Washington State Health Care Authority

Hepatitis C Free WA progress report

Hepatitis C elimination strategy in 2021

Engrossed Substitute House Bill 1109; Chapter 415; Laws of 2019; Section 211(45)

Report Period – July 1, 2021 – September 30, 2021

Hepatitis C Elimination strategy in 2021

Acknowledgements

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Executive summary

The hepatitis C virus (HCV) attacks the liver and can cause serious health problems, including cirrhosis (scarring of the liver), liver failure, cancer, and death. HCV infection is the most common disease in the United States (U.S.) spread through blood-to-blood contact. Estimates indicate that there are between 2.4 million and 3.5 million people in the U.S., and approximately 60,000 in Washington State, living with HCV infection. Both nationally and in Washington, new HCV infections more than tripled between the years 2010 and 2016, primarily due to rising rates of people injecting drugs.

There is no vaccine for HCV. Newly developed direct acting antivirals (DAAs) to treat HCV infection have a cure rate over 95 percent. Most people with HCV can be cured using a DAA in eight to twelve weeks, with few side effects.

In September 2018, Washington State Governor Jay Inslee issued Directive of the Governor 18-13 that called for the "Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach." Governor Inslee directed the Department of Health (DOH) and the Health Care Authority (HCA) to lead the state's elimination efforts.

The Washington State Legislature also provided direction to HCA and DOH regarding HCV elimination in the 2019-2021 operating budget. A budget proviso required HCA to work with DOH and others to establish a comprehensive DAA purchasing strategy and report on HCV elimination progress.

Both HCA and DOH have made progress toward eliminating HCV infections from Washington State. HCA entered into two contracts with drug manufacturer AbbVie to purchase the DAA Mavyret (pronounced MAV-ih-reht) for state-funded health care programs.

- The Medicaid contract is a value-based supplemental rebate agreement that provides a discount on Mavyret for HCA's Apple Health (Medicaid) fee-for-service and managed care programs. As part of the modified subscription model, HCA negotiated an annual threshold, based on the approved state budget. Additional Mavyret purchases above that annual threshold will cost HCA a nominal amount per pill for the rest of the year. This contract also leverages public health services that align with the HCV elimination plan.
- The non-Medicaid contract is a pharmaceutical discount and rebate agreement that provides a discount on Mavyret to non-Medicaid state agency health plans and programs.

Under the new AbbVie contracts, the average cost of treating a client with HCV infection is about 40 percent lower than the average per-client cost before the AbbVie contracts. The total amount spent by the state however will not decrease since we are moving forward with our elimination plan and intend to treat significantly more people with HCV. This quarter, 365 HCA covered lives were treated.

DOH facilitated the development of the "Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030" by establishing Hep C Free Washington — a collective impact initiative composed of multisector partners with the shared goal of eliminating the public health threat of HCV in Washington.

- The Plan outlines 15 recommended goals and 90 action items addressing HCV data and strategic information, community-based responses and interventions, and clinical strategies to eliminate HCV.

- For the 2020 legislative session and supplemental budget, DOH requested funding to scale up HCV testing and linkage to care activities and elimination initiative coordination to begin moving into the implementation phase of the HCV elimination effort.

The COVID-19 pandemic diverted public health and delivery systems attention during 2020 and 2021. The response to the pandemic removed mass screening opportunities which rely on large public gatherings, as well as routine preventive screening accessed in medical offices. During this time the agencies focused on the work captured below including developing and delivering provider education, creating key reporting and information systems and exploring opportunities for service integration with Opioid Treatment Programs and Syringe Service Programs.

As we move out of the pandemic, our attention will turn to:

- Working with the Apple Health Managed Care Organizations to assure patients under their coverage are appropriately screened, connected to care and receiving the needed treatment and medication.
- Working with the local health jurisdictions to understand and support the strategies they will be using within their communities.
- Refining the data infrastructure to support timely reporting of status, opportunities and accomplishments.
- Understanding and addressing systemic issues associated with screening and treatment.

DOH will continue to lead the Hep C Free Washington Coordinating Committee and related work groups as the state transitions from planning to implementation. Washington will continue to progress toward the goal of becoming the first state in the nation to eliminate the public health threat of HCV.

Background

The hepatitis C virus (HCV) is a blood-borne virus that attacks the liver and can cause serious health problems, including cirrhosis (scarring of the liver), liver failure, cancer, and death. The virus spreads through blood-to-blood contact. Currently, sharing equipment for drug injection is the most common route of HCV transmission. Prior to improved screening methods that became available in 1992, HCV was primarily contracted through blood transfusions and organ transplants. HCV can also spread through needlestick injuries in health care settings, from parent living with HCV to their child at birth, through unregulated tattooing or piercing, and by other methods.[1]

HCV infection is the most common blood-borne (spread by blood) disease in the United States (U.S.).[2]

- According to the Centers for Disease Control and Prevention (CDC), the estimated number of people in the U.S. living with HCV infection ranges from 2.4 million to 3.5 million people.[3][4]

[1] Hepatitis C Questions and Answers for Health Professionals, from www.cdc.gov/hepatitis/hcv/hcvfaq.htm# accessed on March 15, 2021.

