



September 4, 2020

Committee on Equitable Allocation of Vaccine for the Novel Coronavirus
The National Academies
500 Fifth St., N.W.
Washington, D.C. 20001

Re: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine (2020)

Dear Committee Members:

Trust for America's Health (TFAH) is grateful for the opportunity to respond to the request for comments on the Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine. TFAH is a nonprofit, nonpartisan public health policy, research and advocacy organization dedicated to promoting optimal health for every person and community and making the prevention of illness and injury a national priority. Since 2003, TFAH has tracked the country's public health emergency preparedness in our annual report, "Ready or Not: Protecting the Public's Health From Diseases, Disasters, and Bioterrorism."¹ It is with this experience in mind that we share our comments on the draft framework to ensure equitable allocation of vaccines for the novel coronavirus.

The COVID-19 pandemic is an unprecedented public health emergency that has strained public health and healthcare resources across the country. Since January 2020, the United States has seen nearly 6 million cases of COVID-19 and more than 180,000 COVID-19-related deaths.² Given the scope of the pandemic, the healthcare system must be discerning about effective allocation of limited resources such as a vaccine.

Overall, we applaud the Committee's diligent work and generally agree upon the approach and recommendations contained in the framework. A lack of national coordination and planning has led to shortages of personal protective equipment (PPE) and COVID-19 testing supplies, strains that have been acutely felt in healthcare systems and long-term care facilities that serve lower income populations and communities of color.³ The creation of a framework to mitigate similar resource distribution and equity issues in distribution of COVID-19 vaccines is a welcome development.

We are encouraged that the draft discussion draws on lessons learned from mass vaccination efforts during previous pandemics and epidemics like the H1N1 influenza A pandemic in 2009

¹ Farberman RK, Lieberman DA, McKillop M. Ready or Not: Protecting the Public's Health From Diseases, Disasters, and Bioterrorism. Trust for America's Health. <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>. February 2020.

² United States COVID-19 Cases and Deaths by State. Centers for Disease Control and Prevention. <https://covid.cdc.gov/covid-data-tracker/#cases>. September 3, 2020.

³ Glenza J. PPE Shortage Could Last Years Without Strategic Plan, Experts Warn. Kaiser Health News. <https://khn.org/news/ppe-shortage-could-last-years-without-strategic-plan-experts-warn/>. August 17, 2020.

and the Ebola epidemic in West Africa between 2013 and 2016. Of these lessons, several appear in both our report “Ready or Not” and the draft framework. Below, we offer a number of recommendations and questions for consideration, informed by our findings in prior “Ready or Not” reports.⁴

Focus on Communities with Disproportionate Impact

TFAH supports the Committee’s intent that the framework “maximizes benefit to patients, mitigates inequities and disparities, and adheres to ethical principles.” Addressing health disparities so that all Americans can live healthy lives has long been one of TFAH’s major pillars. We are overall supportive of the phased approach offered by this framework but have several recommendations and further considerations for the Committee.

Recommendation: Include additional clarification on how those with chronic conditions should be prioritized for vaccination.

Phase 1 also focuses on individuals with multiple chronic conditions like cardiovascular disease (CVD), Type 2 diabetes mellitus, chronic obstructive pulmonary disease (COPD), and obesity and older adults living in congregate settings which protects those who evidence suggests are more vulnerable to COVID-19 morbidity and mortality.^{5,6} The framework notes that as more evidence becomes available, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) may reprioritize some conditions, since “not all comorbid conditions are equal when it comes to their placement in an allocation framework.”

We understand this is an evolving situation but have questions about how phase 1 would be implemented. For instance, how will clinicians and other public health professionals be able to distinguish between more and less serious chronic diseases, particularly during the early stages of COVID-19 vaccination efforts where researchers are still gathering evidence? It is likely vaccines will be very limited during Phase 1, and clinicians will have to make decisions about who will have access to limited vaccine resources. The framework cites several articles that assert “first-come, first-served” approaches are inappropriate for a pandemic. However, allocation approaches may also force clinicians to make difficult decisions. For example, could an individual with a BMI of 31 and well-controlled Type 2 diabetes mellitus be turned away after presenting at a clinic for a COVID-19 vaccine because these conditions are not serious enough? If an individual does not have multiple diagnoses of chronic conditions due to historical lack of healthcare access, would this lack of diagnosis preclude him or her from receiving a COVID-19 vaccine during Phase 1?

