Supporting GPs to prescribe DAA

Aiming for elimination: outcomes of a consultation pathway supporting regional general practitioners to prescribe direct acting antiviral therapy for hepatitis C

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Abstract

To increase access to treatment, the Australian government enabled general practitioners (GPs) to prescribe direct-acting antivirals (DAA) to treat hepatitis C virus (HCV) - in consultation with a specialist if inexperienced in HCV management. This study describes the establishment and outcomes of a remote consultation pathway supporting GPs to treat HCV. Key stakeholders from primary and tertiary healthcare services in the Barwon South Western region developed and implemented an HCV remote consultation pathway. Pharmaceutical Benefits Schedule prescription data was used to evaluate GP DAA prescription 12 months pre and post pathway implementation. A retrospective review of patients referred for remote consultation for 12 months post pathway inception was undertaken to determine the care cascade. HCV treatment initiation by GPs increased after implementation of the remote consultation pathway. In the 12-month study period, 74 GPs referred 169 people for remote consultation; 114 (67%) were approved for GP DAA treatment; 48 (28%) were referred for specialist assessment. In total, 119 (71%) patients commenced DAA; 69 were eligible for SVR12 assessment. Post treatment HCV RNA data was available for 52 (75%) people; 37 achieved SVR12; 15 achieved SVR ranging from week 5 - 11 post treatment. No treatment failure was detected. Collaborative development and implementation of a remote consultation pathway has engaged regional GPs in managing HCV. Follow-up post treatment could be improved, however no treatment failure has been documented. To eliminate HCV as a public health threat, it is vital that specialists support GPs to prescribe DAA.

Keywords: Hepatitis C, treatment access, primary care, direct acting antivirals.

The discovery of direct acting antiviral therapy (DAA) for hepatitis C infection has changed the global approach to hepatitis C. In May 2016, the World Health Organisation (WHO) announced global targets for the elimination of hepatitis C as a public health threat: a 65% reduction in hepatitis C related deaths and an 80% reduction in new hepatitis C infections by 2030 (1). Achieving these goals
will require engagement with priority populations in each country; for Australia a particular focus is people who inject drugs (PWID). For many years, a major barrier preventing people with hepatitis C from commencing treatment was the toxicity of pegylated-interferon based therapy, which was available from specialist physicians in tertiary hospitals (2). In the era of pegylated interferon based therapy, hepatitis C treatment uptake rates were as low as 1%, in Australia and globally (3). As DAAs are safe, highly efficacious, and treatment toxicity is no longer a barrier, increasing access to DAA is now the key to eliminating hepatitis C.

In many countries prescription of DAA is subject to provider restrictions, or patient restrictions based on fibrosis stage or injecting status (4, 5). However on 1 March 2016 the Australian government funded DAA for all Australians with hepatitis C infection (6). To increase access to hepatitis C treatment the government enabled all medical practitioners to prescribe pharmaceutical benefits scheme (PBS) funded DAA, although medical practitioners without experience in the management of hepatitis C were required to prescribe in consultation with a specialist gastroenterologist, hepatologist or infectious diseases physician experienced in the management of hepatitis C (7). Consultation was defined broadly to include telephone, mail, e-mail or videoconference interaction prior to prescribing. The government funded a dedicated hepatitis C primary care consultant at each Primary Health Network (PHN) to provide DAA education to general practitioners (GPs), and to facilitate in consultation referral pathways.

The Australian Liver Association developed a referral form for GPs to complete and send to specialists. The purpose of the form was to identify the minority of patients that needed specialist care - patients with cirrhosis, special populations (people with HIV or hepatitis B virus co-infection, renal failure or decompensated liver disease) or people who failed first line DAA therapy (6). Non-invasive methods for assessing for cirrhosis include calculating an aspartate aminotransferase to platelet ratio index (APRI), or performing transient elastography (with a FibroScan machine) to determine median liver stiffness. The implementation of the referral form, the development of referral pathways and availability of FibroScan was ad hoc and unique to each region, and no standardised form or pathway exists.

