



February 19, 2021

The Honorable Richard E. Neal
Chairman
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Neal:

Thank you for your letter to the Secretary of Health and Human Services (HHS), Alex M. Azar II, regarding efforts at HHS to address health disparities faced by racial and ethnic minority groups as related to COVID-19.

The questions from your letter, dated June 8, 2020 are responded to below. While we have responded to your questions as provided based on efforts that took place during the previous Administration, we want to assure you that we are incredibly focused on addressing disparities resulting from the pandemic. We would welcome the opportunity to talk with you or your staff further about President Biden's National Strategy for the COVID-19 Response and Pandemic Preparedness (<https://www.whitehouse.gov/wp-content/uploads/2021/01/National-Strategy-for-the-COVID-19-Response-and-Pandemic-Preparedness.pdf>), which includes as one of its goals: to "Protect those most at risk and advance equity, including across racial, ethnic, and rural/urban lines.

1. Since 2017, much of OMH's work has been reprogrammed to prioritize focus and resources on rural health, and the recent implementation of the National Advisory Committee on Rural Health and Human Services is the latest proof of this shift. I applaud this Administration's commitment to address disparities within rural communities; however, as noted above, OMH's mission extends to disparities seen across America, including in our cities and suburban areas. Given this deliberate shift toward a rural focus, against the backdrop of half of rural counties having fewer residents now than in 2000, I am concerned about how this decision has impacted OMH's core mission to seek solutions to all health disparities. There is no hierarchy of need that justifies prioritizing disparities impacting 60 million rural residents over the disparities impacting more than 130 million people who are members of racial and ethnic groups and live in rural, urban, and suburban communities. Please provide context by:

a. Describing how the priority focus on rural health incorporates the lessons learned through almost four decades of focus on racial inequities.

The Office of Minority Health's (OMH) mission remains to improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities. OMH's focus continues to be racial and ethnic minority populations residing in urban, suburban or rural locations. OMH defines racial and ethnic minority populations as: (1) American Indian/Alaska Native; (2) Asian; (3)

Black/African American; (4) Hispanic/Latino; and (5) Native Hawaiian or other Pacific Islander.

In response to the Further Consolidated Appropriations Act, 2020, which became Public Law 116-94, OMH was tasked with submitting reports to the Appropriations Committees describing HHS's commitment to address racial and ethnic health disparities. In September 2020, HHS submitted an update on the HHS Action Plan to Reduce Racial and Ethnic Health Disparities. This report provides an update to the Action Plan regarding HHS efforts to address racial and ethnic health disparities in the opioids crisis, maternal and infant health, and the COVID-19 response:

(https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf). Another report undergoing final clearance will summarize all OMH awards made in FY 2020, to include grant awards for eliminating racial and ethnic health disparities in sickle cell disease and sickle cell trait; lupus; Alzheimer's; diabetes and peripheral artery disease; and stomach, liver, and cervical cancer.

In its ongoing programmatic work through the National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities (NIMIC) Initiative, OMH recognizes that many rural communities have racial and ethnic minority populations who experience some of the most severe health disparities. For example, the Navajo Nation has COVID-19 infection and death rates per 100,000 that are 1.9 and 1.2 times, respectively, than that of New York.^{1, 2, 3} Through NIMIC and other initiatives, OMH's mission includes ensuring these racial and ethnic minority communities are reached.

OMH is not involved with the National Advisory Committee on Rural Health and Human Services. This is a federal advisory committee of the Health Resources and Services Administration (HRSA).

b. Describing efforts to ensure a comparable degree of focus and intentional policy development related to eliminating racial disparities regardless of geography.

OMH policy demonstration and program initiatives support national associations, state and local governments, nongovernmental organizations, and institutions of higher education in identifying community-based practices and innovative models that reduce disparities for racial and ethnic minority communities in different geographic settings. OMH's FY 2020 competitive and continuation grants included 84 awardees located in 35 states targeting 57 urban areas, 23 rural areas, 11 mixed areas (urban and rural) and 15 Tribal communities; and included 2 projects that are national in scope.⁴ OMH's FY 2019 grants included 99 awardees located in 37 states

¹ <https://www.navajo-nsn.gov/>

² <https://us-covid19-per-capita.net/>

³ <https://us-covid19-per-capita.net/deaths.html>

⁴ These awardees are located in 35 states including the District of Columbia: Alabama, Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Missouri, Nebraska, New Jersey, New Mexico, New York, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Virginia, Vermont, Washington, and Wisconsin.

targeting 40 urban areas, 7 rural areas, 22 mixed areas (urban and rural), 11 Tribal communities, and 18 state identified health disparity hotspots; and included 4 projects that are national in scope.

Highlighted below are several examples of OMH initiatives that support the elimination of racial and ethnic health disparities in which final award decisions were made with consideration of published notice of funding opportunity criteria that included the geographical distribution of awards.

