

## VIEWPOINT

# Scientific and Ethical Principles Underlying Recommendations From the Advisory Committee on Immunization Practices for COVID-19 Vaccination Implementation

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Supplemental content

**The continued global spread** of the coronavirus disease 2019 (COVID-19) pandemic highlights the pressing need for safe and effective COVID-19 vaccines. Vaccine development efforts of unprecedented scale and speed are being pursued. Since June 2020, the Advisory Committee on Immunization Practices (ACIP) has held 4 public meetings to lay the groundwork for public health recommendations for COVID-19 vaccines. This Viewpoint summarizes the approach ACIP is taking in formulating recommendations, with a focus on the ethical principles and potential groups for allocation of vaccine doses when supply is limited. Recommendations will be issued after reviewing safety and effectiveness data and vaccines are licensed or authorized under Emergency Use Authorization by the Food and Drug Administration (FDA).

The ACIP is an independent federal advisory committee body composed of experts external to the federal government from diverse medical and public health fields, as well as a consumer representative. The committee is charged with recommending how FDA-licensed or authorized vaccines should be used in the US civilian population.<sup>1</sup> These recommendations are provided to the director of the Centers for Disease Control and Prevention (CDC). If the CDC director approves the recommendations, they become official CDC recommendations for immunizations in the US.

ACIP recommendations determine the vaccines that are covered under the Vaccines for Children program, which provides vaccines at no cost for Medicaid-insured, underinsured, and uninsured children. Under the provisions of the Affordable Care Act (ACA), recommended vaccines are covered by health insurers and employer-sponsored health plans established after passage of the ACA.<sup>1</sup> Hence, while not binding, recommendations determine how vaccines are used in the public sector and set the standard for clinical practice in the private sector.

ACIP meetings are open to the public and committee documents are publicly available, ensuring transparency in decision-making. The development of recommendations adheres to a rigorous and transparent process. Grading of Recommendations Assessment, Development, and Evaluation (GRADE) methods facilitate a standardized approach to evaluating scientific evidence.<sup>1</sup> The Evidence to Recommendations framework evaluates factors including feasibility and acceptability.<sup>1</sup> Hence, the ACIP aims to produce national vaccine recommendations that are both evidence-based and implementable.

Implementing COVID-19 vaccination presents a number of unique, interrelated challenges. During its public meetings, the ACIP has characterized guiding principles, assembled and reviewed available data, and summarized considerations for allocation of initial doses. The

ACIP is reviewing and incorporating aspects of frameworks and guidance developed by a number of expert panels.<sup>2-4</sup> An important additional contribution to this approach is the charge to consider the "on-the-ground" realities of vaccine program implementation.

## Ethical Principles

In September 2020, the ACIP endorsed 4 interim ethical principles, central to the development and implementation of recommendations for COVID-19 vaccine use, including in the setting of a constrained supply—maximizing benefits and minimizing harms; equity; justice; and fairness (eTable in the [Supplement](#)). Transparency, a fifth key principle, was considered foundational to ethical decision-making. Transparency is essential to foster public trust and ensures that allocation decisions are clear and open for review and public engagement.

## Potential Groups for Allocation of Initial Doses

Safe and efficacious vaccines are needed for all. The number of available doses likely will initially be constrained and will increase over time, necessitating phased implementation. The first phase includes the period of constrained supply, when more targeted administration will be needed. In the second phase, supply will likely increase to meet demand, allowing for wider administration of more vaccine products. In the third phase, with adequate and ongoing vaccine supply, efforts will continue to improve vaccination coverage. The ACIP reviewed available allocation schemes and applied its ethical principles to define groups to consider for vaccine doses in the first phase of distribution. The committee discussed, but has not voted on, possible prioritization scenarios. Recommendations await the completion of clinical trials and FDA licensure or authorization.

