



The time has come to eliminate hepatitis C in Canada

Executive Summary

CTAC is Canada's non-governmental organization led by and for people living with HIV and HIV/HCV co-infection, focusing on access to treatment. Since 1996, we have been working to secure and ensure equitable, affordable and timely access to testing, treatment, care and support for people in Canada living with HIV and HIV/HCV co-infection and other co-morbidities. We acknowledge that, to realize a place in which all Canadians will have full and equitable access to treatment will necessitate work on multiple fronts. This paper, and its associated calls to action, will focus on treatment access policy issues that must be addressed in order for Canada to fully realize the goal of elimination of viral hepatitis as a global health threat by 2030.

Within Canada, an estimated 220,000-245,000 Canadians are infected with hepatitis C, unfortunately, around 44% of those individuals are unaware of their status¹, and are often only diagnosed incidentally to something else.² Additionally, there is a large population of individuals (ex: baby boomers) currently aging with HCV, whether diagnosed or not, who are now experiencing complications of HCV, some of which are quite severe, such as cirrhosis, liver failure and death.³ Those who remain untreated have a ~5-fold increased all-cause and ~20-fold increased risk of liver-related mortality.⁴ Individuals with chronic hepatitis also face a host of

¹ Current estimates suggest that, globally, there are approximately 71 million individuals living with chronic hepatitis C (HCV).¹ Between 2000-2015, within the 2.45 million deaths from viral hepatitis worldwide, 48% of those deaths was due to HCV infection. (Mason, Kate, et al. "Understanding Real-World Adherence in the Directly Acting Antiviral Era: A Prospective Evaluation of Adherence among People with a History of Drug Use at a Community-Based Program in Toronto, Canada." *International Journal of Drug Policy*, vol. 47, Sept. 2017, pp. 202–208., doi:10.1016/j.drugpo.2017.05.025.)

² Recommendations on Hepatitis C Screening for Adults." *Canadian Medical Association Journal*, vol. 189, no. 16, 24 Apr. 2017, doi:10.1503/cmaj.161521.

³ Fox, D. Steven, and Jeffrey S. McCombs. "Optimizing HCV Treatment:-Moving beyond the Cost Conundrum." *Journal of Hepatology*, vol. 65, no. 1, July 2016, pp. 222–225., doi:10.1016/j.jhep.2016.02.010.

⁴ Janjua, Naveed Zafar, et al. "Twin Epidemics of New and Prevalent Hepatitis C Infections in Canada: BC Hepatitis Testers Cohort." *BMC Infectious Diseases*, vol. 16, no. 1, 19 July 2016, doi:10.1186/s12879-016-1683-z., pg. 1

co-morbidities (ex: diabetes) and face a number of other potential health and psychosocial ramifications.⁵

Canada is currently lagging in terms of our commitment to eliminate viral hepatitis as a public health threat as per the WHO 2030 targets. Under the WHO strategy developed in 2016, Canada has committed to treat 80% of people with the disease by 2030.

The populations living with HCV today are larger than ever before, and are made up of Canada's most marginalized communities including, newcomers, Indigenous peoples, and injection drug users. This does not have to remain the case, and Canada's WHO commitment is achievable. Hepatitis C has a cure, and Canada has had access to these curative medications (highly effective, highly tolerable direct-acting antivirals) since 2015. Additionally, the pan-Canadian Pharmaceutical Alliance (pCPA) announced in early 2017 a new framework that has brought down the price of treatment. However, despite this significant development on the pricing front, too few people are being treated. In Canada, as elsewhere, hepatitis C rates are on the rise because we have not implemented comprehensive public health strategies to stem the tide.

Calls to Action

There is a role for coordinated national response, including collaboration between federal, provincial and territorial governments, to end hepatitis C in the next 10 years. This is a call to action to policy-makers and community leaders to adopt a more comprehensive action plan in order to achieve hepatitis C elimination in Canada.

