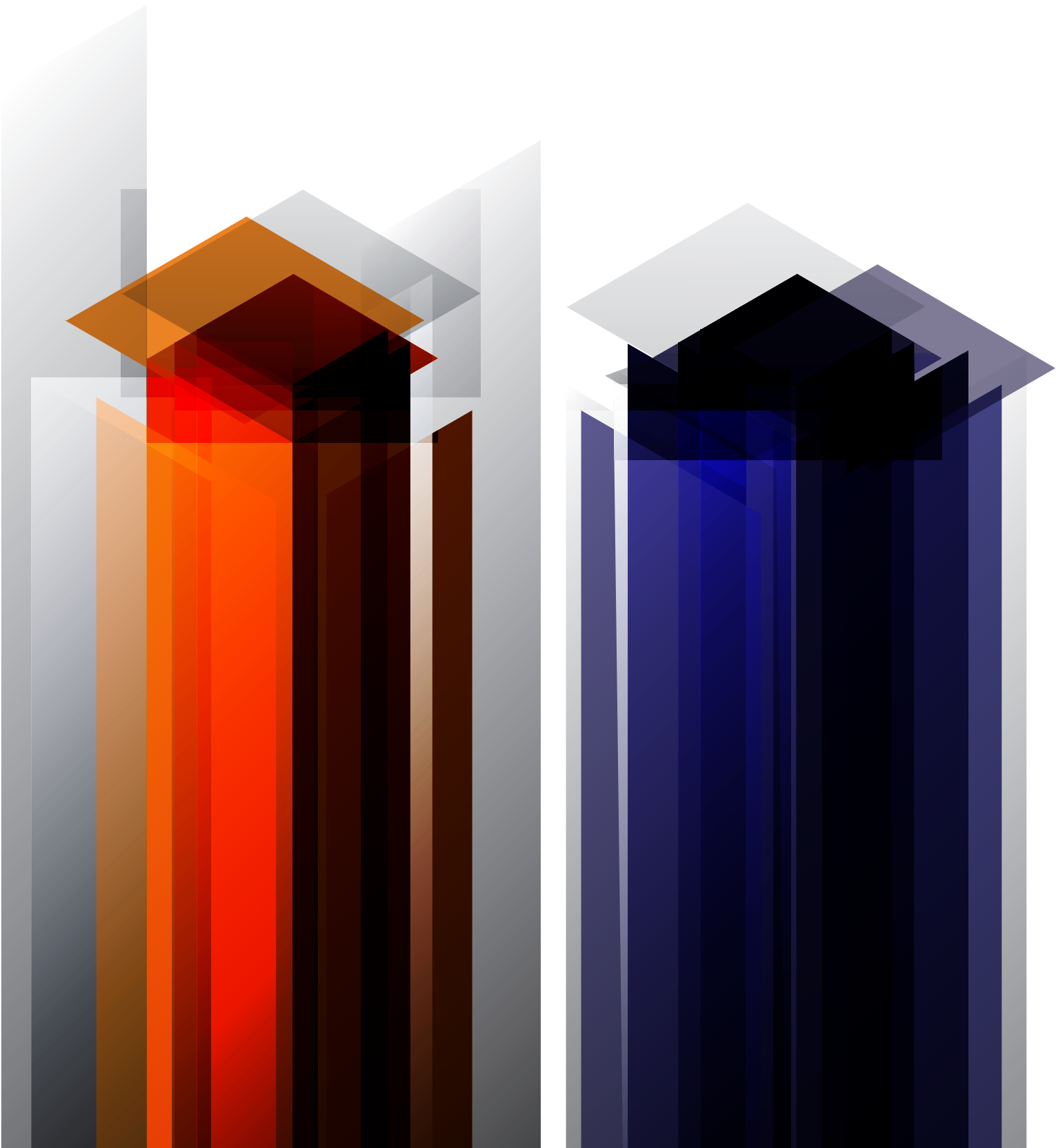


Hepatitis B and C in Australia
Annual Surveillance Report Supplement 2016



UNSW
AUSTRALIA



Kirby Institute

© The Kirby Institute for infection and immunity in society 2016

ISSN 2206-1630 (Online)

This publication is available at Internet address
<http://www.kirby.unsw.edu.au>

Suggested citation:

The Kirby Institute. Hepatitis B and C in Australia Annual Surveillance Report Supplement 2016.
The Kirby Institute, UNSW Australia, Sydney NSW 2052

The Kirby Institute for infection and immunity in society
UNSW Australia, Sydney NSW 2052

Telephone: 02 9385 0900 Facsimile: 02 9385 0920 International prefix: 61 2
Email: recept@kirby.unsw.edu.au

Prepared by: Dr Skye McGregor, Dr Hamish McManus, Dr Behzad Hajarizadeh and Dr Richard Gray

Edited by: Dr Skye McGregor, A/Professor Rebecca Guy, Professor Greg Dore


Other contributors:

- Office of Health Protection, Australian Government Department of Health
- State/Territory health departments
- The Annual Surveillance Report 2016 Advisory Committee
- The National Bloodborne Virus and Sexually Transmissible Infections Surveillance Subcommittee (NBBVSTI) of the Communicable Diseases Network of Australia (CDNA)
- The Australian NSP Survey National Advisory Group and the Australian collaboration of NSPs
- A/Professor Benjamin Cowie and Ms Jennifer MacLachlan, WHO Collaborating Centre for Viral Hepatitis, Victorian Infectious Diseases Reference Laboratory, The Doherty Institute
- Dr Jennifer Iversen, A/Professor Jason Grebely, Dr Denton Callander, Jane Costello, Professor Lisa Maher, Michael Doyle, Megan Tapia; The Kirby Institute
- Dr Homie Razavi, Center for Disease Analysis
- Associate Professor James Ward, South Australian Health and Medical Research Institute

A full list of acknowledgements will be available in the HIV, viral hepatitis and sexually transmissible infections in Australia, Annual Surveillance Report 2016.

The Kirby Institute is funded by the Australian Government Department of Health and is affiliated with the Faculty of Medicine, UNSW. The Surveillance, Evaluation and Research Program at the Kirby Institute is responsible for the public health monitoring and evaluation of patterns of transmission of bloodborne viral and sexually transmissible infections and is a research associate of the Australian Institute of Health and Welfare.

Contents

Introduction	4
Medical and epidemiological terms	5
Figures	6
Tables	
 HCV	7
Hepatitis C infection	8
2015 snapshot	8
New hepatitis C diagnoses	8
Prevalence and morbidity	8
Testing and care	8
Injecting risk behaviour	8
New hepatitis C diagnoses	10
Prevalence and morbidity	15
People living with hepatitis C infection	15
Hepatitis C prevalence	16
Hepatitis C Morbidity	18
Hepatitis C testing and care	19
Hepatitis C diagnosis and care cascade	19
Hepatitis C testing	20
Hepatitis C treatment	22
Hepatitis C prevention	24
Injecting risk behaviour	24
Direct acting antiviral treatment March to July 2016	26
Estimated hepatitis C direct acting antiviral treatment initiations	26
Estimated proportion of individuals living with chronic hepatitis C who initiated direct acting antiviral treatment	27
Hepatitis C direct acting antiviral treatment prescriptions processed by the PBS by month, jurisdiction, PBS scheme, and regimen	28
Hepatitis C incidence	31



Hepatitis B infection	32
2015 snapshot	32
New hepatitis B diagnoses	32
Prevalence and morbidity	32
Testing and care	32
Prevention	32
New hepatitis B diagnoses	34
All diagnoses	34
Newly acquired hepatitis B notifications	39
Prevalence and morbidity	41
People living with hepatitis B infection	41
Hepatitis B prevalence	42
Hepatitis B morbidity	42
Hepatitis B testing and care	43
Hepatitis B diagnosis and care cascade	43
Hepatitis B testing	44
Hepatitis B treatment	45
Hepatitis B prevention	46
Hepatitis B vaccination	46
Methodological Notes	48
Australian National Notifiable Diseases Surveillance System	48
The hepatitis C diagnosis and care cascade	48
The hepatitis B diagnosis and care cascade	49
The Australian Needle and Syringe Program Survey	50
The Australian and New Zealand Liver Transplant Registry (ANZLTR)	51
PharmDash	51
Direct acting antiviral treatment data	51
References	52

Introduction

This *Hepatitis B and C in Australia Annual Surveillance Report Supplement 2016* provides an overview of trends in diagnoses, prevalence, incidence, morbidity, care, testing and prevention of hepatitis B and C viral infections. Hepatitis A, D and E are not included in this report, but information about these infections can be found on the National Notifiable Diseases Surveillance System website.¹

The report is divided into two sections: the first section focuses on hepatitis C, and presents data from a range of sources from 2006 – 2015; within this section there is also a focus on the new direct acting antiviral treatments for hepatitis C infection, which presents data from March to July 2016. The second section focuses on hepatitis B, and also presents data from 2006 – 2015. Diagnosis and care cascades are presented for both hepatitis B and C, and a range of data are used to produce these estimates. Further details on how cascade estimates are generated can be found in the Methodological Notes.

The *Supplement* was produced to coincide with the 2016 *Australasian Viral Hepatitis Conference* and to provide a timely update on the roll out of hepatitis C direct acting antiviral treatments in Australia. With the World Health Organization calling for the elimination of hepatitis B and C by 2030, this report provides vital information on progress and gaps in the Australian response.

Medical and epidemiological terms

Hepatitis B virus infection:

An infection caused by the hepatitis B virus which is transmissible by blood and sexual contact as well as from mother to child. Newly diagnosed hepatitis B infection means that a person previously not known to have the infection has been tested and now found to have the infection. Newly acquired infections are those that have been acquired within the last two years, and are based on testing and laboratory evidence.

Hepatitis C virus infection:

An infection caused by the hepatitis C virus which is transmissible by blood and sexual contact as well as from mother to child. Newly diagnosed hepatitis C infection means that a person previously not known to have the infection has been tested and now found to have the infection. Newly acquired infections are those that have been acquired within the last two years, and are based on testing and laboratory evidence.

Age standardised rate:

The number of notifications occurring per 100 000 population, adjusted by a mathematical technique to account for the age structure of the relevant population, so that comparisons can be made across populations.

Completeness of data on Aboriginal and Torres Strait Islander status:

Incomplete information on Aboriginal and Torres Strait Islander identification has the potential to underestimate the true extent of these infections in the Aboriginal and Torres Strait Islander population. Time trends in the notifications of specific infections by Aboriginal and Torres Strait Islander status, and jurisdiction, were included in this report if information on Aboriginal and Torres Strait Islander status was available for at least 50% of notifications of the infection in every one of the past five years. Therefore there may be jurisdictions who met the 50% threshold in 2015 but not in other years, and thus their data were not included in this report unless otherwise specified. Figures stratified by Aboriginal and Torres Strait Islander status state which jurisdictions are included. It is important to note that with data restricted to jurisdictions with at least 50% completeness, these figures may not be generalizable to the broader Aboriginal and Torres Strait Islander population.

Figures

Figure 1	Hepatitis C notification rate per 100 000 population, 2006 – 2015, by sex	10
Figure 2	Hepatitis C notification rate per 100 000 population, 2006 – 2015, by year and age group	11
Figure 3	Hepatitis C notification rate per 100 000 population, 2006 – 2015, by State/Territory	12
Figure 4	Hepatitis C notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status	13
Figure 5	Hepatitis C notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status and age group	14
Figure 6	Hepatitis C prevalence among people seen at needle and syringe programs, 2006 – 2015, by sex	16
Figure 7	Hepatitis C prevalence among people seen at needle and syringe programs, 2006 – 2015, by Aboriginal and Torres Strait Islander status	17
Figure 8	Estimated number of people at different stages of hepatitis C related liver morbidity, and estimated number of deaths, 2006 – 2015	18
Figure 9	The hepatitis C diagnosis and care cascade, 2013 – 2015	19
Figure 10	Proportion of people who inject drugs seen at needle and syringe programs who reported a hepatitis C antibody test in the past 12 months, 2006 – 2015, by sex	20
Figure 11	Proportion of people who inject drugs seen at needle and syringe programs who reported a hepatitis C antibody test in the past 12 months, 2006 – 2015, by Aboriginal and Torres Strait Islander status	21
Figure 12	Proportion of hepatitis C antibody positive people seen at needle and syringe programs with a history of hepatitis C treatment, 2008 – 2015	22
Figure 13	Proportion of hepatitis C antibody positive people seen at needle and syringe programs with a history of hepatitis C treatment, 2008 – 2015, by Aboriginal and Torres Strait Islander status	23
Figure 14	Proportion of people seen at Needle and Syringe Programs reporting receptive syringe sharing in the last month, 2006 – 2015, by sex	24
Figure 15	Proportion of people seen at needle and syringe programs reporting receptive syringe sharing in the last month, 2006 – 2015, by Aboriginal and Torres Strait Islander status	25
Figure 16	The estimated number of individuals initiating hepatitis C direct acting antiviral treatment per month and cumulative number of initiations, March to July 2016	26
Figure 17	The estimated number of individuals initiating hepatitis C direct acting antiviral treatment during March to July 2016, by jurisdiction	27
Figure 18	The number and proportion of individuals living with chronic hepatitis C who initiated direct acting antiviral treatment during March to June 2016, by jurisdiction	27
Figure 19	Distribution of PBS schedule of chronic hepatitis C direct acting antiviral prescriptions during March to July 2016 in Australia	28
Figure 20	Distribution of chronic hepatitis C direct acting antiviral treatment regimens prescribed during March to July 2016 in Australia	29
Figure 21	Distribution of chronic hepatitis C direct acting antiviral treatment prescriptions during March to July 2016 in Australia, by treatment regimen and treatment course duration	29
Figure 22	Distribution of chronic hepatitis C direct acting antiviral treatment prescriptions March to July 2016 in Australia, by treatment regimen, and jurisdiction	30

Figure 23	Estimated annual incidence of hepatitis C virus infection among people who inject drugs, seen at needle and syringe programs, 2006 – 2014	31
Figure 24	Hepatitis B notification rate per 100 000 population, 2006 – 2015, by sex	34
Figure 25	Hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group	35
Figure 26	Hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group	35
Figure 27	Hepatitis B notification rate per 100 000 population, 2006 – 2015, by State/Territory	36
Figure 28	Hepatitis B notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status	37
Figure 29	Hepatitis B notification rate per 100 000 population, 2011 – 2015, by selected age group and Aboriginal and Torres Strait Islander status	38
Figure 30	Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by sex	39
Figure 31	Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group	40
Figure 32	Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group	40
Figure 33	Estimated prevalence of chronic hepatitis B infection in Australia, 2015, by country of birth	42
Figure 34	The hepatitis B diagnosis and care cascade, 2013 – 2015	43
Figure 35	Proportion of people attending sexual health clinics with immunity to hepatitis B, based on vaccination documentation and serology, 2015, by age group	44
Figure 36	Estimated number of people dispensed treatment for hepatitis B infection, by treatment type, 2013 – 2015	45
Figure 37	Hepatitis B vaccination coverage estimates at 12 and 24 months, 2011 – 2015, by Aboriginal and Torres Strait Islander status	46

Tables

Table 1	Hepatitis C notification rate per 100 000 population, 2006 – 2015, by State/Territory	13
Table 2	Estimated number of people living with chronic hepatitis C, 2015, by State/Territory	15
Table 3	The hepatitis C diagnosis and care cascade estimates, 2013 – 2015	19
Table 4	Hepatitis C direct active antiviral prescriptions by jurisdiction and Pharmaceutical Benefits scheme	28
Table 5	Age standardised rates of hepatitis B notification per 100 000 population, 2006 – 2015, by State/Territory	37
Table 6	Estimated number of people living with chronic hepatitis B, and estimated prevalence, Australia, 2015	41

Main Findings

Hepatitis C infection

2015 snapshot

Information presented below is based on data and estimates up to 31 December 2015.

New hepatitis C diagnoses

- In 2014 there were 10 790 notifications of hepatitis C, with the highest rate of notification in the 25 – 39 year age group.
- The rate of hepatitis C notification in Australia has remained stable in the last four years (2012 – 15), following a 22% decline between 2006 and 2011. A similar trend has been seen in all age groups.
- In contrast, the rate of hepatitis C notification in the Aboriginal and Torres Strait Islander population increased by 43% in the five past years, from 115 per 100 000 in 2011 to 165 per 100 000 in 2015. The 2015 rate is 4 times greater than in the non-Indigenous population (40 per 100 000).

Prevalence and morbidity

- There were an estimated 227 306 (range: 167 623 – 249 707) people living with chronic hepatitis C infection in Australia in 2015.
- The prevalence of hepatitis C antibody in people who inject drugs attending needle and syringe programs in 2015 was 57%, with relatively stable rates in the last five years. At 70%, the prevalence was much higher among Aboriginal and Torres Strait Islander survey respondents than non-Indigenous respondents (55%).
- At the end of 2015, an estimated 29 070 (range: 21 437 – 31 935) people had severe fibrosis, an increase of 73% since 2006, an estimated 17 149 (range: 12 647 – 18 840) people had hepatitis C related cirrhosis, an increase of 96% since 2006, and an estimated 818 (range: 603 – 899) deaths attributable to chronic hepatitis C infection occurred in 2015, an increase of 111% since 2006. Severe fibrosis is a condition in which the liver is severely scarred. When scar tissue builds up and takes over most of the liver, this is a more serious problem called cirrhosis. Over time, cirrhosis can lead to liver failure.

Testing and care

- Among the estimated 227 306 (range: 167 623 – 249 707) people living with chronic hepatitis C infection in Australia in 2015, an estimated 186 763 (82%) were diagnosed by the end of 2015, 50 172 (22%) had ever received antiviral therapy, with therapy ever successfully curing the infection in 32 139 (14%).
- According to the Australian Needle and Syringe Program Survey, among people who inject drugs with prior exposure to hepatitis C, in 2015 12% reported ever receiving hepatitis C treatment and 2% had received treatment in the last 12 months.

Injecting risk behaviour

- The re-use of needles and syringes that have been used by others (receptive syringe sharing) is a major risk factor for the transmission of hepatitis.
- The overall proportion of Australian Needle and Syringe Program Survey participants in 2015 who reported receptive needle and syringe sharing in the past year was 16%. Receptive syringe sharing was higher among Aboriginal and Torres Strait Islander respondents (24%) than among non-Indigenous respondents (14%).

Direct acting antiviral treatment from March to July 2016

Information presented below is based on data available from March to July 2016

- In March 2016, the Australian government provided broad subsidised access to direct acting antiviral treatments, for all adults living with hepatitis C.
- From March to July 2016, 26 360 people were estimated to have initiated direct acting antiviral treatment.
- Considering there are an estimated 227 306 people living with chronic hepatitis C, this equates to an estimated 12% of people living with chronic hepatitis C in Australia initiating direct acting antiviral treatment during March to July 2016.

Interpretation:

The rate of notification of hepatitis C diagnoses has remained stable in the past four years, after declines between 2006 and 2011, including in those aged less than 25 years. As the primary route of transmission is injecting drug use, a practice that primarily starts in late adolescence or early adulthood, trends in the rate of notification in those aged under 25 years can be interpreted as a surrogate for the incidence of hepatitis C infection. Under this assumption, it appears that there has been no further reduction in hepatitis C transmission since 2011. There has also been no change in rates of receptive needle and syringe sharing in the same period, highlighting the need for enhanced focus on prevention efforts.

The trends in hepatitis C notifications among Aboriginal and Torres Strait Islander peoples are very different to those of non-Indigenous people, with a steady increase in the notification rate in Aboriginal and Torres Strait Islander peoples over the past five years and in young people aged <25 years, as compared to no increase in young non-Indigenous people in the same time period. The difference in overall notification rates may reflect differences in injecting risk behaviours, with results from the Australian Needle and Syringe Program survey indicating that Aboriginal and Torres Strait Islander peoples were almost twice as likely to report recent receptive syringe sharing in 2015. The difference could also be accounted for by very high rates of incarceration and hepatitis C diagnosis in this setting and higher case detection among Aboriginal and Torres Strait Islander peoples. There is a need for increased coverage of culturally appropriate harm reduction strategies targeting Aboriginal and Torres Strait Islander peoples in both community and prison settings.

Since March 2016, the Australian Pharmaceutical Benefits Scheme funding of direct acting antiviral treatment has led to a very rapid and substantial uptake of treatment, but the vast majority of people with chronic hepatitis C remain at increased risk of serious liver disease without treatment. Sustained efforts to diagnose chronic hepatitis C and expand treatment coverage will be required to prevent this outcome.



New hepatitis C diagnoses

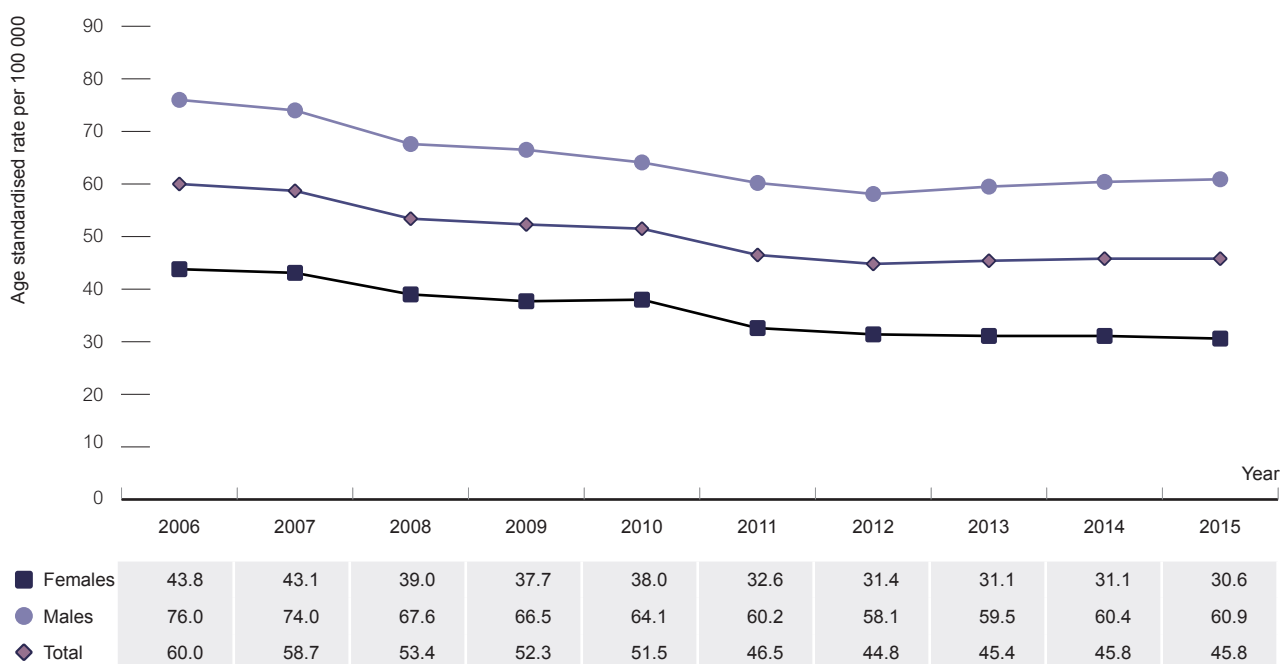
This section focuses on notifications of people newly diagnosed with hepatitis C in Australia (both newly acquired and unspecified cases). It is important to note that changes over time in notification rates may reflect responses to testing policies and programs, different diagnostic tests, and awareness campaigns.

A total of 10 790 cases of newly diagnosed hepatitis C infection were reported in Australia in 2015; 929 (9%) occurred among the Aboriginal and Torres Strait Islander population, 3 442 (32%) were among the non-Indigenous population, and there were a further 6 419 (59%) of notifications for which Indigenous status was not reported. Aboriginal and Torres Strait Islander peoples comprise 3% of the Australian population, yet accounted for at least 9% of all newly diagnosed hepatitis C cases in 2015, reflecting a disproportionate burden of disease.

In 2015, most notifications (66%, 7 137) of newly diagnosed hepatitis C infection were in males, 77% (8 294) were in people aged 30 years and above, and 63% (6 794) were notified in people residing in major cities. The majority of notifications (96%) were reported as unspecified, with only 441 cases reported as newly acquired infections.