**Phase 1a.** Health care personnel (HCP) are being considered for phase 1a, which includes the first available doses and an extremely constrained supply. HCP are defined as all paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials, comprising an estimated 20 million people. Examples include hospital, long-term care and assisted living, home health care, and outpatient facility staff, as well as pharmacies and emergency medical services. HCP are essential for the ongoing COVID-19 response and are at high risk for exposure to SARS-CoV-2.<sup>5</sup>

**Phase 1b.** Groups under consideration for Phase 1b, when more doses will be available and likely more than 1 vaccine product, include essential workers, persons with high-risk underlying medical conditions, and elderly individuals. First, essential (non-health care) workers number

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an estimated 60 million, and conduct operations vital for continuing critical infrastructure, such as food and agriculture, transportation, education, and law enforcement. In doing so, essential workers who must work in close proximity to others as part of their job function are at high risk for COVID-19.<sup>6</sup> Racial and ethnic minority groups are disproportionately represented in low-wage essential work including farms, factories, grocery stores, and public transportation.<sup>6</sup>

Second, at least an estimated 100 million adults in the US have 1 or more high-risk medical conditions (eg, obesity, diabetes, and cardiovascular disease).<sup>5</sup> Persons with 1 or more underlying medical conditions who develop COVID-19 are at increased risk of hospitalization and death. Some racial and ethnic minority groups have a disproportionate prevalence of certain high-risk conditions such as diabetes and obesity.<sup>5</sup> Third, adults aged 65 years and older, approximately 53 million people, are at increased risk of COVID-19-associated hospitalization and make up a disproportionate share of deaths.<sup>7</sup> Approximately an estimated 3 million older adults live in long-term care facilities.

There is overlap among these groups, but precisely how much is difficult to quantify. Nonetheless, it is estimated that phases 1a and 1b include an estimated approximately 200 million people, likely too many for the number of doses available in the first phase. To support efficient implementation, further guidance may be needed. The specific features of this further phased implementation within phase 1 will involve addressing several key unknowns.

### Implementation Considerations and Information Gaps

Key unknowns that affect implementation include the particular characteristics of each licensed vaccine, such as the magnitude and balance of benefits and risks across age groups, the storage/handling requirements, and the number of doses required; the FDA approval pathway; the trajectory of scale up of the number of doses; and COVID-19 epidemiology at the time of licensure. The initial roll out of vaccines will set the tone and affect public confidence.

Keeping vaccination program implementation as simple as possible is key. This includes maximizing the efficiency of individuals who will provide vaccines and minimizing the need to apply overly burdensome or restrictive screening policies for eligibility. National recommendations should be broad enough to offer flexibility, yet specific enough to provide guidance to health care clinicians and facilities, states, and localities as they develop implementation plans.

Initial vaccine recommendations will be influenced by the terms of FDA approval. Even for licensed vaccines, effectiveness and performance may vary in particular populations, influencing the benefit/risk balance. For example, a licensed vaccine with poor immunogenicity or efficacy among older individuals might affect the recommendations for that age group. Also, the timing of availability of different vaccines and differing characteristics of each vaccine will influence the sequencing and pace of the vaccine recommendations. For example, the requirement for ultra-low temperature in shipping and storage for certain vaccines may favor centralized distribution strategies for those vaccines. Because children have not been enrolled in the initial vaccine trials, recommendations for use of the vaccine in children will not be made at this time. In addition, building comprehensive postlicensure surveillance and robust tracking systems will support accountability and strengthen public confidence.<sup>8</sup>

### Conclusions

The CDC, health care facilities, and state and local health departments, which have already begun implementation planning, rely on the ACIP for guidance. However, the ACIP will not make recommendations before phase 3 efficacy and safety data are available for review, GRADE analysis, and synthesis. At this stage, based on available data, there is a clear consensus that initial doses should be used to vaccinate HCP. The ultimate recommendations for use of COVID-19 vaccines will be based on the outcome of review of applications by the Vaccines and Related Biologic Products Advisory Committee and FDA authorization or licensure.<sup>9</sup> The ACIP will conduct its own detailed independent review, in the context of the committee's population-based approach and public health responsibility.

Monitoring implementation of the vaccination recommendations will be critical to identify gaps, ensure equity, and determine best practices. The CDC, working with state and local health departments and health care centers and clinicians, is building the necessary tracking infrastructure. Initial ACIP recommendations will be updated as new information becomes available. The ultimate success of any vaccination program is rooted in public confidence. The ACIP is determined to adhere to the process that has guided the US vaccination program for decades. The ACIP will make recommendations for the use of licensed COVID-19 vaccines based on ethical principles, scientific evidence, and logistical feasibility, using a transparent process that puts safety first.

### ARTICLE INFORMATION

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