

Testing and Treatment

Introduction

- 4.1 In Australia, approximately 80 per cent of people with hepatitis C infection have been diagnosed. However, it is estimated that 40 000 to 50 000 Australians infected with hepatitis C, remain unaware that they are chronically infected.¹
- 4.2 As hepatitis C is a disease that progresses slowly, 'early diagnosis of chronic infection and linkage to appropriate management is necessary to reduce hepatitis C transmission, morbidity and mortality'.²
- 4.3 With only a one per cent³ treatment rate for hepatitis C, it is estimated that the burden on the health system into the future is likely to increase significantly. One study suggested that:
- the number of people with compensated cirrhosis will increase from 13 850 in 2013 to 38 130 people in 2030;
 - the number of cases of hepatocellular carcinoma (a type of liver cancer) will increase from 590 in 2013 to 2040 in 2030; and
 - liver-related deaths will increase from 530 in 2013 to 1740 in 2030.⁴
- 4.4 Australia currently spends between \$224 million and \$300 million per annum to treat one per cent of the hepatitis C infected population. The estimated cost of pursuing current hepatitis C treatment regimens

1 Australian Government, *Fourth National Hepatitis C Strategy 2014–2017*, July 2014, p. 18.

2 Australian Government, *Fourth National Hepatitis C Strategy 2014–2017*, July 2014, p. 18.

3 Australian Government, *Fourth National Hepatitis C Strategy 2014–2017*, July 2014, p. 3.

4 Australasian Society for Infectious Diseases, *Submission 11*, p. 6. The study cited was W Sievert et al, 'Enhanced Antiviral Treatment Efficacy and Uptake in Preventing the Rising Burden of Hepatitis C-Related Liver Disease and Costs in Australia', *Journal of Gastroenterology and Hepatology*, 2014, vol. 29, August Supplement, pp 1–9.

(pegylated interferon and ribavirin) for the next 15 years is approximately \$5 billion.⁵

- 4.5 The low treatment rate for hepatitis C is reliant on several factors, including associated stigma and discrimination which may discourage people from seeking treatment. Being unable to cope with the routine and side effects of treatment regimens may have also served to discourage continued treatment.⁶

Testing

- 4.6 Approximately 40 000 to 50 000 Australians with hepatitis C remain undiagnosed and therefore unaware of their diagnosis status.⁷ Encouraging testing of the virus is of great importance as an early diagnosis can prevent long term liver damage.⁸

- 4.7 The *Fourth National Hepatitis C Strategy (2014-2017)*, details four specific 'priority actions' in relation to testing for Hepatitis C which are to be achieved:

- Increase voluntary testing of hepatitis C in priority populations.
- Improve referral and access to high quality support services at the time of diagnosis for people with or at risk of hepatitis C to initiate a pathway to care.
- Assess the feasibility, accessibility and cost effectiveness of the range of existing and emerging testing methods.
- Implement targeted initiatives to improve understanding and skills related to hepatitis C testing for priority populations, healthcare professionals and services, and the community sector.⁹

- 4.8 In addition to the need for an awareness campaign to encourage voluntary hepatitis C testing, a number of organisations recommended policy changes to increase testing rates in high-risk or vulnerable populations. For example, Professor Margaret Hellard stated that Australia needs clear

5 Queensland Nurses Union, *Submission 32*, p. 3.

6 Ms Justine Doidge, Private Capacity, *Committee Hansard*, Sydney, 22 January 2015, p. 45.

7 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, Melbourne, 21 January 2015, p. 2.

8 Hepatitis Victoria, *Submission 59*, p. 6.

9 Australian Government, *Fourth National Hepatitis C Strategy 2014-2017*, July 2014, p. 18.

- guidelines for testing high-risk populations,¹⁰ and that messages about testing high-risk patients should be targeted at GPs.¹¹
- 4.9 Associate Professor Joseph Torresi suggested that consideration should be given to whether the *National Hepatitis C Testing Policy* should be 'reinvigorated' to align with the *Fourth National Hepatitis C Strategy*, and whether it should be known as a 'strategy' rather than as a 'policy'.¹² While he agreed that there needs to be definite guidelines, Professor Alex Thompson noted that Australia's diagnosis rate is nonetheless 'pretty high' – at approximately 80 per cent.¹³
- 4.10 The *Fourth National Hepatitis C Strategy*, calls for the *National Hepatitis C Testing Policy* to be promoted among primary healthcare professionals and that the guidance provided on testing includes information on 'the frequency of hepatitis C testing for individuals who continue to have exposure risk'.¹⁴ In addition to policy development and promotion, a large number of participants in the inquiry recommended the wide-spread introduction of 'rapid testing' for the virus,¹⁵ with some additional comments about where best to place such testing services.¹⁶

Rapid Testing

- 4.11 Rapid testing, or rapid point-of-care testing (RPOCT), is a testing tool that detects hepatitis C antibodies via a finger prick capillary blood sample at the time of presentation. Taking approximately 30 minutes, the test determines if hepatitis C antibodies are present in an individual and if further confirmatory testing is required.¹⁷
- 4.12 More specifically, RPOCT uses in-vitro diagnostic medical devices and is defined as any test performed 'that provides results at the time of testing, which enables a clinical decision to be made and an action taken that leads

10 Professor Margaret Hellard, Director, Centre for Population Health, Burnet Institute, *Committee Hansard*, Melbourne, 21 January 2015, p. 17.

11 Professor Margaret Hellard, Burnet Institute, *Committee Hansard*, Melbourne, 21 January 2015, p. 23.

12 Associate Professor Joseph Torresi, Australasian Society for Infectious Diseases, *Committee Hansard*, Melbourne, 21 January 2015, p. 20.

13 The diagnosis rate in Australia may be the highest in the world. Professor Alex Thompson, *Committee Hansard*, Melbourne, 21 January 2015, p. 17.

14 Australian Government, *Fourth National Hepatitis C Strategy 2014–2017*, July 2014, p. 19.

15 Kirstie Monson, *Submission 37*, p. 1; Hepatitis ACT, *Submission 56*, p. 2; cohealth, *Submission 87*, pp 1-2.

16 Kirstie Monson, *Submission 37*, p. 1; Hepatitis Victoria, *Submission 59*, pp 7-8; cohealth, *Submission 87*, pp 5-6.

