

American College of Physicians (ACP) Policy Statement on the Ethical Allocation of Vaccines During Pandemics Including COVID-19

Approved by the Executive Committee of the Board of Regents on behalf of the Board of Regents on November 23, 2020

- **ACP supports the conclusions of the National Academies of Sciences, Engineering and Medicine (NASEM) report, *Framework for Equitable Allocation of COVID-19 Vaccine* (NASEM, October 2020) proposing phased allocation of vaccines, including high-risk health care workers and populations most at risk for death or severe illness in Phase 1.**

Note: phasing here includes NASEM recommendations and ACP modifications

Phase 1a

- High-risk health care workers in direct patient care, including trainees and workers in nursing homes, home health care and health care facility services
- First responders

Phase 1b

- Persons (all ages) with 2 or more underlying health conditions (as listed by CDC) putting them at significantly higher risk of severe illness or death from COVID-19
- Older adults and individuals with disabilities of all ages living in congregate settings such as skilled nursing and long-term care facilities, prisons and group homes, and in multi-generational households
- If availability of vaccine allows for it, individuals age 65 and older not already included

Phase 2

- K-12 teachers and school staff; child care workers
- Other critical workers in high-risk settings such as public transit and food supply
- Persons (all ages) with 1 underlying health condition (as listed by CDC) putting them at moderately higher risk
- Persons and staff in homeless shelters, group homes, prisons, jails and detention centers not included in Phase 1
- All individuals age 65 and older not in Phase 1
- If availability of vaccine allows for it, family caregivers of those age 65 and older

Phase 3

- Young adults
- Children
- Critical workers at increased risk of exposure not included in Phases 1 and 2

Phase 4

- All other individuals living in the US

Equity is a crosscutting consideration

- **ACP recommends that the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC) adopt the phased allocation of vaccines proposed in the NASEM report with ACP modifications.**
- **Strategies to reduce transmission—maintaining physical distance, appropriate mask use, self-isolation, quarantine, frequent hand hygiene with soap and water or alcohol-based hand rub, covering cough and sneezes using a bent elbow or paper tissue, refraining from touching the face, and frequent disinfection of frequently touched surfaces—will remain necessary until effective vaccines have been widely administered.**

An explicit framework for the ethical allocation of vaccines during COVID-19 is necessary, especially since initial vaccines supplies will be limited and may have varying levels of effectiveness in different populations. ACP agrees with the NASEM report conclusions (1), which should be implemented in the phases as specified with ACP modifications. ACP differs on some of the report’s assumptions and rationale, however: we broaden and deepen the set of ethical principles and offer additional points on those issues. The application of the framework’s principles—but not the principles themselves-- may change as more scientific evidence becomes available. Also, as ACIP identifies, implementation of a vaccine strategy should be “as simple as possible,” maximize efficiency while “minimizing the need to apply overly burdensome or restrictive screening policies for eligibility” and be flexible “yet specific enough to provide guidance to health care clinicians and facilities, states, and localities as they develop implementation plans” (2). Being flexible requires an allocation scheme that can adapt as the relevant evidence base evolves over time, as pandemic circumstances change at the local, state and national level, and as vaccines are developed that differ, for example, in effectiveness, storage requirements, and administrative and logistical requirements. ACP believes the NASEM phased approach meets these criteria and that an allocation plan based on risk appropriately addresses the likelihood of limited initial vaccine supplies.

1. ACP supports the NASEM’s conclusions regarding a phased approach to vaccine allocation (language in quotes is from the NASEM report):

“Phase 1a (approximately 5 percent of U.S. population)

Includes high-risk health workers who are involved in direct patient care, including those providing care in nursing homes and through home health care, as well as those in health care facility services, including transportation and environmental services. First responders are also included.”

ACP agrees. NASEM clarifies in the report's rationale that this includes workers who provide "other health care facility services and who risk exposure to bodily fluids or aerosols." ACP says high-risk health workers, including medical students, residents and other trainees, are those who are at higher risk of COVID-19 infection and transmission based on the current evidence, taking into account local circumstances such as mitigation strategies in place, work setting (e.g., availability of telehealth), and the current status of the pandemic. Also, this assists physicians and other clinicians to fulfill their duty to limit risk to patients by taking appropriate precautions including immunization (3). Having high-risk health workers "go first" might also help build trust in the health care system and reduce vaccine hesitancy among members of the public.

