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YEARS OF IMPACT

We're
just getting
started.

Effect of point-of-care RNA and dried blood spot testing on initiation of treatment among people who inject drugs with hepatitis C infection attending needle and syringe programs (TEMPO): a cluster randomised controlled trial

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Why TEMPO matters

- A major barrier to improving HCV testing and treatment is that the current diagnostic pathway requires multiple visits leading to frequent loss to follow-up¹
- Dried blood spot collection and point-of-care HCV testing may improve testing and treatment^{2,3}
- Early pilot work suggested high treatment initiation (81%) with point-of-care HCV RNA testing⁴, but a controlled trial was needed

Aim

To compare HCV treatment initiation within 12 weeks following offer of HCV testing by point-of-care HCV RNA, dried blood spot, or standard of care testing among people reporting recent injecting drug use and current HCV infection attending needle/syringe program services

SITE LEVEL

Randomisation
at NSP
(site) level



Participating Australian
needle and syringe programs (NSPs)



NSP sites cluster-randomised to one HCV testing strategy

Allocation at site level—not individual participants
19 sites randomised; 16 sites implemented allocated testing*



Universal testing

Rapid testing

Rapid testing with a confirmatory test

SITE LEVEL

Randomisation
at NSP
(site) level



Participating Australian
needle and syringe programs (NSPs)

NSP sites cluster-randomised to one HCV testing strategy

Allocation at site level—not individual participants
19 sites randomised; 16 sites implemented allocated testing*



STANDARD OF CARE (SOC)
5 sites

PARTICIPANT LEVEL

Adults attending
allocated NSPs
who reported
injecting drug use
in the previous
6 months
(≥18 years)**

Testing according to existing practice at the NSP
(venepuncture or DBS, depending on sites)

OPTION A



Venepuncture
(On- or off-site)

OR

OPTION B



Finger-stick
DBS collection
(On-site)



Laboratory-based
HCV testing
(HCV antibody and/or
HCV RNA)