The notification rate of hepatitis C in 2015 was 46 per 100 000, which reflects stable rates in the last four years, following a 22% decline between 2006 and 2011, and a 24% decline over the ten-year period between 2006 (60 per 100 000) and 2015 (46 per 100 000) (Figure 1). This pattern is seen in both males and females (Figure 1).

Figure 1 Hepatitis C notification rate per 100 000 population, 2006 – 2015, by sex

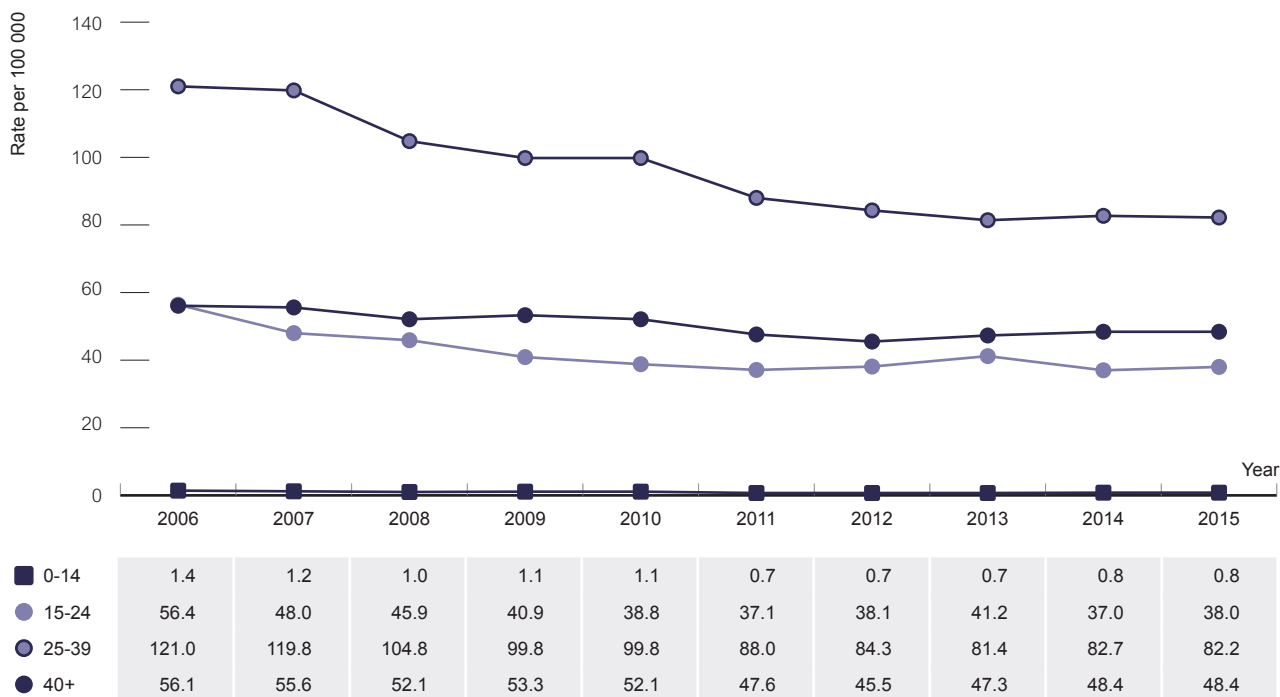


Source: Australian National Notifiable Diseases Surveillance System

Over the past ten years, the notification rate of hepatitis C has followed a similar trend in all age groups, with declines between 2006 and 2011 but stable notification rates thereafter. The 25 – 39 year age group has had the highest rate of notification over the last ten years, and was 82 per 100 000 in 2015, compared to 48 per 100 000 in the 40+ year age group, and 38 per 100 000 in the 15 – 24 year age group (Figure 2).

As the primary route of transmission of hepatitis C is injecting drug use, a practice that typically starts in late adolescence or early adulthood, trends in the rate of notification in those under 25 years can be a proxy for the incidence of hepatitis C infection.² Among those aged under 25 years, there has been a 33% decrease in the rate of notification between 2006 and 2015, from 24 per 100 000 in 2006 to 16 per 100 000 in 2015 (not shown in figure).

Figure 2 Hepatitis C notification rate per 100 000 population, 2006 – 2015, by year and age group

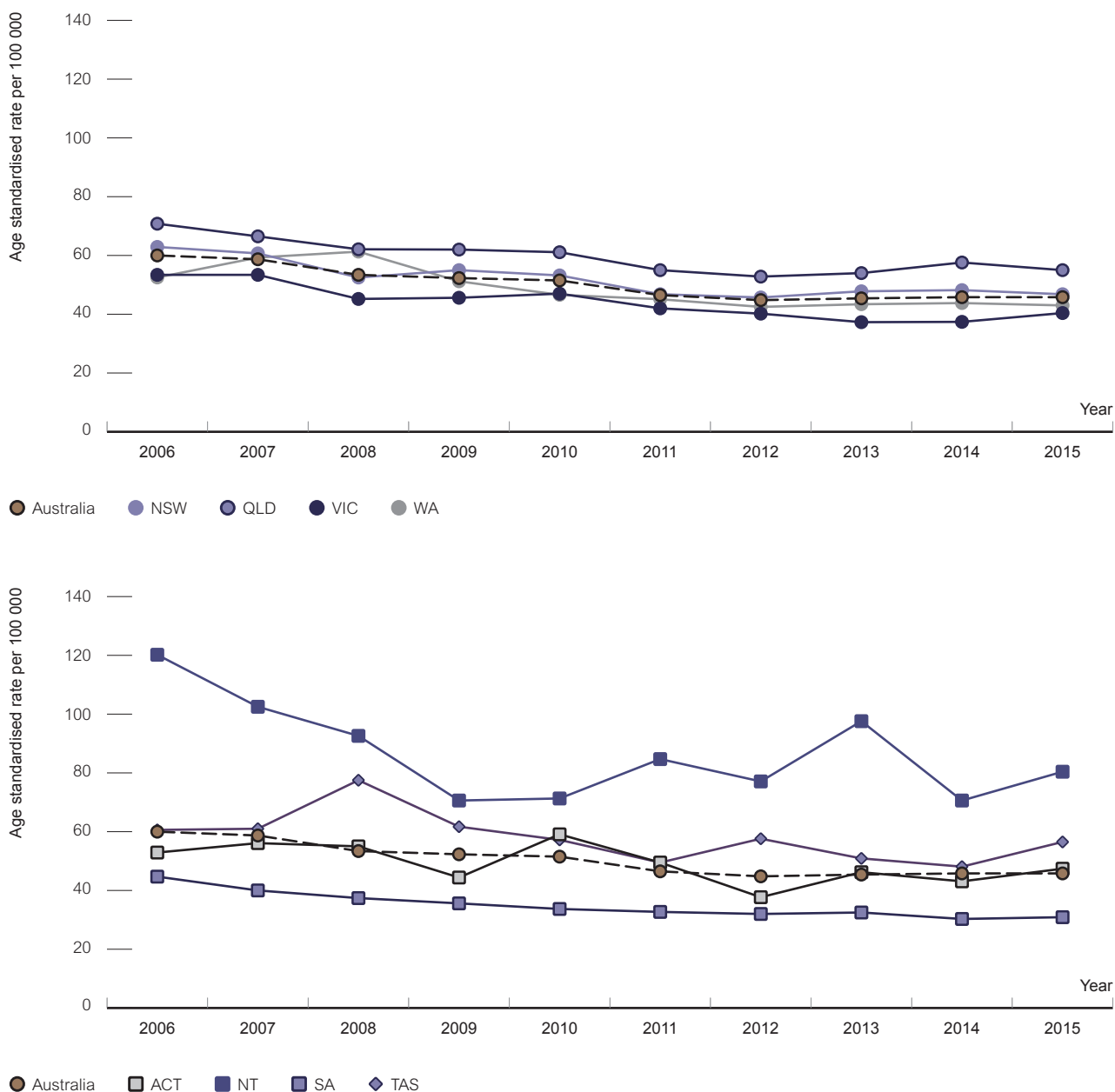


Source: Australian National Notifiable Diseases Surveillance System



The notification rate of hepatitis C infection in Australia in 2015 was highest in the Northern Territory (80 per 100 000) and Tasmania (57 per 100 000) (Figure 3, Table 1). Between 2006 and 2011, rates declined in all jurisdictions, with stable rates since then. While broadly declining rates have been seen in the Northern Territory and South Australia, these jurisdictions have also experienced some fluctuation in notification rates across the ten year period.

Figure 3 Hepatitis C notification rate per 100 000 population, 2006 – 2015, by State/Territory



Source: Australian National Notifiable Diseases Surveillance System

Table 1 Hepatitis C notification rate per 100 000 population, 2006 – 2015, by State/Territory

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
State/Territory										
Australian Capital Territory	52.9	56.1	55.0	44.4	59.1	49.5	37.7	46.2	43.1	47.4
New South Wales	62.9	60.7	52.5	55.0	53.2	46.8	45.7	47.8	48.2	46.8
Northern Territory	120.2	102.5	92.6	70.6	71.3	84.7	77.1	97.6	70.6	80.4
Queensland	70.8	66.5	62.1	62.0	61.1	55.0	52.8	54.0	57.6	55.0
South Australia	44.7	40.0	37.4	35.6	33.7	32.7	32.0	32.5	30.3	30.9
Tasmania	60.6	61.0	77.5	61.7	57.2	49.5	57.6	50.9	48.1	56.5
Victoria	53.4	53.4	45.2	45.6	47.0	42.0	40.2	37.3	37.4	40.4
Western Australia	52.5	59.3	61.3	51.2	46.6	45.1	42.5	43.4	43.8	43.0
Australia	60.0	58.7	53.4	52.3	51.5	46.5	44.8	45.4	45.8	45.8

Source: Australian National Notifiable Diseases Surveillance System

In 2015, the notification rate of hepatitis C was over four times greater among the Aboriginal and Torres Strait Islander population (165 per 100 000) compared to the non-Indigenous population (40 per 100 000). Rates of hepatitis C notification among the Aboriginal and Torres Strait Islander population have increased by 43% in the past 5 years, from 115 per 100 000 in 2011 to 165 per 100 000 in 2015 (Figure 4).

These notification data are from the Northern Territory, Tasmania and Western Australia, which all had $\geq 50\%$ completeness of Aboriginal and Torres Strait Islander status for each year of the five year reporting period. Incomplete information on Aboriginal and Torres Strait Islander status can underestimate the true extent of these infections in the Aboriginal and Torres Strait Islander population and may not reflect national trends.

Notification rates of hepatitis C among the Aboriginal and Torres Strait Islander population were highest in the 25 – 39 year old age group followed by 15 – 24 year olds. In comparison in the non-Indigenous population the highest rates were in 25 – 39 year olds followed by 40+ year olds (Figure 5). Notification rates of hepatitis C in the Aboriginal and Torres Strait Islander population were higher in all age groups than in the same non-Indigenous age groups.

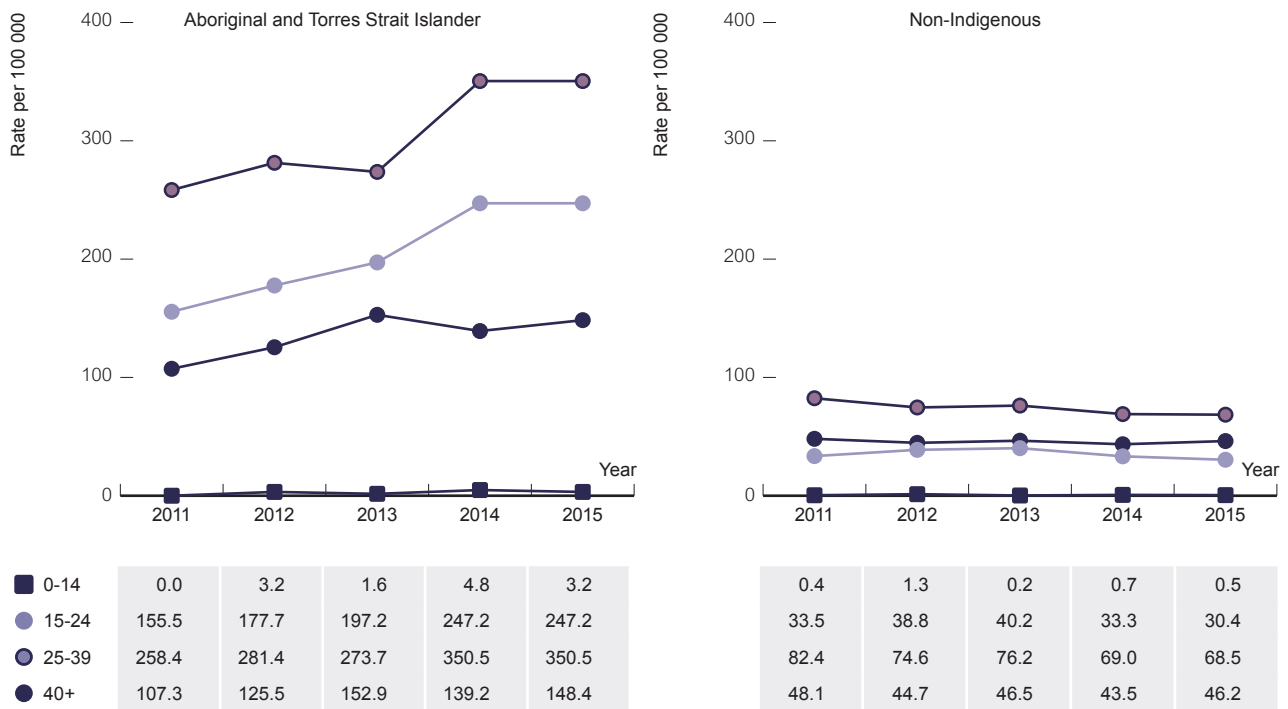


Figure 4 Hepatitis C notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status



Source: Australian National Notifiable Diseases Surveillance System. Includes jurisdictions (Northern Territory, Western Australia and Tasmania) in which Aboriginal and Torres Strait Islander status was reported for $\geq 50\%$ of diagnoses for each year.

Figure 5 Hepatitis C notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status and age group



Source: Australian National Notifiable Diseases Surveillance System. Includes jurisdictions (Northern Territory, Western Australia and Tasmania) in which Aboriginal and Torres Strait Islander status was reported for $\geq 50\%$ of diagnoses for each year.

Prevalence and morbidity

People living with hepatitis C infection

At the end of 2015, an estimated 227 306 (167 623 – 249 707) people were living with chronic hepatitis C infection in Australia.

The greatest estimated proportions were in New South Wales (36%, 80 700); Victoria (24%, 55 261); and Queensland (21%, 47 356) followed by Western Australia (9% 20 549); South Australia (5%, 11 682); Tasmania (2%, 4 561); the Australian Capital Territory (2%, 3 591) and the Northern Territory (2%, 3 606) (Table 2).

Table 2 Estimated number of people living with chronic hepatitis C, 2015, by State/Territory

State/Territory	Chronic hepatitis C infection (range)	Early to moderate fibrosis	Severe fibrosis	Hepatitis C related cirrhosis	Decompensated cirrhosis/HCC
Australian Capital Territory	3 591 (2 648 – 3 945)	2 813	459	274	48
New South Wales	80 700 (59 511 – 88 653)	63 214	10 321	6 089	1 077
Northern Territory	3 606 (2 659 – 3 962)	2 825	461	272	48
Queensland	47 356 (34 922 – 52 023)	37 094	6 056	3 573	632
South Australia	11 682 (8 614 – 12 833)	9 150	1 494	881	156
Tasmania	4 561 (3 363 – 5 010)	3 572	583	344	61
Victoria	55 261 (40 751 – 60 707)	43 287	7 067	4 169	738
Western Australia	20 549 (15 154 – 22 574)	16 097	2 628	1 550	274
Australia	227 306	178 052	29 070	17 149	3 034

Note: HCC = hepatocellular carcinoma

Source: See Methodological Notes for detail

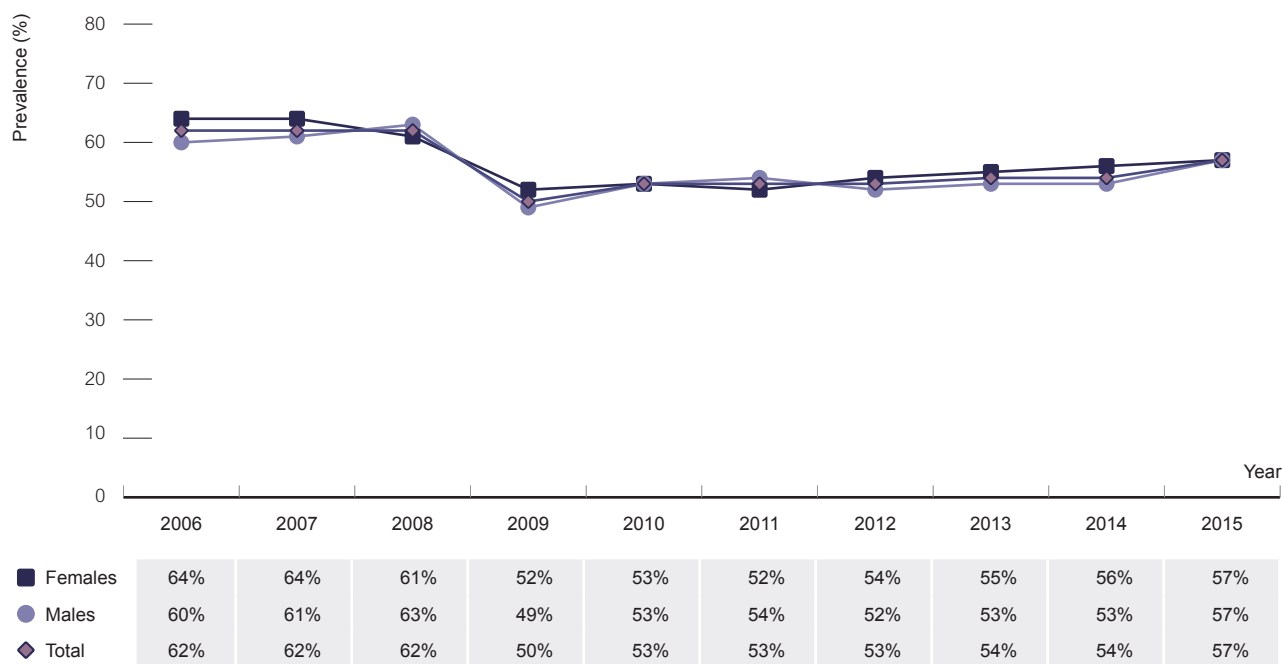


Hepatitis C prevalence

Australia has a concentrated chronic hepatitis C epidemic among priority populations; people who inject drugs, prisoners with a history of injecting drug use, people from high prevalence countries (>3.5%)³ and HIV positive men who have sex with men.

Data routinely collected from the Australian Needle Syringe Program Survey provide insights into the demographic characteristics, risk behaviour, and bloodborne virus prevalence among people who inject drugs who attend needle and syringe programs. Exposure to hepatitis C infection occurs at high levels among people who inject drugs, with a hepatitis C antibody prevalence of 57% among 2015 Australian Needle and Syringe Program Survey participants (Figure 6). Prevalence of hepatitis C antibody decreased among both males and females from over 60% in 2006 to approximately around 50% in 2009, and has remained relatively stable (Figure 6).

Figure 6 Hepatitis C prevalence* among people seen at needle and syringe programs, 2006 – 2015, by sex

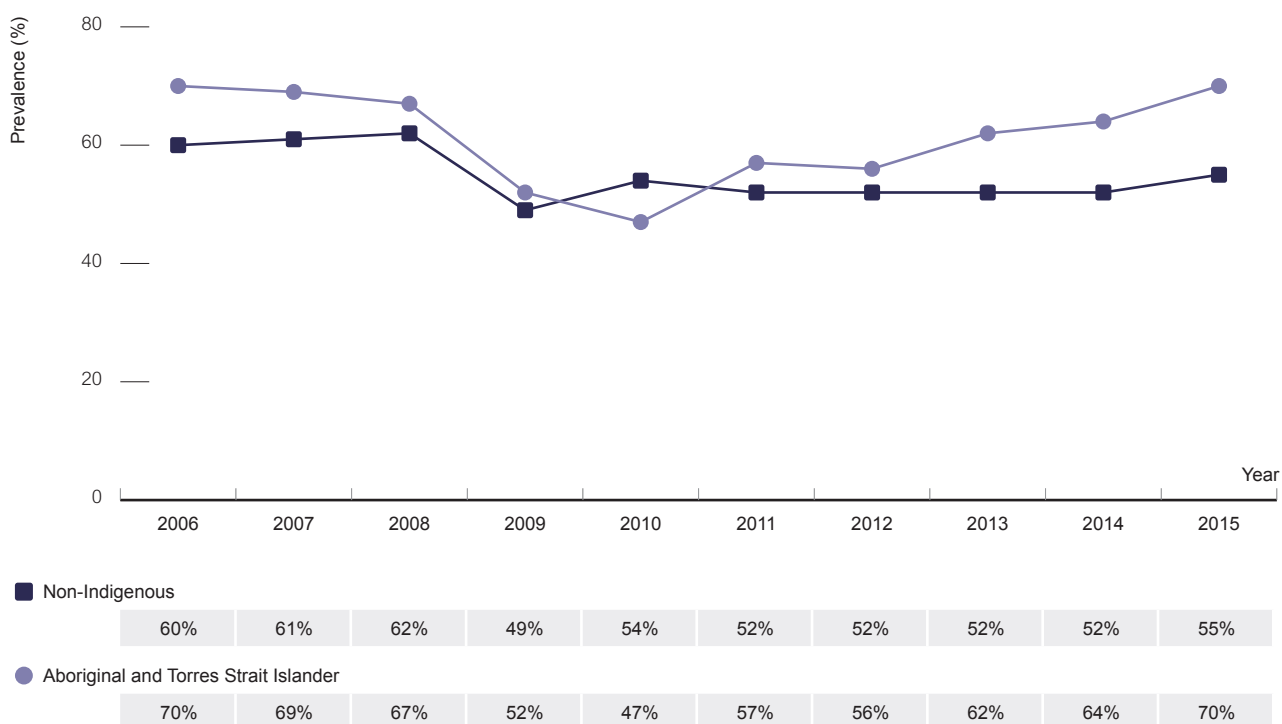


* Among respondents tested

Source: Australian Needle and Syringe Program Survey, see Methodological Notes for detail

In the period from 2006 – 2015, the proportion of participants in the Australian Needle and Syringe Program Survey identifying as Aboriginal and Torres Strait Islander increased from 10 to 15%. Hepatitis C antibody prevalence was higher among Aboriginal and Torres Strait Islander survey respondents compared to non-Indigenous respondents in all years, except for 2010 (Figure 7). The prevalence of hepatitis C antibody among Aboriginal and Torres Strait Islander participants increased from 57% in 2011 to 70% in 2015, compared with a stable prevalence in non-Indigenous respondents at 52 to 55% over the same period (Figure 7).

