

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

The State Disaster Medical Advisory Committee (SDMAC) created the Ethics Subcommittee to develop and propose a statement of ethical principles for the distribution of scarce resources during the COVID-19 pandemic.

Our charge included:

1. Review relevant resources including national, state, and other guidelines in order to identify and define generally agreed-upon ethical principles to provide a framework for decision-making about allocating scarce resources including vaccines and therapeutics.
2. Identify the most important procedural considerations for developing strategies to allocate scarce resources, such that the processes are transparent, inclusive, and worthy of trust.
3. Determine which principles can be applied to both vaccines and therapeutics, and which have unique considerations that must be answered specific to each.
4. Determine whether and when it may be appropriate to give preference in allocation decisions to regions or other geographic areas within Wisconsin that are disproportionately burdened by COVID-19 or other health inequalities.
5. Address whether and when there are circumstances when allocation considerations should give priority to individuals who work in fields that are instrumental to the COVID-19 response, such as health care workers.

This framework was written to guide the work of the vaccine and therapeutics subcommittees, given their charge to promote operational guidelines for how these resources will be allocated. The ethical framework 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.

Principles to guide equitable vaccine and therapeutics allocation

- **Promoting the Common Good:** Promoting the common good means equitably preventing illness and death, caring for the vulnerable, and protecting societal activities, including education and opportunities to sustain livelihoods. The overarching goal is to fairly maximize benefits and responsibly manage risks.
 - **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.
 - **Equity:** Health equity is the ethical goal of eliminating barriers to living healthy lives. Health inequities are systematic differences in health outcomes, and opportunities to be healthy, that adversely affect socially discounted 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 affect different social groups’ vulnerability 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.
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- **Respect for Persons:** 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. Regardless of the type of treatment, 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.
- **Fairness:** When resources are limited, there will not be enough for everyone to receive vaccines and therapeutics. 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 responsive to the scale of the pandemic and the amount of scarce resources available. Fairness requires transparency, consistency, accountability, and protections to avoid practices that sustain unjust discrimination. The following considerations should not be used to unjustly disadvantage individuals in allocation decisions, in no particular order: age, race, color, disability, gender, immigration/citizenship status, incarceration status, national origin, religion, sexual orientation and gender identity, and socioeconomic status, including the ability to pay.
- **Reasonableness:** The public has a basic right to be assured that health care decisions are just and sound. Resource allocation decisions are to be based on science, evidence, practice, experiences, and ethical principles, taking into account personal, social, cultural, and linguistic differences.

Procedural considerations to instill transparency, inclusivity, trustworthiness, and evidence-based allocation

- **Transparency:** Transparency is characterized by openness, communication, and accountability. It requires acting in 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 health care 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, as well as the general public, about the reality of scarce and imperfect resources, the goals of care, and when preferences cannot be honored is vital. Accountability is taking ownership of the results of an action, which leads to a commitment to sound medical choices, resource allocation based on ethical principles, and a recognition of inequities and shortcomings in our health care system that exist today.
- **Inclusivity:** Voices representative of the diversity of Wisconsinites should be represented in resource allocation decision-making 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. To maintain inclusivity, it is necessary to be culturally intelligent, utilize best practices as recommended by diversity and inclusion experts, and work with community leaders that have had success in the COVID-19 response.
- **Trustworthiness:** Trustworthiness involves the obligation to communicate with the public openly, clearly and accurately in a straightforward manner about the resource allocation criteria and framework, as they are being developed and deployed. Strategies to build trust need to be informed by cultural differences and historical injustices. The distribution decisions should be nonpartisan. 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 and the procedures for ensuring their faithful implementation, as grounded in widely accepted societal institutions and culture.

- **Evidence-based:** The allocation of the COVID-19 vaccine and therapeutics should be based on the best available, constantly changing scientific data and information on safety, efficacy, and epidemiology.

Practical applications of ethical principles, including common and unique aspects of COVID-19 therapeutics and vaccines

The ethical principles and procedural considerations mentioned above should inform and guide both the vaccine and therapeutic subcommittees as they determine operational frameworks for allocating scarce resources in Wisconsin. As decisions are being made, the principles could conflict or be in tension with one another in some situations. Through the application of this framework, the goal is to ultimately promote the overall health of Wisconsinites, which is performed through the balance of ethical principles with procedural considerations, in order to operationalize the practical aspects of resource allocation. Additionally, there are practical applications of the ethical principles that may apply to both vaccines and therapeutics or uniquely to one or the other.

