

ASHP principles for COVID-19 vaccine distribution, allocation, and mass immunization

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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 postmarketing 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 premarketing clinical trials. Therefore, rigorous postmarketing 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 policies, 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 (eg, 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 levels. 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 (eg, 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 by 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 vaccine-related adverse events 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 to 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.