This study describes the development of a hepatitis C remote consultation pathway at University Hospital Geelong, and the care cascade for patients referred by GPs for remote specialist consultation in the 12 months following the pathway inception.
Materials and methods

Setting

The Barwon South Western region of Victoria has a population of approximately 366,900 people, and extends from Geelong to the South Australian border covering an area of 32,767 km², see Figure 1 (8). In Australia the prevalence of hepatitis C infection is 0.9%, which would correspond to approximately 3,300 people with hepatitis C infection in Barwon South Western region (6). Services for viral hepatitis in the region are summarized in Figure 1. Publically funded specialist services for people with viral hepatitis are provided at the Liver Clinic, University Hospital Geelong, which is a tertiary level, university-affiliated hospital. The Liver Clinic includes a nurse-led assessment clinic once per week, and a specialist clinic staffed by gastroenterologists, infectious diseases physicians and hepatology nurses once per week. A community hepatology nurse provides outreach patient assessment, and GP education and support at clinics in the following locations; Geelong, Colac, Warrnambool, Portland and Hamilton. One mobile FibroScan machine is used in the nurse-led assessment clinic and travels with the community hepatology nurse to all outreach clinics.

Gastroenterologists and infectious diseases physicians also provide services from private rooms in Warrnambool and Geelong.

Figure 1 Map of Barwon South Western region and viral hepatitis services

Development of a hepatitis C remote consultation pathway

In order to establish a remote consultation pathway a working party was convened in February 2016, with representatives from the following key stakeholders; drug and alcohol services, needle and syringe program, Western Victoria PHN, and representatives from the University Hospital Geelong departments of pharmacy, infectious diseases, gastroenterology, outpatients and administration. The working party developed:

- A paper based remote consultation referral (see Appendix 1) which included the following patient details; demographics, risk factors for cirrhosis, prior hepatitis C treatment history, if signs of chronic liver disease were evident on examination, hepatitis C virus (HCV) RNA (qualitative or quantitative), HCV genotype, HIV and HBV serology, liver function tests, estimated glomerular filtration rate, haemoglobin, platelet count, pregnancy test, APRI and if performed, median liver stiffness result.
• An electronic template of the remote consultation referral for GP practice software (Best Practice, Zedmed and Medical Director).

• A dedicated hepatitis C information page on the existing HealthPathways platform, which included the remote consultation referral, and links to peak body guidelines, an APRI calculator and DAA drug-drug interactions websites. HealthPathways is a website designed for use in primary care and includes key clinical information and details of local referral pathways.

• A paper based specialist response proforma (see Appendix 2), which indicated whether GP DAA treatment was appropriate, or if specialist assessment was required.

• Allocation of hospital UR numbers to patients referred by the hepatitis C remote consultation system, and storage of the referral and response in the hospital medical record.

• A mechanism whereby patients requiring specialist assessment were scheduled appointments in the tertiary hospital specialist clinic.

• Funding for a specialist to; respond to the remote consultation referrals, monitor and update the remote consultation pathway.

The remote consultation pathway was launched with an education session for GPs at the Western Victoria PHN on 15 June 2016. The education component had specialist support, but consisted of peer-based teaching, with two senior GPs presenting cases for discussion and demonstrating the tools available on the hepatitis C HealthPathways page. A further education session was run with a similar format on 6 December 2016, and a modified education session was included in the GP Refresher Weekend on 25/26 February 2017.

In line with national standards, patients were considered not cirrhotic if their APRI was <1.0 or median liver stiffness was <12.5 kPa (6). The specialist physician from the Liver Clinic responded to hepatitis C remote consultation referrals once per week. If a referral was incomplete and unable to be assessed, a request was sent to the GP for further information. The patient was then scheduled an appointment with the specialist, which could be cancelled if the missing patient data was received.