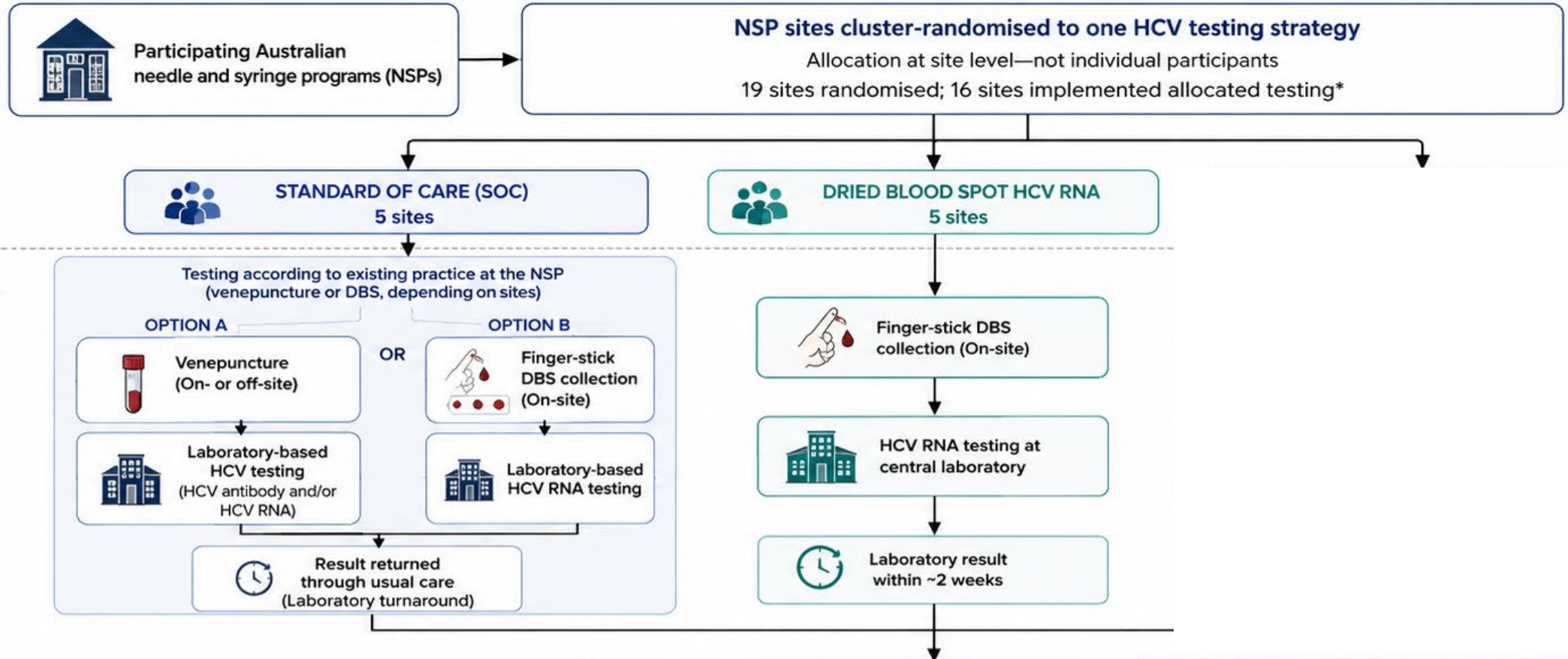
Laboratory-based
HCV RNA testing



Result returned
through usual care
(Laboratory turnaround)

