WISCONSIN DEPARTMENT of HEALTH SERVICES

Ethical Framework for the Allocation of Therapeutics for COVID-19 in Wisconsin

Background

The COVID-19 pandemic has revealed the importance of developing and implementing protocols for the distribution of scarce therapeutics in possession of the state. This framework has been developed by a therapeutics allocation subcommittee of the Wisconsin State Disaster Medical Advisory Committee (SDMAC) and is based upon a foundational ethical framework already developed and adopted by the SDMAC. The Therapeutics Allocation Subcommittee consists of physicians trained in critical care, infectious disease, pediatrics, and internal medicine; hospital pharmacists; and experts in allocation frameworks and ethics.

The intention of this framework is to serve as a guide for the Department of Health Services (DHS) to readily allocate and distribute available therapeutics, avoiding unnecessary delays in treatment. For the purpose of this framework, therapeutics are defined as new or existing pharmaceutical drugs to treat COVID-19, and do not include medical interventions like ventilators.

The design of this framework is based upon the following assumptions:

- Novel therapeutics released under an Emergency Use Authorization (EUA) may not be sufficiently researched to know with certainty which patients are most likely to benefit.
- Therapeutics may be received in quantities that are unpredictable. This may result in situations of temporary scarcity.
- No single framework will address the detailed allocation requirements of every possible therapeutic drug. **A standing subcommittee of content experts from the SDMAC therapeutics committee will meet whenever a new drug is released to apply specifics of the drug to this framework for final recommendations.**

Underlying Principles to Guide Equitable Vaccine and Therapeutics Allocation

Please refer to SDMAC Ethics Subcommittee Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines for a review of underlying principles influencing this document.

Ethical Justification for Proactively Mitigating Health Disparities in COVID-19 Outcomes

COVID-19 has had a disproportionate impact on low-income communities and certain racial and ethnic minorities in the U.S. Equity calls attention to the systematic differences in health outcomes and opportunities to be healthy that adversely affect socially vulnerable and/or marginalized groups. For COVID-19, these inequities may arise from higher burdens of pre-existing comorbid disease, poor health care access, or not having the option for social distancing due to living in densely populated neighborhoods or households. There are also more economically disadvantaged individuals working essential jobs during the pandemic, and many are unable to perform job functions from the safety of their home. This puts them at greater risk of interacting with others who may transmit COVID-19. Public health interventions may be used to attempt to mitigate these disparities in COVID-19 by recognizing the structural inequities that underlie them. One way to do this is to account for a level of social vulnerability in the allocation guidelines used by the state to alleviate disease burden. The CDC's Social Vulnerability Index (SVI) is one measure that uses 15 U.S. census variables (such as poverty and crowded housing) to measure a community's resilience to stressors, including disasters like the

COVID-19 pandemic (https://www.atsdr.cdc.gov/placeandhealth/svi/at-a-glance_svi.html). SVI is preferred over other measures like the Area Deprivation Index (ADI) since it has been shown to provide greater advantage to racial and ethnic minorities than ADI in allocation simulations.[1]

Potential Approaches for DHS distribution of therapeutics in possession of the state.

These approaches show possibilities for distribution of therapeutics in possession of the state by geography, by facility, and to individual patients. These approaches are in no particular order, and may be used in conjunction with one another, or in a hybrid model, as warranted by the context and situational factors encountered in allocating a novel therapeutic to treat COVID-19.

1. **Distribution by geography**: Therapeutics in possession of the state could be distributed on a geographic basis (for example, county, region) based upon size of population, burden of disease, and/or by weighting for baseline health disparities. The geographic unit of distribution may be a county (smallest) or region (largest), with subsequent distribution decisions made by receiving party in light of ethical guidance described in this document.

   Example: Please see the "Ethical Allocation Framework for Bamlanivimab Treatment of COVID-19 in Wisconsin." This drug was allocated based on disease burden and SVI at the county level.