17 Hepatitis Victoria, *Submission 59*, pp 7-8.

to an improved health outcome'.¹⁸ Further, such testing looks for hepatitis C antibodies in the blood, rather than looking for the virus itself, and as such, 'they are a screening test for current or past exposure – not a diagnostic test'.¹⁹ As a result, the Pharmacy Guild of Australia commented:

This requires an appreciation that some results cannot be considered definitive and a patient that receives a negative (non-reactive) result who is identified as within a high risk category should be encouraged to discuss the result with their GP. If a patient receives a positive (preliminary positive or reactive result) they should be counselled and referred to a GP or other appropriate service for PCR testing and confirmation of current HCV infection. Further, it is important to clearly explain to the consumer the difference between an indicative screening test which requires further testing or advice, and a diagnostic test which confirms whether the disease is present.²⁰

4.13 The test can be performed by non-clinical staff and, outside Australia, has been integrated into a range of services including drug and alcohol services or needle and syringe programs, as a strategy to increase screening of high-risk populations.²¹

4.14 The community health organisation, cohealth, commented that rapid testing is used internationally, has a high accuracy rate and is a cost-effective model:

RPOCT are currently used in a variety of settings in other countries including the United States with an accuracy of approx. 98% and have been found to be cost effective. This, in turn, has the effect of earlier detection, limiting disease progression and prevention of transmission to the at risk population.²²

4.15 Further, it was the view of a number of hepatitis-support organisations that rapid testing, especially if targeted for high-risk populations, has the potential to increase the quantum of testing and reduce the extent of undiagnosed infections. These organisations referenced the experiences of rapid testing in the HIV sector where studies have concluded that such

18 Pharmacy Guild of Australia, *Submission 106*, p. 5.

19 Pharmacy Guild of Australia, *Submission 106*, p. 6.

20 Pharmacy Guild of Australia, *Submission 106*, p. 6.

21 cohealth, *Submission 87*, pp 5-6.

22 cohealth, *Submission 87*, p. 5.

services can encourage a person to undergo testing when they might not have otherwise taken up the opportunity.²³

4.16 For example, Hepatitis Victoria commented that as these tests are easy to perform and can be implemented by 'skilled peer workers', the perceived barriers to testing (including stigma and discrimination), can be overcome.²⁴

4.17 Similarly, the National Association of People with HIV Australia stated that rapid testing technologies would allow testing for the virus to be placed in community-based settings, where they are more likely to be accessed.²⁵ Community settings included community pharmacy;²⁶ sexual health clinics;²⁷ needle and syringe programs;²⁸ alcohol and drug centres;²⁹ peer-driven services;³⁰ and street doctors³¹.

4.18 In respect to placing these tests in a community pharmacy, the Pharmacy Guild of Australia commented:

Community pharmacy provides the added benefit of being able to clearly explain to high risk consumers such as those accessing NSP [needle and syringe programs] and ODT [Opioid Dependence Treatment] that a positive screening test may not equate to current infection, as people are more likely to test positive for antibodies due to past exposure and cleared or cured infection.³²

4.19 The potential for placing such services in community settings, in contrast to traditional healthcare settings, where stronger relationships often exist between staff and the community, was recognised by the Government of Western Australia:

23 Hepatitis ACT, *Submission 56*, p. 2; Hepatitis Victoria, *Submission 59*, pp 7-8; Ms Sally Rowell, Community Services Manager, HepatitisWA, *Committee Hansard*, Perth, 10 May 2015, pp 4-5.

24 Hepatitis Victoria, *Submission 59*, pp 7-8.

25 National Association of People with HIV Australia, *Submission 69*, p. 1, 3.

26 Pharmacy Guild of Australia, *Submission 106*, p. 6

27 Hepatitis Victoria, *Submission 59*, pp 7-8

28 Hepatitis Victoria, *Submission 59*, pp 7-8; cohealth, *Submission 87*, pp 5-6; Hepatitis NSW, *Submission 91*, p. 2; Ms Sally Rowell, Community Services Manager, HepatitisWA, *Committee Hansard*, Perth, 10 May 2015, pp 4-5; Australian Injecting and Illicit Drug Users League, *Submission 85*, p. 21.

29 cohealth, *Submission 87*, pp 5-6.

30 Ms Sally Rowell, Community Services Manager, HepatitisWA, *Committee Hansard*, Perth, 10 May 2015, pp 4-5; Australian Injecting and Illicit Drug Users League, *Submission 85*, p. 21.

31 Ms Sally Rowell, HepatitisWA, *Committee Hansard*, Perth, 10 May 2015, pp 4-5.

32 Pharmacy Guild of Australia, *Submission 106*, p. 6.

We understand that [HepatitisWA] have got a different kind of relationship with people that government will always struggle to have directly, so we think the funding of others is important'.³³

- 4.20 Rapid testing for hepatitis C is not currently listed on the Australian Register of Therapeutic Goods (ARTG). An ARTG listing is required before a hepatitis C test can be used in Australia.³⁴ The Pharmacy Guild of Australia explained the regulatory listing process for these tests:

These or similar tests may be approved for entry on the ARTG in future if the sponsors of the tests make application to the [Therapeutic Goods Administration] and the tests meet the Australian regulatory requirements. In order to do so, the testing device must meet the acceptable levels of sensitivity and specificity as outlined by the Advisory Committee on Medical Devices... which recommends that the sensitivity of point of care testing devices for the detection of [hepatitis C] should be at least 99.5% and the specificity at least 99%.³⁵

- 4.21 The *Fourth National Hepatitis C Strategy* recognises:

Development of improved testing technology, including point-of-care tests, [to] assist in simplifying the testing process for individuals, including addressing improved access and acceptability for priority populations. These may prove particularly useful in settings commonly used by people who inject drugs. Testing strategies and models will need to be developed and reviewed to allow new testing technologies to be included as they become available.³⁶

- 4.22 NSW Health also acknowledged the opportunities of rapid testing technologies to reduce undiagnosed hepatitis C infection in hard-to-reach populations.³⁷

Treatment and Delivery

- 4.23 In 2013, less than 3000 Australians were treated for hepatitis C,³⁸ with the majority of treatments occurring in a tertiary hospital setting. The Burnet

33 Professor Tarun Weeramanthri, Executive Director, Public Health and Clinical Services, Department of Health, Western Australia, *Committee Hansard*, Perth, 10 March 2015, p. 10.

34 Australian Government, *National Hepatitis C Testing Policy*, 2012, p. 8, viewed April 2015, <<http://testingportal.ashm.org.au>>.

