

Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies

Introduction

Due to the increasing demand for organs and a lack of available organs, many patients clinically deteriorate or die on the waitlist while awaiting life-saving transplantation. Organ-specific allocation criteria developed by the Organ Procurement Transplant Network/United Network for Organ Sharing (OPTN/UNOS) are applied to all on the waitlist to provide equitable access to life-saving organs.¹

This white paper provides an ethical analysis of physicians' practices of escalating care to waitlisted transplant candidates in order to increase their priority in the allocation system. Many in the transplant community perceive, as expressed explicitly in the medical literature^{2,3}, that this practice of unnecessary escalation of care is widespread, and recognize that physicians may feel compelled to similarly manipulate the waitlist priority system so that their candidates are not disadvantaged as a result of the practices of others.

For example, in heart transplantation, priority status can be influenced by the degree of therapeutic intervention applied to the transplant candidate, based on the assumption that therapeutic measures are a reliable indicator of disease severity.⁴ An unintended consequence of this approach is that a physician can raise the priority status of a patient by instituting more advanced therapeutic measures even in the absence of true medical necessity, a tactic some informally refer to as "gaming."

Due to the organ shortage, the transplant waitlist "is functionally a zero-sum rationing process."⁵ Shortening wait times for some directly increases wait times for others. Thus, the practice of instituting more advanced therapies to shorten an individual's wait time has no beneficial effect on wait times for the patient population in the aggregate. However, manipulating care to achieve a higher candidate priority can generate complications in candidates receiving such care while also jeopardizing public trust in the organ allocation system, which in turn, could reduce organ donation rates.

OPTN/UNOS leadership requested an ethical analysis regarding the manipulation of the organ allocation system, particularly as it pertains to medically unnecessary escalation of interventions that are instituted for the sole purpose of increasing a candidate's waitlist priority. The OPTN has not previously commented on this issue.

Purpose

The purpose of this white paper is to clearly define and present an ethical analysis of physicians' practice of manipulating waitlist priority by unnecessarily escalating care of candidates on the waitlist. This white

¹ Ethical Principles in the Allocation of Human Organs. (2015 June) The Organ Procurement and Transplant Network. Retrieved from <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

² Stevenson LW. *The urgent priority for transplantation is to trim the waiting list*. The Journal of Heart and Lung Transplantation. 32(9), 2013: 861-7.

³ Stevenson LW, Kormos RL, Young JB, Kirklin JK, Hunt SA. *Major advantages and critical challenges for the proposed United States heart allocation system*. The Journal of Heart and Lung Transplantation. 35(5), 2016: 547-549.

⁴ Movsesian, Matthew. (2016, July 24) "Should doctors game the transplant wait list to help their patients". Retrieved from <http://www.npr.org/sections/health-shots/2016/07/24/486787474/should-doctors-game-the-transplant-wait-list-to-help-their-patients>.

⁵ Ibid.

paper examines physicians' dual obligations: the fiduciary obligations to their own patients and the obligations of stewardship of organs in the OPTN allocation system. This white paper addresses physicians' ethical obligations to uphold principles of justice and utility that are integral to the transplant allocation system,^{6 7 8 9} and adhere to systemic safeguards that mitigate the manipulation of waitlist priority.

Numerous examples of manipulation of the U.S. and European organ allocation systems have been discussed in the medical literature and the lay press.^{10,11, 12} However, the OPTN has not formalized a position statement on this issue or offered ethical guidance for providers who may be struggling to adhere to OPTN/UNOS policies. Clinical medical ethics entails careful description of ethically problematic practices. Specificity is important for fostering understanding of the practices being targeted and their contexts, and for providing insight into practices that need to be safeguarded against. Accordingly, this white paper reviews some examples of how physicians can escalate care to gain waitlist priority for their candidates and highlights the components of the various organ allocation systems as examples of systems that can be manipulated. Describing the practice of manipulating the waitlist priority and its unintended consequences is important for raising awareness of this issue, modeling ethical clinical practice, upholding the ethical principles of allocation of human organs, and further developing safeguards to prevent this practice from occurring in the future.¹³