If the specialist response to the remote consultation was for the GP to prescribe DAA, Liver Clinic staff contacted the GP practice 12 weeks after the end of DAA treatment, to determine the outcome of therapy. The follow up phone review collected the following information per patient: DAA prescribed, duration, date of prescription and HCV RNA results collected after DAA treatment had been completed.
Evaluation of remote consultation pathway

PBS data were used to obtain the number of hepatitis C treatment initiations in the Barwon South West region by provider type, for 12 months before and after inception of the remote consultation pathway. Descriptive statistics were used to report the number of GPs that used the remote consultation pathway, and determine the effect of being an opioid substitution therapy (OST) provider.

The digital medical records for patients referred to University Hospital Geelong for remote consultation from pathway inception on 15 June 2016, until 15 June 2017 were retrospectively reviewed and the following de-identified data were entered into REDCap (electronic data capture hosted at Barwon Health) (9): data from remote consultation referral, specialist response to remote referral, attendance and outcome of specialist appointments, commencement of DAA and outcome of DAA treatment. To determine the care cascade; a person who had been prescribed DAA was defined as having commenced treatment (the date of the prescription was considered day one of therapy), all patients at 12 or more weeks post-treatment completion were eligible for sustained virologic response (SVR12) assessment, and SVR12 was defined as a negative HCV RNA PCR 12 or more weeks post treatment completion.

Descriptive statistics were used to report the patients’ baseline characteristics, and treatment outcomes. Data was analysed using STATA 13.1. The study was approved by the Barwon Health Ethics Committee. Written informed consent was not required from patients for the use of their clinical records in this retrospective study.

Results

The number of hepatitis C treatment initiations in the Barwon South Western region, by provider type, was obtained from the PBS (Nick Scott, Burnet Institute, personal communication), see Figure 2. In the 12 months prior to the remote consultation pathway launch (1 July 2015 – 30 June 2016), GPs initiated treatment for 18 of 226 patients (8%). In the 12 months after the remote consultation pathway launch (1 July 2016 – 30 June 2017), GPs initiated treatment for 178 of 442 patients (40%). In quarter two of 2016 when DAA were available, GPs initiated hepatitis C treatment for 12 patients. In quarter three of 2016 following the pathway launch, GPs initiated hepatitis C treatment for 42 patients; the average number of treatment initiations per quarter after the launch was 45.

Figure 2 Number of people treated for hepatitis C in Barwon South Western region by provider type
One hundred and sixty-nine remote consultation referrals were received at the Liver Clinic from 74 GPs in the 12-month study period. The median number of referrals per GP was 1 (range 1-14), however for the nine GPs who were OST prescribers, the median number of referrals was 7 (range 1-14). Seventy referrals (41%) were received from GPs in clinics attended by the community hepatitis nurse.

The characteristics of the patients referred for remote consultation are summarized in Table 1.

Table 1 Baseline patient characteristics

Of the 169 referrals; 114 (67%) were approved for GP DAA treatment, 48 (28%) were referred for specialist assessment, 2 (1%) did not have HCV infection and 5 (3%) were advised to defer GP DAA treatment (non-cirrhotic genotype 6 (1), in prison (1), mental health issues (1), drug-drug interactions precluded use of available DAA (2)).

The care cascade is illustrated in Figure 3. Of the 167 people with hepatitis C infection 119 (71%) commenced appropriate DAA treatment and 69 are eligible for SVR12 assessment. Post treatment HCV RNA data is available for 52 people; 37 people have documented SVR12, and 15 people have SVR ranging from week 5 to week 11 post treatment. No treatment failure has been detected.

