

## GUIDANCE TO SUPPORT THE IMPLEMENTATION OF REGIONAL SERVICES TO DELIVER IDENTIFICATION AND TREATMENT FOR PEOPLE AT RISK OF OR WITH HEPATITIS C

### 1. Background

In 2015/16, implementation began on a revised approach to the delivery of hepatitis C services across New Zealand. This involved the development of more integrated regional hepatitis C services with the focus on a coordinated primary and secondary health care model supported by regional clinical leaders<sup>1</sup>.

This new configuration of hepatitis C services includes resources directed towards targeted detection, management and treatment of hepatitis C in populations who are at increased risk of infection. Primary and secondary care services would be extended to provide improved assessment and follow up services for all people with hepatitis C.

A change in approach was in part informed by a Pilot carried out by the Hepatitis Foundation of New Zealand (HFNZ) from 2012-2014. The HFNZ Pilot focused on improvements to hepatitis C assessment in the four district health board (DHB) areas of Bay of Plenty, Capital & Coast, Hutt Valley and Wairarapa. The HFNZ Pilot included education and awareness activity, targeted testing and identification, community-based assessment and support delivered by nurse specialists, and activity to improve disease surveillance and data collection.

To commence planning and implementation of this approach in 2015, the Ministry of Health (the Ministry) provided advice to DHBs about the recommendations via the Regional Service Planning process. The advice detailed the commitments requested from the regions for hepatitis C service development and implementation during 2015/16.

In the Central and Midland region, the hepatitis C clinical services delivered in the four DHBs involved in the HFNZ Pilot continued while the effective transition of patients was implemented and services rolled-out to the rest of the region. DHBs in the non-HFNZ Pilot Northern and South Island regions were required to identify how they would implement integrated services in their regions, informed by the experience of the HFNZ Pilot DHBs. All four regions had committed to implementing integrated hepatitis C services in their regions by the end of the 2015/16 year.

In June 2015, the Ministry established the Hepatitis C Implementation Advisory Group with initial representation from secondary and primary care clinicians, a consumer panel representative, HFNZ, DHB Funding and Planning and the Ministry's CVD Diabetes Long Term Conditions team. The group was tasked with establishing the national hepatitis C quality assurance framework for primary and secondary care and providing advice and support to DHBs and their regions regarding

Hepatitis C is a blood-borne disease which causes inflammation of the liver. There are an estimated 45,000 people in New Zealand with chronic hepatitis C virus (HCV) infection, with approximately 1,000 new cases each year. Hepatitis C can remain asymptomatic for decades. If diagnosed early, a person is able to make lifestyle changes that may help delay the onset of serious complications, undertake treatment to cure the disease, and take steps to ensure that they do not transmit it to someone else.

If left unchecked, 20–25 percent of chronically infected individuals will develop cirrhosis of the liver, 2–5 percent of whom will develop liver cancer each year. Hepatitis C is the leading cause of liver transplantation in New Zealand. Of the infected population, 40-50 percent remain undiagnosed and unaware of the risks associated with the disease.

<sup>1</sup> Clinical leaders include physicians and nurse specialists in primary and secondary care, including community alcohol and drug services and corrections services.

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design and implementation of services. This group would oversee the establishment of key performance indicators for hepatitis C care, and monitoring the progress of DHBs over the next two years.

In July 2016, PHARMAC funded the first oral direct-acting antiviral (DAA) therapies:

1. Paritaprevir with ritonavir and ombitasvir copackaged with dasabuvir (VIEKIRA PAK) for 8 or 12 weeks in patients with HCV genotype 1b infection.
2. Paritaprevir with ritonavir and ombitasvir copackaged with dasabuvir and ribavirin (VIEKIRA PAK-RBV) for 12 or 24 weeks in patients with HCV genotype 1a infection.
3. Ledipasvir with sofosbuvir (HARVONI) plus ribavirin for 12 weeks for patients with decompensated liver disease, irrespective of genotype.

From 1 July 2016, VIEKIRA PAK and VIEKIRA PAK-RBV were listed for use in patients with HCV genotype (GT) 1, including patients with compensated cirrhosis, with a restriction limiting access to funded treatment to infectious disease specialists, gastroenterologists and hepatologists. This restriction was lifted on 1 October 2016, meaning that any relevant prescriber (including primary care) could access full funding for those products from that date. In the first 12 months of funding, more than 2000 patients were treated with Viekira Pak ± RBV. In the second 12 months an additional 1000 patients had been treated.

From 1 July 2016 until 12 June 2017, access to HARVONI was restricted to patients with decompensated cirrhosis with a Model for End-Stage Liver Disease (MELD) score of 15 or greater patients who were pre or post liver transplant and patients with cryoglobulinaemia. On 12 June 2017, the MELD threshold for patients with decompensated cirrhosis to access HARVONI was lowered from 15 to 12 in order to further widen access for this special population and increase salvage from death or transplantation. In December 2017, the criteria were widened further to include any patient who has decompensated cirrhosis (Child-Pugh class B or C) regardless of MELD score. To date, 161 patients with decompensated cirrhosis have been treated with HARVONI±RBV.

