

**Managing Shortages of Therapeutics in Hospitals**  
**Florida Bioethics Network Guidelines**  
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**Introduction**

The COVID-19 public health emergency has made clear that many hospitals and other institutions in Florida and elsewhere at times have insufficient drugs and other therapeutics to treat their patients. The Florida Bioethics Network (FBN) has prepared this guidance document to offer recommendations and offer points to consider for healthcare institutions trying to manage drug and therapeutics shortages. This document provides neither medical nor legal advice. It was approved by the FBN Board of Advisors in November 2020.

This is a companion to the FBN’s “Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies,”<sup>1</sup> which addresses ventilator allocation and related issues.

Managing supply shortages poses significant ethical challenges. Hospitals must have clear, ethically defensible, and transparent allocation plans and policies in place to meet these challenges. Indeed, such plans and policies should be in place before shortage-induced allocation problems arise. This will support decisions grounded in ethics and evidence. Although plans will differ from institution to institution, the values and ideals of each institution – we presume these to be shared, inter-institutional values – ought to be embedded in a framework to guide resource allocation. These values include nondiscrimination and inclusivity, require a commitment to dignity and respect, and signal the importance of evidence over ideology. The FBN recommends that hospitals and other healthcare institutions consider the following values, principles, and practices in developing or adopting allocation plans and policies.

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<sup>1</sup> Available at [https://fbn.miami.edu/\\_assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf](https://fbn.miami.edu/_assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf).

## 1. Allocation plans/policies should be based on the best available evidence.

**Track scientific research.** The underpinnings of allocation policies must be clear and transparent and identify areas in which there are gaps in scientific knowledge. Biomedical knowledge can be volatile; this requires regular re-evaluation. Changes in the evidence base have been shown to affect drug dosing and efficacy, the utility of additional synergistic treatments, or new treatments altogether. All must be continuously reassessed and revised.

**Determine policy thresholds.** Hospitals should have an explicit mechanism for identifying and selecting “triggers” to activate an allocation policy. These triggers should be based on the evidence just noted, and assessed in light of local availability and expertise, and supply chain considerations. New treatments are constantly being developed and tried; the best generally emerge from successful phase III randomized clinical studies. In the setting of a public health emergency that has overwhelmed existing medical resources, unproven therapies may receive publicity and create public demand which cannot be reined in with scientific resolve. Even clinicians may seek to use, if not insist on using, unproven therapeutics. This can divert attention from treatments which have documented benefit and from other patients receiving care for conditions unrelated to the public health emergency.

**Be transparent.** Hospitals should establish and implement a publicly disclosed and transparent process for determining that an emergency has necessitated a special process to fairly and justly allocate scarce resources. Some hospitals in Florida have successfully established resource allocation or crisis standards teams to ensure an apt process. Participants on such teams should when possible include clinicians with appropriate expertise, institutional leaders, lay community representatives, and ethics committee members. Such teams should have diverse membership. The teams must monitor empirical and ethical guidance from state, regional, and national experts.

## 2. Allocation policy should be based on clearly articulated ethical principles.<sup>2</sup>

**Utility.** When there are inadequate resources in a public health emergency, hospitals should publicly announce that they are shifting to an “emergency” ethical framework in which triage is used to maximize the greatest possible good for the greatest number of individuals.

- To effect such a maximization requires an analysis of consequences, including unintended consequences.

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<sup>2</sup> The principles articulated here rely extensively on those put forward by the Ontario Ministry of Health and Long-Term Care’s “Ethical Framework for Resource Allocation During the Drug Supply Shortage,” Version 1.0, available at [http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical\\_framework.pdf](http://www.health.gov.on.ca/en/pro/programs/drugs/supply/docs/ethical_framework.pdf) (last accessed October 23, 2020). While there are many other lists of principles that are similar in salient respects, we found the Ontario document to be superior. The passages that are direct quotes are italicized.

- The Principle of Utility must be titrated to accommodate higher values related to nondiscrimination and patient rights.
- Mere utility itself might worsen existing disparities.

**Beneficence.** Uphold the highest-possible standard of *safe and effective care*.

- Ensure adoption of evidence-based medical practices whenever possible.
- *Minimize pain and suffering*.
- Avoid or minimize the need to ration resources by using alternative drugs or treatments when available *evidence suggests similar clinical efficacy* [and effectiveness].

**Stewardship.** Utilize existing resources judiciously.

- Ensure drug use aligns with current clinical recommendations.
- *Prioritize access to scarce drugs based on urgency* and likelihood of benefit.
- Establish checks and balances to reduce waste, bias, and secrecy.