Figure 3 Care cascade for remote consultation pathway

GP DAA treatment

Of the 114 referrals approved for GP DAA treatment, DAA were prescribed by the referring GP for 95 (83%) people. This study did not collect data on why DAA prescriptions were not written for the other 19 patients. Ninety-three GP DAA prescriptions were consistent with the recommendation from the specialist service; sofosbuvir/ledipasvir (53 prescriptions), sofosbuvir and daclatasvir (38 prescriptions), elbasvir/grazoprevir (1 prescription) and sofosbuvir and ribavirin (1 prescription). Two GP DAA prescriptions were inconsistent with specialist recommendations; one prescribed another PBS listed regimen for genotype 1 HCV sofosbuvir and daclatasvir instead of sofosbuvir/ledipasvir, and one prescribed 24 weeks of DAA therapy instead of 12 weeks. Neither prescription compromises the chance of cure. Of the 95 people who commenced DAA therapy, 62 are eligible for SVR12 assessment.

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assessment. Forty-five (73%) people who are eligible for SVR12 assessment have had blood taken post the end of treatment, demonstrating the following results: 33 (73%) achieved SVR12, five (11%) achieved SVR11, three (7%) achieved SVR10, one (2%) achieved SVR9, one (2%) achieved SVR8, one (2%) achieved SVR7 and one (2%) achieved SVR5. No treatment failure has been documented.

Treatment outcomes are illustrated in Figure 3.

Specialist DAA treatment

Forty-eight people were referred for specialist assessment. The indications for specialist assessment are detailed in Table 2.

Table 2 Indication for specialist assessment

Of the 48 people referred to specialist services, six did not attend their appointment, and six have appointments scheduled for a future date. Thirty-six people have attended their specialist appointment, the outcomes are as follows; 24 (67%) have commenced DAA (15 received a prescription in the specialist clinic, eight were approved for GP treatment and their GP prescribed DAA, and one had already been started on DAA by their GP), one (3%) was approved for GP treatment but is yet to start DAA, three (8%) have had DAA treatment deferred, six (17%) have further assessment in progress and two (6%) have been referred to other specialist services. Of the 24 people that commenced DAA, seven (29%) are eligible for SVR12 assessment, and six have had blood taken post the end of treatment, demonstrating the following results: four (67%) achieved SVR12, one (17%) achieved SVR11 and one (17%) achieved SVR10.

PBS data demonstrates 178 treatment initiations were performed by GPs in Barwon South West region in the study period. Of these, 95 treatment initiations were following remote specialist consultation, and eight treatment initiations were following face-to-face specialist consultation. One hundred and three hepatitis C treatment initiations by GPs (58%) were supported by the remote consultation pathway.

Discussion

Our remote consultation pathway resulted in a high DAA treatment uptake rate of over 70% in a cohort of people living in regional Victoria. A collaborative approach between the primary and tertiary health sectors resulted in a remote consultation pathway used by 74 GPs, and increased access to DAA treatment in primary care, in the Barwon South-Western region. Providing hepatitis C...
treatment in the local community, within an established healthcare provider relationship, may overcome both travel and trust related barriers to accessing tertiary care.

Although the initial listing of DAA on the PBS on 1 March 2016 required all medical practitioners to prescribe DAA in consultation with a hepatologist, gastroenterologist or infectious diseases physician experienced in the treatment of hepatitis C, this was revised on 1 October 2016 to require only medical practitioners not experienced in the treatment of hepatitis C to seek consultation (7). The Pharmaceutical Benefits Advisory Committee has not defined “experienced” but national guidelines suggest that clinical experience should be gained by attending a formal training session, and treating ten people living with hepatitis C in consultation (6). Therefore the remote consultation pathway should function as a remote training program for GPs, and create links between GPs and specialist services.

Of the 69 people who are eligible for SVR12 assessment, 52 (75%) have had blood taken, 37 have documented SVR12, and 15 had an HCV RNA negative result after the end of treatment, but before their SVR12 time point. Day one of DAA therapy was presumed to be the date the script was written, but it is possible that the treatment course was commenced at a later date, which would impact on when the patient was eligible for SVR assessment. This study did not investigate reasons why SVR12 blood tests were not completed. Failure to have SVR12 blood tests after DAA treatment has been observed in other cohorts (10-12). These findings demonstrate that there is an opportunity to improve follow-up post DAA treatment. In response to this finding, the significance of waiting 12 weeks after DAA completion to assess for cure has been emphasized in GP education sessions, within the referral HealthPathway and in the revised remote consultation response letter (Appendix 3). Of note, national hepatitis C management guidelines from 1 March 2016 recommended testing for HCV PCR at the end of treatment, but the updated guidelines published in January 2017 simplified follow-up by removing the end of treatment HCV PCR (6).