[2] Viral Hepatitis C in Washington State, page 12, from www.doh.wa.gov/Portals/1/Documents/Pubs/420- 159-HCVEpiProfile.pdfaccessed on March 15,, 2021.

[3] Hepatitis C Questions and Answers for Health Professionals, from www.cdc.gov/hepatitis/hcv/hcvfaq.htm#accessed on March 15,2021

[4] Disease Burden from Viral Hepatitis A, B, and C in the United States, from www.cdc.gov/hepatitis/statistics/DiseaseBurden.htm, accessed on August 6, 2019.

- According to the Washington State Department of Health (DOH), the estimated number of people living with HCV in Washington State during 2018 was nearly 60,000.[5][6]

Both nationally and in Washington, reported cases of acute (new) HCV infections more than tripled between the years 2010 and 2016.[7][8] Although HCV infection has historically impacted mostly Baby Boomers (those born between 1945 and 1965), younger people are becoming increasingly infected through sharing of injection equipment, primarily related to the opioid crisis and increases in methamphetamine use.[9]

Unlike hepatitis A and B viruses, which also infect the liver but are unrelated viruses to HCV, there is currently no vaccine to prevent HCV infection. However, there are oral medications (pills) that can cure a person living with HCV.[10] Current HCV treatments use combinations of drugs called direct-acting antivirals (DAAs). DAAs directly target HCV in different ways to stop it from making copies of itself. Newly developed DAAs have a cure rate over 95 percent. Most people living with HCV infection can be cured by taking DAAs for eight to twelve weeks, with few or no side effects.[11]

There is a national movement to eliminate the public health threat of HCV by combining public health strategies, such as improved preventive services, education, harm reduction services, testing, and linkage to care, with access to DAA treatment. In 2017, the National Academies of Sciences, Engineering, and Medicine (formerly the Institute of Medicine) released a national strategy to eliminate viral hepatitis as a U.S. public health problem by 2030.[12] In addition, the U.S. Department of Health and Human Services developed the National Viral Hepatitis Strategic Plan, in 2020 for 2021-2025.[13] These national strategies align with the Hep C Free Washington recommendations to eliminate the public health threat of HCV in our state.

Although effective curative treatment is now available, access to curative medications is a significant issue. Considerable barriers remain, including the difficulty of navigating the health care system, stigma experienced by people who use drugs, and the lack of primary care providers treating HCV.

Some people who use drugs are at risk for or living with co-occurring issues and life domain issues, including other infectious diseases like HIV, syphilis, and skin and soft tissue infections (e.g., cellulitis, endocarditis), mental health challenges, and housing insecurity. With appropriate care, people who use

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[5] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 5, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on March 15,2021.

[6] Hepatitis C Elimination in Washington State, page 2, from www.doh.wa.gov/Portals/1/Documents/Mtgs/2018/HSQAMeetingPackets/OctoberORW/HuriauxORW20181023.pdf,accessed on March 15,2021.

[7] Disease Burden from Viral Hepatitis A, B, and C in the United States, from www.cdc.gov/hepatitis/statistics/DiseaseBurden.htm, accessed on March 15,2021.

[8] 8 Hepatitis C Elimination in Washington State, page 3, from www.doh.wa.gov/Portals/1/Documents/Mtgs/2018/HSQAMeetingPackets/OctoberORW/HuriauxORW20181023.pdf,accessed on March 15, 2021.

[9] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, pages 4-5, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on March 15, 2021

[10] What is Viral Hepatitis?, from www.cdc.gov/hepatitis/abc/index.htm, accessed on March 15, 2021

[11] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 73, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on March 15, 2021.

[12] A National Strategy for the Elimination of Hepatitis B and C: Phase Two Report, from nationalacademies.org/hmd/Reports/2017/national-strategy-for-the-elimination-of-hepatitis-b-and-c.aspx, accessed on March 15, 2021.

[13] National Viral Hepatitis Action Plan, from https://www.hhs.gov/hepatitis/viral-hepatitis-national-strategic-plan/index.html accessed on March 15, 2021.

drugs can have high rates of HCV medication adherence, achieve high rates of virologic cure, and have low rates of reinfection. Despite this, people who actively use drugs continue to face considerable challenges in finding care providers willing to treat HCV. When treated for HCV, people who use drugs report significant improvements in their ability to take charge of their overall health and increases in their ability to engage in health care for other associated infectious diseases.[14] Effectively linking someone to curative medication has a significant public health benefit as curing HCV prevents onward transmission of the virus. It's imperative that effective public health strategies exist to link people at highest risk for transmitting the virus to care and supportive services.

Governor's Directive to eliminate hepatitis C

On September 28, 2018, Washington State Governor Jay Inslee issued Directive of the Governor 18-13. The directive called for the "Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach."[15] Elimination is not the same as eradication.

