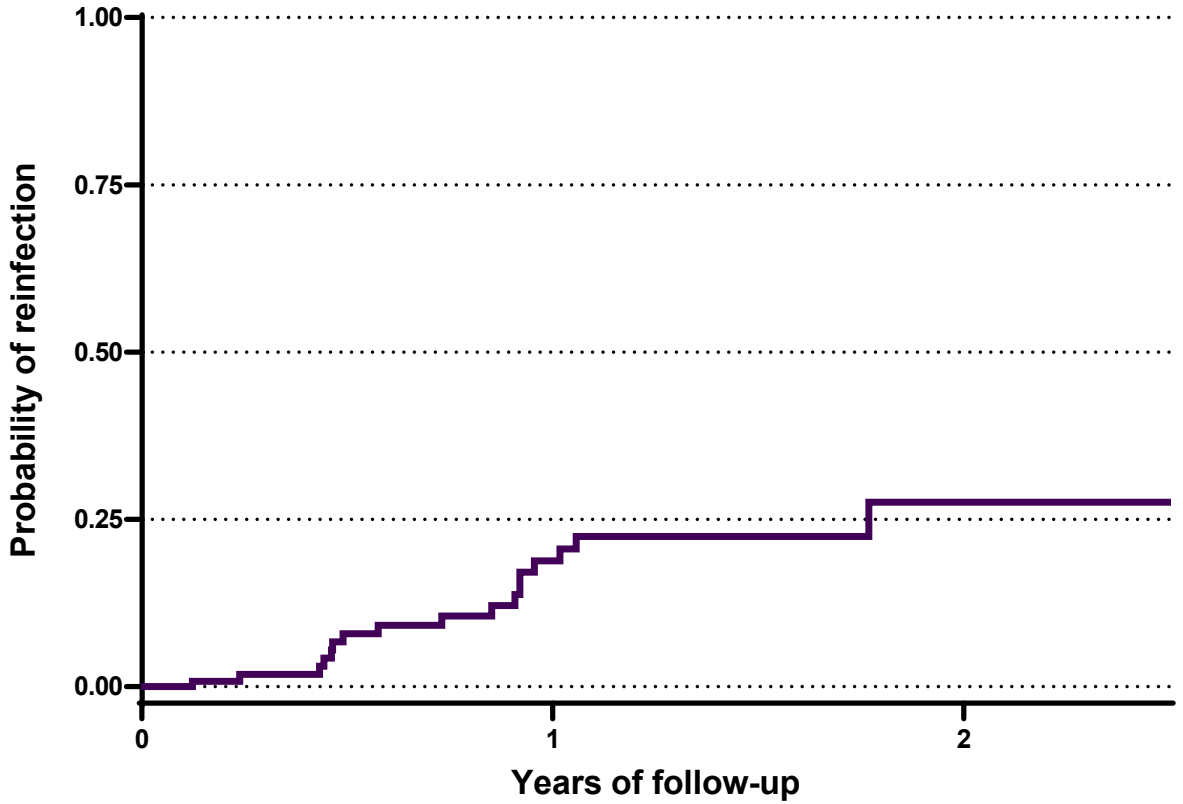
Characteristics reinfection vs no reinfection

	Reinfection (n=18)	No reinfection (n=143)
Male	94%	91%
Median age (IQR) at treatment commencement	32 (26-36)	36 (28-44)
Indigenous identifying	29%	34%
Maximum security prison	83%	75%
Release and reincarcerated during FU	33%	20%
Tattoo or piercing in the last 6 months	26%	11%
Interpersonal violence in the last 6 months	43%	38%
IDU in the last month	83%	34%
Among those with IDU last month	(n=16)	(n=49)
Shared needle/syringe	87%	67%
Opioid agonist therapy	17%	23%
IDU daily or more	51%	56%
Methadone/bupenorphine used most	77%	72%



Abbreviations: IDU, injecting drug use; OAT, opioid agonist therapy; FU, follow up

