Allocating COVID-19 Vaccines in Initial Phases of Distribution: Federal Recommendations and Considerations for States

December 23, 2020

With Emergency Use Authorizations (EUA) now issued by the U.S. Food and Drug Administration (FDA) for the Pfizer/BioNTech and Moderna COVID-19 vaccines,[1] Governors are responsible for ensuring rapid and equitable distribution to millions of Americans across the country. With a limited initial supply of vaccines, Governors will need to prioritize certain populations for vaccine allocation through a transparent and equitable process. Allocation decisions will need to be effectively communicated to the public in order to manage public expectations and ensure vaccine is accessible for all prioritized individuals. Throughout this process, and particularly as more doses become available, collaboration with key stakeholders such as local governments, providers, health plans, communities and the private sector will be critical to an effective and equitable phased COVID-19 vaccine distribution campaign.

This memorandum summarizes federal recommendations regarding who should receive the initially limited vaccine first, how states are approaching allocation and implementation of federal recommendations in initial distribution phases, considerations for addressing challenges that may lie ahead, and appendices with additional information and resources.

I. Phased Allocation of COVID-19 Vaccines: Advisory Committee on Immunization Practices (ACIP) Recommendations and Prospective Allotments to States

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP)[2] is comprised of medical and public health experts who develop recommendations for the safe use of vaccines for the public. In recent weeks, through public deliberative processes, ACIP has issued several recommendations regarding the use and distribution of COVID-19 vaccines.

Following the EUA of each vaccine, ACIP issued interim recommendations for use of the Pfizer/BioNTech COVID-19 vaccine in individuals 16 years of age and older and use of the Moderna COVID-19 vaccine for individuals 18 years of age and older. In addition, ACIP issued

[1] For a comparison of the two authorized vaccines and additional information on safety and efficacy, please see **Appendices A and B.**

[2] ACIP is a federal advisory committee that makes recommendations regarding the use of vaccines in various populations (e.g., specific age groups, professions or other groups at risk of infection). ACIP established a COVID-19 Vaccine Workgroup in April 2020 to help inform evidence-based approaches to COVID-19 vaccination policy and provide draft recommendations to the full committee, using an open and transparent process for decision-making.

interim recommendations to guide state decision-making for vaccine allocation during the first months of distribution when vaccine supply is limited. The allocation recommendations provide a framework for state prioritization of critical populations categorized into Phases 1a, 1b, and 1c.

Critical guidance included in ACIP recommendations through December 20, 2020 include:

Phase 1a: On December 3, ACIP voted to recommend that the initial group to be vaccinated – Phase 1a – include both health care personnel and residents of long-term care facilities (LTCFs), estimated to include approximately 24 million people. To determine who should first get vaccinated, ACIP considered the epidemiology of the disease, vaccination program implementation, and data regarding vaccine candidates, among other factors.

Phases 1b and 1c: On December 20, ACIP voted to recommend that individuals aged 75 years or older and essential frontline workers be included in Phase 1b. This was estimated to include 49 million additional people not already in Phase 1a. Individuals 65 through 74 years of age, individuals 16 through 64 years of age with high-risk medical conditions, and other essential workers 16 years of age or older are included in Phase 1c. It is estimated that this includes approximately 129 million additional people who were not in Phase 1a or 1b.

As outlined by workgroup members, ACIP developed these recommendations with the goal of balancing the prevention of morbidity and mortality and preservation of societal functioning. The expert committee also noted that if vaccine supply remains constrained, additional factors might be considered for sub-prioritization within these phases.

Table 1. ACIP Recommended Phase 1a, 1b, and 1c Populations

Phase 1a	Phase 1b	Phase 1c

• Health care personnel ~21M
• LTCF residents ~3M
	• Adults ≥ 75 years ~19 M
	• Frontline essential workers ~30M
	  • First Responders
	  • Education (teachers, staff, daycare)
	  • Food and agriculture
	  • Manufacturing
	  • Correction Workers
	  • USPS workers
	  • Public transit workers
	  • Grocery store workers
		• Other Essential Workers ~20M
		• Adults 65-74 years ~28M
		• Individuals 16-64 years with high-risk conditions ~81M

*Source: December 20 ACIP Meeting

While there remains a significant amount of uncertainty in the anticipated number of vaccines that states will continue to receive on an ongoing basis, Federal officials at the December 20th ACIP Meeting presented early estimates of national available vaccine supply to help guide state planning. Nationally, these estimates included:

- Doses for 20 million people by end of December 2020[3]
- Doses for 30 million more people by end of January 2021
- Doses for 50 million more people in February 2021
- Approximately 20 million doses per week available thereafter

If actual allotments of vaccines to states follow these estimates and states are able to fully utilize their allotments each week (including administration of 2nd doses), Phase 1b could potentially begin around the week of 1/10/21 and Phase 1c around the week of 2/7/21 with considerable overlap in the phases. This prospective timeline, however, will vary widely across states depending on actual allotments, vaccination scheduling delays or limitations, and vaccine hesitancy in prioritized groups.

