# Eliminating Hepatitis C in New Zealand Green Paper

The urgent need to develop a Hepatitis C National Action Plan

Presented to the Minister of Health by the Hepatitis C Summit Steering Committee October 2018

# New Zealand is required to develop a National Hepatitis C Action Plan to achieve the World Health Organisation 2030 targets to eliminate Viral Hepatitis

New Zealand is one of the 194 Member States to adopt the World Health Organization (WHO) strategy to eliminate viral hepatitis as a major public health threat by 2030. In addition, elimination of viral hepatitis is an integral part of the global movement to achieve the United Nations Sustainable Development Goals.<sup>1</sup>

As stated by the WHO, we are at a turning point. If governments take action to achieve a set of prevention, testing, and treatment targets, we can make the global elimination of viral hepatitis by 2030 our next greatest achievement.<sup>2</sup>

To assist with progress, the WHO published the first <u>Global Health Sector Strategy on Viral Hepatitis</u> <u>2016–2021</u>, (the Strategy) in 2017. The public health approach and commitment to achieving health equity covered in the Strategy align with commitments made by your Government regarding being driven by a concern to promote greater equity of outcomes and to put people's wellbeing at the heart of your policies.

The Strategy lists priority actions for governments, including:

- 1. Develop a national plan on viral hepatitis with a budget based on the global health sector strategy on viral hepatitis and integrate it into the broader national health programme.
- 2. Set national targets and define indicators based on global targets and indicators, to monitor and evaluate, and to report on the national hepatitis response.

Many countries have developed or are developing National Hepatitis Plans, including many of the OECD countries.<sup>3</sup> However, **New Zealand is well behind other nations** as shown in **Exhibit 1**. Australia by comparison is about to release its fifth National Hepatitis Strategy with clear targets and measures to be achieved by 2022, including a specific goal to eliminate the negative impact of stigma and discrimination on people's health. We consider that this is also critical to include in New Zealand's plan.

Both the New Zealand Health Strategy and recently published Director-General of Health's Annual Report on the State of Public Health highlight similar themes that underpin the need for a comprehensive National Hepatitis C Action Plan.

This includes acknowledging that:

- Some populations are affected more than others by disability and ill health, particularly Māori and Pacific peoples, and those living in areas of high socioeconomic deprivation.
- Poor health affects the quality of life of individuals and can also have impacts that ripple out through whānau into the wider community.
- It is a priority for the Ministry of Health to improve equitable health outcomes for all New Zealanders, particularly those that the system does not serve so well at present.

The Hepatitis C Summit Steering Group therefore asks that, as Minister of Health, you commit the resources of your senior Ministry officials to work in partnership with diverse sector leaders and develop a fully funded National Hepatitis C Action Plan. This will achieve the WHO elimination targets and thereby ensure all New Zealanders can have a future free of hepatitis C.

<sup>&</sup>lt;sup>1</sup> https://www.un.org/sustainabledevelopment/sustainable-development-goals/

<sup>&</sup>lt;sup>2</sup> http://www.who.int/hepatitis/strategy2016-2021/portal/vision-goal-targets/en/

<sup>&</sup>lt;sup>3</sup> http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/

# The Hepatitis C Summit Steering Committee 2018

(alphabetical by surname)

#### **Prof Tim Dare**

Professor of Philosophy, Auckland University

# **Dr Tony Farrell**

General Practitioner, Mount Medical Centre

# **Prof Ed Gane**

Chief Hepatologist, Deputy Director NZ Liver Transplant Unit, Auckland City Hospital

#### **Chris Jay**

Manager Practice and Policy, Pharmaceutical Society of New Zealand

#### Dr Emalia Lavemai

GP Fellow, Turuki Healthcare

#### **Kathryn Leafe**

Executive Director, National Needle Exchange Programme

#### **Dr Jed Montayre**

Chair NZNO Nursing Research Section, Lecturer Faculty of Health & Environmental Sciences, Auckland University of Technology

# **Sheridan Pooley**

Community Alcohol & Drug Services Regional Consumer Advisor, Chair Matua Raki Consumer Leadership Group

# **Assoc Prof Catherine Stedman**

Gastroenterologist and Clinical Pharmacologist, Christchurch Hospital

#### Jacqui Stone

Clinical Nurse Specialist, Middlemore Hospital

#### **Tania Tito-Edge**

Project Manager, Te Rau Matatini National Centre for Māori Health, Māori Workforce Development and Excellence

# **Dr Arlo Upton**

Clinical Microbiologist, Southern Community Laboratories

#### **Dr Frank Weilert**

Gastroenterologist Waikato Hospital

**Disclaimer:** This Green Paper is a working paper and represents the opinions of the authors – the members of the Hepatitis C Summit Steering Committee. It is the product of professional research and discussion and the information and views contained are those of the Hepatitis C Summit Steering Committee, and are independent to AbbVie. AbbVie initiated the Hepatitis C Summit 2018 and provided sponsorship support for venue and logistics costs for the committee to convene and for the physical production costs of the paper.

