

The SDMAC Ethics Subcommittee voted to post this document for public comment on October 1, 2020. Public comments may be submitted to DHSSDMAC@dhs.wisconsin.gov. Please include “Ethics Subcommittee” and “public comment” in the email subject line. The public comment period will close at 5:00 p.m. on Thursday, October 15, 2020.

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. Considering progress in the development of vaccines and therapeutics for COVID-19, there is need to formulate and adopt guidance for equitable distribution once they have been proven safe and effective.

Vaccines generally serve two related functions: They protect the vaccinated person against infection and/or severe disease; 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.

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 activity that sustains livelihoods.

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.

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.

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. 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.

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 responsive 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. 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, disability, socioeconomic status (including the ability to pay).

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. The 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 refers to the notion that healthcare providers and public health decision makers use the best available medical evidence to maximize safety and effectiveness in the context of new vaccines or therapeutics, recognizing that the urgency of the moment and the scarcity of resources may justify departures from customary standards of care.

Reasonableness

Resource allocation decisions are to be based on science, evidence, practice, experiences, and ethical principles. Reasonableness is the quality of being acceptable to the average person, taking into account personal, social, cultural, and linguistic differences. The public has a basic right to be assured that health care decisions in a disaster are reasonable.

- 2. Recommendations for how the “Considerations for Allocation of Scarce Resources” guidelines apply to vaccine and therapeutics allocation
 - a. Our subcommittee reviewed this document and integrated applicable components into the ethical principles and recommendations.

- 3. **Recommendations for unique considerations pertaining to vaccines and therapeutics, including whether and when to give preference based on:**
 - o **Disproportionate burden of COVID-19 or other health inequities**
 - o **Workers instrumental to the COVID-19 response, such as health care workers**

The following policy goals align with these ethical principles and are relevant for vaccine and therapeutics allocation:

- 1. Reduce 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.
- 3. Protect those who face increased risk of COVID-19 disease in order to provide essential services for the benefit of others or advance the development of COVID-19 vaccines and therapeutics.

To advance these policy goals, we recommend:

Applies to:		Recommendations
Vaccines	Therapeutics	
X	X	1. Any prioritization of systemically disadvantaged and historically marginalized individuals should consider the reality that inequities in health are likely underestimated due to system failures, which may warrant additional allocation in their favor to advance equity.
X	X	2. Remove barriers to access for those disadvantaged by health inequities, taking into account geographic location, proximity to site of care (empower pharmacists to deliver vaccines), congregate living situations, transportation, those who are uninsured/underinsured, and those without a primary care provider or medical home.

X	X	3. Educate the public about vaccines and therapeutics continuously; starting before they are available, ensuring that content is available in a language that is understandable to each individual at an appropriate reading level.
X	X	4. Build trust in culturally intelligent ways, building upon best practices utilized by diversity and inclusion experts and working with community leaders that have had success in the COVID-19 response, allowing time to establish trust.
X	X	5. Dedicate resources to ensure that the data needed to make resource allocation decisions is made available and maintained.
X	X	6. Strategies to account for disadvantages that increase risk for COVID-19 should be considered, given they can be operationalized.
X	X	7. Modeling of morbidity/mortality should be based on safety and efficacy considerations at both the individual and population level.
X	X	8. Maintain adequate infrastructure to track vaccine and therapeutic location and availability—as long as appropriate logistics can be maintained (e.g. cold chain for vaccine)—and allow for redistribution based on ethical principles if appropriate, but only after due diligence to removing barriers, educating, and building trust is met.
X	X	9. Establish an ongoing review and revision team representative of the diversity of Wisconsinites to adjust the framework based on trends in COVID-19 transmission, vaccination rates, therapeutic or vaccine data, and unique circumstances.
	X	10. Access to palliative care and hospice should be made available to any patient who could benefit from the scope of these services. Use of a therapeutic in some situations may be consistent with palliative care depending on goals of care and therapeutic effect.
	X	11. Lotteries, including weighted lotteries can be ethically appropriate strategies to advance health equity within an allocation framework after other risk-based criteria are applied and immediate need continues to outstrip available resource.

X		<p>12. People working in health care who are at high risk for COVID-19 exposure should be prioritized for vaccine allocation in order to limit the spread of COVID-19, reduce stress on the health system's ability to care for patients, and build trust with the public. The following considerations are relevant:</p> <ul style="list-style-type: none"> • High risk for exposure is defined as those with close patient contact (<6 feet) for ≥ 15 minutes, participation in aerosol generating procedures, performing COVID-19 screening and diagnostic testing, and those in contact with inpatient rooms and biohazardous materials. • Inclusion in this group should not be limited by professional license, education, or job title, but rather by exposure risk. • Data on risk of morbidity/mortality among health care sector workers should inform prioritization decisions. • Allow for local decision making based on risk level of individual job duties. • Those with lack of access to appropriate PPE should be considered for priority within this group when there is not enough vaccine available for all. • This group should be inclusive of health care sector workers in hospitals, clinics, home health, nursing homes, long-term care, rehab facilities, and other similar settings, and state, tribal, local, or territorial health department health care workers. • In no particular order, individuals in this priority group may include and are not limited to: <ul style="list-style-type: none"> ○ Emergency medical services workers, emergency department workers, intensive care unit and critical care workers, physicians, advance practice clinicians, nurses, nursing assistants, therapists, social workers, case managers, technicians, screeners, environmental services and housekeeping workers, and food service workers
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		13. Public and private safety officers (e.g. police, firefighters, health system public safety, correctional facility workers) who have had close contact (<6 feet) for ≥ 15 minutes with community members, including those in congregate living facilities and prisons, during their professional duties.
X		14. Teachers and child care workers may be prioritized for vaccines based on data related to risk of infection and community spread.
X		15. Members of the public who are prioritized for a vaccine but can safely mitigate risk of infection on a personal level (work from home, etc.) are encouraged to allow others to go first until vaccine is more widely available.
X		16. Prioritize individuals meeting multiple risk categories, building in support for local decision making to be able to identify and operationalize allocation accordingly.

The following risk-based criteria is relevant for vaccine prioritization:

- Risk of acquiring infection: Individuals have higher priority to the extent that they have a greater probability of being in settings where COVID-19 is circulating and exposure to a sufficient dose of the virus.
- Risk of severe morbidity and mortality: Individuals have higher priority to the extent that they have a greater probability of severe disease or death if they acquire infection.
- Risk of negative societal impact: Individuals have higher priority to the extent that societal function and other individuals' lives and livelihood depend on them directly and would be imperiled if they fell ill.
- Risk of transmitting disease to others: Individuals have higher priority to the extent that there is a higher probability of their transmitting the disease to others.

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.

Select References

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