SULLIVAN NICOLAIDES PATHOLOGY

JUN 2022

syzygy

Towards Hepatitis C (HCV) elimination: Expediting patient results for rapid access to treatment

The Fifth Australian National Hepatitis C Strategy 2018–2022 outlines goals for the elimination of HCV and Sullivan Nicolaides Pathology will be playing its part. From this month, we will be speeding up the testing process by reflexing to HCV RNA testing if the anti-HCV antibody test is positive or discordant. Our goal is to identify everyone who is currently undiagnosed or partially diagnosed. We hope that these expedited results will improve the opportunity for your patients to rapidly access treatment options.

The advent of the highly effective direct-acting antiviral (DAA) treatments has been the most significant advance in clinical management of HCV in decades and has brought with it an unprecedented opportunity to change the course of the epidemic, even to the point of elimination.

The World Health Organization (WHO) has set goals for the elimination of HCV as a public health threat[1] and the Fifth Australian National Hepatitis C Strategy has five targets that specifically focus on achieving these aspirations.[2] Key features of the Australian HCV response are the availability of DAAs through the PBS and the involvement of non-specialists in prescribing. Two of these goals involve pathology:

- increase the proportion of people living with hepatitis C who are diagnosed to 90 per cent (Figure 1)
- increase the cumulative proportion of people living with chronic hepatitis C who have initiated DAA treatment to 65 per cent.

Between 2016 and 2018, the estimated cumulative proportion of people initiating DAA treatment increased by 23 per cent - from 19 per cent to 42 per cent (Figure 2). While an estimated 81 per cent of people living with HCV had been diagnosed, only 47 per cent of them had received an HCV ribonucleic acid (RNA) PCR test to confirm chronic infection.[2] Therefore, one of the key areas for action in the Fifth Australian National Hepatitis C Strategy is to support the completion of confirmatory testing and instigate treatment.

Changes to SNP testing

To efficiently assess active as opposed to past resolved infection, SNP will now split a single specimen at the time of the anti-HCV test request into two aliquots at the sample-processing stage. This avoids the need for the doctor to request a follow-up sample and an associated second consultation.

This new procedure will provide a dedicated serum or plasma sample to allow for reflex HCV RNA testing for new anti-HCV positive or discordant results (first screening EIA positive but not confirmed with the second screening EIA). The goal is to identify everyone who is currently undiagnosed or partially diagnosed (no confirmatory RNA test) and/or not engaged in active management of their HCV infection. When ordering an anti-HCV test, please request "HCV RNA PCR if indicated", that is, if the result is positive or discordant. Both situations warrant reflex testing.

These expedited results should improve the opportunity to rapidly access treatment options. A negative result will indicate that no active HCV infection is present at the time of collection.

There may be occasions when there is not sufficient sample to provide an HCV RNA PCR result or to test for the HCV genotype, and a recollection is indicated. The availability of effective pangenotypic DAA therapies glecaprevir + pibrentasvir [Maviret®] and sofosbuvir + velpatasvir [Epclusa®] means that HCV genotyping is no longer required before initiating treatment to meet the PBS criteria.

Nevertheless, some genotype-specific treatments remain in use and the HCV genotype may be clinically useful in certain regimens when treating cirrhotic or treatment-experienced patients. A genotype or subtype change can indicate a re-infection rather than treatment relapse. If this is required, then an additional collection will be necessary.

Who should be tested?

- People who inject drugs or who have ever injected drugs
- People in custodial settings
- People with tattoos or body piercing
- People who received a blood transfusion or organ transplant before 1990
- People with coagulation disorders who received blood products or plasma-derived clotting factor treatment products before 1993
- Children born to HCV-infected mothers
- People infected with HIV or HBV
- Sexual partners of an HCV-infected person (individuals at higher risk of sexual transmission include men who have sex with men)
- People who have had a needle-stick injury
- Migrants from high-prevalence regions (Egypt, Pakistan, the Mediterranean, Eastern Europe, Africa and Asia)

Figure 1. Priority groups in which a diagnosis of HCV should be considered.[3]

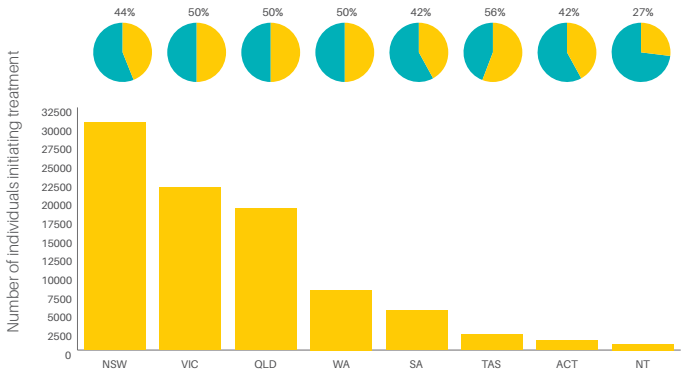

Figure 2. The estimated number of individuals initiating DAA treatment (yellow bars) and the proportion of individuals living with chronic HCV infection who initiated DAA treatment (yellow portions of circles) between 2016 and 2020, by jurisdiction.[4]

References

[1]World Health Organization (WHO). (2021). Hepatitis C. Accessed March 2022 at https://www.who.int/en/news-room/fact-sheets/detail/hepatitis-c.