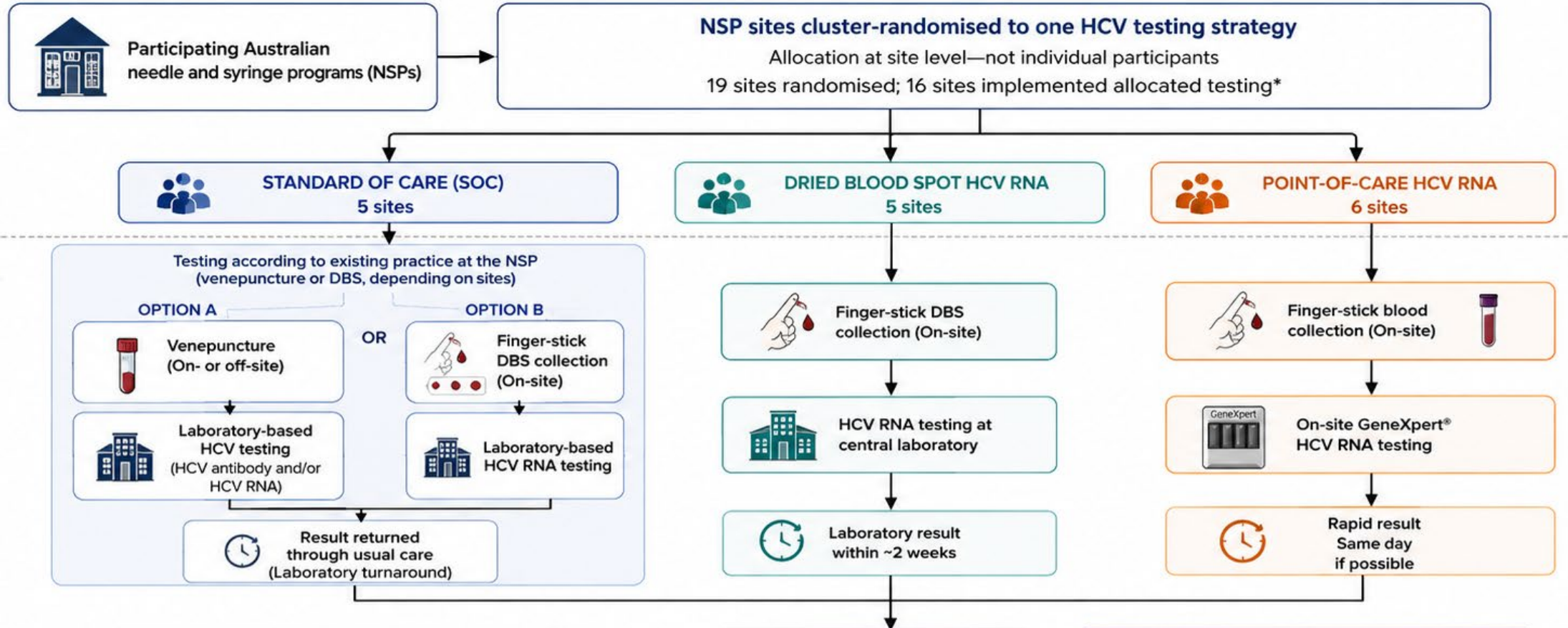
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Randomisation
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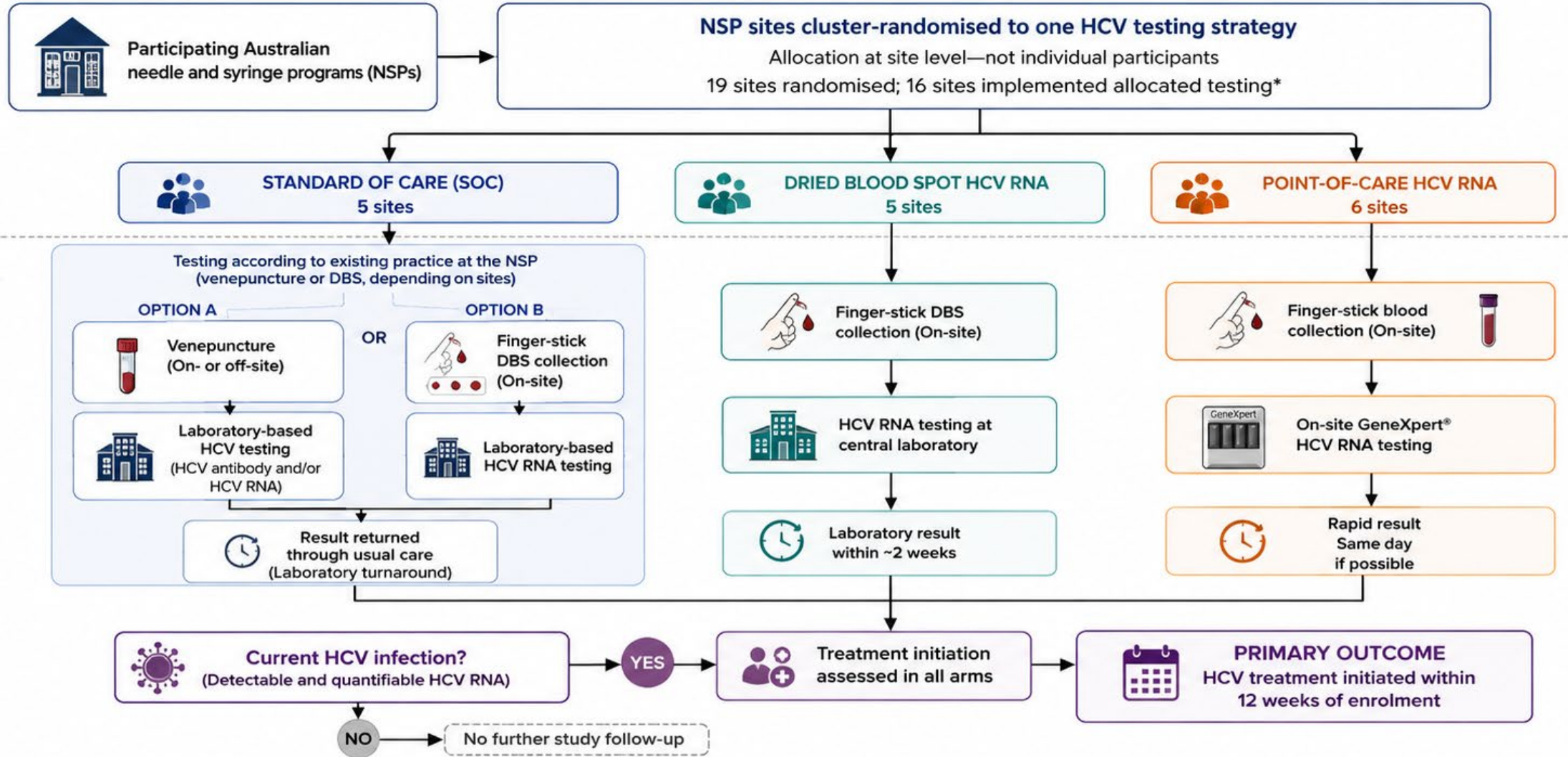
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SITE LEVEL

