Monitoring hepatitis C treatment uptake in Australia

Issue #6 February 2017[1]

Initiations of new treatment for chronic hepatitis C during March to September 2016

An estimated 25,890 individuals initiated direct acting antiviral (DAA) treatment for chronic hepatitis C virus (HCV) infection during March to September 2016, equating to 11% of the people living with chronic HCV in Australia. The total number of DAA initiations in 2016 (March-December) is estimated to be between 30,390 and 33,390. Of individuals initiating DAA treatment during March to September 2016, 66% were men, 34% were women, and 40% were ≤50 years old. The proportion of individuals ≤50 years old increased from 28% in March to 54% in September. The most commonly prescribed regimen was sofosbuvir/ledipasvir for 57%, followed by sofosbuvir+daclatasvir for 38%. Of individuals initiated on sofosbuvir/ledipasvir, 13% were prescribed an 8-week course, 74% a 12-week course, and 13% a 24-week course. Of individuals initiated on sofosbuvir+daclatasvir, 62% were prescribed a 12-week course, and 38% a 24-week course. Most individuals received their prescriptions from gastroenterologists (52%), followed by supervised medical officers (i.e., interns, temporary resident doctors, and non-vocationally registered doctors; 15%), and general practitioners (GPs, 13%). Overall, 65% of individuals received their prescriptions from specialists. The proportion of individuals receiving their prescriptions from GPs increased from 4% in March to 19% in September.

1. The Kirby Institute. Monitoring hepatitis C treatment uptake in Australia (Issue 6). The Kirby Institute, UNSW Sydney, Sydney, Australia, February 2017 (available online at: http://kirby.unsw.edu.au/research-programs/vhcrp-newsletters).
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New treatments for chronic hepatitis C virus (HCV) infection, named direct acting antiviral (DAA) therapy, were listed on the Pharmaceutical Benefits Scheme (PBS): sofosbuvir/ledipasvir (Harvoni®), sofosbuvir+daclatasvir (Sovaldi®+Daklinza®), sofosbuvir+ribavirin (Sovaldi®+Ibavyr®), and sofosbuvir+pegylated interferon-alfa-2a+ribavirin (Sovaldi®+Pegasys®+ribavirin) in March 2016, and paritaprevir/ritonavir/ombitasvir/dasabuvir (Viekira PAK®) in May 2016.

The previous estimates of DAA treatment uptake in Australia (issues #1-5 newsletter) were based on PBS monthly reports of DAA prescriptions processed for reimbursement. These reports do not provide specific data of treatment initiation and are also subject to time lag between drug dispensing and prescriptions reimbursement submissions by pharmacies. The adjustments applied to overcome the limitations of PBS monthly reports data have led to an overestimation of the reported treatment uptake. In this newsletter, more robust data, based on individual DAA initiations, were used to revise the estimates.