This white paper is not intended to propose new enforcement, monitoring, or policing of any transplant hospital's use of therapeutic interventions. This white paper is also not intended to dictate how clinicians should provide care to their patients, or to suggest the indications for using specific therapeutic interventions. Rather, this white paper presents an analysis of the ethics of escalating care for the purposes of increasing waitlist priority, and could serve as guidance for transplant providers who may be confronted with this issue. This white paper offers transplant providers a model of how to engage in ethical clinical practice, and it clarifies safeguards within the transplant system designed to protect justice and utility in organ allocation.

Definition of Manipulation of the Organ Allocation System Waitlist Priority

For the purposes of this white paper, we will focus on waitlist manipulation related to practices and interventions that are not medically required, but are initiated, maintained, or escalated for the sole purpose of increasing a specific candidate's waitlist priority. This definition excludes deliberate and egregious waitlist manipulation that is clearly inconsistent with federal laws, regulations and OPTN/UNOS policies, including accepting financial bribes for access to transplantation, or falsely reporting patient information in order to increase the disease severity to gain additional priority for a patient.

An example of egregious manipulation in the liver allocation system entails a so-called "bait and switch" strategy whereby transplant hospitals could register a large number of sick patients, some of whom the

⁶ Freeman RB1, Bernat JL. *Ethical issues in organ transplantation*. Prog Cardiovasc Dis. 2012 Nov-Dec;55(3):282-9. doi: 10.1016/j.pcad.2012.08.005.

⁷ Willems, D. *Balancing Rationalities: Gatekeeping in Health Care*. Journal of Medical Ethics 27.1 (2001): 25–29. PMC. Web. 6 Apr. 2018.

⁸ Weinstein MC Should physicians be gatekeepers of medical resources? Journal of Medical Ethics 2001;27:268-274.

⁹ Edmund D. Pellegrino, Rationing Health Care: The Ethics of Medical Gatekeeping, 2 J. Contemp. Health L. & Pol'y 23 (1986).

¹⁰ Stevenson LW, Kormos RL, Young JB, Kirklin JK, Hunt SA..

¹¹ Warmbir, Steve. "UIC hospital sued for Medicare fraud" Chicago Sun-Times, July 29, 2003.

¹² Movsesian, Matthew.

¹³ *Ethical Principles in the Allocation of Human Organs*. (2015 June) The Organ Procurement and Transplant Network. Retrieved from <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

transplant hospitals may not intend to transplant. By using this approach, a center could “bait” a procured liver graft to their center, hold the liver to allow sufficient cold ischemia time to accrue to prevent the liver from leaving the center, and then “switch” the allocation to another less sick patient waitlisted at their center. This practice is misleading, dishonest, and violates the OPTN’s ethical standards.

Evidence of Manipulation of the Waitlist Priority

No studies have assessed the prevalence of waitlist manipulation. However, there are numerous well-publicized reports and editorials highlighting alleged or potential purposeful manipulation of the allocation system.^{14,15,16,17,18,19}

During the mid-late 1990s, three transplant hospitals in Chicago, IL were alleged by federal and state authorities to have falsely reported patients as critically ill in order to house them in the intensive care unit for the purpose of moving them to the top of the liver transplant waitlist.²⁰ The hospitals denied any wrongdoing, but did receive financial penalties. These incidents generated questions about the integrity and fairness of the liver allocation system based on the alleged events.^{21,22}

In the last five years, prominent editorials described the widespread use of medical interventions that are not thought to be medically indicated in routine practice, but allow for patients to receive higher waitlist priority.^{23,24} This includes increased utilization of pulmonary artery (PA) catheters with continuous inotropes for the purpose of increasing the priority status on the waitlist of a patient with heart failure.²⁵ While there are situations in which PA catheter use is appropriate, this intervention is associated with excessive adverse complications, which typically prohibits its routine use. When use of PA catheters was aligned with allocation priority, increasing use of PA catheters quickly followed.²⁶ Further, vascular complications that preclude further catheterization have evolved to become a major justification for Status 1A exceptions, which are presumed to be related to overuse of PA catheters.^{27,28}

