NHLBI is developing strategies for conducting community-informed COVID-19 research on vulnerable and underserved populations. During this time of national discourse and unrest, we must continue to work to ensure health equity and justice for all.

**Key Definitions:**

**Underserved:** NIH-designated health disparity populations and/or other groups known to experience barriers to accessing health coverage and basic health care services. NIH-designated U.S. health disparity populations are: racial and ethnic minorities, socioeconomically disadvantaged populations, and underserved rural populations, etc. (see a full description at [https://www.nimhd.nih.gov/about/overview/](https://www.nimhd.nih.gov/about/overview)).

**COVID-19 vulnerable populations:** Residents of nursing homes and assisted living facilities; community-dwelling older adults; individuals with HLBS comorbidities; pregnant and post-partum women; individuals living in congregate housing such as shelters or residential treatment facilities; individuals in overcrowded or public housing; detainees in immigration detention centers; migrant and immigrant communities; residents of tribal lands or reservations; communities exposed to high rates of air pollution or other toxic exposures; and rural and remote communities.

**Community:** We are considering communities from a broad social, cultural, linguistic, and systems perspective and using the Centers for Disease Control and Prevention (CDC) definition, “A specific group of people, often living in a defined geographic area, who share a common culture, values, and norms and who are arranged in a social structure according to relationships the community has developed over a period of time.”

**Background:**

Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), remains a rapidly progressing public health threat, having reached pandemic status in March, 2020. While the proportion of asymptomatic infected individuals remains unclear and most people with COVID-19 do not require hospitalization, the most severe spectrum of the disease is reflected by the mortality rate in settings in which intensive care is available. U.S. data suggests that up to one-third of hospitalized patients require intensive care secondary to acute respiratory distress syndrome (ARDS) and cardiac injury, both of which are highly associated with mortality. In the U.S., the disease has struck racial and ethnic minority communities especially hard. Deaths due to COVID-19 are significantly higher among Black and Hispanic individuals relative to white or Asian individuals, and the burden of illness is also disproportionate among these groups. Communities of underserved and vulnerable populations including those underlying with heart, lung, blood, and sleep diseases and disorders are especially impacted. Developing effective and sustainable community-engaged strategies to prevent and mitigate COVID-19 and its health consequences would enhance our ability to address the significant morbidity and mortality disparities in COVID-19 in urban and rural communities.

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NIH and NHLBI rapidly launched several significant research efforts to address the COVID-19 pandemic, including initiatives to accelerate the development of COVID-19 treatments and vaccines (ACTIV and ACTIV Integration of Host Targeting Therapies for COVID-19), the development of diagnostic tests (RADx), and the establishment of strategies to optimally deliver tests to underserved and vulnerable populations (RADx-UP), in addition to inviting requests for supplementation of existing awards to conduct COVID-19 work. Although RADx-UP is focused on community-engaged research to increase access to COVID-19 diagnostic testing, there is less dedicated research specifically focused on heart, lung, and blood morbidity and mortality disparities for vulnerable and underserved communities that are disproportionately affected by, have the highest infection rates of, and are most at risk for adverse outcomes from contracting the virus. To accelerate research and improve the health of vulnerable communities, this community-engaged roundtable will seek to identify the key scientific questions and challenges in conducting research in this area.

Program Objectives:

• Develop strategies to build trust in, address mistrust, and engage communities in COVID-19-related research;

• Identify existing community-based health care, including community health centers, local health departments, and other local and community resources that have the potential to collaborate to address the needs of vulnerable and underserved communities;

• Consider designs or new models to assess community level interventions to mitigate the spread and impact of SARS-CoV-2 within underserved and vulnerable communities and identify new strategies that are needed, including non-pharmacologic interventions and natural experiments;

• Identify community-engaged strategies that address the long-term health, including HLBS conditions, psychosocial, and behavioral consequences of the pandemic;

• Consider approaches that address underlying health factors contributing to disparities in COVID-19 prevalence and outcomes.

Purpose of Community-Engaged Roundtable Webinar:

The primary goal of this meeting is to identify important scientific questions and critical challenges that require NHLBI leadership to address using community-based networks, working together as a consortium, to conduct research on community-engaged strategies to address the health impact of COVID-19. Panel presentations will address the impact of COVID-19 on specific communities, the potential related research opportunities to increase our understanding of the effectiveness of evolving actionable strategies, and the value and benefit of dissemination and implementation research in support of rapid evolution of COVID-19 efforts (eg, surveillance, contact tracing, uptake of testing and vaccines, and long term sequela of social isolation on heart, lung, blood and sleep disorders and other health conditions). Some of the potential questions to address could include: how can existing approaches to preserve HLBS health be implemented and maximized among underserved and vulnerable communities; what psychosocial, behavioral, and cultural factors and outcomes associated with the pandemic should be considered; and how can partnerships between community health centers, Federally Qualified Health Centers (FQHCs), and other local and community stakeholders be developed and/or adapted to address disparities related to COVID-19? Addressing these questions may be achieved by the development of a consortium of community health organizations, networks of community-based primary care practice-based research networks (PBRNs), and community-based participatory research centers, in partnership with local governments and health departments, community groups, and health systems that serve high risk and vulnerable populations.

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Key Questions:

SESSION I: Building Trusting Relationships with Underserved Communities in the Short-Term for Long-Term Sustainability

What are the central issues to address to help build trusting relationships with underserved communities and researchers in order to advance diversity & inclusion in our clinical research and to maximize the benefits of research findings to the community through sustained adherence to evidence-informed prevention and treatment interventions for COVID-19?

1. How can we gain trust quickly among different communities? What essential elements can we put into place to continue to develop and sustain long-term trusting relationships?

