

COVID-19 VACCINE DISTRIBUTION AND ALLOCATION: ETHICS GUIDELINES AND POINTS TO CONSIDER

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1. Preamble

The COVID-19 pandemic is the worst public health crisis in a century. It has affected every life, every community, every institution on Earth. Economies are in shambles. Vulnerable and too-often under-supported, healthcare systems have struggled to manage shortages of staff, supplies, and therapeutic agents and tools. Moreover, in the United States and other countries, the pandemic is congruent with the awakened realization that our societies have fostered and enabled a culture of racism, bias, and discrimination.

Experts widely agree that a successful COVID-19 vaccine is necessary to impede the virus' spread and to eliminate it. Now that such vaccines have been developed and are becoming available, there is not enough of it and will not be for some time. Challenges with the distribution and allocation of that vaccine are likely to parallel those of previous shortages of ventilators, drugs, and staff.

This document offers ethics guidelines for such distribution and allocation. It provides neither medical nor legal advice. Because different jurisdictions and institutions will face different conditions, needs, and resources – all of which have changed and will continue to change – the document also offers points to consider in all efforts to achieve an ethical and socially responsible allocation strategy and plan. It is intended to complement similar guidelines, including those of the National Academy of Sciences,¹ The World Health Organization,² and the Centers for Disease Control and Prevention.³

Note: “Available at” URLs are accurate as of November 5, 2020.

¹ National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press. doi: [10.17226/25917](https://doi.org/10.17226/25917).

² World Health Organization. More than 150 countries engaged in COVID-19 vaccine global access facility. World Health Organization. 2020. Available at: <https://www.who.int/news/item/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>.

³ Centers for Disease Control and Prevention.

- COVID-19 Vaccination Program: Interim Playbook for Jurisdiction Operations. Available at: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.

COVID-19 Vaccination Record Card

Please keep this record card which includes medical information about the vaccines you have received.
Por favor, guarde esta tarjeta de registro, que incluye información médica sobre las vacunas que ha recibido.

Last Name _____ First Name _____ MI _____

Date of birth _____ Patient number (medical record or IIS record number) _____

Vaccine	Product Name/Manufacturer Lot Number	Date	Healthcare Professional or Clinic Site
1 st Dose COVID-19	_____	mm / dd / yy	_____
2 nd Dose COVID-19	_____	mm / dd / yy	_____
Other	_____	mm / dd / yy	_____
Other	_____	mm / dd / yy	_____

More than 200 vaccines are being developed, studied and tested.⁴ Though there have been vaccine shortages in the past, the unique landscape of the COVID-19 emergency compels authorities and healthcare decision makers to reevaluate traditional bases for vaccine allocation. This document identifies a suite of criteria to guide COVID-19 vaccine distribution and allocation. However, in considering these criteria it is important to emphasize that we do not currently know:

- Which vaccine or vaccines will be delivered
- How effective it/they will be
- How safe it/they will be
- How much of the vaccine will be delivered
- How allocation and distribution decisions will be made at the national level

This guide is intended to support decision makers at vaccine distribution locations: Florida healthcare institutions, counties, and states. At each level, decision makers will have to rank the importance of large amounts of probabilistic, uncertain, and constantly changing data and information. This document is a collection of points to consider. With three exceptions, it does not and cannot provide recommendations such that it would be a mistake not to accept them. Decision makers at each level will need to weigh the available evidence and determine the appropriate allocation strategy. Those decisions are likely to require constant revision.

The three exceptions are these: First, healthcare institutions and county and state governments must establish vaccination allocation teams to guide ethical decision making. Second, healthcare institutions and county and state governments must establish processes to inform and support those teams. These teams should ensure these values are embedded in their decision making (see Table 1): (i) equity, fairness, justice, and nondiscrimination; (ii) harm minimization, or nonmaleficence; (iii) transparency and accountability, i.e., no secret vaccine allocation plan will or should be trusted, and someone should be prepared to take public responsibility for decisions; (iv) need to mitigate health disparities and inequities; and (v) insistence on evidence-based decisions. Third, health authorities should collaborate on a robust effort to gather real-world effectiveness data through “post-market” surveillance.

In addition, this document addresses:

1. Infection transmissibility
2. Types of vaccine
3. Risk factors for the various types
4. Infection mortality criteria
5. Demographic implications

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- McClung N et al. The Advisory Committee on Immunization Practices’ Ethical Principles for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020. *MMWR* 2020;69, November 23, 2020. Available at <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6947e3-H.pdf>.
 - Oliver S. EtR Framework: Public Health Problem, Resource Use and Equity Domains. Available at <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-11/COVID-02-Oliver.pdf>

⁴ Milken Institute. COVID-19 Treatment and Vaccine Tracker. Milken Institute. 2020. Available at: <https://covid-19tracker.milkeninstitute.org/>.

Any good-faith effort to provide fair and objective guidance in the allocation of a valuable scarce resource relies on the good will of institutions, communities and countries. Alas, COVID-19 has emerged as a political issue. It should be uncontroversial – indeed, ought not need to be said – but any effort to place political advantage over public safety is patently, obviously, and dispiritingly wrong. The 2020 COVID crisis will be a sad addition to future collections of case studies on ethics in epidemiology and public health.⁵

1.1 Transparency

Governments, businesses, and institutions need to make clear and to share their vaccine allocation data and analyses. Because there is not yet enough vaccine for everyone, those who endure a delay in vaccination are owed an explanation. Such an explanation becomes a justification when decision makers publicly share the data they had and the reasons they used in determining which groups should receive priority.

This is an uncontroversial position. There is no good reason to oppose it. It is emphasized here because the State of Florida has been strikingly occult in communicating allocation decisions and policies. This has engendered doubt and distrust. “Frontline workers” is not a precise term, and many institutions and communities have struggled, in ignorance, to develop vaccination policies.⁶ Moreover, it is unknown how some hospitals receiving the first doses were chosen, and why. Unfortunately, the state’s ethics community – including government entities – has not been contacted or consulted.

Transparency is not a courtesy, a nicety, or a gesture. It is a bold-faced moral obligation. The importance of transparency will be signaled again later in this document.

2. History and Precedent

Various strains of the influenza A virus have caused four major pandemics in the past century:⁷ in 1918 (H1N1), 1957-1958 (H2N2), 1968 (H3N2), and 2009 (H1N1). The U.S. Centers for Disease Control and Prevention in 2008 established “General Principles and Interim Guidance on Pandemic Vaccination,” which was updated in 2018 as “Allocating and Targeting Pandemic

⁵ Cf. Coughlin S, Soskolne C, Goodman KW. *Case Studies in Public Health Ethics*. Washington, DC: American Public Health Association, 1997. Translated into Mandarin by Xiao Wei as 公共健康伦理学案例研究, Beijing: People’s Publishing House 2008 (ISBN 978-7-01-006666-0, R1-05/K584); and Barrett DH, Ortmann LW, Dawson A, Saenz C, Reis A, Bolan G, eds. *Public Health Ethics: Cases Spanning the Globe*. New York: Springer, 2016. Available at <https://link.springer.com/book/10.1007/978-3-319-23847-0>.

⁶ Washington W. Coronavirus: Doctors outside hospitals unclear when they will get vaccines. Palm Beach Post, December 15, 2020. Available at <https://www.palmbeachpost.com/story/news/2020/12/14/doctors-florida-dont-know-who-get-vaccine-first/6540594002/>.

⁷ Centers for Disease Control and Prevention. Past Pandemics. Centers for Disease Control and Prevention. 2018. Available at: <https://www.cdc.gov/flu/pandemic-resources/basics/past-pandemics.html>.

Influenza Vaccine During an Influenza Pandemic.”⁸ These guidelines identified four concepts to attend to:

Guidance Framework At-A-Glance

Categories – Pandemic vaccination population groups are clustered into four broad categories (homeland and national security, health care and community support services, other critical infra-structure, and the general population). These four categories together cover the entire population.

Population Groups – People targeted for vaccination defined by occupation, age group, or risk level.

Tiers – Across categories, vaccine will be allocated and administered according to tiers where all groups designated for vaccination within a tier have equal priority for vaccination. Groups within tiers vary depending on pandemic severity.