[2]Australian Government Department of Health. Fifth National Hepatitis C Strategy 2018-2022. Commonwealth of Australia as represented by the Department of Health, Canberra, ACT, Australia, 2018. Available online at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/ohp-bbvs-1/$File/Hep-C-Fifth-Nat-Strategy-2018-22.pdf [accessed March 2022].

[3]American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA). (2020). 'When and in Whom to Initiate HCV Therapy'. Accessed March 2022 at https://www.hcvguidelines.org/evaluate/when-whom.

[4]The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 11). The Kirby Institute, UNSW Sydney, NSW, Australia, July 2021. Available online at: https://kirby.unsw.edu.au/report/monitoring-hepatitis-c-treatment-uptake-australia-issue-11-july-2021 [accessed March 2022].

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HPV self-collection update

From July 1 2022, all women due for their 5-yearly cervical screening test will be eligible for self-collection; the previous restrictions for offering this option will no longer apply.

This initiative is designed to improve recruitment into the National Cervical Screening Program because participation in Australia is currently low. Self-collected samples are an option for women who find a clinician-collected sample difficult.

Numerous studies in Australia and overseas have shown that the sensitivity in detecting HPV in self-collected vaginal samples is equivalent to that of a clinician-collected sample.

SNP is one of only three laboratories in Australia accredited to process self-collected specimens.

HPV self-collection kits with illustrated step-by-step instructions are available to order through SNP.

Order HPV self-collection kits for your clinic today.

P 1300 767 284 **E** client.services@snp.com.au

Next steps in non-invasive prenatal testing: genome-wide NIPT now available

Non-Invasive Prenatal Testing (NIPT) for fetal aneuploidy, based on circulating free DNA, has been widely adopted into clinical practice since it was introduced in Australia some years ago. NIPT screens for the common trisomies and offers the option to screen for aneuploidies of the sex chromosomes.

Genome-wide NIPT (g-NIPT) is a form of the test that allows detection of chromosomal abnormalities that are not detectable by conventional NIPT. It can analyse cfDNA from all whole chromosomes, and from large sub-chromosome segments from the autosomes (non-sex chromosomes).

g-NIPT differs from NIPT in that it can:

- screen for duplications and deletions of segments of chromosomes 1–22, and is capable of detecting gains or losses of chromosome material as small as 7 million base pairs, or one-sixth of the size of chromosome 21. g-NIPT detects about 75 per cent of these duplications and deletions. They are uncommon but, if present, typically result in developmental delay or congenital abnormalities.
- screen for rare aneuploidies, that is, monosomies of any chromosome or trisomies of chromosomes other than 21, 18 and 13. These rare aneuploidies are usually mosaic, with a mixture of normal and abnormal cells. The abnormal cells are often confined to the placenta, while the fetus is chromosomally normal. About half of pregnancies with a rare aneuploidy result in a normal birth at term. For the remainder, there is an increased risk of placental dysfunction or fetal abnormalities. The risk varies according to the aneuploidy. Specialist assessment of the fetus, fetal chromosomes and placental function is recommended.

Limitations and benefits

Screening by NIPT provides high levels of accuracy and sensitivity, with high detection and very low false positive rates.

Using g-NIPT to screen for additional targets increases the range of the technique, but also increases the chance of a false positive or false negative result. In addition, the abnormalities it can detect account for only a minority of deletions and duplications that cause intellectual disability, and the clinical implications of some screen-positive abnormalities may be less clear than in the common trisomies.

Concerning rare aneuploidies, g-NIPT is primarily helpful in identifying pregnancies at increased risk of an adverse outcome rather than using it as a screen for a specific fetal chromosome disorder.

Hence, the g-NIPT option may not be suitable for every patient or every pregnancy. As with any prenatal test, the patient must be adequately informed, understand the information that may be revealed, accept the limitations of the test, and consent to the test.

In summary, g-NIPT is a more specialised screening test that may not be the best choice for every patient. This test requires careful pre- and post-test counselling about its benefits and limitations.

Ordering NIPT and g-NIPT

NIPT is requested using a dedicated form, available for download from the **Sullivan Nicolaides Pathology** and **Sonic Genetics** websites, and through some practice management systems.

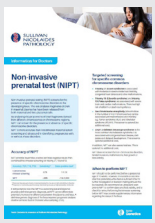
NIPT options:

- Standard NIPT for trisomies 21 (Down syndrome), 18 (Edwards syndrome), and 13 (Patau syndrome)
- Additional options on request:
  - Fetal sex (no charge)
  - Sex chromosome aneuploidy
  - g-NIPT (**additional charge**)

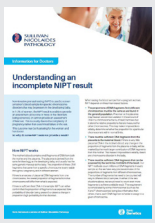
Information and pricing can be found on the Sonic Genetics website, **sonicgenetics.com.au**.

NIPT resources

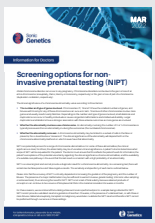
Updated NIPT resources for clinicians and patients are available on request. To order, please contact your medical liaison manager or email client.services@snp.com.au



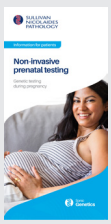
NIPT: information for doctors



Understanding an incomplete NIPT result



Screening options for NIPT



NIPT patient brochure

Correct at time of publication. June 2022

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