2. **Targeted geographical "hot spot" approach**: Therapeutics could be directed to geographic areas of the state that are most in need of relief, due to disease burden or health care system strain. This maximizes the utility of a therapeutic drug as a public health tool while also providing benefit to communities most burdened by COVID-19.

3. **Centralized geographical distribution hub**: Therapeutics in possession of the state could be allotted to a central distribution hub in each region of the state (i.e., county or group of counties). This allotment could be determined by COVID-19 case burden weighted for baseline health disparities, as described in Approach 1, above. The state should set forth a uniform lottery system for use by all health systems and providers in this scenario. The drug would be transferred from the hub to the health care provider for use by each individual. This scheme allows for a more equitable distribution of scarce medications via micro-allocation on the patient level, and works best when the number of qualifying patients is low or when the available supply is low. Difficulties include the need for appropriate lead time, considerations about drug transport and other logistical concerns related to not having therapeutics on-site.

4. **Distribution by facility**: Therapeutics could be distributed to health care facilities or systems, local public health departments, or outpatient clinics based upon disease burden in the community or within a particular institution.

5. **Distribution to individual patients**: Therapeutics could be distributed to individual patients for those meeting clinical criteria for treatment as defined by FDA authorization. Alternatively, therapeutics could be distributed to a subset of patients meeting criteria that have been identified in published research as being most likely to benefit. This scheme allows for a more equitable distribution of scarce medications via micro-allocation on the patient level, and works best when the number of qualifying patients is low or when the available supply is low. Distribution to individual patients by DHS may be impractical for large quantities of medication or if complex clinical criteria must be considered.

6. **Step-wise or tiered approach by patient risk factors and/or criteria.** A tiered approach creates multiple levels of eligibility distinguished by clinical criteria, where those prioritized higher are those most likely to benefit and most likely to have serious adverse effects from COVID-19. Tier-based inclusion and exclusion criteria can be formulated to guide prioritization in times of scarcity. Once all patients within a tier are treated, patients in the next (less stringent) tier would be considered. If there is not enough medication to treat all patients within a tier, then lottery allocation methods (random or weighted) can be used. This has been the approach already used by local health care systems in Wisconsin when supply is limited. This type of allocation differs from those above because it starts with

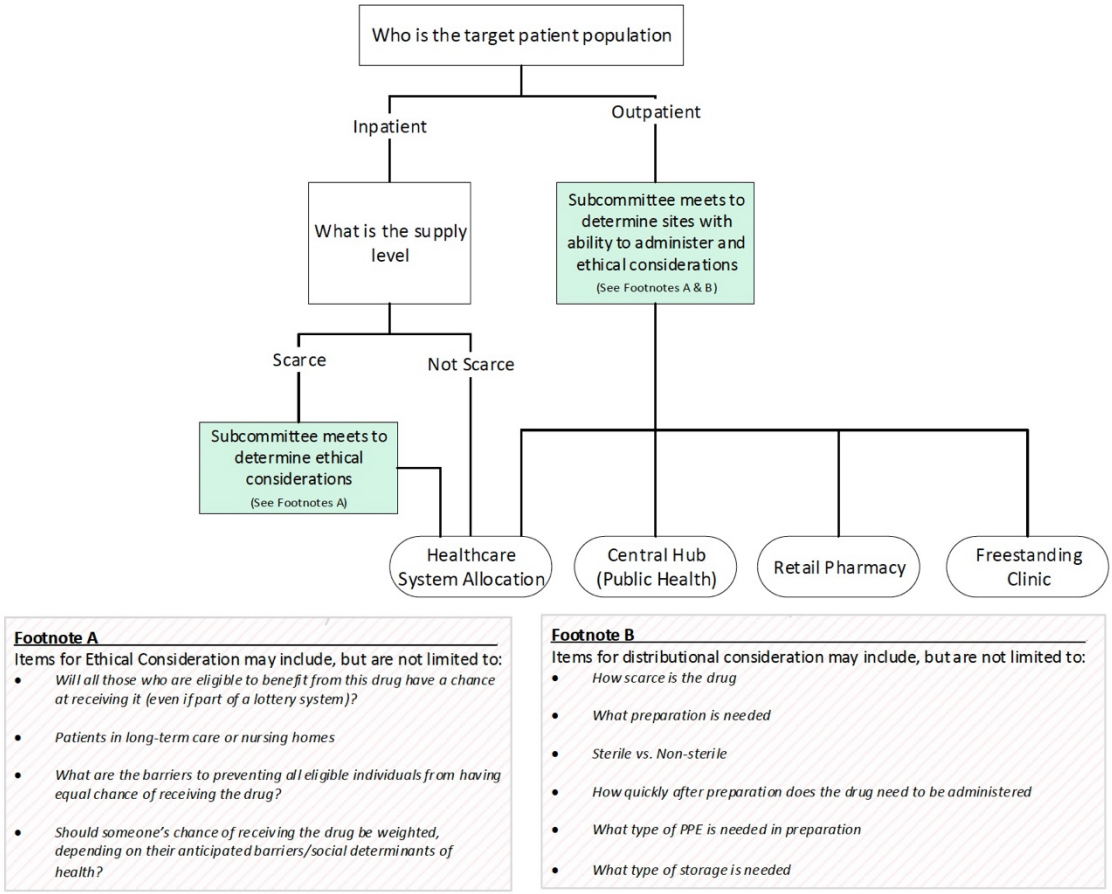
determining the prioritization at the patient level, and then determines how to best allocate the drug to that cohort of patients. This allocation could take place directly to the patient from the state, or could be provided as guidance from the state to sites of care receiving therapeutics, depending on the scarcity of the therapeutic and the criteria for use.

