

# **Hepatitis C and COVID-19 Global Concerns:**

Sustained Financing and Expanded Access to Testing and Pangenotypic Treatments Needed to Recover the Path to Elimination

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# INTRODUCTION

Enormous amounts of public funding and health resources have been reallocated from addressing the blood-borne hepatitis C virus (HCV) to respond to the novel SARS-CoV-2 virus/ COVID-19 pandemic. This has complicated the delivery of essential services and made scale-up of HCV testing and treatment even less likely. As governments and donors send emergency COVID-19 relief aid to countries and jurisdictions, sustained financing and expanded access to prevention, testing, and pangenotypic treatments for HCV (that treat all genetic variations of the virus) need to be included to recover the path to elimination.

Investments in research and development of HCV treatments, diagnostic tools, and lab infrastructure have directly led to the creation of goods that are being put to use for COVID-19.

As governments and donors send emergency COVID-19 relief aid to countries and jurisdictions, sustained financing and expanded access to prevention, testing, and pangenotypic treatments for HCV (that treat all genetic variations of the virus) need to be included to recover the path to elimination.

Lessons from HCV on how to address a largely undiagnosed and untreated infection that includes numerous barriers between patients and effective cures can inform policies on accessing COVID-19 technologies, such as vaccines. Community engagement and advocacy networks can be leveraged to inform COVID-19 R&D, clinical trials, and equitable and affordable access strategies. Investments in COVID-19 can also aid with rolling out the HCV response and strengthening the capacity and infrastructure needed for both epidemics.

# COVID-19 IS THREATENING THE INCREMENTAL HEPATITIS C PROGRESS NEARLY EVERYWHERE

#### **Global HCV Diagnosis and Treatment Gaps**

We can expect COVID-19 to worsen HCV<sup>1</sup> and overdose-related<sup>2</sup> death tolls because people who are disproportionately affected by HCV, particularly people who use drugs, are more likely to be isolated, miss medical appointments, and lack access to essential support systems. The pandemic has also interrupted outreach and prevention programs, including harm reduction services, screening campaigns, and routine health visits that confirm HCV diagnoses and identify new cases. Interruptions to essential health programs are part of efforts to reduce people's risk of exposure to the SARS-CoV-2 virus.

Before COVID-19, global treatment uptake among the general population was already dismal, with a few exceptions, namely Australia, France, Georgia, and Italy (see Figure 1). Since the groundbreaking, highly effective direct-acting antiviral (DAA) sofosbuvir (Sovaldi) for HCV became available in 2013, **more than 90%<sup>3</sup> (or 67 million people) of the world's estimated 71 million people living with chronic HCV remain untreated.**  In the U.S., an estimated 63% of Americans remain untreated,<sup>4</sup> in large part due to high prescription drug prices, prior authorization requirements by payors, and restrictions against treating individuals who are actively using drugs or alcohol or experiencing early stage liver disease. Generic HCV treatments are not as widely available and accessible in high-income settings, including in the U.S., due to patent monopolies. Outside high-income countries, within seven years, global generic competition has reduced prices to less than US\$100 per treatment course, with costs significantly lower in Egypt, India, and Pakistan. High drug prices should no longer be a barrier to treatment; diversifying generic competition and lifting treatment restrictions in all countries will help more people start treatment earlier. Furthermore, the lack of international donor funding and national scale-up remain major challenges.



Interim progress reports by the Coalition for Global Hepatitis Elimination focus on the 20 countries with the highest HCV burdens. That is, if these 20 countries meet the WHO targets by 2030, HCV could effectively be eliminated. However, other than Europe, most regions did not see a major decline in HCV-related mortality in the years 2015-2019.<sup>7</sup> The progress reports highlight the expansion of generic treatment access, mostly in low- and middle-income countries. However, other than in Europe, the majority of countries do not have more than one needle and syringe program (NSP).<sup>8</sup> Few or virtually no people who inject drugs have been treated in the majority of countries. According to the mapCrowd database, less than 2% of people who inject drugs have been treated even in countries where elimination plans have been launched.