1. Increased access to testing, including point-of-care testing, rapid testing, and one-time cohort screening for all baby boomers

We will not achieve elimination without making the testing process for HCV more accessible to all those who desire it. One way to achieve this is through point-of-care testing. Point-of-care testing (POCT) encompasses diagnostic tests that can be performed by a health care professional, or other qualified personnel, whether that be self-tests administered and completed by the patient themselves in the home or in a community setting (pharmacies, community health clinics, etc.). The advantage of this form of testing is that it is extremely convenient. It allows individuals to access testing when, and where, it is easiest for them. If the initial test results are positive, preliminary linkage to care options can be initiated while confirmatory testing is done.

This type of technology is widely used in other countries such as the United States, United Kingdom, and Australia. However, there is a paucity of research around the implementation of

⁵ Global Health Sector Strategy on Viral Hepatitis 2016-2021." *World Health Organization*, World Health Organization, www.who.int/hepatitis/strategy2016-2021/ghss-hep/en/.

POCT testing in Canada, and policies, guidelines and accessible information about POCT testing varies widely across the country.

POCT, and related testing modalities such as dried blood spot testing, could enhance access to HCV testing for many Canadians. Therefore, we encourage the Public Health Agency of Canada and provincial public health agencies to work together to invest in, and expedite the adoption/implementation of, these testing technologies across Canada with clarity and consistency. In conjunction with education and awareness efforts, this would allow those who know they are infected with HCV, even when asymptomatic, to take measures to reduce transmission.

The current screening guidelines for hepatitis C, released by the Canadian Medical Association in 2017⁶, state that testing should remain risk-based. This stance was taken by the taskforce charged with creation of the guidelines, as it was felt that there was not enough compelling evidence to waver from that position, especially when compared against the burdensome effect that testing/treating an entire cohort of individuals would have on the Canadian healthcare system. However, it is important to note that these guidelines were released prior to the pCPA announcement that a significant price reduction had been negotiated for a cluster of HCV medications. The price of treating is dropping and, with this, provinces have committed to considering the loosening of eligibility requirements. Roland Grad, the chair of the taskforce stated that if more provinces were to make these moves towards covering more individuals under public drug plans, these recommendations should be revisited.⁷

CTAC contends that the time for this is now and is calling for one-time HCV testing of the baby boomer cohort.

2. Removal of restrictive eligibility requirements to access treatment

The pCPA and participating drug plans announced in 2017 their new pricing framework to bring down the cost of HCV medications. As such, it is time for treatment eligibility to be opened, so anyone with hepatitis C, no matter where they live, can be cured.

We also recommend that approaches, where HCV specialists and general practitioners can work together to treat patients, be considered by governments, so that wait times for diagnosis and treatment are mitigated. Now is the time to make sure all of us do our part to make sure medications are rolled out to everyone who needs them.

⁶ "Recommendations on Hepatitis C Screening for Adults." *Canadian Medical Association Journal*, vol. 189, no. 16, 24 Apr. 2017, doi:10.1503/cmaj.161521.

⁷ Grant, Kelly. "Canadian Task Force Rejects Calls for Widespread Hepatitis C-Testing." *The Globe and Mail*, 24 Apr. 2017, www.theglobeandmail.com/news/national/canadian-task-force-rejects-calls-for-widespread-hepatitis-c-testing/article34793882/.

Restrictive eligibility requirements continue to exist in Canada, despite commitments from provincial and territorial public drug plans to lower these restrictions⁸, and recommendations from global bodies such as the World Health Organization (WHO) and the European Association for the Study of the Liver (EASL) to open access to all of those infected, regardless of fibrosis score.⁹

3. Access to all hepatitis C medications approved by Health Canada on public drug programs

The populations living with HCV are not well served in Canada's patchwork health care system, with separate jurisdictional responsibilities for health in each province and territory, and at the federal level. A complex web of public and private drug coverage, and in some cases lack of coverage, creates inequity, restricting access for many. What medications people can get, at what cost, varies widely, depending on the forms of public and private insurance available to them.

Current access to HCV treatment in Canada is shaped more by where a person lives than what they need. Canada's patchwork of 18 publicly funded drug programs results in inequitable access to HCV treatments across the country, such as differential drug co-payments that force people to make choices between treatment and other basic needs such as shelter and food.

