

Wisconsin State Disaster Medical Advisory Committee  
Ethics Subcommittee  
DRAFT Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines

The State Disaster Medical Advisory Committee created the Ethics Subcommittee to develop and propose a statement of ethical principles for the distribution of scarce resources. Our charge included reviewing relevant resources including national and other state guidelines in order to identify and define generally agreed-upon principles to guide ethical decision making about allocating resources such as vaccines and therapeutics. This framework includes the following:

1. Ethical principles for scarce resource allocation
2. Recommendations for how the “Considerations for Allocation of Scarce Resources” guidelines apply to vaccine and therapeutics allocation
3. Recommendations for unique considerations pertaining to vaccines and therapeutics, including whether and when to give preference based on:
  - a. Disproportionate burden of COVID-19 or other health inequities
  - b. Workers instrumental to the COVID-19 response, such as health care workers
4. Procedural considerations to instill transparency, inclusivity, and trustworthiness

This framework was written to guide the work of the vaccine and therapeutics subcommittees that will determine how these resources will be allocated. It is also meant to be a resource for the public so Wisconsinites can better understand how ethical principles support difficult resource distribution decisions. This framework may also help inform hospitals, clinics and private sector entities about how resources could be distributed ethically within their own organizations.

### **1. Ethical principles for scarce resource allocation**

A public health crisis demands promotion of the health of the overall population with a focus on minimizing mortality and morbidity. With the development of potential vaccines and therapeutics for COVID-19 progressing, there is need to adopt guidance for equitable distribution once proven safe and effective.

Vaccines serve two related functions: They protect the vaccinated person against infection; and by reducing transmission they protect those not vaccinated by decreasing the number of people who can transmit disease (a concept known as herd immunity). Equitable vaccine distribution is necessary to assure the goals of vaccination are achieved. The ethical principles described below serve as guidelines for assuring equitable vaccine distribution.

#### **Equity**

Health equity is the ethical goal of eliminating health inequities, which are a specific type of barrier to living healthy lives. Health inequities are systematic differences in health outcomes, and opportunities to be healthy, that adversely affect socially excluded and/or marginalized groups. While no single policy can eliminate health inequities by itself, a policy can mitigate or avoid perpetuating health inequities. The goal of health equity is promoted when policies respond to social differences in background health risks, and to the ways in which these differences make members of different social groups more or less vulnerable to new and ongoing threats to health. Health equity calls for cooperation among

organizations and systems to mitigate the effects of power imbalances that unfairly disadvantage some to the benefit of others.

### **Fairness**

The principle of fairness requires that health care resources be allocated using criteria based only on relevant characteristics, using impartial procedures for allocation and distribution. Decisions about scarce resources should be proportional to the scale of the disaster and the amount of scarce resources available. Fairness requires transparency, consistency, accountability and protections to avoid practices that sustain unjust discrimination.

### **Safety, Efficacy and Limiting Harm**

The safety and effectiveness of a vaccine or therapeutic are of paramount importance. Safety refers to the likelihood that the medical intervention will not cause unacceptable harm. Efficacy and effectiveness refer to the likelihood that a vaccine or therapeutic provide protection or improvement from a clinical outcome. Efficacy of a new intervention is estimated through a randomized clinical trial. Effectiveness is the realized benefit once the vaccine or therapeutic is applied to a general population of recipients. The concept of limiting harm is based on the Hippocratic Oath, a code of ethics historically taken by physicians, but more broadly applied in this case to all healthcare professionals. Limiting harm in this framework refers to the notion that healthcare providers use the best medical evidence to maximize safety against the backdrop of using new, effective vaccines or therapeutics under crisis standards of care in which both urgency and scarcity of resources must be considered.

### **Unity**

Unity underlies the phrase “We’re all in this together.” Unity recognizes the mutual interdependence of all Wisconsinites and highlights common responsibilities and interests, purpose and action. When resources are scarce, there is a mutual obligation to care for one another and to prioritize the common good over individual self-interest. Unity calls for those who are most advantaged to advocate for and stand in solidarity with those who experience disadvantages due to historical injustices and unfair power imbalances.