Detailed information is available on the PHARMAC website:

[www.pharmac.govt.nz/hepatitis-c-treatments](http://www.pharmac.govt.nz/hepatitis-c-treatments)

### ***Major advancements in the treatment of hepatitis C***

In February 2019, PHARMAC will fund the first pangenotypic oral DAA therapy glecaprevir with pibrentasvir (MAVIRET).

MAVIRET will be funded in the community and DHB hospitals without restrictions for all compensated patients infected with HCV regardless of genotype, including those with compensated cirrhosis and those with HIV infection. It will replace VIEKIRA PAK in GT 1 patients.

1. Treatment naïve non cirrhotic patients infected with HCV GT 1-6 will receive 3 tablets once daily for 8 weeks
2. Treatment naïve cirrhotic patients infected with HCV GT 1-6 will receive 3 tablets once daily for 12 weeks
3. Interferon-experienced non cirrhotic patients infected with HCV GT 1, 2, 4, 5, or 6 will receive 3 tablets once daily for 8 weeks
4. Interferon-experienced cirrhotic patients infected with HCV GT 1, 2, 4, 5, or 6 will receive 3 tablets once daily for 12 weeks
5. Interferon-experienced non cirrhotic patients infected with HCV GT 3 will receive 3 tablets once daily for 16 weeks
6. Interferon-experienced cirrhotic patients infected with HCV GT 3 will receive 3 tablets once daily for 16 weeks.

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As new DAA regimens become available in New Zealand, the hepatitis C guidance document will be reviewed and updated. This includes guidelines for the current unmet need for example for patients infected with HCV who have already failed a DAA regimen. It is estimated at the current rate of treatment uptake and an estimated virologic failure rate of 3% per annum, that approximately 90 patients have failed VIEKIRA PAK. The virologic failure rate with the new pangenotypic therapies are much lower (<1% per annum) so going forward, we expect to see a much lower number of patients requiring retreatment (approximately 10-20 pangenotypic DAA virologic failures per year).

Pangenotypic treatments (funded or unfunded) which will be available in New Zealand will include (i) MAVIRET- funded (glecapravir-pibrentasvir), (ii) EPCLUSA (sofosbuvir-velpatasvir) and (iii) DAKLINZA (daclatasvir) + SOVALDI (sofosbuvir) + ribavirin.

### **Purpose**

The purpose of this guidance is to outline the national level services that should be included in regionally led hepatitis C services. This includes the high level clinical pathway, minimum requirements, quality assurance frameworks, minimum standards and data collection required across all DHBs.

This guidance has been developed by the Hepatitis C Implementation Advisory Group.<sup>2</sup>

The clinical pathway includes awareness raising, targeted testing in order to identify undiagnosed individuals living with chronic hepatitis C infection, identification of people previously diagnosed but lost to follow-up, and assessment and management. This national clinical pathway will be based on best clinical practice and PHARMAC-funded antiviral therapy.

The national guidance is a living document that is updated regularly<sup>3</sup>.

At this time, none of the pangenotypic DAA regimens are approved for use in individuals under the age of 18 years. However, the label for MAVIRET will be changed in late 2019 to include all individuals over the age of 12 years (different formulation and dose).

New Zealand was one of 194 countries that adopted the World Health Organization (WHO)'s Global Hepatitis Strategy in May 2016. The strategy includes the WHO goal of elimination of viral hepatitis by 2030.

## **2. Minimum requirements**

Health care for people living with hepatitis C in New Zealand should provide integrated, accessible, and sustainable identification assessment and treatment services. These services should increase diagnosis rates, provide individualised care, improve patient-related outcomes, and reduce hepatic and extra-hepatic morbidity and mortality.

The following minimum requirements set parameters for the delivery of hepatitis C service in general practices and other primary, community and hospital settings. These key principles aim to promote national consistency in service delivery and support regional variation in approach to implement the most appropriate services to meet the needs of local populations.

### **Minimum requirements**

Hepatitis C services across New Zealand will provide quality identification, through testing and diagnosis; assessment; triage; and management, including monitoring, support and education to people with HCV.

