

Comments on Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

GENERAL COMMENTS

The National Association of County and City Health Officials (NACCHO), representing nearly 3,000 local health departments across the country, is pleased to submit comments to the Committee on Equitable Allocation of Vaccine for the Novel Coronavirus. Local health departments play a critical role in the distribution and administration of many life-saving vaccines, including an eventual COVID-19 vaccine, and NACCHO appreciates the opportunity to provide comments on the Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine (Framework).

Local health departments serve a vital role in the provision of essential immunization services and counseling. According to NACCHO's 2019 Profile of Local Health Departments, 88% of local health departments provide direct immunization services to both adults and children. Further, all local health departments play a role in other essential immunization activities, such as conducting surveillance, providing education, and developing communication campaigns to bolster immunization rates. As the world and nation face this historic pandemic, it is important to highlight that local health departments have been and continue to be on the frontlines supporting their communities. In a recent assessment, NACCHO explored the current impact of COVID-19 on local immunization programs. Results indicated that 88% of local immunization program staff were re-assigned to respond to COVID-19, nearly 90% indicated that essential immunization program services have been impacted, and 62% reported a noticeable decline in vaccination coverage rates. Alarming, state and local public health officials have reported an increase in job losses, resignations, and threats from the public as they recommend public health guidance to mitigate the threat of COVID-19 in their communities. Regardless, public health professionals remain committed and dedicated to addressing vaccine coverage, prioritizing health equity, promoting vaccine confidence, and preparing for the upcoming COVID-19 vaccine. Any plan for distribution of the COVID-19 vaccine must include local health departments as key stakeholders in the strategy and planning process, not simply as sites to distribute vaccine.

Recent data indicate that significant disparities and inequities in vaccination coverage exist among childhood, adolescent, and adult populations. Adult influenza vaccination coverage of racial and ethnic minorities is consistently lower than that of white populations. Similar trends have been seen for other vaccines such as Hepatitis A and B, and Tdap and across age groups. Moreover, differences have also been observed in childhood and adolescent vaccination coverage by race and ethnicity, health insurance status, and geographic location. Data have revealed coverage disparities among children and adolescents living in non-Metropolitan Statistical Areas (MSAs) and uninsured or Medicaid-insured individuals. Given this information, it will be imperative to address these inequities upon the availability of a COVID-19 vaccine. Health inequities pose serious consequences and exact great social costs that marginalize, exploit, and exclude whole classes of people. Health inequity limits the ability to gain access to the resources needed and during the COVID-19 pandemic, has resulted in greater loss of life among racial and ethnic minority populations.



NACCHO appreciates the considerations taken by the Committee in developing this framework and recognizing that the challenges may be most evident in its implementation. While there is the need for uniform implementation of the allocation criteria, it is also important to recognize the need to be adaptable and dynamic based on the unique capacities and changing epidemiology within the individual state, local, tribal, and territorial (SLTT) jurisdictions (pg 40). NACCHO appreciates the acknowledgement by the Committee that SLTT authorities will have to make final decisions on refining and applying the suggested priorities stated in this draft guidance. In doing so, they can refer to the principles and allocation criteria that guided the formulation of the phases (pg 81). While this framework incorporates evidence-based, equitable, and fair components, it will be more difficult to implement due to the lack of a comprehensive national response plan. This, coupled with the lack of a federal testing plan, has led to a patchwork response across the country, that has not always been based on accurate data or science. Clear, consistent guidance about the vaccine and the prioritization for access must be a key component of any COVID-19 vaccine development strategy.

NACCHO's detailed comments on the Framework can be found below.