Figure 7 Hepatitis C prevalence* among people seen at needle and syringe programs, 2006 – 2015, by Aboriginal and Torres Strait Islander status



* Among respondents tested

Source: Australian Needle and Syringe Program Survey, see Methodological Notes for detail

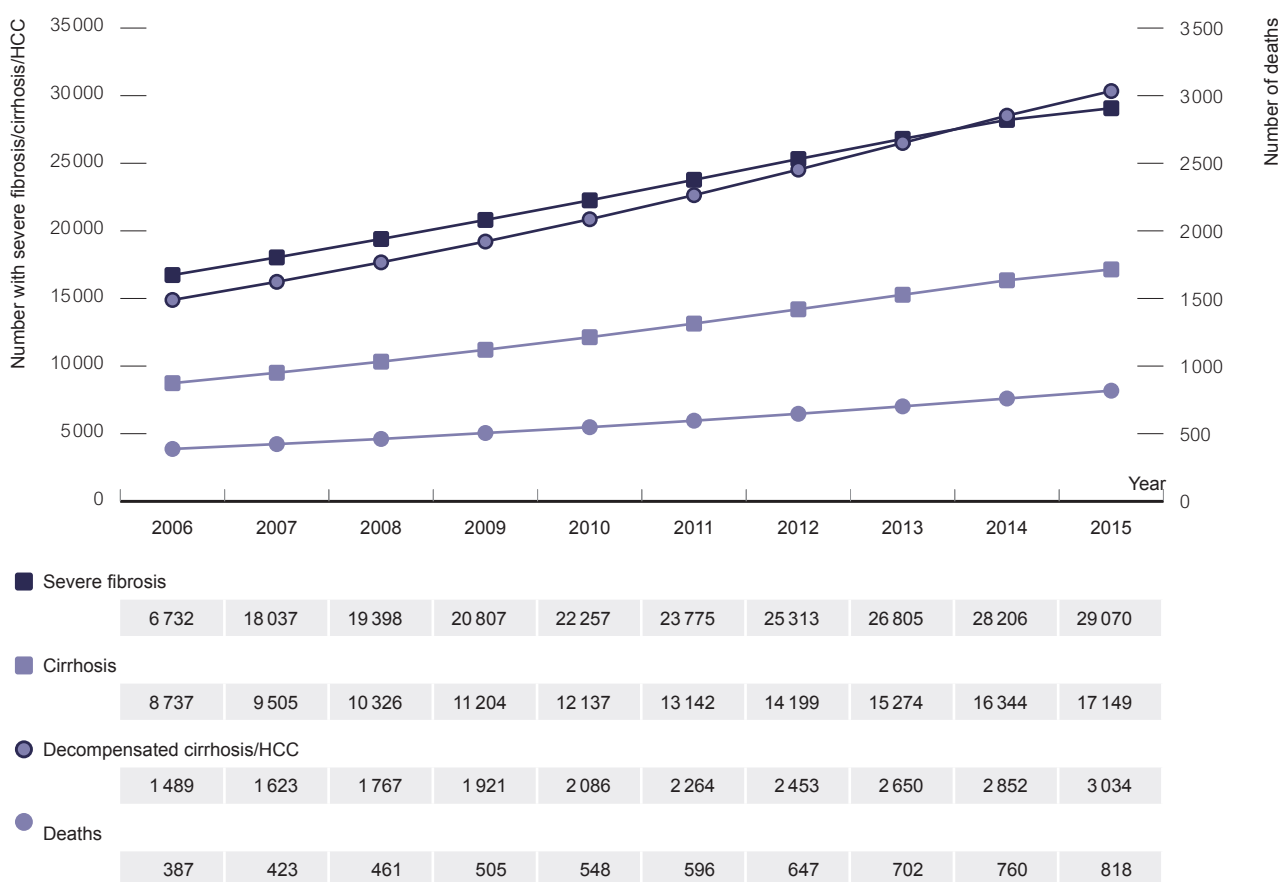


Hepatitis C Morbidity

By the end of 2015, an estimated 178 052 (131 302 – 195 600) people living with chronic hepatitis C had early to moderate fibrosis (stage F0-2), 29 070 (21 437 – 31 935) had severe fibrosis (stage F3), 17 149 (12 647 – 18 840) had hepatitis C related cirrhosis (stage 4), 3 034 (2 238 – 3 333) had decompensated cirrhosis/hepatocellular carcinoma (Table 2) and there were an estimated 818 (603 – 899) deaths attributable to chronic hepatitis C infection.

Since 2006 the estimated number of people with severe fibrosis related to hepatitis C has increased by 73% (16 732), the estimated number of people with hepatitis C related cirrhosis has increased by 96% (8 737) and the estimated number of deaths attributable to hepatitis C has increased by 111% since 2006 (Figure 8).

Figure 8 Estimated number of people at different stages of hepatitis C related liver morbidity, and estimated number of deaths, 2006 – 2015



Note: HCC = hepatocellular carcinoma
Source: See Methodological Notes for detail

There is no comprehensive registry of advanced illness related to hepatitis C in Australia. One indicator of the extent of illness caused by hepatitis C is the number of liver transplants due to chronic infection. Of the 219 people who had a liver transplant in 2015, 72 (33%) had hepatitis C infection.

Hepatitis C testing and care

Hepatitis C diagnosis and care cascade

This section includes the 'Hepatitis C diagnosis and care cascade' which provides a graphical snapshot of the estimated number of people living with chronic hepatitis C, the estimated number and proportion who are diagnosed with hepatitis C in Australia, and the estimated number of people receiving antiviral treatment. These estimates are used to support the improvement of the delivery of services to people with chronic hepatitis C infection across the entire continuum of care—from diagnosis, to treatment and cure. Using available data and accounting for uncertainties, the proportions of people in each stage of the cascade in Australia were estimated (Figure 9, Table 3). Methods and the associated uncertainties are described in detail in the Methodological Notes.

The approach was informed by recommendations from a national stakeholder reference group.

Figure 9 The hepatitis C diagnosis and care cascade, 2013 – 2015

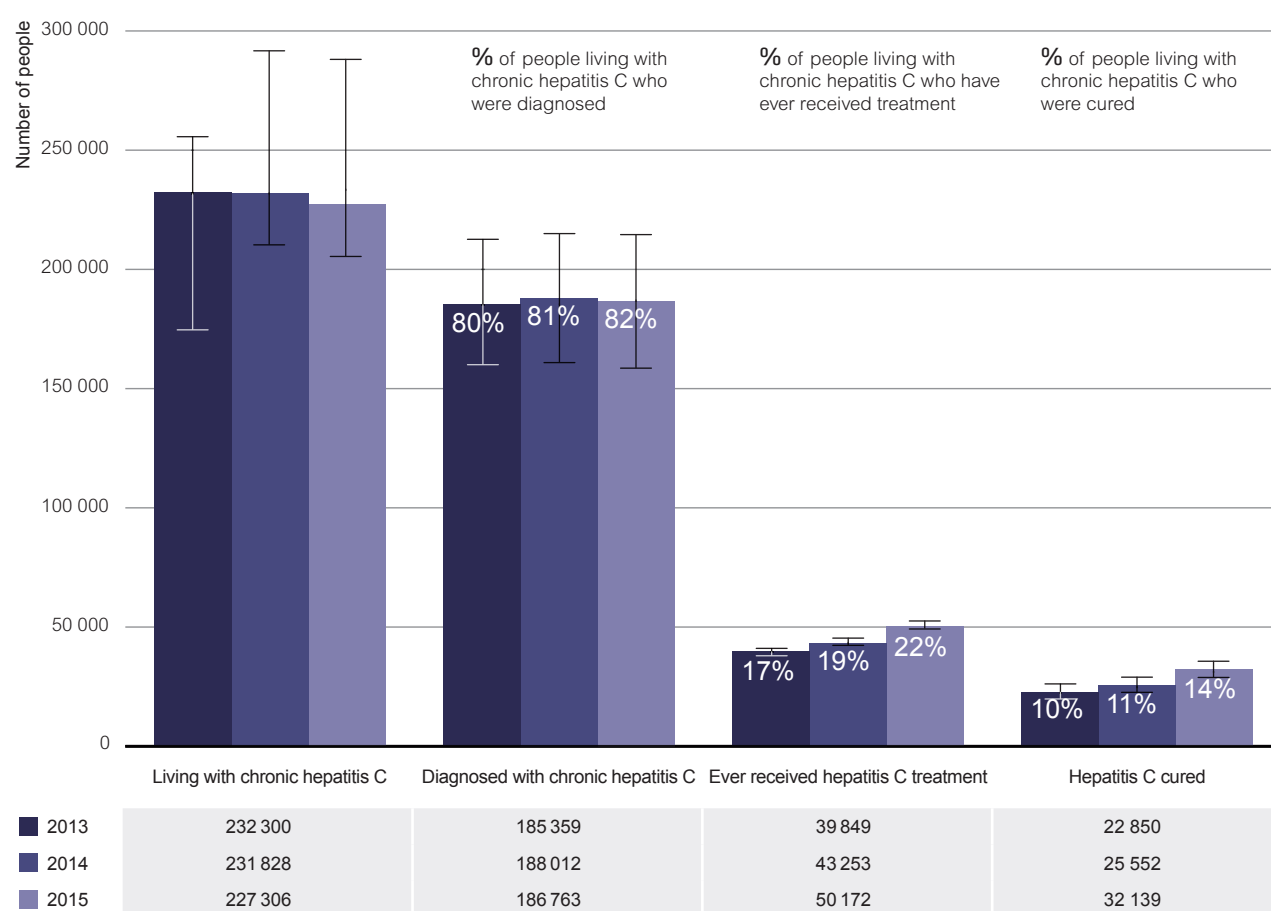


Table 3 The hepatitis C diagnosis and care cascade estimates, 2013 – 2015

Cascade stage	Estimate to end of 2013 (range)	Estimate to end of 2014 (range)	Estimate to end of 2015 (range)
Living with chronic hepatitis C infection*	232 300 (173 771 – 254 536)	231 828 (172 692 – 254 155)	227 306 (167 623-249 707)
Diagnosed with chronic hepatitis C infection	185 359 (160 170 – 212 027)	188 012 (161 836 – 215 743)	186 763 (159 578-215 595)
Ever received hepatitis C treatment	39 849 (38 234 – 40 678)	43 253 (41 342 – 44 189)	50 172 (47 929 – 51 227)
Hepatitis C cured	22 850 (18 293 – 25 466)	25 552 (20 756 – 28 041)	32 139 (27 067 – 34 492)

* Excludes those ever cured

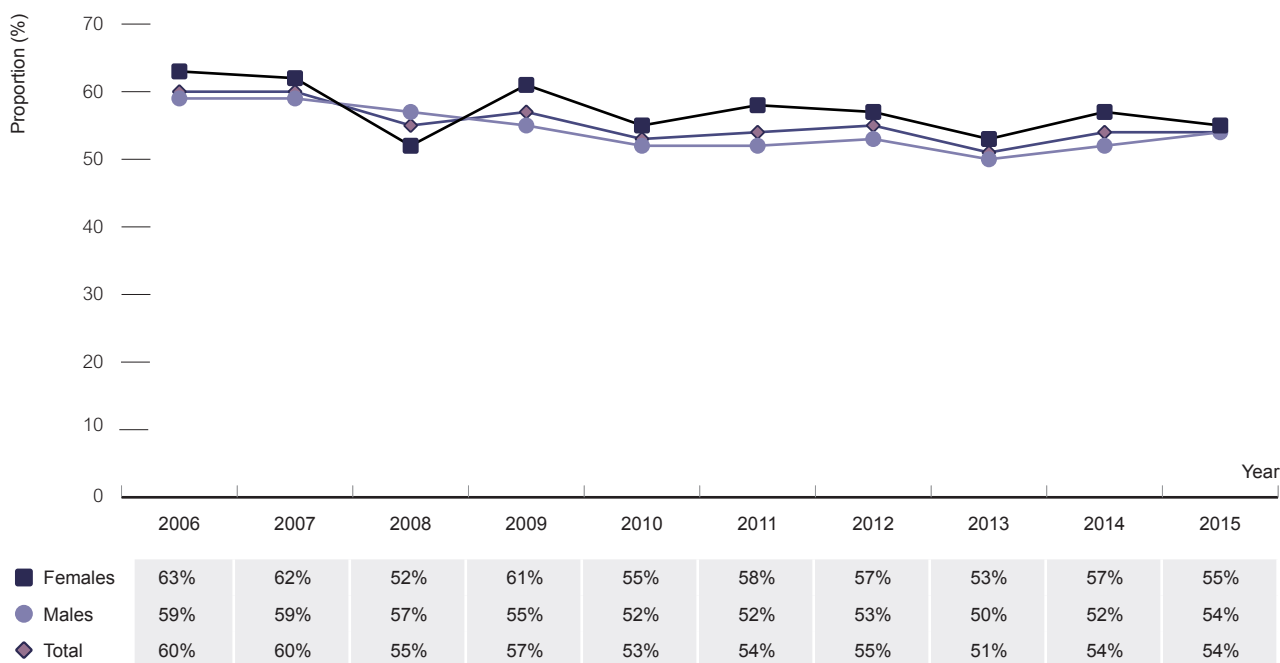
Source: See Methodological Notes for detail

During 2015, an estimated 227 306 (167 623 – 249 707) people were living with chronic hepatitis C infection, an estimated 186 763 (159 578 – 215 595) were diagnosed with chronic hepatitis C, an estimated 50 172 (47 929 – 51 227) were ever on antiviral therapy, and 32 139 (27 067 – 34 492) were cured. This corresponds to 82% of all people with chronic hepatitis C being diagnosed, 22% of people living with chronic hepatitis C ever having been on antiviral therapy, and 14% of people living with chronic hepatitis C were cured. This compares to 75% diagnosed, 19% ever treated and 11% cured in 2014, and similar proportions in 2013.

Hepatitis C testing

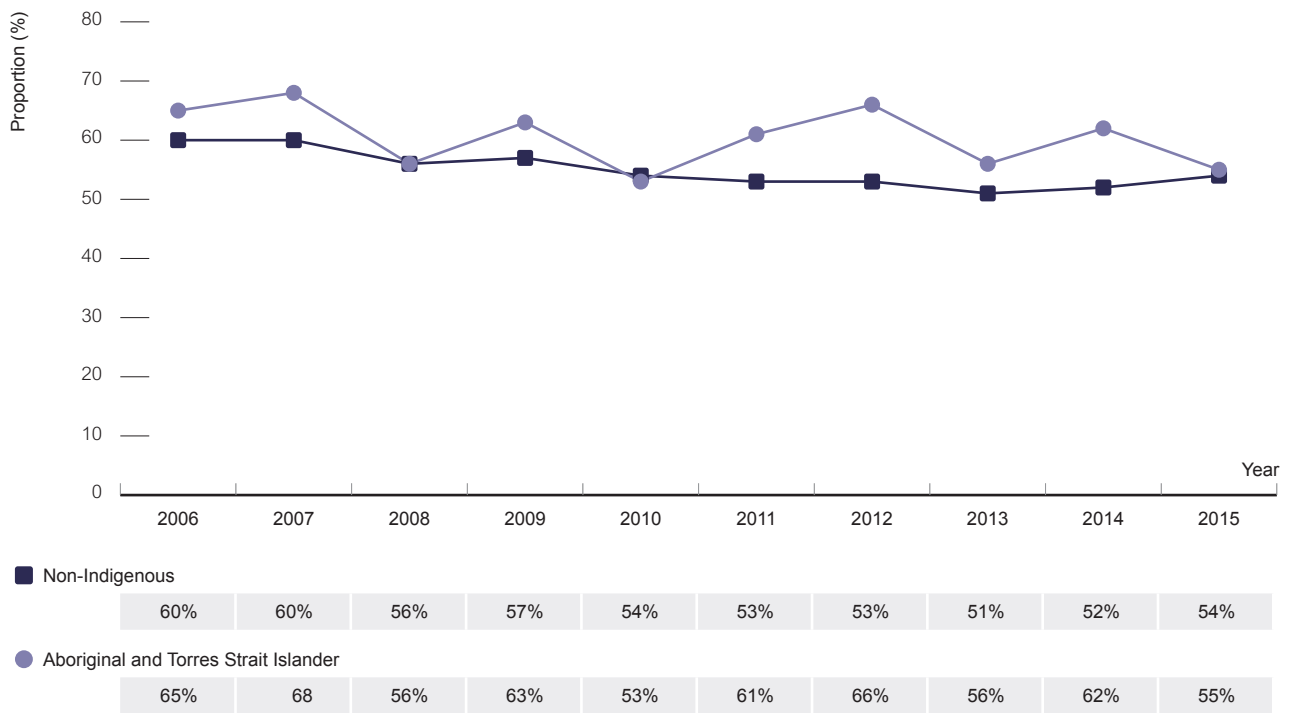
Data from the Australian Needle and Syringe Program Survey show that in 2015, about half (55% of females and 54% of males) reported a hepatitis C antibody test in the 12 months prior to the survey (Figure 10). Over the last ten years the proportion reporting hepatitis C testing, has fluctuated between 51 – 60%. The proportion of Aboriginal and Torres Strait Islander peoples reporting a hepatitis C antibody testing the past twelve months has been higher than the non-Indigenous population in all years, except 2008 and 2010 (Figure 11). In 2015, 55% of Aboriginal and Torres Strait Islander respondents reported a hepatitis C antibody test in the last twelve months, compared to 54% of non-Indigenous respondents.

Figure 10 Proportion of people who inject drugs seen at needle and syringe programs who reported a hepatitis C antibody test in the past 12 months, 2006 – 2015, by sex



Source: Australian Needle and Syringe Program Survey; see Methodological Notes for detail

Figure 11 Proportion of people who inject drugs seen at needle and syringe programs who reported a hepatitis C antibody test in the past 12 months, 2006 – 2015, by Aboriginal and Torres Strait Islander status



Source: Australian Needle and Syringe Program Survey; see Methodological Notes for detail



Hepatitis C treatment

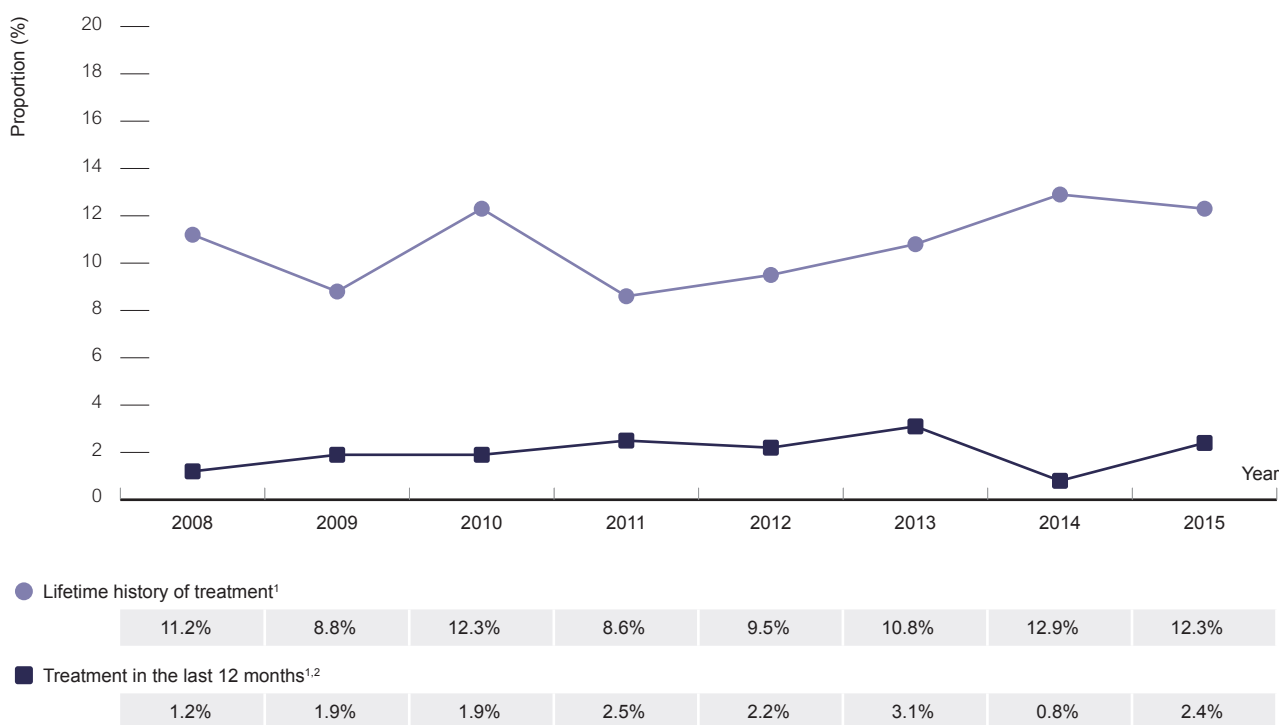
An estimated 7 296 people with chronic hepatitis C received treatment in the 12 months of 2015, compared with 3 749 in 2014 and 3 540 in 2013. The increase in 2015 reflects people accessing direct acting antivirals through personal importation and clinical trials, prior to public funding through the Pharmaceutical Benefits Scheme in March 2016.

According to the Australian Needle and Syringe Program Survey, among people who inject drugs with prior exposure to hepatitis C, in 2015, 12% reported ever receiving hepatitis C treatment and 2% had received treatment in the last 12 months similar to the 11% ever treated and 1% receiving treatment in the last 12 months in 2008 (Figure 12), with some fluctuation in the intervening years.

Among Aboriginal and Torres Strait Islander respondents in the Australian Needle and Syringe Program Survey, 11% reported a lifetime history of treatment, and 4% reported treatment in the last 12 months, similar to the 11% and 1%, respectively, in 2008 (Figure 13).

Interferon-free direct acting antiviral regimens became available in Australia in March 2016, and treatment data from March-July 2016 are reported in the 'Direct acting antiviral treatment post March 2016' section of this report.

Figure 12 Proportion of hepatitis C antibody positive people seen at needle and syringe programs with a history of hepatitis C treatment, 2008 – 2015

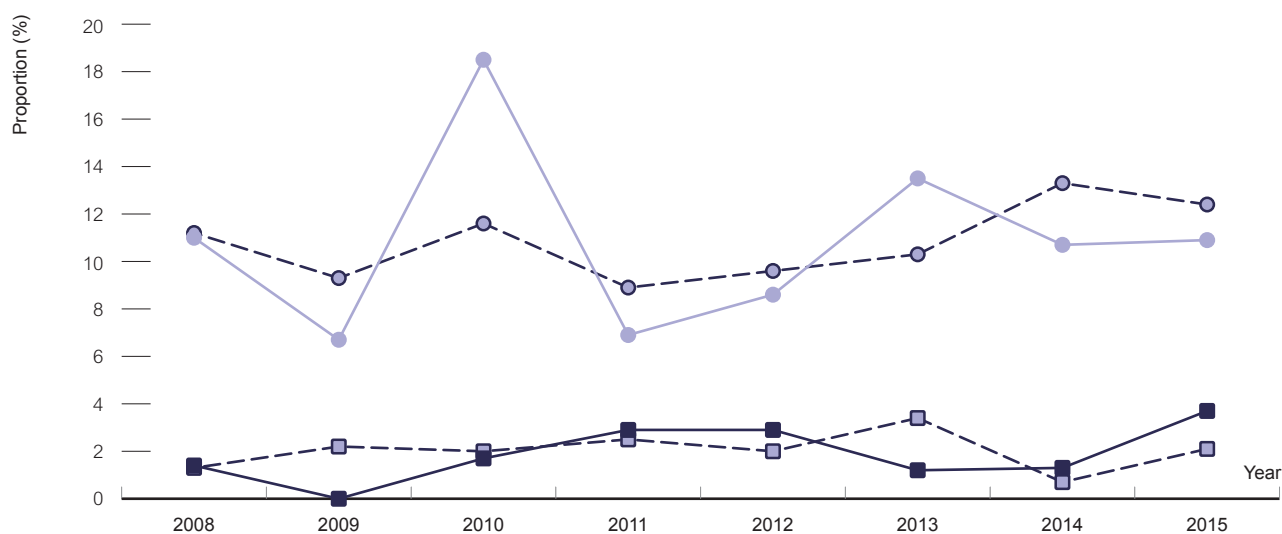


1. Denominator for lifetime history of treatment is restricted to people with hepatitis C antibody positive serology and excludes people who self-reported spontaneous clearance; Denominator for treatment in the last twelve months is restricted to people with hepatitis C antibody positive serology and excludes people who self-reported spontaneous or treatment induced viral clearance

2. Prior to 2012 commenced treatment in the last twelve months was 'current treatment'

Source: Australian Needle and Syringe Program Survey, see Methodological Notes for details

Figure 13 Proportion of hepatitis C antibody positive people seen at needle and syringe programs with a history of hepatitis C treatment, 2008 – 2015, by Aboriginal and Torres Strait Islander status



● Lifetime history of treatment – Aboriginal and Torres Strait Islander¹

11.0%	6.7%	18.5%	6.9%	8.6%	13.5%	10.7%	10.9%
-------	------	-------	------	------	-------	-------	-------

■ Treatment in the last 12 months – Aboriginal and Torres Strait Islander^{1,2}

1.4%	0.0%	1.7%	2.9%	2.9%	1.2%	1.3%	3.7%
------	------	------	------	------	------	------	------

● Lifetime history of treatment – non-Indigenous¹

11.2%	9.3%	11.6%	8.9%	9.6%	10.3%	13.3%	12.4%
-------	------	-------	------	------	-------	-------	-------

■ Treatment in the last 12 months – non-Indigenous^{1,2}

1.3%	2.2%	2.0%	2.5%	2.0%	3.4%	0.7%	2.1%
------	------	------	------	------	------	------	------

1. Denominator for lifetime history of treatment is restricted to people with hepatitis C antibody positive serology and excludes people who self-reported spontaneous clearance; Denominator for treatment in the last twelve months is restricted to people with hepatitis C antibody positive serology and excludes people who self-reported spontaneous or treatment induced viral clearance

2. Prior to 2012 commenced treatment in the last twelve months was 'current treatment'

Source: Australian Needle and Syringe Program Survey see Methodological Notes for details



Hepatitis C prevention

The re-use of needles and syringes that have been used by others (receptive syringe sharing) is the major risk factor for the transmission of HIV and hepatitis among people who inject drugs. Harm reduction strategies such as needle and syringe programs, opioid substitution therapy (OST) and peer interventions can reduce injecting risk behaviour.^{4,5} OST has also been shown to reduce the incidence of HIV and hepatitis C among people who inject drugs.⁶⁻⁸ Education is important to enhance the effectiveness of these harm reduction strategies and to support people to inject safely.