- **Elimination**: In the case of HCV, elimination is a state where HCV is no longer a public health threat and where those few who become infected with HCV learn their status quickly and access curative treatment without delay, preventing the forward spread of the virus.
- **Eradication**: Generally, eradication is the reduction of the worldwide incidence of a disease to zero as a result of deliberate efforts, obviating the necessity for further control measures. True eradication usually entails eliminating the microorganism itself or removing it completely from nature.[16]

Describing the challenge to eliminate HCV in Washington, the Governor stated:

> HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.
> In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan.[17]

Governor Inslee directed DOH and the Health Care Authority (HCA) to lead the state's elimination efforts:

- DOH shall lead the effort to develop the elimination plan as part of this comprehensive public health response; and
- HCA shall lead and coordinate with DOH and other agencies and purchasers to establish a purchasing strategy for DAAs and needed public health interventions to eliminate HCV by 2030.17

[14] Beyond clinical outcomes: the social and health care implications of hepatitis C treatment. September 24, 2020. Torrens et al. BMC Infectious Diseases. (2020) 20:702

[15] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on March 15, 2021.

[16] Hep C Free Washington: Plan to Eliminate Hepatitis C in Washington State by 2030, page 73, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on March 15, 2021.

[17] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on March 15, 2021

Appendix A of this report includes the complete text of Directive of the Governor 18-13.

Hep C Free Washington – plan to eliminate hepatitis C in Washington State by 2030 and progress to date

The Governor's directive included the following detail about DOH developing a strategy to eliminate HCV in Washington:

> DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the [HCA's HCV medication purchasing strategy].[18]

This section briefly summarizes the Hep C Free Washington "Plan to Eliminate Hepatitis C in Washington State by 2030", which was developed by the Coordinating Committee convened by DOH.
Since October 2018, DOH has convened regular meetings of multisector partners to develop the "Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030."[19] Members of the Hep C Free Washington Coordinating Committee include:

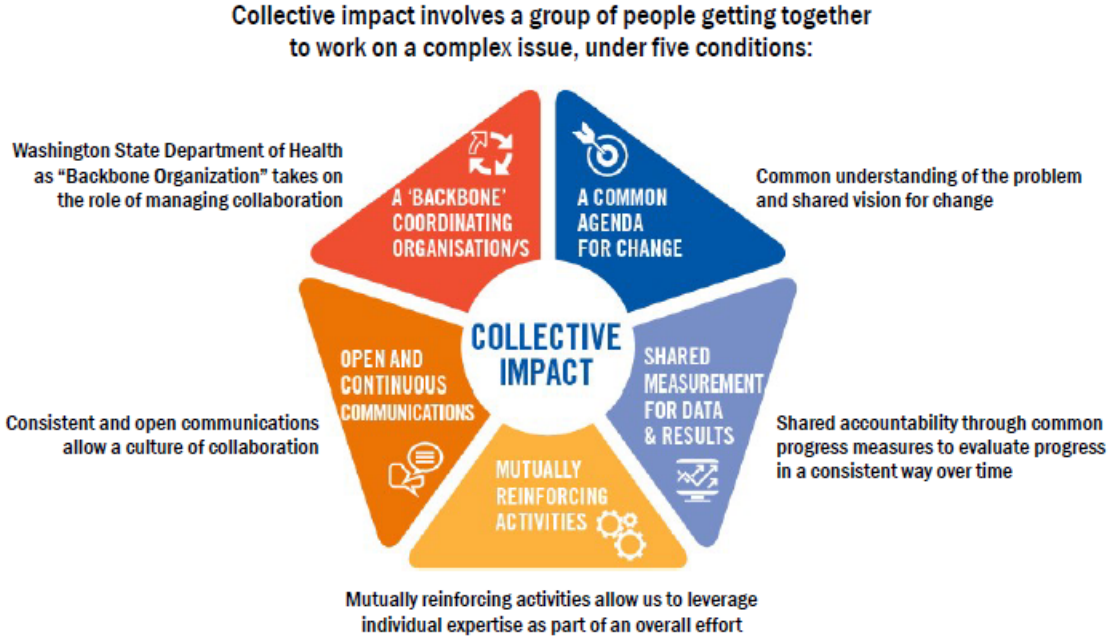
- Representatives from state agencies and offices;
- Tribal health centers;
- Local health jurisdictions;
- Federally qualified health centers;
- Community-based organizations;
- Syringe service programs;
- Opioid treatment programs;
- Academic institutions (i.e., the University of Washington and Washington State University);
- Health plans;
- Professional organizations; and
- People affected by HCV.

DOH acts as the "backbone organization" for Hep C Free Washington. Within a collective impact framework (figure 1), the backbone organization takes on the role of managing the collaboration to tackle a complex issue (in this case, HCV elimination).

[18] Directive of the Governor 18-13, Elimination of Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach, from www.governor.wa.gov/sites/default/files/18-13%20-%20Hepatitis%20C%20Elimination.pdf, accessed on March 15, 2021

[19] Hep C Free Washington Plan to Eliminate Hepatitis C in Washington State by 2030, page 12, from www.doh.wa.gov/Portals/1/Documents/Pubs/150nonDOH-HepCFreeWA-PlanJuly2019.pdf, accessed on March 15, 2021

Figure 1



The Committee established three work groups, Data & Strategic Information, Community-Based Responses & Interventions, and Clinical Strategies to draft recommendations based on their specific expertise. The Committee and three work groups developed 15 goals containing 90 recommended action steps.