Critical Workforce – Workers with critical skills, experience, certification or licensure status whose absence would create severe bottlenecks in or the collapse of critical functions.⁹

The first tier included infants and toddlers, pregnant women, emergency services and health care workers, and deployed military personnel, and comprised 24 million people.¹⁰ The first major H1N1 vaccine shipment, which occurred on December 11, 2009, consisted of 76 million doses.¹¹ All individuals with a first-tier designation were covered. However, the second recipient tier, which included school-aged children, all adults aged 18 and older, and key government personnel, totaled more than 150 million people.¹² There was not enough vaccine to cover everyone in this tier.

For the 2009 Pandemic, groups that demonstrated the highest rate of infection or transmission and the highest rate of complications or mortality were favored after the first tier of individuals was covered. This strategy was developed by determining the stage of the pandemic when vaccine distribution occurred.¹³ Ultimately, the adoption of these criteria and eventual allocation rules were the best way to reduce the impact of the shortage. The CDC’s Advisory Committee on Immunization Practices (ACIP) produced national recommendations, but “state and local health departments were left to develop and implement their own distribution plans,

⁸ Centers for Disease Control and Prevention. Allocating and Targeting Pandemic Influenza Vaccine During an Influenza Pandemic. Centers for Disease Control and Prevention. 2018. Available at: <https://www.cdc.gov/flu/pandemic-resources/pdf/2018-Influenza-Guidance.pdf>.

⁹ Ibid., p. 7.

¹⁰ Ibid., p. 17-20.

¹¹ Centers for Disease Control and Prevention. 2009 H1N1 Vaccine Doses Allocated, Ordered, and Shipped by Project Area. Centers for Disease Control and Prevention. 2010. Available at: <https://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>.

¹² Ibid., p. 9.

¹³ Matrajt L, Longini IM. Optimizing Vaccine Allocation at Different Points in Time during an Epidemic. *PLoS ONE*. 2010;5(11). doi: [10.1371/journal.pone.0013767](https://doi.org/10.1371/journal.pone.0013767).

with some states choosing to closely follow ACIP's recommendations for priority groups and others choosing to adapt them."¹⁴ This engendered conflict and confusion. In some jurisdictions, this was managed with the development of a nimble vaccine management system.

It is not yet known what federal or state guidance will be provided for COVID-19 vaccine allocation, or how well any such guidance will apply at the local or institutional levels.

These guidelines and points to consider are intended to apply to general pediatric, adult, and geriatric populations, and further to individuals who have tested negative for COVID-19 and who are not showing symptoms.

One key consideration is how to ensure adequate coverage in a population with a prominent anti-vaccination movement. Recent estimates suggest that only 49% of Americans plan to receive a COVID-19 vaccine,¹⁵ and that mandatory vaccination requirements may be necessary for their effectiveness. Evidence-based practices, in conjunction with generally uncontroversial duties to contribute to public health systems – systems in which individuals benefit from the contributions of others – point to the need for a mandatory vaccination requirement for those in high transmission groups. There is, indeed, more than a century of legal precedent affirming the constitutionality of mandatory vaccination, beginning with the landmark case *Jacobson v. Massachusetts* in 1905, in which the U.S. Supreme Court upheld mandatory smallpox vaccination laws on the grounds that personal or individual liberty rights were not absolute.¹⁶ This is the basis for the well-accepted view that mandatory vaccination can be simultaneously constitutionally, ethically, and politically justified. One should not avoid a mandatory vaccination policy for fear of legal challenge.

However, there is so far no compelling justification to require a COVID-19 vaccine. Too many variables remain unsolved, especially in light of revelations of political efforts to corrupt and silence government scientists and regulators. These efforts have further undermined trust in vaccination as a basic public health tool:

As with social distancing orders, we can expect that the advent of SARS-CoV-2 vaccines will spark intense clashes of feeling about what people owe to one another in the fight against the pandemic. In contrast to earlier phases of the pandemic, though, we currently

¹⁴ National Academy of Sciences, op. cit., p. 7, citing other sources.

¹⁵ Cf. Mello MM, Silverman RD, Omer SB. Ensuring Uptake of Vaccines against SARS-CoV-2. *New England Journal of Medicine*. 2020;383(14):1296–9. doi: [10.1056/NEJMp2020926](https://doi.org/10.1056/NEJMp2020926).

¹⁶ *Jacobson v. Massachusetts*, 197 U.S. 11 (1905). Justia Law. Available at: <https://supreme.justia.com/cases/federal/us/197/11/> See also

- Reiss DR, Caplan AL. Considerations in mandating a new Covid-19 vaccine in the USA for children and adults. *Journal of Law and the Biosciences*. 2020;7(1):lsaa025. doi: [10.1093/jlb/lsaa025](https://doi.org/10.1093/jlb/lsaa025).
- Fadel M. 360 Years of Measles: Limiting Liberty Now for a Healthier Future. *Journal of Legal Medicine*. 2019;39(1):1-13. doi: [10.1080/01947648.2019.1568937](https://doi.org/10.1080/01947648.2019.1568937).
- Brennan J. A libertarian case for mandatory vaccination. *Journal of Medical Ethics*. 2018;44:37-43. doi: [10.1080/01947648.2019.1568937](https://doi.org/10.1080/01947648.2019.1568937).

have some time on our side. Careful deliberation now about state vaccination policy can help ensure that we have a strategy when the breakthrough comes.¹⁷

3. Principles and Values

Previous work on vaccine allocation has identified a variety of guiding values and principles. Many overlap; no list is exhaustive. We recommend the principles listed in Table 1.¹⁸ It is essential that institutions and governments are mindful of, attend to, and make actual decisions in light of these principles and values. Failure to do so casts suspicion on the motives of allocators, undermines trust in the allocation process, and, indeed, is unlikely to produce a successful outcome. Furthermore, merely to endorse or salute these principles would be deceptive and cynical; Institutions and governments that have access to competent ethics support are more likely to avoid those shortcomings.

Core Principles for Equitable Vaccine Allocation

- | |
|--|
| <ul style="list-style-type: none">▪ Equity, fairness, justice, nondiscrimination▪ Harm minimization, or nonmaleficence▪ Transparency and accountability▪ Mitigation of health inequities and disparities▪ Evidence-based decisions |
|--|

Table 1

Nevertheless, what counts as “fair” or “transparent” or “evidence-based” will be open to debate. It is precisely such a debate that institutions and governments – especially health departments – must foster. What has become clear is that vaccine allocation will be a process, not an event, and that this process will need to be revised continuously. Recommendations such as these aim to link these ethical principles and values to evidence-based vaccine science to establish a framework to (i) inform best practices and (ii) highlight their underlying ethical reasoning.

Resource-allocation guidelines have several aims. In the current socio-political context, one key aim is to eliminate or at least minimize disparity of treatment and outcome across socioeconomic and racial groups. It is well established that COVID-19 has disproportionate transmission rates and treatment outcomes in Black and Latino patients, as well as those of lower socioeconomic status.¹⁹ Concerns about systematic racism are concerns about systematic injustice, and so any vaccine allocation plan must not worsen that injustice. If, therefore, it becomes the case that the vaccine is available too late in the pandemic and must be awarded to high-risk groups first, mechanisms to raise awareness and distribute the vaccine to disadvantaged patients must be developed in collaboration with community leaders

¹⁷ Mello MM, Silverman RD, Omer SB. Ensuring uptake of vaccines against SARS-CoV-2. *New England Journal of Medicine*. 2020;383(14):1296–9. doi: [10.1056/NEJMp2020926](https://doi.org/10.1056/NEJMp2020926).

¹⁸ Moodley K, Hardie K, Selgelid MJ, Waldman RJ, Strebel P, Rees H, et al. Ethical considerations for vaccination programmes in acute humanitarian emergencies. *Bulletin of the World Health Organization*. 2013;91(4):290–7. doi: [10.2471/BLT.12.113480](https://doi.org/10.2471/BLT.12.113480).

¹⁹ DeJong C, Chen AH, Lo B. An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. *JAMA*. 2020;323(23):2367–8. doi: [10.1001/jama.2020.8914](https://doi.org/10.1001/jama.2020.8914).

to produce an equitable distribution scheme. Transparency and accountability in all circumstances are essential to ensure that vaccines are fairly distributed.²⁰

Had the United States begun pandemic lockdowns earlier and prevented transmission more effectively, this document would be focused on saving as many lives as possible and minimizing the duration of the pandemic. As outlined in the next section, if vaccines were distributed early enough – it may already be too late for that – it is preferable to prioritize essential workers aged 18-64 who are most likely to transmit the virus.²¹ Ensuring their safety is fair in part because they comprise a variety of races, religions, ethnicities, and socioeconomic backgrounds. As well, they are in positions and situations more likely to transmit the virus.

