

Model Hospital Policy for Fair Allocation of Scarce Medications to Treat COVID-19

Executive Summary

Introduction: The purpose of this document is to provide ethical guidance for the allocation of medications to treat COVID-19 in the event that need outstrips supply during the pandemic. These allocation recommendations should be implemented only if: 1) the supply of the medication is, or will soon be, insufficient to treat all patients, even after taking all appropriate steps to increase the supply; and 2) a regional authority has declared a public health emergency. This document describes 1) the creation of allocation teams to ensure consistent decision making and 2) allocation criteria for scarce medications to treat COVID-19.

Ethical Framework: This allocation framework is grounded in two public health ethical obligations: the duty to steward scarce resources to promote the public's health, and the duty to lessen the impact of social inequities on COVID-19 outcomes in disadvantaged communities. The development process included engagement with ethicists, community members, legal scholars, public health and disaster medicine experts, and diversity and inclusion experts.

Section 1. Creation of allocation teams: Patients' treating clinicians should not decide which patients should receive scarce COVID-19 medications. Instead, each hospital or health system should create an allocation team to implement the allocation framework described in section 2. The rationale for having an allocation team make allocation decisions rather than treating clinicians is to reduce bias, avoid conflicts of commitment, and minimize moral distress. Ideally, a respected clinical leader in the hospital should lead the allocation team, with assistance from the following key stakeholders and experts: infectious disease specialists, critical care and hospitalist medicine specialists, nurses, pharmacists, ethics committee members, and diversity and inclusion representatives. The allocation team should not have access to information that is not relevant to fairly applying the allocation framework, such as patients' names, age, gender, race, ethnicity, or presence of disabilities.

The allocation team should have expertise and training in implementing the allocation framework, avoiding bias, and communicating difficult news. The allocation team leader or his/her designee should collaborate with patients' treating physicians to disclose allocation decisions to patients and families.

Section 2. Allocation framework for scarce COVID-19 medications: Patients should be eligible to receive the scarce medication only if they meet the clinical eligibility criteria of peer-reviewed RCTs that demonstrate its safety and efficacy. For example, if the medication only has established efficacy for severe COVID-19 disease, the medication should be reserved for patients with severe disease. If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), these groups should receive priority.

If there is insufficient supply to treat all eligible patients, a weighted lottery or categorical reserve system should be used to fairly allocate the drug supply, as detailed in Section 2. The following groups will receive heightened priority: 1) individuals from disadvantaged areas, defined as residing at an address with an Area Deprivation Index score of 8 to 10 (range 1-10; with higher numbers meaning worse deprivation); and 2) essential workers, defined by the state's list of essential businesses that are required to continue physical operations during the pandemic. It is important to note that the category of essential workers includes not only health care workers but also lower-paid workers who may be socially and economically vulnerable, such as grocery store clerks, bus drivers, agricultural workers, and custodial workers. Individuals expected to die within a year from an end-stage condition should not be excluded from access to the medication, but should receive lower priority than individuals who do not have an end-stage condition.

Introduction & Ethical Considerations

The purpose of this document is to provide ethical guidance for the allocation of medications to treat COVID-19 in the event that need outstrips supply during the COVID-19 pandemic. The framework was designed to be broadly applicable to any medication that become available to treat COVID-19. Therefore, this document does not contain medical instructions that will be part of detailed treatment protocols for specific medications. These allocation recommendations should be implemented only if: 1) the supply of the medication is, or will soon be, insufficient to treat all patients, even after taking all appropriate steps to increase the supply; and 2) a regional authority has declared a public health emergency.

This document describes 1) the creation of allocation teams to ensure consistent decision making and 2) allocation criteria for scarce medications to treat COVID-19.

Ethical Framework: The development process for this allocation framework included the input of ethicists, community members, legal scholars, public health and disaster medicine experts, and diversity and inclusion experts. Consistent with accepted standards during public health emergencies, this allocation framework is designed to achieve the following ethical goals:

1. To safeguard the public's health by allocating scarce treatments to maximize community benefit.
2. To lessen the impact of social inequities on COVID-19 outcomes in disadvantaged communities. To ensure that no patient is refused access to treatment based on age, disability, religion, race, ethnicity, national origin, immigration status, gender, perceived quality of life, sexual orientation, or gender identity.
3. To ensure that all patients receive individualized assessments by clinicians based on the best available objective medical evidence.

Ethical Justification for allocation criteria designed to promote the public's health: An established principle of public health ethics is the importance of improving the outcomes of populations of patients.^{1,2} This orientation is distinct from clinical ethics, which generally focuses on the well-being of individual patients. To maximize community benefit, access to the scarce medication should be restricted to patients who meet the clinical eligibility criteria of peer-reviewed RCTs that demonstrate its efficacy. For example, if the medication only has established efficacy for severe COVID-19 disease, the medication should be reserved for patients with severe disease. Exclusion criteria based on research considerations, such as the lack of a surrogate decision maker or inability to speak English, should not be used as exclusion criteria for access to the drug during clinical care. If clear evidence emerges that certain clinical subgroups derive larger benefits from the treatment than others (e.g., a lower number needed to treat to save a life), these groups should receive priority.