Therapeutics and Vaccines:

- Assess individual risk by accounting for the compounding of multiple risk factors, along with safety and efficacy considerations, so that a person with greater overall risk and potential for benefit might be prioritized over someone with fewer risk factors and lesser benefit.
- Promote accessibility by considering factors, such as geographic location, proximity to sites of care, communal living situations, transportation, those who are uninsured/underinsured, and those without a primary care provider or medical home.
- Enhance public understanding and acceptance about vaccines and therapeutics by recognizing the importance of ongoing public educational initiatives as new information becomes available. Provide public education at a reading level that is easy to understand in multiple languages.
- Collect data to ensure that broad resource allocation decisions are well informed and evidence based.
- Consider ongoing review and revision to adjust the framework based on trends in COVID-19 transmission, therapeutic or vaccine data, and unique circumstances.
- Maintain adequate infrastructure to track vaccine and therapeutic location and availability in real time. If appropriate logistics can be maintained (for example, cold chain for vaccine), allow for redistribution based on ethical principles.

Therapeutics:

- After risk-based criteria and ethical principles are applied and there are still not enough resources for each person who meets the criteria, lotteries can be ethically appropriate strategies to use in decision-making. There may be times when a lottery needs to be weighted in order to achieve fairness and health equity.
- Access to palliative care, hospice care, or supportive care for the dying should be made available to any patient who could benefit from the scope of these services. Use of a second order therapeutic in some situations may be appropriate while waiting for another treatment to become available, depending on goals of care and therapeutic effect.

Vaccines: In agreement with the National Academies of Science, Engineering, and Medicine (NASEM), balancing these risk-based criteria is relevant for vaccine prioritization:

- Risk of severe morbidity and mortality: Individuals who have a greater probability of severe disease or death if they acquire infection.
- Risk of acquiring infection: Individuals who have higher probability of being in settings where SARS-CoV2 (COVID-19) exposure risk is high.
- Risk of transmitting disease to others: Individuals who have a higher probability of transmitting the disease to others.

- Risk of negative societal impact: Individuals who have a societal function in which the lives and livelihoods of others who depend on them directly and would be imperiled if they fell ill.

Allocation decisions to regions or other geographic areas within Wisconsin that are disproportionately burdened by COVID-19 or other health inequalities

Based on this ethical framework, it is appropriate to allocate resources to areas or regions disproportionately burdened by COVID-19 and other health inequities with the following goals:

1. Reduce the higher rates of severe COVID-19 illness and mortality being experienced by systematically disadvantaged social groups and marginalized populations.
2. Address disproportionate economic and social impacts on some population groups, especially those that are marginalized or systematically disadvantaged.

Strategies and tools to account for disadvantages that increase risk for COVID-19 should be considered. Examples include the Centers for Disease Control and Prevention's (CDC's) Social Vulnerability Index and the Area Deprivation Index.

Allocation considerations for those who work in fields that are instrumental to the COVID-19 response, such as health care workers

Federal and other state guidelines have prioritized high-risk health care workers and staff for phased allocation of COVID-19 vaccine once available. The goal is to protect those who face increased burden of COVID-19 disease in response to the pandemic, and to maintain a health care work force to serve and provide care to others. The Ethics Subcommittee agrees that it is appropriate to prioritize high-risk health care workers in a phased approach to allocation of COVID-19 vaccine. We affirm the NASEM definition of high-risk health care workers and first responders.

Federal and other state guidelines have also prioritized individuals with jobs critical to the functioning of society beyond high-risk health care workers and first responders, including food supply and service workers, K-12 teachers and staff, school bus drivers, child care providers and staff, correctional center workers, group home workers, personal care workers, and homeless shelter workers. The Ethics Subcommittee agrees that it may be appropriate to prioritize these individuals in a phased approach to allocation of COVID-19 vaccine.

Summary

This framework is grounded in our ethical principles and procedural considerations: promoting the common good, unity, equity, respect for persons, fairness, reasonableness, transparency, inclusivity, trustworthiness, and evidence-based. As emphasized by NASEM, "**Equitable allocation must be supported by equitable distribution and administration.**" We encourage subsequent subcommittees of the State Disaster Medical Advisory Committee to follow this guidance.

Selected References

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In memory of Hilary Bauman, Project Manager for the SDMAC Ethics Subcommittee, for the dedication, optimism, and passion she brought to this work.