Below is an outline of the Hep C Free Washington plan goals and progress made during the reporting period January 2021 through June 2021. Please note that elimination efforts during this reporting period were significantly hampered by the COVID-19 pandemic. All DOH hepatitis C program and surveillance staff were activated to the COVID-19 response for significant parts of 2020, ranging from three months to six months. This meant that many Hep C Free Washington coordinating committee and work group calls were canceled throughout the year and other activities were put on hold. Hep C Free Washington partners were also significantly impacted by COVID-19, particularly partners providing clinical services and direct community services, and were unable to participate in any Hep C Free Washington efforts during this time. DOH's Office of Infectious Disease partners contracted to provide community-based HCV testing and case management services suspended in-person service delivery and very little community-based HCV testing occurred during this time. In addition, many clinics throughout the state suspended non-essential medical visits, including visits that would involve routine HCV testing in primary care. Clinical partners also reported a significant decline in new HCV treatment starts during 2020 because of many clinics limited operating hours and because of patient hesitancy to go to medical facilities during the pandemic.

Overarching Coordination Goal

1. Ensure implementation of the Hep C Free Washington recommendations in order to achieve HCV elimination by 2030.

Create Hep C Free WA work groups focused on how to address the HCV prevention, care, and treatment needs of communities disproportionately impacted by HCV as identified by Hep C Free WA data monitoring and analyses (e.g., people who inject drugs, women of transgender experience, men who have sex with men, Native Americans, African Americans). Create Hep C Free WA community leadership opportunities (e.g., a community leadership program, community engagement events) for and promote the involvement of people affected by HCV and people from communities disproportionately impacted by HCV in the Hep C Free WA coordinating committee and work groups to ensure ongoing engagement in the implementation and refinement of the Hep C Free WA plan over time.

Progress in 2021:

In the second quarter of 2021, the Department of Health continues to re-structure the Hep C Free WA planning focus from developing recommendations to developing implementation work plans. During this quarter, the Hep C free WA quarterly Coordinating Committee meeting convened on August 24th to discuss the upcoming focus shift to prioritization and implementation. The group was introduced to the new focus and was led through the process of prioritizing the elimination plans' recommendations. Group members were asked to score each recommendation on five criteria, which include;

- ***Overall impact**: if implemented, how much would this recommendation help us achieve our goal of a Hep C Free Washington by 2030?*
- ***Equity impact**: if implemented, how much would this recommendation help reduce disparities in HCV diagnosis and treatment?*
- ***Actionable:** if funding was identified for this recommendation, could it be implemented under the current legal and regulatory landscape?*
- ***Identified lead actor**: if funding was identified for this recommendation, is there a clear actor (staff person, organization or group) who could take the lead on implementing this recommendation?*

In an effort to elicit additional feedback on the prioritization process, the Hep C Fee planning group will conduct a similar process for the Community Engagement and Clinical Strategies group during October's monthly meetings. Once complete, the top prioritized recommendations from each goal within the plan will move on to the coordinating committee members to develop action plans for implementation. Developed implementation plans will serve a dual purpose for the remainder of 2021 including; (1) action plan serves as a guide for the Hep C Free WA Coordinating committees and sub committees, and (2) action plans serve as a proposal template that any agency can use to develop programs and apply for funding opportunities.

The Data & Strategic Information Workgroup was unable to meet in 2020-2021 due to the COVID-19 pandemic. Most members of this workgroup are epidemiologists and were activated to COVID response early in the pandemic to assist with assessment and informatics functions. The Department of Health (DOH), lead agency, has temporarily paused the workgroup until a new coordinating process has been developed post the release of the elimination plan and allow time to assess work group members availability during the pandemic.

In response to COVID-19, the Clinical Strategies workgroup paused its regularly scheduled meetings. Most members of this workgroup are clinicians and finding time to join the sub-committee workgroups proved difficult during the pandemic. During this quarter, the Health Care Authority (HCA) and WA State Department of Health (DOH) started meeting with clinicians from Harborview and Pioneer Family Health to discuss how to integrate clinical services within substance use disorder treatment facilities in Thurston County. Through the course of the monthly meetings the topics began to shift focus to discussing how to strengthen the overall healthcare system to respond to HCV. To continue this momentum, the group decided to reconvene the Clinical Strategies sub-workgroup and asked the clinicians from Harborview and Pioneer Family Health to lead this workgroup for the next quarter. This group is scheduled to meet on November 1st.

Data and Strategic Information Goals

2. Identify data sources and strategies to strengthen the characterization of HCV disease burden within Washington State.

2.1 Mandate the reporting of non-positive HCV RNA (viral load) tests to local health jurisdictions, as well as positive ones, to allow tracking of spontaneous HCV clearance and successful HCV curative treatment.

Progress In 2021: This mandate is included in the notifiable conditions WAC update and is expected to be implemented in January 2022. Some laboratories are already submitting non-positive HCV RNA results through electronic lab reporting directly to DOH, so the Washington Disease Reporting System is ready to receive these reports. DOH did observe an increase in laboratories reporting these results. We assume this increase was due to laboratories anticipating the pending WAC change.

3. Obtain resources and build capacity for continuous data monitoring, evaluation, quality improvement, and reporting.

3.2 Add resources and build capacity at the local health jurisdiction level to strengthen data quality and completeness and timeliness of HCV case reporting.