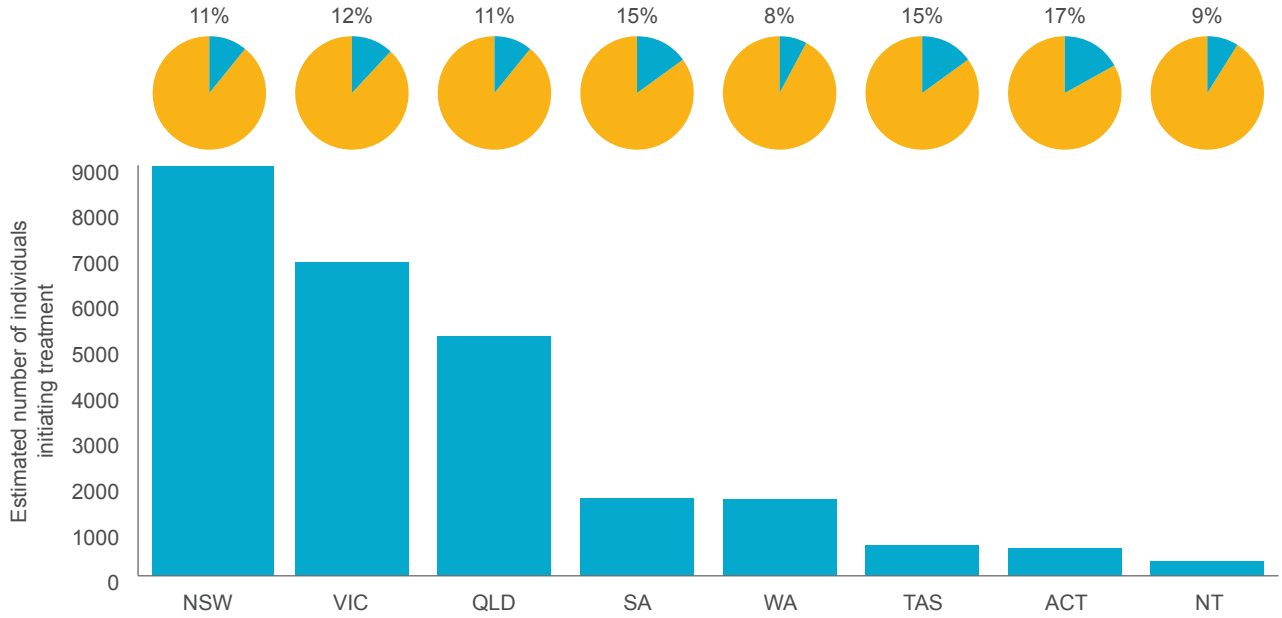
Issue #6 newsletter provides data on:

- Estimated number of individuals initiating DAA treatment during March to September 2016, by jurisdiction, patients' gender and age, treatment regimen, and prescription type.
- Estimated proportion of individuals living with chronic HCV who initiated DAA treatment during March to September 2016, by jurisdiction
- Monthly trend of DAA treatment initiation during March to September 2016, by jurisdiction, patients' age, and prescription type

Estimated DAA treatment initiations

An estimated 25,890 individuals initiated chronic HCV DAA treatment during March to September 2016 in Australia, including 8,970 in New South Wales, 6,880 in Victoria, 5,250 in Queensland, 1,700 in South Australia, 1,670 in Western Australia, 670 in Australian Capital Territory, 600 in Tasmania, and 320 in Northern Territory (Figure 1).

Figure 1: The estimated number of individuals initiating DAA treatment (bar charts) and the proportion of individuals living with chronic HCV who initiated DAA treatment (pie charts) during March to September 2016, by jurisdiction



NSW: New South Wales; VIC: Victoria; QLD: Queensland; SA: South Australia; WA: Western Australia; ATC: Australian Capital Territory; TAS: Tasmania; NT: Northern Territory

Estimated monthly numbers of individuals initiating DAA treatment was 5,070 in March, 4,440 in April, 4,320 in May, 3,680 in June, 2,980 in July, 2,900 in August, and 2,500 in September (Figure 2A). The monthly trend of DAA treatment uptake in each jurisdiction is illustrated in Figure 2B.