At a community level, modelling suggests achieving a high coverage of hepatitis C antiviral treatment can reduce the population prevalence of infection, and therefore lead to reduced incidence of infection (treatment as prevention).⁹ Secondary prevention strategies to reduce the risk of progression to hepatocellular carcinoma include improving access to diagnosis and antiviral treatment.

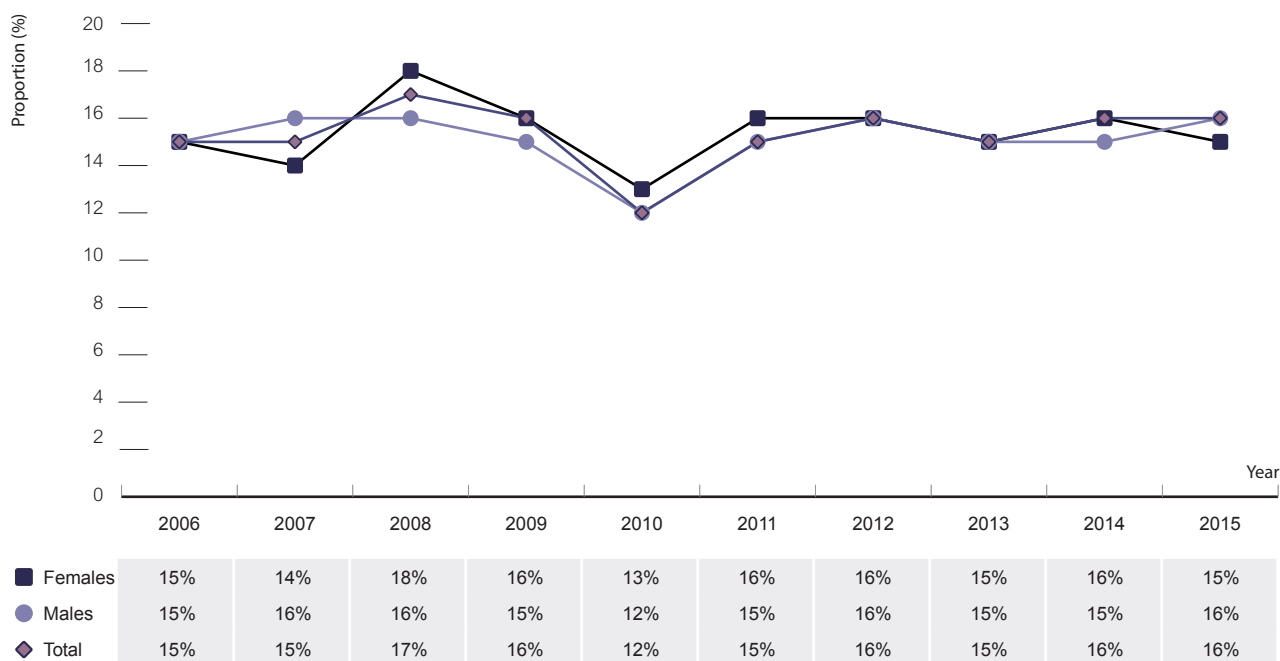
Injecting risk behaviour

Data from the Australian Needle and Syringe Program Survey indicate that rates of receptive syringe sharing have remained stable over the last ten years, at around 15% among people who inject drugs attending needle and syringe programs, similar among males and females (Figure 14). Receptive syringe sharing was determined by the question: “How many times in the last month did you reuse a needle and syringe after someone else had used it, including your sex partner (even if it was cleaned)?”

Aboriginal and Torres Strait Islander people have higher rates of risk factors for hepatitis C acquisition, including through injecting, and incarceration. A higher proportion of Aboriginal and Torres Strait Islander peoples attending needle and syringe programs reported receptive syringe sharing, compared to non-Indigenous participants (24% versus 14% in 2015) (Figure 15). Also in 2015, imprisonment rates for the Aboriginal and Torres Strait Islander population were reported to be 15 times higher than the non-Indigenous population¹⁰.

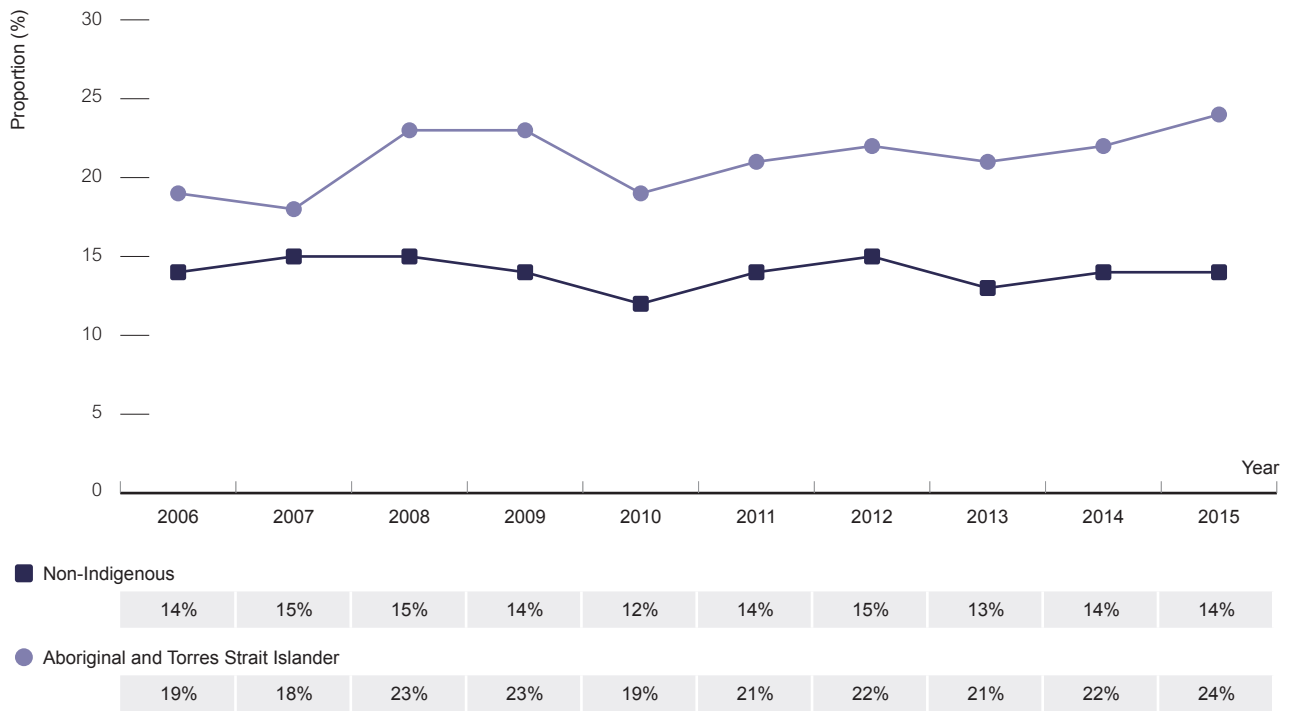
Respondents in the Australian Needle and Syringe Program Survey are broadly similar to the overall population of Needle and Syringe Program attendees in Australia in terms of age, sex and last drug injected. However, while consistent with other sources of surveillance data, the extent to which Australian Needle and Syringe Program Survey results can be generalised to the broader Australian population of people who inject drugs cannot be ascertained.

Figure 14 Proportion of people seen at Needle and Syringe Programs reporting receptive syringe sharing in the last month, 2006 – 2015, by sex



Source: Australian Needle and Syringe Program Survey; see Methodological Notes for detail

Figure 15 Proportion of people seen at needle and syringe programs reporting receptive syringe sharing in the last month, 2006 – 2015, by Aboriginal and Torres Strait Islander status



Source: Australian Needle and Syringe Program Survey; see Methodological Notes for detail



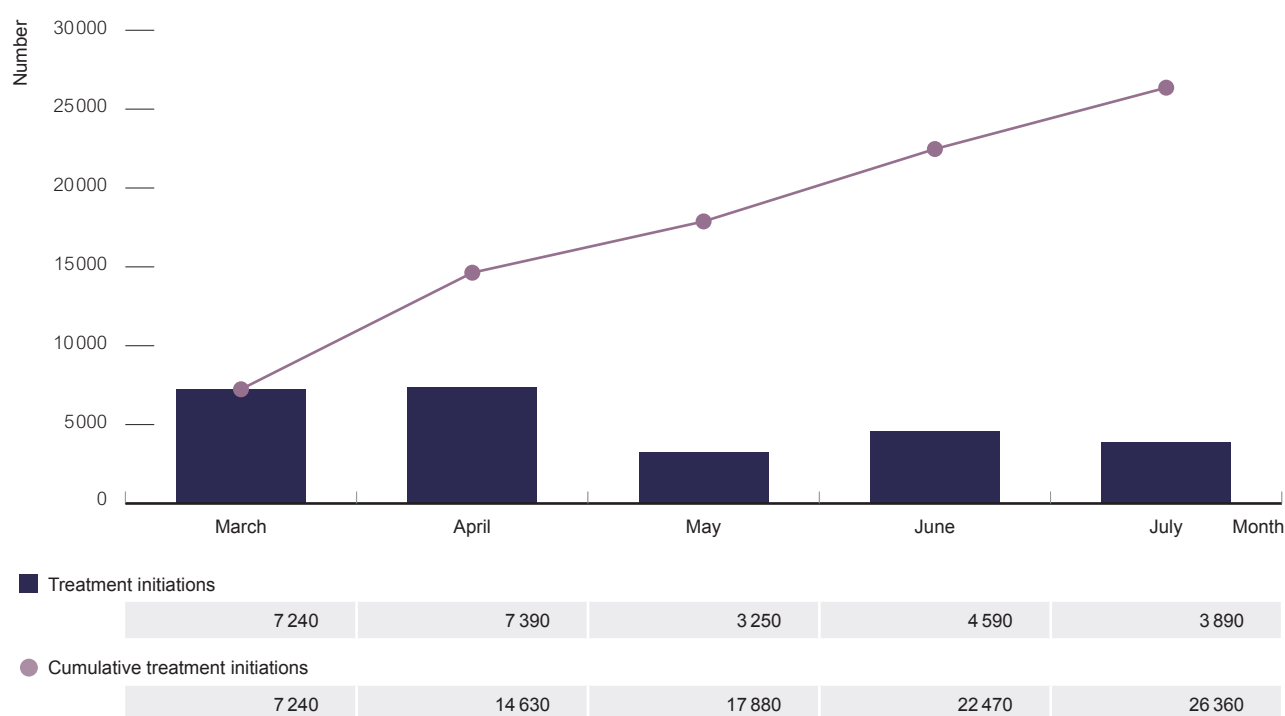
Direct acting antiviral treatment March to July 2016

Estimated hepatitis C direct acting antiviral treatment initiations

Based on extrapolations of Pharmaceutical Benefits Scheme and wholesale expenditure data, an estimated 26 360 (range: 22 304 – 30 415) people initiated chronic hepatitis C direct acting antiviral treatment during March to July 2016 in Australia.

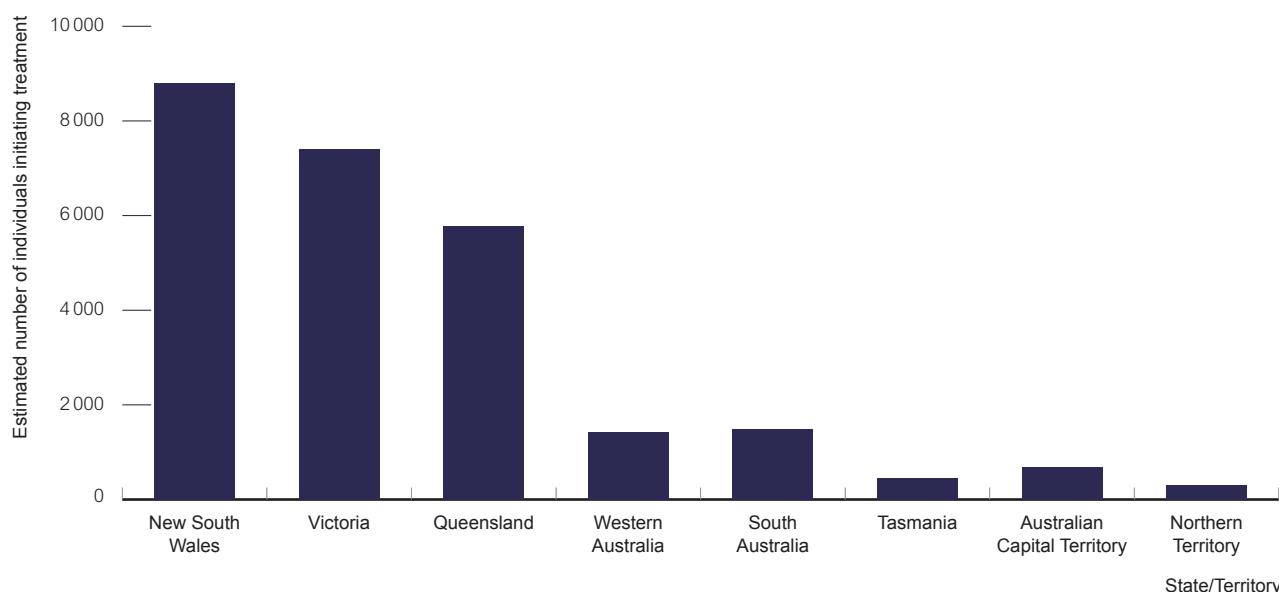
The estimated monthly number of individuals initiating direct acting antiviral treatment was 7 240 in March, 7 390 in April, 3 250 in May, 4 590 in June, and 3 890 in July (Figure 16). The higher numbers in March and April are likely to reflect the initial demand from patients in tertiary clinics, who had been waiting for new treatments to become available. The rise in June may be related to the increasing involvement of general practitioners in prescribing direct acting antivirals.

Figure 16 The estimated number of individuals initiating hepatitis C direct acting antiviral treatment per month and cumulative number of initiations, March to July 2016



By jurisdiction, there were 8 800 people who initiated direct acting antiviral treatment in New South Wales, 7 410 in Victoria, 5 790 in Queensland, 1 490 in South Australia, 1 430 in Western Australia, 680 in the Australian Capital Territory, 460 in Tasmania, and 300 in the Northern Territory (Figure 17).

Figure 17 The estimated number of individuals initiating hepatitis C direct acting antiviral treatment during March to July 2016, by jurisdiction

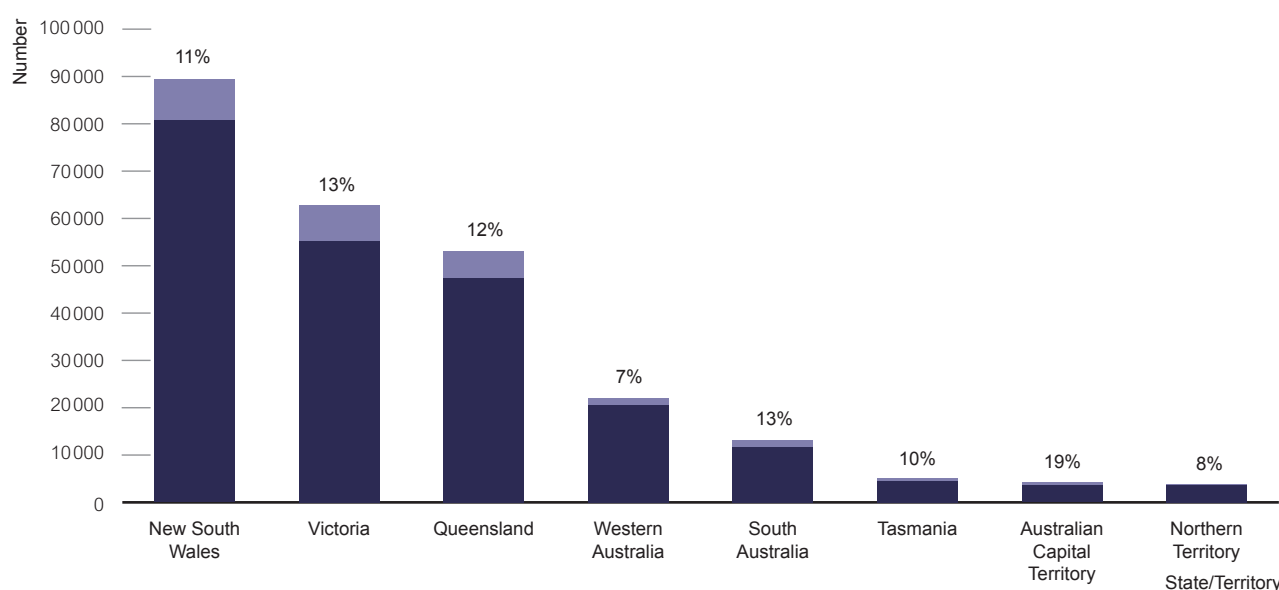


Estimated proportion of individuals living with chronic hepatitis C who initiated direct acting antiviral treatment

Taking into account the population size of people living with chronic hepatitis C in Australia and by State/Territory at the end of 2015 (see *People living with hepatitis C infection* section) it is estimated that 12% (range 10 - 13%) of people living with chronic HCV in Australia initiated direct acting antiviral treatment during March to July 2016; 11% in New South Wales, 13% in Victoria, 12% in Queensland, 7% in Western Australia, 13% in South Australia, 10% in Tasmania, 19% in Australian Capital Territory, and 8% in the Northern Territory (Figure 18). See Methodological Notes for further information on how estimates are produced.



Figure 18 The number and proportion of individuals living with chronic hepatitis C who initiated direct acting antiviral treatment during March to June 2016, by jurisdiction



■ Number of treatment initiations March – July 2016

8 800	7 410	5 790	1 430	1 490	460	680	300
-------	-------	-------	-------	-------	-----	-----	-----

■ Number living with chronic HCV

80 700	55 261	47 356	20 549	11 682	4 561	3 591	3 606
--------	--------	--------	--------	--------	-------	-------	-------

Note: The data of Victoria and Northern Territory should be interpreted conservatively. The number of prescriptions in July reported by PBS was substantially lower than that in the previous month in these two jurisdictions (more details in the methodology section).

Hepatitis C direct acting antiviral treatment prescriptions processed by the PBS by month, jurisdiction, PBS scheme, and regimen

A total of 18 581 individuals had chronic hepatitis C direct acting antiviral initial prescriptions, processed and reimbursed by the Pharmaceutical Benefits Scheme during March to July 2016. This number is lower than the earlier data on initiations, as Pharmaceutical Benefits Scheme data is subject to a time lag between drug dispensing and reimbursement submissions. However, Pharmaceutical Benefits Scheme data provide information about the provider and treatment types to understand how treatment is being implemented in Australia. See Methodological Notes for further detail.

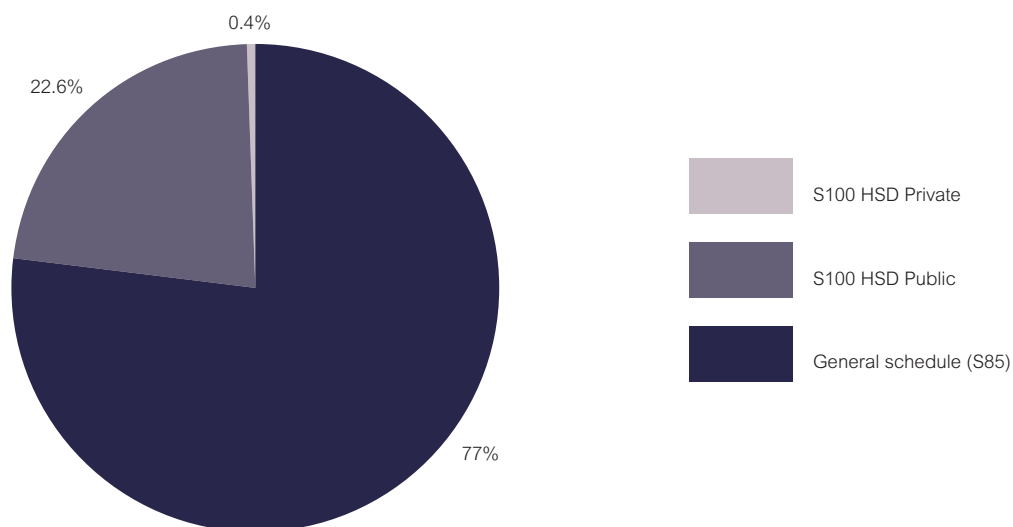
Hepatitis C treatments are available through both the Pharmaceutical Benefits Scheme General Schedule (community pharmacists, S85) and the Section 100 (S100) Highly Specialised Drugs (HSD) Program. Community pharmacists cannot dispense S100 Public HSD prescriptions for hepatitis C treatment, but are able to dispense S100 Private HSD prescriptions. Hospital prescribers are advised to use the S100 HSD listing if patients require dispensing through the public or private hospital pharmacy^{11, 12}.

Table 4 Hepatitis C direct active antiviral prescriptions by jurisdiction and Pharmaceutical Benefits scheme

	NSW	Vic	QLD	SA	WA	Tas	ACT	NT	Total
General schedule	4 149	3 957	3 993	1 145	578	297	167	19	14 305
S100 HSD Private	35	17	10	8	8	0	0	0	78
S100 HSD Public	2 138	486	276	256	632	32	292	86	4 198
Total	6 322	4 460	4 279	1 409	1 218	329	459	105	18 581

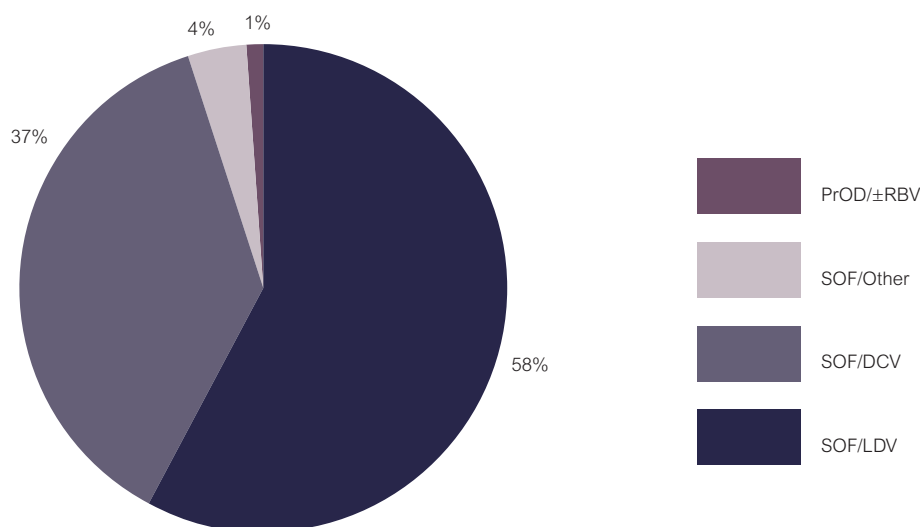
As shown in Table 4, most individuals (77%) were prescribed under the General Schedule (S85), 23% under S100 HSD Public and <1% under S100 HSD Private (Figure 19). The proportion of prescriptions made by S100 HSD Public scheme clinicians varied across jurisdictions: New South Wales (34%), Victoria (11%), Queensland (6%), South Australia (18%), Western Australia (52%), Tasmania (10%), Australian Capital Territory (64%), and Northern Territory (82%). There is considerable variation across and within jurisdictions in relation to public hospital and specialist use of S100 versus S85 prescribing.