Generic algorithm for therapeutic distribution.

Depending on a particular drug's unique considerations, some of the above allocation schemas may be more appropriate than others. A standing subcommittee of content experts from the SDMAC therapeutics committee will meet whenever a new drug is released to apply specifics of the drug to the framework below for final recommendations on allocation and distribution.

The following flow diagram has been constructed in order to assist in determining which allocation schema may work best for a particular drug. Please refer to **Figure 1** for a flow diagram illustrating the process of consideration recommended for new therapeutics.

Figure 1. Consideration process for new therapeutics.



Detailed explanation of flow diagram branch points:

1. **Who is the target population?**
    a. Is this therapeutic indicated for inpatient (severe disease) or outpatient (mild or moderate) disease populations?
    b. Patient eligibility criteria will be outlined in the drug-specific EUA and provider fact sheet.
2. **What is the supply level?**
    a. Scarce: This refers to therapeutics for which demand from eligible patients exceeds current supply of the state.
    b. Not scarce: This refers to therapeutics for which demand and supply are equal, or there is greater supply than demand from eligible individuals.
3. **Distributional Considerations**

    A therapeutics subcommittee will meet to discuss drug-specific considerations about distribution and administration. These considerations include, but are not limited to:

    a. Drug supply.
    b. Preparation required for administration, such as sterile vs nonsterile compounding.
    c. How quickly after preparation the drug needs to be administered.
    d. Type of personal protective equipment (PPE) required for administering personnel.
    e. How the drug is stored.
4. **Ethical Considerations**

    A therapeutics subcommittee will meet to determine the ethical considerations of distributing a scarce therapeutic. The SDMAC Ethics Subcommittee Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines will be consulted. Specific considerations include, but are not limited to:

    a. Will all those who are eligible to benefit from this drug have a chance at receiving it, including patients in long-term care, nursing homes, correctional facilities, or without medical homes?
    b. What are the barriers to preventing all eligible individuals from having an equitable chance of receiving the drug?
    c. Should someone's chance of receiving the drug be weighted, depending on their anticipated barriers or social determinants of health?
5. **Allocation Framework Determination**: After the above questions have been considered, a general allocation framework of one (or more) of the types described above may be relevant. Receiving entities and quantity allocated will be determined based on the target patient population and distributional and ethical considerations.

