# A national program to scale-up decentralized HCV point-of-care testing and treatment in Australia

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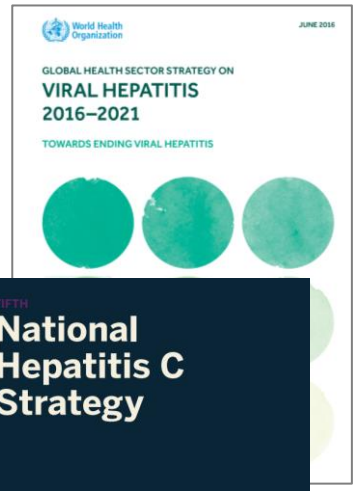
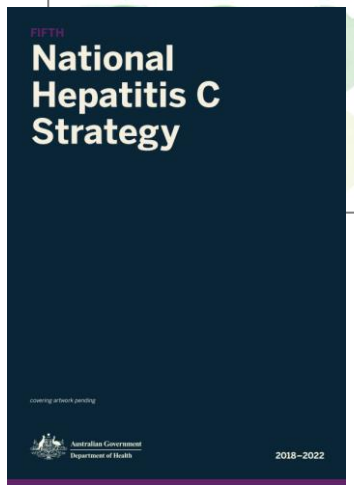
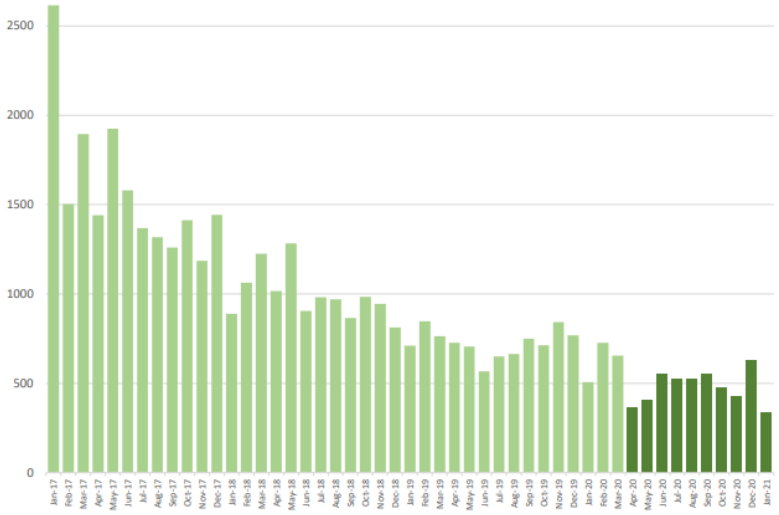
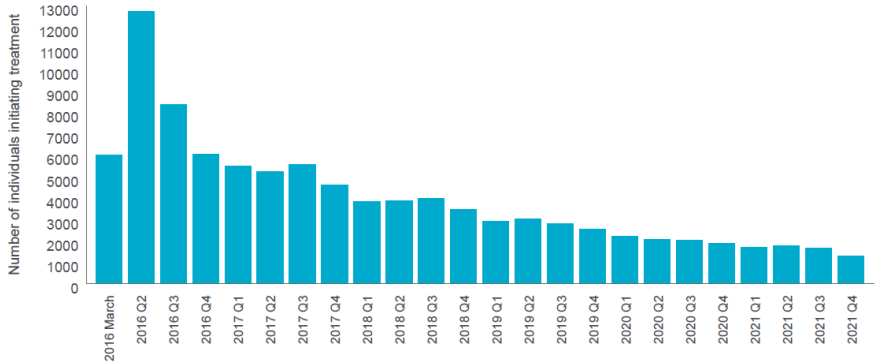
# HCV elimination requires increased testing and treatment