Progress in 2021: Through Foundational Public Health investments, DOH supports improving and standardizing reporting of HCV events across Washington's local health jurisdictions. DOH, Office of Infectious Disease (OID), is working to align indicators and deliverables within Local Health Jurisdictions (LHJ) receiving FPH funding within their contracts. Currently 18 LHJs are funded through FPH to conduct hepatitis C surveillance investigations. OID Surveillance is working in collaboration with Foundation Public Health Services Coordinator to track metrics and deliverables of completed HCV surveillance investigations.

Through a cooperative agreement with the Centers for Disease Control and Prevention, DOH supports an HCV Disease Intervention Specialist (DIS) housed within OID. DOH's HCV DIS conducts HCV surveillance investigations for LHJs that lack sufficient resources to conduct their own HCV investigations. Through OID surveillance investigation support, DOH conducts investigations for high priority cases (acute, children under 3, persons born >1992, pregnant persons, and cases of public health importance) for 18 local health jurisdictions. HCV Case completeness went up when comparing 2019 and 2020 data. Through our efforts case completeness increased in; race/ethnicity variables (+3%), exposure/risk variables (+4.9%), among overall case completeness in all cases, acute and chronic.

During this reporting period, Foundational Public Health Funds were made available to OID to strengthen HCV surveillance investigation activities. Funding will be used to hire three (3)

additional HCV Disease Intervention Specialists and two (2) additional surveillance specialists to conduct surveillance investigation. Additional staff will allow OID to expand the disease intervention services (DIS) program to investigate additional HCV cases, enhance active linkage to care and supportive services, and include partner/at-risk population elicitation and notification. Additional staff will also allow for incorporation of data from additional data sources to support investigations as well as data quality and completeness.

3.7 Use metrics to develop care cascades for the above populations. Metrics collected and evaluated will be used to develop statewide, Medicaid, Department of Corrections, and other sub-population care cascades.

Progress update for 2021: In 2018, DOH and HCA executed a data sharing agreement to exchange Medicaid data in order for DOH to match Medicaid patients with evidence of HCV infection against the DOH HCV surveillance registry, with the goal of developing 1) a true HCV positivity number among Medicaid beneficiaries, and 2) an HCV care/cure cascade of Medicaid beneficiaries. The first data transfer from HCA was completed in 2019 and DOH planned to complete the work in 2020. However, due to staff shortages and COVID response, DOH was unable to commit resources to complete this work.

The additional Foundational Public Health Funds made available to OID will also allow for an increase in epidemiologic capacity. During this reporting period, DOH successfully recruited a new HCV Surveillance Coordinator within the Office of Infectious Disease (OID). This is a new position. With this new position, OID will resume the care cascade project with an anticipated completion date of early 2022. One of two HCV Epidemiologist positions is still vacant as a staff member left OID to take a permanent COVID-related position. This position will be rehired in early 2022. In addition to these staff one additional HCV Epidemiologist and a Drug User Health Epidemiologist will be hired in 2022. The HCV Epidemiologist will focus on data analysis and dissemination efforts to support DOH, LHJ, and other partner organizations program planning and other efforts. The Drug User Health Epidemiologist will support data needs for the OID Drug User Health Program (including Syringe Service Programs), look for additional data sources to support program needs, and address data analysis and dissemination needs for the program area.

3.13 Improve coordination among the Department of Health, local health jurisdictions, and community partners to strengthen HCV disease intervention and to assess levels of service needed to optimize outreach services.

Progress in 2021: The DOH HCV Disease Intervention Specialist (DIS) assists 18 local health jurisdictions by investigating their high-priority HCV cases (i.e.., acute cases, suspected perinatal cases, and young chronic cases). HCV disease intervention includes, but is not limited to, completing all necessary components of the state HCV case report, follow up with the health care provider as needed, informing the case of treatment options and ways to minimize disease progression, and educating the case about HCV and how to reduce the risk of transmission. In addition, the DOH HCV DIS provides ongoing technical support for all jurisdictions conducting HIV DIS activities.

See 3.2 for staffing updates for DOH HCV DIS program and DOH HCV surveillance program. See 3.7 for staffing updates for DOH HCV Epidemiology capacity.

Community-Based Responses and Interventions Goals

4. Improve access to and use of preventive and health care services in non-clinical settings through expansion and co-location of services.

