

**NATIONAL AUSTRALIAN
HEPATITIS C POINT-OF-CARE
TESTING PROGRAM SUMMARY**

Issue 01 | October 2021

HCVPOCT

National Australian Hepatitis C Point-of-Care Testing Program

INTRODUCTION TO THE PROGRAM

The Kirby Institute, UNSW Sydney and the International Centre for Point-of-Care testing at Flinders University have been funded by the Commonwealth Department of Health to establish a National Australian Hepatitis C Point-of-Care Testing Program, consisting of a network of sites to scale up point-of-care HCV testing in settings providing services to people at high risk of acquiring HCV infection.





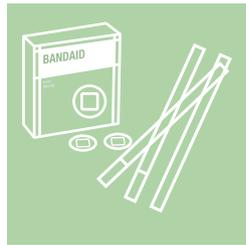
The operational aims of the program are outlined in this summary:

1. STANDARD OPERATING PROCEDURES, LOGISTICS, DEPLOYMENT, AND SET-UP

The program will provide:



Standard operating procedures for HCV point-of-care testing implementation



Specimen collection consumables



Test cartridges and kits



Software/hardware for IT connectivity



Participation in a quality assurance and training program



GeneXpert devices and laptops will be set-up with required software, deployed to services, and provided with remote support to assist with set-up.

2. TRAINING

Site staff nominated as operators will be provided with comprehensive training. Training will consist of online self-paced learning, self-administered assessments, followed by a remote theoretical and practical training session. The operator will be fully certified to perform finger-stick point-of-care HCV RNA testing as in accordance with TGA requirements.

An extensive range of training materials and tools have been developed as part of the program, this includes “how to” illustrative posters and videos for specimen collection, test operation and use of software, results interpretation and recording, waste disposal and environmental decontamination.



3. QUALITY ASSURANCE PROGRAM

To ensure the program is operating in compliance with best practice laboratory and regulatory standards, a robust quality assurance framework has been established through collaborations between the Kirby Institute, Flinders University, St. Vincent's Hospital, and the National Reference Laboratory. Each study site will test a competency panel (a known positive and negative sample) monthly and an external quality assurance panel (five blinded samples) six-monthly to assess the competency of the operator, check for contamination, and ensure the instrument is in working order and correctly detecting samples.

4. CONNECTIVITY AND IT SOLUTIONS

Connectivity is the term used to describe the integration of IT solutions to the GeneXpert platform and point-of-care testing into the electronic health service environment. The main goals of connectivity are to minimise disruption to workflow and through reductions in manual tasks for staff – ensure timely and accurate recording and reporting for clinical and public health needs.

We will implement IT and connectivity systems to meet real-world program, clinical (data transfer to electronic medical records), and public health reporting needs (laboratory notifications), drawing upon systems successfully implemented by Kirby Institute/Flinders University, NSW Pathology, and St. Vincent's Hospital/SydPath for point-of-care testing for STIs and COVID-19.



EVALUATION

A multidisciplinary research approach will be used to assess scale up of HCV point-of-care testing, including an observational cohort, a data linkage cohort, process evaluation, in-depth interviews, and health economics.

OBSERVATIONAL COHORT

The national program will establish an observational cohort to evaluate whether scale-up of finger-stick point-of-care HCV testing increases diagnosis and treatment uptake for HCV infection. Participants will be recruited from settings providing services to people with high risk factors for acquisition of HCV infection (including drug treatment clinics, needle and syringe programs, homelessness settings, mental health services, prisons, mobile outreach, and Aboriginal Community Controlled Health Organisations). Participants will attend a single visit to have their HCV RNA status investigated and complete a self-administered survey. Participants who are HCV RNA positive will be linked to standard of care. Participants will also provide consent for their information to be linked to administrative data.

Study Recruitment



n = 40,000

point-of-care HCV RNA tests



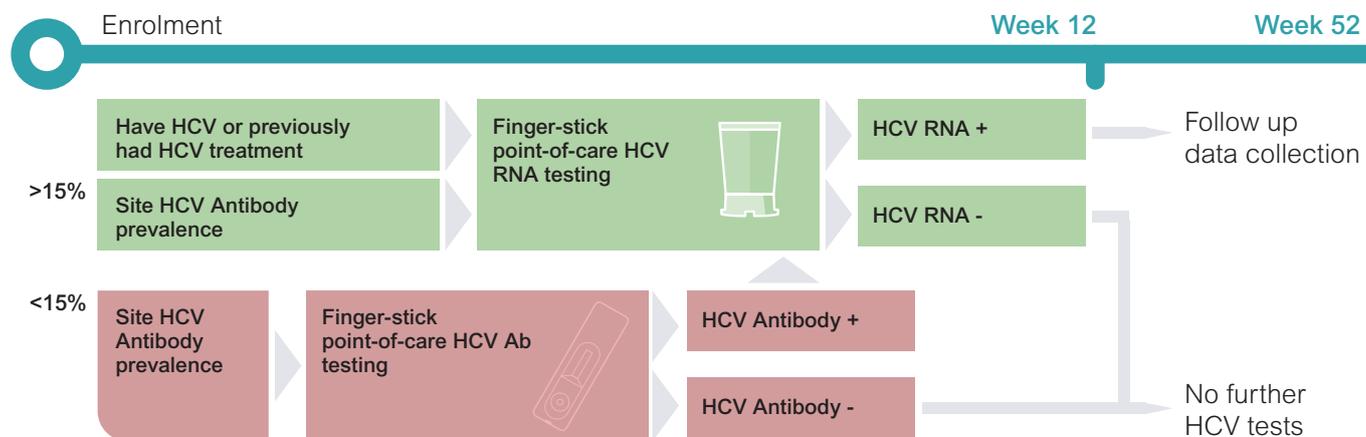
Participants will be recruited from at least **65** sites that provide services to people with a risk factor for the acquisition of HCV infection.