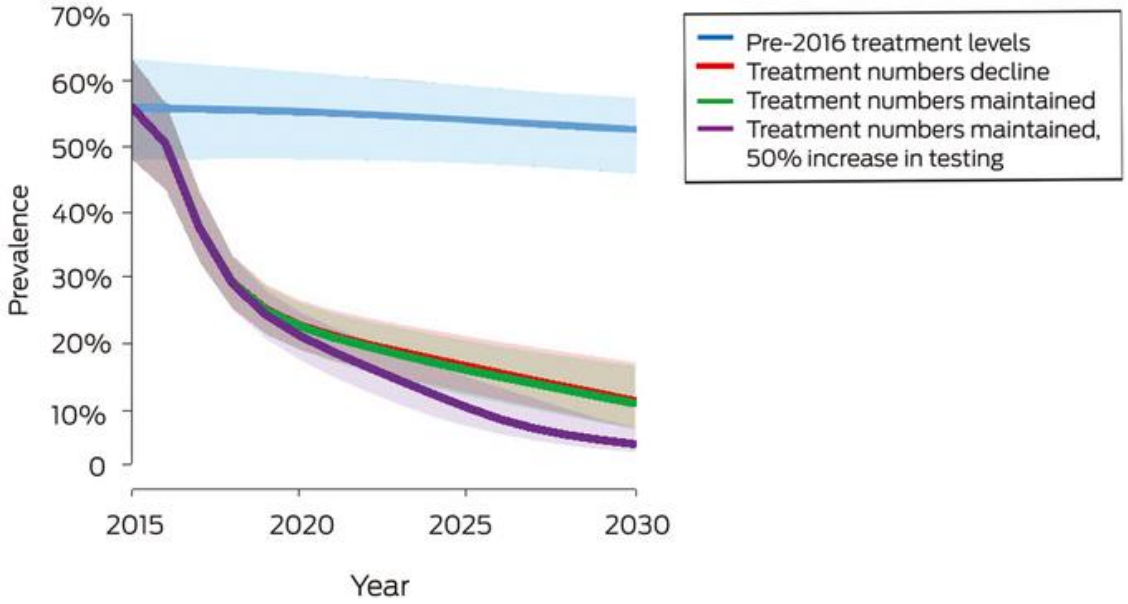



Eliminate viral hepatitis as a major public health threat by 2030

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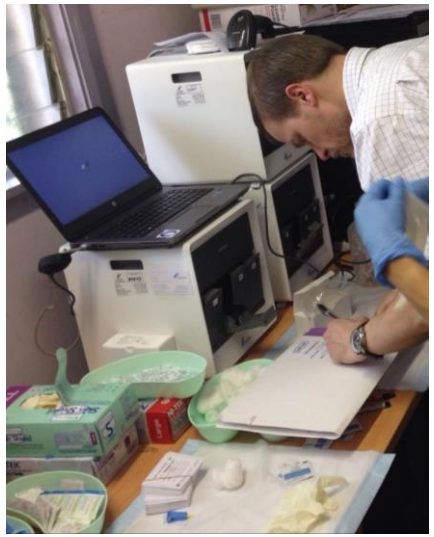
1) Doherty Institute. National Viral Hepatitis Mapping Project (extracted March 2021), 2021; 2) The Kirby Institute, Monitoring hepatitis C treatment uptake in Australia (Issue 11, July 2021), 2021; 3) Scott N, et al Medical Journal of Australia 2020.