	6.1 Expand the provision of clinical services, including HCV and other infectious disease screening and diagnostic testing (e.g., HIV testing, HBV testing, testing for sexually transmitted infections), linkage to care services, HCV treatment, vaccination (e.g., against HAV and HBV), wound care, overdose education and naloxone distribution in high-impact settings (settings that serve a high proportion of clientele who inject drugs, such as syringe service programs, substance use disorder treatment facilities, opioid treatment programs, organizations serving people experiencing homelessness). *Progress In 2021: During this quarter, DOH and HCA continue to build upon the U.S. Department of Health & Human Services Affinity Group project of integrating HCV testing and treatment services within opioid treatment programs (OTPs) and other substance use disorder (SUD) treatment facilities. Upon completion of the OTP Medical Director and Site Administrator survey that was completed in early 2021, HCA is developing a reimbursement technical assistance document to help assist OTP sites in billing for on-site infectious disease screening and linkage to care services. In addition, HCA has drafted a decision package to the Governor's office to increase the payment rate of OTP to match those of Medicare rates and to match Medicare payment methodology. This decision package would provide an opportunity for HCA to work with MCOs to allow contracting with OTP providers to provide patients with infectious disease screening and linkage to care. HCA is also participating in the Pew Charitable Trust's policy academy that focuses on OTPs becoming holistic patient-centered medical homes, including recommended HCV testing and care standards, that will be included in the legislative report recommendations.*
	6.9 Provide resources, including financial resources for Medical Assistant-Phlebotomy training and staff, so that high-impact, non-clinical settings have access to onsite phlebotomy in order to perform immediate blood draws for confirmatory RNA testing for people who have a reactive test result from a point-of-care rapid antibody screening test. *Progress In 2021: DOH scheduled multiple phlebotomy trainings in 2020 for non-clinical testing partners. The first class was held in February 2020, but due to COVID restrictions, all subsequent trainings were cancelled until December 2020 when these trainings resumed on a much smaller scale due to distancing and public health mitigation guidelines. As a result, for calendar year 2020, only 1 staff-person from a syringe service program was able to be trained. For calendar year 2021, phlebotomy trainings resumed and have classes scheduled for July 19th -20th for our community partners (Hepatitis Education Project and Entre Hermanos). In addition, we anticipate scheduling 2-3 additional classes for the remainder of the calendar year.*
	6.10 Explore innovative and evolving approaches to HCV testing in non-clinical settings as new platforms receive approval from the Federal Drug Administration, such as dried-blood spot testing to detect RNA and point-of-care antigen testing. *Progress in 2021: DOH worked with Molecular Testing Labs (MTL) to offer dried blood spot testing for hepatitis C antibody and confirmatory testing for DOH supported community-based test sites. MTL recently became validated to conduct HCV lab testing and is currently building capacity to support high volume submissions. DOH is currently developing protocols and working with community partners to support the adoption and integration of the new platform in existing DOH screening sites. The new technology offers several benefits over the existing rapid HCV Ab testing technology currently being used by community screening sites, including, but not limited to; reduced individual licensure requirements, ability to bundle multiple screening tests on one card (e.g., HIV, hepatitis B, syphilis), and provides confirmatory HCV RNA testing. The ability to conduct confirmatory HCV testing is a critical need among existing screening sites providing services for marginalized and vulnerable populations. DOH*

plans to implement dried blood spot testing within DOH sponsored screening sites in the Winter of 2021.

6.13 Maximize opportunities to integrate HCV services into HIV prevention and care services, such as ensuring that agencies contracted with the Department of Health to provide HIV prevention and/or care services receive education about HCV and share that education with clients, including men who have sex with men, women of transgender experience, and people who inject drugs.

Progress in 2021: DOH, Office of Infectious Disease, is planning to address the syndemic, or braided and interrelated epidemics, of HIV, sexually transmitted infections (STIs), and viral hepatitis through service integration. The testing and linkage strategy is one part of the Office's broader vision to improve health equity and outcomes related to HIV, STIs, and viral hepatitis by applying a syndemic approach to all of our work and investments. This approach would support the integration of multiple siloed services, including HCV and STIs, into existing HIV prevention and care prevention infrastructure. The goal of this approach is to work toward developing a network of in which HIV, STIs, hepatitis B, and hepatitis C testing and linkage services are provided at all programs in which DOH invests resources. The goal is to stand up integrated testing and linkage services at all DOH funded community testing sites by January 1, 2022.

5. Improve access to and use of clinical care and supportive services by sufficiently scaling coverage and widening the scope of community-based navigation and case management programs.

5.3 Allocate funding for case management in high-burden counties and/or high-impact settings to support people diagnosed with HCV who are also experiencing mental health issues, challenges with substance use, and/or histories of trauma and incarceration.

Progress In 2020: DOH provided funding through the CDC Overdose Data to Action grant to support care coordination/patient navigation at three syringe service programs. While the focus of this coordination/navigation is not exclusively related to HCV, HCV services are a need identified by syringe service program participants and we anticipate that in 2021 these care coordinators will be able to connect participants to HCV testing and linkage to care services. Additionally, DOH provides CDC HIV Prevention funds to a syringe service program to provide care coordination specific to connecting participants to care for hepatitis C treatment. During this reporting period, Thurston County Health Department's Hep C Test to Treatment program has enrolled 17 new participants – one of which has already been connected to care for hepatitis c treatment. Additionally, they conducted 42 hepatitis C tests, 23 of which came back as reactive. Engagement in services still proves to be difficult with lingering impacts from COVID-19 in addition to individuals being lost to care due to incarceration.

5.4 Provide community-based medical case managers in high-impact settings.

Progress In 2021: DOH funded the Hepatitis Education Project, a Seattle-based nonprofit organization, to provide linkage to medical care and supportive services for people living with HCV through medical case management services from 2016 – 2021. This funding was a part of a cooperative agreement with CDC for Hepatitis Surveillance. This funding has expired and DOH is identifying new funding opportunities to help continue this vital work.

6. Increase HCV awareness, resources, and education, and reduce stigma.

Clinical Strategies Goals

7. Improve access to and use of clinical care for marginalized populations at risk for or living with HCV through innovative service delivery models.