# Countries with National Hepatitis Plans (May 2017)



Exhibit 1. Countries with a National Hepatitis Plans based on WHO country reports (May 2017).4

<sup>&</sup>lt;sup>4</sup> http://www.who.int/hepatitis/publications/global-hepatitis-report2017/en/

# The Steering Committee recommends key components of a National Action Plan

The Hepatitis C Summit Steering Committee in consultation with the <u>Center for Disease Analysis</u> <u>Foundation</u> have developed preliminary recommendations for the key components and structure of a National Action Plan to eliminate hepatitis C in New Zealand.

Each component contains specific recommendations and potentially unresolved issues to be aware of when committing the Ministry of Health to work with the broader sector and develop a National Action Plan.

The preliminary recommendations were presented to the wider hepatitis C community at the Hepatitis C Summit 2018 (Auckland, 28th July 2018). The summit attendees included consumer groups, specialists, general practitioners, nurses, representatives of people who use drugs, pharmacists, and addiction practitioners.

# New Zealand needs a National Action Plan to meet the 2030 elimination targets

In May 2016 New Zealand, together with 194 other countries, signed up to the WHO target to eliminate viral hepatitis C as a public health threat by 2030. New Zealand must therefore meet the following WHO-prescribed elimination targets:<sup>5</sup>

- Diagnose 90% of the infected population.
- Treat 80% of the eligible population.
- Reduce infection by 90%.
- Reduce deaths from hepatitis C by 65%.

New Zealand's current treatment uptake (approx. 2%/year<sup>6</sup>) is below the estimated treatment rate (>7%/year<sup>7</sup>) required to achieve elimination of hepatitis C by 2030. New Zealand's treatment rate could be increased by:

- 1. Finding the people with hepatitis C who are undiagnosed.
- 2. Improving linkage to care (i.e. all people with active hepatitis C virus infection should be linked to a healthcare professional who is prepared to provide comprehensive treatment).
- 3. Providing access to pangenotypic direct-acting antiviral agents.

Initial first steps toward increasing the treatment rate have started with PHARMAC's proposal to fund a pangenotypic direct-acting antiviral agent, which can cure the infection in nearly all individuals (although no decision has yet been made). The Ministry of Health is also working on a community-based awareness, testing, and treatment programme through the Health Promotion Agency, although it is understood that this will be limited in scope.

# Barriers to achieving the required treatment rate are still significant

There are six major concerns:

- 1. Lack of awareness and education among the public, patients, and healthcare professionals.
- 2. Stigma and discrimination for people with hepatitis C among the public and some healthcare professionals.
- 3. Gaps in the coordination of care and services.
- 4. Lack of peer and healthcare professional support for people with hepatitis C.
- 5. Absence of a co-ordinated and collaborative national elimination strategy.
- 6. Lack of epidemiological data in the New Zealand context.

<sup>&</sup>lt;sup>5</sup> http://www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/

<sup>&</sup>lt;sup>6</sup> Ed Gane (unpublished data)

<sup>&</sup>lt;sup>7</sup> Polaris Observatory (<a href="http://www.polarisobservatory.org/">http://www.polarisobservatory.org/</a>)

A National Action Plan is needed to further address the barriers to diagnosing and treating all people with hepatitis C. Ensuring that hepatitis C is eliminated in New Zealand by 2030 will require the development, financing, and implementation of a National Action Plan as soon as possible.

# There are many health outcome benefits of having a National Action Plan

Starting now, diagnosing and treating nearly all people with hepatitis C by 2030 will deliver the following health outcomes:<sup>8</sup>

- Reduce total hepatitis C infections by 83%.
- Prevent 2,300 deaths.
- Prevent 1,200 cases of decompensated liver cirrhosis.
- Prevent 1,600 cases of hepatocellular carcinoma.
- Prevent 500 liver transplants.

Achieving elimination of hepatitis C by 2030 will avert a 125–140% increase in hepatitis C-related cirrhosis, liver cancer, and liver-related deaths.