Figure 19 Distribution of PBS schedule of chronic hepatitis C direct acting antiviral prescriptions during March to July 2016 in Australia



The vast majority of Australian's with chronic hepatitis C infection are infected with either genotype 1 or genotype 3. Both genotypes can be treated with a combination of two to four direct acting antivirals, the actual regime varies depending on an individual's hepatitis C genotype. A small proportion of people infected with a genotype other than 1 and 3 require ribavirin or pegylated interferon/ribavirin to be added to the direct acting antiviral treatment regime.

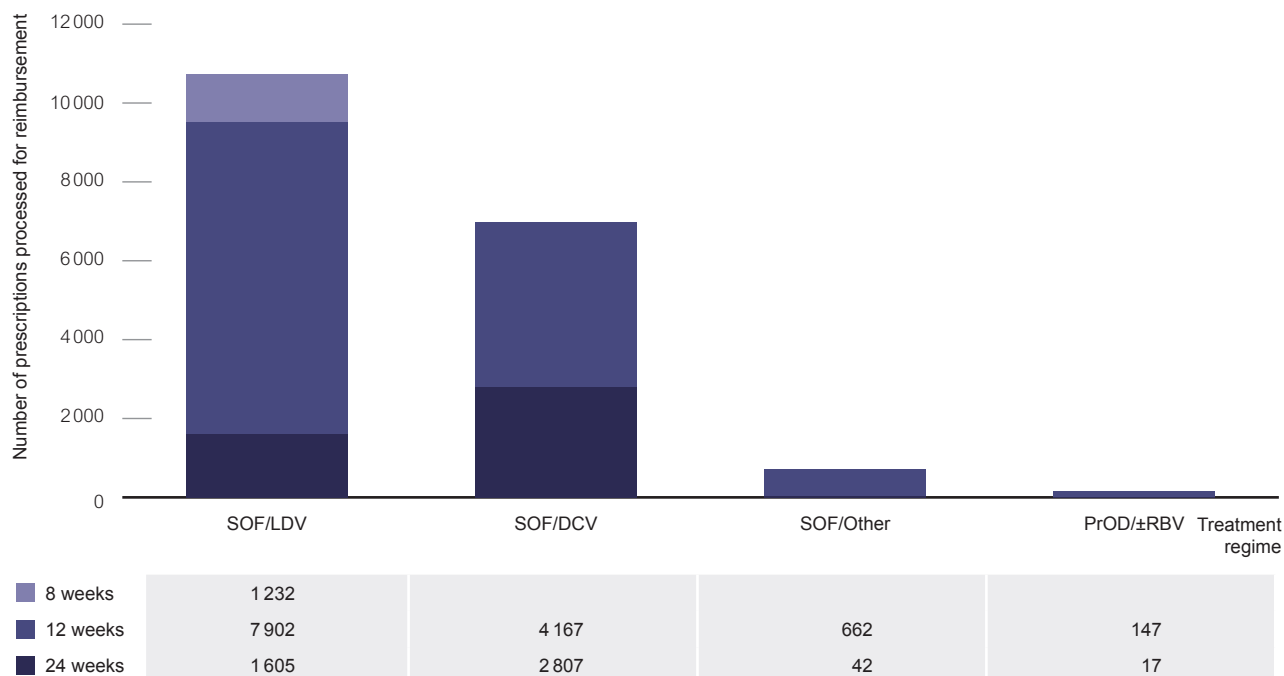
Figure 20 Distribution of chronic hepatitis C direct acting antiviral treatment regimens prescribed during March to July 2016 in Australia



Note: SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvir; RBV: Ribavirin

Most people (76%) were treated with direct acting antivirals for 8-12 weeks. A subgroup of people (24%) with significant liver disease (cirrhosis) were treated with direct acting antivirals for 24 weeks, and a small subgroup (1%) with HCV genotype other than 1 and 3 were treated with direct acting antivirals combined with ribavirin or pegylated interferon/ribavirin (Figure 21), with a similar pattern by jurisdiction (Figure 22).

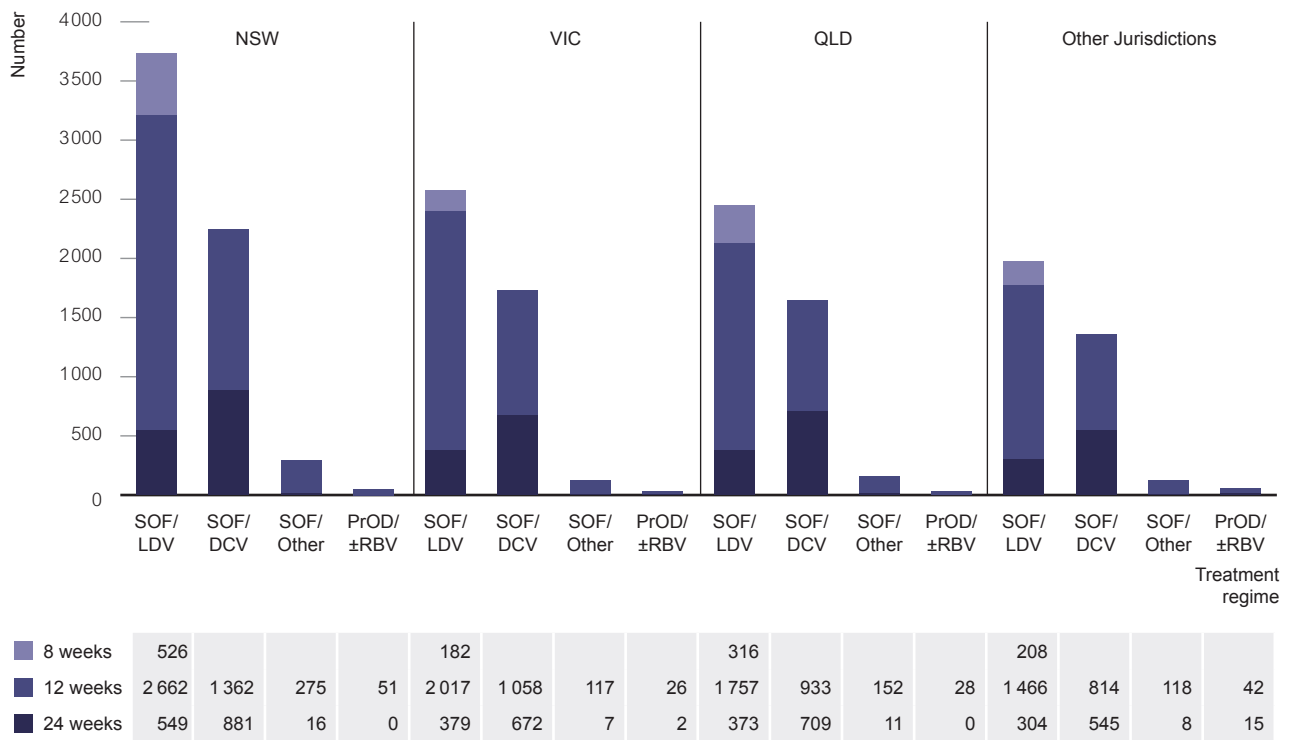
Figure 21 Distribution of chronic hepatitis C direct acting antiviral treatment prescriptions during March to July 2016 in Australia, by treatment regimen and treatment course duration



Note: SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvir; RBV: Ribavirin



Figure 22 Distribution of chronic hepatitis C direct acting antiviral treatment prescriptions March to July 2016 in Australia, by treatment regimen, and jurisdiction



Note: SOF: Sofosbuvir; LDV: Ledipasvir; DCV: Daclatasvir; PrOD: Parataprevir/ritonavir/Ombitasvir/Dasabuvir; RBV: Ribavirin

Hepatitis C incidence

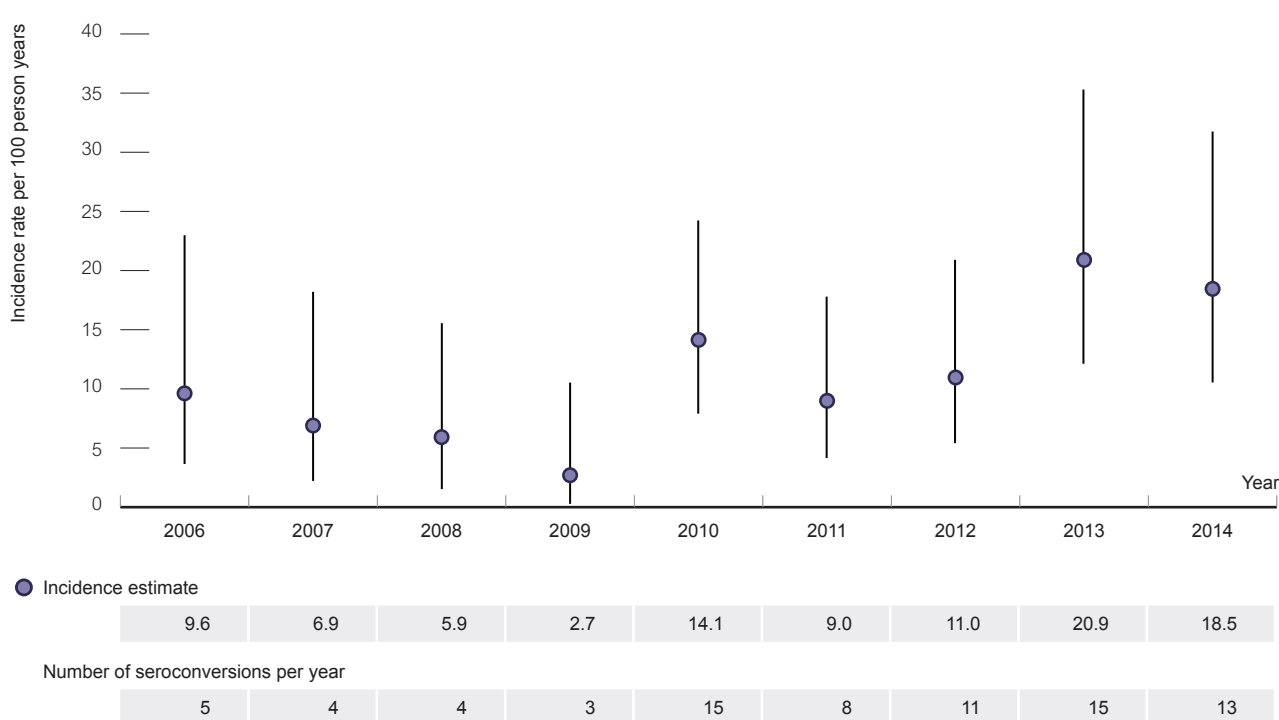
Hepatitis C incidence represents new infections and is an important indicator of the effectiveness of prevention programs to protect people from acquiring hepatitis C infection.

Trends in the rate of diagnoses in those aged under 25 years can be interpreted as a surrogate for the incidence of hepatitis C infection. As shown in the section on new hepatitis C diagnoses, there was a 33% decline in notification rates in those aged less than 25 years between 2006 and 2015.

Hepatitis C incidence can also be estimated from repeat testing data from the Australian Needle and Syringe Program Survey by dividing the number of seroconversions (HCV antibody negative to positive) observed among serologically confirmed HCV negative participants by the person time at risk (time between repeat hepatitis C test in the survey). Further details about the methods used can be found in the Methodological Notes. The incidence estimates below include data from respondents in the Australian Needle and Syringe Program Survey, so are not necessarily reflective of trends in the broader population.

Over a nine year study period (2006 – 2014) among people who inject drugs participating in the Australian Needle and Syringe Program Survey on more than one occasion, there were 78 seroconversions, yielding a pooled hepatitis C incidence of 11.2 per 100 person-years (95%CI: 8.9 – 14.0). Hepatitis C incidence declined from 9.6 in 2006 to 2.7 in 2009, and has remained high in the past five years, at between 9.0 and 20.9 (Figure 23). The confidence intervals between these estimates overlap, meaning the differences observed each year are not statistically significant, and caution should be taken in interpretation due to the small number of seroconversions per year. The incidence rate for 2015 is not available due to the method of calculation (see Methodological Notes for further detail). Incidence estimates are not available by Aboriginal and Torres Strait Islander status, due to the smaller number of participants in the survey.

Figure 23 Estimated annual incidence of hepatitis C virus infection among people who inject drugs, seen at needle and syringe programs, 2006 – 2014



Source: Australian Needle and Syringe Program Survey, see Methodological Notes for detail



Main Findings

Hepatitis B infection

2015 snapshot

New hepatitis B diagnoses

- There were a total of 6 502 notifications of newly diagnosed hepatitis B infection in Australia in 2015.
- Over the ten year period 2006 – 2015, the population rate of notification of hepatitis B infection has declined in Australia in younger age groups, reflecting the impact of the infant and adolescent vaccination program, but remained high in the 25 – 29 and 30 – 39 year age groups. The declining trend in overall notifications in younger age groups was similar to that of notifications of newly acquired hepatitis B infection.
- Notification rates of hepatitis B infection were three times higher among the Aboriginal and Torres Strait Islander population than in the non-Indigenous population in 2015 (66 per 100 000 compared to 22 per 100 000). Similar to the non-Indigenous population, the greatest declines were observed in the younger age groups.

Prevalence and morbidity

- There were an estimated 232 600 (range 190 738 to 283 781) people living with chronic hepatitis B infection in Australia in 2015, of whom 88 621 (38%) were born in the Asia-Pacific and 21 632 (9.3%) were Aboriginal and Torres Strait Islander peoples.
- In 2015, the estimated hepatitis B prevalence was 4.0% in people who inject drugs, 3.9% in Aboriginal and Torres Strait Islander peoples, 3.6% in people born in the Asia-Pacific, 3.5% in people born in Sub-Saharan Africa, and 3.0% in men who have sex with men, with potential overlaps in some of these categories.
- Of 219 people who had a liver transplant in 2015, 17 (8%) had hepatitis B infection.
- An estimated 419 (323 – 683) deaths attributable to chronic hepatitis B infection occurred in 2015.

Testing and care

- In 2015 an estimated 62% of people living with chronic hepatitis B in Australia have been diagnosed.
- Treatment for hepatitis B is considered in people with elevated hepatitis B viral load, abnormal liver function tests, or those who have advanced liver disease (cirrhosis). It is likely about 15% of people would benefit from treatment, yet only 6% (a third of the target) of people living with chronic hepatitis B were receiving antiviral therapy in 2015.
- Of 17 749 people attending sexual health clinics in 2015 for whom vaccination documentation or pathology details were available, 70% had documented evidence of immunity to hepatitis B, highest in the youngest age group 15 – 19 years (79%).

Prevention

- In 2015 coverage of infant hepatitis B vaccination at 24 months of age was 95% in the non-Indigenous population, and 96% in the Aboriginal and Torres Strait Islander population.

Interpretation:

Unlike hepatitis C infection which is strongly associated with injecting risk behaviour in Australia, hepatitis B in adolescents and adults is transmitted through a variety of pathways, including both injecting drug use and sexual transmission. However, most Australians living with chronic hepatitis B acquired infection at birth or in early childhood. There is limited information on uptake of testing, so it is not possible to interpret the rate of diagnosis as a surrogate for incidence, even in young people. However the trends in newly acquired infections in young people are similar to the trends in the overall diagnoses rates. Age specific analysis in both overall and newly acquired infections indicate a decline in younger age groups that are most likely to have benefited from the introduction of universal vaccination of infants in 2000 (1990 in the Northern Territory) and adolescent catch up programs from 1998 (earlier in some jurisdictions). An estimated 62% of people with chronic hepatitis B in Australia have been diagnosed and of these, 16% were in care, and 6% of all people living with chronic hepatitis B were receiving treatment in 2015 based on Pharmaceutical Benefits Scheme reimbursements. These estimates indicate an ongoing gap in both the uptake of testing to diagnose chronic hepatitis B infection and uptake of effective treatment to control viral replication.



New hepatitis B diagnoses

All diagnoses

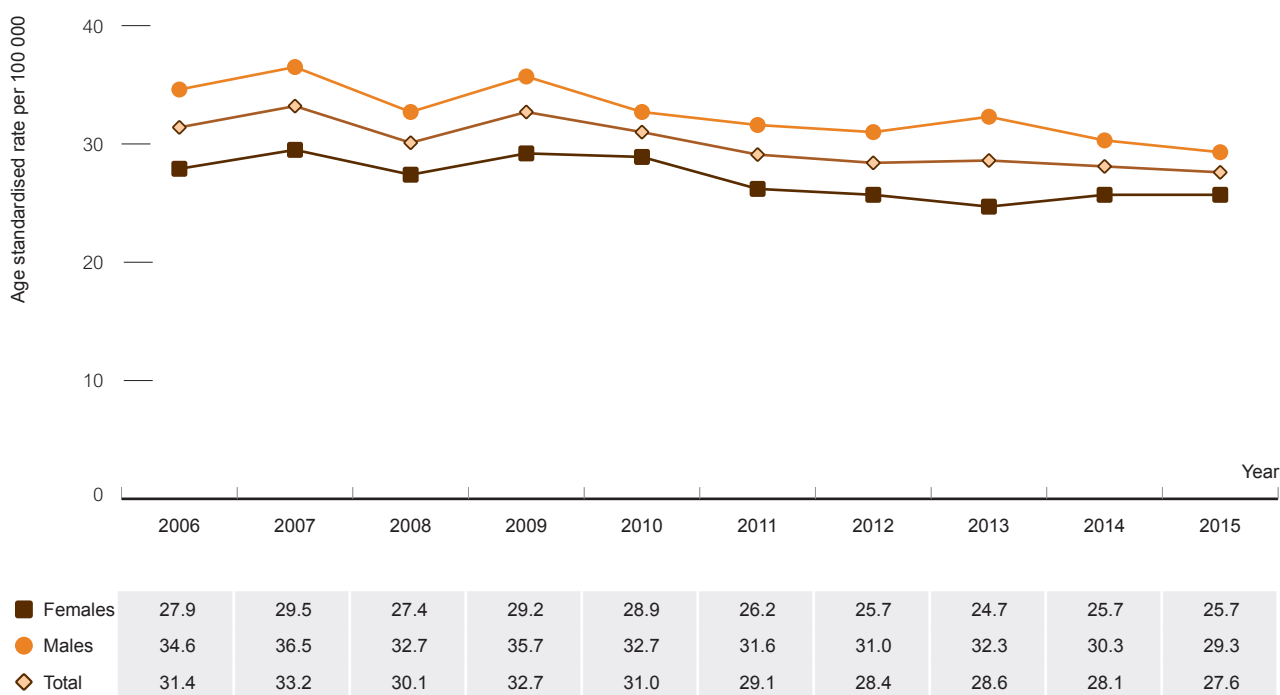
This section focuses on people newly diagnosed with hepatitis B virus infection in Australia (including people with newly acquired and unspecified duration of infection). It is important to note that changes over time in notification rates may reflect responses to testing policies and programs, different diagnostic tests, and awareness campaigns.

There were a total of 6 502 notifications of newly diagnosed hepatitis B infection in Australia in 2015, of these 221 (3%) were among the Aboriginal and Torres Strait Islander population, 2 211 (34%) were among the non-Indigenous population, and there were a further 4 070 (63%) notifications for which Indigenous status was not reported.

In 2015, over half (53%, 3 438) of newly diagnosed hepatitis B notifications were in males, 74% (4 783) were in people aged 30 years and above and 85% (5 530) were in people residing in major cities. Of the 6 502 notifications, the vast majority (98%) were unspecified, likely representing chronic hepatitis B infection.

The notification rate of hepatitis B virus infection in Australia has remained relatively steady in the past ten years, at 31 per 100 000 in 2006 and 28 per 100 000 in 2015. Rates have been consistently higher among males than females, and were 29 and 26 per 100 000 in 2015, respectively (Figure 24).

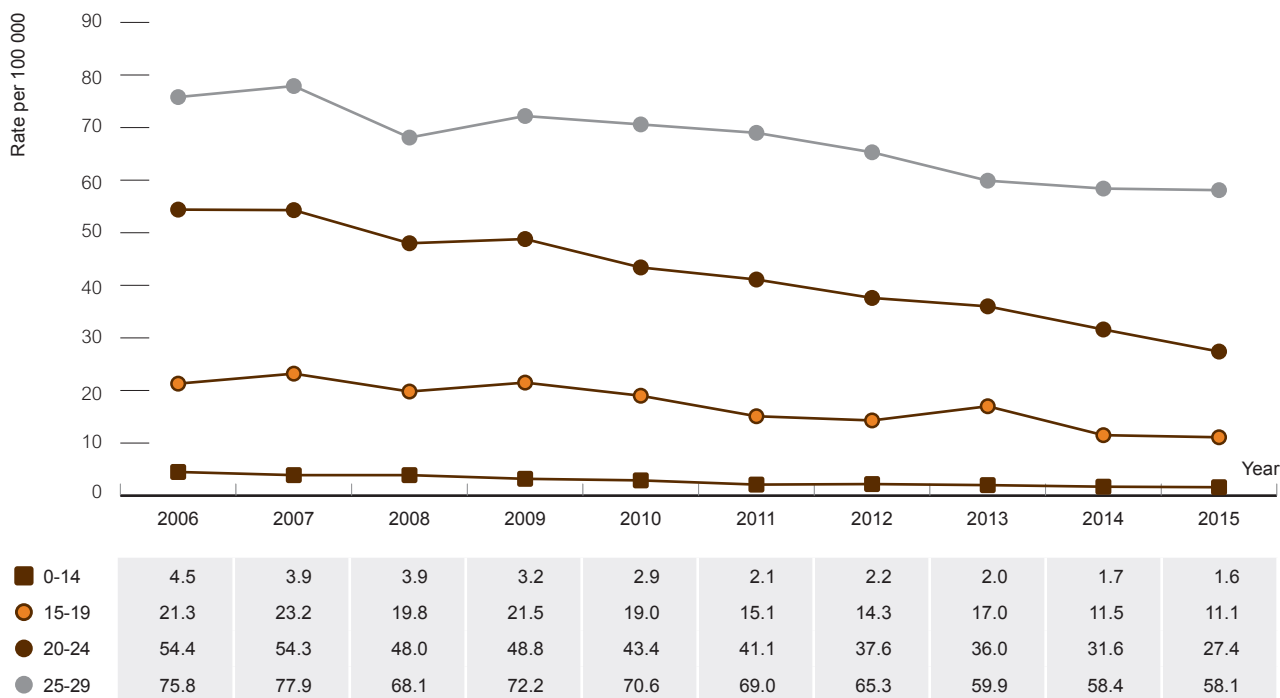
Figure 24 Hepatitis B notification rate per 100 000 population, 2006 – 2015, by sex



Source: Australian National Notifiable Diseases Surveillance System

Over the ten year period 2006 – 2015, the rate of notification of hepatitis B has declined in younger age groups aged 25 – 29 years (from 76 to 58 per 100 000), 20 – 24 years (from 54 to 27 per 100 000), and 15 – 19 years (from 21 to 11 per 100 000) (Figure 25). Overall the rates in those aged less than 25 years have declined by 51%. In contrast, notification rates of hepatitis B have showed little variation in those aged 30 – 39 years (57 per 100 000 in 2006 and 58 per 100 000 in 2015), and 40+ years (25 per 100 000 in 2006 and 26 per 100 000 in 2015) (Figure 26).