As injecting status did not influence hepatitis C management, injecting history was not requested on the remote consultation referral. Therefore, the proportion of active injectors in this cohort is unknown. However, to achieve hepatitis C elimination it is critical to increase treatment uptake amongst this population. In Melbourne, Victoria the annual hepatitis C treatment rate in PWID prior to the introduction of DAAs was estimated to be three per 1000 (13). Recent modelling data has suggested that increasing treatment uptake to 59 per 1000 PWID annually could achieve the WHO incidence target (14). Cohort studies and one small randomised controlled trial conducted in the era of pegylated-interferon based hepatitis C treatment have demonstrated that when compared to
treatment in tertiary centres, provision of treatment in the community results in higher treatment uptake rates, particularly in PWID (15, 16). In order to determine the effect of providing DAA treatment in the community on treatment uptake and SVR outcome, a large, randomised controlled trial is underway in Australia and New Zealand (The Prime Study NCT02555475), in which participants recruited at primary health care centres are randomised to receive DAA treatment at their primary health care centre or a tertiary hospital.

In conclusion, this study demonstrates that collaborative development and implementation of a remote consultation pathway has engaged regional GPs in hepatitis C treatment. Although follow-up post treatment could be improved, no treatment failure has been documented. It is vital that specialists and the tertiary system support GPs to prescribe curative DAA, to stop people dying of hepatitis C, and eliminate hepatitis C as a public health threat.

**Statement of Interests**

AM, CR, MW, KM, NS, EA - no relevant disclosures; AW receives funding for investigator-initiated research from AbbVie; MH receives funding for investigator-initiated research - Gilead, BMS and AbbVie.

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**References**


Table 1 Baseline patient characteristics

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Proportion or mean (SD) or median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients referred (n=169)</td>
<td>169</td>
<td></td>
</tr>
<tr>
<td>Age, years (n=169)</td>
<td></td>
<td>Mean 47 (10.5)</td>
</tr>
<tr>
<td>Sex, male (n=169)</td>
<td>106</td>
<td>63%</td>
</tr>
<tr>
<td>Number of years infected with HCV (n=124)</td>
<td></td>
<td>Median 12 (0 – 35)</td>
</tr>
<tr>
<td>Prior diagnosis of cirrhosis (n=155)</td>
<td>4</td>
<td>3%</td>
</tr>
<tr>
<td>BMI &gt;30 (n=157)</td>
<td>11</td>
<td>7%</td>
</tr>
<tr>
<td>Current or prior alcohol intake &gt;4 standard drinks/day (n=159)</td>
<td>56</td>
<td>35%</td>
</tr>
<tr>
<td>Previous HCV treatment (n=157)</td>
<td>9</td>
<td>6%</td>
</tr>
<tr>
<td>Prior DAA (n=9)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Signs of chronic liver disease on examination (n=154)</td>
<td>5</td>
<td>3%</td>
</tr>
</tbody>
</table>

**Investigation results**

| Number of patients with HCV infection (RNA detected) (n=169) | 167 | 99% |
| HCV genotype (n=167)                                         |     |     |
| Genotype 1                                                   | 89  | 53% |
| Genotype 3                                                   | 74  | 45% |
| Genotype other                                               | 4   | 2%  |
| HIV co-infection (n=164)                                     | 0   | 0   |
| HBV co-infection (n=165)                                     | 0   | 0   |
| ALT (U L-1) (n=168)                                          |     | Mean 74 (55)                           |
| Albumin (g L-1) (n=169)                                      |     | Mean 39 (4)                           |
| Platelets (x10⁹ L-1)(n=169)                                  |     | Mean 243 (81)                         |
| Fibrosis assessment                                          |     | An unknown unit                      |
Table 2 Indication for specialist assessment