The availability of the cure in countries has little impact if harm reduction coverage is lacking and the people who are most in need and disproportionately affected by hepatitis C do not access treatment and care.<sup>9</sup> Few or virtually no people who inject drugs have been treated in the majority of countries. According to the mapCrowd database, less than 2% of people who inject drugs have been treated,<sup>10</sup> even in countries where elimination plans have been launched.

We need to treat 5 million people every year worldwide to achieve hepatitis C elimination by 2030.<sup>11</sup>

# In the U.S., we need to treat an estimated 173,514 people each year to reach the 2030 treatment target.<sup>12</sup>

Despite lifting insurance barriers and treatment restrictions—including levels of liver scarring

# We need to treat 5 million people every year worldwide to achieve hepatitis C elimination by 2030

and sobriety—in more than half of U.S. states,<sup>13,14</sup> the U.S. is failing in its HCV response and will miss the 2030 WHO global targets (see Figure 2).<sup>15</sup> Recent modeling shows only three states (6%; Connecticut, South Carolina, and Washington) are on track to reduce new HCV cases by 80%, and only 16 states (31%) are on track to treat 80% of patients with HCV by 2030.<sup>16</sup> Some progress has been made, however, with 45 states (87%) expected to diagnose 90% of their HCV infections and 46 states (88%) on track to reduce HCV-related mortality by 65% by 2030.



Increasing treatment initiation requires increasing the number of people who are tested and diagnosed with HCV. An estimated **80% of people living with HCV remain undiagnosed worldwide** and, of those, more than 95% live in low- and middle-income countries.<sup>18</sup> COVID-19 has derailed efforts to screen, newly diagnose, and start people on treatment. Modeling estimates<sup>19</sup> of the global impact of COVID-19 predict that a one-year gap and delay in HCV services will result in 44,800 additional cases of liver cancer and 72,300 additional liver-related deaths, mostly in high-income countries, between 2020 and 2030.

# HEALTH NEEDS FOR PEOPLE WITH HCV IN THE COVID-19 ERA

People who recover from COVID-19 have been shown to have elevated liver enzymes;<sup>20</sup> people living with viral hepatitis, liver scarring, liver disease, or other hepatic conditions will need to monitor their liver function following their recovery from coronavirus. It is unclear if people with viral hepatitis have worse health outcomes from COVID-19, however, preliminary studies<sup>21</sup> show that COVID-19 has higher mortality rates for people with chronic liver disease and cirrhosis: 63.2% of people with new decompensated liver disease died from CO-VID-19 compared to 26.2% who did not have new decompensated liver disease.

Protecting lung health, in addition to liver health, is important for people living with HCV, particularly people who formerly or currently vape or smoke tobacco or cannabis or inject or use other substances. Taking opioids slows breathing, decreases oxygen in the blood, and can decrease lung capacity. Methamphetamine use can tighten blood vessels and contributes to pulmonary damage and hypertension.<sup>22</sup> Financing and sustaining peer-driven harm reduction and counseling services can assist with strategies to better protect lung and liver health.

Table 1 outlines different scenarios for people who have HCV and may become sick with COVID-19.

#### People with HCV People need to finish their DAA already taking treatment course while moni-DAAs who betoring for drug-drug interaccome sick with tions. COVID-19 **Protect people's** People should be provided with liver health, resupport to reduce or avoid algardless of HCV cohol and acetaminophen due status, if they to potential liver toxicity<sup>23</sup> when become sick with recovering from COVID-19. COVID-19 People who are People need to defer HCV newly diagnosed treatment until they recover with both HCV from COVID-19 to observe and COVID-19 drug-drug interactions.24 People should be offered treatment and routine HCV care People diagnosed when medications, personal with HCV without protective equipment, and COVID-19 healthcare workers are available. People living with viral hepatitis should be considered priority groups for COVID-19 testing, People living with have access to accurate and viral hepatitis comprehensive information should continue about their specific health conto be diagnosed cerns, and receive early treatment to prevent progression of liver disease.