In addition, volunteers for randomized clinical vaccine trials should be given priority to recognize their contribution to the scientific process and acknowledge that they accepted a variety of risks to make that contribution.

It ought not be controversial to emphasize that, as a global pandemic, COVID-19 should enjoy a global response. That is, there is nothing that could possibly privilege the lives in one country over those in another. Although there is likely to emerge no global requirement to share vaccines equitably, it remains the case that there ought to be. In such a world, a safe and effective vaccine would save more lives than otherwise. Though we have no illusions that universal morality and international collaboration will be able to accomplish such a thing, it remains worth articulating in response to the suggestion by some governments that they explicitly intend to privilege their compatriots to the detriment of others. “Vaccine nationalism” as exemplified by the United States, Russia, and China will find no support under any system of morality.^{22,23,24}

4. Rationing and Allocation

Even putting aside the idea of global cooperation, getting this right will be difficult. Efforts to marshal scientific facts and apply ethical values is complicated by uncertainty. The National Academies of Sciences, Engineering, and Medicine Framework makes clear that

²⁰ Bollyky TJ, Gostin LO, Hamburg MA. The equitable distribution of COVID-19 therapeutics and vaccines. *JAMA*. 2020;323(24):2462–3. doi: [10.1001/jama.2020.6641](https://doi.org/10.1001/jama.2020.6641).

²¹ Longini IM Jr, Halloran ME. Strategy for distribution of influenza vaccine to high-risk groups and children. *American Journal of Epidemiology*. 2005;161(4):303–6. doi: [10.1093/aje/kwi053](https://doi.org/10.1093/aje/kwi053).

²² Branswell H. 64 high-income nations join effort to expand global access to Covid-19 vaccines, but U.S. and China do not. *STAT*. 2020. Available at: https://www.statnews.com/2020/09/21/64-high-income-nations-join-effort-to-expand-global-access-to-covid-19-vaccines-but-u-s-and-china-do-not/?utm_campaign=rss.

²³ World Health Organization. Fair allocation mechanism for COVID-19 vaccines through the COVAX Facility. World Health Organization. 2020. Available at: <https://www.who.int/publications/m/item/fair-allocation-mechanism-for-covid-19-vaccines-through-the-covax-facility>.

²⁴ Kupferschmidt K. Despite obstacles, WHO unveils plan to distribute vaccine. *Science*. 2020;369:1553. doi: [10.1126/science.369.6511.1553](https://doi.org/10.1126/science.369.6511.1553).

... decisions about COVID-19 vaccine allocation must be made under conditions of uncertainty. These unknowns include the safety and efficacy of the vaccines in specific populations (such as children, pregnant women, older adults, and individuals previously infected with COVID-19); the effectiveness of vaccines in tandem with existing preventive measures; public confidence in the vaccine; the possibility of ultra-cold storage requirements for the vaccine; the pharmacovigilance evidence; and many other unknowns.

Such unknowns require the framework to be adaptable to a variety of circumstances, including the state of the pandemic when a vaccine becomes available. Designing the framework to be adaptable to a range of possible circumstances means that the committee must consider how the framework would operate ethically and effectively in a range of plausible scenarios. Planning is crucial, but a rigid framework is unlikely to match the specific circumstances that actually emerge, and will likely change depending on the goal of the COVID-19 vaccination program, the state of the pandemic, the state of the science, and the extent to which people are engaging in social distancing and other preventive measures.

4.1 The Allocation Team

Precedent commends the creation and empowerment of multi-disciplinary teams to assess evidence, supplies, and values in allocating limited resources.^{25,26}

Such teams have the responsibility and authority to make allocation decisions. They must have adequate information about the availability and quantity of the thing to allocate, the population to be served, the need across that population, and, ideally, the likelihood of any of these criteria to change. Vaccine allocation teams will need to depend on each other in a hierarchy shaped by decisions made at the national, state, and county levels. Figure 1 represents a possible structure for relationships between (and

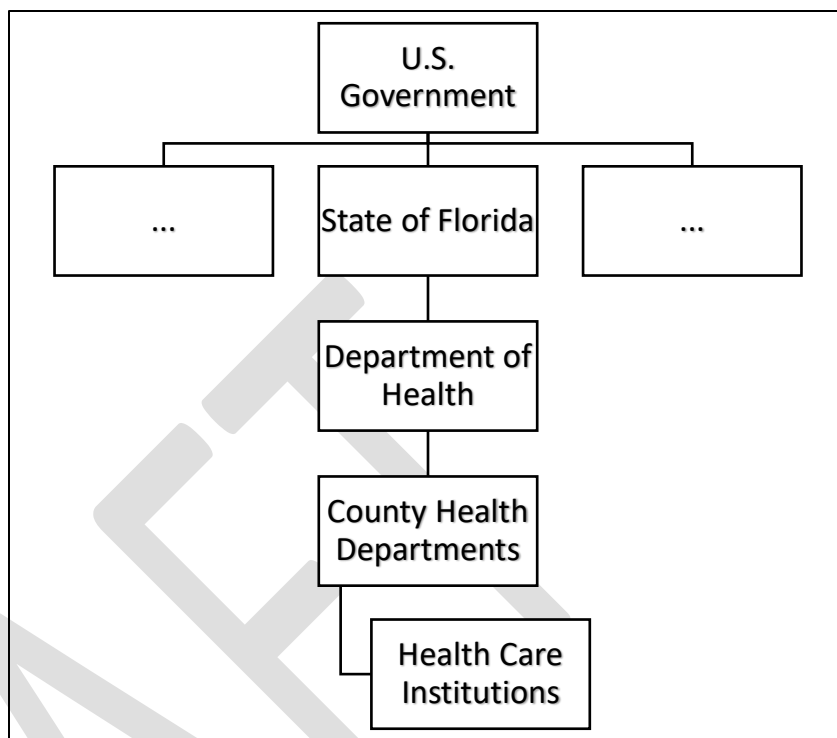


Figure 1

perhaps among) vaccine allocation teams. It is recommended that every entity represented in Figure 1 have a Vaccine Allocation Team.

It is necessary to assume that each unit under the level of “U.S. Government” will be dependent on those above it. It might be the case that any unit starting at the level of “Institutions” will be obliged to one degree or another to adopt guidance from the entity above it. Indeed, this document is motivated in part by the fact that neither the U.S. Government nor the State of Florida has provided the kind of guidance or support necessary for the ethical distribution and use of scarce resources. Neither government has, for instance, made official use of available public health ethics expertise to guide ventilator triage, rationing of therapeutics, or, so far, vaccines.

Vaccine allocation teams will therefore have related but different remits and constituents. They will need to apply guidelines – these or others – if they seek ethical vaccine allocation. For instance, decisions about the number of vaccines to distribute to individual counties will likely be made in the state capital; decisions about the number of vaccines to distribute to individual institutions might be made by county health departments. This means that the scope or magnitude of decisions about allocations are likely to vary at each level, and by each institution.

²⁵ Florida Bioethics Network. Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies. Available at: <https://fbn.miami.edu/assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf>.

²⁶ DeJong C, Chen AH, Lo B. An ethical framework for allocating scarce inpatient medications for COVID-19 in the US. *JAMA*. 2020;323(23):2367–8. doi: [10.1001/jama.2020.8914](https://doi.org/10.1001/jama.2020.8914).

Efforts to obtain ventilators and remdesivir and other therapeutics, for instance, revealed a variety of stratagems, negotiations, and deals between and among institutions, manufacturers, and governments. To allow such maneuvering to influence, let alone guide, vaccine distribution would engender suspicion and mistrust and gravely undermine the goals of achieving widespread COVID-19 immunity. For this reason, transparency will be essential.

Vaccine allocation teams should draw members from those groups with adequate and appropriate expertise. This will include, at a minimum, institutional or organizational leadership, knowledge of infectious disease or immunology, and competence in communication; community members should be included when possible. As available, members should have competence or expertise in epidemiology or public health and bioethics. Such human resources will vary by location, jurisdiction, and institution.

