

**Framework for Equitable Allocation of COVID-19 Vaccine:** Report of the National Academy of Medicine (<https://www.nap.edu/download/25917>)

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The report uses a health equity approach to allocation of COVID-19 vaccine, and uses allocation Phases, not tiers. The foundational principles consist of ethical and procedural principles that reflect this line of thinking:

• **Ethical Principles**

- o Maximum benefit encompasses the obligation to protect and promote the public’s health and its socioeconomic well-being in the short and long term.
- o Equal concern requires that every person be considered and treated as having equal dignity, worth, and value.
- o Mitigation of health inequities includes 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.

• **Procedural Principles**

- o Fairness requires engagement with the public, particularly those most affected by the pandemic, and impartial decision making about and evenhanded application of allocation criteria and priority categories.
- o Transparency includes the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the allocation framework as it is being developed, deployed, and modified.
- o Evidence-based expresses the requirement to base the allocation framework, including its goal, criteria, and phases, on the best available and constantly updated scientific information and data.

Guided by these foundational principles, the goal of the committee’s framework for equitable allocation of COVID-19 vaccine is to:

**Reduce severe morbidity and mortality and negative societal impact due to the transmission of SARS-CoV-2.**

The allocation framework includes the following Phases:

**Phase 1**

Phase 1a: “Jumpstart” phase (5% of population) includes

- high-risk health workers (e.g., in hospitals or nursing homes, or providing home care)—these health professionals are involved in direct patient care.

- workers who provide transportation, environmental services, and other health care facility services and who risk exposure to bodily fluids or aerosols, because of their critical role in maintaining health care system functionality, their high risk of exposure to patients exhibiting symptoms of COVID-19, and their risk of then transmitting the virus to others, including family members.
- First responders whose jobs put them at high risk of exposure to COVID-19 are also included in Phase 1a (although depending on the jurisdiction and outbreak context, this may not include all first responders). Like frontline health workers, first responders play vital roles in both the response to COVID-19 and society's overall functioning.

Phase 1b (10% of population) focuses attention on two groups that are particularly vulnerable to morbidity and mortality due to COVID-19:

- people of all ages with comorbid and underlying conditions that put them at significantly higher risk (cancer, chronic kidney disease, chronic obstructive pulmonary disease (COPD), immunocompromised state from solid organ transplant, obesity (body mass index [BMI]  $\geq 30$ ), serious heart conditions (e.g., heart failure, coronary artery disease, cardiomyopathies), sickle cell disease, and type 2 diabetes mellitus)
- older adults living in congregate or overcrowded settings, including nursing homes, long-term care facilities, homeless shelters, group homes, prisons, or jails.

### **Phase 2 (approximately 30–35 percent of population)**

- K–12 teachers, school staff, and child care workers. This category includes administrators, environmental services staff, maintenance workers, and school bus drivers, all of whom are essential to education and face disease exposure.
- critical workers in high-risk settings—a group of individuals whose occupations are in essential industries and who cannot avoid a high risk of exposure to COVID-19. They include workers in the food supply system, public transit, and other vital services.
- people of all ages with comorbid and underlying conditions that put them at moderately higher risk,
- people in homeless shelters or group homes, and staff who work in those settings.
- people in prisons, jails, detention centers, and similar facilities, and staff who work in those settings
- All older adults not included in Phase 1b are included in Phase 2, because advanced age is in itself a risk factor for severe disease and death due to COVID-19

### **Phase 3 (estimated 40–45 percent of the U.S. population)**

- young adults,
- children: it is important to note that clinical trials of COVID-19 vaccine have not started in children in the United States.

- workers in industries that are both important to the functioning of society and pose moderately high risk of exposure. Workers in this category are important to the functioning of society and are at moderately high risk of exposure represent. Representative industries may include universities, entertainment, and goods-producing industries, whose occupational risk of transmission is lower than those in Phase 2 because they work in settings where protective measures are likely to be implemented without great difficulty.

#### Phase 4

- includes everyone residing in the United States who did not have access to the vaccine in prior phases.