<table>
<thead>
<tr>
<th>Indication for specialist assessment</th>
<th>Number of referrals and proportion (N=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APRI ≥ 1.0</td>
<td>14 (29%)</td>
</tr>
<tr>
<td>Thrombocytopenia (&lt; laboratory reported LLN)</td>
<td>11 (23%)</td>
</tr>
<tr>
<td>Incomplete referral form</td>
<td>8 (17%)</td>
</tr>
<tr>
<td>Significant risk factors for cirrhosis</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>Ultrasound abnormality*</td>
<td>4 (8%)</td>
</tr>
<tr>
<td>Hypoalbuminaemia (&lt; laboratory reported LLN)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Hyperbilirubinaemia (&gt; laboratory reported ULN)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Iron deficiency anaemia</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>HCV genotype 6</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Drug-drug interaction management</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>APRI aspartate aminotransferase to platelet ratio index; LLN lower limit of normal; ULN upper limit of normal; HCV hepatitis C virus.</td>
<td></td>
</tr>
</tbody>
</table>

*Ultrasound report not required for remote consultation referral

Figure Legends

Figure 1 Map of Barwon South Western region and viral hepatitis services

Figure 2 Number of people treated for hepatitis C in Barwon South Western region by provider type

Figure 3 Care cascade for remote consultation pathway

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Barwon Health Remote Consultation for Initiation of Hepatitis C Treatment

Attention:  
Patient name: 
Patient DOB: 
Patient address: 
GP name: 
GP provider number: 
GP practice address: 
GP phone & fax number: 

Please refer patients directly for specialist assessment at the liver clinic if:

- History, examination or investigations suggestive of cirrhosis (i.e. liver stiffness is > 12.5 kPa or APRI > 1.0) or;
- Previously treated with regimens containing direct acting antiviral agents or;
- Concomitant medications not listed on the Liverpool website or drug drug interactions are such that assistance is required or;
- Patient has received amiodarone in the last 3 months or;
- Pregnant or breastfeeding female.

Likely year of HCV acquisition _ _ _ _  Year of chronic hepatitis C diagnosis _ _ _ _

Has the patient ever been diagnosed with cirrhosis?  Yes ☐  No ☐
Is the patient obese (BMI ≥ 30)?  Yes ☐  No ☐
Is there a history of current or prior alcohol intake >4 std drinks/day?  Yes ☐  No ☐
Has the patient previously been treated for HCV?  Yes ☐  No ☐
If yes, did the treatment contain direct acting antiviral agents?  Yes ☐  No ☐
Are there signs of chronic liver disease on examination?  Yes ☐  No ☐

<table>
<thead>
<tr>
<th>Test</th>
<th>Date</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV genotype*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HCV RNA level</td>
<td></td>
<td></td>
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<tr>
<td>HIV serology</td>
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<td>HBV sAg</td>
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<td>HBV cAb</td>
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<td>HBV sAb</td>
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<td>Haemoglobin</td>
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<td>Platelets</td>
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<td>Albumin</td>
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<td>AST and AST upper limit of normal</td>
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<tr>
<td>ALT</td>
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<tr>
<td>eGFR</td>
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<tr>
<td>INR</td>
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<tr>
<td>B-HCG if female</td>
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* Must be within the last 12 months

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<thead>
<tr>
<th>Test</th>
<th>Date</th>
<th>IQR/med(%)</th>
<th>Median liver stiffness (kPa)</th>
<th>Success rate (%) / No. valid shots</th>
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<tbody>
<tr>
<td>APRI</td>
<td></td>
<td></td>
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<tr>
<td>OR</td>
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<tr>
<td>FibroScan</td>
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The management of this patient will be according to the Australian Recommendations for the Management of HCV infection consensus statement 2016