⁴ Farberman RK, Lieberman DA, McKillop M. Ready or Not: Protecting the Public’s Health From Diseases, Disasters, and Bioterrorism. Trust for America’s Health. <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>. February 2020.

⁵ Foley KE. What H1N1 taught the US about delivering pandemic vaccines. Quartz. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>. August 7, 2020.

⁶ Certain Medical Conditions and Risk for Severe COVID-19 Illness. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>. July 17, 2020.

These and other questions suggest there is a need for further clinical guidance – whether from NASEM or other bodies - for Phase 1 as vaccination efforts proceed.

Recommendation: Include those who work in pharmacies among those included in the Phase 1 of vaccination.

By assuring that those directly responsible for our health, such as first responders and hospital workers, are protected in Phase 1, we can better guarantee the availability of human resources to combat the COVID-19 pandemic. Given pharmacists' involvement in the administration of H1N1 vaccines in 2009,⁷ TFAH believes it may be wise to also include pharmacists and pharmacy technicians in Phase 1 of COVID-19 vaccination efforts instead of Phase 2 as they will likely be responsible for administering a significant portion of COVID-19 vaccination.

Recommendation: Provide strong guidance to states and territories on how to apply this the framework most effectively.

The proposed phased approach to COVID-19 vaccination is evidence-based and generally appropriate, but during H1N1, state and territorial governments had some flexibility to determine how to deliver pandemic vaccines to those who need them most. States with older populations may want to prioritize certain subsets of older adults in Phase 1 to account for limited vaccine supplies. States with greater socioeconomically disadvantaged populations may want to prioritize such populations throughout each phase. TFAH believes the Committee or other bodies should provide states with guidance on this flexibility so that they may make decisions that are consistent with the intent of the vaccination efforts to prioritize high-risk populations. We strongly urge clear, science-driven guidance to inform state planning within the Committee's framework.

Considerations for Implementation:

TFAH has several considerations for the implementation of the framework and COVID-19 vaccination efforts.

Equity as a Priority

TFAH appreciates the framework's elevation of equity in its consideration of how the public health and healthcare systems should prioritize COVID-19 vaccination efforts. In addition to bearing a disproportionate burden of COVID-19, low income and minority neighborhoods are also less likely to receive adequate COVID-19 response resources,⁸ and others, such as Asian and Pacific Islander Americans, have faced racist backlash and discrimination during the

⁷ <https://qz.com/1889005/you-could-get-a-covid-19-vaccine-from-a-pharmacy/>

⁸ Servick, K. 'Huge hole' in COVID-19 testing data makes it harder to study racial disparities. Science. July 10, 2020. <https://www.sciencemag.org/news/2020/07/huge-hole-covid-19-testing-data-makes-it-harder-study-racial-disparities#>

pandemic⁹ – issues that could hinder access to a vaccine. Underpinning each phase of the discussion draft is equity, determined by CDC’s Social Vulnerability Index, which uses census data on social determinants of health to identify communities that are particularly vulnerable to disasters and public health emergencies.¹⁰ We agree that the Social Vulnerability Index provides policymakers with an effective tool to identify the populations most at risk for COVID-19 and severe health outcomes. Indeed, there is significant evidence racial and ethnic minorities bear disproportionate disease burden for COVID-19 compared to white people.¹¹ We agree with the Committee that there is not a biological cause for these disparities, but instead they are the result of longstanding systemic and structural racism that has led to disproportionate burden of chronic disease and increased risk of exposure to COVID-19. An effective COVID-19 vaccine distribution framework must prioritize ensuring access to those at the highest risk, and implementation of that framework must address barriers to vaccine access. Successful implementation of the framework will require planning with and resources for organizations and providers in historically marginalized communities

Transparency and Communication

TFAH supports the Committee’s foundational principle of transparency in the development of a COVID-19 vaccine distribution system. As the Committee notes, eligibility criteria for provision of the COVID-19 vaccine—that is, the “principles...and priority groups that will determine people’s chances of getting a vaccine sooner rather than later”—should be made public so that healthcare providers and the lay public may understand the circumstances under which they can provide/receive the COVID-19 vaccine.