	9.4 Support the integration of HCV testing and treatment in opioid treatment programs and office-based buprenorphine treatment programs, and encourage providers to offer medications for HCV in conjunction with medications for opioid use disorder early in the course of substance use treatment. *Progress In 2021: see 6.1 under Community Based Responses and Intervention Goals above.*
8.	Build the capacity of the health care workforce to diagnose and treat HCV.
	10.3 Develop easily accessible and low-barrier provider education materials and information to confront bias and prejudice toward people who use drugs in the medical community, including information on why HCV testing and treatment for people who inject drugs is effective and critical to achieve HCV elimination. *Progress In 2021: The Community-Based Responses and Intervention workgroup (now called the Community Engagement workgroup) met monthly in 2021 (via Microsoft Teams) focused on developing strategies to promote HCV testing and treatment for communities disproportionately impacted by HCV, in particular people who use drugs. Development of educational materials will be a client driven process involving members of the community impacted by HCV. During this quarter, the workgroup sent out an email to all syringe service programs (SSP) and presented to the state SSP monthly meeting to inform programs of the sub-committees work to develop educational materials. In addition, the email and presentation asked programs to recruit interested clients in sharing their stories and/or pictures for the educational materials.*
9.	Improve diagnosis of HCV in primary care settings.
	11.3 Work with all labs in Washington that receive specimens for HCV testing to implement reflex testing, ensuring that all specimens that are reactive for HCV antibody are immediately tested for RNA in order to streamline the diagnosis process. *Progress in 2021: In 2021, DOH was successful in securing federal funding through CDC's combined Viral Hepatitis Surveillance and Prevention cooperative agreement. This funding supports ongoing hepatitis core surveillance and prevention activities conducted in the Office of Infectious Disease. Within the new cooperative agreement, both prevention and surveillance programs will work to scale reflex testing within commercial labs within WA State. Activities and deliverables outlined within the new workplan include, but not limited to, implementing an environmental scan of current lab process within commercial laboratories in WA state, assess and analyze the data collected, develop a report for the Hep C Free WA Coordinating Committee, and develop a plan to increase the number of commercial laboratories conducting automatic reflex testing for all specimens that are reactive to HCV antibody testing. Work is to implement this plan is ongoing and scheduled for completion early 2022.*
10.	Improve HCV disease intervention services.
11.	Improve access to HCV treatment and comprehensive health care.
12.	Improve the ability of people taking HCV direct-acting antivirals to complete treatment.
13.	Improve follow-up clinical care for people who have completed HCV treatment.

Other activities in 2021

- During this reporting period, AbbVie and the Hepatitis Education Project partnered to provide testing and case management services with the AbbVie's elimination bus. Testing at events provides rapid anti-body HCV screening, follow up confirmatory testing, and referrals to HCV providers for those who tested positive/reactive. The bus provides HCV general information and

promotes the state's elimination initiative. The following bus events took place during the reporting period:

Event 1 – Blessings Under the Bridge

- Date: Wednesday August 11, 2021
- Event time: Dinner begins at 5:30 PM-8:30 PM
- Event location: Downtown Spokane under the bridge off 4th and McClellan

Event 2– Summer Blessings

- Date: Saturday August 14, 2021
- Event Time: 12 PM-3PM (testing from 11AM to 4PM)
- Event location: Downtown Spokane under the bridge off 4th and McClellan

Event 3- 20th Annual Hands Across the Bridge

- Date: Monday September 6, 2021
- Event Time: 10 AM to 6 PM
- Event location: Esther Short Park, 605 Esther St. Vancouver, WA

Event-4 Gathered Church Event

- Date: Wednesday September 15, 2021
- Event Time: 10 AM to 4 PM
- Event Location: Rotary Riverside Park Lowe Street North of Harrison, Centralia, WA

Event 5- Project Homeless Connect

- Date: Friday September 17, 2021
- Event Time: 10 AM to 2 PM
- Event Location: Peoples Park 900 Martin Luther King Jr Way, Tacoma, WA

- HCA and DOH worked with UW School of Nursing to apply for funding through the Arnold Foundation for an HCV elimination evaluation project. UW will look at the mechanics of the AbbVie/HCA Medicaid and Non-Medicaid contracts, compare how many people were treated under the Medicaid modified subscription model to the number expected to be treated if the state had not adopted the model, and explore the cost savings to the state after adopting the model. UW received funding for 3 years beginning 02/02/2021 for this effort. DOH staff are currently working with UW staff on establishing a data share agreement and an IRB application to support this work.

Appendix A

JAY INSLEE
Governor

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DIRECTIVE OF THE GOVERNOR
18-13

September 28, 2018

To: Washington State Executive and Small-Cabinet Agencies

From: Governor Jay Inslee

Subject: Eliminating Hepatitis C in Washington by 2030 through combined public health efforts and a new medication purchasing approach

This year, an estimated 65,000 Washingtonians are living with the chronic Hepatitis C Virus (HCV), but fortunately, we now have a cure. HCV is the leading cause of liver cancer and liver transplants. The virus also causes other health problems, including debilitating fatigue, which can significantly impact the quality of life of those affected.