Regarding community members: Teams should consider having several “community members,” that is, people unaffiliated with any government or any institution making allocation decisions. Members of racial and ethnic minorities and the disability community are especially commended. Consideration should also be given to clergy. Thus,

- Leadership
- Infectious disease/immunology
- Communication
- Ethics
- Epidemiology/public health
- Community
- Clergy

Allocation teams should meet regularly and conduct ongoing process reviews. These reviews should aim to ensure the aptness of their processes given changing circumstances, facts, or information (e.g., changes in vaccine availability). Special regard should be given to any patterns or trends that might signal (i) ethical gaps, (ii) inappropriate application of evidence, or (iii) any bias against racial, ethnic, or disability communities.

4.2 Allocation Criteria and Variables

Although there are different schools of thought regarding management of limited quantities of vaccine, any successful distribution and allocation plan must address three key questions: With not enough vaccine to cover all who want to be vaccinated, how much of the supply should be allocated to high-priority groups? Second, how should membership in the groups be determined? Third, how much of the vaccine, if any, should be held back for future use?

One simple solution is First Come First Serve (FCFS), which entails that the vaccine is given to all comers as they arrive. Yet global implementation of First Come First Serve is not an adequate solution, as it discriminates against those with fewer resources in attaining vaccines and does not produce optimal immunity. However, the predominant reserve schemes can be

classified into three approaches: Partitioned Allocation (PA), Standard Nesting (SN), and Theft Nesting (TN).²⁷ Generally,

1. In PA, the high priority group consumes only from the reserved quantity of vaccine, eliminating competition between classes. This is not recommended as it is not a dynamic enough approach to maximize the benefits of broad vaccination.
2. Under SN, the initial reserve is for high priority groups, and once this is used up, high priority groups compete with lower priority groups in an FCFS scheme for remaining vaccine. If a vaccine is administered earlier in the pandemic, and the purpose is to protect groups that are not considered high risk or susceptible, then SN is preferred.
3. In TN, one begins with an agnostic and unreserved vaccine inventory that is administered FCFS. Once this resource is exhausted, remaining vaccines are administered exclusively to high priority groups; requests from low priority groups are rejected. In case a vaccine is administered late in the pandemic, and if the overarching purpose is to reduce mortality in susceptible populations, then TN is the optimal allocation policy.

These approaches were derived for previous influenza pandemics, in which guidance documents identified priority groups differently than in these guidelines. Nevertheless – and underscoring the need for nimbleness and flexibility – a model such as this can support institutions and health departments that need to identify high- and low-risk groups in light of information about local or community need.

The goals of vaccination are primarily two-fold: To minimize spread of the disease and to minimize severity of the disease in affected individuals.²⁸ Since there is yet no approved vaccine, the points to consider in this document will attempt to account for multiple scenarios in order to allow for maximum flexibility and utility in determining high- versus low-priority groups for allocation.

4.2.1 Types of Vaccine

The more than 200 vaccines in various stages of development comprise a wide range of types, regimens, and efficacy profiles. This means that competing varieties might become available. Types of vaccines under development include the following, all of which have various subtypes.^{29, 30}

- **Live attenuated virus** vaccines offer high efficacy and can be delivered in a single dose. These products pose a risk of transmitting the disease to or otherwise sickening the

²⁷ Samii A-B, Pibernik R, Yadav P, Vereecke A. Reservation and allocation policies for influenza vaccines. *European Journal of Operational Research*. 2012;222(3):495–507. doi: [10.1016/j.ejor.2012.05.003](https://doi.org/10.1016/j.ejor.2012.05.003).

²⁸ Cf. Office of Disease Prevention and Health Promotion. Immunization and Infectious Diseases. Available at <https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases>; and <https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases/objectives>

²⁹ Mayo Clinic. COVID-19 (coronavirus) vaccine: Get the facts. Mayo Clinic. 2020. Available at: <https://www.mayoclinic.org/coronavirus-vaccine/art-20484859>.

³⁰ Milken Institute. COVID-19 Treatment and Vaccine Tracker. Milken Institute. 2020. Available at: <https://covid-19tracker.milkeninstitute.org/>.

person being immunized. This is especially a concern in the elderly and immunocompromised.

- **Inactivated** vaccines use a killed version of the pathogen and so are safer for elders and immunocompromised people. Because they trigger a weaker immune response than live attenuated virus vaccines, they generally require additional doses and subsequent boosters to provide long-term immunity.
- **RNA-and DNA-based** products encode pathogen proteins that are not infectious but can pose autoimmunity risks; multiple doses are required.
- **Protein subunit-based** vaccines use recombinant pathogen proteins that are not infectious but which require additional adjuvants to be immunogenic; there is no guarantee of acquired immunity and multiple doses are required.
- **Non-replicating viral vectors** use a nucleic acid containing vector-encoding pathogen proteins. They are not infectious, but vector immunity might reduce vaccine effectiveness depending on the vector chosen; a single dose is required.

Three aspects regarding vaccine production and manufacture need to be considered: the number of doses required, speed of development, and scalability. The fewer the doses needed to induce immunity, the better. Fewer doses entail reduced recipient exposure to places like doctors' offices and health clinics. Dose number also indirectly correlates with vaccine production capacity: more doses mean less capacity. Furthermore, previous measles outbreaks have shown that individuals who do not complete a multi-dose vaccine regimen are at an increased risk of contracting the disease.³¹ "Regimen non-compliance" should be considered in vaccine allocation choices, at least at higher levels of decision making.

Vaccine types also have different development speed and production scalability characteristics. Rapid development and large scalability directly affect how fast and how much vaccine can be delivered to populations. Live-attenuated and non-replicating viral vector vaccines are the only kinds that require a single dose. Live-attenuated, non-replicating viral vector, and protein subunit vaccines are the most scalable. RNA, protein subunit, and non-replicating viral vector vaccines can be produced most quickly.

The success of initiatives such as the United States' Operation Warp Speed³² and Europe's Access to COVID-19 Tools (ACT) Accelerator remains to be determined. The former "aims to deliver 300 million doses of a safe, effective vaccine for COVID-19 by January 2021."³³

³¹ Weaver J. Principles for Managing Vaccine Shortages. *Pharmacy and Therapeutics*. 2002(9):456–62.

³² U.S. Department of Health and Human Services. From the Factory to the Frontlines the Operation Warp Speed Strategy for Distributing a COVID-19 Vaccine. U.S. Department of Health and Human Services. 2020. Available at: <https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf>.

³³ U.S. Department of Health and Human Services. Fact sheet: Explaining operation warp speed. US Department of Health and Human Services. 2020. Available at: <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>. The phrase "warp speed," or movement faster than the speed of light, was popularized by the "Star Trek" television series in the 1970s; it was based on the idea of a "warp drive" or a device to impel a

4.2.2 Risk Factors

Several COVID-19 risk factors have been identified for disease progression. Underlying health conditions are associated with a higher risk of severe outcomes. While these are less common among children and younger populations, the elderly, in particular, have more comorbidities,³⁴ especially cardiovascular disease, diabetes, chronic respiratory disease, hypertension, and cancer.³⁵ Diagnosis of these conditions has been associated with an increased risk of death after a COVID-19 infection. Among Florida residents, for instance, cardiovascular disease is found in 9.8% of the population.³⁶ Florida also has a comparatively high rate of diabetes, in 11.8% of the population,³⁷ and chronic obstructive pulmonary disease in 7.1%.³⁸ As of June 2020, the most common underlying comorbidities accompanying COVID-19 infections nationwide are cardiovascular disease (27.8-32%), diabetes (28.3-30%), chronic obstructive pulmonary disease (8.3-18%), and cancer (8.1%).^{39,40}

Individuals with any of these underlying conditions had a hospitalization rate 6 times higher (45.4%) than those without any conditions (7.6%). Mortality is also 12 times higher among patients with a reported underlying condition (19.5%) compared to those without such conditions (1.6%).⁴¹ The percentages of men who were hospitalized (16%), admitted to the ICU (3%), and who died (6%) were higher than those for women (12%, 2%, and 5%).⁴²

spaceship at superluminal velocities and attributed to the science fiction writer John W. Campbell in the 1930s. Most physicists regard super- or trans-luminal velocities to be impossible.

³⁴ Bhateja S. High prevalence of cardiovascular diseases among other medically compromised conditions in dental patients: A retrospective study. *Journal of Cardiovascular Disease Research*. 2012;3(2):113–6. doi: [10.4103/0975-3583.95364](https://doi.org/10.4103/0975-3583.95364).