# Finger-stick testing for HCV RNA detection


60 mins

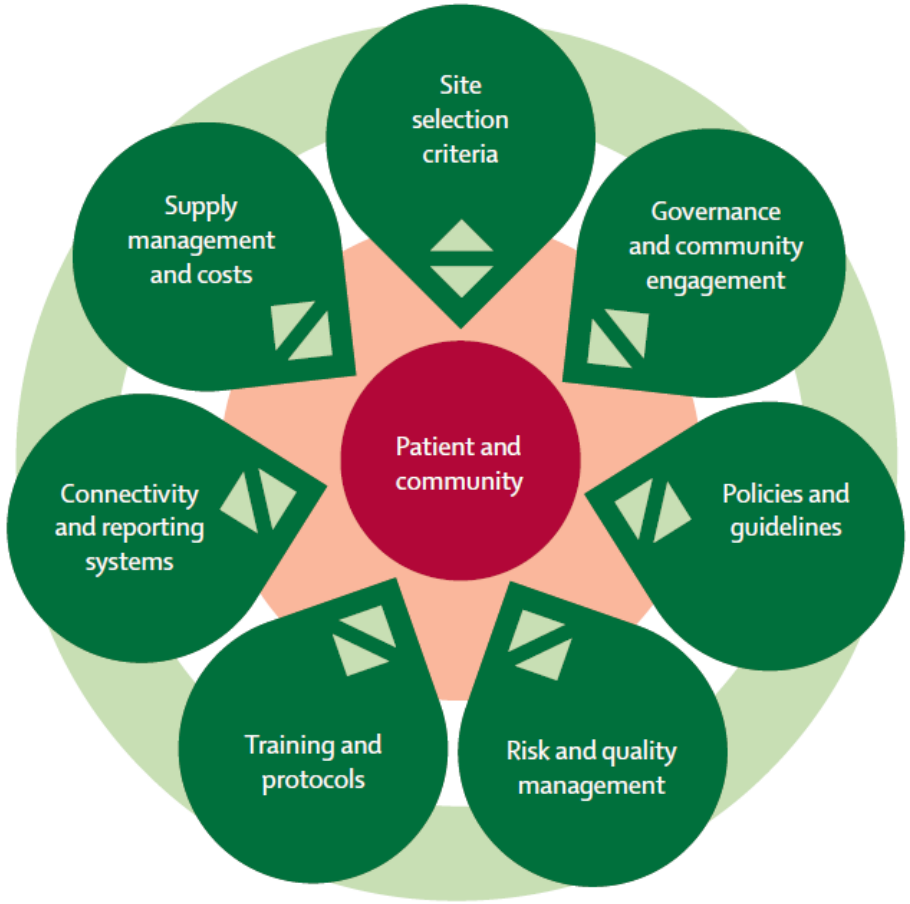


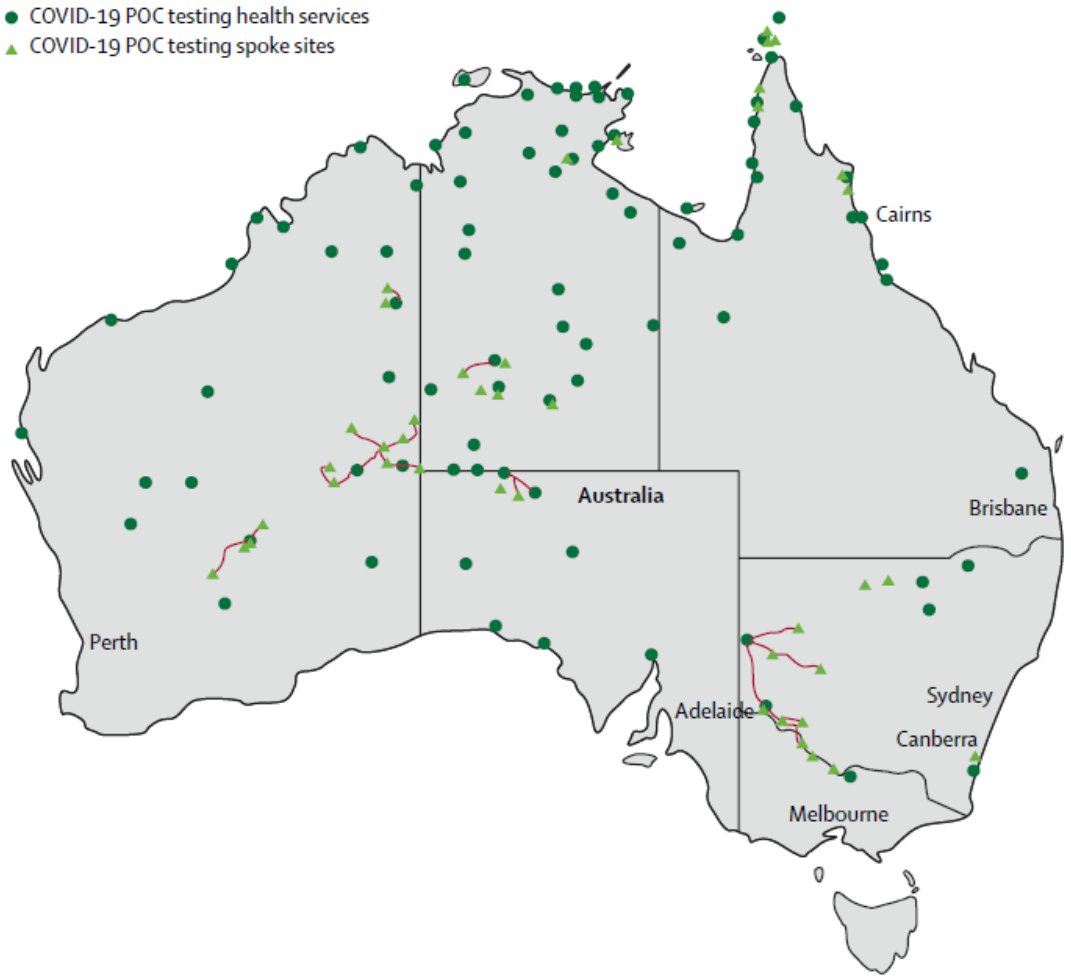
- TGA approval of Xpert® HCV Viral Load Fingerstick for detection of active HCV infection in one hour at the point-of-care is a ‘game-changer’
- Enables diagnosis and treatment in a single-visit, increases testing acceptability and reduces loss to follow-up
