## COVID-19 astho

### **Advisory Committee on Immunization Practices:**

# Considerations for First Phase Vaccine Allocation, Prioritization, and Post-Authorization

Dec. 7, 2020

#### **Background**

During the initial phase, or Phase 1, of the COVID-19 vaccination program, it is expected there will be a limited supply of vaccines. A key policy goal is to determine the critical populations to receive COVID-19 vaccination, including those groups identified to receive the first available doses. The Advisory Committee on Immunization Practices (ACIP), comprised of medical and public health experts who develop recommendations on the use of vaccines in the U.S. civilian population, met on Dec. 1, 2020 to discuss, vote, and ultimately issue the following interim recommendation: When a COVID-19 vaccine is authorized by FDA and recommended by ACIP, vaccination in the initial phase of the COVID-19 vaccination program (Phase 1a) should be offered to both 1) healthcare personnel and 2) residents of long-term care facilities.

Healthcare personnel are defined as paid and unpaid persons who serve in healthcare settings and have the potential for direct or indirect exposure to patients or infectious materials.

Long term care facility residents are defied as adults who reside in facilities that provide a variety of services, including medical and personal care, to persons who are unable to live independently.

#### **State Considerations During Phase 1a**

As jurisdictional health departments plan to prioritize the distribution and eventual administration of the initial shipments of vaccine, below are key considerations that surfaced during the discussions and deliberations from the ACIP meeting that may be helpful in guiding implementation of the ACIP interim recommendation.

#### General Considerations:

- Small community healthcare practices and hospitals may need to partner with larger hospital systems to order and store large amounts of vaccine.
- Pharmacies that have signed up for the Federal Pharmacy Partnership have agreed to make 3 separate visits to long-term care facilities (LTCF) to administer vaccine.
- An EUA Factsheet will be made available for each vaccine that is authorized for distribution to all vaccine recipients. A separate EUA Factsheet will be made available for providers.
- CDC is developing a wide array of COVID-19 training materials.
- Even after vaccine administration commences, other COVID-19 mitigation strategies (e.g. masking) will still be necessary.

#### Clinical and Healthcare Personnel (HCP) Considerations:

- Phase 1a clinical considerations include:
  - o Sub-prioritization may be required with limited supply.
  - Implementation of vaccine programs for HCP will need to consider reactogenicity postvaccination.

- Reactogenicity appears lower in older adult population for mRNA vaccines (there is no data in LTCF residents).
- o Safety monitoring will be critical post-authorization.
- Considerations for sub-prioritization of HCP may include those who have direct patient contact, provide direct services or handle infectious materials, work in LTCF's, and have not had COVID-19 infection in the past 90 days.
- Given that 75% of healthcare personnel are women, implications for vaccinating pregnant or breastfeeding women should be considered.
- Consider administering vaccine to HCP within similar units or positions at different times since some may have to take off work due to side effects.
- Consider the needs of HCP with medical conditions. Some HCP may feel less empowered to disclose their conditions, and therefore might not be appropriately prioritized for vaccination.
- Sub-prioritization is very granular. It may be difficult to weigh the risk of HCP based on age, race, and other factors.

#### Post-Authorization Safety Monitoring:

- Early data on COVID-19 vaccine safety in HCP will be mainly available through VAERS and the
  vaccine safety assessment for essential workers system (V-Safe), a patient, text messagingbased reporting system. Early data on safety in LTCF residents will be mainly available through
  VAERS and systems that report into VAERS.
- Ongoing partner outreach and engagement will be conducted to raise awareness of V-Safe and VAERS reporting requirements and to encourage enrollment into the program.
- There are plans for communication materials to be translated into 5 languages, as well as to ensure that they are culturally appropriate and at the appropriate reading level.

#### Conclusion

The ACIP interim recommendation aims to provide guidance for health departments when ordering COVID-19 vaccine and determining how to implement the vaccination program at the state and local level. An MMWR, meeting minutes, and presentation slides are now available.

Another emergency ACIP meeting is expected to be held after the Dec. 10 Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting to review that committee's decision on the request for the Pfizer vaccine emergency use authorization and make additional recommendations. As needed, CDC will continue to produce interim guidance responsive to new information.

#### **Expected Forthcoming Federal Guidance and Resources:**

- Communications toolkits to provide context for vaccination of prioritized populations. Communication materials will also be disseminated to state and territorial health officials, healthcare providers, and healthcare systems.
- Health System and Healthcare Provider Communications Toolkit will include information on v-Safe, how to enroll patients in v-Safe, and tips for encourage patients to enroll.
- Guidance on handling systemic symptoms in healthcare personnel after COVID-19 vaccination.
- Considerations for use of COVID-19 vaccines in pregnant and breastfeeding Phase 1a populations.
- Several of the clinical considerations including sub-prioritization discussed will be summarized and posted on the CDC website.