Transparency should also help in assuring that non-evidence-based considerations, such as financial incentives and politics, do not unduly affect the provision of the COVID-19 vaccine. We hope that the transparency proposed in the framework for distribution of the COVID-19 vaccine will extend to implementation of COVID-19 vaccine distribution and that regulatory bodies tasked with vaccine distribution will continuously monitor decisions to make sure that they are public and evidence-based. It is important that federal, state, local, tribal, and territorial (SLTT) planners communicate early and effectively with affected populations, including in multiple languages, to ensure understanding of the distribution framework. It is also quite likely that unexpected challenges may arise during the development and distribution of the vaccines that may require the need for updating this framework. We urge the Committee and federal and SLTT planners to communicate these uncertainties and updates to plans as they occur.

Overcoming Vaccine Hesitancy and Vaccination Exemptions

Measles outbreaks across the country in 2019 highlighted that while childhood vaccination rates are generally high and consistent, misinformation about vaccine safety and state vaccination

⁹ Radsken, J. Examining COVID’s impact on Asians and Pacific Islanders. The Harvard Gazette. June 23, 2020. <https://news.harvard.edu/gazette/story/2020/06/new-study-examines-anti-asian-racism-during-pandemic/>

¹⁰ CDC’s Social Vulnerability Index. Centers for Disease Control and Prevention. <https://svi.cdc.gov/>. 2018.

¹¹ Health Equity Considerations & Racial & Ethnic Minority Groups. Centers for Disease Control and Prevention. <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>. July 24, 2020.

exemption laws can create environments conducive to outbreaks.¹² The public health and healthcare system must be prepared to overcome similar challenges in distributing COVID-19 vaccinations.

Based on the draft framework, the Committee appreciates the importance of overcoming vaccine hesitancy through direct-to-consumer educational efforts on its safety and effectiveness. During the H1N1 pandemic, there were disparities in vaccine uptake between Blacks and whites, and there are ongoing seasonal influenza disparities for non-Hispanic Black, Hispanic, and American Indian/Alaskan Native adults relative to White adults.¹³ A better understanding of how communication methods and vaccine distribution strategies affect uptake in communities of color is critically needed before distribution begins.¹⁴ TFAH believes a national vaccine education strategy is imperative to overcoming resistance to vaccination. Within this national strategy, public and private partners should coordinate campaigns to develop messaging around vaccines and COVID-19. Such educational efforts should include not only data but also anecdotes from COVID-19 survivors and vaccine success stories. Educational materials and outreach should be delivered in a linguistically and culturally appropriate manner that is accessible to individuals regardless of health literacy. CDC and SLTT planners must partner with and fund organizations that work with disproportionately impacted populations, use trusted messengers, and use communications methods that reach specific communities, such as radio, television, and places of worship. These cultural competencies are particularly important for racial and ethnic minorities who stand to benefit considerably from COVID-19 vaccination given the disproportionate burden they face with COVID-19.

Likewise, the Committee acknowledges the barriers states may encounter in vaccination efforts because of laws granting wide vaccination exemptions. Vaccination exemptions are only briefly discussed in the draft, but we believe vaccine exemption laws warrant further consideration, as we will not know what entities will require the COVID-19 vaccine as a condition of entry or employment.¹⁵ Outside of medical exemptions, TFAH believes that states should take action to minimize vaccination exemptions as much as possible, especially for school children and healthcare workers.¹⁶ We believe encouraging states to tighten vaccination exemption laws warrants further emphasis so that states with broad vaccination exemption laws do not realize higher rates of COVID-19 infection.

Vaccine Coverage

¹² Farberman RK, Lieberman DA, McKillop M. Ready or Not: Protecting the Public's Health From Diseases, Disasters, and Bioterrorism. Trust for America's Health. <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>. February 2020.

¹³ Grohskopf, L, Liburd, L, and Redfield, R. Addressing Influenza Vaccination Disparities During the COVID-19 Pandemic. JAMA. August 20, 2020. <https://jamanetwork.com/journals/jama/fullarticle/2769837>

¹⁴ Uscher-Pines L, Maurer J and Harris K. Racial and Ethnic Disparities in Uptake and Location of Vaccination for 2009-H1N1 and Seasonal Influenza. Am J Public Health. 2011 July; 101(7): 1252–1255. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3110237/>

¹⁵ Vaccines Prevent Infectious Disease Outbreaks and Protect Communities. Trust for America's Health. <https://www.tfah.org/story/vaccines-prevent-infectious-disease-outbreaks-and-protect-communities/>. August 2019.