Mitigation of Health Inequities

NACCHO supports the incorporation and adoption of principles of social justice into everyday public health practice in order to eliminate the root causes of health inequities. COVID-19 has revealed the harsh inequities seen in infection and death strongly associated with race, ethnicity, socioeconomic status, and occupation. NACCHO appreciates the Committee's focus on equity and the inclusion of a principle around "mitigation of health inequities" along with the more standard "maximization of benefits." With the widespread recognition of systemic racism and persistent inequity, it is important to explicitly consider reduction of inequities. NACCHO also appreciates the Committee recognizing that the plan should also be perceived as equitable by diverse audiences (line 671). This perception is critical to confidence in the system and potentially to uptake by Black and Indigenous people, and people of color (BIPOC) in the United States, as well as to reducing racial and ethnic divisions which may be exacerbated by national emergencies. However, we are concerned that the plan may not match the principle, given local demographics. With disproportionate access to healthcare or living in long-term care facilities, BIPOC may still experience the inequities to accessing COVID-19 vaccination based on the defined priority groups. Moreover, while the Phase 1 priority group also includes older adults who live in overcrowded settings, it is unclear if or how a health department would implement this priority. The Committee has made a reasonable effort to address equity by including persons of any age in the multiple comorbidity priority and by including overcrowded settings along with the congregate facilities priority. Recommendations to strengthen equity in these priority groups include:

- More specifically defining "overcrowded settings" to facilitate actual implementation of this priority – if local and state health departments cannot define it, they are less likely to implement it effectively or consistently;
- Defining the Phase 2 "all older adult" category as ≥ 60 years old rather than ≥ 65 years old (line 1612) – this would, in part, address the higher risk that occurs among a less elderly population among BIPOC reflected by their lower life expectancy; and
- Indicating that self-attestation is an acceptable validation of multiple comorbidities and that written documentation should not be required – since those who have less access to care would be less likely to obtain documentation. Indicating that such documentation should not be required would enhance equity.

Vaccine Allocation and Rationale for Prioritizing Groups

The effective allocation of COVID-19 vaccine will be critical in containing this historic pandemic. Ensuring flexibility in prioritization guidance to accommodate the changing characteristics and epidemiology of the pandemic and its impact is important. As local health departments will be on the frontlines implementing the framework established by this Committee, it is also important to ensure continued support for local public health as they operationalize plans to rapidly identify and contact prioritized populations, and mobilize targeted vaccination efforts. NACCHO recognizes the need for an established framework and the difficulty in applying that framework given the variability in the field and how it will successfully be applied. NACCHO

recommends that for a prioritization strategy to be effective and accepted, there must be clear definitions of who is included so that it can be implemented consistently and without controversy, especially in the current environment where so much of the pandemic response has been politicized.

- Frontline health workers should also explicitly include health professionals serving in public health departments serving the public. Just like healthcare professionals working countless hours in hospitals and primary care settings, public health professionals are essential employees whose work is critical to slowing the spread of disease and helping to reopen our communities. They do so while working extended shifts, often without access to sufficient personal protective equipment, putting themselves—and their families—at risk to protect the lives of others.
- In addition, “crowded environments” for the older adult priority and “critical risk workers...essential to the functioning of society and at substantially high[er] risk of exposure” need further definition. Clarification on who is included as “food supply workers”, “workers in warehouses”, and which transportation infrastructure is included due to the priority on maintaining deliveries is needed. The Rationale section for this priority group does a good job explaining the components of the job and the living situation of the workers associated with increased risk but is less clear about defining who is included.
- The Phase 3 priority group of workers essential to the functioning of society and at moderately high risk of exposure also is not well defined and inclusion of some groups seems arbitrary. Further clarification is needed on why some groups are prioritized over others (i.e., hotel workers, entertainment industry, etc.). A disproportionate number of construction workers have been infected and are subject to the same risks – inability to socially distance, low pay, the need to use public or shared transportation, lack of sick leave, home situations that are crowded – as identified for other occupations, yet construction is not mentioned in either the Phase 2 or Phase 3 priority groups. While it may be outside of the expertise of the Committee to completely and specifically define these groups of workers, it would be useful to acknowledge that this work still needs to be done and to identify how that process will occur. This specificity becomes even more important given the planning assumptions around how vaccine will be allocated for administration. If vaccine is to be distributed to national pharmacy chains and private providers, in addition to local and state public health agencies, implementing a prioritization strategy consistently will be substantially more challenging and a lack of clarity will undermine perceived fairness and public support.
- A phased approach for allocation makes sense and is guided by lessons learned in H1N1 where demand exceeded supply and the tiered approach in the HHS 2017 Pandemic Influenza Plan (pg 7). In draft Table 2: Applying the Allocation Criteria to Specific Population Groups, mitigating factors to consider may make assumptions about the population’s ability to social distance. Given the current reality of community mitigation with schools and businesses reopening, NACCHO recommends that the Committee reconsider the assumption that a group “may” be able to social distance. In addition, the Committee needs to clearly define high risk comorbidities versus moderate risk types as a footnote in the tables.
- In the table on tiering, pregnant people are not listed while children are. It seems that pregnant people should be included in a group of people at high-risk due to their pregnancy status. Clarity is needed as to where pregnant people are placed. While the current vaccine studies have not included pregnant people and children, it is assumed that efficacy will be comparable. However, studies related to immune response should be conducted particularly with children and potentially older people (≥ 65).
- In the section on Estimated Group Size, the text includes the number of adults over the age of 65 living below the poverty line rather than retaining the focus on crowding (pg 65).
- In the Concluding Remarks for the chapter on priority groups (lines 1950-61), the Committee indicates that the allocation framework is dynamic and that “mid-course corrections will be the rule rather than the exception.” While it makes sense to modify recommendations based on emerging information about vaccine effectiveness, for example, among older adults, frequent changes will undermine planning by health departments that will be required to administer vaccine quickly and efficiently.

Rather than emphasize the possibility or even the likelihood of change, it would be preferable to highlight in the concluding remarks that additional work will be done to better define priority groups and their sizes, facilitating planning and implementation.

Vaccine Allocation Under Various Scenarios

While NACCHO commends the Committee for incorporating CDC's Social Vulnerability Index (SVI) (pg 77), it appears that other equity considerations are only partially addressed and there is difficulty implementing SVI during changing scenarios. For example, if vaccination occurs by phase, then the targeted groups in Phase 1 should be immunized before moving to Phase 2. This becomes complicated when targeted groups and social vulnerability begin to overlap. (i.e., healthcare workers living in census tracts with greater vulnerability versus healthcare workers living in less vulnerable census tracts). The SVI has the potential to create barriers to quickly and efficiently dispensing vaccine for local health departments planning to conduct points of distribution (PODs) or even the feasibility of implementing in partnership with national pharmacy chains given they may not be capable of applying geographic limits on who gets immunized. While the concept of linking priority with vulnerability is reasonable, **the lack of feasible and efficient approaches to implementation suggests this should not be included.** It is more feasible and far more important for local health departments to monitor uptake of vaccine by population groups defined by their race, ethnicity, and location, and to ensure that vaccine is equitably administered. If BIPOC populations are more hesitant about being immunized, if there are more barriers to their presenting for vaccination, if trusted voices and communication channels are not as well defined or utilized, local health departments need to be able to detect differences in outcomes and increase outreach or modify strategies to achieve equity.

- Officials involved in Operation Warp Speed (OWS) and the Centers for Disease Control and Prevention (CDC) have discussed that limited doses of vaccine will be available as early as November 2020. Therefore, the need for expedited plans is critical for SLTT authorities to begin implementing an allocation plan equitably. Vaccine efficacy and vaccine safety must be transparent and communicated with administrators and the public to ensure that any shift in the allocation framework is clearly defined and communicated with the general public. In addition, there should be a requirement to have all administrators of this vaccine put their information into immunization information systems (IIS) in order to ensure that data to facilitate surveillance efforts is available, no matter where vaccine is administered. Furthermore, in order for IIS to adequately track vaccine administration, exchange data with other systems in an interoperable manner, and successfully support federal end-to-end data infrastructure, there needs to be continued attention to and resources for ensuring that IIS are appropriately configured and updated.
- Consideration for training and information to healthcare providers (HCPs) and education materials to be disseminated by public health partners will be important for vaccine uptake. Without this, part of the workforce will be unprepared to communicate to patients about the importance of COVID-19 vaccine and to provide information regarding side effects or how to report an injury if necessary. Additionally, it is important that HCPs be trained in effective culturally-competent interactions and healthcare messaging as a critical component of increasing vaccine confidence.
- Additional consideration on the FDA emergency use authorization (EUA) versus the biologics license applications (BLA) should be considered as the trust of an EUA may increase mistrust of the vaccine. Because we are still experiencing epidemic conditions, community mitigation models during the rollout of COVID-19 vaccine will need to be maintained. It will be important to consider what the current reality is related to social/physical distancing, utilization of masks, and handwashing and the need to continue to communicate this is important to the COVID-19 vaccine rollout. Consideration of strong public health messaging will be needed as a dual approach. In addition, hand hygiene should be listed along with masking and social distancing in table 3.
- Ensuring surveillance mechanisms for tracking vaccine type and number of doses will be critically important to ensure completion of series. The responsibility cannot be placed solely on the shoulders of the population. It is vital to have an infrastructure in place to track this information and ensure that data interoperability is available across state lines. In addition, ensuring that private pharmacies have a

mechanism to track or work with their SLTT jurisdictions to maintain surveillance will be key. We have seen challenges with reporting data to public health in other aspects of the response, such as with (1) COVID-19 point-of-care and other diagnostic test results that have not been automatically connected to public health electronic laboratory systems; and (2) missing race and ethnicity data of an individual who has been tested for COVID-19. We must assure that local health departments receive timely and complete information on who is being vaccinated in their jurisdictions. It is also crucial that those data be electronically and automatically available to local health departments to facilitate their analyses and tailor their communities' vaccination approaches as needed.

- Vaccine distribution and administration is key to the successful implementation of the vaccine rollout. Ensuring that distribution is maintained using pre-existing systems that have proven to work will be key. Incorporating Department of Defense personnel is not recommended as this may affect vaccine hesitancy among populations that are in most need of vaccine. Additionally, federal public health organizations have a long-standing, credible history in ensuring efficient and effective vaccine distribution and administration mechanisms.
- NACCHO commends the Committee for recommending that COVID-19 vaccine should be available for free for all populations (pg 77). Ensuring access to vaccine for populations at most need is critical during this time. The federal government should cover the cost of the vaccine for everyone. Having to check insurance status and then bill will add a level of complexity that will slow the process down. While mandates may place additional pressures to have certain groups vaccinated, maintaining an equitable distribution will be imperative.
- Given that adults in congregate settings are at high risk, and acknowledged in Phase 2, consideration of vaccination for all will be important to ensure public health measures for all people. There should be stronger language regarding vaccinating all people irrespective of their immigration status and individuals whose legal status is uncertain should be reassured that their coming forward to receive the vaccine will not lead to deportation or be used against them in immigration proceedings (pg 79).

Transparency

In NACCHO's 2017 assessment on local health department immunization programs, the most common barrier indicated by respondents was vaccine hesitancy. Given this, the rapid pace of distributing this vaccine is undermining confidence in people accepting the vaccine. Among the foundational principles for vaccine allocation that leads to the primary goal, "maximize societal benefit by reducing morbidity and mortality caused by transmission of novel coronavirus," one important principle for consideration and inclusion is "consistency with public values" or "public acceptability." The Committee identified ethical principles and defined priority groups based on those principles; however, this still lacks prioritization from the public through the process of public engagement. In considering vaccine acceptance and uptake, it is recommended that public engagement be considered. While vaccination planning has included allocation, distribution, and administration, the need to ensure a safe and effective vaccine is accepted is critical for vaccine uptake. A large-scale communication plan which addresses different racial and ethnic communities is needed to build trust and acceptance. Engaging with community ambassadors who message to their communities will be vital for getting more people to accept the vaccine. If we do not build community trust, it will be irrelevant that we have an ample supply of vaccine. Further messaging that will further address risk communication and vaccine hesitancy is warranted to help address the hurdles associated with public acceptance of the vaccine.

Thank you for the opportunity to provide feedback on the development of the **Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine** and for your consideration of our comments. NACCHO and local health departments look forward to the final report and working with Committee on Equitable Allocation of Vaccine for the Novel Coronavirus and other immunization stakeholders on implementation of the final plan. This is an unprecedented time and the establishment of this framework has important implications for a successful COVID-19 vaccination campaign.