35 Pharmacy Guild of Australia, *Submission 106*, p. 6.

36 Australian Government, *Fourth National Hepatitis C Strategy 2014–2017*, July 2014, p. 19.

37 NSW Health, *Submission 94*, p. 5.

Institute was of the view that the reasons for poor treatment uptake are ‘multifactorial’, and include ‘long and often toxic treatment regimens, difficulties in accessing care provided from tertiary hospitals by specialists, and (historically) policies of excluding current [people who inject drugs] from treatment’.³⁹

- 4.24 The Australasian Society for Infectious Diseases indicated that as the number of people with compensated liver cirrhosis was estimated to increase from 13 850 in 2013 to 38 130 in 2030, that projected costs of patient management would also increase from \$224 million in 2013 to \$305 million in in 2030.⁴⁰ Other modelling found that increasing the uptake of treatments currently available in Australia by five per cent each year from 2014 ‘would result in savings of \$9 million per year over the next three decades.’⁴¹
- 4.25 In recognition of the cost-savings that can be made by increasing the rate of treatment, the *Fourth National Hepatitis C Strategy* set a target of increasing the number of patients undergoing treatment by 50 per cent.

New Medications

- 4.26 On 30 June 2014, a new medication known as sofosbuvir was registered by the Therapeutic Goods Administration (TGA).⁴²
- 4.27 The large majority of individuals and organisations who participated in the Inquiry outlined the various benefits associated with new hepatitis C medications and what they may mean for treating hepatitis C in the future.⁴³ Professor Margaret Hellard, Director, Centre for Population Health, Burnet Institute, stated:

When used in combination with high-quality rolled out harm reduction approaches ... including opiate substitution therapy and needle and syringe programs, the evidence is mounting that we can eliminate this disease by 2030, if we start today. It requires us

38 Burnet Institute, *Submission 66*, p. 7.

39 Burnet Institute, *Submission 66*, p. 7.

40 ASID, *Submission 11*, pp 2–3.

41 Kathryn Snow, *Submission 4*, p. 1.

42 Therapeutic Goods Administration (TGA), *Australian Public Assessment Report for Sofosbuvir*, August 2014, p. 8, viewed 17 November 2014, <www.tga.gov.au>.

43 Government of Western Australia, *Submission 12*, p. 2; Australasian Hepatology Association, *Submission 23*, p. 2; Queensland Nurses’ Union, *Submission 32*, p. 2; Glenda Clementson, *Submission 40*, p. 2.

to start treating people ... There is no need for hepatitis C related deaths any more. We simply have to understand that.⁴⁴

- 4.28 In addition to noting that 'cure rates' associated with the new medications are 'greater than 95 per cent in most subgroups of patients', Professor Alex Thompson stated:

The treatments are of short duration, with most regimens involving only 12 weeks of treatment. All patients can be considered treatment candidates, including those with liver failure, with decompensated liver disease, as well as those who are intolerant of interferon due to toxicity.⁴⁵

- 4.29 The Burnet Institute stated that the new treatments will:

...avoid the need for expensive genotyping prior to therapy, and probably reduce the frequency of NAT testing during therapy. The licensing of fixed-dose combination therapy of sofosbuvir and ledipasvir for 12 weeks, with high SVR, activity against most genotypes and few side-effects makes treatment simplification realistic.⁴⁶

- 4.30 Associate Professor Joseph Torresi added that the ability of the new medications to treat people with advanced liver disease and cirrhosis 'means you can actually salvage people off liver transplantation lists – that is, they do not end up with a liver transplant which, in itself, is quite a significant cost'.⁴⁷ Ms Sharon Caris from the Haemophilia Foundation of Australia stated that new medications could potentially reduce use of the health system as well as the costs to the taxpayer associated with the disease.⁴⁸

- 4.31 The favourable dropout rate for the new treatments compared to the existing treatments was also highlighted. Professor Thompson advised that for interferon based treatment the dropout rate is about 15 per cent, whereas in studies where interferon-free treatments have been used, the

44 Professor Margaret Hellard, Burnet Institute, *Committee Hansard*, Melbourne, 21 January 2015, pp 5–6.

45 Professor Alex Thompson, Director, Department of Gastroenterology, St Vincent's Hospital, *Committee Hansard*, Melbourne, 21 January 2015, p. 7.

46 Burnet Institute, *Submission 66*, p. 7.

47 Associate Professor Joseph Torresi, Australasian Society for Infectious Diseases, *Committee Hansard*, Melbourne, 21 January 2015, pp 7–8.

48 Ms Sharon Caris, Executive Director, Haemophilia Foundation Australia, *Committee Hansard*, Melbourne, 21 January 2015, p. 5.

dropout rate 'is basically zero' and any dropouts that do occur are 'not related to side effects'.⁴⁹

- 4.32 The Burnet Institute stated that these new treatments will reduce the number of new hepatitis C infections by 90 per cent and reduce hepatitis C related deaths by 90 per cent by 2030.⁵⁰

Listing on the Pharmaceutical Benefits Scheme

- 4.33 In Australia, government subsidies for medicine costs are provided under the Pharmaceutical Benefits Scheme (PBS). Access to reduced cost medicines under the PBS is available for Australian residents and visitors from countries with a reciprocal health care agreement with Australia.
- 4.34 Decisions about whether a particular medicine or medicinal preparation will be subsidised under the PBS are made by the Minister for Health based on the recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC). In formulating its recommendations, PBAC is required to consider the effectiveness and cost of therapy involving the use of the new medicine or medicinal preparation in question, including comparing the effectiveness and cost of that therapy with that of alternative therapies.
- 4.35 During the Inquiry, a number of new hepatitis C medications were simultaneously being assessed for listing on the Pharmaceutical Benefits Scheme for the second time.
- 4.36 Total expenditure under the PBS is uncapped, meaning the overall cost of the PBS increases as new medications are added and as usage increases.⁵¹ In 2012–13, around 750 medicines available in more than 1970 forms were subsidised by the PBS,⁵² at a cost to the Australian Government of \$7.1 billion.⁵³
- 4.37 In an answer to a question on notice, the Department of Health advised the Senate Community Affairs Committee that the cost per person for a course of sofosbuvir was estimated to be 'substantially higher than treatments already available on the [PBS], with a total cost to the Australian Government exceeding \$1 billion over five years.' In contrast,