# Four priority focus areas in the National Action Plan

The Hepatitis C Summit Steering Committee proposes that a National Action Plan for elimination of hepatitis C should focus on four priority areas:

- 1. Reducing hepatitis C health disparities.
- 2. Preventing new hepatitis C infections.
- 3. Averting deaths and disease burden due to hepatitis C.
- 4. Co-ordinating and monitoring elimination activities and reporting on progress.

Structurally, a National Action Plan could consist of eight key components or 'pillars' underpinned by destigmatisation strategies and activities across all of the pillars, and an overarching political commitment to implementation of the pillars (Exhibit 2).

# Two critical success factors of Political Will and addressing Discrimination

Political will is critical to the success of a National Action Plan because it enables the eight pillars to be fully implemented with adequate resourcing and support. Political will is also the only reliable predictor of a country achieving the WHO 2030 elimination targets as its absence is the most common trait among the countries currently not on track (which includes New Zealand).<sup>9</sup>

Destigmatisation ('normalisation' of hepatitis) underpins the eight pillars. Stigma and discrimination, especially against people who use drugs, are barriers to all approaches for eliminating hepatitis C. According to Bulterys and Hamid (Bulletin of the World Health Organization 2018) five population groups (people who inject drugs, people in prisons or other closed settings, men who have sex with men, sex workers, and indigenous populations) require specific public health approaches because of stigma and discrimination, vulnerability, and difficulties in accessing services.

#### Issues to be addressed:

1. Ensure the government is willing to achieve its commitment to the World Health Organisation by supporting and funding a National Action Plan for hepatitis C.

<sup>&</sup>lt;sup>8</sup> Polaris Observatory (<a href="http://www.polarisobservatory.org/">http://www.polarisobservatory.org/</a>) and Ed Gane (unpublished data)

<sup>&</sup>lt;sup>9</sup> Polaris Observatory (2018). 'The authoritative resource for epidemiological data, modelling tools, and decision analytics to support global elimination of hepatitis B and C by 2030': <a href="http://cdafound.org/polaris/">http://cdafound.org/polaris/</a>

2.	Minimise the negative impact of sti	ma and discrim	าination on peop	ole's health and
	wellbeing.			

#### **Political will** \$ 1. 2. 3. 4. 5. 6. 7. 8. **Increase** A national A national **Targeted Improve** A national **Adequate Improve** screening resourcing & prevention screening monitoring awareness registry access & evaluation funding for the & & harm programme programme to care for hepatitis C understanding reduction for hepatitis C duration of the system of hepatitis C elimination strategies programme Include national targets with well-defined Totrack Develop indicators, i.e. screening, diagnosis & Identify & culturally treatment rate enable all NZ responsive >7% of the & enable an people with strategies to **HCV** infected & reinfection. national & effective national hepatitis C the improve access population programme that to testing & care targeted opportunity peryearto address ethics & Secure funding programmes & for populations awareness for a curative meet the 2030 target. for 20 years. at risk. campaigns. privacy issues. treatment. Destigmatisation

**Exhibit 2.** Infographic summarising the eight pillars of the proposed National Action Plan to eliminate hepatitis C in New Zealand. Each pillar requires political will to ensure full implementation and the removal of hepatitis-related stigma and discrimination.

# Increase awareness and understanding of hepatitis C - Pillar 1

Awareness and educational campaigns are necessary to inform people's understanding of hepatitis C and to reduce the stigma associated with hepatitis C among the public, patients, and some healthcare professionals.

#### **Primary recommendations:**

- 1. Implement a national awareness campaign to raise public awareness of hepatitis C as a serious health concern whilst also addressing the stigma associated with this diagnosis.
- 2. Implement targeted awareness campaigns for marginalised populations to encourage testing and to advise people of the availability of a cure.
- 3. Awareness campaigns should be understandable, accessible, and resonant for all people especially Māori.
- 4. Provide patient education on options for care and treatment and reducing risks.
- 5. Provide healthcare professional education on reducing duplicate testing and training for point-of-care workforce and other prescribers.

#### Secondary recommendations:

- 1. Consider developing and implementing community-focussed awareness campaigns to promote the availability of a curative and safe treatment.
- 2. Consider developing and implementing awareness campaigns that specifically target Māori men.

# Improve prevention strategies - Pillar 2

In the absence of a vaccine for hepatitis C, it is necessary to implement strategies that will help to reduce exposure to the virus in people who inject drugs.