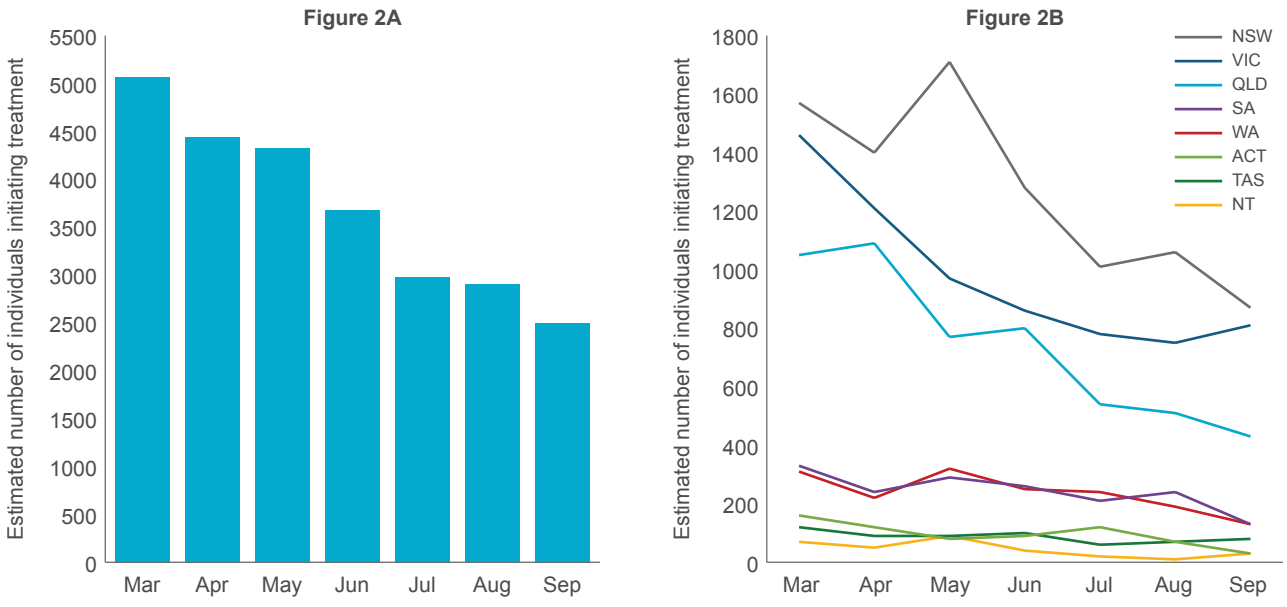
Including projected numbers of treatment initiations during October to December, the total number of individuals initiating DAA treatment in 2016 (March-December) was estimated to be between 30,390 and 33,390. The next newsletter will provide a more precise estimate of DAA initiations in 2016.

Estimated proportion of individuals living with chronic HCV who initiated DAA treatment

In 2015, an estimated 227,306 individuals were living with chronic HCV in Australia, including, 80,700 individuals in New South Wales, 55,261 individuals in Victoria, 47,356 individuals in Queensland, 11,682 in South Australia, 20,549 in Western Australia, 4,561 in Tasmania, 3,591 in Australian Capital Territory, and 3,606 in Northern Territory.[2] Therefore, it is estimated that 11% of total individuals living with chronic HCV in Australia initiated DAA treatment during March to September 2016, including 11% in New South Wales, 12% in Victoria, 11% in Queensland, 15% in South Australia, 8% in Western Australia, 15% in Australian Capital Territory, 17% in Tasmania, and 9% in Northern Territory (Figure 1).

Using the estimated number of DAA initiation in 2016 (March-December), it was estimated that between 13% and 15% of individuals living with chronic HCV initiated DAA treatment in 2016.

Figure 2: The estimated number of individuals initiating DAA treatment in each month during March to September 2016 in Australia (A), and by Jurisdiction (B).



NSW: New South Wales; VIC: Victoria; QLD: Queensland; SA: South Australia; WA: Western Australia; ATC: Australian Capital Territory; TAS: Tasmania; NT: Northern Territory

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

Gender and age distribution of individuals initiating DAA treatment

Of individuals initating DAA treatment during March to September 2016, 66% were men and 34% were women. Age distribution of individuals initiating treatment was similar between men and women with 63% of total individuals being 41-60 years old (Figure 3).

The proportion of individuals ≤50 years old was 40% for the whole period of March to September 2016. However, this proportion increased from 28% in March to 54% in September (Figure 4).

Figure 3: Age distribution of individuals initiating DAA treatment during March to September 2016 in Australia, by gender