Types of sites include:



drug treatment clinics, needle and syringe programs, prisons, mobile outreach services, community health services, mental health services, homelessness services.

STUDY DESIGN



- Settings with high anticipated HCV antibody prevalence (>15%; e.g. drug treatment, prisons, needle and syringe programs), people who have previously been told they have HCV infection, or people who have previously received HCV treatment, testing will be performed using point-of-care HCV RNA testing (results in one hour).

- Settings with a low anticipated HCV antibody prevalence (<15%; e.g. mental health, homelessness), testing will be performed using point-of-care HCV antibody testing (results in 20 minutes) and if positive, point-of-care HCV RNA testing will be performed.



PARTICIPANT ELIGIBILITY



Provide informed consent.



≥ 18 years of age.

AND



Have a risk factor for the acquisition of HCV infection (including current or past injecting drug use, previous incarceration, HIV infection, receiving blood products prior to 1990, having a tattoo or piercing in an unregulated environment, a needle-stick injury, or a mother with HCV).

OR:



Are attending a service caring for people with risk factors for the acquisition of HCV infection (e.g. drug treatment clinics, needle and syringe programs, prisons, mobile outreach services, community health services, mental health services, and homelessness services).

STUDY PROCEDURES

Assessment / Procedure	Enrolment Visit	Follow-up Data Collection*	Follow-up Data Collection*
Study weeks	0	12	52
Informed consent incl. data linkage MBS/PBS	X		
Finger-stick point-of-care HCV testing**	X		
Behavioural questionnaire	X		
Treatment uptake		X	X
Treatment outcome			X
HCV RNA status			X

* No participant visit; medical record review for HCV RNA positive participants at enrolment visit only.

** HCV Antibody or HCV RNA, depending on criteria explained in the study design.



JOIN THE PROGRAM

Phase 1 sites for the program have been selected. We will be launching an expression of interest for phase 2 sites to join the program in October 2021.

The process for selecting phase 2 sites will include consultation with state and territory health departments. Expressions of interest applications will be circulated to potential sites and advertised broadly. Expressions of interest will be assessed by an independent panel of reviewers and determined by a site selection committee (comprised of healthcare providers, policy makers, and the affected community representatives). Key considerations for selection will include prevalence/burden, equitable distribution across all jurisdictions, regionality, and engagement with jurisdictions regarding priority services and service gaps. Overall, half of the sites for each jurisdiction will be selected through merit-based selection, with remaining sites determined based on identified gaps determined through consultation with state/territory health departments.

To be eligible for the National Australian HCV POCT program, sites should meet the following criteria:

- Health service providing care to people with risk factors for HCV infection;
- Service which provides testing for populations with an HCV antibody prevalence greater than 10%;
- Provide HCV testing to more than 250 clients annually;
- Demonstrated evidence of a well-established model of care or potential to establish a novel model of care to support point-of-care HCV RNA testing and treatment;
- Demonstrated need for point-of-care testing (e.g., transient population, high level of loss to follow-up, high HCV burden, regional setting, opportunities for mobile outreach);
- Demonstrated capacity to collaborate with partner organisations (e.g., extending the offer of testing to clients of partner organisations);
- Clearly articulated plan for the proposed implementation of point-of-care testing;
- Have systems in place or be willing to establish systems to support point-of-care testing using the GeneXpert platform.

BENEFITS OF STUDY PARTICIPATION

Participating sites will be provided with a GeneXpert Point-of-Care machine, up to 1,000 HCV RNA testing cartridges, and HIV and HBsAg rapid point-of-care tests (for all HCV RNA positive participants) for a period of up to two years (first phase of the project runs until June 30, 2023). Limited access to HCV Ab tests (up to 200 initially) will also be provided.

Participating sites will also receive extensive Operator Training (for up to 4 staff members), membership in the Quality Assurance and Competency programs and access to a dedicated help desk.

CONTACT DETAILS

Study Chief Investigator:

Jason Grebely

Phone: 02 9385 0957

Email: jgrebely@kirby.unsw.edu.au

Project Coordinator:

David Silk

Phone: 02 9385 0878

Email: dsilk@kirby.unsw.edu.au



Flinders University
International Centre
for Point-of-Care
Testing



UNSW
SYDNEY



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Kirby Institute