³⁵ Stokes EK, Zambrano LD, Anderson KN, Marder EP, Raz KM, El Burai Felix S, et al. Coronavirus disease 2019 case surveillance - United States, January 22-May 30, 2020. *Morbidity and Mortality Weekly Report*. 2020;69(24):759–65. doi: [10.15585/mmwr.mm6924e2](https://doi.org/10.15585/mmwr.mm6924e2).

³⁶ Florida Behavioral Risk Factor Surveillance System. Adults who have ever been told they had pre-diabetes. FL Health Charts Community Health Assessment Resource Tool Set. 2020. Available at: <http://www.flhealthcharts.com/charts/Brfss/DataViewer.aspx?bid=0116>.

³⁷ Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Centers for Disease Control and Prevention. 2020. Available at: <https://www.cdc.gov/diabetes/data/statistics-report/index.html>.

³⁸ Florida Behavioral Risk Factor Surveillance System. Adults who have ever been told they had pre-diabetes. FL Health Charts Community Health Assessment Resource Tool Set. 2020. Available at: <http://www.flhealthcharts.com/charts/Brfss/DataViewer.aspx?bid=0116>.

³⁹ Sanyaolu A, Okorie C, Marinkovic A, Patidar R, Younis K, Desai P, et al. Comorbidity and its Impact on Patients with COVID-19. *SN Comprehensive Clinical Medicine*. 2020;1–8. doi: [10.1007/s42399-020-00363-4](https://doi.org/10.1007/s42399-020-00363-4).

⁴⁰ Zheng Z, Peng F, Xu B, Zhao J, Liu H, Peng J, et al. Risk factors of critical & mortal COVID-19 cases: A systematic literature review and meta-analysis. *Journal of Infection*. 2020;81(2):e16–25. doi: [10.1016/j.jinf.2020.04.021](https://doi.org/10.1016/j.jinf.2020.04.021).

⁴¹ Centers for Disease Control and Prevention. Certain Medical Conditions and Risk for Severe COVID-19 Illness. Centers for Disease Control and Prevention. 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>.

⁴² Stokes EK, Zambrano LD, Anderson KN, Marder EP, Raz KM, El Burai Felix S, et al. Coronavirus disease 2019 case surveillance - United States, January 22-May 30, 2020. *Morbidity and Mortality Weekly Report*. 2020;69(24):759–65. doi: [10.15585/mmwr.mm6924e2](https://doi.org/10.15585/mmwr.mm6924e2).

COVID prognosis has also been shown to be directly related to age. Death was most commonly reported among individuals older than 80 (regardless of underlying conditions), and ICU admissions were highest among people older than 60 (23%).⁴³ The Florida Behavioral Risk Factor Surveillance System examined comorbidity prevalence within three age cohorts (18-44, 45-64, and 65 and older), and confirmed the correlation, as shown in Table 2.⁴⁴ If a goal of vaccination is to protect those at greatest risk of developing complications from the virus, these data support allocation decisions to prioritize elders.

Cardiovascular Disease <ul style="list-style-type: none"> - 18-44 = 2.5% - 45-64 = 9.9% - 65 and older = 22% 	COPD <ul style="list-style-type: none"> - 18-44 = 3.4% - 45-64 = 8.2% - 65 and older = 11.9%
Diabetes <ul style="list-style-type: none"> - 18-44 = 3.4% - 45-64 = 13.4% - 65 and older = 23.5% 	Cancer <ul style="list-style-type: none"> - 18-44 = 2.0% - 45-64 = 6.8% - 65 and older = 17.6%

Table 2: Percentage of underlying conditions reported by age

Obesity is another risk factor. While the prevalence of obesity in Florida is similar to the nation (30.8%), it peaks in those 45-64 years old at 32.1%.⁴⁵ Obesity is known to be associated with increased risks of developing cardiovascular disease, diabetes, and certain cancers; with COVID-19, obesity is itself a risk factor for complications. Individuals with a body-mass index of 30 or greater have an increased risk of severe illness from COVID-19.⁴⁶

4.2.3 Florida Demographics

As noted, the prevalence of lung disease, kidney disease, hypertension, and/or heart disease are all more common in the elderly population. Though a weaker immune system, in the form of decreased T-cell function,⁴⁷ affects prognoses for elderly patients, the presence of these comorbidities is a more significant prognostic factor. As a result, it is essential to understand how Florida’s unique demographics can influence COVID-19 vaccine allocation strategies.

⁴³ Ibid., p. 760.

⁴⁴ Preliminary estimates of the prevalence of selected underlying health conditions among patients with Coronavirus Disease 2019 - United States, February 12-March 28, 2020. *Morbidity and Mortality Weekly Report*. 2020;69(13):382–6. Available at: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e2.htm>.

⁴⁵ Ibid., Florida Behavioral Risk Factor Surveillance System.

⁴⁶ Tartof SY, Qian L, Hong V, Wei R, Nadjafi RF, Fischer H, et al. Obesity and mortality among patients diagnosed with COVID-19: Results from an integrated health care organization. *Annals of Internal Medicine*. 2020;173(M20-3742):773–81. doi: [10.7326/M20-3742](https://doi.org/10.7326/M20-3742).

⁴⁷ Salam N, Rane S, Das R, Faulkner M, Gund R, Kandpal U, et al. T cell ageing: effects of age on development, survival & function. *Indian Journal of Medical Research*. 2013;138(5):595–608. Available at: <https://pubmed.ncbi.nlm.nih.gov/24434315/>.

A quarter of Florida's population is older than 60.⁴⁸ The average age is one of the highest in the nation. Individuals older than 65 are faced with the worst prognosis and the highest risk of developing COVID-19 complications. Vaccine allocation must account for age.

During the 2009 H1N1 Influenza pandemic, 0-4 year-olds and 5-24 year-olds developed the fewest complications and showed the lowest mortality, they had the highest levels of infection and transmission. Conversely, individuals older than 65 faced the second highest mortality rate, but the lowest transmission rate.^{49,50} As a result, authorities were faced with the task of prioritizing vaccine allocation to both groups, i.e., highest transmission and most complications.⁵¹

People with the highest COVID-19 transmission rate are between 25 and 64 years old.⁵² At one point during the summer of 2020, for instance, Floridians aged 25-64 comprised the fastest rising source of cases in the state.^{53, 54} The demographic with the highest rate of complications and mortality are individuals above the age of 50.⁵⁵ ICU admissions have been greatest in people with comorbidities older than 60, while in the general population, independent of comorbidities, mortality from infection has risen sharply in people above the age of 50.⁵⁶

4.3 Reducing Transmission

The ability of a virus to move between hosts is represented by an R_0 or “basic reproduction number,” which is, generally, the number of people to whom a single individual transmits the

⁴⁸ Himes CL, Kilduff L. Which U.S. States Have the Oldest Populations? Population Reference Bureau. 2019. Available at: <https://www.prb.org/which-us-states-are-the-oldest/>.

⁴⁹ Centers for Disease Control and Prevention. 2009 H1N1 Early Outbreak and Disease Characteristics. Centers for Disease Control and Prevention. 2009. Available at: <https://www.cdc.gov/h1n1flu/surveillanceqa.htm>.

⁵⁰ Centers for Disease Control and Prevention. 2009 H1N1 Flu. Centers for Disease Control and Prevention. Available at: <https://www.cdc.gov/h1n1flu/>.

⁵¹ Centers for Disease Control and Prevention. Table 1. Category, vaccination population groups, estimated number in population group, and tiers for low, moderate, and high/very high pandemic severity. Centers for Disease Control and Prevention. 2018. Available at: https://www.cdc.gov/flu/pandemic-resources/national-strategy/planning-guidance/guidance_508.html.

⁵² Harris JE. Data from the COVID-19 epidemic in Florida suggest that younger cohorts have been transmitting their infections to less socially mobile older adults. *Review of Economics of the Household*. 2020;1–19. doi: [10.1007/s11150-020-09496-w](https://doi.org/10.1007/s11150-020-09496-w).

⁵³ COVID-19 in Miami-Dade County. Miami Matters. 2020. Available at: <http://www.miamidadematters.org/indicators/index/dashboard?id=197976374030585798>.

⁵⁴ Harris JE. Data from the COVID-19 epidemic in Florida suggest that younger cohorts have been transmitting their infections to less socially mobile older adults. *Review of Economics of the Household*. 2020;1–19. doi: [10.1007/s11150-020-09496-w](https://doi.org/10.1007/s11150-020-09496-w).