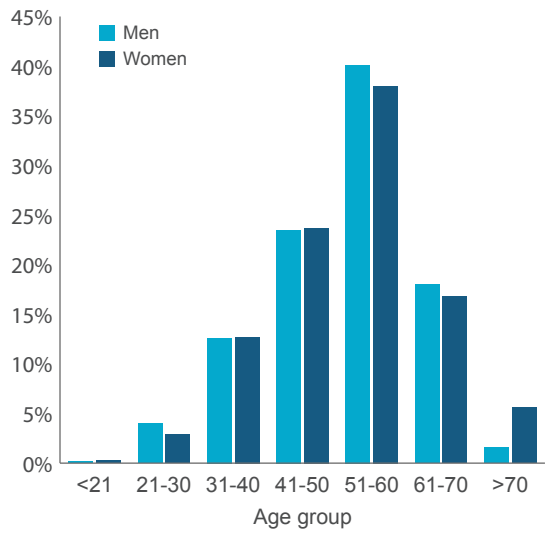
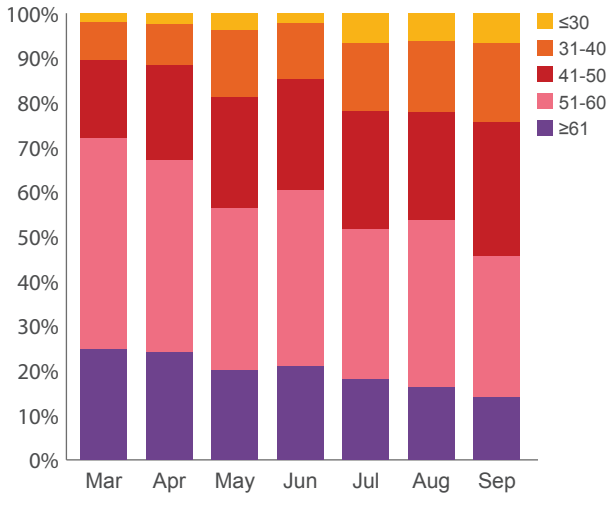


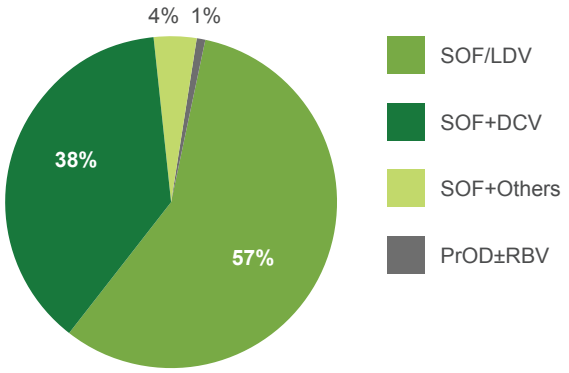
Figure 4: Age distribution of individuals initiating DAA treatment in each month during March to September 2016 in Australia



Distribution of DAA regimens priscribed for individuals initiating DAA treatment

The most commonly prescribed regimen was sofosbuvir/ledipasvir, for 57%, followed by sofosbuvir+daclatasvir for 38%, sofosbuvir+other agents for 4% and paritaprevir/ritonavir/ombitasvir/dasabuvir for 1% (Figure 5). Other agents used in combination with sofosbuvir include ribavirin, or pegylated interferon-alfa-2a+ribavirin.

Figure 5: Distribution of DAA regimens prescribed during March to September 2016 in Australia



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

The breakdown of treatment initiation numbers by treatment regimen and treatment course duration is shown in Figure 6. Of individuals initiated on sofosbuvir/ledipasvir, 13% were prescribed an 8-week course, 74% a 12-week course, and 13% a 24-week course.

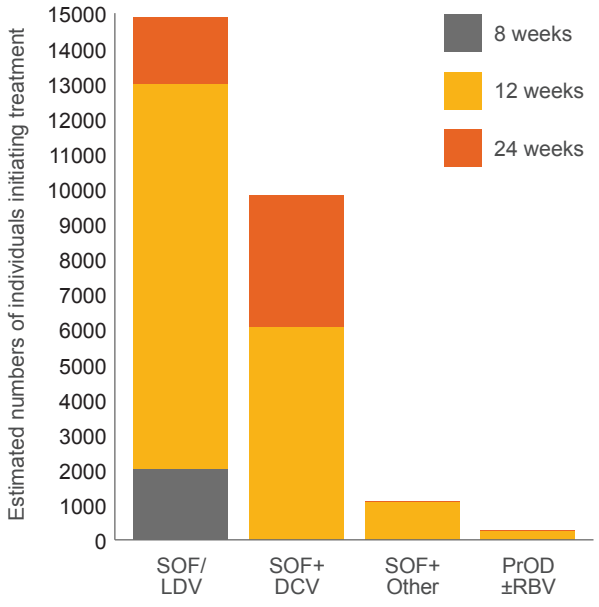
Of individuals initiated on sofosbuvir+daclatasvir, 62% were prescribed a 12-week course, and 38% a 24-week course.