"Phase 1b (approximately 10 percent of U.S. population)

Includes people of all ages with two or more comorbid or underlying health conditions that put them at significant risk of severe illness or death from COVID-19, defined as having two or more of the conditions listed by CDC as being associated with increased risk of severe COVID-19. Phase 1b also includes all older adults living in congregate settings, including nursing homes, long-term care facilities, prisons and group homes, and multi-generational households."

ACP agrees. The CDC's lists (<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>) of 1) conditions that put individuals at increased risk of severe COVID-19 (such as cancer, chronic kidney disease, COPD, certain heart conditions, immunocompromised states, obesity, pregnancy, sickle cell disease, type 2 diabetes mellitus and smoking) and 2) conditions that might put individuals at increased risk, are evidence-based and updated regularly (4). ACIP includes in its thoughts on initial potential groups for Phase 1b an additional 100 million adults with one or more high-risk medical conditions and all adults age 65 and older. This, however, would bring the total for Phase 1 to 200 million people (2), which does not meet the goal of accomplishing prioritization. The NASEM phasing recommendations do meet that goal and recognize there will be overlap among populations. ACP would also include individuals with disabilities of all ages in congregate settings in Phase 1b . If availability of vaccine allows for it, ACP would include all individuals age 65 and older in Phase 1b.

"Phase 2 (approximately 30–35 percent of U.S. population)

Phase 2 includes K–12 teachers, school staff, and child care workers, a group that includes administrators, environmental services staff, maintenance workers, and school bus drivers. Also included in Phase 2 are critical workers in high-risk settings who cannot avoid a high risk of exposure to COVID-19, such as workers in the food supply system and public transit. In addition, Phase 2 covers people of all ages with comorbid and underlying conditions that put them at moderately higher risk, defined as having one of the conditions listed by CDC as being associated with increased risk of severe COVID-19. This phase also includes people in homeless

shelters or group homes for individuals with physical or mental disabilities and all other individuals and staff in prisons, jails, detention centers, and similar facilities who were not included in Phase 1. All older adults not included in Phase 1 are included in this phase.”

ACP agrees (although if availability of vaccine allows for it, ACP would include all individuals age 65 and older in Phase 1b). If possible, Phase 2 should also include family caregivers of those age 65 and older.

“Phase 3 (approximately 40–45 percent of U.S. population)

Includes all children and young adults in the United States 30 years of age or younger. However, children are not currently included in any major vaccine trials for COVID-19 and would need to be included in these trials before mass vaccination of children could take place. Phase 3 also includes workers in industries and occupations important to the function of society and at increased risk of exposure who are not covered in Phases 1 and 2.”

ACP agrees. Trials have now begun with children. ACP supports the need to include children and, also, pregnant women, in vaccine trials.

“Phase 4

Includes all other people living in the United States. The United States should ensure that all U.S.-based individuals who did not have access to the vaccine in previous phases (and for whom the vaccine is not medically contraindicated) have access to the vaccine.”

ACP agrees.

“The framework includes four allocation phases of COVID-19 vaccine to the public, outlined above. Detailed discussions of each population group included in the phases, and the rationale behind their inclusion, can be found in Chapter 3 of the full report. The population groups included in each allocation phase overlap to a certain extent, and there are individuals who will fit into multiple categorizations. Given the current state of the pandemic, the early phases of the committee’s proposed framework emphasize prevention of severe illness and death and maintenance [sic] of essential health and emergency services to support this goal, with a shift toward reducing transmission in later phases. **Within each phase, all groups have equal priority.**”

ACP agrees.

2. “Equity is a crosscutting consideration: In each population group, vaccine access should be prioritized for geographic areas identified through CDC’s Social Vulnerability Index or another more specific index.”

ACP agrees although admittedly, this is complex. The recommended phased roll out appropriately addresses the critical crosscutting consideration of equity. NASEM further clarifies that, “The committee does not propose an approach in which, within each phase, all

vaccine is first given to people in high-SVI areas. Rather the committee proposes that state, tribal, local, and territorial (STLT) authorities ensure that special efforts are made to deliver vaccine to residents of high-vulnerability areas (defined as 25 percent highest in the state).” The use of the SVI or other more specific indices should direct STLT authorities to engage with the potentially hardest hit communities, some of whom may be more likely to distrust the health care system or be vaccine hesitant, in order to promote trust and vaccine confidence.