Patients who are essential workers should be given heightened priority, not because they are intrinsically more worthy, but because of their instrumental value to save others and ensure the continuity of critical societal infrastructure. This heightened priority may also be justified by a reciprocal obligation to provide treatment to individuals who are at heightened risk in occupations needed to safeguard society during the pandemic. It is important to note that the category of essential workers includes not only health care workers but also lower-paid workers who may be socially and economically vulnerable, such as grocery store clerks, bus drivers, agricultural workers, and custodial workers. Therefore, giving essential workers heightened access to treatment may also mitigate the disproportionate impact of COVID-19 on disadvantaged communities.

Individuals expected to die within a year from an end-stage condition should not be excluded from access, but should receive lower priority than individuals who do not have a poor near-term prognosis. The rationale is that doing so will achieve greater improvements in population outcomes by prioritizing individuals with greater ability to benefit from treatment.

Ethical Justification for Steps to Mitigate Health Disparities in COVID-19 Outcomes:

Epidemiological data reveal that the burdens of COVID-19 have been unequally borne, with higher burden in economically disadvantaged groups and certain racial/ethnic minorities. For example, individuals from low-income areas are more likely to be hospitalized with COVID-19 than individuals from higher income areas.³ The death rates from COVID-19 infection are more than twice as high in very high-poverty populations compared to low-poverty populations (242 per 100,000 vs 104 per 100,000, respectively).⁴ In Pennsylvania, African Americans account for just 11% of the state's population but represent 30% of the COVID-19 deaths where the race of the patient was recorded. COVID-19 outbreaks have been reported in essential workplaces like nursing homes and food processing plants that are typically staffed by lower-income workers. These health inequities arise from multiple causes, including higher burdens of comorbid disease, poverty, poor health care access, infeasibility of social distancing due to living in densely-populated neighborhoods and households, and the need to continue to work in public-facing occupations due to economic hardship.⁵

Public health interventions are commonly used to mitigate disparate outcomes across groups within a community, especially when the disproportionate burden is borne by disadvantaged groups.^{6,7} The rationale is that a core goal of public health is to redress social injustices that make health and safety less accessible to disadvantaged groups. We show equal respect for all members of society by mitigating the negative circumstances that cause disadvantaged persons to bear the greatest burden of the pandemic.⁸ Providing heightened access to treatment for patients with severe COVID-19 who are from disadvantaged groups is one way to mitigate the unequal effects of the pandemic.

Section 1. Creation of allocation teams

Overview: Patients' treating clinicians should not make allocation decisions regarding which eligible patients should receive scarce COVID-19 medications. Instead, each hospital or health system should create an allocation team to implement the allocation framework described in section 2. This section describes the role, composition, and training of allocation teams, as well as the appeals process if allocation decisions are challenged by patients, their surrogate decision makers, or the clinicians treating the patient.

Role of the allocation team: There are two main reasons to have an allocation team make allocation decisions rather than the treating clinicians. The first reason is to avoid bias and ensure the consistent application of the allocation framework. The second reason is to prevent role conflicts and moral distress among the clinicians treating the patient. This allocation framework is grounded in public health ethics and designed to improve population outcomes. Population health goals are distinct from the ethical obligations that arise in individual doctor-patient relationships, where the physician's main obligation is to act for the benefit of his/her individual patients. These public health goals and clinical goals can conflict in individual cases. Therefore, we recommend a clear separation between the role of the treating clinicians, who should advocate for their individual patients' benefit, and the allocation team, who should enact the allocation framework that is oriented toward population health.

When making allocation decisions, the allocation team should not have access to information that is not relevant to fairly applying the allocation framework, such as patients' names, age, gender, race, ethnicity, or presence of disabilities. The allocation team leader or his/her designee should collaborate with patients' treating physicians to disclose allocation decisions to patients and families.

Composition of the allocation team: Ideally, a respected clinical leader in the hospital should lead the allocation team, with a small support team of other clinicians to ensure appropriate data collection and transparency of processes. Desirable qualities of allocation team members include strong leadership ability, effective communication and conflict resolution skills, and commitment to faithfully implement the allocation framework. In addition, there should be an oversight committee that regularly reviews the allocation process for adherence to defined procedures. The oversight committee should be composed of the following key stakeholders and experts: critical care, infections diseases, and hospitalist medicine specialists, nurses, pharmacists, ethics committee members, and diversity and inclusion representatives.