Cumulative hazard graph of time to reinfection



Number at risk	0	1	2
	168*	59	13

*7 participants re-entered the reinfection analysis following successful retreatment or spontaneous clearance

161 individuals
18 reinfection cases

Reinfection incidence
12.5 per 100 person years

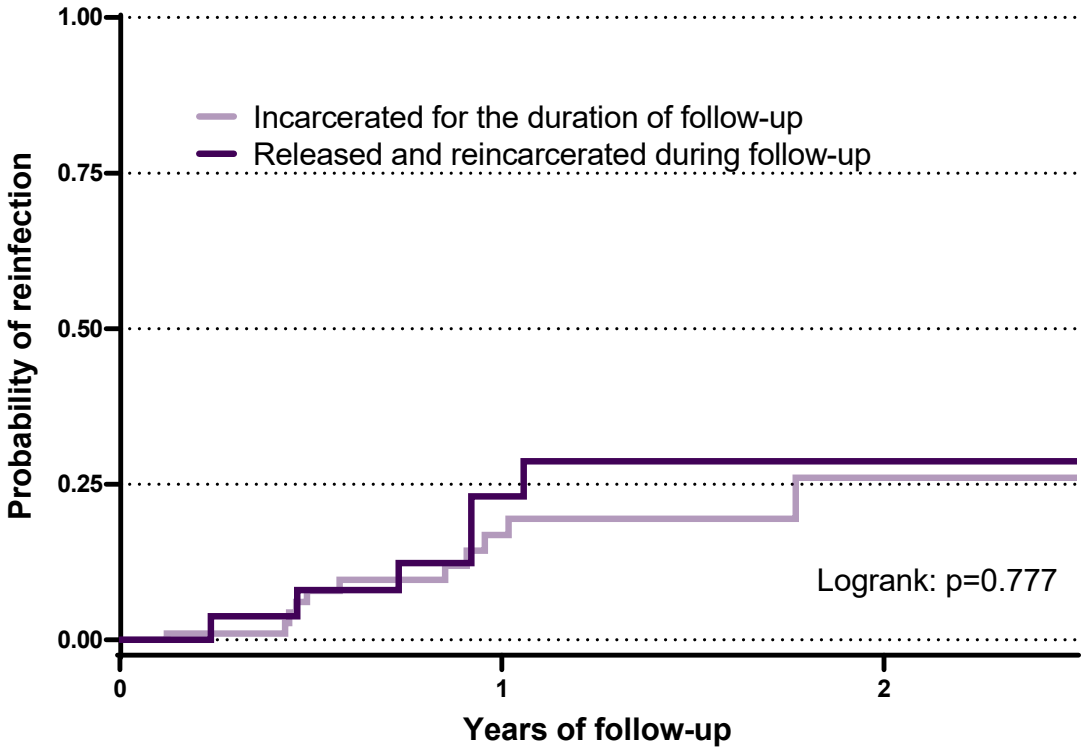
Total FU 144 person years
Median FU 9 months
(IQR 3-17)

Estimated date of reinfection was the mid-point between last post-treatment HCV RNA negative test and the first HCV RNA positive test.

