

Addressing challenges to improve access to hepatitis C diagnostic testing to enhance treatment in Australia

A national roundtable summary report

On the 10th and 11th March 2022, ASHM in collaboration with Hepatitis Australia convened a sector round table, to discuss the opportunities and challenges of implementing expanded sustainable testing strategies for hepatitis C infection in Australia, such as Point-of-Care and Dried Blood Spot (DBS) testing, as well as discuss optimising current laboratory-based testing to enhance diagnosis and linkage to care in Australia. The aim of the roundtable was to identify and progress key policy outcomes and implementation strategies.

# **Roundtable Objectives**

- Integrate point-of-care and dried-blood-spot testing as acceptable, accessible, and affordable interventions for the affected community
- Exploration of opportunities for alternative testing strategies (including reflex RNA testing and registries), with the view to increasing testing and treatment rates to achieve WHO and strategy targets
- Outline sustainable future funding models for point-of-care and dried-blood-spot testing to enable better integration into clinical practice
- Plan the development of a business case for the Therapeutic Goods Administration (TGA) requirements and costs, to encourage registration of new products by industry registrations and further investment in the sector
- Development of cohesive and shared messaging and advocacy positions on the needs of the sector, for state/territory and federal government policy makers, to support the sectors engagement in the refresh of the national strategies



Increasing hepatitis C testing uptake in Australia is hampered by current diagnostic pathway requiring multiple visits to health professionals and frequent loss to follow-up, amplified in key target populations, such as people who inject drugs and people in prison. The consensus among participants at the roundtable was that action across the following areas will improve hepatitis C testing, diagnosis, and linkage to care. Over 125 stakeholders attended the roundtable, and key questions were proposed to participants across three breakout sessions. The discussion themes are summarised below.

# **Key Questions**

What are the current implementation challenges for optimising laboratory-based HCV testing in Australia?

What are the current implementation challenges for optimising point-of-care and dried-blood-spot testing in high prevalence settings in Australia?

What are the current implementation challenges for optimising point-of-care and dried-blood-spot testing in low prevalence settings in Australia?

# A range of testing strategies and technologies

To achieve national hepatitis C elimination targets by 2030, Australia needs a range of testing strategies and technologies to suit different settings and populations. Point-of-care testing and DBS testing offer flexible options that overcome accessibility barriers such as location and acceptability and reduce the number of visits required to be diagnosed and commence on treatment. The consensus among roundtable participants was that more technologies (e.g., DBS, plasma separation cards, and point-of-care antibody, antigen, and RNA tests) approved by the Therapeutics Goods Administration would allow for a range of testing strategies to be tailored to settings and populations. Challenges identified by the participants included regulatory requirements, financial viability for manufacturers, sustainable funding models to support testing, systems to support notifications, supporting linkage to hepatitis C care, workforce education and training, and ensuring that community perspectives (including stigma and discrimination) were considered across all testing strategies. Further discussion considered taking learnings from the COVID response such as the acceptability and effectiveness of self-testing and strategies based on settings and risk.





Currently, laboratory-based reflex RNA testing following a positive/indeterminable antibody test is not routine and must be requested by the diagnosing clinician. Among providers, it was determined that there were lack of guidelines to support reflex RNA testing and further education is needed to enhance provider knowledge about ordering reflex hepatitis C RNA testing. Among pathology services, questions about how best to implement reflex RNA testing included whether to collect two samples at the time of blood collection or to establish mechanisms for reflex HCV RNA testing from a single sample. Reflex hepatitis C RNA testing is an important solution to improve hepatitis C diagnostic testing in Australia and further work is needed to support implementation.

## Sustainable funding models

In Australia, current funding frameworks do not support decentralised testing models that would facilitate hepatitis C testing to be undertaken in the community by a range of health professionals, including peer workers. Participants at the roundtable acknowledged the need for transitioning point-of-care and DBS testing programs from existing research programs into sustainably funded models that can be embedded in clinical practice. A range of funding options were considered including a revision of existing MBS billing numbers for hepatitis C (including items for reflex RNA and point-of-care testing), removing restrictions on the number hepatitis C tests that can be performed annually, and Commonwealth and jurisdictional funding arrangements. The cost of critical quality assurance programs was noted as a barrier, and it was highlighted that future funding models must include provision for program costs.

#### Updated evidence-based guidelines, frameworks, and infrastructure

Implementing sustainable testing strategies in Australia will require robust guidelines, frameworks, and systems to support them. Participants recognised that current guidelines and billing frameworks are based on complex historical interferon-based treatment paradigms managed in specialist settings. Updated consensus guidelines, a review of the general statement on HCV treatment prescribing by the Pharmaceutical Benefits Scheme, and guidelines to support reflex RNA testing and pathologist determinable testing were identified as priority actions to support simplified testing and treatment. Participants highlighted barriers such as poor communication between stakeholders in the health system and the need to support testing accreditation and quality assurance program frameworks.





# What's Next?

The roundtable planning committee will be expanded to form an advocacy working group. A full detailed report with recommendations will be available mid-year. If you would like to contribute to the activities of the working group, please email: <u>HepatitisC@ashm.org.au</u>

## Acknowledgments

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