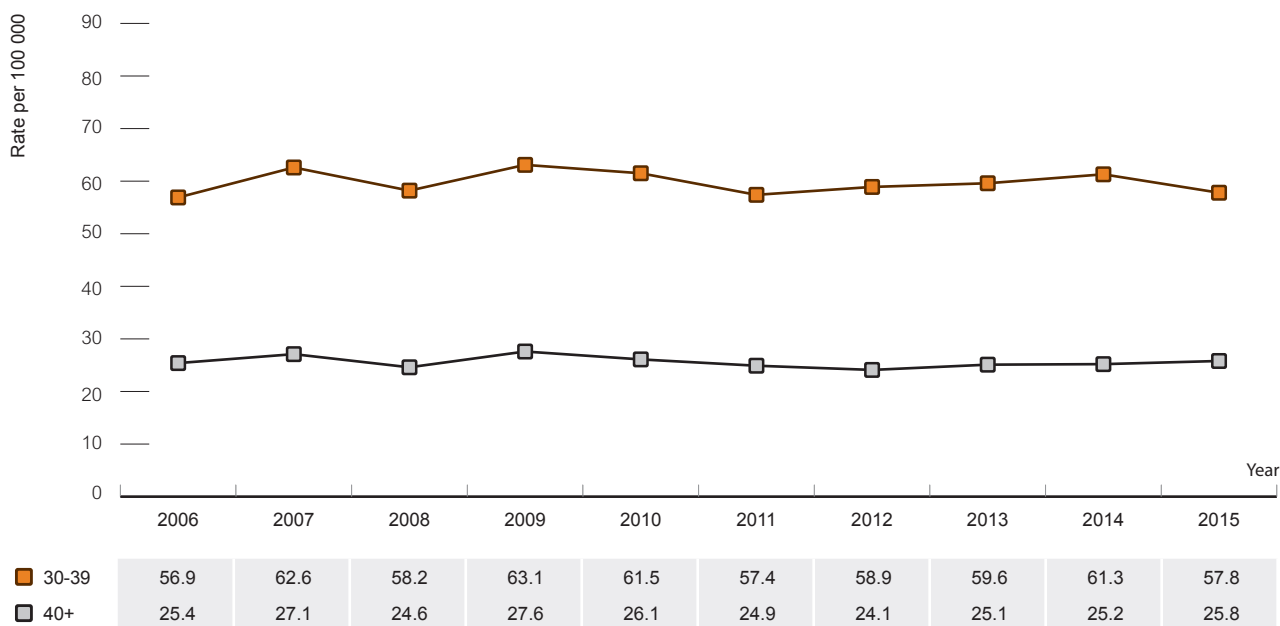
Figure 25 Hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group



Source: Australian National Notifiable Diseases Surveillance System



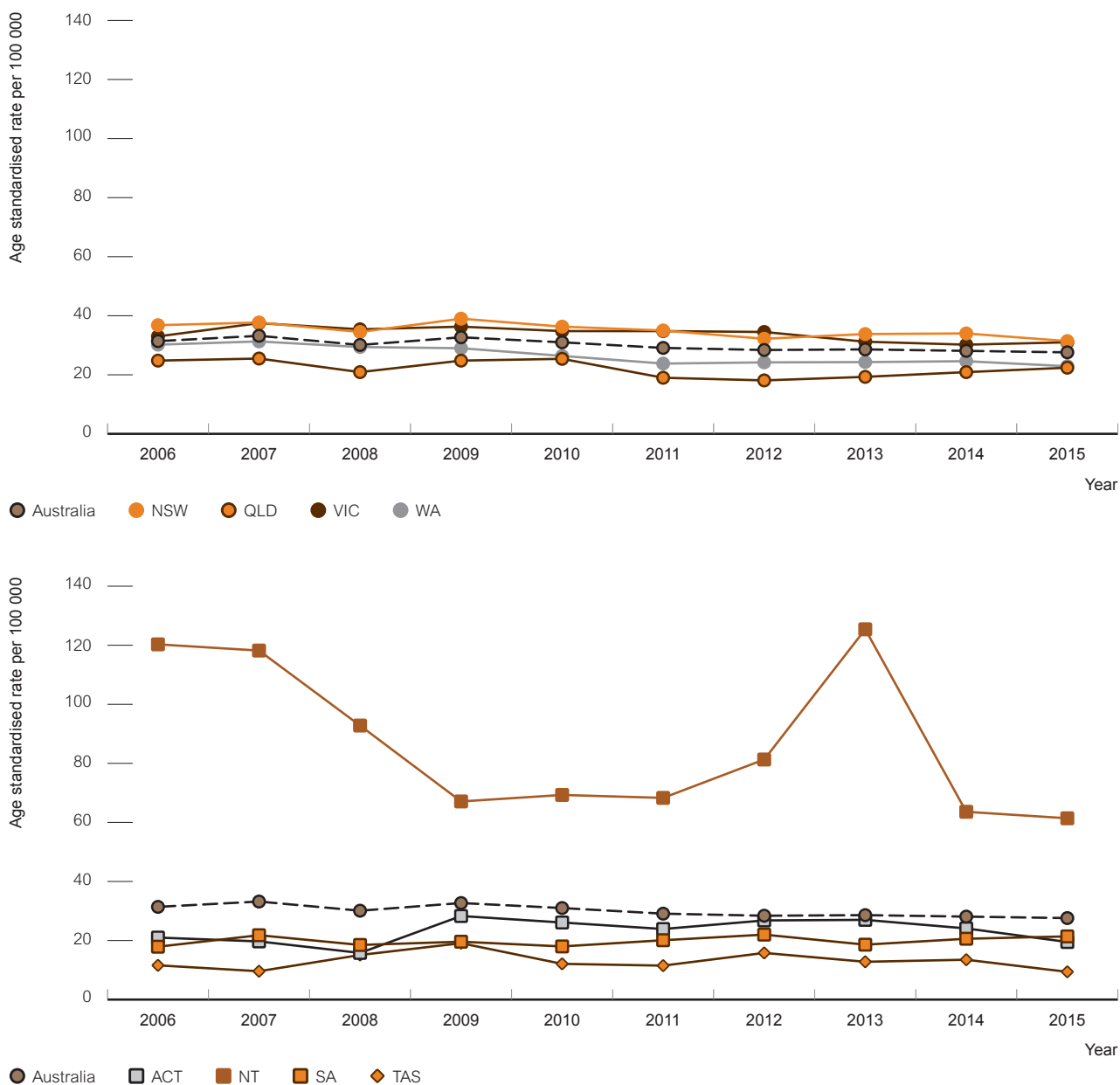
Figure 26 Hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group



Source: Australian National Notifiable Diseases Surveillance System

The notification rate of hepatitis B infection in Australia has consistently been highest in the Northern Territory, but has declined over the past ten years (from 120 per 100 000 in 2006 to 61 per 100 000 in 2015). In most other jurisdictions the rate of hepatitis B diagnosis has fluctuated over the last ten years, with a small decline observed in New South Wales (37 in 2006 to 31 in 2015) and Victoria in recent years (38 in 2007 to 31 in 2015) (Figure 27, Table 5).

Figure 27 Hepatitis B notification rate per 100 000 population, 2006 – 2015, by State/Territory



Source: Australian National Notifiable Diseases Surveillance System

Table 5 Age standardised rates of hepatitis B notification per 100 000 population, 2006 – 2015, by State/Territory

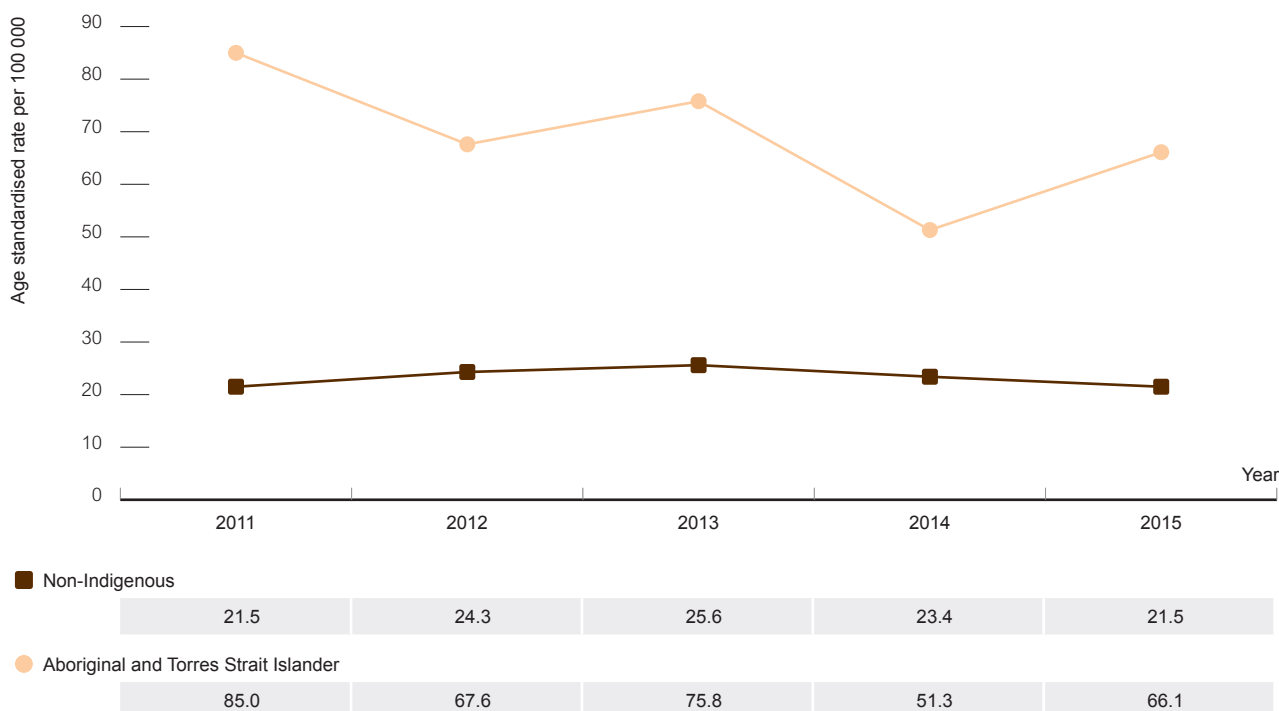
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
State/Territory										
Australian Capital Territory	21.0	19.7	15.8	28.3	26.1	23.9	26.8	27.0	24.1	19.5
New South Wales	36.8	37.7	34.5	39.0	36.3	35.0	32.2	33.8	34.0	31.4
Northern Territory	120.3	118.2	92.8	67.1	69.3	68.3	81.3	125.4	63.6	61.4
Queensland	24.8	25.5	20.9	24.8	25.4	19.0	18.1	19.3	20.9	22.4
South Australia	17.9	21.8	18.5	19.6	18.0	20.1	22.0	18.6	20.6	21.4
Tasmania	11.6	9.6	15.1	19.1	12.1	11.5	15.8	12.8	13.5	9.4
Victoria	33.0	37.5	35.4	36.3	34.8	34.8	34.5	31.2	30.2	31.0
Western Australia	30.2	31.3	29.4	29.0	26.4	23.8	24.2	24.3	24.6	22.9
Australia	31.4	33.2	30.1	32.7	31.0	29.1	28.4	28.6	28.1	27.6

Source: Australian National Notifiable Diseases Surveillance System

In 2015, the notification rate of newly diagnosed hepatitis B infection for the Aboriginal and Torres Strait Islander population was 3 times higher than the non-Indigenous population (66 per 100 000 compared to 22 per 100 000) (Figure 28). In the Aboriginal and Torres Strait Islander population the rate decreased from 85 per 100 000 in 2011 to 66 per 100 000 population in 2015 compared to the non-Indigenous population where it was stable at 22 per 100 000 in both 2011 and 2015. This likely reflects the Aboriginal and Torres Strait Islander population being eligible for childhood vaccination, whereas non-Indigenous notifications also include people born overseas where vaccination programs vary considerably. These data are from the Northern Territory, South Australia, Tasmania, Western Australia and the Australian Capital Territory where reporting of Indigenous status is $\geq 50\%$ complete in each of the past five years. It is important to note that incomplete Aboriginal and Torres Strait Islander status in other jurisdictions means that the data presented below may not be representative of national trends.



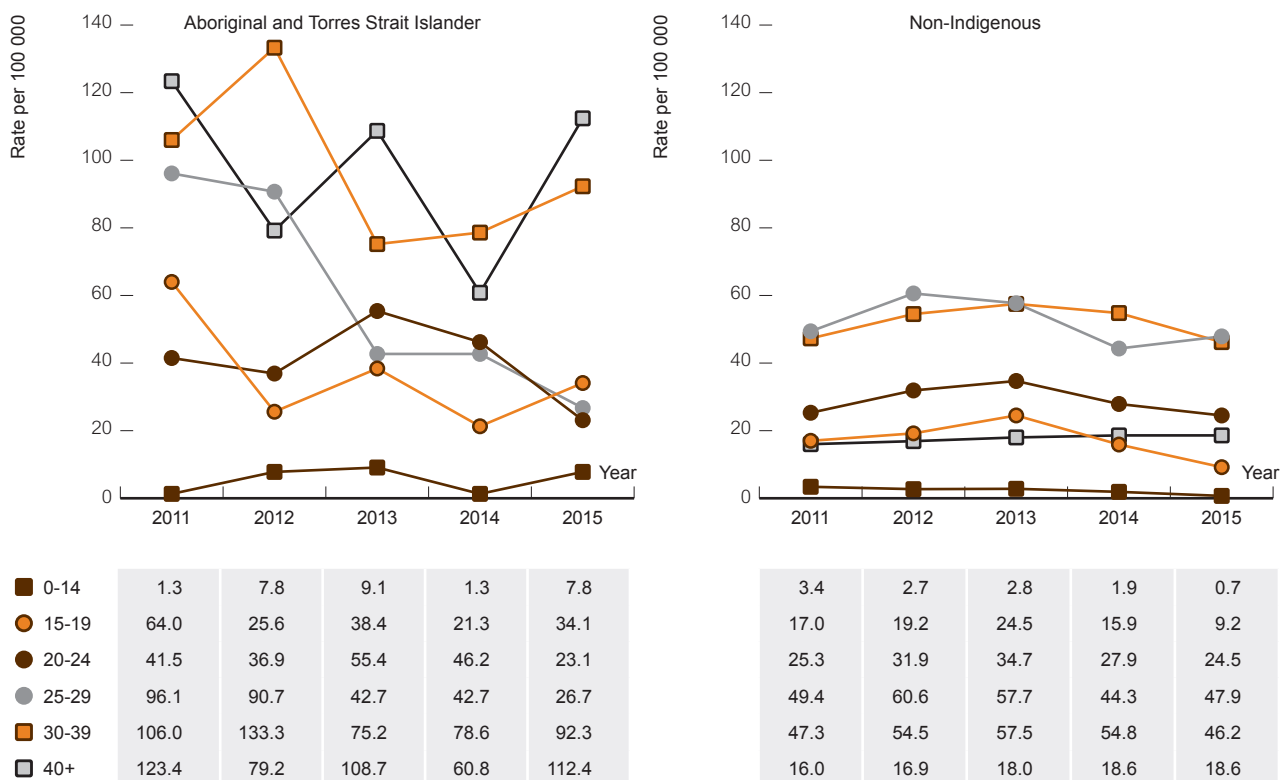
Figure 28 Hepatitis B notification rate per 100 000 population, 2011 – 2015, by Aboriginal and Torres Strait Islander status



Source: Australian National Notifiable Diseases Surveillance System. Includes jurisdictions (Australian Capital Territory, Northern Territory, South Australia, Tasmania, Western Australia) in which Aboriginal and Torres Strait Islander status was reported for more than 50% of diagnoses for each year.

Notification rates among the Aboriginal and Torres Strait Islander population have declined in the younger age groups over the last five years. Rates have fluctuated in the older age groups, but in general remained higher than the non-Indigenous population in the last five years (Figure 29). Rates were higher in all age groups in the Aboriginal and Torres Strait Islander population, compared to the non-Indigenous population (Figure 29), with differences greatest in the older age groups not covered by the infant and adolescent vaccination program.

Figure 29 Hepatitis B notification rate per 100 000 population, 2011 – 2015, by selected age group and Aboriginal and Torres Strait Islander status



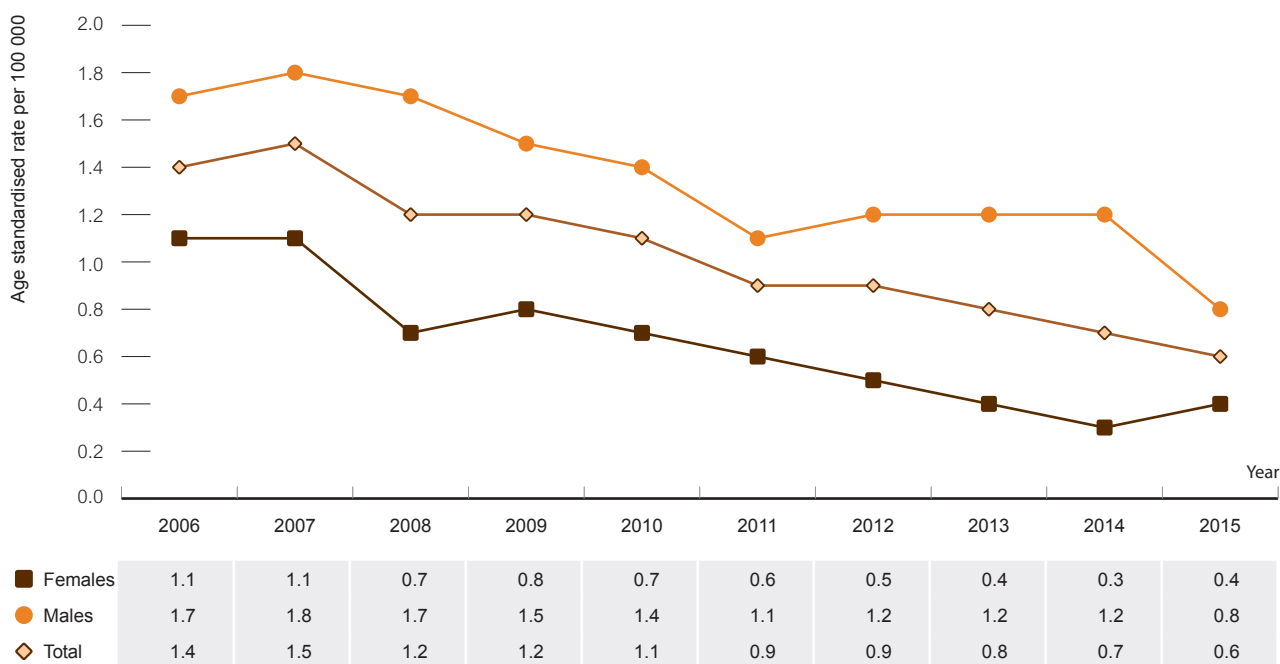
Source: Australian National Notifiable Diseases Surveillance System. Includes jurisdictions (Australian Capital Territory, Northern Territory, South Australia, Tasmania, Western Australia) in which Aboriginal and Torres Strait Islander status was reported for more than 50% of diagnoses for each year.

The higher rates of newly diagnosed hepatitis B in the Aboriginal and Torres Strait Islander population compared to the non-Indigenous population reflect the higher prevalence of chronic hepatitis B infection among Aboriginal and Torres Strait Islander peoples. This relates to historical vertical and early childhood transmission, particularly in the pre-vaccine era, with some additional infections through sex and blood contact in adolescence and adulthood. Aboriginal and Torres Strait Islander peoples also have higher rates of risk factors for adult hepatitis B acquisition, including receptive syringe sharing (see Figure 15) among people who inject drugs.

Newly acquired hepatitis B notifications

For some newly diagnosed hepatitis B cases, it is possible to determine that they were acquired in the two years prior to diagnosis, on the basis of a prior negative test or other serological factors. There has been a 58% decline in the rate of newly acquired hepatitis B cases (acquired in the past 2 years) over the past ten years, from 1.4 per 100 000 in 2006 to 0.6 per 100 000 in 2015. In 2015, the rate of newly acquired hepatitis B was two times greater in males than in females (0.8 vs 0.4 per 100,000) (Figure 30).

Figure 30 Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by sex

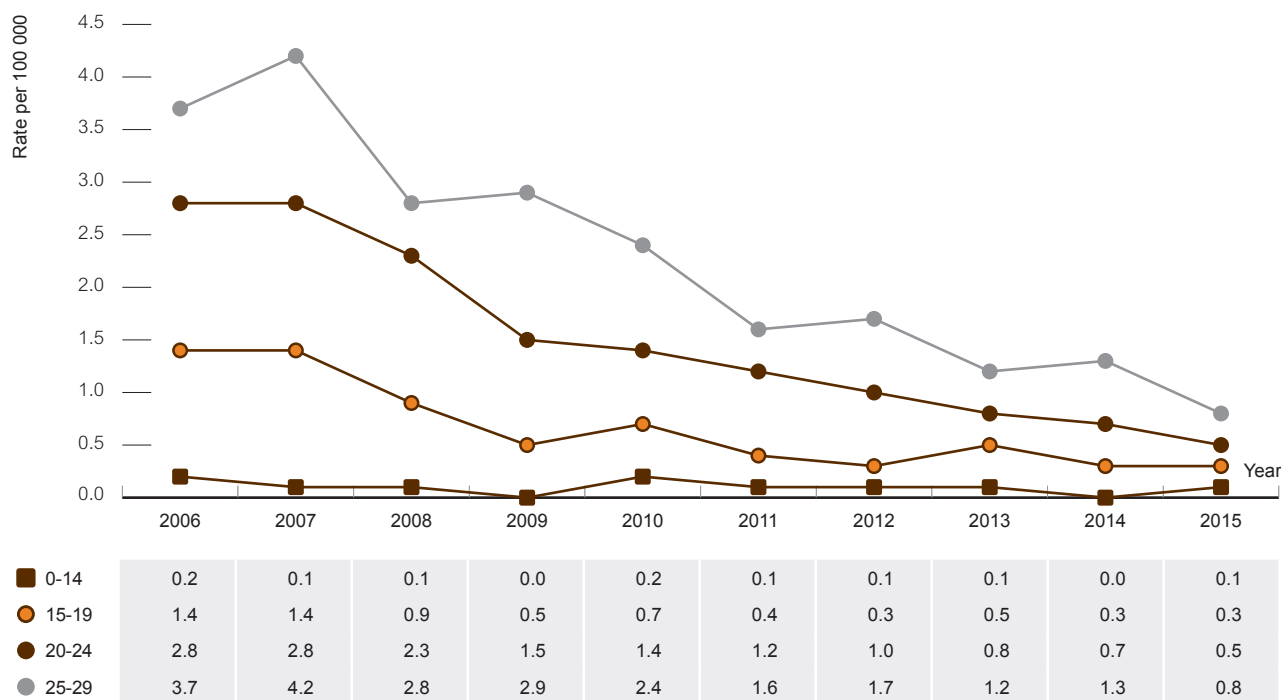


Source: Australian National Notifiable Diseases Surveillance System



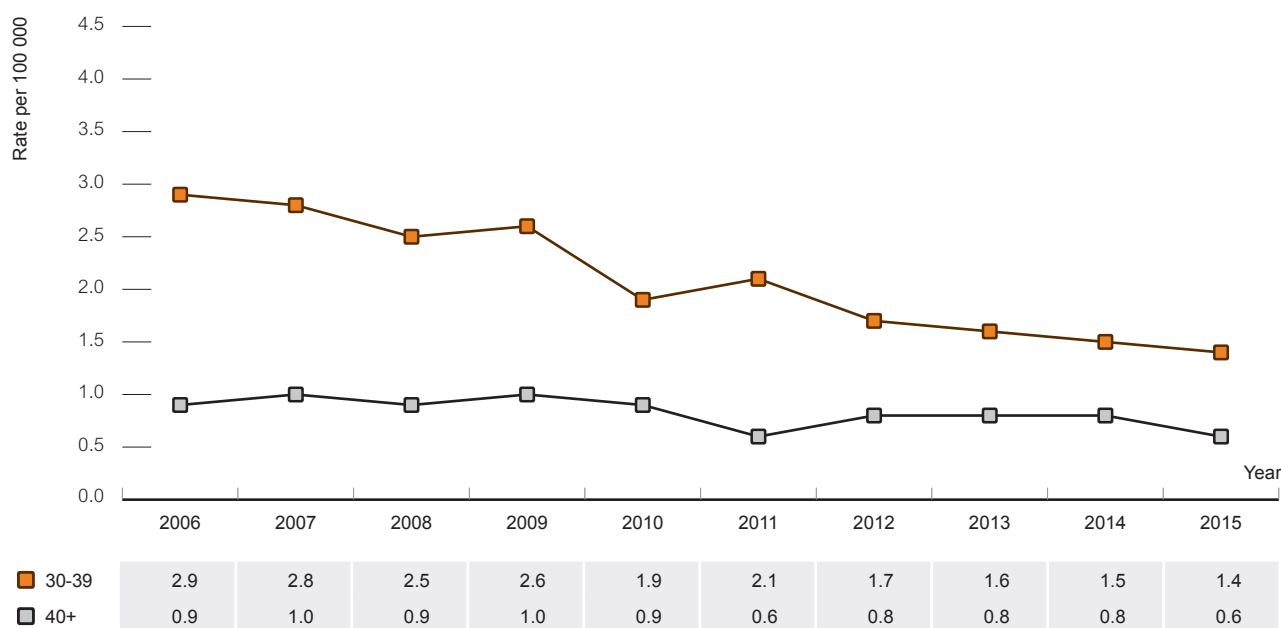
The rate of notification of newly acquired hepatitis B has declined in younger age groups aged 25 – 29 years (from 3.7 to 0.8 per 100 000), 20 – 24 years (from 2.8 to 0.5 per 100 000), and 15 – 19 years (from 1.4 to 0.3 per 100 000), with a smaller decline in those aged 30 – 39 years (2.9 per 100 000 in 2006 and 1.4 per 100 000 in 2015) (Figures 31 and 32). Notification rates have fluctuated and remained low in those aged 40+ years (Figure 32).