Training of the allocation team: To optimize effective functioning, the allocation should ideally be well prepared and trained in advance to implement the allocation framework by means of drills or exercises. Advanced training should address: applying the allocation framework, implicit bias, disability rights, communicating with clinicians and families about allocation decisions, and documenting allocation decisions.

Appeals process for individual triage decisions

It is possible that patients, families, or clinicians will challenge individual allocation decisions. Procedural fairness requires the availability of an appeals mechanism to resolve such disputes. Appeals based in an objection to the overall allocation framework should not be granted. Appeals should be allowed when they are based on a claim that an error was made by the allocation team in determining the characteristics of the patient relevant to the weighted lottery (i.e., whether the patient is from a disadvantaged area, is an essential worker, or has a poor near-term prognosis). The process of evaluating the appeal should include the allocation team verifying the accuracy of each determination. For example, if there is an appeal regarding the accuracy of whether the patient lives in a disadvantaged area, it would be appropriate to recalculate the patient's Area Deprivation Index score. If there is an appeal of a determination that a patient is expected to die within a year from an end-stage condition despite successful treatment of the COVID-19 infection, it may be appropriate to obtain a second medical opinion from an appropriately trained physician.

If disagreement persists, the appeal should be referred to an Appeals Review Committee that is independent of the allocation team and of the patient's care team. This committee should be made up of at least three individuals, recruited from the following groups or offices: Chief Medical Officer or designee, Chief Nursing Officer or designee, Legal Counsel, hospital Ethics Committee or Consult Service, and members of an institution's ethics faculty. Three committee members are needed for a quorum to render a decision, using a simple majority vote. The process can happen by telephone or in person, and the outcome will be promptly communicated to whomever brought the appeal.

- The allocation team should explain the grounds for the decision that was made.
- The person who requested the appeal should explain the nature of their concern.
- The appeals process must occur quickly enough that delays do not negatively impact the patient's clinical eligibility for the scarce medication.
- The decision of the Allocation Review Committee for a given hospital will be final.

SECTION 2: Allocation framework for scarce COVID-19 medications

Introduction: If there is insufficient supply to treat all eligible patients, a weighted lottery should be used to fairly allocate the drug supply. The following groups will receive heightened priority: 1) individuals from disadvantaged areas, defined as residing at an address with an Area Deprivation Index score of 8 to 10 (range 1-10; with higher numbers meaning worse deprivation); and 2) essential workers, defined by the Commonwealth of Pennsylvania list of essential businesses that are required to continue physical

operations during the pandemic. Individuals expected to die within a year from an end-stage condition should not be excluded from access, but should receive lower priority than individuals who do not have an end-stage condition.

Procedures to Conduct Weighted Lottery for Allocation of Scarce COVID-19 Medication: This section provides hospitals step-by-step instructions for how to conduct for the weighted lottery for each patient who is eligible to receive the scarce COVID-19 medication.

Preliminary steps. The following three steps should be completed at the time that a shipment of COVID-19 treatment is allocated to the hospital that is insufficient to meet the expected need.

- 1. Determine the number of available courses of the scarce COVID-19 therapy.** This information will be provided by the agency responsible for distribution of the scarce drug.
- 2. Estimate the number of eligible patients over the time period in question for which the drug is allotted.** To accomplish this, first determine the average number of patients admitted daily over the last week who met eligibility criteria for the scarce COVID-19 medication. Next, determine the number of days the supply of drugs is expected to last. This information may be provided by the agency responsible for distributing the drug.
- 3. Determine the chances for each eligible “general population” patient to receive the drug.** These chances are determined by dividing the number of available courses of scarce drug by the projected number of eligible patients. For example, if there are 25 courses of drug available and 100 patients expected to be eligible over the time period in question, the “general population” chances to receive the drug are 25 out of 100 (25%). This number will be used in step 4 below to calculate the chances for other populations.

NOTE: There may be uncertainty or changes in the number of treatment courses available, the time period that the supply of medication needs to last, or the average number of eligible patients per day. It is appropriate to recalculate the lottery chances as new information becomes available about these parameters.

Daily Steps to Allocate Scarce COVID-19 Medications

- 1. Proactively identify eligible patients with COVID-19.** Daily, hospitals should take proactive steps to identify eligible patients, rather than placing this burden solely on treating physicians, who may not be aware of the availability of the medication for their patient. This approach increases the chances that all eligible patients will be offered the opportunity to be in the lottery for the drug. There are a variety of ways to accomplish this, including using a central COVID-19 allocation team to screen each COVID-19 patient in the hospital. Another potential approach is to use EHR-based screening mechanisms to identify patients with COVID-19 who are eligible to receive the scarce therapy. The optimal approach will depend on each hospital’s resources.