**Trust and accountability.** *Foster and maintain public, patient, and health-care provider confidence in the institution.*

- Communicate truthfully, clearly, in a timely fashion.
- Decision-making should be transparent and inclusive, with accountability clearly denoted.
- Establish quality improvement processes to evaluate relevant procedures.

**Equity.** *Promote fair access to resources.*

- Do not worsen disparities
- Actively engage those most affected by disparities in the design and implementation of allocation guidelines.
- Racism and other forms of bias are often difficult to identify. Attend to the risks of racism and other forms of discrimination.

**Autonomy.** Maintain respect for decision-making by patients and their representatives.

- Within the constraints of any allocation policy, provide opportunities for shared decision-making if possible.
- Communicate clearly to patients about risks and benefits of various treatment alternatives – and about the (un)availability of certain therapeutics.

### **3. Resource management teams should address allocation issues and manage protocols.**

Such teams should be well-informed and guide difficult allocation decisions for their institutions. They should have the following traits.

**Multidisciplinary.** Teams should include scientific/medical experts, social workers, nurses, members of the hospital ethics committee, pharmacists, legal advisors, and the community served by the institution. Consideration should be given to including people with disabilities and the clergy.

**Nimble.** Teams must have adequate administrative resources, be well-coordinated, meet as needed, and enjoy open communication channels to support inquiries from health care workers and the community.

**Accountable.** Decisions made by the resource management team should be reviewed or audited regularly to ensure that the allocation policy is being applied as intended and that implicit or explicit patient selection bias has been avoided. Ideally, a group separate from the team should perform the reviews. For small hospitals, it might make sense to outsource this function.

#### **4. Therapeutics allocation policies should articulate bases or criteria for allocation.**

This means, for instance, that rationing or triage decisions should be made explicit. The following are among the criteria to be addressed.

**Priority.** Several approaches have merit depending on drug availability, patient population, urgency in individual cases, comorbidities, etc. These include: likelihood of success; lotteries; or a combination of two or more approaches.

**Decision procedure.** Within allocation categories, teams should specify how decisions will be made between categories/tiers of patients. Any “tie-breakers,” i.e., secondary validated prognostic information, randomization process, etc. should be specified.

#### **5. Communication materials and channels should be established.**

Patients and their families should understand how allocation decisions are made. Patients in an allocation pool should receive information about the institution’s allocation process as handouts. Appropriate language translations should be obtained as best as possible under emergency circumstances .

- Handouts should be accurate and use language appropriate across education levels
- Regular and clear communication with hospital leadership, staff, affected patients, and the general public is essential. A public information phone line and website are recommended during crisis allocation periods.
- The values of veracity and transparency should guide this communication.

## 6. Clinicians should not make allocation decisions for their own patients.

- The clinician’s primary duty of loyalty is to her/his own patients, generally without regard for other patients
- Conflicts of interest can occur if a patient’s treating physician or nurse is directly involved in a specific allocation decision. Instead, resource allocation teams should determine which patients receive limited therapeutics.
- If there are not enough clinicians to separate allocation decisions from treating physicians or nurses, more robust audits and reviews should be conducted.

## 7. An appeal process should be established.

- Such a process should be available to patients, families, and treating clinicians.
- Appeals should assess whether the allocation protocol was properly followed, not the clinical correctness of any individual administration of a therapeutic agent. Of course, the very idea or existence of an allocation protocol or team is not open to appeal.
- All hospitals should have a functioning ethics resource or process, if not a full ethics committee. Such resource, process, or committee should be involved in any appeal.

## 8. Resources

Centers for Disease Control and Prevention. COVIDView: A Weekly Surveillance Summary of U.S. Covid-19 Activity. Available at <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

Florida Bioethics Network. Ethics Guidelines for Crisis Standards of Care in Public Health Emergencies. Available at <https://fbn.miami.edu/assets/pdf/resources/covid-19-resources/csc-fbn-6.pdf>.

Food & Drug Administration. Information for Health Care Facilities and Providers on “in-use time” | COVID-19. Available at <https://www.fda.gov/drugs/coronavirus-covid-19-drugs/information-health-care-facilities-and-providers-use-time-covid-19>.

Ontario Ministry of Health and Long-Term Care. Ethical Framework for Resource Allocation During the Drug Supply Shortage. Version 1.0. Available at <http://www.health.gov.on.ca/en/>.

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