- Good technical accuracy (100% sensitivity/specificity)[1-3]



1) Grebely Lancet Gastro Hep 2017, 2) Lamoury Journal of Infectious Diseases 2018, 3) Catlett B Journal of Infectious Diseases 2022

# Scale-up of testing for STIs and COVID-19

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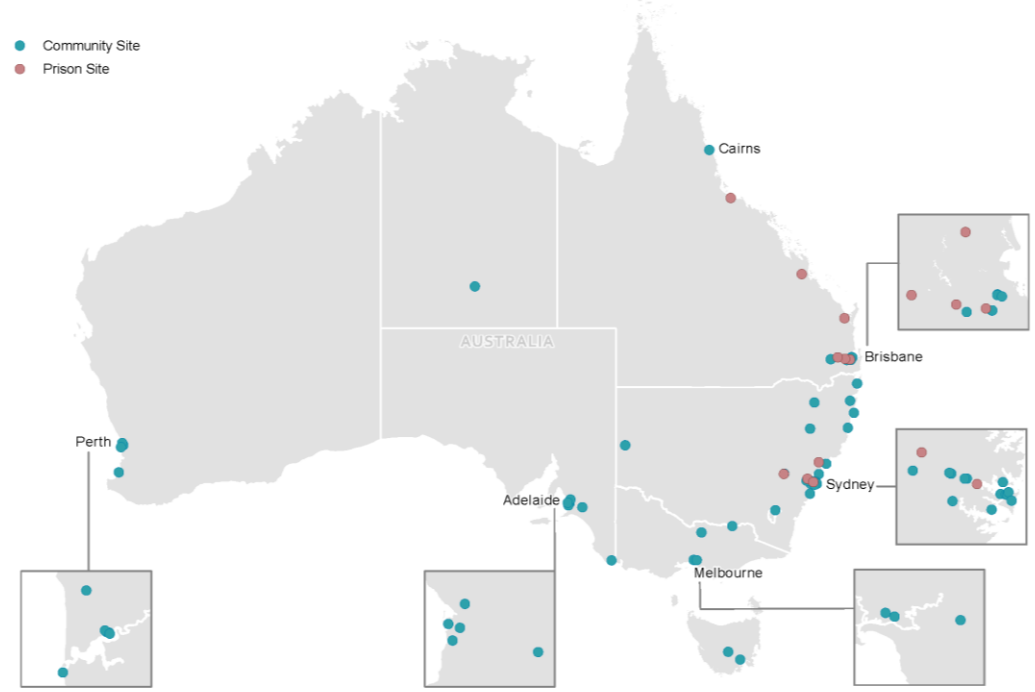
1) Hengel B, et al *Lancet Infectious Diseases* 2021; 2) Guy R, et al. *Lancet Infectious Diseases* 2018

