September 4, 2020

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus
National Academies of Sciences, Engineering, and Medicine
500 5th St, NW
Washington DC, 20001

Dear Committee:

On behalf of the American Heart Association (AHA) and its American Stroke Association (ASA) division, we appreciate the opportunity to comment on the "Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine (2020)," released by the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus; National Academy of Medicine; National Academies of Sciences, Engineering, and Medicine. The COVID-19 pandemic has put a significant strain on the health and financial wellbeing of all countries and hundreds of millions of persons globally. In the United States, COVID-19 has affected some more than others for a myriad of reasons.

The public health response to COVID-19 has met several challenges. However, the AHA is encouraged by the vast collaboration and research dedicated to the rapid discovery and development of COVID-19 treatments and vaccines. The AHA believes that any vaccine distribution framework should adhere to the following principles:

- All protocols and decisions for FDA vaccine approval, for distribution, and for administration must be based solely on rigorous scientific evidence of the highest quality.
- To maximize benefit, all people living in the United States should have guaranteed access to FDA-approved COVID-19 vaccines with no cost sharing (no out of pocket cost) and regardless of insurance status.
- Access to FDA-approved COVID-19 vaccines should be prioritized by job categorization (starting with critical health care workers and first responders, and extending to other essential workers including those in food production, pharmacy, and other essential retail), risk of severe illness if infected by COVID-19, and high risk of exposure to COVID-19.

- Any disparities by race, sex and/or gender, disability status, health insurance status, citizenship status, and geographic location in the delivery and availability of, and accessibility to, FDA-approved COVID-19 vaccines must be anticipated and planned for and mitigated to assure equity.
- Public health infrastructure should be strengthened to effectively engage diverse stakeholders in multiple sectors to plan COVID-19 vaccination campaigns and distribution that include transparency and education that is health literacy appropriate and focused on a particular vaccine's manufacturer and development, evidence base, intended effects, potential side effects, and administration sites.
- The U.S. COVID -19 public health and healthcare systems should employ a diverse workforce that is representative of the diversity of the general population and the communities they serve and culturally and linguistically competent in order to increase public trust in, and optimize uptake of, FDA-approved COVID-19 vaccines among all populations in the US.
- Public and private investment in and support of biomedical and health services research related to COVID-19 should be continued and expanded as a national priority.

The AHA believes that the principles outlined above are aligned with NASEM's phase-based approach and its foundational principles. We appreciate NASEM's application of lessons learned from past pandemics and its thoughtful, evidence-based approach to recommending that populations with disproportionate vulnerability and exposure to COVID-19 and risk for severe COVID-19 are prioritized for vaccination and that no one is denied access based on their lack of privileged status. However, we encourage NASEM to place stronger emphasis on providing full transparency and education to the public on how vaccines were developed and tested, as well as factors considered in the decision to approve it. Our comments on specific sections of the framework are below.

Phases 1 – 4

The AHA supports the committee's phase-based framework for prioritizing vaccine access. However, the AHA encourages the committee to recommend that all measures to reduce COVID-19 transmission (i.e. masks, social distancing, hand washing, restrictions on large group gatherings, etc.) should remain in place through the early phases of vaccination until public health authorities recommend otherwise. These measures will help mitigate the spread of COVID-19 among populations whose access to vaccines comes in later phases.

Additionally, the committee should recommend the creation of a national oversight committee that would function as a monitoring board for the safe allocation and administration of COVID-19 vaccines. Its members would serve in an individual capacity and provide their expertise and recommendations. The primary responsibilities of the oversight committee would be to 1) periodically review and evaluate the accumulated vaccination data for adherence to principles, delivery to priority populations, progress, and problems; and 2) make recommendations concerning the continuation, modification, or termination of vaccination efforts by state jurisdictions and local jurisdictions.

Ensuring Equity

Social Vulnerability Index

The AHA supports the committee's proposed application of the CDC's Social Vulnerability Index to determine equitable access to FDA-approved COVID-19 vaccines. COVID-19 has a higher rate of infection, hospitalization, and death among communities of color, people who are older, and the poor. The disproportionate burden of the pandemic among communities deemed socially vulnerable has been explained in part by endemic inequities, including lower income, lower levels of education, use of public transportation, difficult housing situations, "essential" jobs, lower quality environments, decreased availability of health care, and lower likelihood of health insurance – each of which contributes to poor health. The Index assesses for many one of these variables. We support the framework's application of the Index to assure the equitable availability and delivery of vaccine.

Costs Associated with Vaccination

The AHA commends and supports the committee's proposal that FDA-approved COVID-19 vaccines be available to all, regardless of ability to pay. As reported in the framework document, the pandemic has disproportionately impacted persons and groups of people that are socioeconomically disadvantaged. There should be no payment expected for COVID-19 vaccine.

Citizenship or Immigrant Status

The AHA commends and supports the committee's proposal that FDA-approved COVID-19 vaccines should be available to all, irrespective of citizenship or immigrant status.

Conclusion

Thank you for this opportunity to comment on the NASEM's "Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine." Please contact Dr. Eduardo Sanchez, Chief Medical Officer for Prevention at Eduardo.Sanchez@heart.org if you have any questions.

Sincerely,

Mitchell Elkind, MD, FAHA
President, American Heart Association