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December 7, 2020

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Request for Information- Inviting Comments and Suggestions on the NIH-Wide Strategic Plan for COVID-19 Research (NOT-OD-21-018)

The Association of American Medical Colleges (AAMC) appreciates the opportunity to comment to the National Institutes of Health (NIH) on the NIH-wide strategic plan for COVID-19 research. The AAMC is a not-for-profit association dedicated to transforming health care through medical education, patient care, medical research, and community collaborations. Its members are all 155 accredited U.S. and 17 accredited Canadian medical schools; more than 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools and teaching hospitals and their more than 179,000 full-time faculty members, 92,000 medical students, 115,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

Taken as a whole the NIH-wide Strategic Plan for COVID-19 Research (the "Strategic Plan") presents a comprehensive and ambitious set of priorities and objectives to ensure that the NIH and its grantee organizations remain at the cutting edge of understanding SARS-CoV-2 and detecting, diagnosing, and treating COVID-19.

Since the Strategic Plan was first was published in July 2020, the state of the pandemic has only become more severe in the United States, with case numbers steadily on the rise and deaths upward of a quarter of a million people. To stem the spread of SARS-CoV-2 infection and COVID-19, it is not only essential that the public to adhere to public health measures, but also for the scientific community to continue to develop an understanding of the virus's basic biology, and strategies for its detection, treatment, and ultimately, prevention. Since the start of the pandemic, researchers and physicians at academic medical centers have been on the front lines of this work. The AAMC has encouraged its member institutions to respond directly to this request and know that their expertise will be essential in informing effective ways to move forward. We are pleased to provide comments here to help ensure that the Strategic Plan allows the NIH to both prioritize its efforts and respond nimbly to the evolving needs of the pandemic response.

For each of the objectives listed in the NIH Strategic Plan, we have listed the additional considerations, approaches, or refinements that we recommend be incorporated into the Strategic Plan or emphasized in its implementation.

Priority 1: Improve Fundamental Knowledge of SARS-CoV-2 and COVID-19

A fundamental understanding of SARS-CoV-2 and COVID-19, not only at a basic scientific and systemic level but also its broader societal impacts, is an essential building block for applied research and strategies to manage the multiple effects of the pandemic. The AAMC encourages the NIH to continue conducting studies in these areas, and recommends the following additions.

Objective 1.1: Advance fundamental research for SARS-CoV-2 and COVID-19

- The AAMC applauds the commitment to continue the fundamental research for SARS-CoV-2 and urges continued investment in funding opportunities for the extramural community to continue study of the basic mechanisms of SARS-CoV-2 infection and the immune response.
- Integrate specific NIH initiatives, such as the COVIDCode study, into the Strategic Plan, so that it is clear where the agency has ongoing efforts in basic science.
- Fund opportunities for meta-analysis to gain new insights from already published research.

Objective 1.2: Support research to develop preclinical models of SARS-CoV-2 infection and COVID-19

- Build NIH efforts in concert with other work on animal models, including the WHO working group on COVID-19 modeling.
- Maintain a policy environment that is conducive to and facilitates ethical animal research. NIH should continue its efforts on increasing rigor and reproducibility in animal research as well as efforts to pursue regulatory reform to increase consistency between OLAW and USDA and to decrease investigator burden.[1]

Objective 1.3: Advance the understanding of SARS-CoV-2 transmission and COVID-19 dynamics at the population level

- The Strategic Plan discusses the intention to study spread of SARS-COV-2 and different populations, disease susceptibility, behavioral and social factors of transmission. This population-level research is essential to facilitate the nation's recovery from the COVID-19 pandemic and also to prepare for future viruses that are similarly spread through asymptomatic transmission.

Objective 1.4: Understand COVID-19 disease progression, recovery, and psychosocial and behavioral health consequences

- As the virus continues to spread rapidly throughout the country, there is a dearth of research on the so-called COVID "long-haulers," those who no longer show signs of infection, but struggle with myriad debilitating effects of the virus weeks or months after infection. Consider whether specific attention should be paid to research on the medical and psychosocial impact on this population.

[1] See also the recommendations in the 2017 multi stakeholder report "*Reforming Animal Research Regulations.*" Available at: https://www.aamc.org/data-reports/faculty-institutions/report/reforming-animal-research-regulations.

Priority 2: Advance Detection and Diagnosis of COVID-19

Objective 2.1: Support research to develop and validate new diagnostic technologies

- The Strategic Plan appropriately supports the development of new tests and testing technologies. Despite the possibility of safe and effective vaccines, there remains a critical need for new testing technology to track the spread and virulence of the virus.[2] The RADx funding mechanism continues to be one important source of new testing technologies and approaches and should be continued.

Objective 2.3: Support research to develop and validate serological assays

- The Strategic Plan proposes that NIH accelerate the availability and validation of antibody tests. We support this approach. As vaccination rates increase, we will need not only rapid tests and surveillance tests, but also antibody tests that demonstrate the immune correlates of protection.

Priority 3: Advance the Treatment of COVID-19

Objective 3.1 and 3.2: Identify and develop new or repurposed treatments for SARS-CoV-2; Evaluate new, repurposed, or existing treatments and treatment strategies for COVID-19

- The AAMC underscores the critical importance of continuing to assess existing therapeutics for efficacy in treating COVID-19. While some therapeutic agents have been authorized that show success for certain patients, we still do not have a highly effective, scalable therapeutic for COVID-19. We encourage the NIH to support and actively seek out well-designed, well-controlled clinical trials with novel and repurposed therapeutic treatments based on screening methods and animal models as described in the Strategic Plan.
- The NIH COVID19 Clinical Guidelines are helpful to the clinical and research communities and should be emphasized in NIH communications.