49 Professor Alex Thompson, St Vincent's Hospital, *Committee Hansard*, Melbourne, 21 January 2015, p. 18.

50 Burnet Institute, *Submission 66*, p. 3.

51 Department of Health, 'About the PBS', viewed 30 January 2015, <<http://www.pbs.gov.au>>.

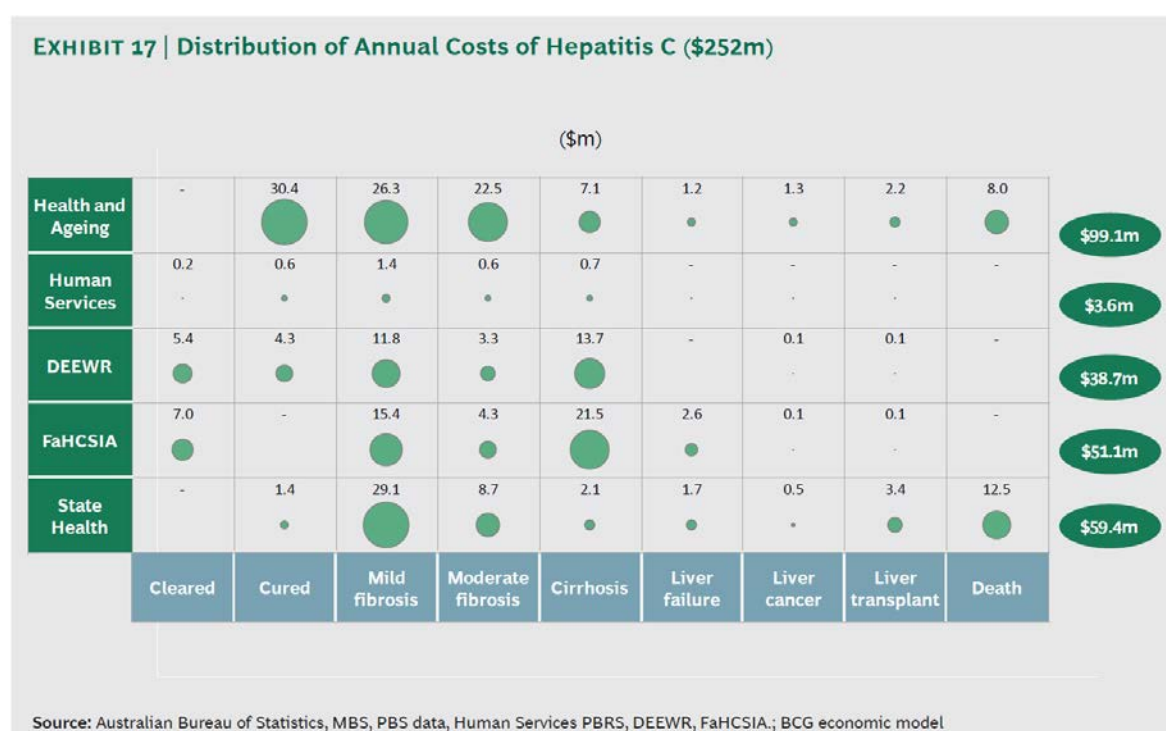
52 Steering Committee for the Review of Government Service Provision, *Report on Government Services 2014*, vol. E, Health, Productivity Commission, p. E. 69.

53 Steering Committee for the Review of Government Service Provision, *Report on Government Services 2014*, vol. E, Health, Productivity Commission, p. 11.8.

the cost to the PBS of existing drugs to treat hepatitis C totalled \$72.5 million in 2013-2014.⁵⁴

- 4.38 The Boston Consulting Group Report *The Economic Impact of Hepatitis C in Australia*⁵⁵ commissioned by the pharmaceutical company Janssen examined the broader costs of treating hepatitis C through the context of new treatments available overseas.
- 4.39 The listing of these new medications was first considered by the PBAC in July 2014, and was then reconsidered by the PBAC in March 2015. On 24 April 2015, the PBAC released its recommendation to the Minister for Health that two of these new generation treatments be listed on the PBS.

Figure 4.1 Distribution of Annual Costs of Hepatitis C (\$ million)



Source Boston Consulting Group, *The Economic Impact of Hepatitis C in Australia*

Prioritising Access

- 4.40 A number of organisations discussed the priority that should be afforded to different categories of people with hepatitis C should new treatments become available in Australia. Professor Thompson suggested that if restrictions were put in place, then prisoners, one of the groups at highest

54 Department of Health, *Answer to Question on Notice, Senate Community Affairs Legislation Committee, Supplementary Budget Estimates 2014-15*, no. SQ14-001138, viewed 13 January 2015, <<http://www.aph.gov.au>>.

55 Boston Consulting Group, *The Economic Impact of Hepatitis C in Australia*, August 2012, <<http://www.hepatitisaustralia.com>>.

risk of hepatitis C infection, should be considered as a high-priority population for treatment.

- 4.41 In contrast, Hepatitis Australia was of the view that access to new treatment should not be restricted to certain groups of people.⁵⁶ Hepatitis Australia recommended that as these new medications offer positive outcomes regardless of the stage of liver disease experienced, all people with chronic hepatitis C should be given equal access to new treatments.⁵⁷ Hepatitis Australia stated:

Any approach other than equal access would be discriminatory and potentially lead to litigation if denial of curable treatment to any person later led to development of cirrhosis, liver cancer or to death.⁵⁸

- 4.42 Similarly, Hepatitis NSW recommended that new treatments should be made available to 'all people living with hepatitis C, and not restricted on the basis of liver disease stage or previous treatment experience'.⁵⁹ Professor Hellard also commented that limitations on access to treatment should not be set:

... if somebody needs to have treatment because they have severe liver disease, they should be given it – and also those who want to be treated. So, if my 25-year-old daughter, who might want to have children, is hepatitis C infected, she could be treated – or my son or whoever it might be. We should not be setting limits. People will talk about the costs, but this is affordable and Australia can afford it.⁶⁰

- 4.43 Although the prioritisation debate was also reflected in the different approaches by state and territory health departments, they agreed that the decision to commence treatment should be a clinical decision. For example, ACT Health advocated that effective treatment should be accessible to all people with hepatitis C:

Effective treatments should be accessible on the PBS for all genotypes of [hepatitis C]. It appears discriminatory when effective treatments for some genotypes of [hepatitis C] are accessible through the [PBS] but access to effective treatments for other genotypes is withheld.

56 Ms Helen Tyrrell, Hepatitis Australia, *Committee Hansard*, Melbourne, 21 January 2015, p. 28.

57 Hepatitis Australia, *Submission 84*, p. 5.

58 Hepatitis Australia, *Submission 84*, p. 5.

59 Hepatitis NSW, *Submission 91*, p. 3.

60 Professor Margaret Hellard, Burnet Institute, *Committee Hansard*, Melbourne, 21 January 2015, p. 6.

The decision about whether to treat an individual with chronic [hepatitis C] should rest with the clinician. The PBS should not specify restrictions on accessing medications, such as the duration of infection or the level of liver damage.⁶¹

- 4.44 The Government of Western Australia similarly commented that the decision to commence treatment for hepatitis C should remain a clinical decision focussing on the ‘capacity to benefit’.⁶²

Waiting for New Treatments

- 4.45 Throughout the Inquiry, it became evident that large numbers of people living with hepatitis C are being advised by healthcare professionals to delay current PBS-listed treatments until the PBAC considers the listing of these new treatments for a second time.⁶³ A number of participants used the analogy of a ‘warehouse’ of patients waiting for new treatments to be made available.⁶⁴
- 4.46 Ms Saroj Nazareth, a nurse practitioner specialising in hepatology at Royal Perth Hospital, stated that treatment rates have significantly decreased as ‘a lot of patients have been waiting for the newer treatments to arrive’.⁶⁵ In light of this, and if new treatments are listed on the PBS, the number of people undertaking treatment is ‘poised to escalate’.⁶⁶

Models of Care

- 4.47 Only accredited GPs have a role in managing treatment prescribed within specialist liver clinics. As current treatments are listed subsidised by the Pharmaceutical Benefits Scheme (PBS) under Section 100 of the *National Health Act 1953* as Highly Specialised Drugs (HSDs). HSDs are ‘medicines that treat chronic conditions and because of their clinical use or other

61 ACT Health, *Submission 105*, p. 3.

62 Professor Tarun Weeramanthri, Department of Health, Western Australia, *Committee Hansard*, Perth, 10 March 2015, p. 14.