While the committee's phased allocation approach is limited by imperfect data, information unknowns, and potential unintended consequences, it is intended to be adapted by STLT partners based on their needs, and should rely on mid-course corrections and real-time updates based on the science about effectiveness of different vaccines in different populations.

The Committee also made the following recommendations:

**RECOMMENDATION 1.** Adopt the committee's framework for equitable allocation of COVID-19 vaccine. The guidelines seek to maximize benefit, mitigate health inequities, manifest equal regard for all, be fair and transparent, and build on the best current evidence. Important considerations include:

- This framework can also inform the decisions of other groups, such as the Advisory Committee on Immunization Practices and those in the global health community.
- STLT authorities will have to make final decisions on refining and applying the framework and should plan for situations when prioritization has to be adapted midway through the process. In doing so, they should refer to the principles and allocation criteria that guided the formulation of the phases.

**RECOMMENDATION 2.** Leverage and expand the use of existing systems, structures, and partnerships across all levels of government and provide the necessary resources to ensure equitable allocation, distribution, and administration of COVID-19 vaccine. Equitable allocation must be supported by equitable distribution and administration. Specific action steps to implement this recommendation are as follows:

- Provide resources (including resources for staff) to state, tribal, local, and territorial (STLT) authorities and their implementation partners and adequately fund indirect assets (e.g., needles, syringes, personal protective equipment for vaccinators, resources for ultra-cold chain management, and so forth) necessary for effective vaccine allocation, distribution, and administration.
- To ensure identification and delivery of COVID-19 vaccine to priority population groups, develop the capacity and systems to collect and integrate the necessary data (digital and other)

from public health and private providers of care to facilitate the identification and monitoring of people with preexisting conditions and other high-risk characteristics.

- Establish a robust and comprehensive surveillance system to monitor, detect, and respond to identified problems, gaps, inequities, and barriers. Monitoring should encompass equitable vaccine allocation and distribution, vaccine delivery, adverse events following immunization, promotion and communication, and uptake and coverage.
- Ensure that a rigorous COVID-19 vaccine safety monitoring program, built on existing systems, is in place, with an emphasis on rapid reporting and timely and transparent assessment of adverse events to determine whether events are associated with receipt of vaccine or occurring by chance.

**RECOMMENDATION 3.** Provide and administer COVID-19 vaccine with no out-of-pocket costs for those being vaccinated. Specific action steps to implement this recommendation are as follows:

- Apply Patient Protection and Affordable Care Act regulations regarding no cost-sharing for preventive services for COVID-19 vaccinations for insured individuals, while addressing instances where these regulations fail to protect the beneficiary from out-of-pocket costs. Require health insurance providers and self-insured employers to waive co-pays and deductibles for vaccine administration based upon a reasonable nationally determined administrative rate set by the Centers for Medicare & Medicaid Services for all providers, irrespective of site of care or network participation status.
- To reach uninsured individuals, federal support and funding should be provided for mass vaccination clinics and for reimbursement for providers serving uninsured individuals directly. In all cases, a billing code of some kind will be needed to monitor uptake, for pharmacovigilance, and to monitor disparities.
- Keep barriers to provider participation in administration of the vaccine as low as possible, especially for those providers who are in communities that are disproportionately impacted by COVID-19 by assuring vaccines are available at no cost and that administration of the vaccine is adequately reimbursed even if there is no cost sharing for the patient.

**RECOMMENDATION 4.** Create and appropriately fund a COVID-19 vaccine risk communication and community engagement program. The program should:

- Ensure public understanding of the foundational principles, procedures, expected outcomes, and performance of vaccination efforts, including changes in response to research, experience, and public input.
- Be informed by the concerns and beliefs, as revealed by surveys, news media, public discourse, and social media channels, with special attention to information gaps and misinformation.
- Support STLTs in their engagement and partnership with community-based organizations, local stakeholders, and others to provide two-way communication with their constituencies and most effectively reach diverse populations.