#### Table 1. Health Scenarios for People With HCV

# HCV PROGRAMMATIC IMPACTS OF COVID-19

The pandemic has paused global hepatitis C testing and treatment and disrupted healthcare and harm reduction services, including needle and syringe programs (NSP) and provision of opioid substitution therapy (OST). The results of a 32-country survey<sup>25</sup> conducted by the World Hepatitis Alliance between March 30 and May 4, 2020 further demonstrate the severe impacts on global hepatitis programs: 94% (121 of 132 total respondents; 50% from the U.S.) responded that their viral hepatitis services were affected by COVID-19. Lack of testing was reported by 66 (or 65%) of 101 respondents; this was attributed to avoiding healthcare facilities altogether due to a fear of exposure to COVID-19. Shortages in HCV testing reagents have been reported due to supply chain disruptions. About one-third (23 of the 68 respondents outside the U.S., more than half from low- and middleincome countries) reported lack of access to HCV medication since the beginning of the pandemic, attributed to the inability to travel outside immediate residential areas. Interruption and closure

of essential harm reduction services has been widely experienced. For example, the number of people accessing NSPs in England fell by

There are a number of challenges to HCV programs, research, and funding caused by COVID-19.

36% and distribution of needles was cut by 50% due to the stay-at-home orders.<sup>26</sup> Disruption in HCV programs has been attributed to redeploying medical providers and healthcare workers for the COVID-19 emergency.

In response to decreased economic activity due to business closures and social distancing measures, governments have implemented or are considering austerity measures in the form of funding cuts to essential services, including for viral hepatitis, and civil society organizations risk losing funding that supports affected communities.

There are a number of challenges to HCV programs, research, and funding caused by CO-VID-19. Scaling up HCV prevention, treatment, and testing has largely been disrupted, and R&D into new technologies, such as long-acting injectables and a preventative vaccine, have been delayed. From a budgetary perspective, additional funding will be necessary to account for extended timelines, recruitment, and any unforeseen expenses (see Table 2).

# Table 2. COVID-19-Related Challenges for HCV Response<sup>27</sup>

Patient monitoring and support	In-person health facility visits during the COVID-19 outbreak have been limited or paused to protect patients and staff from exposure. Telehealth visits and phone counseling have been used for patient care coordination and follow up. However, new treatment starts are paused for patients newly diagnosed with HCV, which leads to more chronic liver disease and failure if left untreated. Patients require liver function tests and tests to confirm they have been cured, yet these monitoring and follow-up tests are paused.
Continuity of treatment	Patients newly diagnosed with HCV are not starting treatment early, potentially contribut- ing to onward transmission among peers or family members during stay-at-home orders. Health facilities and clinics have developed alternative methods to deliver medications typically provided during in-person health facility visits, including pick up or home deliv- ery of medications. The United States has also used mail delivery of medications; though disruptions to mail services were reported in summer 2020 due to service cuts and the refusal to provide the U.S. postal service a short-term funding bailout.
Supply chain disruptions	Supply chain disruptions and unexpected export bans have created challenges to ensuring the availability and continuity of treatment and availability of trial drugs. In India, shortages of the hepatitis C medications sofosbuvir, daclatasvir, and ribavirin have been reported because they were diverted for the treatment of COVID-19 in other countries. Manufacturing disruptions in India and China (where most HCV medicines and their ingredients are produced), as well as the earlier threat of an export restriction in India, could further impede access to medicines for patients.
Collection and transportation of samples	Screening and testing for HCV have largely been de-prioritized in COVID-19-affected countries so that laboratories can increase and run COVID-19 testing. Lack of PPE has prevented the continuity of saliva, blood, or plasma sample collection for HCV and other infectious disease testing. Limited transportation services also add to delays and costs in getting samples to laboratories.
Appropriate laboratory infrastructure and staff	Laboratories are being diverted for or overwhelmed by the COVID-19 response. The diver- sion of these key resources impedes ongoing HCV responses.
Engagement with regulatory authorities and ethics bodies	Given the swift changes to research procedures and study protocols as a result of CO-VID-19, studies have had differing levels of engagement and guidance from regulatory authorities and ethics bodies (i.e., IRBs). Rapid guidance from regulatory authorities and IRBs on acceptable protocol deviations and changes due to COVID-19 has facilitated the continuation of research, such as for long-acting injectables and a preventative vaccine, <sup>28</sup> in some locations. Conversely, where regulatory and IRB activities have been suspended or delayed, research activities have been impeded.
Community engagement	Community engagement structures, such as community advisory boards (CABs) or state hepatitis task forces, enable national policy-making bodies to identify and respond to COVID-19-related challenges in particular key populations. These structures also facilitate critical engagement with affected communities regarding the potential impacts of CO- VID-19 and disruptions on HCV and harm reduction services. However, critical community engagement activities, such as those planned by the New York State HCV Elimination Task Force, <sup>29</sup> have been disrupted due to COVID-19. Moreover, the Civil Society Engagement Mechanism for Universal Health Coverage 2030 conducted a survey that reported little to no involvement of civil society organizations in the COVID-19 response of their country. <sup>30</sup> Community members in this mechanism are often from the most overlooked and mar- ginalized key populations, such as people who use drugs and incarcerated populations; excluding them from national COVID-19 responses could lead to disproportionate impacts and the failure to contain the pandemic.