Figure 31 Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group



Source: Australian National Notifiable Diseases Surveillance System

Figure 32 Newly acquired hepatitis B notification rate per 100 000 population, 2006 – 2015, by year and selected age group



Source: Australian National Notifiable Diseases Surveillance System

Prevalence and morbidity

People living with hepatitis B infection

During 2015, an estimated 232 600 (190 738 – 283 781) people were living with chronic hepatitis B.

Australia has a concentrated hepatitis B epidemic among key populations; migrants from high prevalence countries, particularly from Asia and the Pacific (see Table 6) and Aboriginal and Torres Strait Islander peoples. Other priority populations include people who inject drugs, and men who have sex with men. At the end of 2015, there were an estimated 88 621 (38%) people with chronic hepatitis B born in the Asia-Pacific, 21 632 (9%) Aboriginal and Torres Strait Islander peoples, 13 258 (6%) people who inject drugs, 10 234 (4%) men who have sex with men and 10 002 (4%) born in Sub-Saharan Africa (Table 6).

People from the Asia-Pacific represent 10% of the Australian population and accounted for an estimated 38% of those living with chronic hepatitis B infection in 2015. People from Sub-Saharan Africa represent 1% of the Australian population but accounted for an estimated 4% of those living with chronic hepatitis B infection. Aboriginal and Torres Strait Islander peoples represent 3% of the Australian population but account for an estimated 9% of those living with chronic hepatitis B infection.

Table 6 Estimated number of people living with chronic hepatitis B, and estimated prevalence, Australia, 2015

Population	Proportion of total	Total chronic hepatitis B infection	Hepatitis B prevalence
Overall	100%	232 600 (190 738-283 781)	1.0%
Born in Asia-Pacific [^]	38.1%	88 621	3.6%
Aboriginal and Torres Strait Islander peoples	9.3%	21 632	3.9%
People who inject drugs	5.7%	13 258	4.0%
Men who have sex with men	4.4%	10 234	3.0%
Born in Sub-Saharan Africa	4.3%	10 002	3.5%

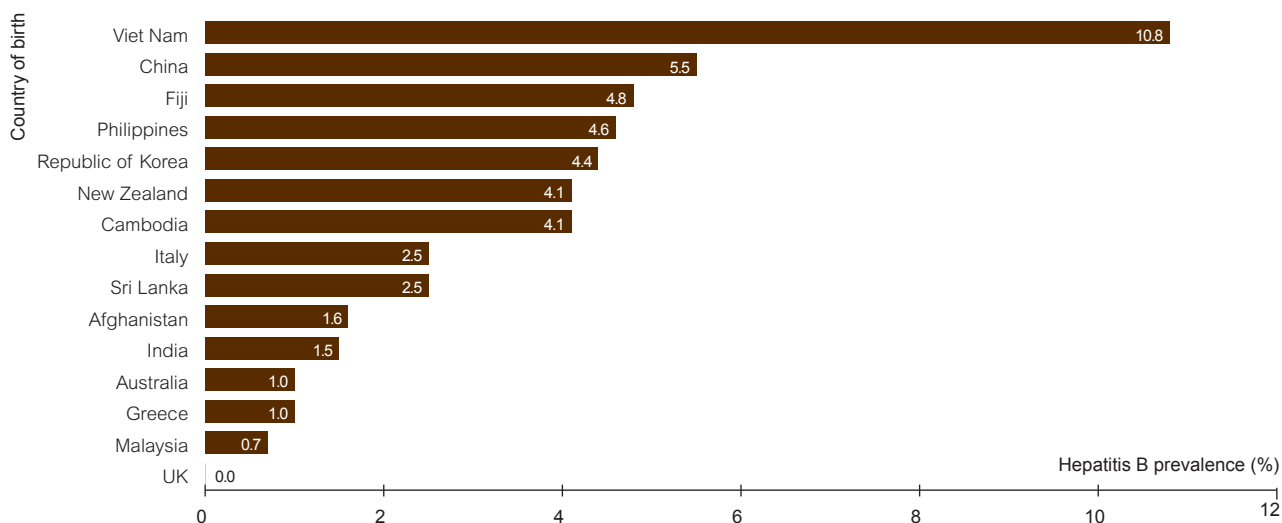
[^] South East Asia according to Census/International Classifications does not include China, which excludes the largest population group for overseas born PLWCHB. Asia Pacific grouping has been used instead.



Hepatitis B prevalence

The estimated prevalence of chronic hepatitis B infection among people born in Australia is 1.0%, which is higher than people born in the United Kingdom and living in Australia (0.0%) but lower than in many other countries in Asia and the Pacific (Figure 33).

Figure 33 Estimated prevalence of chronic hepatitis B infection in Australia, 2015, by country of birth



Source: WHO Collaborating Centre for Viral Hepatitis, Victorian Infectious Diseases Reference Laboratory, Doherty Institute

Hepatitis B morbidity

There is no comprehensive registry of advanced illness related to hepatitis B in Australia. One indicator of the extent of illness caused by hepatitis B is the number of liver transplants due to chronic infection. Of the 219 people who had a liver transplant in 2015, 17 (8%) had hepatitis B infection.

There were an estimated 419 (363 – 683) deaths from hepatitis B in 2015, compared to 395 (304 – 640) in 2014.

Hepatitis B testing and care

Hepatitis B diagnosis and care cascade

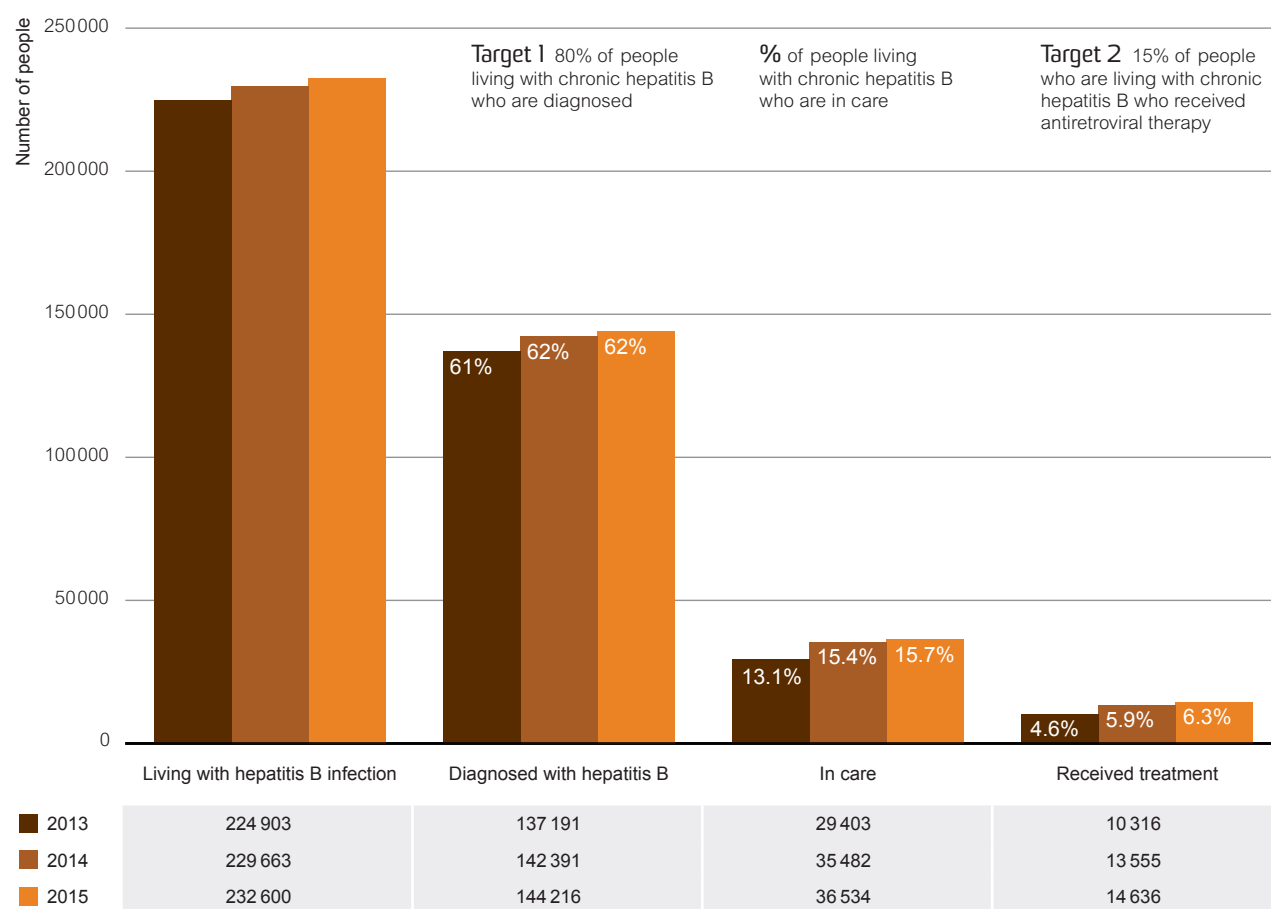
This section includes the ‘Hepatitis B diagnosis and care cascade’, which estimates the number of people with chronic hepatitis B infection, the number and proportion diagnosed in Australia, and the number receiving care or antiviral treatment.

These estimates are produced by the WHO Collaborating Centre for Viral Hepatitis and VIDRL and the Doherty Institute and are intended to support improvements in the delivery of services to people with hepatitis B infection. Using available data, the proportions of people in each stage of the cascade in Australia were estimated (Figure 34). The approach was informed by recommendations from a national stakeholder reference group (see Methodological Notes for further detail).

During 2015, an estimated 232 600 (190 738 to 283 781) people were living with chronic hepatitis B, an estimated 144 216 had been diagnosed with hepatitis B, 36 534 were in care (monitored or received antiviral therapy) and 14 636 were receiving antiviral therapy. This equates to an estimate of 62% of all people with hepatitis B being diagnosed, 16% of those diagnosed were in care and 6.3% of people diagnosed received antiviral therapy (Figure 34). The Australian Second National Hepatitis B Strategy 2014 – 2017 has a diagnosis target of 80%.¹³ and a treatment target of 15% for people living with chronic hepatitis B.¹³

This compares to 2014, when there was an estimated 229 663 (188 324 to 280 189) people living with chronic hepatitis B, with an estimated 142 391 (62%) diagnosed, 35 482 (15.4%) in care, and 13 555 (5.9%) were receiving antiviral therapy.

Figure 34 The hepatitis B diagnosis and care cascade, 2013 – 2015



Source: WHO Collaborating Centre for Viral Hepatitis, Victorian Infectious Diseases Reference Laboratory, Doherty Institute



Hepatitis B testing

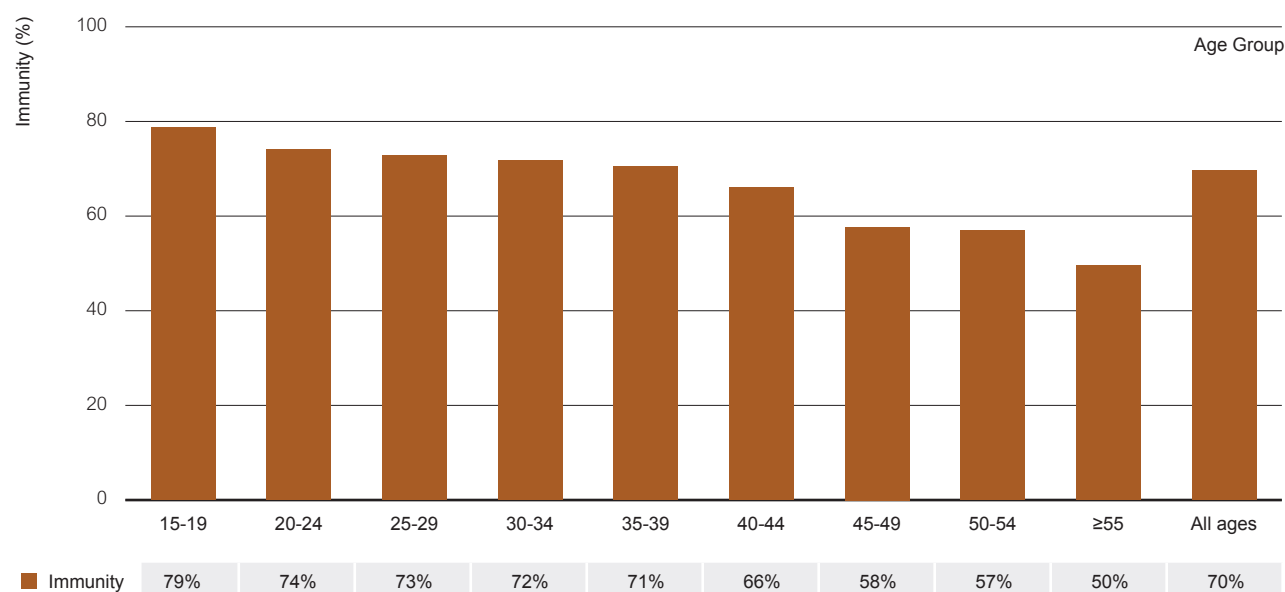
An important strategy for the prevention of hepatitis B related morbidity is targeted testing of people at risk. Guidelines recommend hepatitis B testing of people from culturally and linguistically diverse communities that include people from the Asia-Pacific region and Sub Saharan Africa and Aboriginal and Torres Strait Islander peoples. Other identified populations include children born to mothers with chronic hepatitis B infection, and the following unvaccinated people at higher risk of infections:

- men who have sex with men
- sex workers
- people who inject drugs
- partners and other household and intimate contacts of people who have acute or chronic hepatitis B infection
- people in custodial settings
- people with HIV or hepatitis C or both

At sexual health clinics in Australia, all patients should be asked about past hepatitis B vaccination at their first visit. If no prior vaccination is reported or the patient's vaccination status is uncertain, in line with national guidelines the patients at risk should be offered testing for hepatitis B infection and immunity and if susceptible, to offer vaccination.

In 2015, there were 17 749 people attending sexual health clinics in the ACCESS network for whom vaccination documentation or pathology details were available, with 70% of these people having documented evidence of immunity to hepatitis B. The proportion was highest among those aged 15 – 19 years (79%), decreasing by age, to 50% among those aged 55 years or more (Figure 35).

Figure 35 Proportion of people attending sexual health clinics with immunity to hepatitis B¹, based on vaccination documentation and serology, 2015, by age group²



¹ Vaccinated or immunity from past exposure

² Data from 41 sexual health clinics across Australia

Source: The Australian Collaboration for Coordinated Enhanced Sentinel Surveillance of Sexually Transmissible Infections and Blood Borne Viruses (ACCESS Project)

Further details about the classification scheme used are detailed in the Methodological Notes. It is also important to note that a negative anti-HBs result, as defined by a titre of <10 mIU/mL, does not necessarily indicate the absence of vaccination, as titres decline to below this level in up to 50% of people receiving a full course of vaccination after less than a decade. Protection appears to be durable following vaccination in healthy individuals who achieved an initial response to vaccine. Therefore, a proportion of the study sample defined serologically as “susceptible” will still be immune through vaccination.

The data presented in Figure 35 demonstrate that although a highly effective vaccine is now available and has been offered universally for newborns since 2000, many of those born before universal vaccination remain susceptible or are from countries with different or no vaccination programs, and are at risk of infection, including young adults not reached by adolescent catch-up programs.

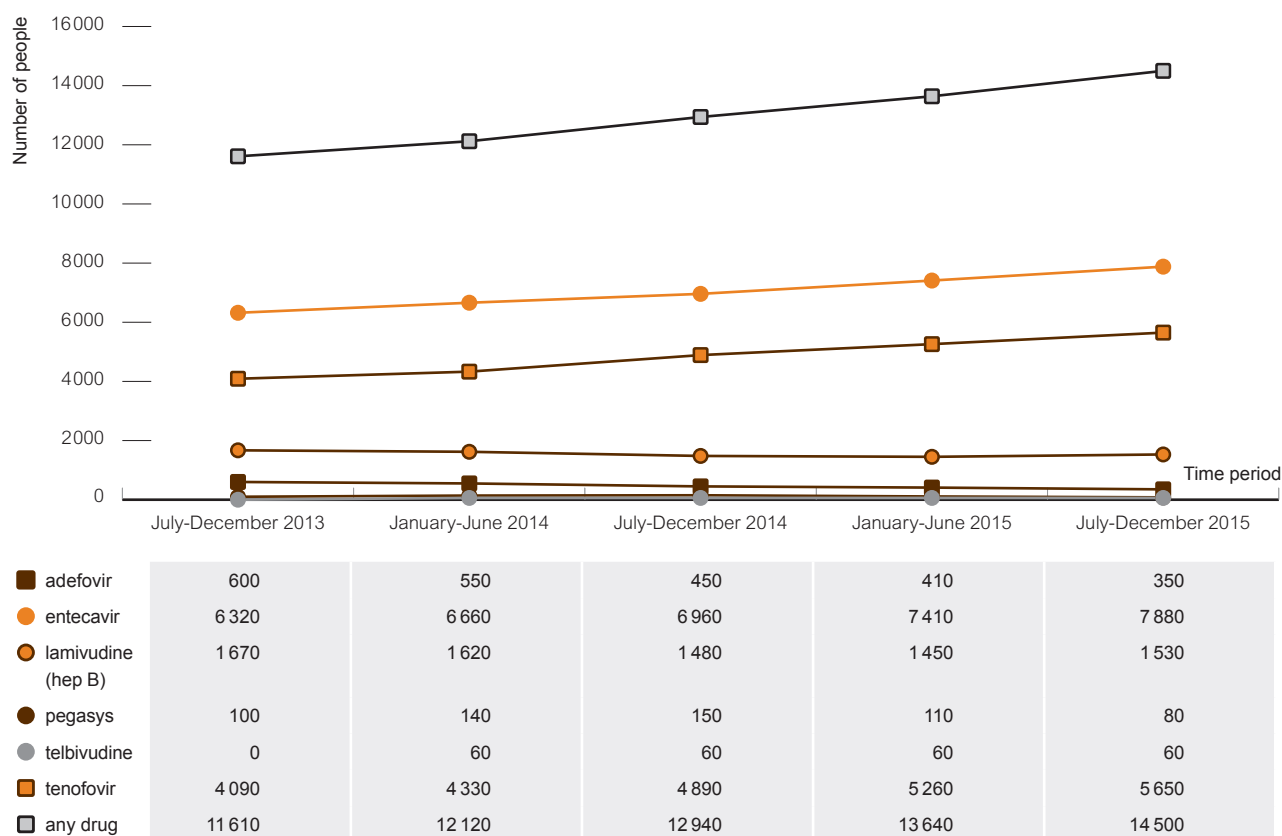
Hepatitis B treatment

Treatment for hepatitis B virus infection can prevent morbidity and mortality associated with infection but treatment is not a cure. In general, people who are chronically infected but do not have any signs of significant viral replication or active liver damage do not need treatment. However, it is important to closely monitor liver health with regular (at least 12 monthly) liver function tests and quantitative viral DNA tests. Treatment for hepatitis B is considered in people with elevated hepatitis B viral load, abnormal liver function tests, or those who have advanced liver disease (cirrhosis).

The number of people receiving antiviral treatment for hepatitis B has been rising in recent years. Between July 2013 and December 2015 there has been a 25% increase in the number of people on treatment, from 11 610 to 14 500. However the population of people living with chronic hepatitis B has also grown in recent years due to migration (see Figure 34).

Of people receiving hepatitis B antiviral treatments in 2015, 54% were receiving entecavir treatment, and 37% were receiving tenofovir treatment (Figure 36). These treatment data are sourced from the Pharmaceutical Benefits Scheme which does not record Aboriginal and Torres Strait Islander status. Through data linkage projects, information on hepatitis B treatment coverage, and morbidity, will be available in future years.

Figure 36 Estimated number of people dispensed treatment for hepatitis B infection, by treatment type, 2013 – 2015



Note: Excludes tenofovir dispensations for HIV co-infected patients
Source: PharmDash



Hepatitis B prevention

Primary prevention strategies to protect people from acquiring hepatitis B infection include: vaccination, use of sterile needles and syringes and ancillary equipment among people who inject drugs, condom use, universal precautions in health care settings and screening of blood donors.¹⁴ Secondary prevention strategies to reduce the risk of progression to hepatocellular carcinoma include improving access to diagnosis, monitoring, and antiviral treatment for those with evidence of active liver disease. Treatment for hepatitis B is used to control viral replication and resulting liver damage, which profoundly reduces progression to advanced liver disease and liver cancer.