# Study design and participants

- Observational study
- Participants recruited from sites in ACT, QLD, NSW, SA, and TAS (planned 90 sites)
- Drug treatment clinics, NSPs, prisons, mental health, mobile outreach models, homelessness services, Aboriginal Community Controlled Health Organisations

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# Study design and participants

- Participants enrolled between January 2022 and March 14, 2023

- High-intensity testing campaigns at 10 prisons (Queensland, n=7; NSW, n=1; South Australia, n=2)

- Inclusion criteria
  - ≥ 18 years of age
  - At risk of HCV or attending a service providing care for people at risk of HCV

# Procedures

- Program includes:
  - SOPs, logistics, deployment, and set-up of point-of-care testing
  - Operator training
    - 151 operators have received point-of-care testing training[1]
  - Quality assurance program
  - IT/connectivity
  - Research and evaluation framework


1) Markus C, et al POC 2023 (Session G, March 14th)

# Procedures

- Testing is triaged:
  - Immediate HCV RNA testing: Settings with high HCV antibody prevalence (>15%, drug treatment, needle syringe programs and prisons)
  - HCV antibody testing with reflex RNA testing (among people who are HCV antibody positive): Settings with low HCV antibody prevalence (<15%, mental health, homelessness)

- Point-of-care HCV antibody testing: HCV Bioline (Abbott, negative: 20 minutes; positive: 5 minutes) – not TGA approved

- HCV RNA testing: Xpert HCV Viral Load Fingerstick (GeneXpert II or IV platforms, Cepheid, 60 minutes) – TGA approved

- People who are HCV RNA detectable can receive:
  - Point-of-care HIV testing (Alere™ HIV Combo, 20 minutes)
  - Point-of-care hepatitis B surface antigen testing (Alere Determine 2™ HBsAg, 15 minutes)

# Procedures

- Community data collection
  - HCV Antibody testing: REDCap
  - HCV RNA testing: ONDAS (middleware)
  - Behavioural survey (demographics, drug use, HCV testing/treatment): REDCap
  - HCV treatment (medical chart review): REDCap
  - Consent for linkage to administrative databases

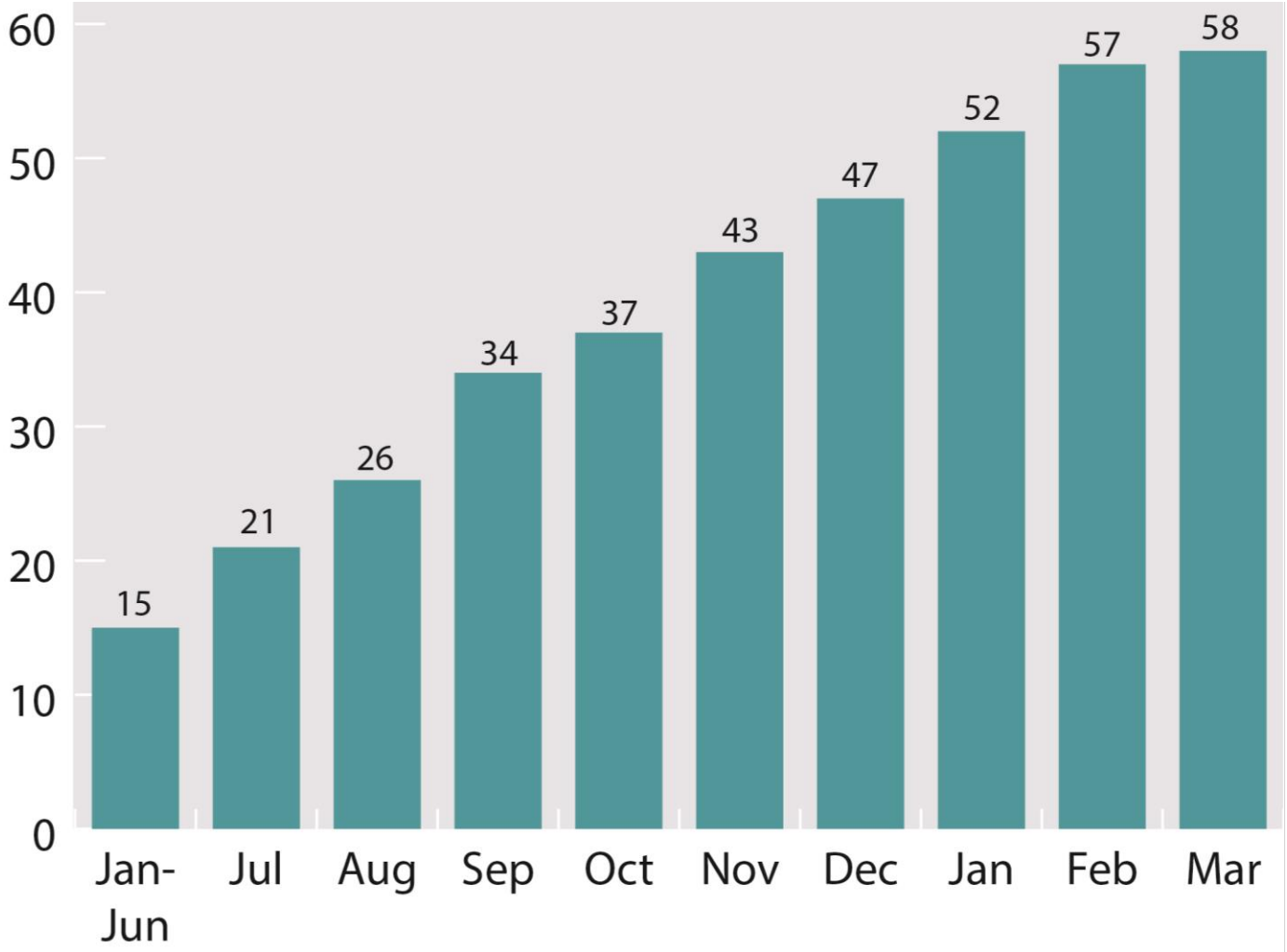
- Prison data collection
  - HCV RNA testing: ONDAS (middleware)
  - HCV treatment (medical chart review)