#### **Box 1: Pharma Pandemic Profiteering in a Nutshell**

Pharmaceutical monopolies, pandemic price gouging and profiteering, and obstacles to generic competition subvert the public health response to both pandemics. To date, three HCV drugs have demonstrated marginal clinical benefits in treating COVID-19: remdesivir, sofosbuvir, and daclatasvir.

Remdesivir, an older injectable treatment previously studied for hepatitis C and Ebola, had initially been shown to be marginally beneficial<sup>31</sup> in reducing the SARS-CoV-2 viral load,<sup>32</sup> the severity of the illness, and the duration of hospital stays for patients with COVID-19. Significant effects on mortality or recovery time have not been confirmed by later studies." (Please see COVID-19 Pipeline for the latest developments). The U.S. government funded an estimated \$70 million<sup>33</sup> of remdesivir's R&D. As is common in pharmaceutical development, Gilead is profiting from a failed drug, and the U.S. government has not leveraged its role in R&D to negotiate lower prices. Gilead has set a price of \$2,340-\$3,120 per treatment course in high-income countries such as the U.S. and European nations.<sup>34</sup> Generic manufacturers in Bangladesh and India have priced each treatment course at US\$600. Meanwhile, Andrew Hill and researchers at the University of Liverpool estimate the raw ingredients and manufacturing cost, with a reasonable profit of 10%, amounts to 93 cents per treat-

ment course.<sup>35</sup> By contrast, dexamethasone, an older and more effective drug, costs the equivalent of a few U.S. dollars per patient.<sup>36</sup>

Scaling up generic competition of remdesivir has been stalled because 73 countries (30 are low- and middle-income countries) have been excluded from Gilead's licenses.<sup>37</sup> Even in countries under the license, such as the U.S., drug shortages have been documented. Since July 2020, 38 hospitals in 12 states reported remdesivir shortages.<sup>38</sup> The scandalous development of sofosbuvir by Gilead is a well-documented example of pharmaceutical corporations socializing costs and privatizing benefits.

Oral direct-acting antivirals, such as sofosbuvir (Sovaldi) and daclatasvir (Daklinza), may also demonstrate efficacy by reducing mortality and improving recovery time from COVID-19.<sup>39,40</sup> However, the effective generic sofosbuvir/daclatasvir combination is not accessible in high-income countries, including the U.S., due to exclusive licensing by two separate patent holders, Gilead (sofosbuvir) and BMS (daclatasvir). BMS stopped manufacturing Daklinza in countries where it is no longer prescribed and stopped enforcing its patents in March 2020;<sup>41</sup> the corporation has shared it in the Medicines Patent Pool since 2015. Therefore, there is potential to scale up treatment when used in combination with sofosbuvir.

The scandalous development of sofosbuvir by Gilead is a well-documented example of pharmaceutical corporations socializing costs and privatizing benefits. In addition to NIH-funded basic science laying the groundwork for the DAA breakthrough, significant public funding bankrolled a small biofirm to do translational research and risky early stage development. Once the drug showed promise, Gilead acquired the biofirm and filed multiple patents, placing the drug under monopoly control. Once sofosbuvir was FDA-approved, the manufacturer's jaw-dropping launch price of \$84,000 per treatment course resulted in payors and health systems in high-income countries implementing treatment restrictions. Treatment restrictions and prior authorizations by insurance companies contradict medical advice and clinical treatment guidelines. People living with HCV are prevented from starting treatment early, risking further liver damage, cancer, hospitalizations, and passing the virus to other people. In 2018, Gilead made nearly \$60 billion in HCV treatment sales while treating less than 2 million patients worldwide.