<sup>2</sup> See appendix one for a list of members of the Hepatitis C Implementation Advisory Group

<sup>3</sup> See appendix two for a history of the updates to the national guidance document

Hepatitis C pathways will be based on best clinical practice and available antiviral therapy. A common clinical pathway will be followed across New Zealand to ensure equity of care for all New Zealanders living with HCV within the constraints of currently funded treatments.
Regionally led hepatitis C services will deliver integrated services across primary and secondary care. The national clinical pathway will be tailored to meet the needs of regional populations.
Hepatitis C identification will be primarily directed towards targeted testing for people who are at increased risk including: those who have ever injected drugs; ever received a tattoo or body piercing using unsterile equipment; had a blood transfusion before 1992; ever lived or received medical treatment in a high-risk country; ever been in prison or have been born to a mother with HCV. Those who have been previously diagnosed and lost to follow up will also be identified and treatment offered where possible and appropriate.
Primary and secondary care services will be extended to provide improved assessment and follow up services for people with HCV, including community-based Liver Elastography Scans and use of the calculator APRI, which uses blood tests available in all community laboratories.
Providers of hepatitis C services will be required to work with local organisations in their region that provide services to the population that are at high risk for HCV infection. This includes needle exchange services, community alcohol and drug services, prisons and community-based services hepatitis C clinics.

### **3. Clinical pathway for hepatitis C**

#### **3 (a) Introduction**

A single clinical pathway for hepatitis C care should be implemented across all regions of the country in order to provide consistent services which maximise the wellbeing of all New Zealanders living with HCV.

Key components include:

- raising community and GP awareness and education of the HCV and the risk factors for infection
- providing targeted testing of individuals at risk for HCV exposure
- raising patient and GP awareness of long-term consequences of HCV and the benefits of treatment, including lifestyle management and antiviral therapy
- providing community based access to HCV testing and care that will include education about non-invasive staging method of APRI and Liver Elastography Scans as a means for assessment of disease severity and as a triage tool for referral to secondary care and prioritisation for antiviral therapy
- providing community based ongoing education and support (including referral to needle exchange services, community alcohol and drug services, GP primary and community care services or social service agencies)
- providing long-term monitoring (long-term in people with cirrhosis and until cured in people without cirrhosis)
- providing good information sharing with relevant health professionals
- working collaboratively with primary and secondary care to improve access to treatment.

Note: The term 'Liver Elastography Scans' used within this document includes mobile and fixed Fibroscan machines and Shear Wave machines being used in radiology departments.

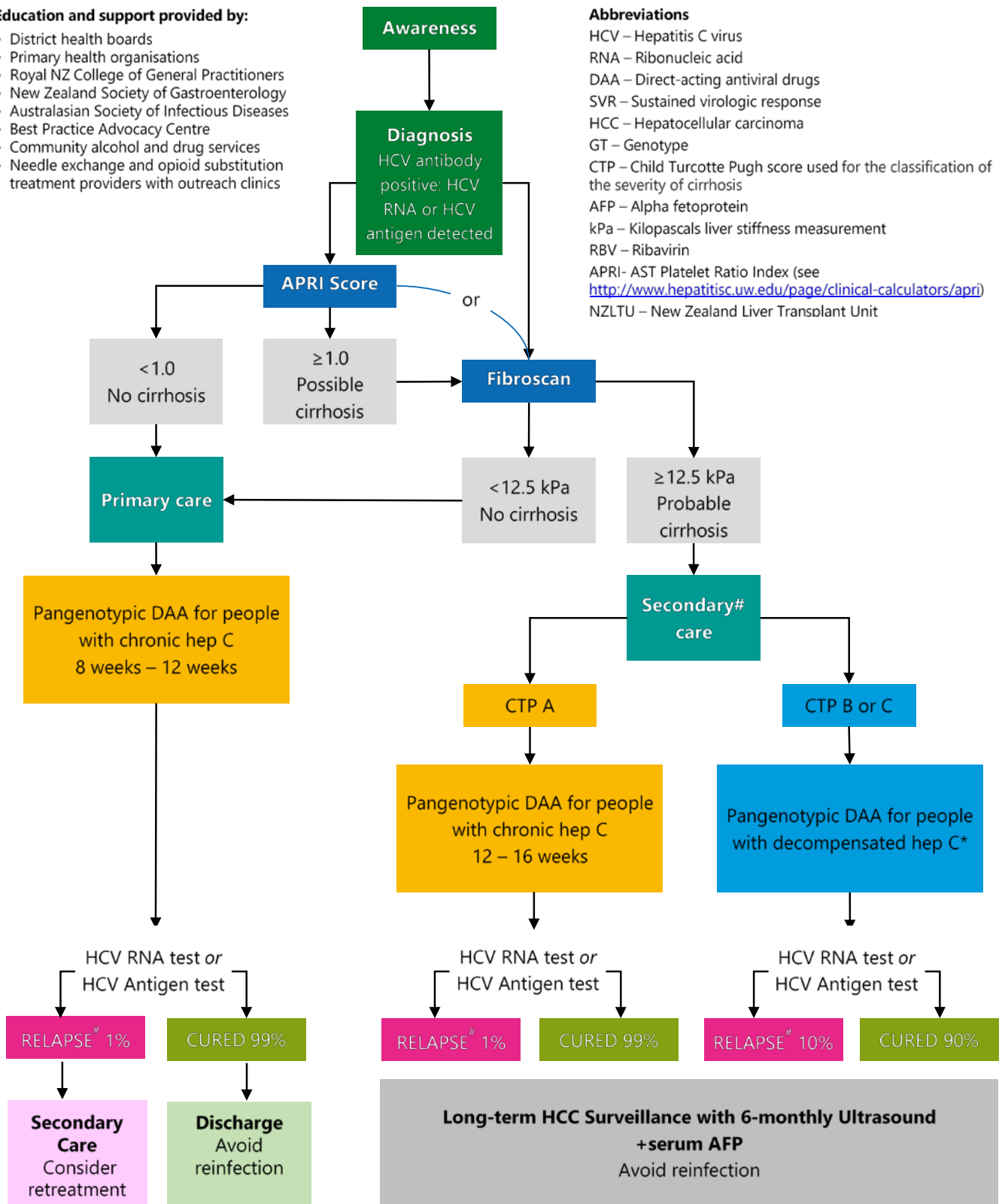
Figure one: Clinical pathway for hepatitis C based on integrated primary and secondary services