### **Promoting the Common Good**

Promoting the public good means equitably preventing illness and death, caring for the vulnerable, and protecting societal activities, including education and activity that sustains livelihoods.

### **Reasonableness (to be revisited)**

Resource allocation decisions are to be based on science, evidence, practice, experiences, and ethical principles. The public has a basic right to be assured that health care decisions in a disaster are reasonable. Reasonableness is the quality of being believable by and acceptable to the average person, taking into account personal, social, cultural, and linguistic differences. Given misinformation about COVID-19 in news and social media and the rapid pace of vaccine and therapy development, we need reasonable efforts to ensure that decisions are made based on science and evidence, and informed by people’s experience and ethical principles.

Notes/Comments:

- *Reasonableness is the quality of being believable by the average person. What’s reasonable? Belief systems vary.*

- *Is this already being captured somewhere else? For example science, evidence, accurate info may be within Safety and Efficacy. What is unique to Reasonableness that needs to be said on its own or could this be incorporated elsewhere?*
- *Importance of including science and evidence – Reasonableness and Trustworthiness or Transparency combined?*

## **Respect for Persons**

This value states that each person is unique and is to be valued and treated as an individual prioritized on the totality of their circumstances and not just on limited demographic categories. Respect requires that everyone be considered and treated as having equal dignity, worth and value. It presupposes that no one person is intrinsically more valuable or worthy of regard than another. With limited resources, some people will receive full treatment, some will receive limited treatment and some will receive no treatment at all. Regardless of the treatment level, the individual must give informed consent for treatment and retains the right to refuse treatment. To the extent possible, an individual's choice of provider and/or place of treatment should be honored. Each person must know regardless of their choices, they will always be respected and treated with fairness. The following considerations should not play a discriminatory role in allocation decisions: race, color, national origin, gender, sex, age, religion, immigration/citizenship status, incarceration status, sexual orientation and gender identity, pre-existing physical or mental disability unrelated to the medical diagnosis or need, socioeconomic status (including the ability to pay).

- 2. Recommendations for how the “Considerations for Allocation of Scarce Resources” guidelines apply to vaccine and therapeutics allocation**
- 3. Recommendations for unique considerations pertaining to vaccines and therapeutics, including whether and when to give preference based on:**
  - **Disproportionate burden of COVID-19 or other health inequities**
  - **Workers instrumental to the COVID-19 response, such as health care workers**
- 4. Procedural considerations to instill transparency, inclusivity, and trustworthiness**
  - **Transparency.** Transparency is characterized by openness, communication and accountability. It requires acting in a such a way that others can see what actions are performed and why they are chosen. The effectiveness of transparency is dependent upon strong public engagement with all populations including those with distrust of the healthcare system; those suffering significant health disparities; and those most vulnerable in this pandemic. Openness is an honest way of talking and behaving. It leads to an outcome where people affected by decisions can access and review the processes and arguments that lead to those decisions and they can comment on and respond to them. Communication with decision makers and the public about the reality of scarce and imperfect resources and the goals of care, as well as when preferences cannot be honored, is vital. Accountability is taking ownership of the results of an action and leads to a commitment to sound medical choices, resource allocation based on ethical principles, and a recognition of inequities and shortcomings in our healthcare system that exist today.

- **Inclusivity.** Voices representative of the diversity of Wisconsinites should be partners at the table for resource allocation decisions in order to help mitigate bias and move toward a plan that is acceptable to all. These voices can elevate concerns, bring awareness to issues that might not otherwise be at the forefront of discussion, and highlight potentially unknown needs.
- **Trustworthiness.** A principle of trustworthiness involves the obligation to communicate with the public openly, clearly, accurately, and straightforwardly about the resource allocation criteria and framework, as they are being developed and deployed. The public has a basic right to be assured that resource allocation decisions in a disaster are reasonably based on science, evidence, practice, historical experiences, and ethical principles. These requirements are necessary to generate and sustain public trust in any allocation criteria and program. The allocation process must clearly articulate and explain all allocation criteria. These explanations must include the principles underlying the criteria, as grounded in widely accepted societal institutions and culture, as well as the procedures for ensuring their faithful implementation.

**List of References (include full names and links)**

Johns Hopkins

National Academies

WHA

Minnesota

WHO

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