#### **Primary recommendations:**

- 1. Upscale harm reduction measures to prevent ongoing transmission and re-infection in people who inject drugs (and identify and treat re-infection when it does occur).
- 2. Promote peer worker counselling and education of people who inject drugs to facilitate prevention of transmission.

#### Issues to be addressed:

1. How can point-of-care education and testing be conducted in a way that doesn't alienate or discourage people who become re-infected from engaging with care?

# A national registry - Pillar 3

A national registry is necessary to facilitate an effective national screening programme for hepatitis C as well as to track diagnosis and ensure that there is linkage to care.

To link people newly diagnosed with hepatitis C to clinical care, a national registry will need to be identifiable and will need to address people's concerns about privacy.

Key components of a national registry for hepatitis C:

- Identifiable data. This is necessary to (i) prevent duplication of testing and thereby reduce costs of finding new cases and (ii) ensure every new diagnosis is linked to care.
- Automatic notification of all new laboratory diagnoses.
- Patient management system (to ensure recall and linkage to appropriate treatment).
- Generation of epidemiological data (to identify trends and inform policy).
- Independent and trusted ownership.

- Linking to the current REACH-C treatment registry to track the progress of the national hepatitis C elimination strategy.
- Linking to liver cancer and liver transplant registries to provide trends of hepatitis C-related disease burden.
- Public funding provided by the government/district health boards.

#### Issues to be addressed:

- How would a national hepatitis C registry be funded? It is important to emphasise that
  unlike any other national registries (including infectious diseases and cancer), the need for
  funding for a national hepatitis C registry will be finite. The pan-genotypic treatment
  combined with improved awareness and testing should increase treatment uptake to >7%
  per annum, a rate that will meet the 2030 WHO Elimination Targets. This would enable
  disestablishment of the registry by 2035.
- 2. Is there an existing registry that meets the needs or can be adapted to meet the needs of a national hepatitis C registry?
- 3. Who should own/manage this registry?
- 4. To prevent duplicate testing (which will reduce the cost of diagnosis), can the registry be designed/adapted to generate hepatitis C test requests only for those people who require one?
- 5. How can personal data be protected without limiting the functionality of the registry?
- 6. Will individuals be able to access and correct their personal data?
- 7. How to gain patient and physician trust and acceptance so the registry does not become a barrier to care?
- 8. What are the legal requirements of an identifiable registry?

# A national screening programme for hepatitis C - Pillar 4

A national screening programme is necessary to ensure that every person with hepatitis C in New Zealand is diagnosed and offered a curative treatment.

The current strategy of targeted testing is not diagnosing enough people with hepatitis C. Testing of the general population is therefore needed to increase the rate of diagnosis to ensure that the required treatment rate to eliminate hepatitis C (i.e. >7% of the infected population per year) is met and maintained.

### Options for population-level testing:

- Universal testing of all adults. <u>Note:</u> For the majority of people this will be a once-in-a-lifetime test, unless they have ongoing risk factors.
- Birth-cohort testing of all adults born between 1955 and 1975.
- Targeted testing of high-risk populations, in particular people who inject drugs who attend
  needle exchanges and opioid substitution treatment services. <u>Note:</u> This option will help to
  reduce the spread of hepatitis C but will not identify all of the undiagnosed people who are
  at risk of hepatitis C-related severe liver disease because of the long duration of infection.

#### Essential components for universal screening:

- Less expensive antibody test kits.
- Combining lower cost hepatitis C virus antibody tests with reflex hepatitis C virus ribonucleic acid antigen tests if positive.
- Incentivising healthcare professionals to prioritise awareness and testing for hepatitis C, which includes elevating the role of practice nurses.
- Increasing community access to testing, e.g. point-of-care testing by addiction services, needle exchange, and potentially pharmacists.

- Patients to have a national health index number so that the results are fed into the national registry (via integrated laboratory services).
- A reduction in multiple testing.

# **Primary recommendations:**

- 1. Implement laboratory standardisation/harmonisation for hepatitis C testing.
- 2. Develop guidelines on rational screening for healthcare professionals (general practitioners, pathologists, practice nurses, Community Alcohol and Drug Services practitioners, and potentially pharmacists).