Randomisation
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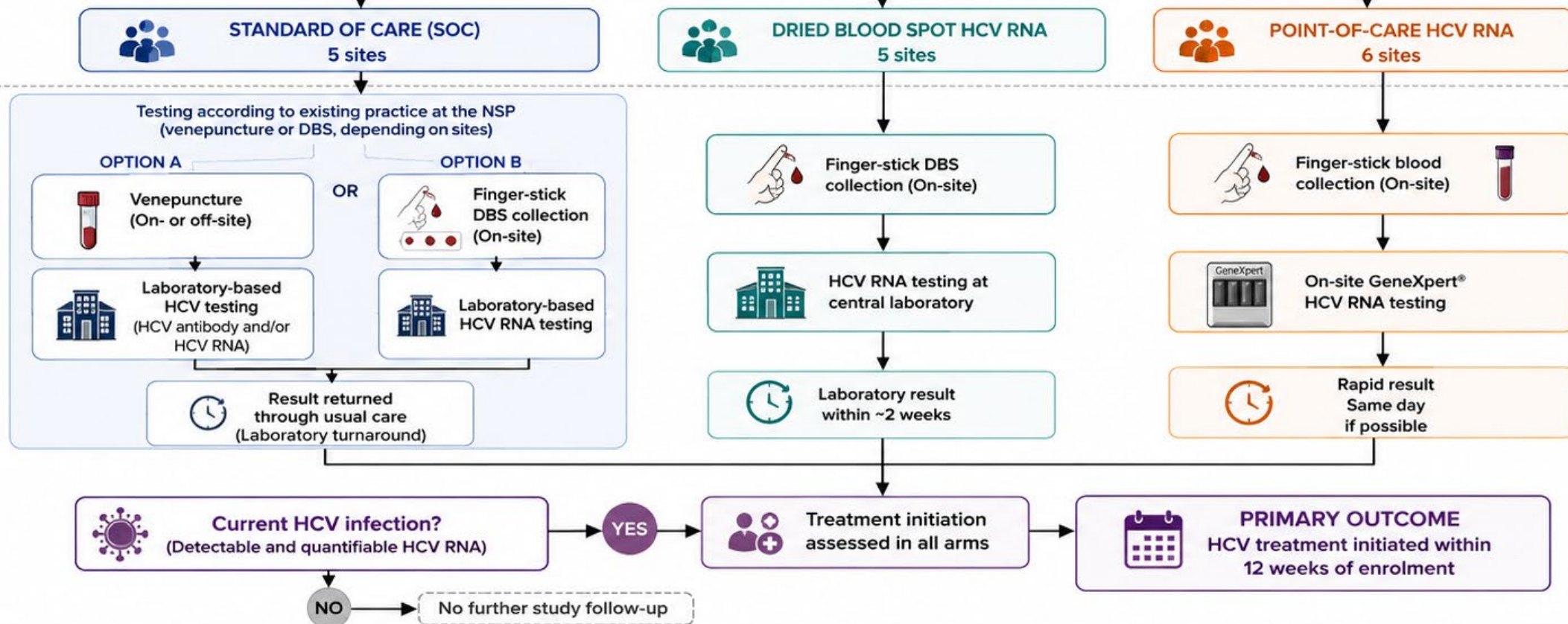
SITE LEVEL