Learning from the development and slow access to the HCV cure can inform strategies for CO-VID-19 treatments and, possibly, future vaccines. If proven effective, drug approval and registration for the generic sofosbuvir/daclatasvir combination will be essential to scaling up treatment for CO-VID-19, including in high-income countries such as the U.S. The full use of legal mechanisms—compulsory licensing, patent oppositions, pricing and clinical trials cost transparency<sup>42</sup>—guarantee that this potential treatment option is produced rapidly and is accessible to everyone who needs it.

#### Timeline of Gilead's Price Gouging and Profiteering on Sofosbuvir:43

**1998:** Pharmasset, Inc. is founded in Tucker, Georgia.

**Before 2004:** Beginning at Emory University with \$880 million in public funds from the National Institutes of Health, Raymond Schinazi's research leads to the development of sofosbuvir.

**2004:** Schinazi works at the drug corporation Pharmasset while earning a salary, funded by taxpayers, at the Veterans Administration. Begins the earliest phase of medical discovery of the sofosbuvir molecule.

**2006:** Pharmasset becomes a publicly traded corporation.

**2007:** The sofosbuvir molecule shows promise and moves into the next phase of clinical trials by Pharmasset.

**2011:** Pharmasset's clinical trials show that sofosbuvir is safe and more effective than previous hepatitis C treatments. Gilead buys Pharmasset, including sofosbuvir, for \$11.2 billion.

**December 6, 2013:** Receiving Food and Drug Administration (FDA) approval, Gilead Sciences releases Sovaldi<sup>®</sup> (sofosbuvir). It is priced at \$84,000 for a 12-week treatment course or \$1,000 per pill.

**July 24, 2014:** Global activists, as part of the hepCoalition, hold an action at the International AIDS Conference to protest Gilead's extortionately priced hepatitis C drug, Sovaldi<sup>®</sup> (sofosbuvir).

**December 6, 2018:** Estimates showed that Gilead sold \$58.6 billion worth of their sofosbuvirbased treatments, yet only an estimated 1.85 million patients were treated worldwide.

COVID-19 R&D has benefited from the treatments, diagnostic tools, and lab infrastructure developed for HCV R&D. Investments in COVID-19 can aid with rolling out the HCV response and strengthening the capacity and infrastructure needed for both epidemics. Community engagement and advocacy networks can be leveraged to inform COVID-19 R&D, clinical trials, and affordable, equitable access strategies. HCV advocates networks and community engagement have been integral to improving global epidemic preparedness. Lessons from HCV on how the vast majority of people remain undiagnosed and untreated and face barriers in accessing the cure can inform policies on accessing COVID-19 technologies such as vaccines (see Table 3).

## Table 3. Cross-Disease Benefits for COVID-19 From HCV<sup>44</sup>

Treatment	COVID-19 R&D has benefited from HCV R&D: remdesivir, originally developed by Gilea to treat HCV, shows some potential <sup>45</sup> to reduce the SARS-CoV-2 viral load, <sup>46</sup> decreasin the severity of the illness and the duration of hospital stays for patients with COVID-19 Preliminary studies <sup>47</sup> show the hepatitis C medications sofosbuvir and daclatasvir can potentially reduce mortality and improve recovery time. DISCOVER, a larger placebo- controlled, double-blind trial with 600 participants is underway with results anticipate in fall 2020 <sup>48</sup> (see Box 1).	id ig ).
Diagnostic tools	COVID-19 tests have been developed for many HCV diagnostics platforms, such as CC BAS TaqMan (Roche), GeneXpert (Cepheid), Genedrive, RealTime (Abbott), and ARCH TECT (Abbott). Cepheid's GeneXpert multi-disease PCR testing platform is used for rapid diagnosis of HCV, as well as HBV, TB, HIV, and HPV. GeneXpert was developed with substantial inverse ment from public tax revenue, U.S. government grants, <sup>49</sup> and philanthropic donors. Wi support from BARDA, <sup>50</sup> Cepheid has now developed a COVID-19 test that can be used the 23,000 GeneXpert diagnostics machines already used worldwide.	)- HI- f est- ith d on