63 Glenda Clementson, *Submission 40*, p. 2; Hepatitis Victoria, *Submission 59*, p. 9; Merck Sharp & Dohme (Australia) Pty Limited, *Submission 80*, p. 2; Hepatitis NSW, *Submission 91*, p. 16; Hepatitis ACT, *Submission 56*, p. 3; Mr Frank Farmer, Executive Director, HepatitisWA, *Committee Hansard*, Perth, 10 March 2015, p. 2; Mr Rodney Hatch, Prisons Education Officer, HepatitisWA, *Committee Hansard*, Perth, 10 March 2015, p. 4; Mrs Saroj Nazareth, Private Capacity, *Committee Hansard*, Perth, 10 March 2015, p. 29; Australian Injecting and Illicit Drug Users League, *Submission 85*, p. 22.

64 Hepatitis ACT, *Submission 56*, p. 3; Mr Frank Farmer, Executive Director, HepatitisWA, *Committee Hansard*, Perth, 10 March 2015, p. 2; Mr Rodney Hatch, Prisons Education Officer, HepatitisWA, *Committee Hansard*, Perth, 10 March 2015, p. 4;

65 Mrs Saroj Nazareth, Private Capacity, *Committee Hansard*, Perth, 10 March 2015, p. 29.

66 National Drug and Alcohol Research Centre, *Submission 55*, p. 5.

special features, they are restricted to being prescribed in public and private hospitals with appropriate specialist facilities'.⁶⁷

Primary and Tertiary Healthcare Settings

4.48 To enable more people to access hepatitis C treatment, Hepatitis Australia advocated that Australia move treatment and care for hepatitis C from hospital-based clinics into community-based primary care. Hepatitis Australia stated:

The latest medicines for treating hepatitis make a shift to primary care a safe and cost-effective option for the delivery of hepatitis C treatment. Without this, Australia will not meet the treatment targets outlined in the National Strategy.⁶⁸

4.49 In light of possible access to new medicines, Hepatitis ACT stated that 'access to treatment through different models of care' is also required.⁶⁹

4.50 The Australasian Society for HIV Medicine also commented that:

It will be necessary to ensure that treatments are available at acceptable and appropriate services to the priority populations by improving access through primary care, alcohol and drug services, Aboriginal medical services, needle and syringe programs, mental health services and in custodial settings.⁷⁰

4.51 The Australian Research Centre in Sex, Health and Society commented that new models of care should 'focus on the needs of the individual rather than the specialist'.⁷¹

4.52 The Queensland Nurses' Union (QNU) was also of the view that new treatments 'will increase rates of treatment significantly [and]... there needs to be a proportionately large response to meet the needs of the public and remove barriers to treatment by utilising primary health care settings'.⁷² QNU was consequently supportive of an expanded role for nurse-led and GP-led models of care, commenting that as new treatments have a 'high safety profile', and that these treatments can be delivered to patients through alternative models, allowing for more complex cases to be efficiently managed at tertiary health services.⁷³

67 Pharmacy Guild of Australia, *Submission 106*, p. 8.

68 Hepatitis Australia, *Submission 84*, p. 7.

69 Hepatitis ACT, *Submission 56*, p. 2.

70 Australasian Society for HIV Medicine, *Submission 58*, p. 6.

71 The Australian Research Centre in Sex, Health and Society, *Submission 19*, p. 6.

72 Queensland Nurses Union, *Submission 32*, p. 3.

73 Queensland Nurses Union, *Submission 32*, p. 4.

4.53 Mr Ross Williams, appearing in a private capacity, stated to the Committee that '[t]he best information, the best treatment, is available from hospital clinics'. However, he added:

... given the size and the scope of the hepatitis C problem, we simply cannot inundate [hospital clinics] with people who have hepatitis C. They are very busy already with people who have other liver related problems, plus those who have advanced hepatitis C related problems. If we can get treatment and support information out into the wider system, that will take an intolerable pressure off very hard-working institutions.⁷⁴

4.54 Hepatitis Australia commented that there would be no specific need for specialist liver clinics to manage patients undertaking new treatments, freeing up places for complex cases or those with comorbidities. Hepatitis Australia stated:

The new direct-acting antivirals have a very low risk profile. Their safety profile is very good. Their side effects are quite minimal. In terms of actual provision of safe care, there is no reason for them to be delivered in a liver clinic, unless the patient is someone with complex conditions or comorbidities that need specialist care. We need to really change that around. Liver clinics should be the province of people who really need that specialist care, not the routine care.⁷⁵

4.55 Similarly, the Government of Western Australia stated:

As new hepatitis C treatments are emerging, it is likely that there will be a greater role for primary care in the delivery of hepatitis C treatment, and this sector needs to be prepared for this. GP-initiated treatment, supported by approved Section 100 prescriber status by the Pharmaceutical Benefits Scheme, is essential to improved access to hepatitis treatment.⁷⁶

4.56 The following paragraphs examine the evidence received about the potential for increased hepatitis C care in a primary care setting.⁷⁷

74 Mr Ross Williams, Private Capacity, *Committee Hansard*, Melbourne, 21 January 2015, p. 46. See also Mr Frank Carlus, Private Capacity, *Committee Hansard*, Melbourne, 21 January 2015, p. 41.

75 Ms Helen Tyrrell, Hepatitis Australia, *Committee Hansard*, Melbourne, 21 January 2015, p. 13.

76 Government of WA, *Submission 12*, p. 6.

77 Primary health care providers include general practitioners, nurses (including general practice nurses, community nurses and nurse practitioners), allied health professionals, midwives, pharmacists, dentists, and Aboriginal health workers. See Australasian Society for HIV Medicine, *Submission 58*, p. 7.