- OMH funds the Empowered Communities for a Healthier Nation Initiative (ECI) to identify innovative approaches for: (1) preventing opioid abuse, increasing access to opioid treatment and recovery services, and reducing the health consequences of opioid abuse; (2) reducing obesity prevalence and disparities in weight status among children and adolescents; and (3) reducing the impact of serious mental illness and improving screening for serious mental illness at the primary care level.
- OMH funds the State/Territorial/Tribal Partnership Initiative to Document and Sustain Disparity Reducing Interventions (SPI 2.0) to build the capacity of state, tribal, and territorial health agencies to achieve two main goals: (1) test modifications to existing public health programs or practices (interventions) to assess if the modified interventions are successful in significantly improving health outcomes for selected health issues; and (2) develop an effective plan(s) to sustain successful interventions after the award period.
- OMH and the Office of the Assistant Secretary for Health (OASH) Office on Women's Health jointly fund the Youth Engagement in Sports: Collaboration to Improve Adolescent Physical Activity and Nutrition (YES) Initiative. The YES Initiative intends to identify effective collaborations and community partnerships that aim to improve physical activity and nutrition by increasing sports participation by racial and ethnic minority and/or socio-economically disadvantaged youth.
- In consultation with the OASH Office of Infectious Disease and HIV Policy and the Centers for Disease Control and Prevention (CDC), OMH funds the Hepatitis B (HBV) Demonstration Program to identify best practices for establishing comprehensive HBV programs that have capacity to scale-up testing and health care services and ultimately reach Healthy People and National Hepatitis B Elimination Goals.

2. Please describe how OMH is engaged across HHS and within the coronavirus task forces to fulfill its mission to “improve the health of racial and ethnic minority populations through the development of health policies and programs that will help eliminate health disparities,” particularly during this pandemic that so evidently has a disproportionate impact on communities of color.

OMH has worked and continues to work closely with the Office of the Secretary, OASH, CDC and other offices of minority health/health equity across HHS as part of the overall HHS response to the COVID-19 pandemic. Below are some examples of OMH’s engagement.

- OMH provided counsel to Senior FEMA/HHS leaders for the Federally-supported community-based testing sites that resulted in the collection of racial and ethnic testing data.

OMH served as a liaison to the FEMA/HHS Community-Based Testing Sites Joint Task Force and participated in weekly partners meetings led by FEMA and HHS.

- OMH convenes HHS agency offices of minority health/health equity monthly to discuss COVID-19 and related work occurring within their agencies and to promote collaboration and synergy. The agencies participating in these meetings include ARHQ, CMS, CDC, FDA, HRSA, NIH and SAMHSA.
- OMH identified a gap in activities related to the engagement of trusted community voices to disseminate COVID-19 public health messages and to link racial and ethnic minorities to testing and other services. OMH subsequently obtained supplemental COVID-19 funding for its National Infrastructure to Mitigate the Impact of COVID-19 in Racial and Ethnic Minority Communities Initiative, which is described on page 4 in more detail.
- OMH identified the need to disseminate state and local practices that are successfully mitigating the impact of COVID-19 within racial and ethnic communities. Thus, OMH hosted a national virtual symposium on COVID-19 in September 2020. The symposium resources remain available to the public is on the OMH website: <https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=3&lvlid=114>.
- OMH is collaborating with the CDC to expand its Social Vulnerability Index (SVI), which has been used to determine locations for COVID-19 community-based testing sites (<https://svi.cdc.gov/>). The expanded index will better identify the geographic locations of specific racial and ethnic minority communities that are more vulnerable to worse COVID-19 outcomes and inform public health professionals in efforts to provide culturally and linguistically appropriate recovery and response actions.
- OMH has worked collaboratively with CDC to support their efforts to expand the languages in which COVID-19 resources have been translated, including facilitating a request for materials in the Pacific Island languages of Marshallese, Tongan and Chuukese.
- OMH has amplified HHS COVID-19 messaging to racial and ethnic minority populations through all OMH communications channels, including its website, partner communications, newsletters and social media platforms.

Please detail the following for the funding announcement, “National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities:”

- a. Why is there one national award rather than several awards to meet such a wide goal? Are future awards planned?***

The National Infrastructure for Mitigating the Impact of COVID-19 within Racial and Ethnic Minority Communities (NIMIC) Initiative is a three-year project with the primary goal of developing and coordinating a strategic network of national, state, tribal, territorial and community-based organizations across the nation to deliver education and information through trusted community voices to help address the disproportionate impact of COVID-19 on racial and ethnic minority populations. In highly impacted areas, NIMIC also will support community-based organizations’ efforts to link individuals to COVID-19 testing,

vaccination, healthcare and social services and will seek to identify effective response, recovery and resilience strategies.

To ensure that we reach all states, territories, and tribes with consistently accurate and culturally and linguistically responsive messaging, NIMIC was designed to have one national entity coordinate communication efforts across state/territorial/tribal/local partners and community-based organizations throughout the country.

National, state, territorial, tribal and local organizations wanting to join in the efforts of the NIMIC Initiative can obtain additional information on the National COVID-19 Resiliency Network from the OMH website:

<https://www.minorityhealth.hhs.gov/omh/Content.aspx?ID=18512&lvl=2&lvlid=12>.