⁵⁵ Garg S, Kim L, Whitaker M, O'Halloran A, Cummings C, Holstein R, et al. Hospitalization rates and characteristics of patients hospitalized with laboratory-confirmed Coronavirus disease 2019 - COVID-NET, 14 states, March 1-30, 2020. *Morbidity and Mortality Weekly Report*. 2020;69(15):458–64. Available at: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6915e3.htm>.

⁵⁶ Severe outcomes among patients with Coronavirus disease 2019 (COVID-19) - United States, February 12-March 16, 2020. *Morbidity and Mortality Weekly Report*. 2020;69(12):343–6. Available at: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6912e2.htm>.

virus. In the case of SARS-CoV-2 in Florida, the R_0 averaged 3.25 as of March 1, 2020.^{57, 58} This is significantly greater than that of H1N1 (1.4-1.6), seasonal influenza (0.9-2.1), and the 1918 influenza flu pandemic (1.4-2.8).⁵⁹ Though R_0 values dropped to 0.80 during social isolation orders imposed in April, there was a rapid rise to 1.40 in June when the order was relaxed.⁶⁰ SARS-CoV-2 demonstrates greater infectivity than those other diseases, and had a U.S. mortality rate of approximately 7.8% as of August 23, 2020, and 6.6% as of September 19, 2020,⁶¹ as compared to H1N1 (0.02%) and the 1918 flu (2.5%).⁶² This suggests that SARS-CoV-2 is more transmissible and fatal than previous pandemics. The more fatal a disease, the more likely it is to result in hospitalizations and use of critical care resources.⁶³

Which group is most likely to transmit the virus? Will this coincide with the group at highest risk of mortality? Traditionally, school-aged children are viewed as a primary mode of transmission for seasonal influenza, and children and elders are at higher risk of disease complications requiring hospitalization.⁶⁴ Vaccination for influenza reduces transmission and risk of complications, and is therefore prioritized for the young and elderly, while young adults and adults are recommended to get the vaccine to reduce transmission to at-risk subpopulations.

However, this paradigm may be flipped for COVID-19. First, and at least until school starts, children will have been home and, generally, under their parents' supervision; this prevents us from knowing the true extent of pediatric transmission.⁶⁵ Second, unlike other pandemics and the seasonal influenza, children were initially shown to be infected at lesser rates and showed fewer severe symptoms.⁶⁶ This is likely due, at least in part, to the summer holiday, but also to the relative lack of contact children had with people outside the family.⁶⁷ If the primary outcome of the vaccine is to minimize symptom severity, children will not be the highest priority group to vaccinate.

⁵⁷ Systrom K, Vladeck T. Florida Rt. Rt COVID-19. 2020. Available at: <https://rt.live/us/FL>.

⁵⁸ D'Arienzo M, Coniglio A. Assessment of the SARS-CoV-2 basic reproduction number, R_0 , based on the early phase of COVID-19 outbreak in Italy. *Biosafety and Health*. 2020;2(2):57–9. doi: [10.1016/j.bsheal.2020.03.004](https://doi.org/10.1016/j.bsheal.2020.03.004).

⁵⁹ Coburn BJ, Wagner BG, Blower S. Modeling influenza epidemics and pandemics: insights into the future of swine flu (H1N1). *BMC Med*. 2009;7(1):30. doi: [10.1186/1741-7015-7-30](https://doi.org/10.1186/1741-7015-7-30).

⁶⁰ Systrom K, Vladeck T. Florida Rt. Rt COVID-19. 2020. Available at: <https://rt.live/us/FL>.

⁶¹ Centers for Disease Control and Prevention. COVIDView: A Weekly Surveillance Summary of U.S. Covid-19 Activity. Centers for Disease Control and Prevention. 2020. Available at: <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>.

⁶² *Ibid.*, p. 1741.

⁶³ Ji Y, Ma Z, Peppelenbosch MP, Pan Q. Potential association between COVID-19 mortality and health-care resource availability. *The Lancet Global Health*. 2020;8(4):e480. doi: [10.1016/S2214-109X\(20\)30068-1](https://doi.org/10.1016/S2214-109X(20)30068-1).

⁶⁴ Longini IM Jr, Halloran ME. Strategy for distribution of influenza vaccine to high-risk groups and children. *American Journal of Epidemiology*. 2005;161(4):303–6. doi: [10.1093/aje/kwi053](https://doi.org/10.1093/aje/kwi053).

⁶⁵ Robinson J, Freire D. COVID-19 – What does a paediatrician need to know? *Paediatric Respiratory Reviews*. 2020;35:3–8. doi: [10.1016/j.prrv.2020.05.001](https://doi.org/10.1016/j.prrv.2020.05.001).

⁶⁶ Zachariah P, Johnson CL, Halabi KC, Ahn D, Sen AI, Fischer A, et al. Epidemiology, clinical features, and disease severity in patients with Coronavirus disease 2019 (COVID-19) in a children's hospital in New York City, New York. *JAMA Pediatrics*. 2020;174(10):e202430. doi: [10.1001/jamapediatrics.2020.2430](https://doi.org/10.1001/jamapediatrics.2020.2430).

⁶⁷ Li X, Xu W, Dozier M, He Y, Kirolos A, Theodoratou E, et al. The role of children in transmission of SARS-CoV-2: A rapid review. *Journal of Global Health*. 2020;10(1):011101. doi: [10.7189/jogh.10.011101](https://doi.org/10.7189/jogh.10.011101).

While the elderly have the greatest COVID-19 mortality rate, the CDC reports that the highest level of ICU admission occurs in adults aged 18-49, at 32.8%.⁶⁸ As of August 23, 2020, the median age of infection in Florida was 41.⁶⁹ Therefore, age should only be used as a criterion for vaccination if the vaccine is able to reduce symptom severity in affected individuals. The primary outcome of vaccination in such a scenario would be reduction of mortality. However, because the median age of infection is much lower than the median age of death, it is more important to prevent the transmission of COVID-19 to high-risk groups than to prevent mortality in high-risk groups.

Some jurisdictions have set criteria for re-openings and lockdowns in part based on ICU bed availability, and therefore this metric may be important in determining how to allocate vaccines.

A crucial determinant of priority groups for vaccination is the point during the pandemic when the vaccine will be available and administered. Models suggest that during the early phase of a pandemic, vaccination should be prioritized for high-transmission groups, while administration of the vaccine at the peak or after the early phase should be aimed at groups at high risk of mortality.⁷⁰ The change in R_0 value is also a factor in determining which groups to immunize. For influenza, as the value increases, there is reduced need to vaccinate children if the outcome is to minimize deaths. Conversely, vaccinating high-risk patients becomes more important as acquired immunity increases. Scheduled releases of batches of vaccine also influence who should receive doses first, and must be taken into account in deciding whether to allocate each batch to a particular group or distribute each batch equally among priority groups.⁷¹ From July through September 2020, Florida has had an R_0 value below 1.0 (0.93-0.98).⁷²

The foregoing supports the prioritization of essential workers as key to controlling the spread of the virus. Immunizing people in the supply chain for services consistently required during a lockdown or partially reopened status may be adequate to prevent the spread to at-risk populations with reduced access to vaccines or to those who cannot tolerate a live vaccine or other high-risk formulation.

4.4 Reducing Mortality in High Risk Populations

If we assume an early pandemic phase and the ability to reduce transmission to at-risk populations, then reducing mortality in such populations is a credible goal. However, the success of any such strategy will be shaped by COVID-19's effects on children and whether

⁶⁸ Centers for Disease Control and Prevention. COVID-19 Hospitalizations. Centers for Disease Control and Prevention. 2020. Available at: https://gis.cdc.gov/grasp/covidnet/COVID19_5.html.

⁶⁹ Florida Department of Health. COVID-19: Summary of Persons Monitored, Persons Tested, and Cases. Florida Department of Health. 2020. Available at: https://www.floridadisaster.org/globalassets/covid19/dailies/sept-2020/state_reports_20200903.pdf.

⁷⁰ Longini IM Jr, Halloran ME. Strategy for distribution of influenza vaccine to high-risk groups and children. *American Journal of Epidemiology*. 2005;161(4):303–6. doi: [10.1093/aje/kwi053](https://doi.org/10.1093/aje/kwi053).