II. State Considerations for Operationalizing ACIP Recommendations

Based on guidance contained in the *CDC Vaccination Program Interim Playbook for Jurisdictional Operations*, all states, territories, and vaccine jurisdictions submitted detailed COVID-19 vaccination plans to the CDC in October that included information on allocation decision-making across distribution phases. While a number of state plans identified the creation of advisory committees to help guide allocation or outlined anticipated frameworks for distribution to critical populations, states also acknowledged that making allocation decisions would be an ongoing process that would need to be readjusted based on incoming information and ACIP recommendations. Since October, at least forty-five states have updated their initial prioritization criteria to follow ACIP's recommendations for Phase 1a populations. Similarly, many states will need to readjust based on new guidance for Phases 1b and 1c, which may pose significantly more planning and implementation challenges given that these populations (e.g., individuals over 75, frontline essential workers) may be more difficult to define or efficiently reach than clearly defined and located health care or LTCF populations.

Approaches for Phase 1a

Governors and their partners have already begun the process of directing allotments of vaccines to Phase 1a health care personnel and LTCF residents. Although all states have included these two groups in Phase 1a, some states are planning to include additional priority populations based on the unique characteristics of their states. For example, **Nevada**, **New Hampshire**, and **Wyoming** plan to vaccinate law enforcement in Phase 1a, and in **Massachusetts**, people in prisons and homeless shelters are eligible for Phase 1a vaccination. Several more states are still deciding whether to include additional populations

[3] Early data indicates that first week targets have been downwardly adjusted

in this initial phase. Additional state oversight of the vaccine supply will be necessary in states with expanded Phase 1a populations.

Although specific approaches to tailoring federal recommendations vary across states, there are cross-cutting strategies that have emerged as states begin the first wave of distribution. As part of distribution planning, states have worked to identify and estimate the number of eligible health care personnel in their jurisdictions to inform distribution to health systems and other closed points of dispensing (PODs) during Phase 1a. States are primarily distributing initial allotments to their larger health systems, and hospitals are being tasked with sub-prioritizing staff based on local factors such as the burden of COVID-19 disease and the number of workers in direct patient contact. Distribution to community-based health care settings is expected to occur as supply expands in each state, which could occur more quickly with the Moderna COVID-19 vaccine since it does not require ultra-cold storage

States have also leveraged a number of strategies to further sub-prioritize within the health care workforce or LTCF populations while vaccine remains limited. According to the Kaiser Family Foundation, at least 20 states plan to further sub-prioritize within health care personnel and/or LTCF resident populations, based on criteria such as risk of severe outcomes from COVID-19 or likelihood of exposure. For example, in **South Dakota**, frontline and LTCF health care workers will be prioritized before other health care workers, such as clinic and laboratory staff and EMS. In **Idaho**, the state's COVID-19 Vaccine Advisory Committee has recommended that health care personnel be sub-prioritized based on seven subgroups. While a number of states are providing guidance on these issues, many health systems are also making their own internal decisions on how to further prioritize among their staff. Notably, some are weighing staggered vaccination plans to ensure adequate workforce capacity should recipients experience side effects that may require absence from work, a concern that is particularly acute for LTCFs facing significant staffing challenges.

Preparing for Phases 1b and 1c

While ACIP recommendations provide guidance to states and providers on priority populations, states have significant flexibility to sub-prioritize or expand population categories based on local factors such as population size, disease transmission, geography, and vaccine storage and administration capacity. As Governors make time-sensitive operational decisions to ensure that vaccines are efficiently and equitably distributed to Phase 1a populations, they must also make critical planning decisions for allocating and distributing to populations in Phases 1b and 1c. Planning and implementation challenges for Phases 1b and 1c include:

- **Identifying and estimating critical populations:** As outlined in state vaccination plans, states have already undergone processes for identifying, estimating, and locating critical populations. However, with new ACIP guidance for Phases 1b and 1c, states will likely need to reassess existing prioritization frameworks, engage advisory groups to update planning assumptions, consider approaches to sub-prioritization

within populations, and engage businesses, organizations, and healthcare providers to support planning for distribution and administration to adults at highest risk and within critical workplace settings. States must also remain agile and prepared to incorporate updated and forthcoming ACIP recommendations into ongoing plans.

- **Sub-prioritizing within populations:** As vaccine demand is anticipated to continue to exceed supply in the coming months, states will need to make critical decisions on sub-prioritization within critical population groups. ACIP has recommended that when further sub-prioritization is needed within frontline essential workers, that states may consider prioritizing: 1) locations where rates of transmission are highest, 2) workers at highest risk of severe illness based on age or underlying conditions, or 3) workers who have not had a documented COVID-19 infection in the previous 90 days.

- **Developing criteria for transitioning between phases:** Although ACIP has identified population categories within each phase, Governors will be responsible for determining when and how to move to the next phase of distribution when supply exceeds demand at a given stage. Importantly, phases may overlap in order to ensure that vaccines are efficiently distributed and wastage is avoided. Moving forward, states may choose to identify "gating criteria" for moving to subsequent phases, which may include reaching a set target for individuals vaccinated within a given phase (e.g., 60-70% of a target population is vaccinated), a threshold for when vaccination capacity exceeds supply (e.g. vaccine appointments <80% filled), or upon authorization of additional vaccines or an increase in supply of an already authorized vaccine.