- b. Given the OMH mission is focused on racial and ethnic minority populations, please explain the rationale for expanding the focus of this OMH funding opportunity to include “rural” and the “socially vulnerable.”***

Racial and ethnic minority groups who experience social vulnerability characteristics are at greater risk for exposure to and adverse outcomes from COVID-19. Individuals experiencing social vulnerability characteristics tend to have living and working conditions that limit the ability to comply with public health measures to prevent infection, such as physical distancing, handwashing and quarantine measures. Another social vulnerability characteristic, lacking access to a vehicle, can create a barrier to accessing care for COVID-19. Understanding social vulnerability characteristics helps frame the full extent of challenges racial and ethnic minority communities face in confronting COVID-19 and supports the design of a network that can effectively provide public health information and linkages to healthcare and social services.

Rural populations may be at higher risk for infection and severe illness because they tend to be older than non-rural populations, have higher rates of chronic underlying disease, are more likely to have a disability, have a limited health care infrastructure, and may work in agricultural and food processing facilities in which public health measures are difficult to implement. These factors especially effect tribal communities, who face challenges such as high rates of chronic conditions, limited health services, public funding inequities and limited infrastructure (e.g., running water, broadband). Reports have shown a devastating impact to racial and ethnic minority groups in some rural communities in Alabama ([link](#)), Mississippi ([link](#)) and other southern states; and among the Navajo Nation ([link](#)) and other tribes in rural communities of Western states ([link](#)).

- c. How does OMH define “socially vulnerable?”***

The OMH funding opportunity announcement defined social vulnerability as follows.

Socially vulnerable groups refer to individuals, communities or populations that have characteristics that affect their capacity to anticipate, confront, repair, and recover from the effects of a disaster.⁵ Such characteristics include the following:^{6,7,8,9}

- Individual and household traits, such as low socioeconomic status, being a racial or ethnic minority, having limited English proficiency, being a child or elderly, being unemployed, lacking access to a vehicle or being dependent on public transportation, having low educational attainment, living in overcrowded conditions, or being homeless
- Systemic and structural factors, such as residing in areas that are densely populated, lack healthcare facilities and resources, are rural or urban, or have weak economies

d. Given the application period has closed, how many applicants sought funding, who are these applicants, and against what criteria are their applications being reviewed/ranked?

Forty-five applicants sought funding. Applications were reviewed by the criteria published in the MP-CPI-20-006 Notice of Funding Opportunity ([link](#)) Application Review Criteria (Section G1 on pages 67-79). Under HHS grant policy, we do not release the identity of the applicants not receiving awards because of the privacy interests involved.

3. Most of the experts at the hearing noted the need for data disaggregated by race, making this issue one of the most important in terms of COVID-19 response and recovery. The Centers for Disease Control and Prevention (CDC) submitted a Report to Congress on Disaggregated Data on U.S. Coronavirus Disease 2019 (COVID-19) Testing in May that provides additional insight into the efforts referenced in the letter. In that report, CDC states that it, “continues to work with states, localities, territories, and tribal organizations to collect public health, clinical, and commercial laboratory testing data disaggregated by race, ethnicity, age, sex, geographic region, and other relevant factors. Revisions to the [Case Report Form] (CRF) reflect one of the ways that CDC’s data collection will continue to be improved and refined over time.” Accordingly:

a. Please provide information on the frequency and scope of coordination with states, localities, territories, and tribal organizations (including the number of such entities CDC is currently and actively engaging) and a detailed timeline for the revisions to the CRF described in the Report to Congress on testing.

⁵ Flanagan, B.E., E.J. Hallisey, E. Adams, and A. Lavery, 2018. “Measuring community vulnerability to natural and anthropogenic hazards: The Centers for Disease Control and Prevention’s social vulnerability index.” J. Environ. Health 80(10): 34-36.

⁶ Ibid.

⁷ Cutter, S.L., Boruff, B.J., & Shirley, W.L. (2003). Social vulnerability to environmental hazards. Social Science Quarterly, 84(2), 242–261.

⁸ Bergstrand, K., Mayer, B., Brumback, B., & Zhang, Y. (2015). Assessing the Relationship Between Social Vulnerability and Community Resilience to Hazards. Social indicators research, 122(2), 391–409. <https://doi.org/10.1007/s11205-014-0698-3>

⁹ Flanagan, Barry E.; Gregory, Edward W.; Hallisey, Elaine J.; Heitgerd, Janet L.; and Lewis, Brian (2011) "A Social Vulnerability Index for Disaster Management," Journal of Homeland Security and Emergency Management: Vol. 8: Iss. 1, Article 3. DOI: 10.2202/1547-7355.1792

In early May 2020, the Centers for Disease Control and Prevention (CDC) revised the case report form (CRF) to reflect the changing epidemiology of COVID-19 cases in the United States (www.cdc.gov/coronavirus/2019-ncov/downloads/pui-form.pdf). These revisions are aligned with the Council of State and Territorial Epidemiologists interim position statement (https://cdn.ymaws.com/www.cste.org/resource/resmgr/2020ps/Interim-20-ID-01_COVID-19.pdf), which outlines case definitions for COVID-19 and makes COVID-19 a nationally notifiable disease.