Increasingly, heart transplant candidates are being listed as Status 1A (the highest priority), which is largely based on the intensity and risk of the intervention used to treat the patient. This category was originally intended for potential transplant candidates expected to survive less than one week. Now, it’s not uncommon for Status 1A patients to have longer waitlist survival, and they may wait 6-12 months before transplant. The trend to waitlist patients in the highest severity group has diluted the urgency, and in many regions, transplantation has become unlikely for patients who are not listed as Status 1A. As such, providers may have become incentivized to “list early and list high”.²⁹ Another author noted that “although the system is arguably transparent, all experienced physicians recognize that the decision to continue a patient on a low-dose inotropic agent therapy or to manage his or her heart failure on an outpatient basis may be influenced by the effect it will have on his or her status as a potential transplant

¹⁴ Stevenson LW.

¹⁵ Stevenson LW, Kormos RL, Young JB, Kirklin JK, Hunt SA.

¹⁶ Warmbir, Steve. “UIC hospital sued for Medicare fraud” Chicago Sun-Times, July 29, 2003.

¹⁷ Movsesian, Matthew.

¹⁸ Shaw D. “Lessons from the German Organ Scandal”. *The Intensive Care Society* 14(3), 2013: 200- 203.

¹⁹ Scanlon DP, Hollenbeak CS, Lee W, Loh E, Ubel PA. *Does competition for transplantable hearts encourage ‘gaming’ of the waiting list?* *Health Affairs* 23(2), 2004: 191-198.

²⁰ Warmbir, Steve.

²¹ Burton TM, Merrick A. “U.S. Alleges Liver-Transplant Fraud”. *Wall Street Journal*, July 29, 2003.

²² O’Connor M. “Transplant scandal hits 3 hospitals”. *Chicago Tribune*, July 29, 2003.

²³ Stevenson LW.

²⁴ Stevenson LW, Kormos RL, Young JB, Kirklin JK, Hunt SA.

²⁵ Stevenson LW.

²⁶ *Ibid.*

²⁷ *Ibid.*

²⁸ Stevenson LW, Kormos RL, Young JB, Kirklin JK, Hunt SA.

²⁹ Stevenson LW.

recipient”.³⁰

The issue was further brought to the surface by a 2016 report on National Public Radio (NPR) that raised concerns about heart transplant providers escalating medical care in the absence of medical indication.³¹ While this behavior has been justified by the position that the provider is acting in the best interest of the patient, the NPR report suggested, “When ‘gaming the system’ goes from being an aberration to a standard strategy ... then dishonesty becomes normal”.³²

Evidence that competition for organs drives physicians’ clinical behavior has been reported for both liver and heart transplantation. For instance, prior to Model For End-Stage Liver Disease (MELD)-based liver allocation, which removed intensive care unit status as a parameter for allocation priority, the number of transplant centers in an Organ Procurement Organization (OPO) directly correlated with utilization of the Intensive Care Unit (ICU) even though ICU use was not justified by a higher degree of critical illness.³³ A similar analysis of heart transplant centers in the 1990s found that transplant centers in competitive Donation Service Areas (DSAs) were most likely to list patients as Status 1.³⁴ These studies suggest that when opportunities to engage in manipulation are present, some physicians will take them, even though manipulation is not an ethically sound practice.

Transplant allocation manipulation is not unique to the United States. In Germany, a group of transplant providers was charged with manipulating the liver allocation system by significantly exaggerating their patients’ illness severity.³⁵ This practice led to multiple convictions and eroded public confidence in the transplant system in the aftermath of the scandal. Donation rates declined by 20 to 40 percent and resulted in a significant decline in the number of overall organ transplants performed.³⁶

Ethical Implications of Manipulating the Waitlist Priority

Use of therapeutic measures that would not otherwise be implemented or maintained, for the sole purpose of advancing a candidate’s priority status on the transplant waitlist, violates the ethical principles of justice and utility. This practice is incompatible with the ethical principles by which the OPTN/UNOS operates.³⁷ In this section, we consider physician- and transplant system-level ethical considerations including utility (beneficence and non-maleficence), autonomy, and justice.