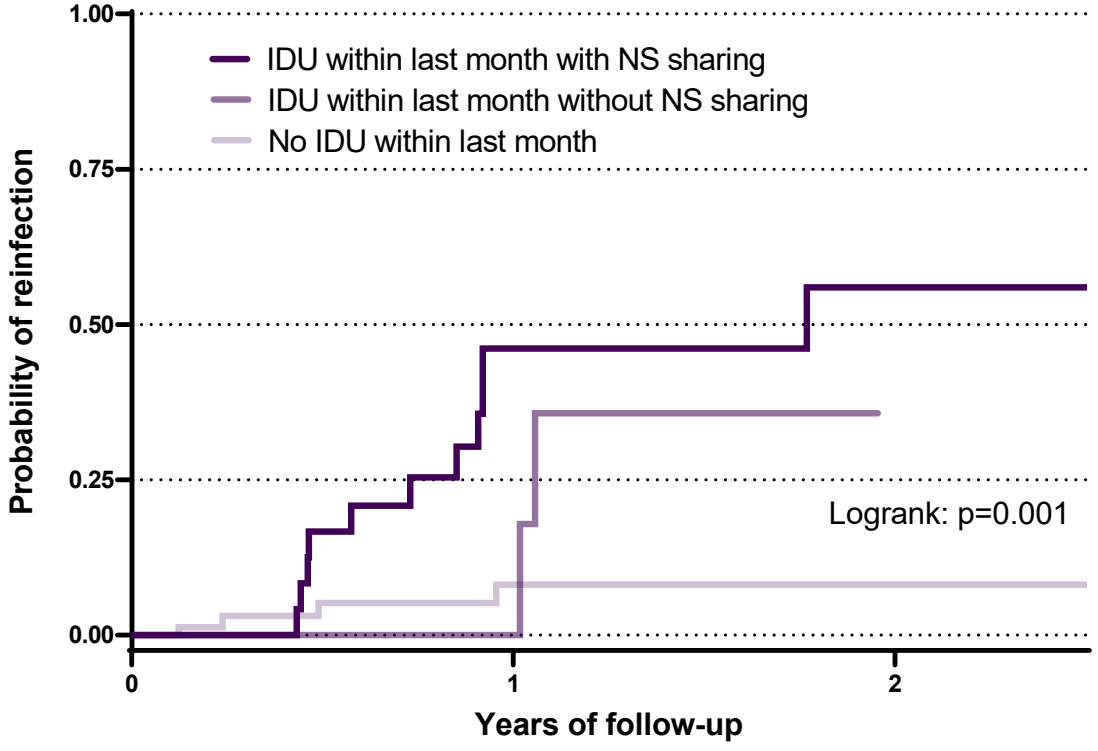
Time to reinfection was calculated from confirmed viral clearance at ETR/SVR12 to estimated date of reinfection

Abbreviations: IDU, injecting drug use; NS, needles or syringes: FU follow up; ETR, end of treatment response; SVR12, sustained virological response 12 weeks post-treatment

