

A Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Statement of

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before the
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives

September 30, 2020

Good morning, Chair DeGette, Ranking Member Guthrie and members of the subcommittee. Thank you for the opportunity to testify today. My name is Helene Gayle, and I am president and CEO of The Chicago Community Trust. I am speaking to you today in my capacity as co-chair of the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus of the National Academies of Sciences, Engineering, and Medicine.

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In July, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) asked the National Academies to convene an ad hoc committee to develop an overarching framework for COVID-19 vaccine allocation in order to assist policymakers and inform the work of national health authorities and additional advisory bodies, including CDC's Advisory Committee on Immunization Practices (ACIP), during the development of national and local guidelines.

On September 1, our committee made available a discussion draft of its framework, *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*, to obtain input from members of the public and to inform our final report. The discussion draft presented lessons learned from other allocation efforts, our draft allocation framework, and how this framework might be applied in various scenarios. I have been asked to summarize this

discussion draft today. Our final report will be released to the public this Friday, October 2. Therefore, it is important to keep in mind that the information I present here today reflects our discussion draft, which is subject to change in response to public comment and peer review. Furthermore, the final report will address topics related to implementation, risk communication, community engagement, vaccine hesitancy, and global considerations. I will not be speaking on these issues today.

This is not the first time the nation has been faced with the issue of allocating scarce resources in the midst of a public health emergency. In developing our draft framework for equitable COVID-19 vaccine allocation, our deliberations were informed by practical lessons from previous efforts to allocate vaccines for the 2009 H1N1 influenza pandemic and for Ebola virus disease, as well as by the goals, ethical principles, and prioritization strategies set forth in other allocation frameworks—including several that have recently been developed to distribute scarce inpatient medications for COVID-19. Guiding principles from these allocation frameworks for scarce inpatient medications for COVID-19 include:

- Ensure that allocation maximizes benefit to patients, mitigates inequities and disparities, and adheres to ethical principles.
- Promote the common good through fairness, transparency, accountability, and trustworthiness.
- Save the greatest number of lives possible—while respecting rights and fairness—to maximize benefit to the community as a whole.
- Use the best available evidence to assess benefit to communities and address uncertainty.
- Allocate scarce resources responsibly to reduce risk while providing benefit.

- Provide clear and transparent criteria for prioritization strategies.
- Ensure that allocation policies are flexible, responsive to the concerns of the affected population, and proportionate to the epidemiological situation and the vaccine supply relative to need.

Drawing on prior work, our committee proposed six foundational principles (consisting of ethical and other principles) which informed our deliberations about allocation criteria. Our committee immediately invoked a principle of *maximization of benefits* that sets a **primary goal of maximizing societal benefit through the reduction of morbidity and mortality caused by the transmission of the novel coronavirus**. While spread throughout the society, the pandemic's damage has more significantly harmed some populations more than others, particularly causing higher rates of infection, serious illness, hospitalization, and death among people of color due to the longstanding impact of systemic racism and inequity. This reality led us to formulate a principle of *mitigation of health inequities* to address the higher risks faced by such persons in work environments and living arrangements that correspond to higher risk of transmitting and acquiring infection and with having a higher prevalence of certain health problems that make it more likely that they will suffer severe outcomes and even die from COVID-19. In difficult choices about vaccine allocation, the principle of *equal regard* directs attention to the equal worth and value of every person, protecting each one from discrimination, while the principle of *fairness* requires impartiality and the engagement and participation of affected populations in setting allocation criteria and determining priority groups. Furthermore, the principle of *transparency* ensures the disclosure of the principles, criteria, and priority groups that will determine people's chances of getting a vaccine sooner rather than later. Finally, none

of these principles can accomplish its goals without the principle that all decisions must be *evidence-based*.

The ethical principle of transparency, as well as the practical requirement of efficient, consistent administration of the framework led us to develop and propose four risk-based criteria for operationalizing the foundational principles to achieve its primary goal.

- **Risk of acquiring infection:** Individuals have higher priority to the extent that they have a greater probability of being in settings where COVID-19 is circulating and exposure to a sufficient dose of the virus.
- **Risk of severe morbidity and mortality:** Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- **Risk of negative societal impact:** Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.
- **Risk of transmitting disease to others:** Individuals have higher priority to the extent that there is a higher probability of their transmitting the disease to others.

