



## **Policy Recommendations for Addressing COVID-19 Health Inequities**

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This document was developed by IDSA and HIVMA to offer recommendations from infectious diseases and HIV physicians, scientists, public health professionals and other clinicians working on the frontlines of the coronavirus pandemic for Congress and federal agencies to reduce COVID-19 health disparities.

Key strategies for reducing COVID-19 health inequities are centered around the need to 1) increase engagement with community-based organizations and leaders; 2) address barriers to COVID-19 services, including vaccinations; 3) improve national and state planning, coordination and data collection to strengthen the response; 4) optimize the clinical trial infrastructure to be more inclusive of key populations and community-based clinical trial sites; 5) foster an inclusive and diverse research workforce and 6) strengthen the Food and Drug Administration's emergency use authorization process for therapeutics.

### **1) Increase Community Engagement and Education in All Aspects of the COVID-19 Response**

- HHS: Increase support to directly fund community-based organizations (CBOs) serving populations at higher risk of experiencing health disparities to provide COVID-19 related public health education. These populations include Black, Indigenous and other people of color; Latinx; immigrant communities; people with substance use disorders, individuals who are experiencing homelessness, justice-involved populations and LGBTQ+ communities. These organizations also should be funded to provide health care services when appropriate, including vaccination, testing, contact tracing and providing support or coordination in accessing COVID-19 therapies or other COVID-19 related services. These efforts should be coordinated with local public health systems.
- Congress and HHS: Increase funding for local community providers, health centers and pharmacies to provide COVID-19 testing, vaccines and outpatient therapies with attention to ensuring sufficient funding to support an adequate public health workforce and sufficient funding for rural areas.
- HHS: Incentivize health systems to partner with CBOs and Indian Health Services/tribal entities serving Black, Indigenous, immigrant, Latinx and other underserved communities to support COVID-19 educational activities and provide COVID-19 related health care and public health services, including care coordination and other services, such as transportation, to support individuals seeking to access these services.
- HHS: Support culturally appropriate and linguistically accessible mass campaigns to educate community-based clinics and clinicians across the country on the availability of COVID-19 therapeutics and vaccines and how to encourage and assist their patients who are seeking access to them. Leverage partnerships with the IDSA, HIVMA and other

professional associations to extend the reach of these campaigns. A significant increase in resources for translation services and to improve communications for non-English speakers will be critical to this effort.

### **1) Address Barriers to COVID-19 Services, including Vaccinations**

- HHS: Support the expanded and regular use of mobile units to bring COVID-19 testing and vaccinations to underserved and rural communities and other vulnerable populations, such as people with disabilities and who are experiencing homelessness.
- HHS: Support the expanded use of peer-based community health worker programs to provide culturally relevant COVID-19 vaccination education, facilitate registration for vaccination appointments and provide information on COVID-19 testing sites and locations for outpatient treatment for COVID-19.
- HHS: Disseminate best practices and provide technical assistance for ensuring the use of non-internet-based mechanisms for vaccine education and registration to help address the inequities created by the digital and technology divide. For example, registrants should not be required to have an email address; allow registration by phone and ensure materials are accessible for individuals at all literacy levels.

### **2) Improve National and State Planning/Coordination/Data Collection to Strengthen the Response**

- HHS: Support coordination at the state and local level regarding vaccine allocation, distribution plan and administration sites to ensure programs are implemented in a coordinated and thoughtful way to prioritize key populations.
- HHS: Incentivize complete reporting of public health data, including vaccine distributions and vaccines administered, and ensuring the collection of demographic data, such as race/ethnicity, age and zip code of residence. Urge states to require reporting of race/ethnicity data and urge health care systems to ensure they are collecting the information through their electronic health records. Provide funding to support the use of complementary databases to collect this information in areas where underreporting is present.
- HHS: Support and incentivize streamlined and centralized public health data reporting systems, including for vaccines and vaccinations.
- HHS: Ensure transparency in data reporting (including demographics) and the timely and regular public release of public health data.
- HHS: Support the use of data analytics and geospatial mapping to direct vaccine allocations to heavily impacted populations and communities, including people over 65 years of age, Black, Indigenous and other people of color and Latinx populations.
- HHS: Map outpatient treatment sites for monoclonal antibodies and other authorized COVID-19 therapies with COVID-19 case and death rates and provide technical assistance to expand access to these sites where needed.