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(continued) ity for a TrueNAT COVID-19 test, expanding the number of existing diagnostics platf that can be repurposed for the current pandemic. <sup>52</sup>	
<ul> <li>Lab infrastructure and capacity used for HCV, including laboratory facilities, research clinical expertise, and members of community advisory boards, are being activated COVID-19 research and responses.</li> <li>HCV medical providers and community health workers have supported COVID-19 responses through a range of activities, including training medical workers on the use personal protective equipment, guiding and assisting contact tracing efforts, provide epidemiologic and modeling support, and even researching COVID-19 interventions.</li> <li>HCV community advisory boards established to enable community engagement on implementation of national hepatitis plans and treatment access are being consulte regarding proposed research for COVID-19.</li> </ul>	h, for of ding

# MAKE CHANGES TO SERVICE DELIVERY PERMANENT IN THE POST-PANDEMIC ERA

The COVID-19 crisis has led to the adoption of service delivery models that center the lives and needs of those seeking care, which have been long sought by advocates for patients' rights and harm reduction. These currently temporary measures in response to the pandemic should be continued post-COVID-19 times, and provider payment systems should be adapted to sustain and incentivize these models of care. Countries with histories of harm reduction services have included NSPs and medication-assisted treatment (MAT)/opioid substitution therapy (OST) as essential services. Wide community distribution of naloxone, as well as take-home and delivered DAA and OST treatment for people already diagnosed or using treatment, combined with telemedicine for treatment initiation, monitoring, and social support should be made permanent in the post-pandemic period.

Infrastructure and capacity used for HCV, including laboratory facilities, research, clinical expertise, and members of community advisory boards, are being activated for COVID-19 research and responses. COVID-19 tests have been developed for many HCV diagnostics platforms; there is potential in simplifying, decentralizing, and integrating COVID-19 testing into HCV testing strategies. Dried blood spot testing for antibody and viral load allows for samples to be mailed or couriered to laboratories, which could be regularized in countries' testing strategies.

HCV medical providers and community health workers have supported COVID-19 responses through a range of activities, including training medical workers on the use of personal protective equipment, guiding and assisting contact tracing efforts, providing epidemiologic and modeling support, and even researching COVID-19 interventions. Rapid mobilization of healthcare workers for the COVID-19 response can assist with HIV/HCV service delivery. This could include shifting and integrating tasks into the COVID-19 response, such as HIV/HCV screening, testing, and counseling to community health workers and peer educators, which can help link patients to treatment and care in more community-friendly settings. Peers, particularly people who use and inject drugs, should remain involved in the decision-making processes, such as around COVID-19 contact tracing and testing.

Implementation and expansion of communitycentered diagnostics and treatment requires personal protective equipment, enforceable memorandums of understanding with local law enforcement to prevent disruption of services and harassment or arrest of individuals seeking care, and equitable payment for work done by peer educators and community health workers, particularly as they take on new tasks and build technical skills and knowledge.

#### **Box 2: Structural Barriers to Positive Change**

- Racist, stigmatizing, and discriminatory policies and practices that blame, shame, and deny
  people dignity and the human rights to science, equitable health, harm reduction, and other
  essential services.
- Housing instability, lack of physical and mental health services, and lack of social supports for the most vulnerable and marginalized members of our communities.
- Intensified criminalization resulting from "shelter-in-place" and other legally mandatory distancing measures, especially when enforced by police, such as using COVID-19 to justify clearing out homeless encampments and providing no safe alternatives to shelter-in-place, or criminal fines for not wearing masks. To counter this and prevent the spread of the coronavirus, 10,000 individuals in New York City were relocated from shelters to self-isolate in empty hotel rooms.<sup>54</sup>
- Crowded, poorly ventilated, and inhumane incarceration. Countries must immediately release all elderly and vulnerable people from prisons and jails, end pretrial detention and cash bail, and free those held in immigration detention centers. In fact, in response to the pandemic, countries should follow the lead of Iran, Poland, and Turkey, who have temporarily released incarcerated individuals or allowed them to carry out sentences under house arrest.<sup>55</sup>
- Ongoing violent criminalization of drug use and people who use drugs; lack of access to a safe supply<sup>56</sup> of opioids, sterile drug using equipment, and drug consumption spaces to prevent onward transmission of viral hepatitis and overdose deaths. Access to home delivery of injection equipment and MAT/OST and prescription hydromorphone should be considered and implemented.
- Donors, agencies, researchers, pharmaceutical corporations, and other industries that have received government funding must be held accountable to ensure transparent, fair, and equitable access to the science, technologies, and services created.
- Speculative, proprietary prospective purchasing agreements that inflate corporate profits and the commandeering of medical supplies, medicines, and vaccines by high-income country governments, which deny access for low-and middle-income countries.