To determine the population groups that comprise each allocation phase, our committee operationalized the above criteria by characterizing certain population groups in terms of the risks faced by their typical members and the ability of a vaccine to reduce those risks.

Our committee proposes a four-phased approach to COVID-19 vaccine allocation. **Within the population groups included in each of these four phases, our committee recommends that vaccine access should be prioritized for geographic areas identified as**

vulnerable through CDC’s Social Vulnerability Index. It is also important to note that within each phase, all groups have equal priority.

The first phase includes a “jumpstart” phase, Phase 1a. Included in Phase 1a would be “frontline” health workers—health professionals who are involved in direct patient care, as well as those in transport, environmental services staff, or other health care facility services, who risk exposure to bodily fluids or aerosols. Under conditions of such scarcity, access should not be defined by professional title, but rather by the individual’s actual risk of exposure to COVID-19. The rationale for including “frontline” health workers in the first phase is manifold: their contact with patients with SARS CoV-2 (despite the use of PPE, which can be limited in some settings); the fact that they work in an essential industry, but may be precluded from performing their professional duties if not adequately protected; and the reality that many who are in low wage jobs may also contribute to further transmission due to living in crowded, often multi-generational living situations where social distancing is unrealistic. The latter is especially true for many of those who work in nursing homes and as home health aides. In addition to frontline health workers, first responders are included as well. The “jumpstart” phase is followed by Phase 1b—which includes those older adults living in congregate settings, such as nursing homes, skilled nursing facilities, and other similar settings. Last, individuals with select high-risk comorbid and underlying conditions are included in Phase 1b.

In Phase 2, expansion of vaccine supply would allow for the immunization of another cohort of individuals with comorbid and underlying conditions that put them at increased risk, as well as all older adults not already included in Phase 1. Current knowledge of the relative risks stemming from specific underlying risk factors is evolving quickly and will be better known by the time vaccines actually become available. This may allow decision makers to target those at

greatest risk of serious morbidity and mortality more effectively than is possible today. This could also allow the identification of younger people who are at high risk of infection or serious morbidity/mortality so that they can also be prioritized.

Recognizing the importance of education and child development, teachers and school staff are included in Phase 2. It is important to include this group relatively early to facilitate the reopening of schools, and to protect the most high-risk adults present when this occurs given current knowledge about morbidity and mortality due to COVID-19.

People who are incarcerated or detained and people who live in group homes and homeless shelters are also included in Phase 2 along with the staff who work in such settings. With respect to these groups, our committee stressed the importance of recognizing their reduced autonomy and the recognized difficulty of preventing spread in such settings should COVID-19 be introduced. Last, the first cohort of critical workers who are both in industries essential to the functioning of society and at high risk of exposure are included in Phase 2.

In Phase 3, vaccine supply will become more widely available and allow the broader immunization of workers essential to restoring full economic activity. In this phase, the broad immunization of children and young adults is included. An important caveat here is that broad immunization of children will depend on whether new COVID-19 vaccines have been adequately tested for safety and efficacy in childhood age groups.

Finally, once vaccine supply becomes more broadly available (Phase 4), vaccines would be made available to healthy adult individuals who would be interested in receiving the vaccine for personal protection.

It is important to acknowledge that uncertainties about the COVID-19 vaccine and the nature of the pandemic itself persist, but our committee approached its draft framework under the best available evidence today.

There are many uncertainties regarding if and when vaccines against COVID-19 will become available, under what regulatory framework they will be approved for first use, what their ultimate product profiles will be (e.g., in terms of efficacy among different age groups, dosage schedule(s), and safety/adverse reactions), as well as the schedule and timelines for expanding vaccine supply availability (e.g., when doses will become available and how quickly supply will expand). Our committee's discussion draft also discusses how the framework will adapt in the face of these uncertainties.

This is only a brief summary of the our committee's discussion draft work—the complete and final report will be available for free download in PDF format from the National Academies Press website on Friday, October 2. The discussion draft is available at <https://www.nap.edu/catalog/25914/discussion-draft-of-the-preliminary-framework-for-equitable-allocation-of-covid-19-vaccine>.

Thank you for the opportunity to testify. I would be happy to address any questions that you might have.