**Education and support provided by:**

- District health boards
- Primary health organisations
- Royal NZ College of General Practitioners
- New Zealand Society of Gastroenterology
- Australasian Society of Infectious Diseases
- Best Practice Advocacy Centre
- Community alcohol and drug services
- Needle exchange and opioid substitution treatment providers with outreach clinics

**Abbreviations**

- HCV – Hepatitis C virus
- RNA – Ribonucleic acid
- DAA – Direct-acting antiviral drugs
- SVR – Sustained virologic response
- HCC – Hepatocellular carcinoma
- GT – Genotype
- CTP – Child Turcotte Pugh score used for the classification of the severity of cirrhosis
- AFP – Alpha fetoprotein
- kPa – Kilopascals liver stiffness measurement
- RBV – Ribavirin
- APRI- AST Platelet Ratio Index (see <http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>)
- NZLTU – New Zealand Liver Transplant Unit



# In addition to all patients with cirrhosis, refer the following to Secondary Care:  
 1. Patients with HIV co-infection  
 2. Patients with HBV co-infection  
 3. DAA Failures (including VIEKIRA PAK, HARVONI and Fix HepC Generics)  
 4. Under 18 years of age

\*All applications for DAAs in decompensated HCV cirrhosis will be assessed by Expert Panel  
 Patients with CTP-B or C or CTP-A with suspected hepatocellular carcinoma who are potential candidates for liver transplantation should be discussed with NZLTU prior to initiating treatment. Deferring treatment until after transplant may be preferred in some cases.

### 3 (b) Notes on key components of the clinical pathway for hepatitis C

#### Clinical considerations

##### **AST Platelet Ratio Index (APRI) and Liver Elastography Scan assessment**

Current duration of PHARMAC funded treatment is based on disease stage – 8 weeks for non-cirrhotic and 12 weeks for cirrhotic. There are two commonly used non-invasive methods for determining cirrhosis status – APRI and liver elastography. Because the APRI can be calculated from a blood test in the community, many GPs may now prefer to use this as the first line staging method rather than refer for a Fibroscan (Liver Elastography Scan).

1. **AST Platelet Ratio Index** The patient needs a blood test to measure serum aspartate aminotransferase (AST) and platelet count. These values are then inserted into the on-line calculator to determine the AST Platelet Ratio Index (APRI Score Calculator website: <http://www.hepatitisc.uw.edu/page/clinical-calculators/apri>). If APRI is <1.0 then the patient does NOT have cirrhosis and can be treated for 8 weeks. If APRI is ≥ 1.0 then the patient has a 50% chance of having cirrhosis and should be referred for a Fibroscan to confirm whether or not cirrhosis is present.
2. **Liver Elastography Scan assessment:** Liver stiffness is measured with a Fibroscan or Shear wave machine. It can be ordered by the GP through e-referrals and does not require a First Specialist Appointment. Services delivering Liver Elastography Scans will communicate results with the person's GP and refer to secondary care if required. A liver stiffness measurement of greater than 12.5 kPA is consistent with cirrhosis and an indication for referral to hospital clinic for secondary care physician and nurse specialist management, including treatment when appropriate, and surveillance for hepatocellular carcinoma (HCC) and varices.

#### Notes

- If a patient has not been treated or has failed DAA therapy and is awaiting retreatment then Liver Elastography Scan or APRI should be repeated every three years.
- If a patient has evidence of recent infection (either recently documented seroconversion or episode of acute icteric hepatitis with only recent history of high-risk behaviour including injecting drug use and MSM) then staging of liver fibrosis with either Liver Elastography Scan or APRI is not required.
- If a patient has already had documented cirrhosis by any means (such as Liver Elastography, radiology or laboratory tests), there is no need to repeat the scan.
- **Always perform APRI or Liver Elastography Scan BEFORE starting treatment.** If the patient has been cured with DAA therapy, both will significantly underestimate the severity of liver disease and therefore miss the diagnosis of cirrhosis and need for long-term surveillance for HCC). The only indication to repeat the Liver Elastography Scan or APRI after successful treatment if the patient has ongoing risk factors for disease progression such as obesity or heavy alcohol intake.