Priority 4: Improve Prevention of SARS-CoV-2 Infection

Since the initial publication of the Strategic Plan, vaccine clinical trials have advanced rapidly, with two efforts (Pfizer-BioNTech and Moderna-NIH) resulting in vaccine candidates with applications for emergency use authorization currently under consideration by the FDA. To build on this remarkable progress, we agree that the NIH should continue its groundbreaking work in this area.

Objective 4.1: Develop novel vaccines for the prevention of COVID-19

- Continue investment in public-private partnerships through Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).
- Analyze the enrollment of underserved populations, older adults, and people with comorbidities, in current COVID-19 Phase 3 vaccine trials to identify gaps, study recruitment strategies, determine implementable strategies for improvement in future trials.

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[2] See AAMC Road Map recommendations on COVID-19 Testing at www.aamc.org/covidroadmap/testing.

- Encourage specific vaccine trials in children to understand the effectiveness and appropriate dosage in this population.

Objective 4.2: Develop and study other methods to prevent SARS-CoV-2 transmission

- Develop a strong evidence base, similar to our understanding of mechanisms of vaccine action and effectiveness, to inform the use of any additional prevention strategies such as antibody treatments.
- Build on advances in contact tracing applications currently employed by hospitals, universities, and cities in the U.S. and worldwide, with a particular focus on pooling data from these platforms to better understand risk factors for virus transmission.

Objective 4.3: Develop effective implementation models for preventive measures

- Leverage existing research on barriers to vaccine uptake and literacy to maximize the effectiveness of any new infrastructure.
- Work with community partners who have significant experience in immunization programs.
- Continue to engage with federal agencies and working groups which have focused specifically on these efforts, including the HHS National Vaccine Advisory Committee and the CDC Advisory Committee on Immunization Practices.

Priority 5: Prevent and Redress Poor COVID-19 Outcomes in Health Disparity and Vulnerable Populations

Health inequities exacerbated and revealed by COVID-19 reflect centuries of health injustice. RADx-up, an important and crucial initiative, would benefit from the same health equity research relevant to other diseases (both chronic and infectious) with marked and longstanding inequities. Specifically, beyond the areas currently described, AAMC encourages NIH to consider the following.

Objective 5.1: Understand and address COVID-19 as it relates to health disparities and COVID-19–vulnerable populations in the United States

- Create a national, standardized set of demographic, individual social risk, and community-level social determinants variables that all communities and sectors should deploy so that efforts are comparable, data can be aggregated, and opportunities for intervention are identified.
- Develop measures of health/health care equity that go beyond disparities surveillance to capture patient- and community-defined and operationalized "state of equitable health opportunity."
- Add to our understanding of practical, effective trust-building strategies to mitigate vaccine and treatment seeking hesitancy, specifically, and mistrust more broadly.
- Invest in evaluation and implementation science to develop the ability to scale and spread successful interventions across communities.
- Focus on systems science since solutions will require multi-sector (e.g. public health, health care, transportation, social services, etc.) collaboration. How should these partnerships be organized? What are the optimal roles for each sector?
- Invest in policy analysis to estimate before a policy is implemented its potential differential impact on marginalized communities. Additionally, policy evaluation is needed to assess current policy impacts on health inequities.

Objective 5.2: Understand and address COVID-19 maternal health and pregnancy outcomes

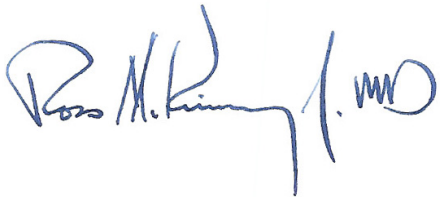
- Investigate the virus's impact on outcomes such as preterm birth and severe newborn illness, particularly among birthing peoples from underserved and racial/ethnic minority populations.
- Investigate the relationship between mother and fetus exposure to environmental pollutants and increased risk of fatality from COVID-19.
- Assess the effectiveness of telemedicine and related interventions (online provider communication, lactation support, and at-home monitoring) to address pandemic-related disruptions in maternal health access and care. Additionally, a deeper understanding of the impact of culturally sensitive tailoring is critical.
- Utilize diverse and innovative partnerships with community stakeholders to explore and evaluate recent trends in maternal health and birth settings/teams, e.g., doulas, CHWs, and other support persons.
- Evaluate clinical tools to assess and manage pregnant women who test positive for COVID-19 and capture a comprehensive view of factors contributing to potential disparities in the use and outcomes of therapeutics among subsets of pregnant women.

Objective 5.3: Understand and address age-specific factors in COVID-19

- Evaluate messaging related to COVID-19 transmission/prevention/treatment/research (e.g., trial enrollment) among various age groups with a focus on adolescents, young adults, and the aging (65 and over) in order to better understand disparities in knowledge/behavior. Additionally, more insight into changing age distribution of pandemic prevalence and outcomes long-term can help to identify areas of intervention and/or protective factors.
- Explore the relationship with the biology of aging in conjunction with other social and clinical risk factors and the severity of COVID-19 and its long-term effects.
- Research to further investigate and provide needed evidence of various age groups' susceptibility to COVID-19 over the lifespan.

The AAMC greatly appreciates the NIH's engagement with the community to identify key research approaches to COVID-19. Please feel free to contact me or my colleagues Heather Pierce, Senior Director for Science Policy (hpierce@aamc.org) or Anu Dev, Senior Policy Specialist (adev@aamc.org) with any questions about these suggestions.

Sincerely,



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