Incorporating the SDMAC ethical framework into the allocation of therapeutics.

This document outlines some initial frameworks for the allocation of therapeutics to hospitals and health systems. Health care systems, hospitals, and other institutions receiving a supply of therapeutics are encouraged to develop a process of allocation to individual patients consistent with the ethical principles outlined in the accompanying SDMAC Ethics Subcommittee Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines. We recommend that ethics committees and crisis triage teams be involved in determining a process for allocation that is equitable, fair, and reasonable, and provide the following additional guidance.

In general, treating clinicians should not be responsible for operationalizing the allocation framework. This should be led, instead, by crisis triage officers or clinical leadership teams. The principle of fairness as outlined in the SDMAC Ethics Subcommittee Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines requires that health care resources be allocated using criteria based **only on relevant characteristics**, using impartial procedures for allocation and distribution. This means that the team making allocation decisions should be blinded to information that is not relevant. As stated in the SDMAC Ethics Subcommittee Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines, the following considerations should not be used to unjustly disadvantage individuals in allocation decisions, in no particular order: age, race, color, disability, gender, immigration or citizenship status, incarceration status, national origin, religion, sexual orientation and gender identity, socioeconomic status, and ability to pay.

Decision-makers should attend to the ways in which allocation to individuals might exacerbate existing social inequities. For example, in many contexts a first-come, first-served approach to allocation does not allow for equitable access and promotion of the common good. First come, first served refers to a model that provides the therapy to the first patients to present with the diagnosis who meet criteria until the supply is depleted. First come, first served can unfairly disadvantage those who, through no fault of their own, are unable to seek needed care quickly or spend time needed to schedule and attend an appointment to receive a therapeutic before others who have more advantages.

When a therapeutic supply is expected to be greater than demand, or when health systems face difficult logistical burdens related to patient recruitment or to the administration of a given therapy, a first-come, first-served approach might be ethically permissible. Decision-makers should be sensitive to the possibility that a low level of demand for a therapy may stem from informational or other inequities that prevent disadvantaged individuals even from inquiring about a treatment for which they are eligible. There may still be issues of equity even when supply exceeds demand, and allocation protocols should proactively aim to mitigate background barriers to health care information and access.

Allocation decision-makers must weigh the ethical appropriateness of different allocation approaches by applying ethical principles and frameworks within the context of eligibility criteria, risks and benefits, supply and demand, operational challenges, and other unique factors. In general, it is best to use drug-specific factors to determine the breadth of ethically appropriate options, as well as options that should be avoided. Such factors may reveal that certain patient groups can benefit from a given drug more so than others. In that case, a completely randomized lottery or a first-come, first-served process among all who meet EUA criteria would not align with ethical goals of maximizing benefits and minimizing risks of morbidity and mortality. As an alternative, tiers of patient groups could be developed, and a lottery could be held among individuals within a prioritized tier if there is not enough therapeutic to treat those in that particular tier. If there are no differences in capacity to benefit between different eligible patient groups, or if such capacities are clinically uncertain, then a random or weighted lottery instead of first come, first served may be the best way to equitably promote the common good.

Based upon the following SDMAC "Ethical Principles," these are some topics for **ethics committees and crisis triage teams to consider** in the development of hospital and/or health system level allocation frameworks:

1. **Common Good**
    a. Therapeutics used for prevention and early treatment may significantly reduce transmission, offering community benefit. Done well, this could contribute to economic recovery and expedite return to normal community activities and interactions.
    b. Consider and/or discuss prioritization of essential workers.
2. **Unity:** In order to provide unity among Wisconsinites, patient care responsibility for patients tested outside the hospital or health system should be considered. Health systems that participate in community

testing should include all those tested as possible recipients of allocation if they meet criteria. Plans should be made with non-affiliated testing sites to ensure those who test positive and meet criteria have a chance to receive the drug.