#### Education, awareness and finding those lost to follow up on the clinical pathway

##### **Awareness**

Targeted public awareness is required as it is estimated that half of those infected with HCV are unaware of this. Raising awareness and education for GPs and other primary and community care providers is also required, using a risk factor approach to target testing in primary care for people who have:

- ever injected drugs
- ever received a tattoo or body piercing using unsterile equipment
- had a blood transfusion before 1992
- ever lived or received medical treatment in a high risk country
- ever been in prison
- been born to a mother with HCV

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- ever been previously jaundiced or have unexplained abnormal liver function.

### **Identification / diagnosis**

Identification includes finding those previously diagnosed but lost to follow up. This is likely to happen in a range of primary and community care settings and occasionally in secondary care.

Actions to increase identification/diagnosis include:

- engaging with Māori
- engaging with immigrants from SE Asia and Middle East, at-risk and hard to reach groups including people who inject drugs and prisoners
- engaging with needle exchange services, prisons, opioid substitution treatment providers and community alcohol and drug services
- supporting primary and community care to trace those previously identified with HCV but lost to follow-up
- opportunistic targeted testing at general practice.

### **Diagnosis**

Laboratories will be encouraged to work together to:

- ensure consistent laboratory practices throughout New Zealand, where possible
- explore mechanisms for laboratory-generated APRI scores.

The NZ Microbiology Network will produce a diagnostic algorithm focusing on:

- removing barriers to testing – explore possibility for reflex testing for all relevant patient specimens
- minimising unnecessary / repeat testing
- appropriate and consistent commenting to help guide further investigations and therapy, particularly for primary care.

### **Health advice, education and support**

Education and support will be provided by a range of services including:

- District health boards
- Primary health organisations
- Royal New Zealand College of General Practitioners
- New Zealand Society of Gastroenterology
- Australasian Society of Infectious Diseases
- Best Practice Advocacy Centre
- Hepatitis Foundation of New Zealand
- Community alcohol and drug services
- Needle exchange services
- Hepatitis C community clinics
- Māori health providers
- Pacific health providers.

These services will provide support, advice and information for HCV patients, including referral to non-government support organisations. Appropriate education packages on HCV diagnosis, management and support will be made available to GPs, primary care nurses and other primary and community care providers. General practice and secondary care services will ensure that people in their care identified as having HCV are not lost to follow-up.

### **Recall process for Liver Elastography**

It is important to include a recall process for Liver Elastography Scanning in untreated patients when the service delivery model is developed at the regional level. This will include an audit process to ensure people receive hepatitis C services consistently with no gaps in the delivery of these services.

The four DHB regions will share their plans to support national consistency. A handover process when patients move between regions needs to be developed to ensure continuity in Liver

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Elastography Scanning recall. Appendix three provides identification of training and accreditation requirements for health professionals utilising the fibroscanners.

### **3 (c) Horizon scanning**

Future DAA regimens will also provide effective retreatment options for patients who have failed to respond to current DAA regimens including VIEKIRA PAK, HARVONI, generic DAAs such as those sourced from the FixHepC Buyers Club (LDV/SOF, DAC/SOF, SOF/VEL) and MAVIRET. These will need to be with a different DAA regimen containing at least one different class of DAAs. Any such patient should be referred to a hospital clinic for further assessment and monitoring. He/she will require resistance analysis prior to retreatment.