I have used [www.hep-druginteractions.org](http://www.hep-druginteractions.org) to check and will manage interactions between the patients current medications (including over the counter & herbal preparations) and

- Sofosbuvir/ledipasvir for genotype 1
- Elbasvir/graaprevir for genotype 1 or 4
- Sofosbuvir and ribavirin for genotype 2
- Sofosbuvir and daclatasvir for genotype 3

GP declaration: I declare all of the information provided above is true and correct

GP signature: 
Date:
Dear Doctor,

In response to your request for approval dated __/__/__ for hepatitis C treatment for the patient named above, I advise:

- That assessment in a specialist service is required because of ____________, and I have listed your patient to be seen at the Barwon Health Liver Clinic
- You prescribe medication for hepatitis C as indicated below

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Genotype</th>
<th>Duration</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir / ledipasvir</td>
<td>1</td>
<td>12 weeks</td>
<td>☐</td>
</tr>
<tr>
<td>Sofosbuvir and ribavirin*</td>
<td>2</td>
<td>12 weeks</td>
<td>☐</td>
</tr>
<tr>
<td>Sofosbuvir and daclatasvir</td>
<td>3</td>
<td>12 weeks</td>
<td>☐</td>
</tr>
<tr>
<td>Elbasvir / grazoprevir</td>
<td>1 or 4</td>
<td>12 weeks</td>
<td>☐</td>
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</table>

*As ribavirin is teratogenic, male and female patients that receive ribavirin must use two forms of contraception whilst on treatment and for 6 months after.

There are no safety data for the use of sofosbuvir, ledipasvir, daclatasvir, elbasvir or grazoprevir during pregnancy or breastfeeding, which are listed as Category B. Therefore treatment with these drugs during pregnancy or breastfeeding is not recommended.
Patients should be monitored during treatment as outlined in the Australian Recommendations for the Management of HCV infection consensus statement 2017, which is referenced in the Chronic Hepatitis C HealthPathway: westvic.healthpathways.org.au Log on: westvic Password: xxxx.

Patients must be tested for HCV RNA at least 12 weeks after completing treatment to determine outcome. Our clinic will contact you to collect the outcome of treatment.

Kind regards,

Specialist Physician
Liver Clinic
University Hospital, Geelong.
Dear Doctor,

In response to your request for approval dated _ _ / _ _ / _ _ for hepatitis C treatment for the patient named above, I advise:

☐ That assessment in a specialist service is required because of _ _ _ _ _ _ _ _, and I have listed your patient to be seen at the Barwon Health Liver Clinic

☐ You prescribe medication for hepatitis C as indicated below

<table>
<thead>
<tr>
<th>Regimen</th>
<th>Genotype</th>
<th>Duration</th>
<th>Select</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sofosbuvir / velpatasvir</td>
<td>1,2,3,4,5,6</td>
<td>12 weeks</td>
<td>☐</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>☐</td>
</tr>
</tbody>
</table>

There are no safety data for the use of sofosbuvir or velpatasvir during pregnancy or breastfeeding, which are listed as Category B. Therefore treatment with these drugs during pregnancy or breastfeeding is not recommended.

Patients should be monitored during treatment as outlined in the Australian Recommendations for the Management of HCV infection consensus statement 2017, which is referenced in the Chronic Hepatitis C HealthPathway: westvic.healthpathways.org.au Log on: westvic Password: xxxx.

Patients must be tested for HCV RNA at least 12 weeks after completing treatment to determine outcome, see below.
DAA treatment

Outcome assessed with HCV PCR:
HCV PCR not detected = cure
HCV PCR not detected = sustained virologic response (SVR12)

0  12  24
Time (weeks)

Kind regards,

Specialist Physician
Liver Clinic, University Hospital Geelong.
Referred for remote consultation

HCV RNA detected

Outcome of HCV remote consultation

Commenced DAA treatment

Eligible for SVR12 assessment

Blood taken post-treatment

Achieved SVR

Number of people

169

167

48

24

95

7

6

SVR<12

SVR12

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