2. What data can we draw from regarding the cultural and historical barriers to conducting research at the community level?
   a. What are specific examples of how those barriers have been successfully addressed?
   b. Are there other COVID-19-specific barriers?

3. Are there specific examples of how trust can be built between researchers and underserved communities?

4. What are the safety and ethical issues to consider?
   a. How should these be assessed with regard to specific communities?
   b. What evidence can we draw from regarding directly addressing safety and ethical issues?
   c. Are there safety implications for communities when delivering new therapeutics/vaccines/diagnostic tests?

5. How should we consider availability of resources in terms of impact on relationships?

6. What research or recruitment strategies or approaches have only served to further distance communities from efforts to address disparities?

7. What community assets could be leveraged to overcome barriers in engagement?

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SESSION II: Building a Community-Engaged Implementation Research Strategy

What are the key scientific questions that, if answered, stand to have an impact for community-engaged implementation research on COVID-19? What could be prioritized as having the most short-term feasibility and impact?

1. How do we leverage the experiences of the Community Engagement Centers of our NHLBI cohort studies to advance community-engaged research?

2. How can NIH leadership work with communities hardest hit by the COVID-19 pandemic to be ready to benefit from the results of initiatives such as ACTIV, RADx, and OWS?

3. What is the evidence that community-level implementation strategies are effective in these and other contexts?
   a. How do we ensure that these strategies can be sustainably implemented in low resource settings?
   b. What are the specific community characteristics that predict or indicate success or failure in other contexts?
   c. What are the primary barriers to uptake and acceptance in these contexts?

4. What specific implementation strategies are likely to be most effective at the community level, both in the short-term and longer-term?
   a. What might be most effective in the near-term?
   b. What are the potential challenges to implementation at a broader level?
   c. What specific expertise is needed?
   d. When have these strategies not been effective?
   e. Are there innovative and novel approaches that could be rapidly deployed that should be considered?

5. What are the most appropriate endpoints to target for determining community engagement, uptake, and sustainability?
   a. What is the priority of outcomes such as per capita rates of testing, test positivity, hospitalizations, and deaths?
   b. What HLBS-related outcomes should be prioritized?
   c. What other outcomes, e.g., psychosocial, behavioral, and economic, should be prioritized?
   d. What is the most appropriate and feasible spatial level of measurement for these outcomes below the level of the county?

6. What is the optimal timing for engaging communities, in the absence of current therapeutics/vaccine/prophylaxis?

7. What are examples of accessible and acceptable technologies that are available and could be leveraged to maximize efficient and accurate data collection in the near-term?
   a. Could there be community-level concerns specific to these technologies?
   b. What are the operational (i.e., cost) barriers?

8. How might availability of healthcare access influence study viability?

9. What is an appropriate control arm?
   a. Would there be concerns about a UC community?
   b. How to ensure similar access?

10. What community interventions are mostly likely to mitigate the consequences of COVID-19 on underlying HLBS and other health conditions beyond clinical trials designed to establish the efficacy of specific medications and devices?
SESSION III: Building a Community Implementation Science Network of Networks

How can a network of community health organizations, networks of primary care PBRNs, community-based participatory research centers, and other community and local stakeholders be developed, leveraged, and sustained to maximally benefit from the outcome of initiatives such as ACTIV, RADx, and OWS?

1. What specific design strategies should be considered to develop and test community-wide implementation?
   a. What are specific, tactical, and practical steps for building a sustainable network of networks involving PBRNs and CBPRs?

2. What are the considerations for developing a master protocol for community-engaged studies?
   a. What specific elements are essential to incorporate?
   b. In what ways would a master protocol for community studies differ from standard master protocols?
   c. In what ways would a master protocol for community studies provide utility?
   d. How do we leverage master protocol designs for implementation research?

3. What are the key operational issues to consider for sustained community engagement?
   a. What criteria for identifying and engaging community leaders should be employed?
   b. What communication platforms can be leveraged for community engagement?
   c. What is the feasibility of a timeframe that includes engagement prior to release of therapeutics or vaccine?
   d. What are the major barriers for engagement and participation?
   e. What is the feasibility to launch within a few months?

4. What evidence can we draw from regarding specific ways to develop, strengthen, and sustain links to community health centers, FQHCs, and other partners?

5. What are the community level risk factors for COVID-19 and how do they vary among different communities?
   a. What is the role of characteristics related to housing, including homelessness, reliance on shelters, housing occupancy, and crowding?
   b. What is the role of characteristics related to employment, including worksite crowding, protective practices, job characteristics, and sick leave?
   c. What is the role of access to safe and attractive outdoor venues for recreation, activity, and stress reduction?
   d. What is the role of characteristics related to healthcare access, including crowding, wait times, and separation of patients for well and sick visits?
   e. What is the role of crowding in community venues, including grocery and retail stores, places of worship, community centers, and schools?

6. How could natural experiments be employed across different communities with meaningful outcomes?

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Anticipated Outcomes of the Community-Engaged Roundtable Webinar:

1. Identification and prioritization of key scientific questions to address using practice-based networks, community-based participatory research principles, and other community-based care systems for the short and long-term impact on HLBS and community-wide amelioration of the HLBS consequences of COVID-19.

2. Strategies to leverage community health organizations, networks of primary care PBRNs, community-based participatory research centers, and other community, government, and local stakeholders to create partnerships to understand and address COVID-19 impact on health.

3. Discussion of challenges, opportunities, and potential partnerships.

4. Roundtable summary published on the NHLBI website.

Participants/Expertise:
Given the multi-organ/multisystem pathophysiology underpinning the morbidity and mortality of COVID-19 and the unique aspects of community-based research, it is critical to hear perspectives from key leaders among multiple clinical disciplines and public and community health. Approximately 40 invited experts are anticipated.