## 4. Key performance indicators for hepatitis C

Outcomes	Key Performance Indicators (KPIs)	Data source
<b>A. REGIONAL MEASURES</b>		
<b>Design process indicators (initial phase only)</b>		
<b>Stakeholders involved in regional design of services</b>	<ul style="list-style-type: none"> <li>Primary health care providers including general practice, primary health organisations, relevant community providers, Māori/ Pacific providers, needle exchange/methadone programme providers, community drug and alcohol services, secondary care, and tertiary providers of national services such as liver transplants and liver cancer, involved in regional design.</li> <li>Electronic pathways, such as the HealthPathways, are updated to show an integrated hepatitis C clinical pathway.</li> </ul>	
<b>Service delivery process and outcome measures – All data to be broken down by ethnicity and age, reported six monthly</b>		
<b>Increased diagnosis</b>	1. Number of people diagnosed with hepatitis C per annum (by age)	<b>Data and source:</b> Total number of people with a positive hepatitis C virus (HCV) Polymerase Chain Reaction (PCR) or antigen test in the DHB region (data from 5 reference labs provided to DHB regions and in future from community labs who perform antigen tests).
<b>Better care</b>	2. Number of people receiving PHARMAC funded antiviral treatment (by age, ethnicity and medication type (note NHI, date of prescription and prescriber data will be also provided where possible))	<b>Data and source:</b> Total number of people prescribed antiviral treatment who have hepatitis C (data from PHARMAC provided to DHB regions).  Note that from 1 February 2019 community pharmacy data will be used to report on Maviret prescribing. Harvoni data will continue via central dispensing reports provided by PHARMAC.
<b>B. NATIONAL MEASURES<sup>4</sup> – All data to be broken down by ethnicity and age</b>		
<b>Decreased morbidity and mortality</b>	3. Incidence of HCV-related hepatocellular carcinoma (HCC)	<b>Data source:</b> Liver Transplant Unit HCC national data collection (reported nationally and broken down by region)
	4. Number of liver transplants for people with hepatitis C performed each year	<b>Data source:</b> Liver Transplant Unit (reported nationally and broken down by region)
<b>Increased diagnosis</b>	5. Percentage of patients with HCV that has caused HCC who have new HCV diagnosis at the time of HCC cancer diagnosis	<b>Data source:</b> Liver Transplant Unit HCC national data collection (reported nationally and broken down by region – data from Research Fellow review of case notes)

<sup>4</sup> Data from the three national measures will be provided to regions, rather than any additional DHB data collection processes.

## 5. Minimum standards

Outcomes	KPIs	Minimum Standards (Data would be compared with year one baseline)
<b>A. REGIONAL MEASURES</b>		
Increased diagnosis	1. Number of people diagnosed with hepatitis C per annum (by age).	Increasing year-on-year diagnosis
Better care	2. Number of people receiving PHARMAC funded antiviral treatment per annum (by age, ethnicity (note NHI and date of prescription data will be also provided where possible)).	Increasing number of people with hepatitis C receiving antiviral treatment
<b>B. NATIONAL MEASURES</b>		
Decreased morbidity and mortality	3. Incidence of HCV-related HCC	Decreasing numbers of HCV related HCC over time
	4. Number of liver transplants for people with hepatitis C performed each year	Decreasing numbers of hepatitis C related liver transplants
	5. Incidence of HCV-related HCC	Decreasing numbers of HCV related HCC over time
Increased diagnosis	6. Percentage of patients with HCV caused HCC who have new HCV diagnosis at the time of HCC cancer diagnosis	Decreasing number of patients with HCV caused HCC who have new HCV diagnosis at time of HCC diagnosis

## 6. Data collection

### Regional measures

As part of the Regional Service Planning (RSP) requirements in 2015/16, DHB regions reported on the design process indicators outlined in KPI section 4. This took place during the initial phase of planning of implementation planning from July 2015 to June 2016 for Midland and Central regions, and from July 2015 to September 2016 for South Island and Northern regions.

From the commencement of an integrated regional hepatitis C service in 2016/17, DHB regions are reporting on the service delivery process and outcome measures in section 4 as outlined in the table below. Data is broken down by ethnicity and age bands (by decade), reported six monthly.

### ***Regional Service Planning Measures – Hepatitis C***

Quarterly narrative report on progress of the key actions

Report six monthly at the end of quarter two (20 January) and the end of quarter four (20 July) on the following measures:

Measures	Data collection process
1. Number of people diagnosed with hepatitis C	DHB regions to obtain data (by age bands) from 5 reference labs, and in future from community labs who perform antigen tests, on the total number of people with a positive HCV PCR and/or antigen test and report to the Ministry of Health via six monthly RSP reports

### National measures

PHARMAC will provide the following quarterly data to the Ministry that will be shared with DHB regions.

Measures	Data collection process
2. Number of people receiving PHARMAC funded antiviral treatment per annum	Ministry of Health to obtain data (by age, ethnicity) from PHARMAC and provide this to DHB regions via annual reporting in the RSP (Note that from 1 February 2019 community pharmacy data will be used to report on Maviret prescribing. Harvoni data will continue via central dispensing reports provided by PHARMAC)

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National hepatitis C data collection will also take place from the Liver Transplant Unit at Auckland DHB. Data will be collected on the measures below to DHB via regional service planning.