HCV is the most common blood-borne disease in the United States, and in Washington, from 2012 to 2017, nearly 40,000 new cases of HCV were reported, increasing each year. And while deaths from other infectious diseases have steadily declined over the past decade, HCV-related deaths continue to rise, now exceeding all deaths from other reportable infectious conditions combined.

Newly acquired HCV-infection reports show a 126% increase in Washington between 2013 and 2017 when compared to the prior five years, an increase linked to the opioid crisis. And while the disease has historically impacted Baby Boomers (those born between 1945 and 1965), younger people are now contracting the disease with greater frequency, again related to opioid use. Ultimately, Washington's HCV-related hospitalization charges totaled $114 million between 2010 and 2014.

Confronting the HCV crisis is challenging because many Washingtonians living with HCV do not know they are infected. So, to reach affected communities, we must make enhanced public health efforts, including efforts to improve education, preventive services, and early detection of HCV to treat and cure existing infections and curb the onward transmission of the virus.

Fortunately, we see an opportunity to take action against HCV. In 2017, the National Academies of Sciences, Engineering, and Medicine released "A National Strategy" outlining how the United States can save nearly 30,000 lives from HCV-related deaths and eliminate HCV by 2030. Moreover, medications now exist to cure HCV in nearly all people appropriately linked to, and retained in, care. HCV drugs are expensive, but we can drive down costs by applying new purchasing strategies in which state agency health care purchasers collaborate with

manufacturers in combination with using key public health interventions to reduce the costs of treating and ultimately curing HCV.

In curing HCV, we can stem the tide of liver disease and liver cancer and save individuals the physical, emotional, and financial damage caused by HCV infection. Curing this disease will also support HCV-affected persons to engage in healthy behaviors, such as accessing treatment for opioid-use disorder, general primary care, and mental health services, which will help them live full, satisfying, and productive lives. This is an important part of the opioid response plan.

Accordingly, I direct my health sub-cabinet and the health and human service state agencies under my authority to begin immediately to work with Tribal governments, local public health officials, and other partners across the state, to develop and implement a statewide HCV elimination plan. The Department of Health (DOH) shall lead the effort to develop the elimination plan as part of this comprehensive public health response. The Health Care Authority (HCA) shall lead and coordinate with DOH and other agencies and purchasers, in a corresponding effort to establish a comprehensive procurement strategy for the purchase of HCV medications that also includes financing the needed public health interventions to affordably eliminate HCV by 2030. Furthermore, I direct the following:

1. DOH, in collaboration with any other relevant state agencies that it identifies, shall convene and facilitate an HCV-elimination coordinating committee comprised of stakeholders from various sectors, including individuals personally affected by HCV. The committee shall draw on existing efforts, best practices, and community knowledge to develop, by July 2019, a comprehensive strategy to eliminate the public health threat of HCV in Washington by 2030. The strategy will address needed improvements to the public health systems to help ensure that all people living in Washington who have or are at risk for contracting HCV, have access to preventive services, know their status, and connect to care and ultimately the cure. The elimination strategy shall include a major public health communications plan financed, to the extent possible, by the funds saved through the purchasing strategy described below.

2. HCA shall collaborate with the Department of Corrections, Office of the Insurance Commissioner (OIC), Department of Labor and Industries, Department of Social and Health Services, Department of Veterans Affairs, DOH and Tribal governments, to initiate an innovative strategy to purchase curative HCV medications and ensure timely access to curative treatment for Washingtonians with HCV. Given that several state agencies each year purchase HCV treatment medications for over 4,000 people, by January 2019, HCA shall collaborate with these agencies and issue a single request for proposals for a joint value-based purchasing agreement for curative HCV medications from one or more pharmaceutical manufacturer(s). This joint purchasing agreement shall aim to reduce the costs of the drug(s) and incorporate key known public health strategies to address the needs described above.

3. HCA, in collaboration with DOH, shall request that the Centers for Medicaid and Medicare Services (CMS) enter into a shared-savings agreement for Medicare-program-cost avoidance resulting from the implementation of the state's HCV prevention and

treatment strategy. Our state program will save Medicare significant costs by not only treating people sooner, alleviating Medicare from needing to pay for HCV medications, but also the dire costs of liver disease and cancer and other health effects that would occur later in one's life while they are covered under Medicare.

4. HCA and DOH shall work with CMS, the Centers for Disease Control and Prevention, the Surgeon General, Veterans Affairs, other federal agencies, and Tribal governments to consider additional health care purchasing and disease elimination strategies, especially for rural and underserved populations—including Vietnam veterans living in rural areas—to address HCV in a cost-effective manner.

5. HCA, in collaboration with other state agencies shall, as the next phase of this plan, engage a multi-state or national organization to develop a strategy to assess the interest and ability of extending our purchasing and public health strategy to not only Washington's other major purchasers of health care and commercial insurers, but also other states or purchasers. As part of this next phase, HCA shall work with Washington's Health Benefit Exchange and OIC to explore purchasing options for the health insurance markets.

6. DOH and HCA shall also use data and information to detect cases of HCV, monitor HCV-related morbidity and mortality, monitor HCV-curative treatment access, and evaluate the impact of interventions and activities designated by this directive.

7. DOH and HCA shall develop a communications plan for this project. This communications plan shall include filing quarterly reports to my office and the health committees of the legislature to ensure the status and outcomes herein.