



NEHI (Network for Excellence in Health Innovation)  
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June 26, 2020

Senator Lamar Alexander  
Chairman  
U.S. Senate Committee on Health, Education, Labor and Pensions  
428 Senate Dirksen Office Building  
Washington, DC 20510

Dear Chairman Alexander,

Thank you for the opportunity to comment on the comprehensive recommendations outlined in your White Paper, "Preparing for the Next Pandemic." The Network for Excellence in Health Innovation<sup>1</sup> (NEHI) has been focusing on [the challenges associated with adult immunizations](#) since 2018. It submits these comments based on its [continuing work](#) to clarify the steps needed to ensure the rapid and effective administration of vaccines, especially those needed to stem the COVID-19 pandemic. We must now take action to rectify current gaps in leadership, partnership, and coordination as well as plan more systemic changes for future pandemics. NEHI's comments reflect its own views but were shaped by a gathering that included a group of its members and expert stakeholders who focused on recommendations 3.4 and 5.1 in the White Paper, as these squarely raise issues affecting the administration of vaccines now and in the future.

Sincerely,

A handwritten signature in blue ink that reads "Wendy Warring". The signature is fluid and cursive, with a long horizontal stroke at the end.

Wendy Warring  
President and CEO

A handwritten signature in blue ink that reads "Tom Hubbard". The signature is cursive and somewhat stylized, with a prominent loop at the end.

Tom Hubbard  
Vice President of Policy Research

Enclosure: NEHI's Comments on Recommendations 3.4 and 5.1

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<sup>1</sup>[NEHI](#) is a non-profit, non-partisan organization with the mission of advancing innovations that improve the value of health care. It was founded almost 20 years ago on the premise that bringing together leaders from across the health care industry would produce workable solutions to problems in the health care system.

**Recommendation 3.4:** The Centers for Disease Control and Prevention (CDC) must continue to play a leading role in federal pandemic preparedness for vaccine distribution and administration. Congress should carefully, but quickly, review the CDC’s current state of planning, including its connections to federal agency, state government and private sector partners. Congress must be ready to redirect or provide new resources and, where necessary, legal authority, to fill existing gaps in order to ensure that COVID-19 vaccines are distributed and rapidly administered to those who need them most, recognizing that this will be an unprecedented immunization effort.

- (1) **Assessment of Need:** The federal government must clarify, in a transparent manner to all stakeholders, how its agencies, the states, and the private sector should coordinate to assess the need for vaccines.

Federal definitions for assessing vaccine need: The [criteria](#) that were used in previous pandemics (H1N1) for prioritizing populations for immunization are still salient. The CDC established these for both present and future pandemics. It should maintain responsibility for updating and adapting these. We offer the following observations.

- The prioritization criteria should be published, communicated and explained. The criteria should be flexible enough to accommodate public health and economic factors unique to individual states, such as differing population patterns (urban concentration vs. rural dispersion).
- Definitions used in the current criteria require reconsideration. As this pandemic has clarified, the current definition of “health care and community support services” personnel is likely too narrow. Occupations that have proven essential to community health and welfare include delivery personnel and grocery store employees. Child-care workers, teachers and school personnel, among others, will prove essential to full recovery. New definitions may require supplemental guidance to assist states in prioritization decisions.
- The CDC must develop a way to account for the unique characteristics of available vaccines in setting priorities for vaccination. Vaccines that require multiple doses may be more appropriately designated for first responders and front-line health care workers for whom compliance may be more straightforward. The CDC, along with State Health Departments, should also communicate how they will allocate immunizations if multiple types are available.
- Need must account for the number of individuals in priority populations, the prevalence of disease, and the incidence of infection. As these factors display wide inter-state variation, the CDC and State Health Departments must work together to monitor changes and adjust calculations of need accordingly. The CDC and peer agencies must immediately share a transparent plan for such decision-making.

State and territory determination of need: States and territories should remain responsible for estimating need based on the prioritization criteria established by the federal government.

- Not all states have the same ability to determine and document their vaccine needs. The CDC should provide logistics support for states that request or require assistance in producing timely information. Congress must prepare to provide additional, needed resources immediately.
- The CDC should coordinate with the Secretary’s 10 Regional Directors to update assessments of need and be prepared to deal quickly with regions that become “hot spots.”

- The CDC (or Congress) should encourage states to form councils or other coordinating bodies that correspond to the 10 HHS regions to facilitate planning and information exchange among state Governors.
- (2) **Coordinated Distribution:** The CDC has published an [interim pandemic distribution plan](#) that we understand is the basis for routine communication and preparedness planning with state agencies and public health organizations. Given the stresses that all agencies (federal, state and private sector) have faced in the initial months of COVID-19 response, CDC and its partners should take prompt action to re-examine the plan for vaccines. This review should include a review of readiness at FEMA and other federal agencies to further augment vaccine distribution on an emergency basis. It should identify gaps in preparedness that need to be rectified now by the Administration and Congress to enable the distribution of COVID-19 vaccines. Results should be communicated clearly to the medical and public health communities, and the public at large.
- Congress should review the current capability of CDC and its VtrckS system to perform adequate intake of state vaccine orders, allocate available supply in compliance with guidelines, fill orders and ensure prompt delivery to end-users. With provider requests (through VTrckS) likely to exceed the CDC's vaccine supply, there is a need to clarify whether (or under what circumstances) states' public health departments or the CDC Distributor will determine to which sites vaccines are delivered.
    - State public health departments, many of which are not well funded, may lack the infrastructure necessary to make and execute site allocation decisions. The CDC must develop some way to assess state capacity (perhaps through a checklist of required competencies).
  - The CDC must clarify how they will alter existing arrangements between vaccine manufacturers and distributors for distribution of COVID-19 vaccines. Manufacturers need to prepare for these changes in advance to ensure a smooth transition in their logistics practices.
- (3) **Vaccine Administration:** Successful COVID-19 administration will require ease of access through an adequate immunization infrastructure, removal of financial barriers to immunization, and consistent and accurate messaging to ensure vaccine acceptance. Further, as with all public health efforts, real-time access to information will be needed to monitor the success of ongoing vaccination efforts.

Expansion of existing immunization infrastructure: The existing immunization infrastructure is likely to be overwhelmed by the demand for the COVID-19 vaccines. The ability to flex the number of immunization sites and immunization providers will be needed to respond to changing demands for vaccinations.

- State immunization information systems (registries) supply immunizers with patient immunization histories and enable public health authorities to track immunization rates and target immunization programs. The capabilities of state immunization registries, however, vary significantly from state to state, and data exchange both within states and between states is uneven.
  - Congress should review state registry preparedness for mass COVID-19 immunization and take steps to harmonize capabilities across all states. It may be necessary for Congress to require states to upgrade existing capabilities. Some states currently will struggle to accept and track COVID-19 vaccination, as well as testing results.

- Further, orderly and equitable vaccine management will require bi-directional data exchange within and between states. This capability is long overdue. Although funding will remain an issue, the pandemic clearly provides motivation and justification for accurate access to vaccination data across state lines and at the federal level.
- Congress should support further development of national capability to generate accurate, real time progress reports on immunization and the analytical support that will enable state public health authorities, health care providers, and all immunizers to use immunization for rapid and efficient administration of immunization programs. Robust data is key to any mass vaccination campaign and the continued improvement of immunization programs.

To this end Congress must identify the core data elements and reporting requirements needed to monitor State vaccine implementation. Congress should review and, if necessary, augment resources that will enable the CDC to evaluate and publish for review, vaccination rates in all jurisdictions and subpopulations, identifying gaps in care and developing strategies to improve and monitor outcomes.

- Congress should incentivize states to train community health workers and others now to supplement existing licensed providers.
- The CDC should re-enunciate guidance on how states can avoid critical access issues by increasing the number of eligible immunizers. Examples include:
  - Reviewing restrictive scope of practice laws and regulations to allow qualified immunizers (e.g. pharmacists, nurses) to carry out tasks on their own authority attendant to vaccinations, including screening, review, and documentation. States should be encouraged to undertake this review immediately.
  - Congress should evaluate now whether the CDC and states require additional funds or other incentives to revise emergency immunization planning to encourage a full range of innovative immunization delivery and administration, such as mobile immunization units or “pop-up” immunization sites.
- Secondary distribution sites will likely play an important role in the rapid deployment of pandemic vaccines. States should provide clear regulatory guidance on how these should be established but the CDC should create guidelines for certifying emergency vaccination sites. Given anticipated issues of access to vaccines by vulnerable populations, as well as issues of trust (see discussion below), states should solicit input from cities, towns, and community agencies regarding the most effective supplemental sites for vaccine administration.

Elimination of financial barriers for providers and patients: Congress should adopt legislation that defines the Medicare and Medicaid reimbursement for vaccine administration and eliminate all financial disincentives for vaccination.

- Cost-sharing in the Medicare program should be eliminated for all ACIP-recommended vaccines to encourage compliance with prescribed vaccinations in conjunction with the COVID-19 vaccination program.
  - CMS should immediately review, and report to Congress on, the current Medicare and Medicaid reimbursement to immunizers to ensure that provider reimbursements will be adequate to ensure successful mass immunization.
  - Congress must make provisions for the vaccination of uninsured individuals; this group will include some of the most vulnerable individuals.

Public Health Messaging: Vaccine adoption will require coordinated and credible messaging at the federal, state, and local levels. The CDC must retain ultimate responsibility for coordinating information on which states can rely. Regional networks (perhaps formed in connection with the assessment of vaccine needs and/or the distribution of vaccines) may be required to further enhance the coordination of both information and messaging at the state and local levels.

- Access to information will be critical in managing vaccinations and adapting vaccine policies to changing circumstances.
  - The CDC must clarify how it will track outcomes related to vaccine effectiveness. While the current federal processes for reporting and tracking immunization adverse events are well established, the accelerated development of COVID-19 vaccines creates a need to continue monitoring their long-term effectiveness. The CDC should outline how to conduct this ongoing monitoring and consider the role the private sector and individual immunization recipients may play in this effort.
- Providers, faith-based organizations, and other community groups will be critical trusted agents to provide clear and accurate messaging regarding COVID-19 vaccines. With the financial burdens imposed by COVID-19, however, it is unlikely that they can take on the additional burden of widespread messaging campaigns. Congress needs to provide funding for states to shore up these local communication channels.
- Given the increased use of social media platforms for communication, the CDC should consider how to best use these outlets to promote vaccination and combat the spread of misinformation around COVID-19 vaccines. The incorporation of prominent figures on social media to help conduct targeted outreach to different population segments should also be considered as part of a comprehensive communications strategy

**Recommendation 5.1:** There is a need for a clear lead in coordinating relevant agencies (e.g. HHS agencies, DHS agencies such as FEMA, state governments, private sector organizations). As the White Paper notes, the role of the Assistant Secretary for Preparedness and Response (ASPR) was intended to fulfill this responsibility during a pandemic, but it currently has not aligned with Congress' expectations. Congress should re-establish ASPR's leadership role and clarify the exclusive authority the position holds—or designate an alternative with similar accountability. The CDC should remain responsible for the distribution and administration of vaccines.

- Congress should ensure that the ASPR has clear and established channels to call upon the expertise of all relevant responders, including FEMA and state emergency and public health authorities. It must also be able to issue directives to pursue necessary activities to support the CDC.
- Congress should evaluate the balance of authority delegated to ASPR against necessary checks on ASPR's powers. It should ensure that the CDC and the State Departments of Health have the statutory authority they need to execute its obligations in minimizing the impact of this pandemic and those that follow.
  - Congress should have a role in ensuring that political issues do not interfere with the execution of authorized plans.
  - The deployment of military resources by either the states or the federal government should be subject to clear process constraints.

- Congress should establish a central data repository that enables ASPR and relevant federal and state agencies to track and disseminate information that affects planning and provides feedback on tactics deployed to address the pandemic.

### Conclusion

The White Paper has provided a valuable framework for promoting actions that must be taken now to address COVID-19, as well as those that are needed to prepare for future pandemics. It is unlikely that there is one correct way to address them. There are, however, certain steps that should be taken as universal matters of preparation—no regret strategies. We have tried to enumerate some of these and to echo the White Paper’s emphasis on the need for ongoing coordination among key federal, state, local and private sector parties. We realize that we have also identified areas that require additional resources and funding. It is beyond the scope of this paper to offer opportunities for coordination that can yield savings to make additional funds available. NEHI will, however, continue its efforts to develop pathways that enable this coordination around critical issues in vaccination administration.