# Outcomes

- Number of sites
- Number of tests (HCV RNA and antibody)
- Number of people receiving testing (HCV RNA and antibody)
- Proportion HCV RNA detectable
- Proportion who initiated treatment within 12 weeks of testing

# Results – Number of sites

- 59 sites now enrolled in the national program (17 prison sites)

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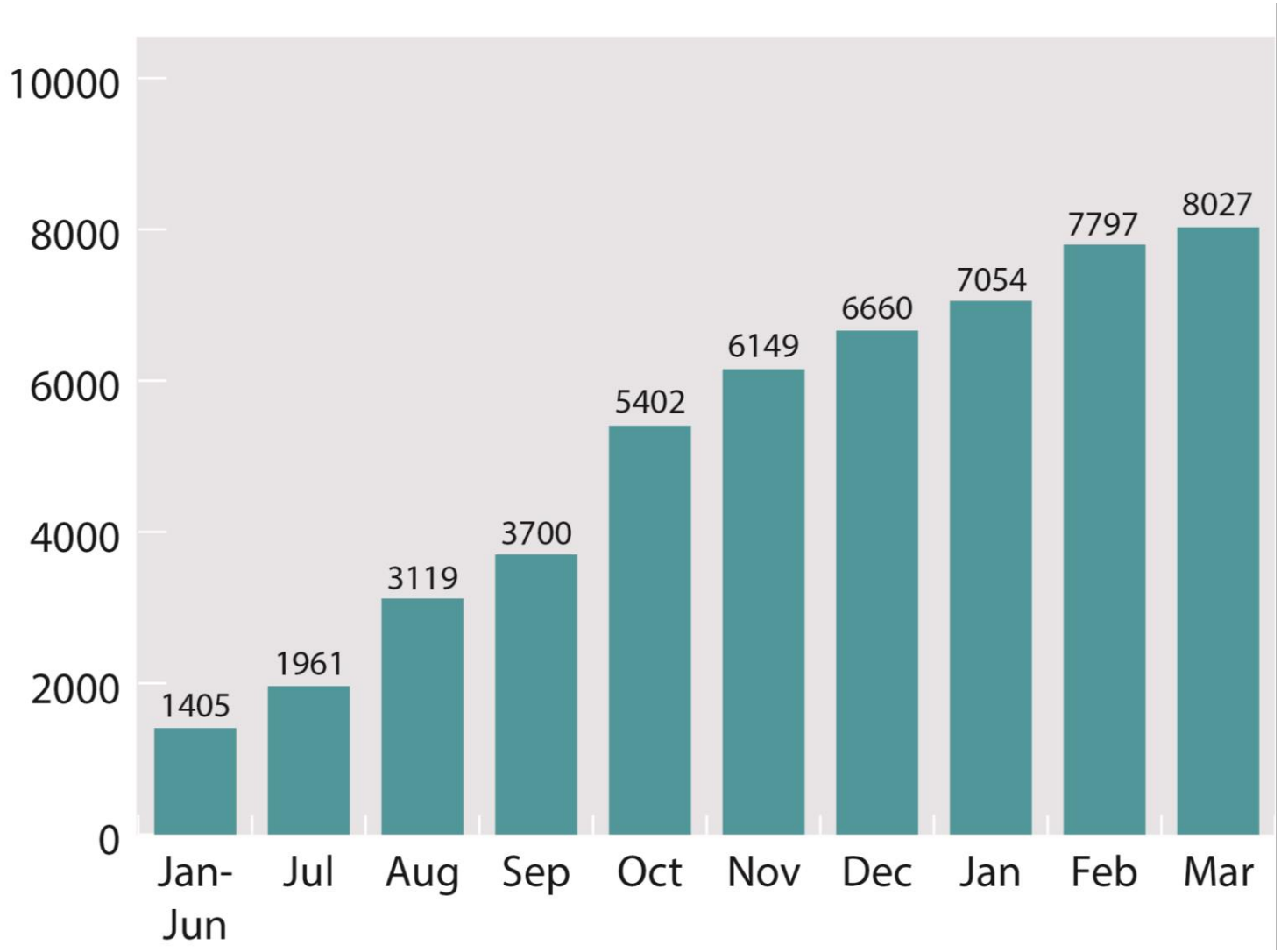
# Results – Testing uptake