General Practitioners

- 4.57 As briefly discussed above, GPs have a limited role in providing healthcare for their patients undergoing treatment for hepatitis C. Current pegylated interferon and ribavirin drugs are subsidised by the PBS under section 100 of the *National Health Act 1953* as highly specialised drugs (HSDs). To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with specialist hospital units.⁷⁸
- 4.58 A GP or non-specialist hospital doctor may only prescribe listed-HSDs to provide maintenance therapy under the guidance of the treating specialist.⁷⁹ These GPs must also complete accredited training programs which are established by each state and territory jurisdiction.⁸⁰
- 4.59 GPs trained in the management and treatment of hepatitis C can only prescribe maintenance treatments already initiated by those medical practitioners located in specialist hospital units.⁸¹ Currently there is a network of over 100 GPs around Australia who have completed advanced training in hepatitis C diagnosis and treatment and are accredited to prescribe therapy for the maintenance treatment of hepatitis C.⁸² These GPs are required to undertake regular continuing medical education in order to maintain their accreditation.
- 4.60 Associate Professor Joseph Torresi commented that GPs who wanted to treat hepatitis C would require upskilling ‘so that they understand the disease but also the new treatments’.⁸³
- 4.61 The Royal Australian College of General Practitioners noted that although the number of accredited GPs to dispense HSDs under section 100 of the *National Health Act 1953* remains ‘quite small’, there is ‘potential for GPs to become more involved in treating high volumes of patients safely and appropriately, so that we can lower costs of treatment and cut transmission rates’.⁸⁴

78 Department of Health, Pharmaceutical Benefits Scheme, *Section 100 – Highly Specialised Drugs*, accessed 15 May 2015, <<http://www.pbs.gov.au>>.

79 Department of Health, Pharmaceutical Benefits Scheme, *Section 100 – Highly Specialised Drugs*, accessed 15 May 2015, <<http://www.pbs.gov.au>>.

80 Dr Anthony Hobbs, Principal Medical Adviser, Therapeutic Goods Administration, *Committee Hansard*, Canberra, 20 March 2015, p. 66.

81 Australasian Society for HIV Medicine, *Submission 58*, p. 10.

82 Australasian Society for HIV Medicine, *Submission 58*, p. 10.

83 Associate Professor Joseph Torresi, Australasian Society for Infectious Diseases, *Committee Hansard*, Melbourne, 21 January 2015, pp 13–14. See also Dr Tuck Meng Soo, Private Capacity, *Committee Hansard*, Canberra, 20 March 2015, p. 43.

84 Dr Larissa Roeske, Chair, Sexual Health Medicine Network, Royal Australian College of General Practitioners, *Committee Hansard*, Canberra, 20 March 2015, p. 13.

- 4.62 A number of witnesses expressed a desire for adequately resourced and trained GPs to have a greater role in treatment delivery.⁸⁵
- 4.63 The Australasian Society for HIV Medicine advocated for GP treatment delivery similar to how HIV has been treated and stated:
- Appropriately trained general practitioners have successfully managed and treated HIV with antivirals for decades and the majority of people living with HIV see a GP prescriber for their HIV treatment. The Australian approach to HIV management, with the focus of care being in primary care, has resulted in the arguably some of the best outcomes in the world in term of retention in care and optimal control of HIV. This model will undoubtedly reflect similar levels of effectiveness and acceptability for other blood-borne viruses including hepatitis C.⁸⁶
- 4.64 The Australasian Society for HIV Medicine similarly stated that ‘the inclusion and support of general practice in hepatitis C testing, management and treatment is essential to increase treatment uptake for hepatitis C and free up tertiary services for more complex management issues’.⁸⁷ In evidence to the Committee, the Australasian Society for HIV Medicine noted findings from the *Community Prescriber Hepatitis C Treatment Initiation Pilot Final Evaluation Report* published in September 2013, which supported the initiation of hepatitis C therapy in primary care as an effective, safe treatment option and demonstrates both patient and practitioner satisfaction with the model.⁸⁸
- 4.65 Dr Tuck Meng Soo, an accredited GP prescriber, commented on the delivery of treatment by GPs in regard to HIV. Dr Tuck Meng Soo stated:
- ...when HIV started becoming recognised as a problem in Australia, a coalition of consumers and GPs went to government and said: 'We do not want this disease to be taken over by hospitals; we want to be able to access treatment in communities; we want to work with doctors who want to work with it.' So a system was devised where GPs who wanted to work in this area could get extra training to be able to manage people with HIV, and

85 Peter Tanczos, *Submission 6*, p. 2; Frank Carlus, *Submission 10*, p. 2; Ms Melanie Eagle, Hepatitis Victoria, *Committee Hansard*, Melbourne, 21 January 2015, p. 3. See also Mr Frank Carlus, *Committee Hansard*, Melbourne, 21 January 2015, p. 41

86 Australasian Society for HIV Medicine, *Submission 58*, p. 10.

87 Australasian Society for HIV Medicine, *Submission 58*, p. 7.

88 Australasian Society for HIV Medicine, *The Community Prescriber Hepatitis C Treatment Initiation Pilot Final Evaluation Report* (incorporating the Kirby and Centre for Social Research in Health Evaluation Reports). Darlinghurst, NSW: ASHM, September 2013, referred to in Australasian Society for HIV Medicine, *Submission 58*, p. 10.

doctors like me undergo a certain amount of education every year to keep my registration up. And I do not see any reason why the same system could not apply to hepatitis C. After all, if you have 230,000 people with hepatitis C in Australia, the specialist units in Australia could not possibly treat all of them.⁸⁹

4.66 Hepatitis Victoria commented that the GP model of care could be extended to hepatitis C. Hepatitis Victoria stated:

Treatments must be available at locations appropriate and accessible to all those affected by hepatitis C, which is predominately within the primary care sector, including GP clinics, youth health services, sexual health services, community health services, alcohol and drug services, Aboriginal medical services, needle and syringe programs and custodial settings. Allowing treatment to be accessed by all will result in significant personal and public health benefits.⁹⁰

4.67 The Victorian Department of Health and Human Services recommended a number of reforms in the transition from tertiary to primary care models, including:

- The removal of restrictions on the section 100 Highly Specialised Drugs program for hepatitis C so that treatment can be initiated and maintained by accredited community-based general practitioners. This will increase access to treatment, reduce waiting times to care, and avoid costly hospital admissions. Where cases are complex, care can occur under the supervision of hospital-based specialists
- The removal of the public/private dispensing demarcation for hepatitis C, as for HIV
- An integrated curriculum for general practitioners who wish to become section 100 prescribers for hepatitis B, C and HIV, in order to increase incentives and reduce the education and training burden
- A national standard for community-based (general practice) models of care to treat hepatitis C.⁹¹