Of individuals initiated on sofosbuvir+other agents, 99% were prescribed a 12-week course, and 1% a 24-week course.

Of individuals initiated on paritaprevir/ritonavir/ombitasvir/dasabuvir based regimen, 23% were prescribed this regimen with ribavirin, and 77% without ribavirin. Of these individuals, 96% were prescribed a 12-week course, and 4% a 24-week course.

The vast majority of individuals prescribed sofosbuvir+daclatasvir for 24 weeks will be individuals with genotype 3 and cirrhosis. Those prescribed sofosbuvir/ledipasvir for 24 weeks or paritaprevir/ritonavir/ombitasvir/dasabuvir + ribavirin for 24 weeks should represent individuals with genotype 1, prior treatment and cirrhosis.

Figure 6: Distribution of DAA regimens prescribed during March to September 2016 in Australia, by treatment regimen and treatment course duration



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

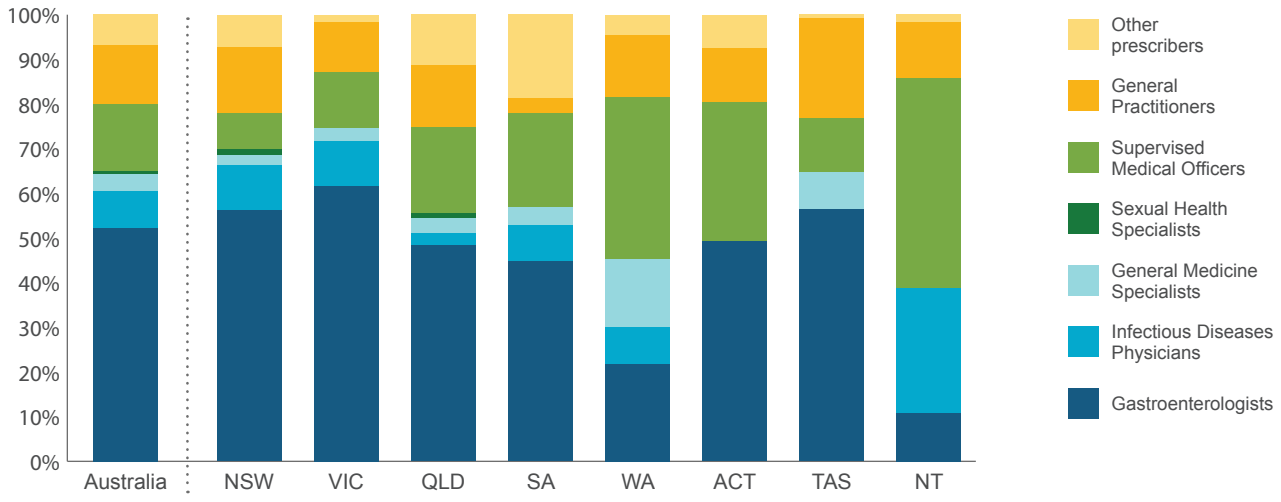
Distribution of health care providers prescribing for individuals initiating DAA treatment

The majority of individuals initiating DAA treatment received their prescriptions from gastroenterologists (52%), followed by supervised medical officers (i.e., interns, temporary resident doctors, and non-vocationally registered doctors; 15%), general practitioners (GPs, 13%), infectious diseases physicians (8%), general medicine specialists (4%), and sexual health specialists (1%). Overall, 65% of individuals received their prescriptions from specialists (Figure 7).

Distribution of prescription types varied across jurisdictions (Figure 7). Gastroenterologists were the prominent prescriber in most jurisdictions, except for Western Australia and Northern Territory in which most individuals received their prescriptions from supervised medical officers (36% and 47%, respectively). Across jurisdictions, the proportion of individuals who received their prescriptions from GPs was highest in Tasmania (22%) and was lowest in Southern Australia (3%).