- Be grounded on scientific foundations, incorporating the expertise of individuals with the cultural competency to hear and speak to diverse communities that have a stake in successful vaccination efforts.
- Rely on transparent, trustworthy assessments of vaccine safety and efficacy, as reviewed by the federal government and independent external scientists.
- Begin immediately and sustain proactive two-way communication. Achieving Acceptance of COVID-19 Vaccine Recent polling data suggest that approximately one-third of U.S. residents would not accept

**RECOMMENDATION 5.** Develop and launch a COVID-19 vaccine promotion campaign. The Centers for Disease Control and Prevention should rapidly develop and launch a national, branded, multi-dimensional COVID-19 vaccine promotion campaign, using rigorous, evidence-informed risk and health communication, social marketing, and behavioral science techniques. The COVID-19 vaccine promotion campaign should:

- Be consistent in its messaging but also flexible and modular to allow state, tribal, local, and territorial authorities to tailor it to specific communities and audiences, similar to the truth campaign against tobacco use.
- Partner with diverse stakeholders (e.g., health care providers, Historically Black Colleges and Universities research centers, Hispanic Association of Colleges and Universities, Tribal Colleges and Universities research centers, social marketing firms and other groups with specific expertise reaching underserved communities) and prioritize promoting the vaccine to Black, Hispanic or Latinx, American Indian and Alaska Native, Hawaiian Native and Pacific Islander, and other communities in which vaccine hesitancy and skepticism have been documented.
- Engage thought and opinion leaders, such as celebrities, to help promote COVID19 vaccination acceptance and uptake.
- Incorporate messaging (in a variety of languages) and graphical elements that increase motivation, counter misinformation, and overcome perceived or actual practical barriers to vaccination.
- Include print, radio, television, and social media formats; incorporate toolkits, educational materials, and guidebooks to support community discussion about the COVID-19 vaccine; and make materials available in multiple languages.
- Be incorporated into broader messaging that provides consistent information on COVID-19 public health strategies that include nonpharmaceutical interventions, such as mask usage, physical distancing, hand washing, and so forth; expanded and accessible diagnostic testing linked to contact tracing, isolation, and quarantine strategies aimed at containing transmission, suppressing outbreaks, and interrupting super-spreading events; and the deployment of therapeutic measures that mitigate morbidity and mortality.

**RECOMMENDATION 6.** Build an evidence base for effective strategies for COVID-19 vaccine promotion and acceptance. Specific action steps to implement this recommendation include:

- Support innovation in vaccine promotion at the state, tribal, local, and territorial levels and among community-based organizations through existing and expanded

program grant mechanisms, with an emphasis on supporting existing entities, programs, and infrastructure with community knowledge and expertise; and on expanding CDC's existing Vaccinate with Confidence programs.

- Support a new rapid response research grant mechanism to advance the science of COVID-19 vaccine acceptance through grants that:
  - o Foster partnership among research entities, public health agencies, and community-based organizations;
  - o Evaluate existing or novel theory-driven strategies and interventions to decrease COVID-19 vaccine hesitancy, increase COVID-19 vaccine uptake, and eliminate social, cultural, logistic, and legal barriers to COVID-19 vaccination in focal populations; and
  - o Support research grounded in diverse theoretical and methodological approaches, with an emphasis on novel approaches and data sources.

**RECOMMENDATION 7.** Support equitable allocation of COVID-19 vaccine globally. The U.S. government should commit to a leadership role in the equitable allocation of COVID-19 vaccine globally, including:

- Opt in to the COVAX Facility at the Global Alliance for Vaccines and Immunization (GAVI). The U.S. government can pledge its support while still pursuing its bilateral national efforts through Operation Warp Speed and executing its own robust vaccine manufacturing and distribution plans.
- Deploy a proportion (e.g., 10 percent) of the U.S. vaccine supply for global allocation, both as a means to help contain the COVID-19 pandemic and as an effort to build global solidarity in addressing this pandemic—and the next. This deployment should be implemented through the COVAX Facility led by GAVI, which is developing a fair and equitable allocation for global distribution in concert with the member states of the World Health Assembly.
- Engage with and support the World Health Organization and its member states to optimize the fair and equitable allocation of COVID-19 vaccines both between and within all nations, regardless of their income level.