4.68 Hepatitis NSW also called for funded programs to expand the number of GPs 'who are able to prescribe new hepatitis C drugs, assuming that section 100 restrictions remain in place in this area even with new drugs approved'.⁹²

89 Dr Tuck Meng Soo, Private Capacity, *Committee Hansard*, Canberra, 20 March 2015, pp 45-46.

90 Hepatitis Victoria, *Submission 59*, p. 10.

91 Victorian Department of Health and Human Services, *Submission 96*, p. 2.

92 Hepatitis NSW, *Submission 91*, p. 28.

- 4.69 A limited number of people are already undergoing treatment for hepatitis C in primary settings. In New South Wales, a ‘modest’ number of general practitioners are accredited to prescribe treatment in a shared-care arrangement with a specialist.⁹³ Adjunct Associate Professor Levinia Crooks from the Australasian Society for HIV Medicine informed the Committee that she is aware of primary care practitioners with significant experience, having treated up to 150 hepatitis C patients. She noted that primary care providers ‘do not want to place any of their patients in jeopardy and are quite able to notice when a patient needs to receive a higher level of care and refer them on for that purpose’.⁹⁴
- 4.70 Despite the limited number of GPs deciding to become accredited, NSW Health stated that this model was ‘an effective, safe treatment option for some patients’, further commenting, that ‘if implemented at scale, this approach has the potential to significantly increase access to hepatitis C treatment’.⁹⁵
- 4.71 The *NSW Hepatitis C Strategy 2014–2020* considered that the limited numbers of GPs seeking accreditation under the shared-care arrangements with a specialist available in the State may be a result of several factors, including:
- ... competing clinical demands, patient choice, dissatisfaction with shared care protocols and the complexity of care not being adequately supported under the Medicare Benefits Schedule to justify the ongoing training and prescribing accreditation requirements for general practitioners.⁹⁶

Regional and Remote Access to Care

- 4.72 Expanding the role for GPs in initiating and managing treatment services presents a significant opportunity for regional and remote areas. Dr David Learoyd, a rural GP, stated:

On several occasions I have attended special seminars to train GPs about Hepatitis C treatment. Despite this, I have not been able to prescribe treatment for Hepatitis C to my patients... So the patients in my town have to travel over 200 km return trip to see a specialist, and to have treatment [and] this is a huge barrier to access to adequate effective treatment.⁹⁷

93 NSW Government, *NSW Hepatitis C Strategy 2014–2020*, p. 27.

94 Adjunct Associate Professor Levinia Crooks, Chief Executive Officer, Australasian Society for HIV Medicine, *Committee Hansard*, Sydney, 22 January 2015, pp 10–11.

95 NSW Health, *Submission 94*, p. 5.

96 NSW Government, *NSW Hepatitis C Strategy 2014–2020*, p. 30.

97 David Learoyd, *Submission 50*, p. 1.

- 4.73 The Australasian Society for HIV Medicine commented that ‘in rural communities there is a greater need for interested GPs to be involved in hepatitis C care due to the scarcity of tertiary and specialist services’.⁹⁸

Nurse-led care

- 4.74 South Australia, New South Wales, Victoria and Western Australia have commenced delivery of hepatitis C treatments through nurse-led models of care. A nurse-led model of care requires a specialist and an advanced practice nurse to coordinate and facilitate the delivery of health care for the patient, and collaborate with and manage communication between members of a multidisciplinary team regarding the patient’s management plan.⁹⁹
- 4.75 Hepatology nurses, in collaboration with a medical specialist, are involved in testing and diagnosing hepatitis C, as well as educating, supporting and clinically managing patients during treatment.¹⁰⁰
- 4.76 Hepatology nurses currently work in metropolitan, regional and rural settings in: tertiary care, primary care including general practice, sexual health clinics, mental health clinics, alcohol and other drugs services, multicultural health services and community health centres, custodial settings, antenatal services and Aboriginal medical services.¹⁰¹
- 4.77 The Australian Hepatology Association (AHA), which represents hepatology nurses, stated that the role of hepatology nurses should be ‘significantly enhanced’ to utilise its ‘cost-effectiveness of delivery and flexible, adaptive, specialist nursing care’.¹⁰² The AHA highlighted treatment models for other chronic diseases to demonstrate how specialist nurses have contributed to improved outcomes. The AHA stated:

As we have seen in the management of other chronic diseases, such as diabetes and cardiovascular disease, enhancing the role of specialist nurses expands access to care, provides safe and efficient care, improves communication within the multidisciplinary team and improves patient outcomes through the delivery of tailored patient education and support.¹⁰³

98 Australasian Society for HIV Medicine, *Submission 58*, p. 7.

99 Australasian Hepatology Association, *Submission 23*, pp 1-2.

100 Australasian Hepatology Association, *Submission 23*, p. 1.

101 Australasian Hepatology Association, *Submission 23*, p. 1.

102 Ms Megan Phelps, Australian Hepatology Association, *Committee Hansard*, Melbourne, 21 January 2015, p. 9.

103 Ms Megan Phelps, Australian Hepatology Association, *Committee Hansard*, Melbourne, 21 January 2015, p. 9.

- 4.78 The AHA also commented about the development of nurse-led models internationally which has led to better patient-care outcomes:

The development of nurse-led clinics is expanding around the world due to their established benefits including increased patient satisfaction, longer consultation times and timely access to specialists services across a range of chronic diseases. Nurse-led services do not simply replace the doctor with a nurse but provide an opportunity for patients to access the skills of a specialist nurse which enhances the quality of care through the provision of extensive patient education and support.¹⁰⁴

- 4.79 Adjunct Associate Professor Levinia Crooks from the Australasian Society for HIV Medicine agreed that nurses could provide care for hepatitis C in a primary care setting. Not only do nurses already provide ‘a considerable amount of care in the tertiary setting’, nurses that provide care in a primary care setting could ‘act as a very good liaison, assisting when a person needs to be moved from one level of care to another’.¹⁰⁵

- 4.80 Commenting on its nurse-led model of care, the Government of Western Australia stated:

A recent evaluation of this program found that the waiting time to start treatment and support services available to patients undergoing hepatitis C treatment in regions with a nurse-supported shared care hepatitis C program, seemed to be as good, if not better, than the service provided through metropolitan treatment centres. The majority of patients who participated in the evaluation expressed high levels of satisfaction with the services available and preferred to access treatment locally.