¹⁶ Vaccines Prevent Infectious Disease Outbreaks and Protect Communities. Trust for America's Health. <https://www.tfah.org/story/vaccines-prevent-infectious-disease-outbreaks-and-protect-communities/>. August 2019./

Historical vaccination efforts have also revealed inadequate insurance coverage of vaccines as a major barrier to wider vaccination uptake. Vaccinate Your Family’s 2020 vaccination report, State of ImmUnion, found that vaccination rates continue to vary widely by race/ethnicity, socioeconomic status, and insurance status.¹⁷ Children on Medicaid were as much as 21 percent less likely to receive certain childhood vaccinations than their privately insured counterparts, and the disparity for uninsured children was as much as 33 percent.¹⁸ Among adults, there are lower vaccination rates among Blacks, Latinx, and Asian Americans compared with whites for some vaccines.¹⁹

To address these disparities, TFAH continues to advocate for first-dollar coverage for recommended vaccines under Medicaid, Medicare, and commercial insurance.²⁰ As the draft framework notes, the 2020 Coronavirus Aid, Relief, and Economic Security (CARES) Act requires group and individual health insurance plans to offer COVID-19 vaccination without patient cost-sharing. The CARES Act, coupled with the Patient Protection and Affordable Care Act (ACA), also requires private insurers to cover vaccinations with a favorable Advisory Committee on Immunization Practices (ACIP) rating within 15 days of the ACIP recommendation. Similarly, Americans covered by Medicare Part B and Medicare Advantage would not have to pay copays or administrative charges for the COVID-19 vaccine.

In contrast, as the Committee notes, traditional (i.e. non-expansion) Medicaid beneficiaries have no federal statutory protections for no-cost vaccine coverage. Consequently, the availability of no-cost vaccinations for Medicaid beneficiaries varies by state. Despite the financial incentive to do so, 12 states have yet to adopt Medicaid expansion offered under the ACA.²¹ Further, despite the lessons learned from previous vaccination efforts, only 22 states offered all ACIP-recommended adult vaccinations for their state Medicaid beneficiaries before the COVID-19 pandemic.^{22,23}

TFAH is concerned that a reliance on state Medicaid programs to universally offer no-cost vaccine coverage may result in a lack of COVID-19 vaccine access for some state Medicaid beneficiaries. We urge the Committee to acknowledge the importance of statutory protections for Medicaid beneficiaries in non-expansion states and traditional Medicaid populations so that they may be guaranteed no-cost access to the COVID-19 vaccines and other vaccinations as

¹⁷ 2020 State of the ImmUnion. Vaccinate Your Family. 2020. <https://www.vaccinateyourfamily.org/join-us-in-support-of-vaccines/make-a-national-impact/state-of-the-immunion-report/>

¹⁸ 2020 State of the ImmUnion. Vaccinate Your Family. 2020.

¹⁹ Koppaka, R. Racial and Ethnic Disparities in Adult Immunization. CDC. Feb 8, 2018.

https://www.hhs.gov/sites/default/files/For%20Posting_Koppaka_Racial%20and%20Ethnic%20Disparities%20in%20Adult%20Immunization_16x9_remediated.pdf

²⁰ Farberman RK, Lieberman DA, McKillop M. Ready or Not: Protecting the Public’s Health From Diseases, Disasters, and Bioterrorism. Trust for America’s Health. <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>. February 2020.

²¹ Status of State Medicaid Expansion Decisions: Interactive Map. Kaiser Family Foundation.

<https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>. August 17, 2020

²² Granade CJ, McCord RF, Bhatti AA, Lindley MC. State policies on access to vaccination services for low-income adults. *JAMA Network Open* 3(4):e203316. 2020.

²³ Shen AK, Orenstein W. Continued challenges with medicaid coverage of adult vaccines and vaccination services. *JAMA Network Open* 3(4):e203887. 2020

expansion Medicaid populations are. In addition, states and private insurers should ensure full coverage for the cost of the vaccine, its administration, and associated supplies, including for uninsured individuals. The ability to pay should not be a barrier to receiving the vaccine, which will be an important tool for controlling the pandemic.

