Ethical Allocation of Covid-19 Vaccines[1]

The COVID-19 pandemic is the worst public health crisis in a century. It has affected every life, every community, every institution on Earth. Experts widely agree that a successful COVID-19 vaccine is necessary to impede the virus' unchecked spread and to eliminate it. This document offers ethics guidelines for confronting the challenges of distributing and allocating the vaccine when supply is insufficient to meet demand. It provides 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,[2] The World Health Organization,[3] the Centers for Disease Control and Prevention,[4] and the Florida Department of Health Covid-19 Vaccination Plan (October 16, 2020).

1. Principles and Values

Previous work on vaccine allocation has identified a variety of guiding values and principles. Many overlap; no list is exhaustive. Baptist Health System has utilized the principles listed in Table 1.[5] To be sure, vaccine allocation will be a process, not an event, and this process will need to be revised continuously. These guidelines 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.

Core Principles for Equitable Vaccine Allocation
▪ Equity, fairness, justice, nondiscrimination
▪ Harm minimization, or nonmaleficence
▪ Transparency and accountability
▪ Mitigation of health inequities and disparities
▪ Evidence-based decisions

Table 1

Commented [AS1]: Our allocation team needs to identify how our health system will operationalize these priniciples in our guidelines to avoid the error of endorsing principles in name only.

[1] Based on the Florida Bioethics Network, COVID-19 VACCINE DISTRIBUTION AND ALLOCATION: ETHICS GUIDELINES AND POINTS TO CONSIDER [October 26, 2020]

[2] National Academies of Sciences, Engineering, and Medicine. 2020. *Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press. Available at https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine.

[3] World Health Organization. More than 150 countries engaged in COVID-19 vaccine global access facility. WHO, 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; accessed ___.

[4] 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.

[5] Adapted from the National Academy of Sciences, (p. 35), op. cit., which users of this document are urged to consult; and Moodley K. et al. Ethical Considerations for Vaccination Programmes in Acute Humanitarian Emergencies. *Bulletin of the World Health Organization*, vol. 91, no. 4, 2013, pp. 290–297., doi:10.2471/blt.12.113480.

2. Vaccine Allocation Team (VAT)

A System Vaccine Allocation Team (VAT) will be created for and activated during conditions of scarcity, where the supply of Covid-19 vaccines cannot meet demand, to ensure that a single approach to allocation decisions is implemented across the health system and aligns with the most current scientific data in addition to state and federal guidance. Vaccine allocation teams should draw members from those groups with adequate and appropriate expertise, including but not limited to: institutional or organizational leadership, knowledge of infectious disease or immunology, and competence in communication; community members should be included when possible; competence or expertise in epidemiology or public health and bioethics.

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

The BHS VAT will meet regularly and conduct ongoing process reviews. To this end, VAT should be provided an administrative staff member to conduct data gathering and documentation. These reviews should aim to ensure the aptness of the 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.

3. Allocation Criteria to Consider

5.1 Allocation Tiers (Please note that these are the tiers from the FBN document. We may amend as is necessary to align with the FDOH document. However, while the FDOH document does not contain a robust rationale as to WHY tiers were prioritized as they were, the FBN document provides such reasons).

An equitable prioritization framework will be required when vaccine supplies are first delivered. 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 3 and 4 are derived from Florida's Bureau of Labor Statistics Census, Occupational Employment Statistics (OES),[6] Department of Elder Affairs,[7] and Department of Transportation.[8]

Sub-Tier	Examples	Count
COVID-19 Response Workers	• Frontline health workers • EMS personnel • Public health workers • Vaccine supply chain personnel • Immunization teams	1,040,000
Greatest Risk of Complications and Mortality	• 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	• Frontline public transport • Food supply • School infrastructure	941,000

Table 3: Tier 1

Commented [AS2]: Determining the composition of groups in this sub-tier will be discussed at our next meeting set for 11/18).

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. In addition, ensuring the safety of frontline healthcare workers is fair in part because they comprise a variety of races, religions,

[6] Florida May 2019 OES State Occupational Employment and Wage Estimates. 2020. Available from: https://www.bls.gov/oes/current/oes_fl.htm
[7] Profile of Older Floridians. Department of Elder Affairs. 2019. Available from: http://elderaffairs.state.fl.us
[8] Florida's Rural Areas. Office of Policy Planning Florida Department of Transportation; 2018. Available from: https://fdotwww.blob.core.windows.net/sitefinity/docs/default-source/planning/policy/ruralsupport/florida-39-s-rural-areas_final-appb.pdf?sfvrsn=ac5f9ea2_2

ethnicities, and socioeconomic backgrounds. As well, they are in positions and situations more likely to transmit the virus.

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.[9] 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 use of public transportation and to encounter other factors increasing their risks of exposure and worse health outcomes.[10]

Sub-Tier	Examples	Count
Broader Health Provision	• HCWs with direct non-COVID-19 contact • Pharmacy staff	1,040,000
Decreased Access to Healthcare	• Native American reservations • Isolated rural communities	382,000
Other Essential Services	• Warehouse, delivery workers • Deployed military • Police and fire personnel	167,000
Elevated Risk of Infection	• 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

[9] National Academies of Sciences, Engineering, and Medicine 2020. *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. Washington, DC: The National Academies Press. https://doi.org/10.17226/25914.
[10] E. J. Emanuel *et al*., *Science* 10.1126/science.abe2803 (2020).

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"[11] during any type of gathering, especially when groups of people live in close proximity.

Sub-Tier	Examples	Count
Children and young adults	• School-aged children • Young adults	4,231,000
General population	• Florida citizens not accounted for in previous phases	?

Table 5: Tier 3

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%).[12]

Commented [AS3]: Our VAT may consider the following in terms of equitable allocatino of vaccines.

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 outcomes across socioeconomic and racial groups. Allocation guidelines should be developed in collaboration with community leaders to produce an equitable distribution scheme. Transparency and accountability in all circumstances are essential to ensure that vaccines are fairly distributed.[13]

Commented [AS4]: Another consideration in achieving equitable, fair allocation of vaccines.

4. Communication and Consultation

[11] Frieden TR, Lee CT. Identifying and interrupting superspreading events-implications for control of severe acute respiratory syndrome coronavirus 2. *Emerg Infect Dis*. 2020;26(6):1059-1066.
[12] FLHealthCHARTS Data Viewer. Available from: http://www.flhealthcharts.com/Charts/

[13] Bollyky TJ, Gostin LO, Hamburg MA. The Equitable Distribution of COVID-19 Therapeutics and Vaccines. .JAMA. 2020 May 7. doi: 10.1001/jama.2020.6641.

(Action item) Work with PR and Marketing to develop materials to use for communication with different audiences (e.g. team members, general public, etc.).

Additional Considerations

1. The institution's Ethics Committee(s) shall be available at all times for consultations. It is understood that, as per professional standards, ethics committees do not dictate or direct patient care.
2. These guidelines promote the needs of the community over the preferences of individuals. This will cause moral distress in those clinicians who, despite agreeing with this stance because of a public health emergency, are still aware of the effect it will have on individual patients' lives. Doing the right thing for public health can pose difficult challenges for the traditional clinician-patient relationship. The purpose of this document is to maximize efficient and fair use of a limited resource and to make explicit the ethical underpinnings of our vaccine allocation decisions. During this pandemic BHS must continue efforts to care for healthcare providers working under such morally distressing conditions.