<b>Measures</b>	<b>Data collection process</b>
3. Incidence of HCV related HCC  4. Number of liver transplants for people with hepatitis C performed each year  5. Percentage of patients with HCV caused HCC who have new HCV diagnosis at the time of HCC cancer diagnosis	Ministry of Health to obtain data (by age and ethnicity) from the Liver Transplant Unit HCC national data collection and provide this to regional DHB regions via annual reporting in the RSP

## 7. Quality Assurance Framework

Quality Assurance Framework for Hepatitis C						
The framework is based on the principle that all people in New Zealand with long term conditions live longer, healthier and more independent lives <sup>5</sup>						
Outcomes (Regional)	Awareness and Diagnosis	Access to care and information	Care better coordinated	Decreased morbidity and mortality	Increased self-management	Improved personal wellbeing
<b>Patient level indicator / benchmark</b>	<ul style="list-style-type: none"> <li>• More hepatitis C diagnoses</li> <li>• Earlier diagnosis</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Community-based assessment</i></li> <li>• <i>Informed discussion / communication</i></li> <li>• Increasing number of people with hepatitis C receiving antiviral treatment</li> </ul>	<ul style="list-style-type: none"> <li>• <i>People with complex conditions have care plans</i></li> </ul>	<ul style="list-style-type: none"> <li>• Less people develop cirrhosis and liver cancer</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Self-rated self-management</i></li> </ul>	<ul style="list-style-type: none"> <li>• <i>Personal wellbeing</i></li> </ul>
<b>Measures</b>	<ul style="list-style-type: none"> <li>• Number of people diagnosed with hepatitis C per annum (by age)</li> <li>• Decreasing number of patients with HCV that has-caused HCC who have new HCV diagnosis at the time of HCC cancer diagnosis</li> </ul>	<ul style="list-style-type: none"> <li>• # % who seek treatment following diagnosis</li> <li>• #% in a monitoring programme following Liver Elastography Scans</li> <li>• Number of people receiving PHARMAC funded antiviral treatment per annum (age and ethnicity) (PHARMAC)</li> <li>• Proportion being treated in the community</li> </ul>	<ul style="list-style-type: none"> <li>• # % of people with hepatitis C with care plans <sup>6</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Incidence of HCV related HCC (Liver transplant unit broken down by region-national collection)</li> <li>• Number of liver transplants for people with hepatitis C performed each year (Liver transplant unit – national collection)</li> </ul>	<ul style="list-style-type: none"> <li>• Survey</li> </ul>	<ul style="list-style-type: none"> <li>• Survey</li> </ul>

<sup>5</sup> The text in italics is an example of some of the indicators and measures being considered for the Long Term Conditions work programme in the Ministry of Health which also provides an overarching framework for Hepatitis C

<sup>6</sup> DHB reporting not currently available but could be included in annual planning guidance

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<p><b>System level performance measure</b></p>	<ul style="list-style-type: none"> <li>Increasing year-on-year hepatitis C diagnosis</li> <li>More people with HCV are diagnosed earlier</li> </ul>	<ul style="list-style-type: none"> <li><i>Access to self-management support and treatment options</i></li> </ul>	<ul style="list-style-type: none"> <li><i>Access to coordination by multi-disciplinary teams</i></li> </ul>	<ul style="list-style-type: none"> <li>Decreasing numbers of HCV related HCC over time</li> <li>Decreasing numbers of hepatitis C related liver transplants</li> </ul>	<ul style="list-style-type: none"> <li><i>Level of use of patient portal<sup>7</sup></i></li> </ul>	
<p><b>Measures</b></p>	<ul style="list-style-type: none"> <li>Number of people diagnosed with hepatitis C per annum (<i>as defined by positive RNA or antigen testing</i>)</li> <li>Decreasing number of patients with HCV-that has caused HCC who have new HCV diagnosis at the time of HCC cancer diagnosis</li> </ul>	<ul style="list-style-type: none"> <li><i>Availability of self-management programmes</i></li> <li>Number of people receiving PHARMAC funded antiviral treatment per annum (age and ethnicity) (PHARMAC)</li> <li>Number of HCV patients who have had a Liver Elastography Scan in the last year in primary and secondary care (by age and ethnicity) – new patients – follow-up</li> </ul>	<ul style="list-style-type: none"> <li><i>Number of patients with support from Multi-Disciplinary Teams across services guidance</i></li> </ul>	<ul style="list-style-type: none"> <li>Incidence of HCV related HCC (Liver transplant unit broken down by region-national collection)</li> <li>Number of liver transplants for people with hepatitis C performed each year (Liver transplant unit – national collection)</li> </ul>	<ul style="list-style-type: none"> <li><i>Percentage of total people with hepatitis C using patient portal</i></li> </ul>	
<p><b>Improved equity outcomes – indicators by ethnicity and gender</b></p>						

<sup>7</sup> Patient portals are offered to patients by GPs with large variation in uptake (very limited adoption by practices generally) and functionality

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### Appendix One

Members of the Hepatitis C Implementation Advisory Group involved in developing and updating the hepatitis C guidance document.