There is no reason why such a nurse supported program could not operate in other regions, nor in settings other than general practice (as demonstrated in drug and alcohol services, or trialled in other settings, for example, in needle and syringe exchanges or through other community based agencies providing services to people with hepatitis C).¹⁰⁶

- 4.81 The Government of Western Australia estimates that an additional \$1.7 million per annum is required to provide a state-wide nurse-supported hepatitis shared care program in WA. Further, ‘increasing the already very low number of patients treated would

104 Australasian Hepatology Association, *Submission 23*, pp 1-2.

105 Adjunct Associate Professor Levinia Crooks, Australian Society for HIV Medicine, *Committee Hansard*, Sydney, 22 January 2015, pp 10-11.

106 Government of Western Australia, *Submission 12*, p. 7.

generate significant long-term health-care cost-savings, meaning this model would ultimately pay for itself'.¹⁰⁷

- 4.82 HepatitisWA also advocated for an expanded nurse-led primary care model and referenced the key successes of such a system operating at a hepatitis C clinic in New Zealand where its clients:
- became better informed about hepatitis C;
 - made positive lifestyle changes;
 - were more likely to consider starting treatment; and
 - experienced less discrimination than in other health care settings.¹⁰⁸
- 4.83 In addition to describing the benefits of a nurse-led model of care, inquiry participants also pointed out some of the challenges such a model would encounter:
- current nursing salaries – in particular, nurses are not supported to ‘go out into the community and treat people with hepatitis C’;¹⁰⁹
 - concern about the ability of nurses to provide hepatitis C treatment;¹¹⁰ and
 - the number of nurses available to provide treatment would need to significantly increase.¹¹¹
- 4.84 Hepatitis Australia advised that although there ‘are certainly some very good nurse-led models of care’ these models are ‘not the norm’. Professor Margaret Hellard advised that the evidence on the best models of care ‘is poor’, with few published reports on the subject (although she added there ‘are a lot of quality anecdotal reports’). Professor Hellard and Professor Alex Thompson, will soon start two trials to assess the feasibility of nurse-led models of care. Professor Hellard was optimistic about the likely results and stated:

In my view we are doing that to prove something which we think inherently will be successful, but you have to sometimes provide evidence for people who want scientific evidence. They have certainly been shown anecdotally – like various ones – to be successful, but there is not a great review that you will find if you

107 Government of Western Australia, *Submission 12*, p. 7; See also Australasian Hepatology Association, *Submission 23*, p. 2.

108 HepatitisWA, *Submission 9*, p. 3.

109 Professor Alex Thompson, St. Vincent’s Hospital, *Committee Hansard*, Melbourne, 21 January 2015, p 13.

110 Professor Alex Thompson, St Vincent’s Hospital, *Committee Hansard*, Melbourne, 21 January 2015, p 13.

111 Associate Professor Joseph Torresi, Australasian Society for Infectious Diseases, *Committee Hansard*, Melbourne, 21 January 2015, p 13.

are looking at the literature or asking anybody to show you that, as such.¹¹²

Concluding Comment

Testing

- 4.85 Taking into consideration the high rate of hepatitis C diagnosis at approximately 80 per cent, the Committee supports the priority actions relating to testing identified in the *Fourth National Hepatitis C Strategy*. A focus on improving testing among priority populations may further increase the rate of diagnosis.
- 4.86 The Committee believes the *Fourth National Hepatitis C Strategy* would benefit from the inclusion of more specific targets in relation to testing for hepatitis C. Further, reporting on progress towards these targets would enable regular evaluation of progress towards the goal of increasing testing and improving the hepatitis C diagnosis rate.
- 4.87 The Committee heard that the use of rapid point of care testing (RPOCT) enabled people at risk of hepatitis C transmission to be tested in approximately 30 minutes, and that testing could be performed by non-clinical staff, such as peer workers or in community pharmacy settings.
- 4.88 Taking into consideration evidence received, the Committee believes the RPOCT may have benefits in reaching Australians at a higher risk of hepatitis C infection. The Committee understands that RPOCT is not currently available as a testing method in Australia, and believes that the Department of Health should consider ways in which the deployment of RPOCT in Australia could assist in increasing voluntary hepatitis C testing.

Pharmaceutical Benefits Scheme Listing of New Medicines

- 4.89 The Committee received evidence about the Pharmaceutical Benefits Advisory Committee process. While it is relatively straight forward to determine the cost of current hepatitis C treatment, it is difficult to reliably determine the broader costs and potential long term savings that may be achieved through the approval of new hepatitis C treatments. Additional current costs of providing hepatitis C treatment may include hospital services, and lost productivity.

112 Professor Margaret Hellard, Burnet Institute, *Committee Hansard*, Melbourne, 21 January 2015, p. 13.

- 4.90 Additionally, there was some concern about the time taken to approve new hepatitis C treatments that had previously been approved in other international jurisdictions, noting that this may have broader cost implications in regard to continued reliance on the current treatments.
- 4.91 The broader issue of the Pharmaceutical Benefits Advisory Committee process, including a broader measurement of costs, and treatment approval times may warrant further investigation by the Department of Health.

The Role of Primary Care

- 4.92 Evidence provided to the Committee suggests that more can be done to treat hepatitis C in primary health care settings. While many general practitioners may not be able to prescribe the treatments currently available to treat hepatitis C, there is still a role for general practitioners in recommending testing, providing patient support, and encouraging treatment uptake. Current caps by a number of health care facilities on the number of patients seeking treatment, also suggests that an expanded role for general practitioners should be considered.

Access to New Treatments

- 4.93 The Committee heard that the development of new treatments for hepatitis C would enable treatment to be more easily provided in primary care settings, and through nurse-led models. The Committee believes that the Department of Health should review the ways in which hepatitis C treatment is delivered if new methods of treatment become available in Australia. In addition, the Committee believes, the Department of Health should also consider improved treatment delivery methods for people living with hepatitis C in regional and remote Australia, and amongst Aboriginal and Torres Strait Islanders.

PBS Listing of New Medicines

- 4.94 The Committee understands that the process for listing new treatments for hepatitis C on the Pharmaceutical Benefits Scheme has been ongoing throughout the inquiry. As the listing and approval process is not yet complete, the Committee makes no further comment or recommendations relating to these treatments.

Recommendation 3

- 4.95 The Committee recommends that the Department of Health, in consultation with relevant stakeholders, devise a specific target or targets for hepatitis C testing and report on progress towards reaching the target or targets annually.

Recommendation 4

- 4.96 The Committee recommends that the Department of Health consider the ways in which rapid point of care testing (RPOCT) can assist in implementing the goals of the *Fourth National Hepatitis C Strategy* and the *National Hepatitis C Testing Policy*.

Recommendation 5

- 4.97 That the Department of Health work with the Royal Australian College of General Practitioners and liver clinics to examine appropriate information provision, treatment processes, and patient counselling for people diagnosed with hepatitis C.