Physician-Level Considerations

Physicians have a moral and fiduciary obligation to improve the situation of an individual patient, and have discretion in making recommendations regarding the most appropriate care.

³⁰ DiSesa VJ, Mull R, Daly ES, Edmunds H, Mancini DM, Eisen HJ. *Cardiac Transplant Donor Heart Allocation Based on Prospective Tissue Matching*. *Ann Thorac Surg* 1994; 58:1050-3.

³¹ Movsesian, Matthew.

³² Ibid.

³³ Snyder, J. *Gaming the Liver Transplant Market*. *The Journal of Law, Economics, and Organization* 49:126(3), 2010: 546-568.

³⁴ Scanlon DP, Hollenbeak CS, Lee W, Loh E, Ubel PA. *Does competition for transplantable hearts encourage ‘gaming’ of the waiting list?* *Health Affairs* 23(2), 2004: 191-198.

³⁵ Shaw D. “Lessons from the German Organ Scandal”. *The Intensive Care Society* 14(3), 2013: 200-203.

³⁶ Ibid.

³⁷ *Ethical Principles in the Allocation of Human Organs*. (2015 June) The Organ Procurement and Transplant Network. Retrieved from <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

Utility

Beneficence

Most situations in which therapies are manipulated for the sole purpose of raising a candidate's waitlist priority occur to promote the patient's best interest, and, in the spirit of saving a life, to uphold the principle of beneficence. The principle of beneficence states that actions should maximize the net amount of overall benefit (to promote good) for individual patients.³⁸ For transplant providers, beneficence dictates an active effort to advocate for the best medical treatment for a specific candidate, which often means timely transplantation. Providers often feel compelled to do whatever is reasonably acceptable to optimize a candidate's opportunity to receive a transplant. Manipulation of waitlist priority at times may be in the best interest of the candidate, if the benefit (earlier transplantation) outweighs the risk of complications from the therapy.

Non-Maleficence

This principle has been traditionally premised on the physician commitment to "first, do no harm", and has come to reflect the need to minimize harm, recognizing that many treatments incur harms. Thus, to be ethically acceptable, the benefits must outweigh the harms of treatment. Manipulation of waitlist priority may harm individual candidates in two ways:

1. Candidates who may be harmed are those who received a manipulated medical therapy. Candidates who receive medical interventions that are not necessary but serve only to elevate candidates' status on the waitlist can be directly harmed by undertaking unnecessary risks and by complications arising from the medical intervention. Examples include increased risk of arrhythmias with continuous inotropic medications and ventilator-associated pneumonia with prolonged continuous mechanical ventilation.
2. Manipulation of waitlist priority may harm the doctor-patient relationship. If candidates hear stories of some physicians showing a willingness to manipulate waitlist priority for other candidates, they may lose trust in their own physician who may be unwilling to intentionally manipulate waitlist priority. Additionally, candidates might lose faith in their physician if their physician manipulates their therapy to advance waitlist priority because they may recognize this behavior as dishonest, even if they might benefit.

Autonomy

If physicians were to engage in escalation of care, then respect for patient autonomy would require that they educate patients about the potential harms (including societal harms) and benefits of manipulation of waitlist priority so that patients could provide informed consent.

Justice

As stewards of scarce organs, transplant physicians have a responsibility to maximize health outcomes, preserve the integrity of the organ allocation system and ensure that the system offers equitable access to transplantation for all patients.³⁹ Providers must consider competing professional duties of advocating for a particular patient's best interests, while also upholding obligations to society as a whole.⁴⁰ The key ethical dilemma pertains to clinicians' role in addressing their obligation to their patient with their obligation to the transplant system and society.

