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Ethical Considerations in the Allocation Out-Of-Sequence Deceased-Donor Organs

Multiple ethical principles are relevant to the consideration of organ allocation, including allocation out-of-sequence for deceased donor organs (AOOS): respect for persons, utility, and justice. In addition to these foundational principles, medical professional obligations are also relevant. These ethical considerations frequently come into conflict with each other.

The rising numbers of AOOS reflect the current system’s focus on increasing organ utilization and efficiency (utility) but risks negatively impacting fairness and transparency (justice). The responsibility for revising the system to achieve a more ethically optimal system for the utilization of the gifts of deceased donor organs lies with the entire system, from regulators to organ procurement organizations, transplant centers, patients and other stakeholders.

Table 1 summarizes the ethical principles relevant to AOOS. The following text expands upon these points.

Table 1: Summary of ethical considerations relevant to AOOS

Key principle	Ethical considerations for AOOS	Ethical considerations against AOOS	Ethical considerations neutral in respect to (or can be applied for or against) AOOS
Respect for persons	<ul style="list-style-type: none"> Honoring the donor and donor family’s gift by placing organs for transplantation 		<ul style="list-style-type: none"> Transplant candidates’ right to make an informed decision about organ acceptance
Utility	<ul style="list-style-type: none"> Maximizing organ utilization Expanding organ donation Enhancing efficiency 	<ul style="list-style-type: none"> Social value of public trust in the transplant system 	
Justice		<ul style="list-style-type: none"> Procedural justice, ensuring accountability for and transparency of factors that affect allocation decisions Fairness to patients on the waiting list who are skipped as a result of AOOS 	
Professional obligations			<ul style="list-style-type: none"> Medical providers’ duty of care to their patients

1. Respect for persons

- a. *Donors and donor families:* Respect for persons underlies the transplant community’s obligation to honor the intentions and hopes of deceased donors and their families by doing all that is possible to place each donated organ for transplant. The decision to donate one’s own or a loved one’s organs after death to help another individual is a great and unique act of generosity. However, it should be



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recognized that this is not always possible due to organ quality or logistical considerations.

- b. *Patients in need of a transplant:* Respect for patients means that they are treated as autonomous individuals who have the right to accept or decline organs that are offered to them. The transplant community has a responsibility to provide patients with clear information about the risks and benefits of accepting organs including medically complex organs for transplant so that patients can make informed decisions that align with their values and interests.
2. Utility
 - a. *Maximizing organ utilization:* AOOS may increase the number of donated organs that are used to save lives via transplantation. This is in line with the principle of utility, which demands that we maximize the expected net amount of benefit. This, in part, argues for maximizing the percentage of donor organs that are transplanted. Other aspects of utility maximization are taken into account to varying degrees in the allocation system for each organ, such as post-transplant survival and medical urgency.
 - b. *Expanding organ donation:* More patients with end-stage organ disease can be helped if there are more donors. Recent developments in technology and procurement techniques have expanded the range of potential donors to include individuals and organs that previously would have been ruled out as donors. As a result, the number of medically complex but potentially life-saving organs procured is increasing. Because it may be more difficult to match these organs with candidates that benefit from them, these organs can be harder to place for transplantation, increasing the impetus for AOOS.
 - c. *Enhancing efficiency:* The allocation and distribution of organs require significant resources, including time and money.
 - i. The amount of time that it takes to place an organ after donor surgery can negatively impact its function or viability. AOOS may allow for more rapid placement of an organ for transplant, particularly when it is close to its maximal cold ischemic time.
 - ii. Donor and recipient-side financial costs must be taken into account to ensure that the use of a given organ for transplant offers the desired net benefit. Transplantation with medically complex organs may also generate recipient-side costs (e.g., financial, psychological, time) related to surveillance for or management of post-operative complications.
 - d. *Public trust:* Bypassing the established allocation sequence can create a perception of unfairness and erode trust in the system. Trust in the organ donation and transplant system, including in the allocation process, is a common good. Without trust in the transplant system, deceased organ donation rates may decline and patients may be less likely to seek evaluation for transplantation.



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3. Justice

- a. *Procedural justice*: While different factors are given different weights for the determination of the ranking system for each type of organ, each algorithm has undergone extensive professional and public review to achieve consensus.
 - i. The debate among diverse stakeholders during OPTN allocation policy development is a form of requiring accountability for policy decisions that is fundamental to procedural justice.
 - ii. Procedural justice also requires that decisions about organ allocation are transparent and open to deliberation. Transparency mitigates concerns about biased or subjective allocation, enables patients and the public to understand why decisions are being made, and fosters trust in the allocation system,
- b. *Fairness*: As a result of AOOS, certain transplant centers and waitlist candidates with higher priority may be bypassed, raising concerns about fairness and equality of access to transplantation. It potentially disadvantages patients who have waited longer or are in greater medical need. AOOS may decrease transplant rates for groups who are disadvantaged as a result of race, ethnicity, socioeconomic status, or geography.
 - i. Adherence to organ allocation policy established via a procedurally just system is a matter of fairness to all transplant candidates.
 - ii. Fairness also requires that organ allocation policies be applied system-wide to avoid regional heterogeneity that may exacerbate variations in access to organs. Ensuring fairness is essential to preserving public trust in the allocation system.

4. Professional obligations

- a. *Duty of care*: Medical providers are obliged by a professional duty of care to decline an organ offer if they believe that the use of the organ would harm a patient.
 - i. Providers must use their professional judgment to determine if their center possesses sufficient resources and expertise to optimize outcomes for recipients of the medically complex organs that are more likely in the AOOS pathway.
 - ii. The duty of care likewise requires that providers carefully consider all organ offers for their patients, taking into account patient well-being and preferences.

Future directions

While it may seem like utility and justice considerations inevitably come into conflict, there may be ways to increase organ utilization, donation rates, and efficiency without relying so heavily on AOOS. The transplant community should explore alternative allocation methods and policies that can enhance utility while preserving fairness. Regulatory revisions that could enhance utility while maintaining waitlist priority include requiring OPOs to begin organ allocation prior to the start of the



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donor surgery to allow identification of primary and multiple back-up centers for medically complex donors and disincentivizing late organ declines for donor data available at the time of initial organ acceptance.

AOOS may still be required to avoid organ non-use without significant negative implications for justice because other attempts at allocation have been exhausted or are not feasible. In these cases, AOOS should be pursued according to a transparent, nationally consistent policy that has been reviewed and, adopted by relevant stakeholders with plans to review the policy outcomes within an acceptable timeframe