- **Addressing other distribution challenges:** As states move toward distribution to Phase 1b and 1c populations, strategies used to identify and distribute to health care providers and LCTFs may not be directly translatable to Phase 1b and 1c. In contrast to healthcare workers and LTCF populations who operate in relatively limited settings, Phase 1b and 1c include diffuse populations (e.g., adults over 65, individuals with chronic conditions) that may be significantly more difficult to identify, notify of eligibility, or schedule for appointments in a targeted manner. Feasibility will also be a key consideration in developing distribution plans to these critical populations—determining eligibility, reaching essential workers in rural locations or shift workers, and barriers to access for elderly individuals are all challenges acknowledged by ACIP. Many states have already begun the process of engaging key partners, including employers in critical infrastructure industries, to begin planning for distribution and administration.

- **Communicating with the public:** Communicating regularly with the public about prioritization and the progress of vaccination efforts (i.e., who has received the vaccine and who will qualify next) will be necessary to increase readiness,

transparency, and trust to promote uptake of COVID-19 vaccines. As vaccines become available in a wider array of settings, concerns have already emerged regarding the ability of individuals to "skip the line" and gain access before their designated phase. States should consider approaches for working with partners to verify the eligibility of vaccinated populations, without creating undue burdens on individuals and providers. Furthermore, as vaccine availability and guidance continue to shift, states will want to ensure that they are working with partners to transparently communicate with the public regarding vaccine supply and where they can go to access vaccines. These trusted partners may expand to primary care offices, employers and other locations where individuals can be supported with information and access to vaccines.

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Appendix A: ACIP Review of Evidence on Use for the Pfizer/BioNTech and Moderna Vaccines

To assess the use of the Pfizer/BioNTech vaccine among the general population, ACIP reviewed all publicly available data and was primarily informed by an ongoing randomized, double-blind, placebo-controlled Phase II/III clinical trial that had enrolled approximately 43,000 participants aged 16 years or older. Findings from the clinical trial indicated the vaccine was 95.0% effective in preventing symptomatic COVID-19 from 7 days after the second dose in individuals without prior COVID-19 infection. Based on these data, ACIP recommended use of the Pfizer/BioNTech vaccine in persons aged 16 years and older. For the Moderna vaccine, ACIP reviewed the body of available evidence, primarily informed by an ongoing, randomized, double-blind, placebo-controlled Phase III clinical trial that enrolled approximately 30,000 participants aged 18 years or older. Findings from this clinical trial indicate the Moderna COVID-19 vaccine was 94.1% effective in preventing symptomatic COVID-19 from 14 days after the second dose. Similar to the Pfizer/BioNTech vaccine, there were no specific safety concerns identified. Based on these data, ACIP recommended the use of the Moderna vaccine in persons aged 18 years or older for the prevention of COVID-19.

Appendix B: Comparing the Pfizer/BioNTech and Moderna Vaccines

	Pfizer/BioNTech (BNT162b2)	**Moderna (mRNA-1273)**
Doses	2 doses given **21 days** apart	2 doses given **28 days** apart
Storage Temperature	-70°C±10°C (-94°F)	-20° C (-4°F)
ACIP Recommendations	Individuals 16 years or older under the FDA's EUA. (source)	Individuals 18 years or older under the FDA's EUA (source)
Safety Profile	In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)	In clinical studies, the adverse reactions in participants 18 years of age and older were pain at the injection site (92.0%), fatigue (70.0%), headache (64.7%), myalgia (61.5%), arthralgia (46.4%), chills (45.5%), nausea/vomiting (23.0%), axillary swelling/tenderness (19.8%), fever (15.5%), swelling at the injection site (14.7%), and erythema at the injection site (10.0%).
Efficacy Profile	95.0% (95% Confidence interval was 90.3% to 97.6%)	94.1% (95% Confidence interval was 89.3% to 96.8%)
Initial Allocations	First Dose: 2,980,575 Second Dose: 2,943,525 (source)	First Dose: 5,990,000 Second Dose: 5,948,600 (source)
U.S. Purchase Agreements (to date)	100 million (source) *(Potential for additional 500 million)*	200 million (source, source) *(Potential for additional 500 million)*
Projected Global Allotment	2020: 50 million doses 2021: 1.3 billion doses (source)	2020: 20 million doses (domestic) 2021: 500 million to 1 billion doses (source)

Appendix C: Additional Resources

- CDC Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine
- CDC Advisory Committee on Immunization Practices' Vaccine Recommendations and Guidelines - Evidence Table
- CDC Advisory Committee on Immunization Practices' - Clinical Considerations for Sub-Prioritization
- CDC COVID-19 Vaccine Initial Allocations - Pfizer/BioNTech
- FDA Vaccines and Related Biological Products Advisory Committee - December 10 Meeting Materials
- FDA Emergency Use Authorization for Vaccines Explained