- HHS: Disseminate information on therapies authorized for COVID-19 to primary care providers and health care facilities and on how and where to access them to increase use of treatment options in the most heavily impacted areas.

### 3) Optimize the Clinical Trial Infrastructure

- Congress: Increase federal funding for research to study and develop COVID-19 *outpatient* treatment options, to address barriers to timely identification of patients for trials and to support clinical trial engagement and outreach to those most vulnerable to COVID-19, including older individuals; Black, Indigenous and other people of color; Latinx communities; immigrants; LGBTQ+ individuals and other populations that are underserved and most heavily impacted by COVID-19 and other infectious diseases.
- HHS: Support collaborations between the Food and Drug Administration (FDA), the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC) and the clinical research community to strengthen and improve the clinical trial infrastructure. This should include expanded funding mechanisms, increased research staff, and development of better analytical and predictive tools to allow rapid start-up and to simplify enrollment.
- HHS: Provide an integrated framework to link individuals diagnosed with COVID-19 to appropriate trials and encourage large-scale collaboration across many different types of facilities. Strengthen and expand clinical trials sites to include safety-net and other community hospitals and clinics to increase access to promising therapeutics for populations that are typically omitted from studies. Including settings outside of traditional urban tertiary care academic centers provides opportunity for enrolling a more diverse study population more rapidly and increases patient access to treatments.
- HHS: Fund mobile units to allow equitable access to research for people in rural areas, many of whom live at considerable distance from any hospital or community health center.

### 4) Foster a More Inclusive and Diverse Research Workforce

- Congress: Increase funding for targeted biomedical research initiatives, adopt actionable policies and strategies to promote inclusivity through a diverse research workforce, and direct NIH to provide training and technical assistance to help funding recipients achieve diversity goals. This new funding should supplement, not supplant, existing appropriations and create sustainable and predictable funding for research agencies. Diversity policies that Congress and NIH promote for funding should ensure that:
  - Federal and private industry clinical trial sponsors prioritize a diverse research workforce, including Black, Indigenous and people of color and LGBTQ+ individuals, and provide funding to facilitate partnerships between safety-net hospitals, community-based hospitals, clinics and well-established research centers;

- Safety-net hospitals have the resources and education they need to value and participate in clinical trials;
- Clinical trial sponsors ensure that research practices, trial designs and enrollment processes directly address the history of racism in clinical research by engaging Black, Indigenous and other people of color, Latinx communities and other underserved populations throughout the research process;
- Clinical trial sponsors engage with community leaders, including community-based participatory research groups, to support education about enrollment in research studies;
- Clinical trial sponsors ensure that study enrollment processes include comprehensive information about clinical trials and research studies with a transparent informed consent process;
- Clinical trial sponsors promote and expand access to the appropriate training on Good Clinical Research Practice (GCP), including medical ethics for medical and medical support staff;
- Clinical trial sponsors are encouraged to provide funding that would allow research sites to offer extended morning, evening and weekend hours to broaden access to people whose jobs or family responsibilities do not permit weekday participation;
- Federal clinical trial sponsors be allowed to cover trial participants' expenses related to participation, including transportation and childcare costs.

## **5) Strengthen the Emergency Use Authorization (EUA) Process for Therapeutics**

- FDA: Require the sponsor of a therapeutic receiving an EUA to include plans for recruiting children, individuals who are pregnant and breastfeeding, and others who are immunocompromised, including people with HIV. In addition, require inclusion of populations heavily impacted by the pandemic, including Black, Indigenous and other people of color, immigrant, Latinx communities and other underserved populations.
- HHS: For therapeutics granted EUAs, facilitate and support collaborations with manufacturers, health care facilities, private and federal payers and other federal agencies to collect additional evidence to monitor utilization and outcomes by adapting existing COVID-19 registries and data platforms and, if necessary, create new data collection mechanisms.
- HHS: Develop and regularly update guidance and best practices for states and facilities to ensure access to outpatient COVID-19 treatment for older Americans, communities of color and other populations most heavily impacted by COVID-19.
- CMS: Increase payments to providers to better reflect the costs of administering COVID-19 therapeutics (particularly those requiring infusion) and to support data collection, including information on whether medications are being used equitably among disproportionately affected communities.