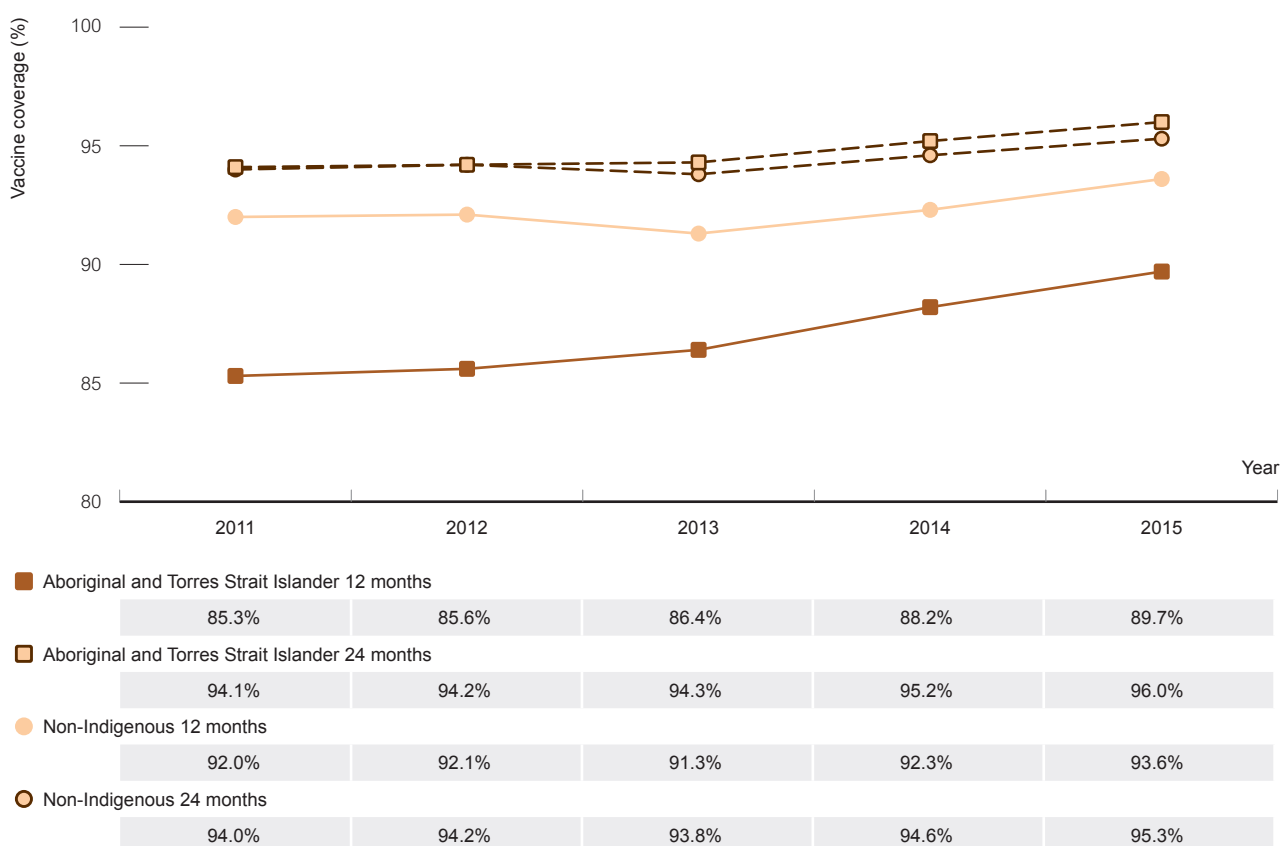
Hepatitis B vaccination

Understanding patterns of hepatitis B infection in Australia is facilitated by knowledge of the history of hepatitis B immunisation program which is described briefly below.

In the Northern Territory (NT) in 1985, hepatitis B screening was introduced for all pregnant women and vaccination to infants born to mothers living with chronic infection; in 1990, universal infant vaccination was implemented, and in 1998 a catch-up program targeting 6 – 16 year olds was introduced. In other States and Territories of Australia, hepatitis B vaccination of all infants commenced in 2000 and the introduction of a universal adolescent (teenagers aged 12 – 15 years) school based hepatitis B vaccination catch-up program commenced in 1998.

Over the period 2011 – 2015, hepatitis B vaccination coverage rates for children were high overall, at around 95%. For Aboriginal and Torres Strait Islander children coverage was lower than for non-Indigenous children for the 12 months age group, but there was no difference at 24 months of age, with vaccination coverage of 96% in Aboriginal and Torres Strait Islander children and 95% in non-Indigenous children (Figure 37). The lower rates at 12 months suggest issues around timeliness of completion of the vaccination course in Aboriginal and Torres Strait Islander children, which may lead to increased risk of disease acquisition.

Figure 37 Hepatitis B vaccination coverage estimates at 12 and 24 months, 2011 – 2015, by Aboriginal and Torres Strait Islander status



Source: National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases



Methodological Notes

Australian National Notifiable Diseases Surveillance System

The National Notifiable Diseases Surveillance System (NNDSS) (<http://www.health.gov.au/internet/main/publishing.nsf/content/cda-surveil-ndss-ndssintro.htm>) was established in 1990 under the auspices of the Communicable Diseases Network Australia. NNDSS co-ordinates the national surveillance of more than 50 communicable diseases or disease groups. Under this scheme, notifications are made to the States or Territory health authority under the provisions of the public health legislation in their jurisdiction. Computerised, de-identified unit records of notifications are supplied to the Australian Government Department of Health on a daily basis, for collation, analysis and publication on the Internet, (updated daily), and in the quarterly journal Communicable Diseases Intelligence.

Notification data provided include a unique record reference number, state or territory identifier, disease code, date of onset, date of notification to the relevant health authority, sex, age, Aboriginal and Torres Strait Islander status and postcode of residence.

Viral hepatitis

New diagnoses of hepatitis B and C were notifiable conditions in all State/Territory health jurisdictions in Australia. Cases were notified by the diagnosing laboratory, medical practitioner, hospital or a combination of these sources, through State/Territory health authorities, to the National Notifiable Diseases Surveillance System (NNDSS). Population rates of diagnosis of viral hepatitis were calculated for each State/Territory using yearly population estimates, provided by the Australian Bureau of Statistics.

Hepatitis B infection and hepatitis C infection was classified as newly acquired if evidence was available of acquisition in the 24 months prior to diagnosis (Communicable Diseases Network Australia 2004). Diagnoses of newly acquired hepatitis B infection was notifiable in all health jurisdictions. Diagnoses of newly acquired hepatitis C infection were recorded in all health jurisdictions other than Queensland.

The hepatitis C diagnosis and care cascade

This cascade was developed collaboratively between the Kirby Institute and the Center for Disease Analysis: <http://www.centerforda.com/>. The approach taken to develop the 'Hepatitis C diagnosis and care cascade' was informed by recommendations from a national stakeholder reference group. This included representatives from: The Kirby Institute; ASHM; Hepatitis Australia, NSW Ministry of Health; Queensland Department of Health; Department of Health and Human Services, Tasmanian Government; Department of Health and Human Services Victoria; Australian Department of Health, South Australia Health; WHO Regional Reference Laboratory for Hepatitis B, Victorian Infectious Diseases Reference Laboratory, The Doherty Institute; Centre for Social Research in Health; Australian Injecting and Illicit Drug Users League; Burnet Institute; Australasian Sexual Health Alliance; Australian Liver Association; The National Aboriginal Community Controlled Health Organisation; Scarlet Alliance.

Number of people living with hepatitis C

This estimate was derived using a difference equation mathematical model, as described below:

- To determine hepatitis C incidence as a result of injecting drug use, the model used estimates of the number of people who had injected drugs in Australia over the last three decades, the pattern of injecting drug use and estimates of hepatitis C incidence among people who inject drugs derived from cohort studies.
- The relative change in incidence since 2005 was informed by hepatitis C notifications in 15 – 29 year olds reflecting the population most at-risk of acquiring infection. As the primary route of transmission is injecting drug use, a practice that primarily starts in late adolescence or early adulthood, trends in the rate of diagnoses in those aged under 25 years can be interpreted as surrogate for the incidence of hepatitis C infection.
- The estimates of hepatitis C incidence due to injecting drug use were then adjusted in accordance with epidemiological data to allow for hepatitis C infections through other transmission routes, including infection in migrants.
- The model also includes the effects of treatment with associated sustained virological response (SVR) rates reflecting treatment regimen, genotype, and access to direct-acting antivirals (DAA) through compassionate access and clinical trials in 2014 – 15, and generic supply in 2015.
- Estimates of the number of people experiencing long-term sequelae of chronic hepatitis C infection were then obtained from the estimated pattern of hepatitis C incidence using rates of progression derived from cohort studies.
- Estimates of the numbers of people living with chronic hepatitis C infection in 2015 were adjusted to allow for mortality related to hepatitis C infection, injecting drug use and unrelated to hepatitis C infection or injecting.

Further information about the methods can be obtained by contacting the Center for Disease Analysis <http://www.centerforda.com/>.

Number of people diagnosed and living with chronic hepatitis C infection

This estimate was derived from totalling all hepatitis C notifications from 1991 to 2015 and adjusting for spontaneous hepatitis C clearance, mortality, hepatitis C cure through treatment, and overseas migration, with adjustments as follows.

- The proportion with spontaneous hepatitis C clearance was estimated at 25%.
- The annual proportion with mortality among people with a hepatitis C notification in NSW (1993 – 2015) was extrapolated to the total number of hepatitis C notifications in Australia.
- The estimated number of individuals with cure of hepatitis was deducted from the number of total hepatitis C notifications.
- The level of overseas migration was assumed to be small, given the characteristics of the infected population, and given by the annual number of permanent departures for the general population divided by the estimated resident population as estimated by the Australian Bureau of Statistics (series 340102).

Number of people who have ever received HCV treatment

To estimate the numbers of people treated for hepatitis C we totalled the number prescriptions dispensed to public patients, reported by the Pharmaceutical Benefits Scheme (PBS), since 1997.

- For estimates in 2013 – 2015, data from longitudinal tracking of a 10% random sample of PBS prescriptions were used.
- For the 2014 and 2015, we included estimates for the number of patients receiving DAA therapies through clinical trials, patient access programs and generic drugs.
- The numbers of interferon based hepatitis C treatments dispensed were adjusted for multiple counting considering the duration of treatment for each regimen, and treatment compliance rate.
- For genotype-specific regimens, a distribution of 50% genotype 1 and 50% genotypes 2/3 was assumed.
- The total number treated was adjusted for annual mortality and overseas migration (using the same overseas migration rate as for the diagnosed stage).
- The general population mortality rate was used for those who were successfully cured. The hepatitis C mortality rate from people with a hepatitis C notification in New South Wales was used for patients who did not achieve SVR.

Number of people who have ever achieved treatment-induced hepatitis C cure

This component was estimated by taking the number of people receiving hepatitis C treatment in each year and multiplying it by the proportion with SVR reported in the literature (regimen-specific). We assumed the following:

- Australian data on the proportion with SVR were prioritized, if available. A distribution of 50% genotype 1 and 50% genotypes 2/3 among people receiving hepatitis C treatment was assumed for interferon based therapies.
- A 95% SVR rate was used for DAA therapies.
- The total number cured was adjusted for annual mortality and overseas migration as for the diagnosed and treated stages.

The hepatitis B diagnosis and care cascade

Cascade estimates were developed by the WHO Collaborating Centre for Viral Hepatitis, Victorian Infectious Diseases Reference Laboratory at the Doherty Institute. The approach taken to develop the 'Hepatitis C diagnosis and care cascade' was informed by recommendations from a national stakeholder reference group. This included representatives from: The Kirby Institute; ASHM; Hepatitis Australia, NSW Ministry of Health; Queensland Department of Health; Department of Health and Human Services, Tasmanian Government; Department of Health and Human Services Victoria; WA Health; Australian Department of Health, South Australia Health; WHO Regional Reference Laboratory for Hepatitis B, Victorian Infectious Diseases Reference Laboratory, The Doherty Institute; Centre for Social Research in Health; Australian Injecting and Illicit Drug Users League; Burnet Institute; Australasian Sexual Health Alliance; Australian Liver Association; Scarlet Alliance.

Diagnosis

The proportion of people living with chronic hepatitis B who have been diagnosed was estimated using model-derived estimates of the total number of people who have ever had chronic hepatitis B in Australia as the denominator and the cumulative number of notifications of hepatitis B from 1971- 2015 as the numerator. Mortality is not included in this aspect of the analysis, and therefore the proportion derived represents those ever having lived with chronic hepatitis B that have ever been diagnosed.

Monitoring

The number of people who received monitoring for chronic hepatitis B in 2015 was determined using Department of Human Services data regarding rebate for an annual hepatitis B viral load test, which is recommended for all people living with chronic hepatitis B. This item is specific to people living with chronic hepatitis B who are not receiving treatment, and is limited to one test per year.

Treatment

The number of people receiving treatment for chronic hepatitis B in 2015 was derived using pharmaceutical dispensing data from the Department of Human Services Australia regarding the number of individuals receiving a treatment indicated for hepatitis B virus infection (adefovir, entecavir, lamivudine, telbivudine, tenofovir, and pegylated interferon). Patient-level estimates were provided, allowing removal of those receiving tenofovir for the treatment of HIV and to avoid duplication of people receiving combination therapy.

Detailed methodology and source references can be found in the published paper which described the derivation of these estimates¹⁵ and in the 2nd National Report of the Hepatitis B Mapping Project (www.ashm.org.au/HBV/more-about/hepatitis-b-mapping-project).

A combined estimate of people in care for chronic hepatitis B was derived by combining the number who received monitoring while not on treatment and those on treatment. Each of these estimates are expressed as a proportion of the total number living with chronic hepatitis B as derived using the prevalence methodology outlined above.

Number of people living with hepatitis B

Estimates of the number of people living with hepatitis B virus infection in Australia were developed by the WHO Collaborating Centre for Viral Hepatitis, Victorian Infectious Diseases Reference Laboratory at the Doherty Institute. These estimates were derived from two sources:

The overall prevalence of chronic hepatitis B was determined using a deterministic compartmental mathematical model of hepatitis B virus infection in the Australian population from 1951 – 2050. The model was parameterised using a wide range of data sources including the Australian Bureau of Statistics, existing mathematical models, surveillance notifications, epidemiological research and clinical studies. Important factors such as migration, attributable and all-cause mortality, the ageing of the population, the variable natural history of chronic hepatitis B infection and the impact of vaccination were all incorporated. Model construction included sensitivity analyses around critical parameters such as the force of infection (Fol) and migration estimates. Model outcomes have been validated using a range of external data, particularly national and Victorian serosurvey results. These were not used to parameterise the model to allow independent comparison with modelled outcomes. The plausible range around estimates of hepatitis B prevalence was generated using the range of uncertainty inherent in original prevalence estimates applied in the Census-based methodology described above, with the range in estimated attributable deaths derived by adopting low and high mortality estimates directly in the model.

The proportion of people living with chronic hepatitis B in each population group and the relative prevalence in each was determined using the Census method, attributing prevalence of chronic hepatitis B by country of birth, Aboriginal and Torres Strait Islander status, and other risk status applied to population data provided in the 2011 Australian Census. The estimated prevalence in these groups was derived as a proportion of the total Census population as estimated in 2011, and then applied of the estimated number of people living with chronic hepatitis B in 2015 derived using the mathematical model as outlined above. Detailed methodology and sources, including individual seroprevalence estimates and population figures, can be obtained from the published paper¹⁶.

HBV prevalence

The estimated prevalence of chronic hepatitis B according to country of birth was derived from combining multiple published sources into an average point estimate. The estimates used comprised two Australian antenatal seroprevalence studies^{17, 18}; a study of hepatitis B prevalence in migrants to the United States¹⁹; and the most recent global seroprevalence study conducted as on behalf of the World Health Organisation²⁰. The Australian prevalence figure was obtained from local modeled estimates¹⁶.

The Australian Needle and Syringe Program Survey

Briefly, the Australian Needle and Syringe Program Survey is conducted annually over a 1-2 week in October at more than 50 needle and syringe programs (NSP) to provide serial point prevalence estimates of HIV and hepatitis C and to monitor injecting behaviour among people who inject drugs (PWID). All clients attending needle and syringe program (NSP) sites during one week in 2009 (51 sites), 2010 (53 sites), 2011 (53 sites), 2012 (52 sites) and 2013 (50 sites) were asked to complete a brief, self-administered questionnaire and to provide a finger prick blood spot sample for HIV and hepatitis C antibody testing. The Australian Needle and Syringe Program Survey methodology has been described in detail elsewhere²¹.

The Australian and New Zealand Liver Transplant Registry (ANZLTR)

ANZLTR is a network of liver transplant centres in Australia and New Zealand which has collected information on the characteristics of people undergoing liver transplantation. People undergoing liver transplantation have been routinely tested for hepatitis B infection and for hepatitis C infection since antibody testing became available in 1990. Information was sought on the primary and secondary causes of liver disease including the results of tests for hepatitis B virus and hepatitis C virus. The information was forwarded to the Liver Transplant Registry located at Princess Alexandra Hospital in Brisbane. The number of liver transplants by primary cause of liver disease and hepatitis status where the primary diagnosis was hepatocellular carcinoma was obtained from the ANZLTR.

PharmDash

Data on dispensed prescriptions for a Pharmaceutical Benefits Scheme (PBS) 10% sample is updated every quarter and supplied to a number of approved users or clients including Prospecion which provides a dashboard interface (PharmDash) for querying the PBS 10% sample (see <http://www.pbs.gov.au/info/industry/useful-resources/sources/>). The 10% sample of the PBS is a randomised patient level, de-identified PBS script claims data set from 2006-present. Currently the data set has 170 million script claims and 3 million patients. It includes all PBS listed drugs with HIV, hepatitis B and hepatitis C indications.

Direct acting antiviral treatment data

Two data sources were used for analysing direct acting antiviral treatment uptake during March to May 2016: PBS monthly reports of prescriptions processed for reimbursement; and wholesale expenditure data.

PBS reports the number of prescriptions processed for reimbursement on a monthly basis. Pharmacies submit prescriptions for reimbursement 2 – 12 weeks (generally 2-4 weeks) after dispensing. Therefore, PBS reports of the number of prescriptions are subject to a time lag between drug dispensing and reimbursement submissions. This lag may also vary by pharmacy type, with potentially longer lags for public hospital-based pharmacies (S100 scheme) compared to community-based pharmacies (S85 scheme).

The wholesale price expenditure on chronic HCV direct acting antiviral treatment drugs during March to May has been estimated at 1.33 times wholesale price equivalent for PBS reimbursements reported for the same period. For the estimate of the number of individuals initiated on HCV treatment during March to May 2016, we have used 1.30 as the adjustment factor with a range of 1.10-1.50 given inherent uncertainties within this methodology. In the jurisdiction level, the proportion of cumulative PBS prescription number from March to July in each jurisdiction to the total was applied to the total estimated number of individuals initiating HCV treatment. Cumulative PBS prescription number (instead of July number) was used given that the July reported number was lower than the previous months in some jurisdictions. This difference was substantial, particularly for Victoria and Northern Territory where the July numbers were 36% and 77% less than June numbers, respectively. Therefore, the estimated number for these two jurisdictions should be considered conservatively until the accuracy of reported PBS data is confirmed.

PBS provided aggregated monthly data, rather than individual patient data. Then three assumptions have been made in reporting of the PBS reimbursement data, and in extrapolation:

1. All individuals who initiated a 12-week or a 24-week DAA treatment course in March have continued treatment in July.
2. All individuals who initiated any DAA treatment in April (8-week, 12-week or 24-week) have continued treatment in July.
3. The time lag is similar for individuals initiated in March, April, May, June and July.

Therefore, the aggregated numbers reported for the month of July for each regimen, duration, and scheme will represent all individuals initiated in March, April, May, June, and July, except for March and April initiations on an 8-week or 12-week treatment course and May initiations on an 8-week treatment course given that these treatment courses have been completed before July. Then the numbers of 8-week treatment courses initiated in March, April, and May as well as 12-week treatment courses initiated in March and April were added to the total number reported in July.

It is also assumed that 5% of patients who were initially authorised for 12 weeks treatment with sofosbuvir/ledipasvir, stopped treatment after 8 weeks due to the clinician's decision after re-evaluating the patient's situation. Then a 5% drop-out was added to the number of individuals initiated on a 12-week sofosbuvir/ledipasvir course.

Treatment courses in the prescriptions are by week while PBS reports are monthly. Then a 4-week prescription (28 days) is reported in monthly PBS reports (30 days). For the time period of five months (March to July), it causes a discrepancy between 140 days prescription versus 150 days PBS reports. Then the PBS reported prescription number was adjusted by adding 7% as a conversion of 28 days prescription to 30 days of a month.

References

1. Introduction to the National Notifiable Diseases Surveillance System 2015 [cited 2016 31 August]. Available from: <http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-surveil-nndss-nndssintro.htm>.
2. Iversen J, Maher L. Australian NSP Survey National Data Report 1995 – 2014, Prevalence of HIV, HCV and injecting and sexual behaviour among NSP attendees. Sydney: Kirby Institute, University of New South Wales, 2015.
3. Mohd Hanafiah K, Groeger J, Flaxman AD, Wiersma ST. Global Epidemiology of Hepatitis C Virus Infection; New Estimates of Age-Specific Antibody to HCV and Seroprevalence. *Hepatology*. 2013; 57:1333–1342
4. Turner KM, Hutchinson S, Vickerman P, Hope V, Craine N, Palmateer N, et al. The impact of needle and syringe provision and opiate substitution therapy on the incidence of hepatitis C virus in injecting drug users: pooling of UK evidence. *Addiction*. 2011;106(11):1978-88.
5. World Health Organization. Guidance on prevention of viral hepatitis B and C among people who inject drugs. Geneva, Switzerland: WHO, 2012.
6. White B, Dore GJ, Lloyd AR, Rawlinson WD, Maher L. Opioid substitution therapy protects against hepatitis C virus acquisition in people who inject drugs: the HITS-c study. *The Medical journal of Australia*. 2014;201(6):326-9.
7. Nolan S, Dias Lima V, Fairbairn N, Kerr T, Montaner J, Grebely J, et al. The impact of methadone maintenance therapy on hepatitis C incidence among illicit drug users. *Addiction*. 2014;109(12):2053-9.
8. Tsui JI, Evans JL, Lum PJ, Hahn JA, Page K. Association of opioid agonist therapy with lower incidence of hepatitis C virus infection in young adult injection drug users. *JAMA internal medicine*. 2014;174(12):1974-81.
9. Martin NK, Vickerman P, Grebely J, Hellard M, Hutchinson SJ, Lima VD, et al. Hepatitis C virus treatment for prevention among people who inject drugs: Modeling treatment scale-up in the age of direct-acting antivirals. *Hepatology*. 2013;58(5):1598-609.
10. Australian Bureau of Statistics. 4517.0 - Prisoners in Australia, 2015 2015 [cited 2016 31 August]. Available from: <http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4517.0~2015~Main%20Features~Aboriginal%20and%20Torres%20Strait%20Islander%20prisoner%20characteristics~7>.
11. Hepatitis C Medicines Fact Sheet for Public & Private Hospital Prescribers & Dispensers: The Pharmaceutical Benefits Scheme; [cited 2016 16 August]. Available from: <http://www.pbs.gov.au/info/publication/factsheets/hep-c/hep-c-medicines-factsheet-for-public-and-private-hospital-prescribers-and-dispensers>.
12. Hepatitis C Medicines Fact Sheet for Community Pharmacy Dispensers: The Pharmaceutical Benefits Scheme; [cited 2016 16 August]. Available from: <http://www.pbs.gov.au/info/publication/factsheets/hep-c/hepatitis-c-medicines-factsheet-for-community-pharmacy-dispensers>.
13. Department of Health. Second National Hepatitis B Strategy 2014 – 2017. Canberra, Australia: Commonwealth of Australia; 2014.
14. World Health Organization. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. Geneva, Switzerland: WHO, 2015.
15. Allard N, MacLachlan JH, Cowie BC. The cascade of care for Australians living with chronic hepatitis B: measuring access to diagnosis, management and treatment. *Australian and New Zealand journal of public health*. 2015;Epub ahead of print.
16. MacLachlan JH, Allard N, Towell V, Cowie BC. The burden of chronic hepatitis B virus infection in Australia, 2011. *Australian and New Zealand journal of public health*. 2013;37(5):416-22.

17. Turnour CE, Cretikos MA, Conaty SJ. Prevalence of chronic hepatitis B in South Western Sydney: evaluation of the country of birth method using maternal seroprevalence data. *Australian and New Zealand journal of public health*. 2011;35(1):22-6.
18. Reekie J, Gidding HF, Kaldor JM, Liu B. Country of birth and other factors associated with hepatitis B prevalence in a population with high levels of immigration. *Journal of gastroenterology and hepatology*. 2013;28(9):1539-44.
19. Kowdley KV, Wang CC, Welch S, Roberts H, Brosgart CL. Prevalence of chronic hepatitis B among foreign-born persons living in the United States by country of origin. *Hepatology*. 2012;56(2):422-33.
20. Schweitzer A, Horn J, Mikolayczyk R, Ott J. Worldwide prevalence of chronic hepatitis B virus infection: estimations based on a systematic review of data published between 1965 and 2013. *The Lancet*. 2015;online.
21. MacDonald M, Wodak AD, Ali R, Crofts N, Cunningham PH, Dolan KA, et al. HIV prevalence and risk behaviour in needle exchange attenders: a national study. *The Collaboration of Australian Needle Exchanges*. *Med J Aust*. 1997;166(5):237-40.