#### Issues to be addressed:

- 1. Can low-cost HCV antibody tests be used across community laboratories to reduce the costs of initial testing in the national testing programme?
- 2. Can the hepatitis C virus ribonucleic acid antigen test replace the current hepatitis C virus ribonucleic acid PCR (polymerase chain reaction) test to reduce the costs of confirming hepatitis C infection in individuals who test hepatitis C virus antibody positive in the national testing programme?
- 3. Can reflex hepatitis C virus antibody/hepatitis C virus antigen testing be introduced in community laboratories using their current Abbott Architect biochemical analysers?
- 4. Can rapid point-of-care anti-hepatitis C virus antibody diagnostic tests employing serum, plasma, fingerstick whole blood, or saliva be used as alternatives to standard enzyme immunoassays as a part of the national screening programmes?
- 5. Can rapid point-of-care hepatitis C virus ribonucleic acid tests (e.g. GeneXpert) be used in high-risk populations such as needle exchanges and opioid substitution treatment centres?
- 6. Can point-of-care screening include combined hepatitis C virus and hepatitis B virus testing?

# Targeted screening programme for hepatitis C - Pillar 5

Ongoing targeted testing will be necessary (in addition to universal testing) to ensure that the required treatment rate to eliminate hepatitis C (>7% of the infected population per year) is met and maintained because some people are less likely to access universal screening (including Māori, people who are marginalised, and those engaging in activities that place them at higher risk of contracting the virus).

The foundation of a targeted screening programme will be culturally-responsive strategies to improve access to testing and care for populations that are at ongoing risk of contracting hepatitis C.

# Issues to be addressed:

- 1. How can specific target populations that are not engaged with primary care be reached (e.g. transient people and people or who live in rural areas)?
- 2. Is it feasible to screen for hepatitis C in community mental health centres?

# Improve access to care - Pillar 6

The objective of improving access to care is to provide access to pangenotypic treatment with no restrictions and broaden the prescriber base to include nurses and pharmacists.

Improving access to care will require:

- Treatment with no restrictions.
- Pangenotypic treatment.
- Expanding access to prescribing to include nurses and pharmacists.

- Providing financial support through the current regional District Health Board Steering Committee funding or Primary Options for Acute Care funding to incentivise prescribers to test and treat.
- Providing financial support through Work and Income New Zealand to incentivise individuals with a community services card to get tested and treated (e.g. to cover cost of a GP visit and/or travel to see a GP/community laboratory for testing).

#### Issues to be addressed:

- 1. Is national point-of-care testing by pharmacists feasible?
- 2. How to best equip nurses in primary care (i.e. practice nurses, needle exchange nurses) to deliver treatment?
- 3. Is there a need for post-cure ongoing care and support, especially for people who continue to inject drugs and if so what might that consist of?
- 4. How can mental health and homeless services be targeted for screening and linkage to care (populations using these services are likely to have a high prevalence of infection and low treatment uptake)?
- 5. Negotiate with Jill Clendon, Chief Nursing Officer, and the New Zealand Nursing Council, for direct-acting antiviral drugs to be added to the Medication List?

# National monitoring and evaluation system - Pillar 7

Ongoing monitoring and evaluation using national targets with well-defined indicators will be essential to track the effectiveness of a National Action Plan.

The most reliable measure for tracking progress to achieving the 2030 elimination targets is to treat >7% of the hepatitis C-infected population every year for the next 12 years.

# **Primary recommendations:**

- 1. Establish an independent steering committee to:
  - o Monitor and report healthcare sector response to guide future response.
  - Track the rate of new diagnosis and linkage to care (treatment uptake).
  - o Ensure quality of data collection and analysis.
  - Inform Ministry of Health and PHARMAC of progress towards the WHO 2030 hepatitis C elimination targets.
  - o Ensure that personal data is being not being shared.

# Adequate resourcing and funding for the duration of the programme - Pillar 8

Adequate resourcing of **all components** of a National Action Plan is essential to ensure elimination of hepatitis C by 2030. This includes considering the impact on General Practices, pharmacies, community organisations and other allied health.

Countries that are currently on track to eliminate hepatitis C by 2030 have National Action Plans with budgets that are fully funded by governments or charitable organisations.

#### **Primary recommendations:**

1. Resourcing and funding for all components will need to be secured for at least 15 years.

# Further information available to support the Ministry of Health

In developing this Green Paper, the Steering Committee has drafted an additional document that captures further details covered under each pillar. The Steering Committee therefore welcomes the opportunity to work in collaboration with the Ministry of Health, Ministry of Social Development,

Department of Corrections, and other organisations and groups as required in drafting the Hepatitis C National Action Plan.

The Steering Committee look forward to this Government's commitment to eliminating hepatitis C in New Zealand by 2030.