3. Report Framework: Maximum Benefit, Equal Concern and Mitigation of Health Inequities

The NASEM framework’s overall goals are stated as “reducing severe morbidity and mortality and negative social impact due to the transmission of SARS-CoV-2.” These goals are not in themselves controversial. How to balance ethical tensions in achieving them, however, is more complex. ACP agrees with the ethical concepts stated in the report but sees their definitions and application somewhat differently. The NASEM report seems to adopt the perspective only of public health ethics. ACP would include focus on ethical responsibilities to individual patients, given the ethical principles of nonmaleficence, beneficence, respect for autonomy, and justice, and the duties they entail for physicians and the profession. During public health emergencies, “While the physician’s responsibility remains with the health and welfare of individual patients under the physician’s care, the well-being of the community as a whole must also be considered at a systems level including in institutional policies and other guidelines... Along with the traditional duty to care, fairness and equality must be promoted and guide health care delivery during health system catastrophes such as pandemic coronavirus” (5).

In brief, looking at what the NASEM report calls foundational principles in its framework:

A. Maximum benefit

The NASEM report states this is “the obligation to protect and promote the public’s health and its socioeconomic well-being in the short and long term.”

ACP frames maximum benefit in vaccine allocation as having two prongs, based in balancing the principles of nonmaleficence, beneficence, and justice:

- i. Maximize benefit to individuals: save the most lives, care for those most in need first*
- ii. Maximize benefit to public health: prevent infection/transmission to others while maximizing societal good*

In allocating treatment resources, ACP says maximizing benefit means prioritizing those most likely to survive (5). By contrast, in allocating preventive services, ACP says maximizing benefit means prioritizing those most likely to become severely sick or die. Moreover, receiving a vaccine benefits both the individual and the public’s health.

B. Equal concern

NASEM report: “The obligation to consider and treat every person as having equal dignity, worth, and value.”

ACP agrees, based on principles of respect for autonomy, beneficence, and justice, and adds that in implementing equal concern, we must promote equity and non-discrimination. ACP does not support proposals that discriminate against the elderly, persons with disabilities, or minorities or other groups. Allocation of vaccines must maximize saving those most likely to die without the vaccine, not the number of “life-years,” which is inherently biased against the elderly and the disabled. The physician’s duty to care for all prohibits discrimination against classes or categories of patients (3). In light of the equal concern principle, care must be taken that use of a criterion of “negative societal impact” does not invite discriminatory consideration of social worth (6), even if there is no intent to discriminate. ACP instead focuses on ethical principles and on risk of mortality/severe morbidity and risk of exposure/transmission—medical criteria (5)—and reaches similar conclusions about phasing.

An approach based on equal concern aligns with the crosscutting consideration of equity, but may require special outreach and engagement efforts to promote trust in the vaccine and its use among vulnerable or marginalized groups.

C. Mitigation of health inequities

NASEM says this is “The obligation to explicitly address the higher burden of COVID-19 experienced by the populations affected most heavily, given their exposure and compounding health inequities” and that mitigating health inequities is “a moral imperative of an equitable vaccine allocation framework.”

ACP agrees, based in principles of justice and beneficence. The elderly and members of minority racial and ethnic groups are disproportionately represented among COVID-19–associated deaths according to the CDC (7) and others (2).

4. Fair Process and Open Communication

The NASEM report discusses what it calls foundational procedural principles: fairness—that decisions include input from those affected, especially, groups disproportionately impacted by the pandemic; transparency—open communication with the public about the vaccine allocation criteria and framework; and being evidence-based in light of the best available scientific data.

ACP agrees and adds that consistency in applying principles and accountability mechanisms (i.e., oversight and documentation that allocation programs work as intended) are also required in resource allocation frameworks (5). Open communication and community engagement about the allocation framework and process will be key. This is especially important as the scientific evidence may change over time and there may be multiple approved vaccines that differ in

effectiveness among population subgroups, dosing regimens, storage requirements, and in other characteristics. Humility in the face of uncertainty about vaccine effectiveness in populations, duration of protection and other issues (e.g., whether to vaccinate those previously infected with COVID-19), are also required. This framework is meant to provide fundamental ethical guidance to assist in the equitable allocation of vaccines.

References

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