Role of ACIP/CDC in Efforts

TFAH appreciates the Committee's effort to develop this framework but seeks clarification about the exact role it will play moving forward. Our understanding is that ACIP/CDC will be responsible for making decisions about COVID-19 vaccination efforts, and we hope ACIP will take the Committee's recommendations into consideration in developing vaccine prioritization plans. If this is correct, we urge the Committee and CDC to clarify the role of the Committee after the finalization of the framework.

We also strongly urge Operation Warp Speed and federal planners to build upon existing vaccine planning and distribution systems led by CDC and informed by ACIP, rather than create entirely new distribution systems. CDC and public health agencies have experience with mass vaccination campaigns and are specifically funded to do so. During the H1N1 pandemic, CDC built upon the Vaccines for Children program to rapidly enroll health care providers in order to efficiently distribute the vaccine.

Provider Compensation for COVID-19 Vaccination Services

The CARES Act guarantees no-cost COVID-19 vaccination for privately insured individuals, which TFAH supports. However, the Committee also suggests it is in the national interest that "providers should not charge private plans or consumers...for vaccine administration." We agree that costs should not be passed onto consumers, but TFAH is concerned that if providers are not compensated for the labor of delivering COVID-19 vaccines, even if sterilization materials, syringes, and bandages are provided by the federal government, some providers will decline to participate in vaccination efforts. The federal government should also compensate for the costs of becoming a vaccinators, such as appropriate storage and refrigeration supplies.

As frontline workers dealing with COVID-19, vaccine administration puts healthcare providers at increased risk for COVID-19 infection. It is reasonable for providers to expect compensation for the time, labor, and risk required to administer COVID-19 vaccines. If providers do not receive such compensation and opt to not participate in vaccination efforts, many Americans could lose access to COVID-19 vaccines. COVID-19 vaccines should remain accessible at patients' traditional sources of healthcare. Compensating providers for labor associated with COVID-19 vaccination will help ensure this access remains consistent.

Strengthening Public Health Infrastructure

The COVID-19 pandemic is a challenge, but it is ultimately a symptom of a larger systemic issue: the chronic under-funding of the nation's public health infrastructure. TFAH has long

advocated for larger investment in public health infrastructure in reports like “Ready or Not”²⁴ and “The Impact of Chronic Underfunding on America’s Public Health System: Trends, Risks, and Recommendations, 2019.”²⁵ The draft framework acknowledges vaccination efforts conducted by the Indian Health Service (IHS) require additional funding and oversight to be successful, but IHS is far from the only entity responsible for public health that has been underfunded.

CDC, SLTT health departments, and ACIP need additional funding to effectively lead vaccination efforts. Health departments need increased funding to strengthen their capacity to undertake the massive effort COVID-19 vaccination will require. Investments are needed for contracts with community partners, purchase of supplies and equipment such as refrigerators, program planning and staffing, immunization information systems (IIS) data modernization, and uncovered costs to administer the vaccine through governmental public health, medical providers, and pharmacists. Without greater investment in public health infrastructure, the United States will encounter more public health emergencies for which it is unprepared in the future.

Conclusion

Overall, TFAH supports the work the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus has done in this draft framework. The framework’s focus on evidence, science and equity is commendable. We hope that as vaccines become available, decisionmakers will look to this framework for guidance and continue to seek the Committee’s recommendations moving forward.

Should the Committee have any questions about our comments, please contact Dara Lieberman, TFAH’s Director of Government Relations at 202-864-5942 or dliberman@tfah.org.

Sincerely,



John Auerbach
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Trust for America’s Health

²⁴ Farberman RK, Lieberman DA, McKillop M. Ready or Not: Protecting the Public’s Health From Diseases, Disasters, and Bioterrorism. Trust for America’s Health. <https://www.tfah.org/wp-content/uploads/2020/01/2020ReadyOrNotFINAL.pdf>. February 2020.

²⁵ McKillop M, Ilakkuvan V. The Impact of Chronic Underfunding on America’s Public Health System: Trends, Risks, and Recommendations. https://www.tfah.org/wp-content/uploads/2020/03/TFAH_2019_PublicHealthFunding_07.pdf. April 2020.