CDC is appreciative of all the efforts of its state partners to collect and report data on COVID-19 cases as part of the national response (www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html). Revisions to the CRF improve CDC's understanding of the epidemiology of COVID-19, thus informing public health action. Changes to the CRF include:

- Variables added to better capture data on populations at increased risk, include:
 - Tribal populations,
 - Individuals who are experiencing homelessness,
 - Individuals requiring translation services,
 - Individuals with disabilities, including physical disabilities, intellectual disabilities, and mental health conditions.
- Variables added related to healthcare, workplace, and specific community exposures, such as correctional facilities or schools/childcare settings;
- Variables added related to whether cases are associated with an outbreak, and if so, which outbreak specifically;
- An expanded list of underlying medical conditions, including severe obesity, hypertension, and autoimmune disorders;
- An expanded list of COVID-19 symptoms; and
- Improved collection of information related to specimen testing for COVID-19.

States have improved reporting to CDC with the CRF. For example, the completeness of race/ethnicity data improved from 18% in April 2020 to 48-51% in early July 2020.

On June 4, 2020, the Department of Health and Human Services (HHS) announced new guidance that specifies additional data that must be reported to HHS by laboratories along with COVID-19 test results, including race, ethnicity, and sex. The guidance, *COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115* (www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf), standardizes reporting to help ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19 to better prevent and mitigate further illnesses among Americans.

The requirement to include demographic data will allow for more accurate determination of the burden of COVID-19 on disproportionately affected groups. Protecting racial and ethnic minorities, as well as other populations at risk is a priority for CDC; doing so requires that CDC have robust data that describe the impact of COVID-19 on these populations. For more information on CDC's outreach to communities who are disproportionately impacted by COVID-19, see: www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html.

- b. Describe barriers common among states, localities, territories, and tribal organizations that impede data reporting and integrity efforts. If small sample size is a challenge for collecting data for certain groups, please describe HHS's methodological approach for collecting and publicly reporting these data.***

In order to monitor COVID-19 and protect communities at increased risk, CDC's goal is to get as complete a picture as possible of the overall situation in the United States and share findings with the American public. State health departments work to get complete information on every case, including race/ethnicity, but during a large-scale pandemic it is understandable that these health departments may not be able to gather all the case-specific information. Data collection begins on the front lines of this public health emergency with a clinician or laboratory worker completing case information about individuals. During a pandemic, these front line healthcare workers may be understandably limited in the amount of data they can collect and report from patients when faced with real time decisions regarding patient care. As CDC works to improve the ability to capture data in healthcare settings, we are leveraging existing surveillance systems, such as those that capture hospitalization and mortality data, to provide a fuller picture of the outbreak and how it is impacting racial and ethnic minorities.

CDC uses several surveillance systems to collect data on COVID-19. Each of these systems has strengths and limitations in collecting demographic data from reporting entities such as clinicians, states, hospitals and laboratories. Below is a description of each source of data, their strengths and limitations and the progress made by reporting entities to share more complete data. More information regarding CDC surveillance systems can be found at [COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity | CDC](#).

Data collection begins with clinicians and laboratory workers reporting demographic information about patients with COVID-19. Data are reported voluntarily to CDC. CDC continues to work with each state and jurisdiction to develop long-term, sustainable systems that enable complete and timely reporting, which will be used for COVID-19 and adapted to other public health priorities in the future.

COVID-19 case-based surveillance is conducted primarily at the state level. COVID-19 is a nationally notifiable disease and is reportable in all 50 states, Washington, DC, and the U.S. territories. When a jurisdiction confirms a case, it submits that report to CDC through the National Notifiable Diseases Surveillance System and, in turn, to the Data Collation and Integration for Public Health Event Response platform. With these data, CDC collects daily patient-level, state-reported case counts. These case reports include

clinical, epidemiologic, and outcome data (e.g., age, underlying conditions, race/ethnicity, hospitalization, death), though some case reports may be missing some of these elements. As of December 17, 2020, 16,756,581 COVID-19 cases had been reported to CDC through the reporting system. Of these, 306,427 had reported deaths.

CDC is also strengthening reporting on race/ethnicity data by posting the available race/ethnicity data received through case-based reporting from public health departments on the CDC website. This information can be viewed on CDC's *CDC COVID Data Tracker* Demographic trends page (<https://www.cdc.gov/covid-data-tracker/index.html#demographics>), which is updated daily.