# HOW DO WE GET BACK ON TRACK AND FUND HCV ELIMINATION IN THE TIME OF COVID-19?

Funding is shrinking as countries confront the COVID-19 health emergency and grapple with austerity and budget cuts due to the global economic recession. Eliminating viral hepatitis globally is estimated to cost \$51 billion<sup>57</sup> by 2030, yet we receive only 10% of the needed annual funding. Other estimates show that a 1.5%, or \$58.7 billion, increase to the overall health-related Sustainable Development Goals could achieve hepatitis elimination.<sup>58</sup> Estimates for eliminating HCV in the U.S. by 2030 have ranged from \$100 to \$390 million per year, but more detailed cost analysis for a comprehensive package of services needs to be conducted at the federal level.

Governments and donors have mobilized CO-VID-19 relief packages that could provide muchneeded catalytic funding to serve cross-disease purposes, such as strengthening laboratory infrastructure and health systems. Large funders such as the Global Fund, USAID, and PEPFAR could participate in Overseas Development Assistance (ODA) grants that could be leveraged for HCV. PEPFAR could increase contributions to GAVI to integrate and scale up the universal HBV birth dose and adult vaccines, or governments could follow through with their commitments (see TAGline Fall 2020). Governments could provide resources to the Global Drug Facility or UNDP to scale up generic DAA access for people who are living with HCV or are coinfected with HIV/HBV.

Governments can strategically use funding to reinforce existing health infrastructure, pool resources across regions, states, or jurisdictions, and negotiate and procure volume-based deals for HCV treatments and diagnostics. Increasing the number of community health workers and peer educators can raise awareness, build more trusted networks for rolling out COVID-19 testing and contact tracing, distribute naloxone and sterile drug using equipment, and prevent overdose deaths.

Not only would these measures speed up progress, but hepatitis treatment with generic medications and harm reduction services is proven to save lives, save costs, and be cost-effective. The average cost of an NSP is estimated at \$23-\$71 per person per year.<sup>59</sup> The estimated costs are between \$360-\$1,070 for providing methadone and between \$1,230-\$3,170 for providing buprenorphine per person per year.<sup>60</sup> The costeffectiveness increases<sup>61</sup> when compared to cost per new HCV infection, per treatment and care for liver cancer, per liver transplant, or with crime and incarceration rates.<sup>62</sup>

The WHO and global health experts have developed frameworks<sup>63</sup> for investing in HCV elimination and HCV financing strategies<sup>64</sup> to support countries with implementing and sustaining programs. The economic impact of investing in HCV elimination, based on modeling, shows that global elimination efforts would be cost-saving by 2027, with net economic benefits amounting to \$22.7 billion<sup>65</sup> by 2030. The investment framework promotes public-private partnerships with diverse funding sources, widescale access to generic medications and simpler, point-of-care testing, and positioning HCV within countries' universal health coverage (UHC), which can integrate HCV into a minimum package of healthcare services. However, the UHC approach<sup>66</sup> that relies on medication or equipment donations from pharmaceutical corporations, patient user fees to cover diagnostics or liver function tests, and increased privatization of the public health system limits access to care for the poor and marginalized and is unsustainable. Instead, governments (and advocates aiming to influence them) should frame the upfront funding for HCV programs as needed investments that will catalyze cost savings and cost effectiveness in the long-term. When considering different financing strategies, countries that promote universal, equitable treatment, diagnostics, and wrap-around healthcare services that are free at points-of-care provide a fairer shot to people who are most disproportionately affected by HCV-i.e., people who inject drugs who often cannot afford out-of-pocket costs and then remain undiagnosed and untreated.