3. **Equity**
   a. If after risk-based criteria and ethical principles are applied, there still are not enough resources for each person who meets the criteria, lottery systems can be ethically appropriate strategies to use in decision-making. In this way, lotteries allow for each eligible patient to have an equitable chance of receiving the drug. One approach is to randomly allocate among eligible patients. Another is to weight the lottery based on relevant factors in order to advance fairness and health equity.
   b. Disadvantages in access to therapeutics due to existing social and health disparities should be identified, and steps should be taken to proactively mitigate them. Barriers include inadequate access among some individuals to technology for health information and scheduling, or location of available therapeutics in proximity to disadvantaged communitites.
4. **Evidence-Based**
   a. Allocation decisions should be based on the best available science. All sources, whether peer-reviewed or not, should be critically appraised.
   b. Allocation frameworks should be regularly updated as available evidence evolves.
5. **Respect for persons**
   a. Consider the risk versus benefit of the therapeutic for each individual patient and how to implement a robust informed consent process.
   b. Use of authorized experimental therapies requires disclosure of the investigational nature of the treatment. Medical jargon should be avoided, and translation available whenever necessary. Additionally, presentation should not bias groups of patients towards accepting or refusing treatment.
6. **Fairness**
   a. Allocation principles should be applied with transparency, accountability, and consistency. Protections to avoid backlash against those administering medications should be built in.
   b. Consider whether this therapeutic shows benefit for a particular population or cohort for whom no or few other therapeutics have shown benefit or been available.
7. **Reasonableness**
   a. Consider whether there is anything about this therapeutic in the current context of the pandemic that would make it higher or lower priority for allocation than another therapeutic needing allocation, given that allocation itself requires resources that may be limited.
   b. Consider the risk of wasted therapeutic if allocated to geographical areas or entities unable or unlikely to administer it.

For an example of a lottery-based policy that is consistent with the ethical principles underlying this document, please refer to Appendix A from the state of Pennsylvania, about halfway down the page. Note that while the Pennsylvania example includes a weighted lottery, the Ethics Subcommittee Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines provides that an unweighted lottery, as well as non-lottery allocation, can be ethically permissible in some circumstances.

References

Harald Schmidt, Utku Ünver, Michelle Williams, Parag Pathak,Tayfun Sönmez, and Lawrence Gostin. “What prioritizing worse-off minority groups for COVID-19 vaccines means quantitatively: practical, legal, and ethical implications.” SEII Discussion Paper #2020.10 October 2020.

The following are member of the **Therapeutics Allocation Subcommittee** of the SDMAC who provided valuable expertise for the creation of this framework:

Committee Members

Alyson Capp, PhD (co-chair)
Director of Ethics
Advocate Aurora Health

Sarah Sorum, PharmD (co-chair)
Executive Vice President & CEO
Pharmacy Society of Wisconsin

Dennis Brierton, Pharm D, BCPS, FASHP
System Director, Clinical Pharmacy
Advocate Aurora Health

Gina Dennik-Champion, MSN, RN, MSHA
Executive Director
Wisconsin Nursing Association

Helen Marks Dicks, JD
State Issues Advocacy Director
AARP Wisconsin

J. Paul Kelleher, PhD
Associate Professor
UW-Madison

Mohammad (Mo) Kharbat - MBA, BPharm, R.Ph., BCPS
Regional VP of Pharmacy Services
SSM Health

Elizabeth (Liz) Laubach, PharmD, BCPS
Regional Director of Pharmacy
Ascension Wisconsin

Steven R Leuthner, MD, MA
Neonatal-Perinatal Medicine and Center for Bioethics
MCW & Children's Wisconsin

Eric Marty, MD
Director of Palliative Care
Agrace

Sridevi Mohan, MPH, MA
Epidemiologist
Public Health Madison & Dane County

Carlo Nevicosi, APSW
Deputy Director
Walworth County Health & Human Services

J. Njeri Wainaina, MD, FACP
Associate Professor of Medicine and Surgery
Medical College of Wisconsin

Staff

Margaret Nolan, MD, MS
Physician-Scientist
UW-Madison

Preston Leavitt
Program Support
WI COVID-Coalition