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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. 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.

U.S. Messages and Recommendations

Funding Recommendations:

1. **The U.S. Government must allocate new funding for remaining HCV research,** including real world studies on treatment algorithms, diagnostic markers and tests for difficult-to-treat HCV genotype 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.¹

2. **Federal and state governments and donors must increase their investments in HCV programs.** In the U.S., the Centers for Disease Control and Prevention's Professional Judgment Budget estimates the Department of Viral Hepatitis needs at least \$390 million per year² to meet unmet needs and advance the elimination of viral hepatitis. Advocates are calling for 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 federal and state 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.** USAID, PEPFAR, and U.S. contributions to the Global Fund, and Overseas Development Assistance grants could be leveraged for the HCV response, particularly for key populations and people who are coinfecting with HIV/HBV. PEPFAR could increase contributions to GAVI, the Vaccine Alliance, to integrate and scale up the universal HBV birth dose and adult vaccines.

Policy Recommendations:

1. **Allow Medicare Part D to negotiate and states to 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 direct-acting antivirals and medication-assisted treatment (MAT)/opioid substitution therapy (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. The U.S. government 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 advance international cooperation in science include (among others):
 - a. Participating in joint financing instruments and pools (access to COVID-19 Tools Accelerator,³ People's Vaccine⁴).
 - 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 Pledge⁵).
 - 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.⁶
 - 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 USC § 1498, competitive 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.

REFERENCES

¹ Centers for Disease Control and Prevention. Professional Judgement Budget. 2016 December.

<http://www.theaidsinstitute.org/sites/default/files/attachments/CDC%20DVH%20-%20Professional%20Judgment%20FY2018-FY2027.pdf>

² Ibid.

³ World Health Organization. The access to COVID-19 tools (ACT) accelerator. Geneva: World Health Organization; 2020. <https://www.who.int/initiatives/act-accelerator>

⁴ UNAIDS. World leaders unite in call for a people's vaccine against COVID-19. Press release. 2020 May 14. https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/may/20200514_covid19-vaccine

⁵ <https://opencovidpledge.org/>

⁶ World Health Organization. COVID-19 technology access pool. Geneva: World Health Organization; 2020. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool>