



September 4, 2020

[Submitted electronically to <https://www.nap.edu/vaccine/>]  
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Dr. Helene D. Gayle, Co-Chair  
Committee on Equitable Allocation of Vaccine for the Novel Coronavirus  
National Academies of Science, Engineering and Medicine (NASEM)  
500 Fifth St., N.W.  
Washington, D.C. 20001

**Re: NASEM Draft of the Preliminary Framework for Equitable Allocation COVID-19 Vaccine**

ASHP is pleased to submit comments to the National Academies on the recently released *Draft of the Preliminary Framework for Equitable Allocation COVID-19 Vaccine* (hereinafter the “Framework”). ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization’s more than 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety, including the safe and effective use of vaccines.

ASHP commends the committee members for their efforts to inform decisions related to the equitable allocation of the highly anticipated vaccine against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) – a critical countermeasure to the COVID-19 global pandemic. We appreciate the opportunity to react to the framework. Our comments are focused on the allocation prioritization of pharmacists in the preliminary framework and are based on the ASHP Principles for COVID-19 Vaccine Distribution, Allocation, and Mass Immunization, which is enclosed for the committee to consider as they finalize the remaining aspects of the report. Underscoring all of our comments, however, is our profound commitment to improving patient and public health by vaccinating against further spread of SARS-CoV-2.

- 1. As the committee finalizes its allocation recommendations, we request the creation of a targeted vaccination framework that prioritizes the most vulnerable populations and critical occupational groups. We specifically request that the committee include pharmacists in Tier 1 as a high-priority target group that meets important societal needs.**

All front-line healthcare workers, including pharmacists, need to be included in the first phase of vaccination efforts. Pharmacists and pharmacy technicians are on the front lines of COVID-19 patient care. ASHP members provide direct patient care on interprofessional care teams in all hospital areas, including emergency departments and critical care units, where

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they provide care for patients with COVID-19 who require mechanical ventilation. Pharmacists also provide direct patient care in ambulatory and community settings, addressing the chronic care needs of patients at high risk of morbidity and mortality from COVID-19 and providing testing for COVID-19 across all 50 states, as authorized by the Department of Health and Human Services under the Public Readiness and Emergency Preparedness Act.

### **2. As the committee considers allocation of the COVID-19 vaccine, including ancillary supplies and personal protective equipment, we request that pharmacists are afforded the authorization and supplies needed to vaccinate against SARS-CoV-2.**

Pharmacists in every state are authorized to administer vaccines, contributing greatly to the public health of their communities as vaccine providers. Recently, the U.S. Department of Health and Human Services declared that all State-licensed pharmacists can order and administer vaccines to patients aged 3 through 18 years as a means to increase patient access to routine immunizations during the COVID-19 pandemic. When a vaccine against SARS-CoV-2 becomes available, pharmacists must be authorized to administer it and be allocated the vaccine and supplies needed to do so.

### **3. As the committee continues to work on its charges to develop an overarching framework for vaccine allocation and consider the collateral decisions that will support that effort, we offer 10 guiding principles related to COVID-19 vaccine development, distribution, allocation, administration, and monitoring and surveillance.**

These principles aim to bridge lessons learned from previous mass vaccination efforts, current experience with the COVID-19 pandemic, and best practices in effective pandemic preparedness, supply chain management, and clinical practice. The principles, approved by ASHP's Board of Directors, emphasize the role of hospital and health-system pharmacists who, as medication experts, have a deep understanding of how to optimize vaccine supply and use from vaccine approval by the Food and Drug Administration to patient administration by immunizing professionals. They include:

- Ensure a transparent and rigorous process for vaccine development, approval, and post-marketing surveillance.
- Collaboration and coordination domestically and internationally to ensure ethical and equitable global distribution of vaccine(s).
- Engaging, preparing, and protecting the immunizer workforce.
- Expanding patient access to a highly qualified and empowered clinical pharmacy workforce in all settings of care.
- Adhering to established best practices for proper storage and handling of vaccines throughout the supply chain.
- Ensuring equitable allocation of COVID-19 vaccine(s), prioritized for greatest public health impact.
- Achieving high acceptance and uptake of COVID-19 vaccine(s) by minimizing vaccine hesitancy and misinformation.

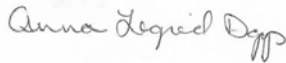
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- Seeking innovative solutions for vaccine adverse event reporting.
- Ensuring patient access by preventing and removing financial barriers.
- Remaining vigilant with continued research and comprehensive surveillance.

This will be the largest single vaccination effort the global community has undertaken. It is imperative that COVID-19 vaccines are distributed in an ethical, equitable, efficient, and transparent manner to maximize population protection from SARS-CoV-2. ASHP acknowledges the multifaceted approaches required for the continuum of mass immunization efforts and is standing by to collaborate in and support those efforts.

ASHP appreciates this opportunity to provide comments on the Framework. Please contact me if you have any questions on our comments. I can be reached by telephone at 301-664-8889 or by email at [adopp@ashp.org](mailto:adopp@ashp.org).

Sincerely,



Anna Legreid Dopp, Pharm.D.  
Senior Director, Clinical Guidelines and Quality Improvement  
American Society of Health-System Pharmacists

Enclosed: ASHP Principles for COVID-19 Vaccine Distribution, Allocation, and Mass Immunization

# ASHP Principles for COVID-19 Vaccine Distribution, Allocation, and Mass Immunization



Vaccinating against the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly anticipated countermeasure to the coronavirus disease 2019 (COVID-19) global pandemic. High COVID-19 vaccination rates are essential to protect our communities from worsening and future outbreaks. Mass distribution, allocation, and administration of hundreds of millions of doses of vaccine will require extraordinary planning and execution. Although this may be the largest single vaccination effort the global community has ever undertaken, there are best practices and lessons learned in pandemic preparedness, supply chain management, distribution, and clinical practice to guide us as we immunize against SARS-CoV-2.

Deliberate planning and collaboration with domestic and international partners is paramount to efficiently coordinate vaccine distribution and administration to hundreds of millions of people. ASHP offers the following 10 principles for COVID-19 vaccine development, distribution, allocation, mass vaccination, monitoring, and surveillance.

## **1. Enforce a transparent and rigorous process for vaccine development, approval, and post-marketing surveillance.**

The need for vaccine development to advance at an unprecedented rate requires special safeguards to ensure patient safety and instill public trust. Ethical, rigorous, and transparent procedures for informed consent, inclusion of key populations, evidence evaluation for safety and efficacy, and sustained surveillance are critical. Although vaccine candidates will have undergone multiple phases of testing before approval, it is not possible to detect all potential adverse effects and/or additional factors that may affect vaccine effectiveness during pre-marketing clinical trials. Therefore, rigorous post-marketing surveillance is required to monitor the safety and effectiveness of COVID-19 vaccines.

## **2. Collaborate and coordinate with domestic and international public health partners to establish and implement a framework for the ethical and equitable global distribution of COVID-19 vaccines.**

Despite differences in international, federal, state, and local health policy, regulatory frameworks, and practice models, a concerted effort to ensure widespread global vaccination is necessary to contain COVID-19 and limit continued devastation of public health, economies, and geopolitical relations. Effective communication, collaboration, and coordination with government agencies, public health organizations, regulatory agencies, and health departments are critical to synchronize lines of effort and ensure a successful mass immunization campaign.

### **3. Engage, prepare, and protect the immunizer workforce.**

A robust, trained workforce of immunizers ready and available to administer COVID-19 vaccines is vital to mass immunization efforts. Assembling such a workforce will require mobilization of traditional and nontraditional immunizers, including appropriately trained and supervised clinical learners such as pharmacy, nursing, physician assistant, and medical students to assist with patient screening and referral as well as vaccine preparation and/or administration. To safely accomplish mass immunization, shortages of personal protective equipment must be mitigated to protect the immunizing workforce and maximize infection control efforts.

### **4. Expand patient access to COVID-19 vaccines by leveraging a highly qualified and empowered clinical pharmacy workforce in all settings of care.**

Pharmacists and pharmacy technicians contribute significantly to vaccine awareness and immunization rates through clinical efforts such as patient screening and education, vaccine administration, and accurate reporting of adverse events. The pharmacy workforce should be mobilized nationwide to administer COVID-19 vaccines and as clinical team members in the community. State and federal legal, scope of practice, and reimbursement barriers that prevent or limit pharmacist COVID-19 vaccine administration must be removed.

### **5. Adhere to established best practices for proper storage and handling of COVID-19 vaccines throughout the supply chain, from distribution to patient administration.**

Vaccine supply chain capacity and integrity are dependent not only on manufacturing but also on availability of vaccine components and ancillary resources (e.g., vials, syringes, alcohol swabs), cold-chain management, distribution strategies, and storage. To distribute COVID-19 vaccines effectively, storage procedures must be employed to ensure maximum shelf-life capacity and minimize deterioration and waste of what will likely be a constrained supply of vaccine. Another important aspect of judicious vaccine allotment includes the ability to track and monitor vaccine distribution at the organizational, state, federal, and international level. Efforts to track and trace COVID-19 vaccines in a manner that promotes real-time, reliable tracking while minimizing reporting inefficiencies is required.

### **6. Ensure equitable allocation of COVID-19 vaccines across populations and communities, prioritized for greatest public health impact.**

In anticipation of a constrained supply of vaccine immediately after approval, efforts to prioritize and target vaccination of the most vulnerable populations and critical occupational groups, including healthcare and other essential workers, are required. Enabling and operationalizing multiple, broad access points of administration (e.g., physician offices, pharmacies, churches, community centers) will ensure vaccination efforts reach vulnerable and at-risk populations. Systematic approaches to evaluating whether distribution strategies align with allocation decisions must be considered. This information will inform ongoing prioritization adjustments as more vaccine becomes available for the general population.

## **7. Achieve high acceptance and uptake of COVID-19 vaccines of by minimizing vaccine hesitancy and misinformation.**

Hesitancy and misinformation surrounding administration of a COVID-19 vaccine are significant barriers to vaccination rates. Ensuring a coordinated, transparent nationwide education campaign that is culturally and health-literacy sensitive from public health experts, community organizers, and the healthcare community will be vital in gaining and maintaining trust within the community. Pharmacists, as one of the most trusted and accessible healthcare providers, serve as vaccine champions ready to educate the public. ASHP is committed to providing evidence-based information to pharmacists, other health professionals, and the public related to the safe and effective use of COVID-19 vaccines. Furthermore, ASHP is committed to countering misinformation about COVID-19 vaccines while expanding public outreach and building trust.

## **8. Seek innovative solutions for adverse drug event monitoring and documentation to improve the thoroughness, accuracy, and usefulness of data collection for improved vaccine safety.**

To meet the challenge of COVID-19 in the United States and worldwide, multiple types of vaccines with different risk profiles are anticipated. Although adverse events to vaccines are rare compared to the millions of doses administered yearly, it will be critical to identify any adverse event signals with accuracy and expediency. The national Vaccine Adverse Event Reporting System and state immunization information systems are important tools to detect concerning safety signals and track administered doses from multiple suppliers. These programs must receive the necessary resources to enable real-time, efficient, and interoperable reporting processes. Prioritization of accurate and timely reporting of any adverse events due to COVID-19 vaccine administration will assist healthcare personnel in providing the best care and prevention services to their patients and ensure individuals feel empowered regarding their self-care decisions.

## **9. Ensure patient access to COVID-19 vaccines by preventing and removing financial barriers.**

Cost and reimbursement barriers for COVID-19 vaccine administration will reduce the impact of sustained immunization efforts within communities. High costs for patients and reimbursement barriers for immunizers will negatively affect patient access and result in lower vaccination rates. To mitigate these impacts, it is important to identify potential financial barriers and work collectively to ensure reasonable costs and fair reimbursement.

## **10. Remain vigilant with continued research and comprehensive surveillance procedures for COVID-19 vaccine use, safety, and effectiveness.**

Ongoing research and surveillance will expand the body of evidence related to COVID-19 vaccine use, safety, and effectiveness as well as inform current and future mass immunization efforts. ASHP calls for the support of research and the development of measures to evaluate the impact of vaccination on population protection from SARS-CoV-2, allocation to vulnerable populations, mobilization of the immunizer workforce, and other population and global health indicators.

## Summary

It is imperative that COVID-19 vaccines are distributed in an ethical, equitable, and efficient manner to maximize population protection from SARS-CoV-2. To achieve this goal, extraordinary efforts will be required to coordinate, prepare, and mobilize an immunization workforce while operationalizing the critical infrastructure for the vaccine supply chain. ASHP acknowledges the multifaceted approaches required for the continuum of mass immunization efforts and is committed to advancing resources and support.

## About ASHP (American Society of Health-System Pharmacists)

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 55,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 78 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. Visit ASHP online at [ashp.org](https://www.ashp.org). Access our COVID-19 Resource Center at [ashp.org/COVID-19](https://www.ashp.org/COVID-19).