Cumulative hazard graphs of time to reinfection



Number at risk	0	1	2
Incarcerated	131	41	9
Reincarcerated	37	18	4

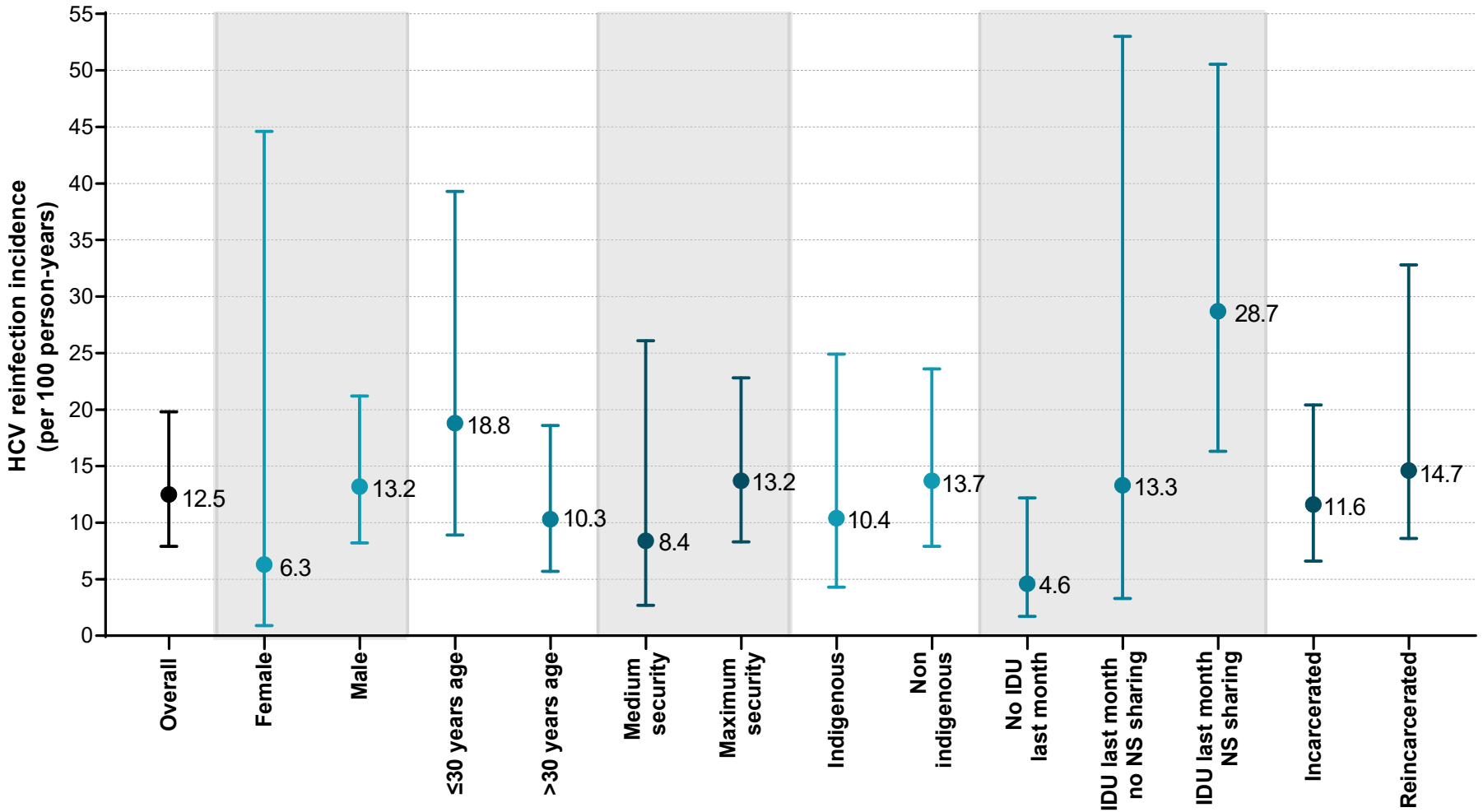


Number at risk	0	1	2
No IDU last month	101	39	8
IDU no NS sharing	17	7	0
IDU with NS sharing	50	13	5

Abbreviations: IDU, injecting drug use; NS, needles or syringes

Reinfection incidence rates in prison

161 individuals // 18 reinfection cases // total FU 144 person years // median FU 9 months (IQR 3-17)



Only factor associated with reinfection in adjusted Cox regression analysis was **IDU last month with sharing of needles/syringes**