The distribution of prescription types in each month during March to September 2016 is shown in Figure 8. The proportion of individuals receiving their prescriptions from GPs increased from 4% in March to 19% in September.

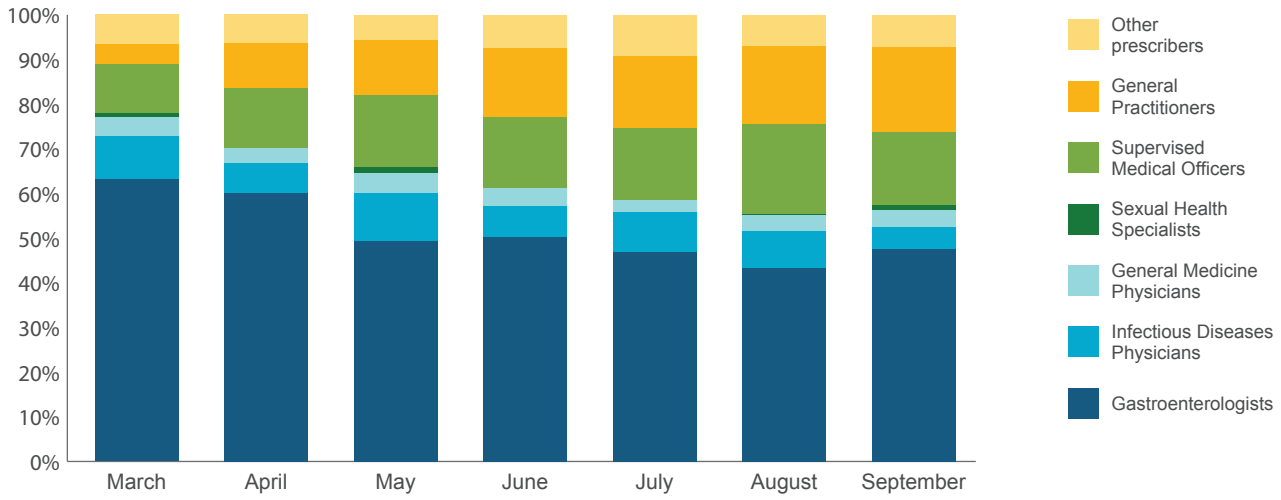
Figure 7: Distribution of prescription types for individuals initiating DAA treatment during March to September 2016 in Australia, in total and by jurisdiction



Supervised Medical Officers included interns, temporary resident doctors, and non-vocationally registered doctors

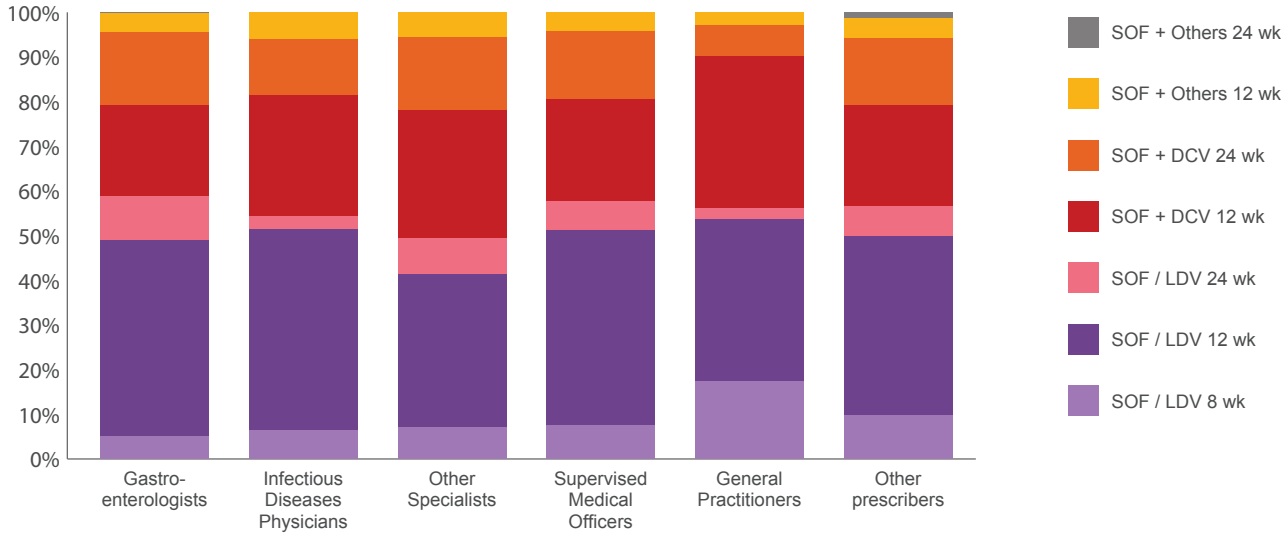
NSW: New South Wales; VIC: Victoria; QLD: Queensland; SA: South Australia; WA: Western Australia; ATC: Australian Capital Territory; TAS: Tasmania; NT: Northern Territory