Physicians are not expected to 'balance' these obligations, per se. When ethical principles are in conflict,

³⁸ Ibid.

³⁹ Griffin L. *Retransplantation of multiple organs: how many organs should one individual receive?* Progress in transplantation. Jun 2002;12(2):92-96.

⁴⁰ Gordon, EJ, Jensen, SE, Lok-Ming Lehr, A, Franklin, J, Becker, Y, Sherman, L, Chon, WJ, Beauvais, N, Hannerman, J, Pernod, D, Ison, MG, Abecassis, MM. *Opportunities for Shared Decision Making in Kidney Transplantation*. American Journal of Transplantation 13(5), 2013: 1149-1158.

physicians may feel compelled to prioritize the principles of beneficence and non-maleficence over justice given their fiduciary obligation to their individual patients.⁴¹ As such, providers may feel that they are acting ethically by promoting their patients' best interest. Considering the interests of their own patients neglects the interests of other patients, who may be harmed when physicians manipulate waitlist priority. Because fiduciary obligations of physicians towards individual patients are so strong, and because even well-intentioned physicians may be unable to effectively consider justice considerations against utility at the individual-level, safeguards (see below) can help ensure that all patients are treated equally.

System-level considerations

The use of standardized organ allocation criteria that are equally accepted and applied are meant to strike a balance between utility and justice. However, if the criteria are not applied equally across transplant hospitals, then both justice (fairness) and utility (waitlist or post-transplant outcomes) may be compromised. If physicians escalate care for the sole purpose of helping patients gain waitlist priority, organs may be allocated in a non-equitable manner (e.g., to patients who are "less sick", who have been waiting less time, or who may have a higher likelihood of finding a suitable organ in the future). Such manipulation has the potential to increase waitlist morbidity and mortality for the patients who were bypassed by the patient whose care was escalated. Manipulating waitlist priority so that patients receive organs before they are sick enough to achieve priority for those organs diminishes the allocation system's capacity to maximize the health benefits and life years of transplantation for all waitlisted patients (utility).

Utility

Beneficence

"The principle of utility holds an action or practice to be right if it promotes as much or more aggregate net good than any alternative action or practice. The principle of utility, applied to the allocation of organs, specifies that allocation should maximize the expected net amount of overall good (adjusted for accompanying harms), thereby incorporating the principle of beneficence (do good) and the principle of non-maleficence (do no harm)."⁴²

In this context, the ethical principle of utility in transplantation seeks to preserve efficiency and avoid organ wastage: to achieve the maximum net benefit of an organ (rather than promoting the well-being of any particular transplant candidate, per se).⁴³ Post-transplant survival of the patient and organ and likelihood of death on the waitlist are factors involved in determining utility. A successful allocation system provides suitable candidates with transplants prior to clinical deterioration, optimizes post-transplant outcomes and minimizes futile transplants. Utility in the transplant context focuses on maximizing benefit to the population of all waitlisted candidates. As such, manipulating care to prioritize some patients over others does not achieve this broader goal.

Non-Maleficence

Manipulating waitlist priority may harm transplant candidates on the waitlist in two ways: Patients who may be harmed are those unknown patients ("statistical victim")⁴⁴ whose waitlist status is affected when a physician manipulates waitlist priority for other patients. The unknown victim is the patient who should have received higher priority for transplantation, but is harmed because access to transplantation is delayed by being "jumped in line" by another candidate with equal or lesser disease severity, or other allocation priority criteria.

⁴¹ *Ethical Principles in the Allocation of Human Organs*. (2015 June) The Organ Procurement and Transplant Network. Retrieved from <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

⁴² Ibid.

⁴³ Ibid.

⁴⁴ *Identified Versus Statistical Lives: An Interdisciplinary Perspective*. I.Cohen, Oxford Press 2015.

News of actual manipulation practices (as well as news about the potential for such practices) can harm the entire transplant system by eroding public confidence in the system, and thereby reducing organ donation rates.