2. **Confirm each COVID-19 patient's eligibility with the attending physician.** The allocation team should contact the attending physician of each patient with COVID-19 who is potentially eligible in order to confirm eligibility. This conversation should ascertain the following: 1) that the patient meets inclusion criteria to receive the scarce therapy; and 2) that the patient does not meet any exclusion criteria for the drug.
3. **Determine patient's characteristics relevant to the weighted lottery.** The allocation team should engage with the patient's attending physician to assess the three characteristics relevant to the weighted lottery:
 - a. **Is the patient from a disadvantaged community?** The allocation team should determine whether the patient resides in a disadvantaged community, defined as their residential address being in an area with score of 8, 9, or 10 on the Area Deprivation Index. This can be determined by entering the patient's address in the following website: <https://www.neighborhoodatlas.medicine.wisc.edu/> (under the "mapping" tab).
 - b. **Is the patient an essential worker?** In conjunction with the patient's attending physician, the allocation should determine whether the patient meets the state's definition of an essential worker, as specified in this document: <https://www.scribd.com/document/452553026/UPDATED-8-45pm-May-11-2020-Industry-Operation-Guidance>.
 - c. **Is the patient expected to die within a year from a chronic, end-stage condition?** In conjunction with the patient's attending physician, the allocation should determine whether the patient is likely to die within a year from underlying end-stage condition(s) despite successful treatment of the COVID-19 infection. The objective medical evidence supporting this determination should be documented. If needed, specialist consultation should be sought (e.g. oncology, geriatrics, palliative care) to ensure the prognostication is an objective medical determination.
4. **Conduct the lottery for each eligible patient.**
 - a. **The first step is to determine the lottery threshold for each eligible patient.** Table 1 contains a summary of the adjusted chances for each patient group, which are based on the chances of a "general community" member, with adjustments for priority considerations. Table 2 provides an example of this when there are only enough courses of treatment to treat 25 out of 100 (i.e., 0.25) of general community members.

Table 1. Weighted chances to receive treatment for each patient group

Group	Chances to receive treatment
General community chances	Number of available treatment courses/ Number of eligible patients in the determined time period
Disadvantaged community member	$(1 + 0.25) \times$ (general community chances)
Essential worker	$(1 + 0.25) \times$ (general community chances)
Death likely within 1 year	$(1 - 0.5) \times$ (general community chances)
Disadvantaged community member + Essential worker	$(1 + 0.25 + 0.25) \times$ (general community chances)
Disadvantaged community member + death likely within 1 year	$(1 + 0.25 - 0.5) \times$ (general community chances)
Essential worker + death likely within 1 year	$(1 + 0.25 - 0.5) \times$ (general community chances)

Table 2. Example when the chances for treatment for the general community are 25 out of 100

Group- Individuals who are...	Chances to receive treatment	
General community members	0.25	(25 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10	$1.25 \times 0.25 = 0.31$	(31 out of 100)
Essential workers	$1.25 \times 0.25 = 0.31$	(31 out of 100)
Expected to die within a year from an end-stage condition	$0.5 \times 0.25 = 0.13$	(13 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10 AND are Essential workers	$1.5 \times 0.25 = 0.38$	(38 out of 100)
From an area with Area Deprivation Index score of 8,9, or 10 AND Expected to die within a year from an end-stage condition	$0.75 \times 0.25 = 0.19$	(19 out of 100)
Essential worker AND Expected to die within a year from an end-stage condition	$0.75 \times 0.25 = 0.19$	(19 out of 100)

- b. The second step is to randomly select a lottery number for each eligible patient.** This can be done with a random number generator such as found at random.org; the range of the lottery should be set to “1 to 100”. The drawing of each patient’s lottery number should be witnessed by two individuals and recorded. Each patient is entered into the lottery only once, not every day that they are eligible to receive the scarce COVID-19 medication.
 - c. Determine whether each patient’s lottery number is within the range to offer the scarce COVID-19 therapy.** For example, if the lottery chances for the patient is 31 out of 100 and the patient’s randomly drawn lottery number is ≤ 31 , she should be offered the scarce COVID-19 therapy. If her lottery number is >31 , then she should not be offered the scarce COVID-19 therapy.
- 5. Inform the patient’s attending physician of the lottery result.** Immediately after the weighted lottery is conducted, the allocation team should contact the patient’s attending physician to inform him/her of the lottery results (i.e., whether the patient will be offered the scarce COVID-19 therapy). The treating team or the allocation team should also inform the patient or their surrogate about the lottery result.
- 6. If patient is to receive the drug, contact the pharmacy to provide the patient-specific medication order and authorize release of drug.** Facilities may have different ways to order the medication, because the drug may not be made readily available to order by all prescribers.
- 7. Documentation:** For each eligible patient, the allocation team should document that each of the steps above was performed. Two members of the allocation team should witness and attest to the correct conduct of the lottery, and should record each patient’s lottery number, as well as each patient’s lottery threshold to receive the scarce COVID-19 therapy.

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