⁷¹ Medlock J, Meyers LA, Galvani A. Optimizing allocation for a delayed influenza vaccination campaign. *PLoS Currents*. 2009;1:RRN1134. doi: [10.1371/currents.RRN1134](https://doi.org/10.1371/currents.RRN1134).

⁷² Systrom K, Vladeck T. Florida Rt. Rt COVID-19. 2020. Available at: <https://rt.live/us/FL>.

pediatric transmission remains stable when schools widely reopen. If transmission increases but outcomes remain good, then children can be vaccinated with priority over elderly populations and, in some cases, over the general population.

Contrarily, if children both increase transmission and are a high-risk group for hospitalization and negative prognoses, vaccination recommendations will parallel those for previous influenza pandemics in which vaccines were developed later in the pandemic phase.

A credible recommendation is to reduce mortality in high risk populations. This is shown for various vaccine types in Table 6 under the “Mortality” column.

In some of these scenarios, one’s status as an essential worker is not always a factor in vaccine access, as enough people have been infected that reducing transmission through vaccination, especially with limited quantities of vaccines, is not an effective method of reducing hospitalizations and mortality.

5. Allocation Criteria to Consider

5.1 Allocation Tiers

An equitable prioritization framework will be required when vaccine supplies are first delivered. The first batch of vaccines is estimated to cover 3-5% of individuals.⁷³ Here is represented a two-tier and sub-tier approach based on Florida census data and the rationales laid out in previous sections.

Phases of vaccine supply are directly correlated with the number of individuals designated to be in each tier and sub-tier. All preliminary vaccine supply will inevitably be regarded as Phase I. Phase II begins when vaccine supply reaches a predetermined threshold; then Tier 2 and its sub-tiers will be preferentially vaccinated. This threshold-and-supply approach will also apply to Phase III and Tier 3’s sub-tiers. Tables XX and YY are derived from Florida’s Bureau of Labor Statistics Census, Occupational Employment Statistics (OES),⁷⁴ Department of Elder Affairs,⁷⁵ and Department of Transportation.⁷⁶

⁷³ Slaoui M, Hepburn M. Developing safe and effective covid vaccines - operation warp speed’s strategy and approach. *The New England Journal of Medicine*. 2020;(NEJMp2027405). doi: [10.1056/NEJMp2027405](https://doi.org/10.1056/NEJMp2027405).

⁷⁴ Florida May 2019 OES State Occupational Employment and Wage Estimates. 2020. Available at: https://www.bls.gov/oes/current/oes_fl.htm.

⁷⁵ Profile of Older Floridians. Department of Elder Affairs. 2019. Available at: <http://elderaffairs.state.fl.us>.

⁷⁶ Florida’s Rural Areas. Office of Policy Planning Florida Department of Transportation. 2018. Available at: https://fdotwww.blob.core.windows.net/sitefinity/docs/default-source/planning/policy/ruralsupport/florida-39-s-rural-areas_final-appb.pdf?sfvrsn=ac5f9ea2_2.

Sub-Tier	Examples	Count
COVID-19 Response Workers	<ul style="list-style-type: none"> • Frontline health workers • EMS personnel • Public health workers • Vaccine supply chain personnel • Immunization teams 	1,040,000
Greatest Risk of Complications and Mortality	<ul style="list-style-type: none"> • Adults aged > 65 years • All aged individuals with identified comorbidities • Front line long-term care providers • High-risk condition HCWs 	4,133,000
Maintaining Core Social Functions	<ul style="list-style-type: none"> • Frontline public transport • Food supply • School infrastructure 	941,000

Table 3: Tier 1

Tier 1 covers 6,114,000 individuals. The sub-tiers prioritize individuals responsible for maintaining core civil and social functions (i and iii), and prevent mortality within highest risk populations (ii). Tier 1 makes up 29% of Florida’s population and documents the large number of people working in critical infrastructure jobs.

Prioritization of frontline health workers serves both goals due to their increased rates of direct exposure, their function in medical emergencies, and their role in a sustained COVID-19 response. The same rationale supports prioritizing EMS personnel, especially because of their increased exposure to individuals with unknown viral status.

The sub-tiers and examples in Tier 1 are listed in no particular order; allocation decisions should prioritize fair and equal access.

The ethical principles underlying the tiered groups reflect the need to promote the common good through inclusive public health policy, to treat people fairly and equally, to promote trust and accountability, and to promote economic wellbeing as a mechanism for ensuring the functional integrity of essential services.⁷⁷ Marginalized groups and those with lower access to health care must be prioritized for the sake of justice and to preserve their autonomy and economic stability; people in these groups are less likely to be able to work remotely or avoid

⁷⁷ National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press. doi: [10.17226/25917](https://doi.org/10.17226/25917).

use of public transportation and to encounter other factors increasing their risks of exposure and worse health outcomes.⁷⁸

Sub-Tier	Examples	Count
Broader Health Provision	<ul style="list-style-type: none"> • HCWs with direct non-COVID-19 contact • Pharmacy staff 	1,040,000
Decreased Access to Healthcare	<ul style="list-style-type: none"> • Native American reservations • Isolated rural communities 	382,000
Other Essential Services	<ul style="list-style-type: none"> • Warehouse, delivery workers • Deployed military • Police and fire personnel 	167,000
Elevated Risk of Infection	<ul style="list-style-type: none"> • Prison workers • Incarcerated individuals • Those living in shelters 	182,000

Table 4: Tier 2

Tier 2 includes 1,771,000 people and prioritizes individuals who face barriers to healthcare, including those in rural areas. Because it is more difficult for rural residents to obtain healthcare than urban or suburban individuals, the effort to prevent mortality in infected rural populations justifies their prioritization. Likewise, incarcerated and shelter-dwelling people live in high-density locations. COVID-19 is known to “superspread”⁷⁹ during any type of gathering, especially when groups of people live in close proximity.

Sub-Tier	Examples	Count
Children and young adults	<ul style="list-style-type: none"> • School-aged children • Young adults 	4,231,000
General population	<ul style="list-style-type: none"> • Florida citizens not accounted for in previous phases 	?

Table 5: Tier 3

⁷⁸ Emanuel EJ, Persad G, Kern A, Buchanan A, Fabre C, Halliday D, et al. An ethical framework for global vaccine allocation. *Science*. 2020;369(6509):1309–12. doi: [10.1126/science.abe2803](https://doi.org/10.1126/science.abe2803).

⁷⁹ Frieden TR, Lee CT. Identifying and interrupting superspreading events-implications for control of severe acute respiratory syndrome Coronavirus 2. *Emerging Infectious Diseases*. 2020;26(6):1059–66. doi: [10.3201/eid2606.200495](https://doi.org/10.3201/eid2606.200495).

Though adhering to principles of beneficence, equality, and justice might prevent more highly prioritized sub-tiers from receiving all of a supply when other Tier 1 sub-groups receive proportionally less, an objective measure is available to prevent abuse and unfair access to vaccination.

A model proposed by the World Health Organization recommends a population-dependent supply strategy. Each participating nation would initially receive a vaccine supply that covers 3% of its population. Countries will then continue to receive vaccine supply until they reach 20% coverage. In the tiered system here, Tier 1 would be vaccinated first until it reaches a 20% coverage rate. Then Tier 2 would be vaccinated up to 20% with leftover doses being used to vaccinate the remainder of Tier 1 to a 100% vaccination rate. Remaining doses would then be distributed via lottery or at random to Tier 3, while Tier 2 will receive priority until it is 100% vaccinated.^{80, 81} This is meant to ensure fairness and equal access, and to prevent unfair vaccine access by the wealthy as was seen during the 2009 Influenza Pandemic.⁸² The goal is to prevent sustained unequal access while optimizing the expected initial supply.

An important consideration is whether to give added weight to counties/cities that have higher disease burden and higher potential to spread disease. The goal of equitable vaccine distribution is counterbalanced by the principle of reducing mortality and hospitalizations. Depending on the severity of disease prevalence in a given area, the need to reduce mortality and negative health outcomes might take the highest priority and should be determined on a case-by-case basis by vaccine allocation teams. In Florida, Glades, Levy, and Hardee counties have the highest rates of prevalence of cardiovascular disease at 20.8%, 19.3%, and 19.2%, respectively. The higher burden of disease these counties face relative to other counties can justify their increased vaccine allocation. A similar trend is seen with diabetes, COPD, and cancer. Diabetes is most prevalent in Hardee, Gadsden, and Baker counties (23.6%, 23.4%, and 22.3%); COPD is seen most in Dixie, Okeechobee, and Putnam counties (16.7%, 16.2%, and 16.1%); and cancer is most prevalent in Sumter, Dixie, and Nassau counties (16.6%, 14.6%, and 14.4%).⁸³

⁸⁰ World Health Organization. More than 150 countries engaged in COVID-19 vaccine global access facility. World Health Organization. 2020. Available at: <https://www.who.int/news-room/detail/15-07-2020-more-than-150-countries-engaged-in-covid-19-vaccine-global-access-facility>.