Randomisation
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PARTICIPANT LEVEL

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FOLLOW-UP

After enrolment



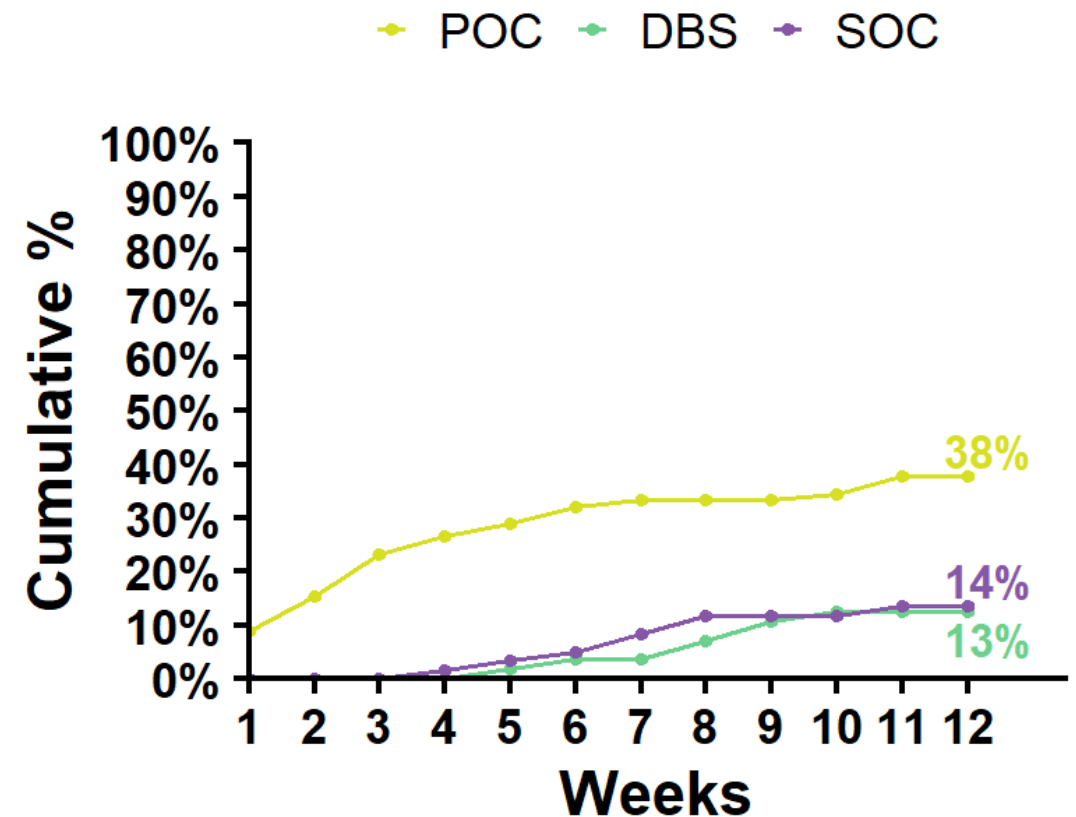
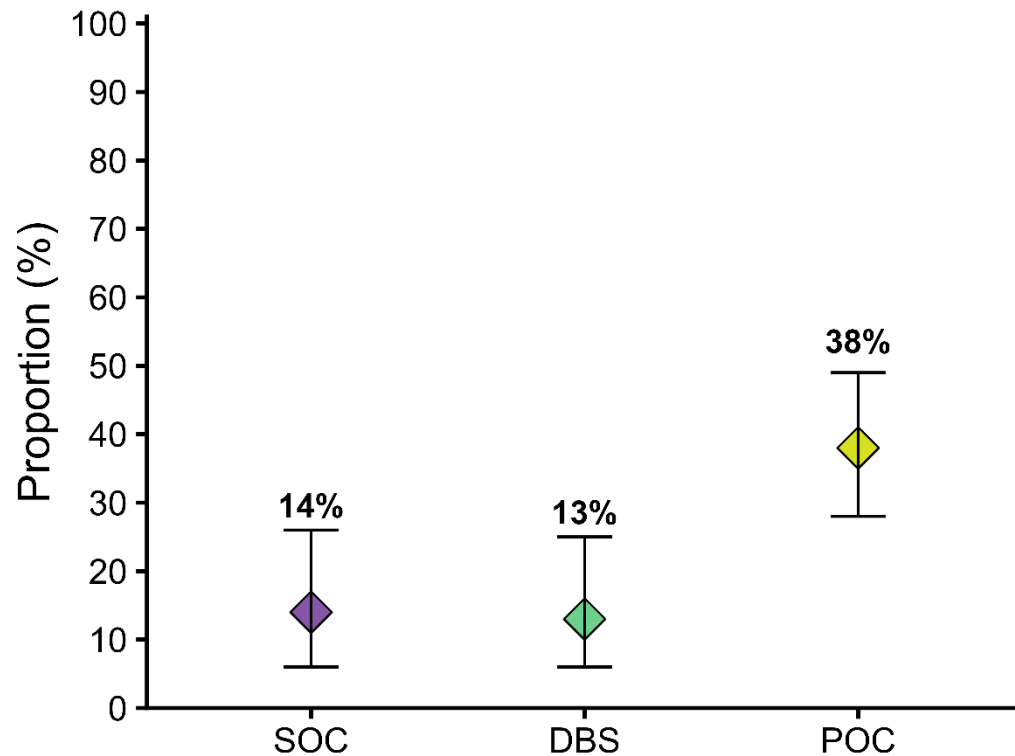
* Three sites withdrew before implementing allocated testing and did not contribute data (1 SOC, 1 DBS, 1 POC).