CDC uses other public health surveillance systems, such as hospitalizations and mortality data, to provide a complete picture of the COVID-19 pandemic and its impact:

- CDC's Cases, Data and Surveillance (www.cdc.gov/coronavirus/2019-ncov/cases-updates/index.html) reports hospitalization and mortality data that include race/ethnicity.
- Provisional counts of deaths related to COVID-19 are reported through the National Vital Statistics System and include deaths occurring within the 50 states and the District of Columbia (www.cdc.gov/nchs/nvss/covid-19.htm). These counts are based on death certificates that contain COVID-19 as a cause of death and include race/ethnicity information. COVID-19 death counts shown in these reports may differ from other published sources, as data currently are lagged by an average of one to two weeks. Provisional counts of deaths related to COVID-19 are reported through the National Vital Statistics System (www.cdc.gov/nchs/nvss/covid-19.htm). These counts are based on death certificates that contain COVID-19 as a cause of death and include race and ethnicity information. COVID-19 death counts shown in these reports may differ from other published sources, as data currently are lagged by an average of one to two weeks.
- CDC maintains a COVID-19–Associated Hospitalization Surveillance Network (COVID-NET) to conduct population-based surveillance for laboratory-confirmed COVID-19-associated hospitalizations in all ages. COVID-NET gathers data from 99 counties in 14 states, covering about 10% of the US population. This system produces high-quality information on hospitalization rates and risk factors for hospitalization because the data have high completion rates and survey a population similar to the total U.S. population.

Additionally, CDC publishes a weekly surveillance report, COVIDView (www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html), which summarizes data from these and other surveillance systems. Periodic reports in CDC's *Morbidity and Mortality Weekly Report* also provide additional race and ethnicity information from these and other systems (www.cdc.gov/mmwr/index.html).

The COVID-19 crisis has highlighted the need to modernize the public health data systems that CDC relies on for accurate surveillance data. Thanks to support from

Congress, CDC received resources in Fiscal Year 2020 COVID supplemental funds in the CARES Act to invest in modernizing public health data systems. This investment will help improve data collection to better access real time data for COVID-19 decision making and fulfill a long-term strategy to improve data access, sharing, and innovations.

Early in the pandemic, the number of cases in certain racial and ethnic groups were low and could have posed privacy concerns if the data were disaggregated and publicly reported. By mid-May 2020, CDC deemed that the number of cases was enough in these groups to disaggregate and post the data publicly. Below is additional detail on these changes:

- Prior to May 2020, COVID-NET displayed race and ethnicity data using four categories in COVIDView reports and on COVID-NET Interactive (https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html): non-Hispanic White, non-Hispanic Black, Hispanic/Latino, and Other, which included Asian/Pacific Islander, American Indian/Alaska Native, persons of multiple race, and persons for whom race and ethnicity data were unknown. COVID-NET data on race and ethnicity were missing for approximately 32 percent of persons during this time period, and CDC was unable to disaggregate the “Other” category due to small counts and concerns about protection of privacy.
- As the result of concerted effort working with COVID-NET sites, by late May 2020, completeness of race and ethnicity data for hospitalized cases had increased to 82%. Additionally, CDC now had enough cases in the Asian/Pacific Islander and American Indian/Alaska Native groups to display these groups separately but still protect their privacy, and so were able to disaggregate them from the “Other” category. Since June 2020, completeness of race and ethnicity data in COVID-NET has maintained at a level around 96% and continues to be available for public view at: https://gis.cdc.gov/grasp/COVIDNet/COVID19_5.html.

In early June 2020, COVID-NET interactive was updated with the ability to look at several different characteristics of COVID-19 associated hospitalizations by the six race and ethnicity categories.

- In October 2020, CDC published COVID-NET age-adjusted hospitalization rates among health care personnel from March 1–May 23, 2020 by the six race and ethnicity categories on the weekly COVIDView report: non-Hispanic White, non-Hispanic Black, Hispanic/Latino, Asian/Pacific Islander, American Indian/Alaska Native, and Other.

c. As data are intended to help CDC manage response and any occurrences of resurgence, provide a timeline on the planned translation of data into tools for clinical management, health education, and resource allocation.”

To accelerate progress toward reducing COVID-19 disparities and achieve health equity, CDC recently established within the COVID-19 Incident Management Structure a Chief Health Equity Officer whose focus is to ensure an all-of-response approach to identifying and addressing COVID-19 disparities. CDC’s COVID-19 Health Equity Strategy

(<https://www.cdc.gov/coronavirus/2019-ncov/downloads/community/CDC-Strategy.pdf>) aims to ensure that key data are available and that high impact programs and initiatives – that are culturally and linguistically responsive and tailored to address the unique circumstances of groups at increased risk for COVID-19 – are being implemented.

The health equity strategy prioritizes:

- Expanding the evidence base to increase CDC’s understanding of the impact and factors that lead to the disproportionate burden of COVID-19 in communities at highest risk;
- Expanding testing, contact tracing, isolation options, and preventive care and disease management in populations at increased risk for COVID-19;
- Expanding programs and practice activities to support essential and frontline workers to prevent the spread of COVID-19; and
- Expanding an inclusive workforce equipped to assess and address the needs of an increasingly diverse U.S. population.