Justice

Use of the OPTN/UNOS allocation criteria is intended to ensure equity and transparency in access to organ transplantation.⁴⁵ Manipulation of care in an attempt to improve the chances of any given patient to gain access to transplantation violates principles of both procedural and distributive justice.

Procedural justice requires that the process by which priority is determined is applied equally to all eligible transplant candidates, and is transparent and predictable. Procedural justice is critical to preserving public trust and participation in the transplant system, as it ensures that all patients in need will receive similar treatment. Standardized criteria used and applied equally across all transplant hospitals provide a systematic and just method for providing lifesaving and quality of life-improving treatment to all patients.

Distributive justice in organ allocation dictates fairness in the distribution of scarce resources so that similarly needy patients have an equal opportunity to benefit from transplantation. When a patient's clinical care is escalated for the sole purpose of increasing his or her status on the waitlist, distributive justice is undermined. Such manipulation may move a patient higher on the waitlist at the expense of other patients, who may have equal or more urgent need for the organ, but whose care was not escalated by their treating provider.

In sum, manipulating waitlist priority by escalating therapies that are not indicated serves no net benefit to the waitlist as a whole (and may harm patients receiving unnecessary medical interventions and others on the waitlist). While manipulating waitlist priority may sometimes benefit a given patient, this practice is not ethically sound because it violates the principle of justice.

Who stands to gain from allocation system manipulation?

Multiple stakeholders stand to gain from manipulating the allocation system, including the candidate and the transplant hospital.

1. An individual transplant candidate may gain by obtaining a transplant sooner than dictated by their "true" disease severity. An earlier transplant may provide better outcomes and less risk of clinical deterioration while on the waitlist. While an individual patient may stand to benefit, the aggregate waitlist as a whole derives no net benefit when manipulation occurs (and in fact, net benefit to the aggregate waitlist may be diminished by manipulation). Thus, if one patient derives the benefit, another patient experiences the harm.
2. Transplant hospitals and providers stand to gain by manipulations designed to increase a patient's standing on the transplant list. There exists an incentive for transplant hospitals to increase transplant volume in order to: a) benefit financially (based on number of transplants performed); b) enhance the institution's reputation; and c) decrease the risk of regulatory scrutiny from adverse outcomes by growing the transplant denominator. The more candidates who are waitlisted at high priority, the more likely that higher volumes can be achieved. However, in the context of the organ shortage, when one transplant hospital strives to improve its volumes by manipulating the system to transplant its own patients, it does so at the unfair expense of other transplant hospitals and the populations those hospitals serve.

⁴⁵ *Ethical Principles in the Allocation of Human Organs*. (2015 June) The Organ Procurement and Transplant Network. Retrieved from <https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

Summary

While physicians' fiduciary duty to "do all they can" for their patients is understandable,⁴⁶ the practice of initiating, augmenting, or maintaining therapeutic measures that are not otherwise indicated for the sole purpose of advancing a patient's status on the waitlist is contrary to the OPTN's ethical principles of organ allocation, and is thus not ethically supported by the transplant system. While ethical principles conflict at the individual-level, analysis of ethical principles at the system-level clearly rejects escalation of care for the purposes of prioritizing individual patients. Uniform and consistently practiced ethical medical practices can maximize principles of justice and utility in organ allocation, and minimize harms to individual patients and to society.

Responsibility for mitigating the risk of manipulating the waitlist priority falls upon the OPTN and the transplant community. OPTN/UNOS organ allocation criteria, with its embedded safeguards, can help to mitigate the risk of manipulation of the waitlist priority. Yet, as such manipulation still occurs, further safeguards are needed. Allocation policies that rely on objective criteria and minimize subjective criteria are most likely to mitigate the risk of manipulation. It is incumbent upon the OPTN and the transplant community to ensure that providers understand expectations for upholding the principles of organ allocation.

⁴⁶ *AMA Code of Medical Ethics' Opinions on Allocating Medical Resources*, <http://virtualmentor.ama-assn.org/2011/04/coet1-1104.html> (accessed May 20, 2018).