<b>Dr Carol Atmore and Dr Tony Farrell</b>	General Practitioners and Royal New Zealand College of General Practice representatives
<b>Karen Browne</b>	Consumer panel representative
<b>Dr Cheryl Brunton</b>	Public Health Specialist, Canterbury DHB
<b>Professor Ed Gane (Chair)</b>	Hepatologist, Auckland City Hospital
<b>Sandy McLean</b>	Team Leader Planning and Funding, Canterbury & West Coast District Health Boards
<b>Dr Arlo Upton</b>	Clinical Microbiologist
<b>Matthew Tyson and Meena Vallabh</b>	Therapeutic Group Manager, PHARMAC Senior Implementation Lead, PHARMAC
<b>Dr Jeffrey Wong</b>	Gastroenterologist, Hutt Hospital

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### Appendix Two

The national guidance is a living document that is updated regularly. A history of the updates are summarised below.

- Version 1.0 was published on the Ministry's website and on the Nationwide Service Framework Library (NSFL) site on April 2016.
- Version 2.0 was updated in June 2016 following the announcement from PHARMAC that DAA therapy would be funded from 1 July 2016 (Viekira Pak and Harvoni).
- Version 3.0 was updated in August 2017 to take into account the lowered threshold for Harvoni.
- Version 4.0 was updated in January 2019 following the announcement from PHARMAC that they will fund the first pangenotypic oral DAA therapy (glecaprevir with pibrentasvir (MAVIRET)) for people with chronic hepatitis C regardless of genotype from 1 February 2019.



## Appendix Three

### Identification of training and accreditation requirements for health professionals utilising the fibroscanners

#### Principles for Fibroscan Training

It is important that the Fibroscan service is able to provide reliable and reproducible results with minimal inter and intra-observer variability

It is important that everyone is trained to a worldwide standard and undergoes regular refresher training. A national Fibroscan Operator User Group is being set up in 2015 with the inaugural meeting in Auckland scheduled for mid-2016.

#### Manufacturer's training policy

To deliver the training of a Fibroscan, a person must have a trainer's certificate issued by Echoscens©.

This involves one day of e-learning using PowerPoint presentations supplied by the New Zealand Liver Transplant Unit, one day introductory course by an accredited Echoscens trainers (usually supplied by Medical Technologies, Sydney).

Only persons appointed by Echoscens© are authorised to deliver training and issue certificates for the use of FibroScan® range of products and its probes.

Persons that may undergo training in the use of FibroScan® products are those who will be in charge of operating the devices.

The number of trainees is limited for the practical part of the course and depends on the type of training given.

#### In-house Training

Selection of Operators for training - It is preferred that Fibroscan operators have hands-on experience in managing patients with chronic viral hepatitis, given that over 90% of procedures are performed to stage disease severity in patients with chronic viral hepatitis and this will facilitate the interpretation of the scan result. Previous Liver Biopsy experience may be an advantage, but is not essential. Clinical nurse specialists in the field of hepatology should be encouraged to train in this. But notwithstanding this, Nurses not trained in liver biopsy can achieve up to the same success rate. Note - results will sometimes require interpretation and therefore should be discussed with a specialist, especially if compared with severe fibrosis or cirrhosis.

To gain accreditation, Fibroscan operators are required to perform 50 Fibroscans under supervision from an experienced operator before they function as independent providers. Additional supervision will be required in order to gain competency in complex cases such as patients with non-alcoholic fatty liver disease and liver transplant recipients and in using the portable Fibroscan and the XL probe (obese patients), Fibroscans on the morbidly obese and other complex patients. Although the newest machines in New Zealand have continuous attenuation parameter (CAP) technology which allows measurement of hepatic steatosis, CAP measurements should not be reported given the lack of regulatory approval of this new technology.

## **Skill Maintenance**

In order to maintain competency, it is recommended that a trained operator should perform a minimum of 50 Fibroscans per annum to maintain skills. In order to ensure this, most centres should employ a maximum of two operators.

## **Audit Requirements**

Fibroscan operators should be audited on a regular basis. The key performance indicator is the proportion of reliable procedures. It is suggested that every operator provide a log of how many scans he/she performs on an annual basis for all indications.

The success of the procedure is assessed according to ability to obtain at least one valid result.

The reliability of the procedure is assessed according to the following parameters updated in November 2013:

1. Minimum of 10 valid readings per patient
2. Interquartile range <30% ONLY if median LSM >7.1 kPa

It is important that in addition to these figures a case-mix is provided (including the primary diseases sampled, proportion of obese patients, and availability of the XL probe). The operator's understanding of the factors which influence the liver stiffness values and validity of that measurement plus the ability to interpret a reading according to aetiology (i.e. different cut-offs) should also be assessed during these audits.

Audits will be undertaken after the first year and then subsequently every five years at each centre, using data from the Fibroscan Hard Drive for all procedures performed over the previous 12 calendar months. These should be reviewed anonymously by an agreed national body (Note it is suggested that initially this should be an individual within the New Zealand Liver Transplant Unit (either Professor Gane or Dr Orr) or Dr Frank Weilert at Waikato Hospital).