Figure 8: Distribution of prescription types in each month for individuals initiating DAA treatment during March to September 2016 in Australia



Supervised Medical Officers included interns, temporary resident doctors, and non-vocationally registered doctors

Figure 9: Distribution of prescribed DAA regimens by prescription type for individuals initiating DAA treatment during March to September 2016 in Australia



Other specialists included general medicine specialists and sexual health specialists; Supervised Medical Officers included interns, temporary resident doctors, and non-vocationally registered doctors

Distribution of prescribed DAA regimens by prescription type

The distribution of the three most commonly prescribed DAA regimens (i.e., sofosbuvir/ledipasvir, sofosbuvir+daclatasvir, and sofosbuvir+other agents) by prescription type is shown in Figure 9. Paritaprevir/ritonavir/ombitasvir/dasabuvir was not included in this analysis because of small numbers.

Across all prescription types, the most commonly-prescribed regimens included 12 weeks sofosbuvir/ledipasvir, followed by 12 weeks sofosbuvir+daclatasvir. Of prescriptions by specialists, 9% included 24 weeks sofosbuvir/ledipasvir and 16% included 24 weeks sofosbuvir+daclatasvir. These proportions were lower among prescriptions by GPs (2% and 7%, respectively). These two regimens are primarily prescribed for patients with cirrhosis.

Across all prescription types, the highest proportion of 8 weeks sofosbuvir/ledipasvir regimen was observed in prescriptions by GPs (18%). This regimen is prescribed for treatment naïve patients with genotype 1, no cirrhosis, and HCV viral load<6 million IU/mL.

Methodology

Data on dispensed DAA prescriptions for a longitudinal cohort of individuals, representing a 10% random sample of the PBS database, were used for estimating the number of individuals initiating DAA treatments and all subgroup analyses. These data provided the number of unique individuals receiving HCV treatment in overall and in a monthly basis rather than the crude number of dispensed treatments which is available through the PBS monthly reports. These data are currently available up to September 2016.

To estimate the total treatment uptake for 2016 (March-December), the treatment initiations during October to December were projected using two following scenarios:

- Maximum estimate scenario: It was assumed that the treatment initiation in September (n=2,500 per month) continued constantly during October to December.
- Minimum estimate scenario: It was assumed that treatment initiation decreased after September to 1,500 individuals per month and remained at this level during October to December

The estimated numbers of individuals living with chronic HCV infection were extracted from a modelling study[3].

Although more robust data and more sophisticated analyses were used in the current issue than the previous issues, there are still some considerations to be taken into account for interpreting these results. Given that the results are extrapolated from 10% random sample of the PBS database, the results in subgroups with small numbers might be subject to uncertainties. This analysis provided data of treatment initiations. It does not reflect the number of individuals who completed their treatment course, although treatment discontinuation is expected to be low. The jurisdiction-specific treatment initiation estimates in this report are based on data of dispensing pharmacy location, and not patient's residence location while the estimated numbers of individuals living with chronic HCV are based in part on the number of HCV notifications which are reported based on residence. Thus cross-jurisdiction dynamics should be considered in interpreting the jurisdiction-specific data. It could have more impact on the estimates from smaller jurisdictions given their smaller population as the denominator.

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