The COVID-19 supplemental package titled the *Paycheck Protection Program and Health Care Enhancement Act, Public Law 116-139* (www.congress.gov/bill/116th-congress/house-bill/266/text) requires the HHS Secretary to work with other departments and agencies to report data on COVID-19 testing, positive diagnoses, hospitalizations and deaths disaggregated by race, ethnicity, age, sex, geographic region, and other relevant factors. Updates on these data are required to be reported to Congress every 30 days until the end of this public health emergency. CDC released its second 30-day report to Congress on July 15, 2020. The report provides further COVID-19 demographic data and highlights CDC’s progress. CDC continues to collaborate with hospitals, academic institutions, and state public health partners to gather and report more complete demographic data. These collaborations allow CDC to obtain and disseminate additional data to learn more about COVID-19 disparities. These data can also help inform improvements in clinical management of patients, allocation of resources, and targeted public health information.

Access to testing is a key part of the clinical approach to defeating COVID-19. Therefore, CDC is taking the following steps to increase testing rates in racial and ethnic minority communities.

- CDC is working with state and local health departments to support forward-looking testing strategies that ensure that populations placed at high risk of complications from COVID-19, such as racial and ethnic minority groups, have adequate access to testing.
- CDC is working with HRSA and the Federally Qualified Health Centers to develop and implement a strategy to increase testing in these clinics and to provide the clinics with the tools and resources to diagnose, treat, and monitor COVID-19 illness in the populations they serve.

- CDC has participated in calls with every state to provide supplies and plan for increased testing. This increased testing capacity in every part of the country should make getting a test more equitable.

CDC also has many communication tools at its disposal to share useful COVID-19 information with racial and ethnic minority communities.

- CDC is engaging with community and faith-based organizations, including the National Council of Churches and Martin Luther King III, to enhance its reach and to develop educational public service announcements designed to reach communities that have been highly impacted by COVID-19, such as the African American community.
- CDC hosted a webinar on June 2, 2020, *COVID-19 Response: Promising Practices in Health Equity* (<https://youtu.be/2jGvVbfaLiQ>), which focused on sharing public health practices to reduce COVID-19 related disparities. Presenters discussed the actions their cities have taken to mitigate the disproportionate impact on racial and ethnic minority populations and how these steps can be integrated into longer-term strategies that strengthen future responses and advance health equity.
- CDC is also supporting several hyperlocal activities in African American, Hispanic/Latino, American Indian and Alaska Native, and Asian American, Pacific Islander and Native Hawaiian communities. Through the engagement of trusted community-based organizations and institutions, CDC is forging partnerships nationwide, developing tailored communications, and mobilizing community health navigators and Promotores trained to deliver COVID-19 prevention messages and community mitigation strategies. These investments include engaging historically Black colleges and universities and minority-serving organizations.

4. The National Institutes of Health (NIH) is responsible for ensuring the nation's clinical science supports vaccine development, the National Institute on Minority Health and Health Disparities acknowledged the need for research on the impact of the pandemic on NIH-designated health disparity populations, and the Secretary agrees that vaccines must be accessible and affordable. What specific efforts is the Department taking to ensure drug development and clinical trials demonstrate the efficacy of potential vaccines across racial and ethnic groups, many of whom have been traditionally excluded from clinical trials? How will HHS work to ensure the vaccine is widely and equally available to all residents, without regard to means?

NIH has a long-standing commitment to eliminating health disparities and ensuring the inclusion of individuals from racial and ethnic minority groups in clinical research studies. In Fiscal Year (FY) 2020, 32 percent of participants in U.S. NIH-funded clinical research identified as racial or ethnic minorities, including 15 percent Black or African American, 11 percent Hispanic or Latino, 4 percent Asian, 3 percent more than one race, 1 percent American Indian or Alaska Native, and 0.3 percent Native Hawaiian or Pacific Islander.

NIH recognizes that racial and ethnic minority groups are disproportionately affected by COVID-19, with current data suggesting a higher burden of infection, illness and/or death among

these populations. NIH strives to ensure that all clinical research includes the appropriate populations to help us better understand and address these disparities. As NIH responds to the current pandemic, scientists leading the development and evaluation of medical countermeasures against COVID-19 are working closely with pharmaceutical companies, manufacturers, biotechnology firms, and others to encourage that diverse populations be considered for inclusion in clinical studies. Current NIH efforts to include racial and ethnic minority groups in NIH clinical research, including responses to your specific questions, are outlined below.

a. What specific efforts is the Department taking to ensure drug development and clinical trials demonstrate the efficacy of potential vaccines across racial and ethnic groups, many of whom have been traditionally excluded from clinical trials?

NIH and HHS are engaged in several efforts to ensure inclusion of racial and ethnic minority groups in COVID-19 clinical research, including the following:

- The NIH-Wide Strategic Plan for COVID-19 Research¹⁰ addresses the importance of inclusion of racial and ethnic minorities in COVID-19 research. Specifically, it ensures that diagnosis, treatment, and prevention options are accessible and available for underserved and vulnerable populations which have been at greatest risk for the most severe threats of the disease.
- The NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research¹¹ and the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects¹² require that women, racial and ethnic minorities, and individuals across the lifespan be included in NIH-funded clinical research studies unless there is a compelling rationale for exclusion. NIH peer reviewers assess each application for the appropriateness of enrollment in the context of the scientific question. This assessment is factored into the overall priority score and applications found to be unacceptable may not be funded until concerns are resolved. NIH program staff confirm the acceptability of inclusion plans and monitor actual enrollment in progress reports throughout the funding cycle. Annual progress reports include participant data on sex/gender, race, and ethnicity, which are compiled and reported by the NIH Institutes and Centers (ICs) in the NIH Triennial Report and the Biennial Full Report on Research on Women's Health. The most recent reports can be found at <https://dpcpsi.nih.gov/oepr/nih-triennial-report> and <https://orwh.od.nih.gov/research/funded-research-and-programs/research-reports/biennial-report>.
- A June 2019 FDA guidance document “Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry”¹³ recommends approaches that sponsors of clinical trials to support a

¹⁰ <https://www.nih.gov/research-training/medical-research-initiatives/nih-wide-strategic-plan-covid-19-research>

¹¹ <https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm>

¹² <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html>

¹³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial>

new drug application or a biologics license application can take to broaden eligibility criteria, when scientifically and clinically appropriate, and increase enrollment of underrepresented populations in their clinical trials.

- In its first phase, the RADx Underserved Populations (RADx-UP)¹⁴ initiative leverages existing NIH-funded researchers with robust, proven community partnerships to rapidly build community-engaged implementation projects focused on understanding the factors associated with testing for SARS-CoV-2, the virus that causes COVID-19. These projects seek to increase understanding of the health disparities in morbidity and mortality and to inform strategies to reduce disparities for those underserved and vulnerable populations who are disproportionately affected by, have the highest infection rates of and/or are most at risk for complications or poor outcomes from the COVID-19 pandemic. In addition to NIH-designated health disparity populations, RADx-UP will specifically reach persons in nursing homes, jails, rural areas, or underserved urban areas; pregnant women; and persons experiencing homelessness. NIH has published four RADx-UP funding opportunity announcements¹⁵ focused on COVID-19 research to enhance access to and availability of testing in populations who are underserved or at increased risk.
- NIH has issued several Notices of Special Interest focused on COVID-19 social and behavioral research in racial and ethnic minority and other health disparity populations:
 - Notice of Special Interest (NOSI): Competitive and Administrative Supplements for the Impact of COVID-19 Outbreak on Minority Health and Health Disparities¹⁶ is focused on: (1) how state and local policies and initiatives mitigate or exacerbate disparities in health services use and health outcomes; (2) the role that community-level protective and resilience factors and interventions have in mitigating the effects of the sector disruptions that the COVID-19 outbreak causes; and (3) how behavioral and/or biological mechanisms may contribute to COVID-19 manifestations.
 - Notice of Special Interest (NOSI): Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19¹⁷ solicits research to address secondary health effects of social, behavioral, and economic changes, particularly among populations who experience health disparities and populations at increased risk, through the use of digital health assessments and interventions to yield measurable near-term impact.
 - Notice of Special Interest (NOSI): Competitive and Administrative Supplements for Community Interventions to Reduce the Impact of COVID-19 on Health Disparity and Other Vulnerable Populations¹⁸ is focused on

¹⁴ <https://www.nih.gov/research-training/medical-research-initiatives/radx>

¹⁵ <https://www.nih.gov/research-training/medical-research-initiatives/radx/funding#closed-funding-opportunities>

¹⁶ <https://grants.nih.gov/grants/guide/notice-files/NOT-MD-20-019.html>

¹⁷ <https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-053.html>

¹⁸ <https://grants.nih.gov/grants/guide/notice-files/NOT-MD-20-022.html>

testing community interventions focused on the prevention (or slowing) of COVID-19 transmission and evaluation of local and state policies and programs intended to mitigate COVID-19 exposure, improve adherence, and reduce the negative impact of the multifaceted consequences of COVID-19 on the health of populations who experience health disparities and other groups at increased risk for COVID-19.

- Through the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)¹⁹ public-private partnership, NIH is leveraging infrastructure from existing networks with experience and expertise in recruitment of diverse populations, including the AIDS Clinical Trials Group, the Clinical and Translational Science Awards Program, the National Cancer Institute (NCI) National Clinical Trials Network, and the Prevention and Early Treatment of Acute Lung Injury (PETAL) Clinical Trials Network.
- NIH is leveraging the National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS Clinical Trials Networks, including the AIDS Clinical Trials Group²⁰ (ACTG), HIV Prevention Trials Network²¹ (HPTN) and the HIV Vaccine Trials Network²² (HVTN). The ACTG, HPTN, and HVTN have well-established programs to engage diverse community members and participants, including the ACTG's Underrepresented Populations Committee and Minority HIV Investigator Mentoring Program.²³
- NIAID is capitalizing on long-term investments in clinical research sites, many of which engage with diverse populations, to conduct clinical trials evaluating medical countermeasures for COVID-19 and SARS-CoV-2, the virus that causes COVID-19. The COVID-19 Prevention Network (CoVPN)²⁴ aims to enroll thousands of volunteers in large-scale clinical trials testing a variety of investigational vaccines and monoclonal antibodies intended to protect people from COVID-19. These efforts are designed to meet the growing public health needs of communities of vulnerable populations, including the African American community that have been disproportionately impacted by COVID-19.
- In addition, the National Institute on Minority Health and Health Disparities and the National Heart, Lung, and Blood Institute are leading an NIH-wide effort to ensure community engagement in addressing the disproportionate impact of COVID-19 on racial and ethnic minorities and other underserved and vulnerable populations through the Community Engagement Alliance Against COVID-19 Disparities (CEAL).²⁵ CEAL is an NIH-wide effort to mobilize groups of existing NIH-funded researchers with expertise in community engagement developed over