** Most participants were ≥18 years; at one site younger participants were eligible as permitted locally.

DBS, dried blood spot; HCV, hepatitis C virus; NSP, needle and syringe program; POC, point-of-care; SOC, standard of care.

Results – Treatment initiation within 12 weeks

- 1,801 participants screened, with 205 participants with current HCV infection enrolled
- Median age 44 years, 31% female, 85% injected in the last month, 51% injected $\geq$ daily
- Standard of care (n=59, 4 sites), DBS testing (n=56, 5 sites), and point-of-care testing (n=90, 6 sites)



Results – Treatment initiation within 12 weeks

Variable	Standard of care N (%)	Dried blood spot N (%)	Point-of-care N (%)	Intracluster correlation coefficient	Unadjusted odds ratio (95% CI)	P-value
Number of NSP sites (clusters)	5	5	6			
Number of participants with current HCV	59	56	90			
Treatment initiated within 12 weeks	8 (14%)	8 (14%)	34 (38%)			
Control (SOC) vs intervention (POC/DBS)				0.18 (0-0.36)	2.10 (0.55-8.09)	0.281
Control (SOC) vs POC				0.05 (0-0.18)	3.96 (1.40-11.20)	0.010
Control (SOC) vs DBS				0.20 (0-0.47)	0.90 (0.16-5.01)	0.904

Conclusions

- Compared to standard of care, among people with HCV with recent injecting drug use attending NSP services:
 - Combined intervention of dried blood spot testing or point-of-care HCV RNA testing was not associated with an increased proportion who initiated HCV treatment at 12 weeks following enrolment
 - Point-of-care HCV RNA testing was associated with an increased proportion who initiated HCV treatment at 12 weeks following enrolment [38% vs 14%, odds ratio 3.96 (1.40-11.20)]
- Further work is needed to understand the long-term impact of these interventions on initiation of HCV treatment (e.g. does point-of-care HCV testing just improve time to treatment initiation)
- Further research is needed to understand the barriers/enablers for implementation of point-of-care testing and develop strategies to further improve treatment initiation in this population

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