4. Creation of a framework by the pan-Canadian Pharmaceutical Alliance (pCPA) to standardize processes and timelines and add transparency

Through the pCPA, all 13 provinces and territories, as well as the federal government, have been working together to achieve greater value for brand name and generic drugs for publicly funded drug programs.

A lack of standardized timelines for review and price negotiation, both between the manufacturer and the pCPA, and the manufacturer and individual drug formularies across the country, has resulted in bottlenecks in the availability of new medications.

These delays in the listing of drugs are extremely problematic, especially given the fact that the pCPA, in its current form, has no governing rules that establish how provincial and territorial governments interact with each other or their obligations.

CTAC calls on the pCPA to create a framework to address the lack of standardization around timelines for the negotiation of drugs, enhance transparency around the decision-making

⁸ TIP, Hep C. "BC Ministry of Health Press Release: More Patients to Benefit from Hepatitis C Treatments." *Hepatitis C Treatment Information Project*, 21 Feb. 2017, www.hepctip.ca/drug-pipeline-2/bc-ministry-health-press-release-patients-benefit-hepatitis-c-treatments/.

⁹ Zahnd, Cindy, et al. "Modelling the Impact of Deferring HCV Treatment on Liver-Related Complications in HIV Coinfected Men Who Have Sex with Men." *Journal of Hepatology*, vol. 65, no. 1, July 2016, pp. 26–32., doi:10.1016/j.jhep.2016.02.030.

process, and ensure all drugs that have a positive recommendation from CADTH and/or INESS proceed quickly to the pCPA negotiating table.

5. Removal of the time delay between the close of pCPA negotiations and the signing of Product Listing Agreements with individual provincial and territorial formularies

Innovative treatments need to be available to all Canadians in a timely manner. It is a growing trend that provinces complete pricing negotiations, through the pCPA, yet are waiting several months to put a product on their formulary.¹⁰ It is crucial that the time delay between the close of pCPA negotiations and the signing of Product Listing Agreements with individual formularies is removed to allow timely access to crucial medications.

6. Lower drug costs

CTAC acknowledges that much work has been done to try to bring down the cost of HCV therapies. However, the current price still remains quite high and places an economic barrier to some individuals being able to access the medications they need, despite the fact that treating individuals early has also been proven to be cost-effective.¹¹

Canada has access to the medications necessary to cure people and eliminate HCV as a public health threat; especially as newly emerging drugs have broadened the populations that could be effectively treated. Therefore, it is imperative that the cost of medication continues to decline in order to maximize the number of individuals being able to access publically funded, curative treatments in a timely manner.

7. A standalone viral hepatitis plan

Canada lacks a stand-alone hepatitis action plan, and a clear commitment to the well-being and quality of life of people living with HCV. Strategies at the provincial, territorial, and federal levels are needed that set measurable goals, and are in line with WHO goals and measures of success.

An HCV specific plan, and associated funding, is necessary to:

- Adequately support existing services;
- Achieve the goals established by international targets;
- Scale-up innovative integrated health care models that will help to address quality of life;
- Scale-up treatment and harm reduction efforts that would target priority populations;

¹⁰ Husereau, Don, et al. "Evolution of Drug Reimbursement in Canada: The Pan-Canadian Pharmaceutical Alliance for New Drugs." *Value in Health*, vol. 17, no. 8, Dec. 2014, pp. 888–894., doi:10.1016/j.jval.2014.08.2673, pg. 893

¹¹ Chidi, Alexis P., et al. "Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients." *Value in Health*, vol. 19, no. 4, June 2016, pp. 326–334. doi:10.1016/j.jval.2016.01.010.

- Preserve and strengthen the exceptional networks of community- based organizations that respond most effectively to the needs of people at risk of or living with HCV;
- Support the engagement of people living with HCV in shaping their care; and
- Support the continuation of services in smaller communities.

With this would come the need for not just measurable targets but comprehensive and accurate data with an emphasis on the importance of community adding to this and validating the data to help ensure its accuracy. This data will be key to a well-informed, comprehensive, strategic national hepatitis plan/response.