- 8,027 HCV point-of-care tests (RNA: n=6,923; antibody: n=1,104)

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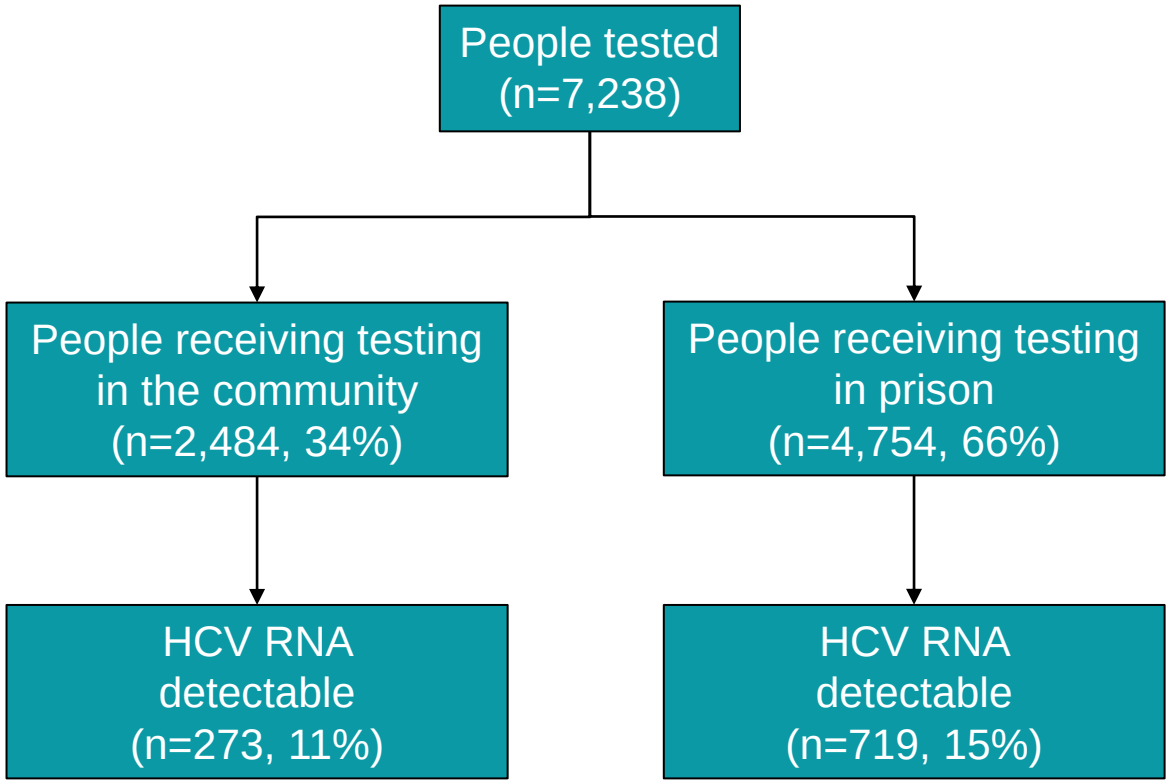
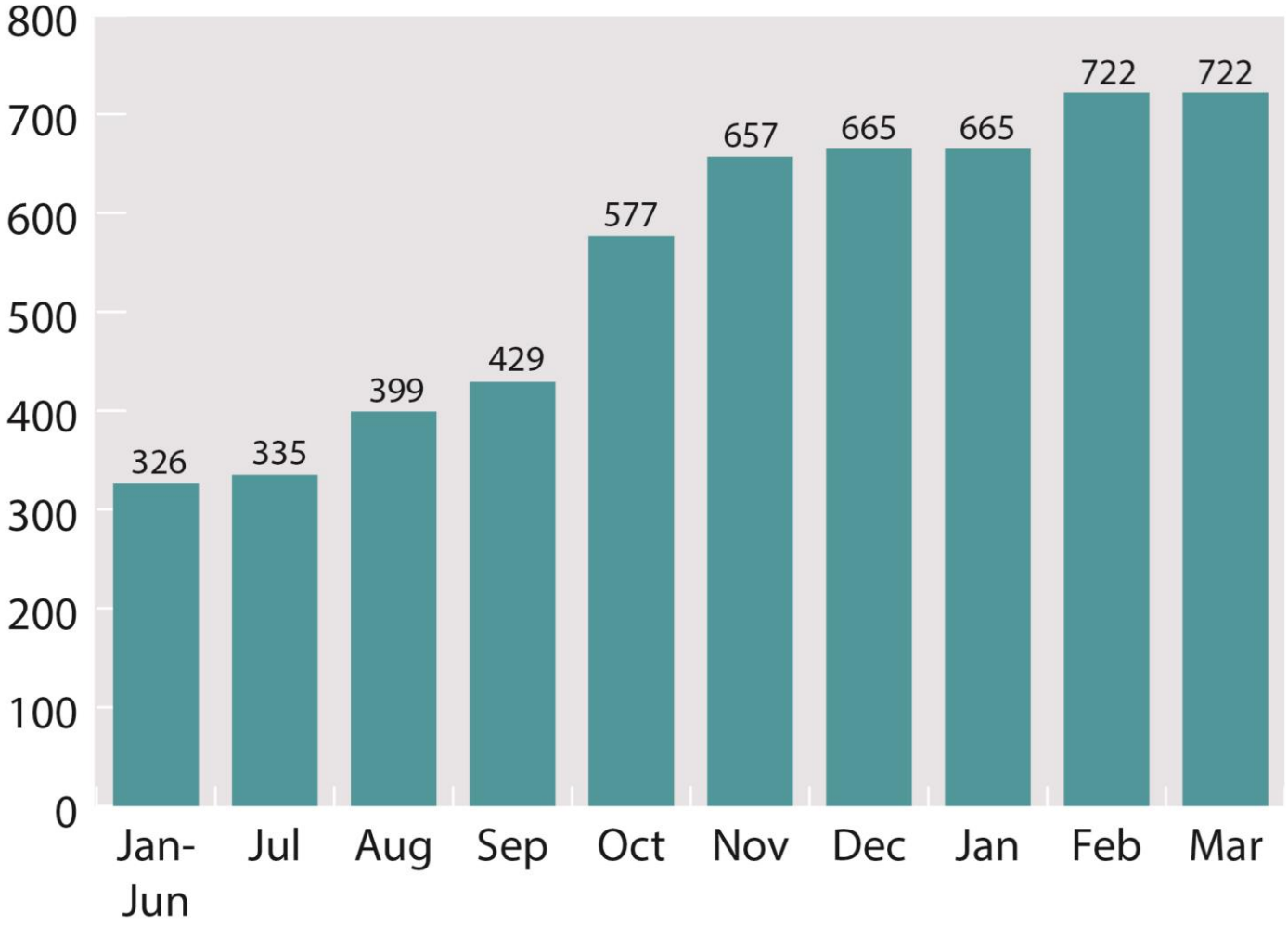