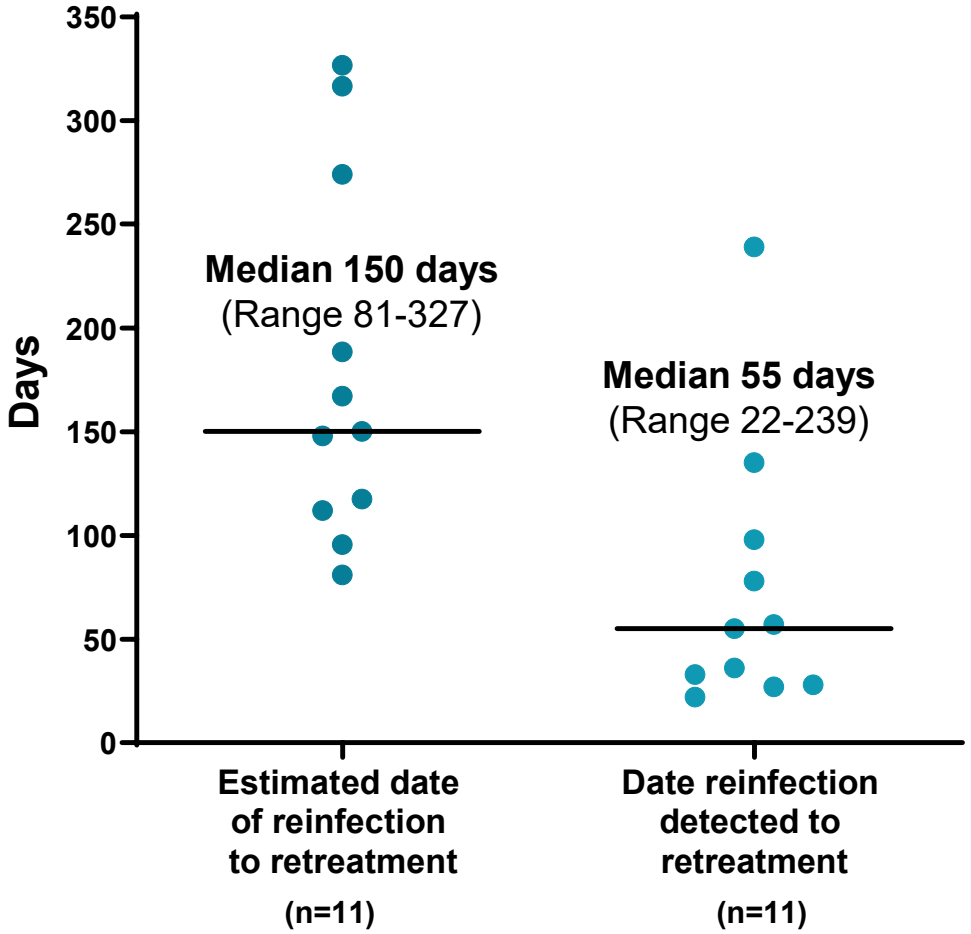
AHR 14.62
95% CI 1.84-116.28
p=0.011

Abbreviations: IDU, injecting drug use; NS, needle or syringe sharing

STOPC

Retreatment uptake and outcomes

18 reinfection cases // 11 retreated // 1 spontaneous clearance // 6 not retreated by last study visit



PP SVR 100%

ITT SVR 63%*

*All individuals with an unknown treatment outcome were released prior to SVR12

Per protocol (PP) including only those with known retreatment outcomes

Intention to treat (ITT) including all those receiving treatment and considering those that had unknown retreatment outcome as treatment failures

Conclusions…

Excessive rate of post-DAA reinfection in prison may reduce the benefits of treatment expansion.

Risk for reinfection is **strongly associated with needle and syringe sharing** among people who recently injected drugs.

→ **Increased access to harm reduction strategies** in the prisons including NSPs and increased coverage of OAT

→ Access to strategies that restrict opportunity for transmission among those reinfected including **regular reinfection surveillance and rapid initiation of retreatment**

Acknowledgments

Study partners:

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Hepatitis NSW

changing lives reducing crime

NSW GOVERNMENT Health Justice Health & Forensic Mental Health Network

NSW GOVERNMENT Health

NSW GOVERNMENT Justice Corrective Services

For further information about this analysis please contact: jcarson@kirby.unsw.edu.au

SToP-C implementation toolkit available: https://staging.pictura.com.au/stopc/

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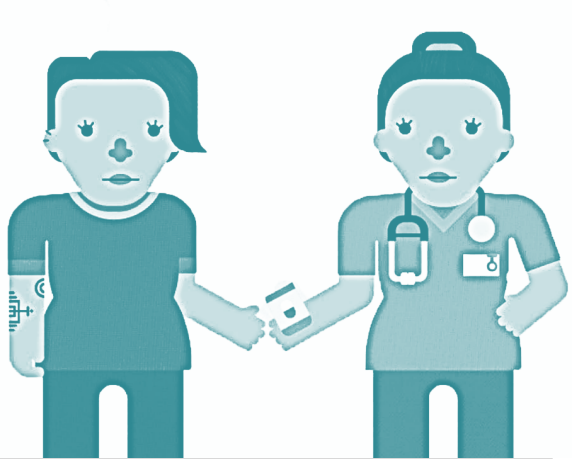

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