Strategic funding and swift policy action can regain lost ground in HCV elimination.

# **Box 3: Global Messages and Recommendations**

#### **Funding Recommendations:**

- 1. Governments must allocate new funding for remaining HCV research, including real world studies on treatment algorithms, diagnostic markers and tests for difficult-to-treat HCV geno-type subtypes, long-acting formulations, and a preventative vaccine. The U.S. should increase HCV research funding each year by at least the same percentage that overall funding to the National Institutes of Health is increased.<sup>67</sup>
- 2. Governments and donors must increase their investments in global HCV programs to \$5 billion per year; the U.S. should have parity in its global HIV and TB funding. In the U.S., the Centers for Disease Control and Prevention's Professional Judgement Budget estimates the Department of Viral Hepatitis needs at least \$390 million per year<sup>68</sup> to meet unmet needs and advance the elimination of viral hepatitis. Advocates are calling for at least \$134 million to begin to scale up the national response. Cost estimates for implementing the 2021–2025 Viral Hepatitis National Strategy are in process.
- 3. As governments and other donors commit emergency funding to confront COVID-19, they must **not shift or divert funding away from critical HCV responses**. HCV remains an urgent global health crisis requiring investment, political commitment, and prioritization throughout and after the COVID-19 pandemic.
- 4. COVID-19 relief packages can fund efforts to strengthen lab infrastructure and health systems. Global Fund, USAID, and PEPFAR could participate in ODA grants that could be leveraged for HCV, particularly for key populations and people who are coinfected with HIV/HBV. PEPFAR could increase contributions to GAVI to integrate and scale up the universal HBV birth dose and adult vaccines.

#### **Policy Recommendations:**

- 1. Negotiate and procure volume-based deals that include HBV and HCV treatments and diagnostics.
- 2. Fix administrative and legal barriers to treatment. Facilitate generic competition and lift treatment restrictions, prior authorizations, and insurance coverage barriers for DAAs and MAT/OST.
- **3.** Decentralize, simplify, and integrate testing into the COVID-19 response, where relevant and feasible, particularly in high HCV-burden settings:
  - a. Health departments can integrate HCV screening and confirmatory testing into COVID-19 testing.
  - b. Scale up community health workers and peer educators to include HCV and harm reduction outreach and linkage to care in the COVID-19 response.
- **4. Enhanced international cooperation in science** is needed to advance research efforts for both COVID-19 and HCV and to avoid hoarding technologies developed with public funding. Governments should encourage and require collaboration and openness to accelerate the development of new knowledge and public health tools and to avoid costly research duplication and silos. Mechanisms available to governments to advance international cooperation in science include (among others):
  - a. Participating in joint financing instruments and pools (access to COVID-19 Tools Accelerator,<sup>69</sup> People's Vaccine<sup>70</sup>).
  - b. Requiring open access to research data and results.
  - c. Providing any intellectual property developed with public funds free of charge for use in ending pandemics (Open COVID Pledge<sup>71</sup>).
  - d. Requiring binding commitments and mandates for industry to participate in technology pools to share patents, know-how, and data through the COVID-19 Technology Access Pool.<sup>72</sup>
  - e. Prohibiting anti-competitive, exclusive, and restrictive patenting and licensing practices.
  - f. Requiring broad transparency regarding the pricing, sale, and distribution of health technologies.
- 5. During and after COVID-19, reclaim public health and pharmaceutical R&D systems for the public good and across diseases:
  - a. Codify open science practices that accelerate innovation, reduce costs, and strengthen the evidence base on which our medicines system rests.
  - b. Create public sector capacity for full-cycle pharmaceutical innovation and production of essential medicines.
  - c. Use the full power of compulsory licensing and other legal intellectual property flexibilities to ensure access to essential medicines.
  - d. Take pharmaceutical R&D into public ownership to assure its products are available and equitably accessible to all.

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