⁸¹ Emanuel EJ, Persad G, Kern A, Buchanan A, Fabre C, Halliday D, et al. An ethical framework for global vaccine allocation. *Science*. 2020;369(6509):1309–12. doi: [10.1126/science.abe2803](https://doi.org/10.1126/science.abe2803).

⁸² Bollyky TJ, Gostin LO, Hamburg MA. The equitable distribution of COVID-19 therapeutics and vaccines. *JAMA*. 2020;323(24):2462–3. doi: [10.1001/jama.2020.6641](https://doi.org/10.1001/jama.2020.6641).

⁸³ FL Health Charts. FL Health Charts Community Health Assessment Resource Tool Set. 2020. Available at: <http://www.flhealthcharts.com/Charts/>.

APPENDIX: Balancing Health Goals and Vaccine Types

Public health interventions, including vaccination strategies, require analysis of an interconnected suite of variables. Many of the variables can be named, but few are consistently associated with accurate values or quantities, and all the numbers change. A plan made here yesterday might not work there (or even here) today. It is a paradigm case of decision-making under uncertainty. Moreover, the stakes are very, very high.

Two goals – reducing transmission and reducing mortality – must be approached by considering the different kinds of possible vaccines. In what follows, the risks and potential benefits of various vaccine types are given. Color coding of the text corresponds to the text in Table 6.

Minimizing transmissibility (column 1)

- **LIVE-ATTENUATED VACCINE:** Prioritizes the general population, healthcare workers, state-mandated essential workers, and school-aged children. This vaccine type offers high efficacy in a single dose but poses a higher risk of infectivity in the elderly and the immunocompromised; preclinical tests have produced vaccine side effects.
- **INACTIVATED VACCINE:** Prioritizes elderly people, healthcare workers, state-mandated essential workers, and those who are immunocompromised. Requires two doses followed by a booster for long-term immunity. The need for multiple doses administered on different days entails increased environmental exposure and hence the risk of infection.
- **RNA-BASED VACCINE:** Prioritizes the elderly population, healthcare workers, and state-mandated essential workers. This vaccine is safe to administer to those in an immunocompromised state who have the greatest chance of developing an active infection from a live-attenuated vaccine. However, a low autoimmunity risk may be present. This vaccine generally requires multiple doses. Although this kind of vaccine is favored for the elderly and immunocompromised, it also entails additional environment exposure and consequent infection risk.
- **PROTEIN SUBUNIT VACCINE:** Prioritizes the elderly population, healthcare workers, state-mandated essential workers, school-aged children, immunocompromised people, and those with the highest chance of developing an active infection from live-attenuated vaccines. This vaccine type requires multiple doses. There is therefore an increase in environmental exposure and infection risk in individuals receiving this vaccine.
- **NON-REPLICATING VIRAL VECTOR:** Prioritizes the elderly population, healthcare workers, state-mandated essential workers, and school-aged children. Although this vaccine requires a single dose, it still might be best for those in an immunocompromised state and those with the highest chance of developing an active infection from a live-attenuated vaccine. However, no non-replicating viral vector vaccine has ever reached the general public, and prospects for long-term immunogenicity are unclear. Individuals

receiving this vaccine type would face a minimized risk of infection because of lower environment exposure, but various viral vector options have provided varying levels of acquired immunity.⁸⁴

Minimizing Mortality (column 2)

As opposed to the goal of reducing transmissibility, that of minimizing mortality emphasizes risk factors. While school-aged children have shown they have a lower mortality risk than transmissibility potential, they should still be prioritized due to increasing evidence of autoimmune reactions. Minimizing mortality will prioritize high-exposure professionals, individuals with relevant risk factors, and a large proportion of the general population.

- Minimizing Mortality & Live-Attenuated Vaccine: favoring the general population with risk factors, healthcare workers, state-mandated essential workers, and school-aged children is implicated. Because this vaccine offers high efficacy and usually only poses a risk to the elderly and immunocompromised, a prioritization of risk factor-burdened individuals is logical.
- Minimizing Mortality & Inactivated Vaccine: favoring the general population with risk factors, the elderly population, healthcare workers, and state-mandated essential workers is implicated. This vaccine type, because of its lowered risk of infectivity and reactivity, favors administration to the elderly. Vaccination of school-aged children is favored less because of the multiple dose nature of this vaccine. Increased environment exposure will increase infectivity and transmission of the infection beyond what is currently seen because of school closures.
- Minimizing Mortality & RNA-Based Vaccine: favoring the general population with risk factors, the elderly population, healthcare workers, and state-mandated essential workers is implicated. Due to lower infectivity, immunocompromised individuals are favored. The multiple dose aspect of this vaccine disfavors school-aged children.
- Minimizing Mortality & Protein Subunit Vaccine: favoring the general population with risk factors, the elderly population, healthcare workers, state-mandated essential workers, and school-aged children is implicated. This vaccine favors those in an immunocompromised state and with the highest risk of mortality from developing an active infection. The rationale for prioritizing school-aged children is based on a lower guarantee of acquiring immunity compared to other vaccines. Children have thus far shown less adverse effects than the elderly and this unique aspect of protein subunit vaccines would have the least adverse effect in children compared to other demographics if no active immunity is acquired.
- Minimizing Mortality & Non-Replicating Viral Vector: favoring the general population with risk factors, the elderly population, healthcare workers, state-mandated essential

⁸⁴ Robert-Guroff M. Replicating and non-replicating viral vectors for vaccine development. *Current Opinion in Biotechnology*. 2007;18(6):546–56. doi: [10.1016/j.copbio.2007.10.010](https://doi.org/10.1016/j.copbio.2007.10.010).

workers, and school-aged children is implicated. The rationale for vaccinating school-aged children is based on the lower immunogenicity found with this vaccine type. The combination of a single-dose and less infectivity favors vaccination of risk factor ridden individuals and the elderly population.

Recall that deciding between minimizing transmissibility and minimizing mortality will be guided in part by pandemic phase, as ICU bed use and infection and mortality trends will help direct these decisions.

6. Data, Surveillance, and Effectiveness Analysis

Whenever a vaccine is or vaccines are made available, public health authorities must arrange to collect, share, and analyze data about effectiveness. This must be a collaborative effort and it must emulate the most effective models of post-market surveillance, that is, the kind of tracking that measures the success of a drug or device after it is made available to many people. It is already well-established that post-marketing surveillance can identify signals that were not apparent in clinical trials or tests.

Such real-world evidence should be collected and available at the local and statewide levels. It should be analyzed by competent scientists. This analysis and its public communication must not be shaped or influenced by political or ideological considerations.

The resource allocation teams described here should be able to review this data and information and, as appropriate, modify previous allocation decisions.

The entire process should enjoy comprehensive and ongoing ethics review by trusted experts.

	TRANSMISSIBILITY	MORTALITY
LIVE-ATTENUATED VACCINE	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. School-aged children (aged 5-17) 	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) w/ RISK FACTORS <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. School-aged children (aged 5-17)
INACTIVATED VACCINE	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) w/ RISK FACTORS <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities
RNA-BASED VACCINE	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) w/ RISK FACTORS <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities
PROTEIN SUBUNIT VACCINE	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 4. School-aged children (aged 5-17) 	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) w/ RISK FACTORS <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 5. School-aged children (aged 5-17)

<p style="text-align: center;">NON-REPLICATING VIRAL VECTOR</p>	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 5. School-aged children (aged 5-17) 	<ol style="list-style-type: none"> 1. Frontline healthcare workers <ol style="list-style-type: none"> a. Essential workers b. Volunteers for RCTs 2. State designated essential workers 3. General Population (18-64) w/ RISK FACTORS <ol style="list-style-type: none"> a. Prioritized pregnant women and medical comorbidities 4. Elderly Population (>65) <ol style="list-style-type: none"> a. Prioritized medical comorbidities 5. School-aged children (aged 5-17)
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Table 6

Acknowledgements

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