¹⁹ <https://grants.nih.gov/grants/guide/notice-files/NOT-MD-20-022.html>

²⁰ <https://actgnetwork.org/>

²¹ <https://www.hptn.org/>

²² <https://www.hvtn.org/en.html>

²³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6419986/>

²⁴ <https://www.nih.gov/news-events/news-releases/nih-launches-clinical-trials-network-test-covid-19-vaccines-other-prevention-tools>

²⁵ <https://covid19community.nih.gov>

decades. The CEAL research consortiums leverage established relationships among NIH-funded researchers, state or city health departments, community-based organizations, and federally qualified health centers with trusted local leaders to identify appropriate strategies to reach underserved communities in the states that have been hardest hit by COVID-19. CEAL creates links to COVID-19 clinical research recruitment sites and addresses the mistrust in institutions that has permeated communities, with the goal of fostering greater trust in science.

- The NCI Community Oncology Research Program (NCORP), which studies cancers which disproportionately affect racial and ethnic minorities and underserved population and aims to accrue individuals who do not have access to traditional academic research settings into NCI clinical trials, is playing a key role in the NCI COVID-19 in Cancer Patients Study (NCCAPS). Launched in May 2020, this natural history study is now open at over 400 sites across the country and will examine how COVID-19 affects cancer patients of all ages.
- Phase 3 efficacy trials of candidate SARS-CoV-2 vaccines will be conducted in higher risk populations. Generating a diverse group of participants is a major focus of recruitment and community engagement activities coordinated and overseen by NIAID and Operation Warp Speed²⁶ (OWS) team members. NIAID is applying novel real-time data tracking tools and outbreak data analytics to inform trial design, site selection, and recruitment of at-risk individuals. These tools are expected to enable more effective recruitment of diverse populations.
- The first iteration of the NIAID-sponsored Adaptive COVID-19 Treatment Trial (ACTT-1) assessed the efficacy of Gilead Sciences' antiviral remdesivir in the treatment of patients hospitalized with COVID-19. The final findings of the ACTT-1, including data on diversity of trial participants, were published on November 5, 2020 (preliminary findings were released May 22, 2020) in the *New England Journal of Medicine*. Overall, 53.3 percent of the patients identified as White, 21.3 percent identified as Black, 12.6 percent identified as Asian, and 12.7 percent were designated as other or not reported. Additionally, 23.5 percent of study participants identified their ethnicity as Hispanic or Latino.
- NIH and FDA have partnered with the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by Duke University and FDA, to create a webinar to share strategies for including ethnically diverse populations in COVID-19 trials. The June 18, 2020 webinar²⁷ addressed barriers and solutions to enrolling a diverse participant population and summarized useful insights gathered from key stakeholders, including institutional review board (IRB) professionals, investigators, sponsors, participants, and others.
- NIH held a Tribal Consultation with Tribal Nations on May 28, 2020 to receive recommendations and hear about specific needs in American Indian/Alaska

²⁶ <https://www.hhs.gov/about/news/2020/06/16/fact-sheet-explaining-operation-warp-speed.html>

²⁷ <https://www.ctti-clinicaltrials.org/news/webinar-share-strategies-including-ethnically-diverse-populations-covid-19-trials>

Native communities to combat the COVID-19 pandemic.

b. How will HHS work to ensure the vaccine is widely and equally available to all residents, without regard to means?

Operation Warp Speed²⁸ (OWS) is the Administration's national program to accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics. OWS is a public-private partnership that aims to speed the typical development and distribution process for medical countermeasures by selecting the most promising candidates and providing coordinated government support to support their development. As a condition of receiving support from OWS, companies will provide an allocation of countermeasures developed.

- OWS coordinates existing HHS-wide efforts, including NIH's ACTIV public-private partnership, which aims to coordinate and streamline processes to make the best use of biomedical research resources and testing of preclinical compounds and move promising vaccine candidates into clinical trials in a way that is safe and efficient. The ACTIV partnership has brought together stakeholders from across the U.S. government, industry, and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic

Thank you for the work you do to protect the American people and for your interest in minority health. HHS remains committed to doing our part to help save lives and control the outbreak. We encourage you and your constituents to visit the U.S. government's dedicated COVID-19 website www.coronavirus.gov for the latest and most up-to-date information, resources, and guidance.

Sincerely,

Roslyn Holliday Moore
Acting Director, Office of Minority Health

²⁸ <https://www.hhs.gov/sites/default/files/fact-sheet-operation-warp-speed.pdf>