People tested
(n=7,238)
People receiving testing in the community
(n=2,484, 34%)
People receiving testing in prison
(n=4,754, 66%)
HCV RNA detectable
(n=273, 11%)
HCV RNA detectable
(n=719, 15%)

# Results – Treatment uptake

- 992 people with current HCV infection
- Treatment uptake: 73% (722 of 992) overall, 87% (625 of 719) in prison

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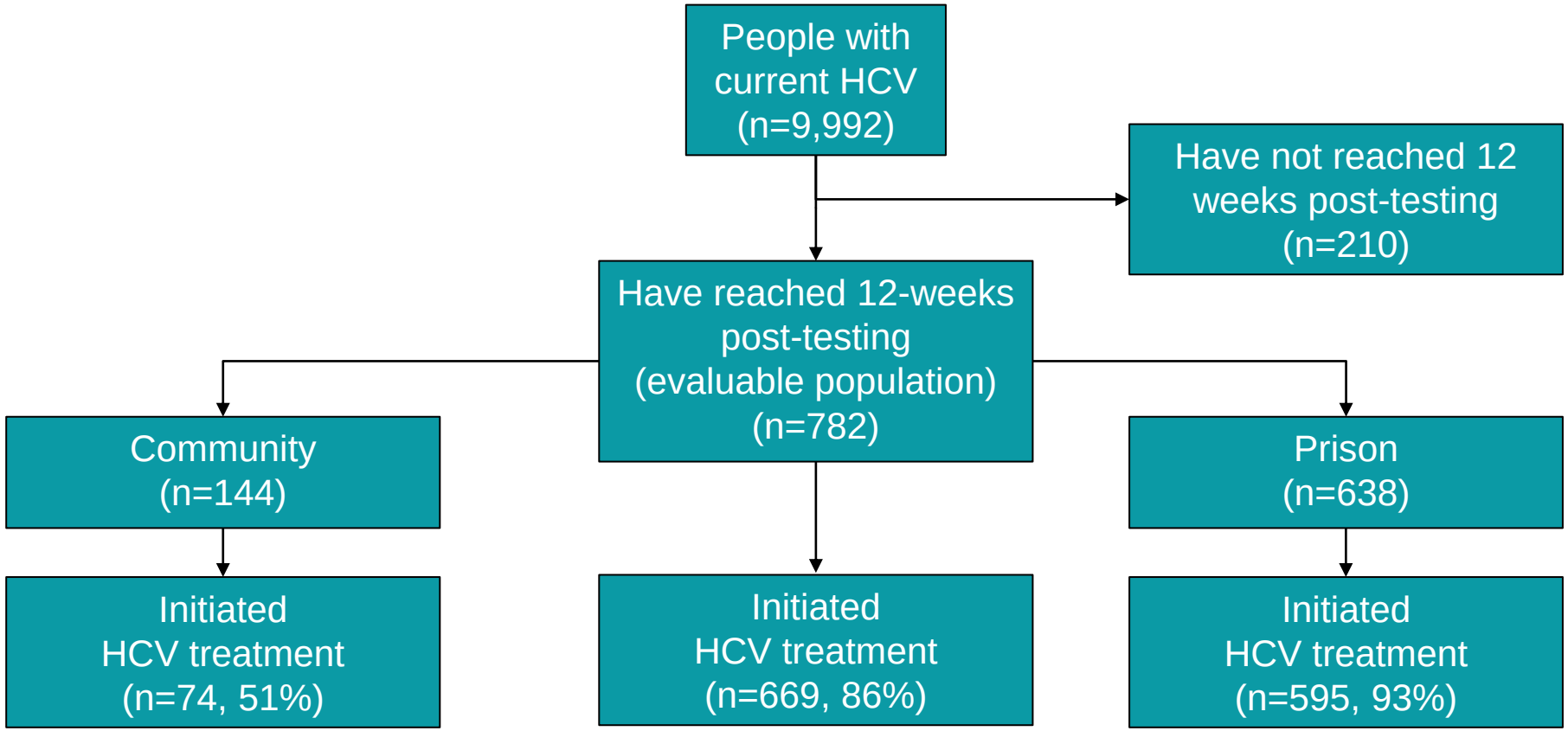
People with current HCV (n=9,992)
Have not reached 12 weeks post-testing (n=210)
Have reached 12-weeks post-testing (evaluable population) (n=782)
Community (n=144)
Prison (n=638)
Initiated HCV treatment (n=74, 51%)
Initiated HCV treatment (n=669, 86%)
Initiated HCV treatment (n=595, 93%)

# Program challenges

Ethical and regulatory requirements

Extensive training requirements

Paperwork, survey, and data entry

Connectivity solutions for data reporting

Programme funding does not include staffing costs

Absence of an HCV antibody test approved by the Australian Therapeutics Goods Administration

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# Program successes

Early stakeholder engagement has facilitated strong collaborative relationships

Improvements in consent process

Training has reduced proportion of error/invalid tests

Quality assurance program has been critical

Point-of-care testing has improved access to testing for people with poor venous access

Prison-led initiatives (including high-intensity testing campaigns) critical

Community-led testing in collaboration with service providers

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# Conclusions and future directions

- The National Australian Hepatitis C Point-of-Care Testing Program has been able to leverage other existing point-of-care testing programs to quickly scale-up HCV testing at a range of sites nationally
- Onsite point-of-care HCV testing has led to high treatment uptake across Australia, particularly in prison settings
- Standardised operator training and quality assurance delivery and management have been critical for test performance
- Further work is required to optimise systems to enhance implementation (e.g. training, IT/connectivity)
- The approval of a TGA-approved point-of-care antibody test should further facilitate scale-up


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RIGHT


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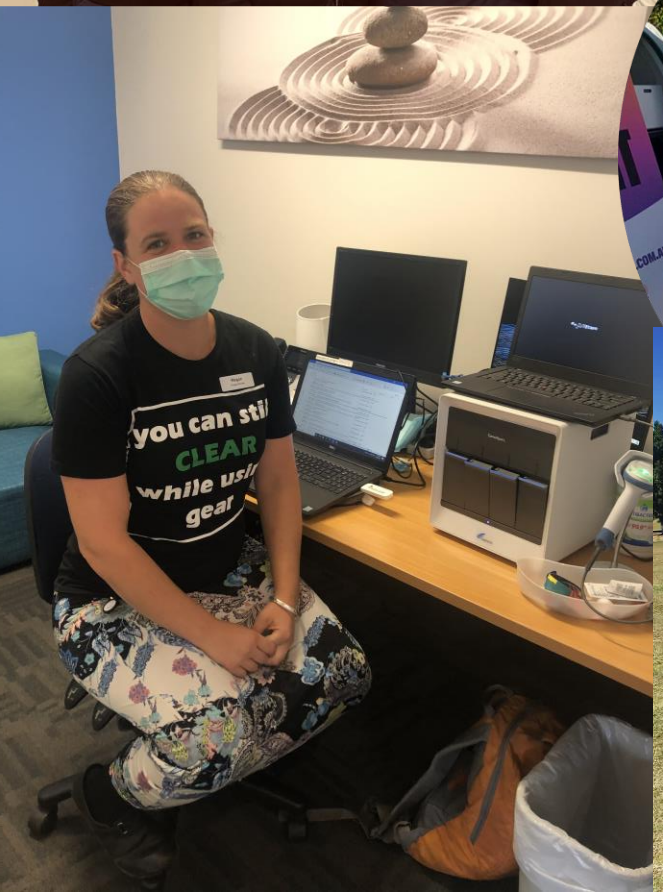
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