OPTN | UNOS

Public Comment Proposal

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

OPTN/UNOS EthicsCommittee

Prepared by: Lee Bolton
UNOS Policy Department

Contents

Executive Summary 2
What problem will this resource address? 3
Why should you support this resource? 3
How was this resource developed? 3
Which populations are impacted by this resource? 4
How does this resource impact the OPTN Strategic Plan? 4
How will the OPTN implement this resource? 4
How will members implement this resource? 4
Will this resource require members to submit additional data? 4
How will members be evaluated for compliance with this resource? 4
White Paper 5

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

Affected Policies: *N/A*
Sponsoring Committee: *Ethics*
Public Comment Period: *January 22, 2018 – March, 23, 2018*

Executive Summary

Beginning in 1993, the Ethics Committee (the Committee) developed a series of white papers that are available through the Organ Procurement and Transplantation Network (OPTN) website. A white paper is an authoritative report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision.

There have been recent reports describing the manipulation of waitlist priority of the organ allocation system in both the medical literature and the lay press. To date, the OPTN and the United Network for Organ Sharing (UNOS) have not offered guidance or established a formal position statement on this issue.

This white paper will define and present an ethical analysis of manipulation of the waitlist priority of the organ allocation system through the use of medically unnecessary interventions that are used to increase a transplant candidate's priority on the waitlist. The white paper will delineate the potential harms to transplant candidates, the wait list as a whole, transplant providers, and transplant hospitals involved in the manipulation of the organ allocation system.

What problem will this resource address?

UNOS has received feedback regarding how waiting list priority could be manipulated through the use of unnecessary medical interventions. For example, public comment responses for the *Proposal to Modify the Adult Heart Allocation System* (2016) included concerns about manipulating waiting list priority through the use of cardiac assist devices. These concerns have not been unique to any specific type of organ transplant, but if it did occur, it could result in an inequitable organ allocation system.

A recent news report on National Public Radio (NPR) raised concerns about heart transplant providers escalating medical care in the absence of medical indication for the treatment.[5] This behavior has been largely justified by the position that the provider is acting in the best interest of his or her patient, but this report suggested that when "gaming" the system goes from being an aberration to a standard strategy, — then dishonesty becomes the norm.

While there may be a number of different ways or opportunities to manipulate an allocation system, this paper will focus on the use of unnecessary medical interventions to raise a transplant candidate's priority on the waiting list. Such practice may violate the principle of equity and result in an inequitable organ allocation system. It should be helpful for OPTN/UNOS to provide guidance regarding this issue.

Why should you support this resource?

This white paper demonstrates that the OPTN continues to consider and provide guidance on important and timely ethical issues faced by the transplant community. This white paper will be a resource that members could consult if concerned about the manipulation of the organ allocation system to advance a transplant candidate's status on the waiting list.

How was this resource developed?

In January 2017, the OPTN/UNOS President asked the Committee to provide an ethical analysis regarding the manipulation of the organ allocation system, particularly as it pertains to medically unnecessary interventions that are used for the sole purpose of increasing a transplant candidate's priority on the waiting list.

The Committee proposed developing a white paper on the manipulation of the organ allocation system through the escalation of medical interventions. A workgroup of Committee members completed a literature review on this topic and began meeting by web conference. In April 2017, the lead author provided at update during a full Committee meeting. The Committee agreed that the white paper should limit its focus to the escalation of medical interventions to raise a transplant candidate's priority on the waiting list.

In May and September 2017, representatives of the Thoracic Organ Transplantation and Liver and Intestinal Committees participated on two web conferences with the workgroup developing the white paper. These representatives provided their perspectives on manipulating waiting list priority in their specific area of organ transplantation expertise. Of note, these representatives reported that, in their personal opinions, manipulating the waiting list through the use of unnecessary medical interventions occurs, and they supported the development an ethical analysis or guidance addressing this practice.

The full Committee met in October 2017 to review the white paper. After this meeting, a draft of this resource was sent to representatives of the Thoracic, Liver, Operations and Safety, Transplant Administrators and Transplant Coordinators Committees to obtain pre-public comment regarding the white paper. Representatives from four Committees provided feedback regarding the white paper. Most responses commented on the importance of addressing this topic although several responses raised concern about introducing this problem in a public forum. There were several comments regarding the need to further refine organ allocation policies to reduce opportunities for manipulating waiting list priority and for determining how to identify and intervene when clinical practice veers into potential manipulation

of waiting list priority. One response suggested “abuses” of the system could occur if physicians don’t fundamentally support the concept of transplanting the sickest transplant candidates first and at the expense of other metrics. All comments were considered and the white paper was modified to address some comments. The Committee met in December 2017, and supported sending the white paper for public comment.

Which populations are impacted by this resource?

Transplant hospitals could voluntarily review the ethical principles and recommendations outlined in this white paper if considering the escalation of treatment for the purpose of advancing a candidate’s status on the waiting list.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants*: There is no impact on this goal.
2. *Improve equity in access to transplants*: The escalation of treatment to advance a transplant candidate’s status of the waiting list may violate the principle of equity.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes*: There is no impact to this goal.
4. *Promote living donor and transplant recipient safety*: The escalation of treatment to advance a transplant candidates status on the waiting list could expose the candidate to invasive medical procedures with associated risks.
5. *Promote the efficient management of the OPTN*: There is no impact to this goal.

How will the OPTN implement this resource?

If this resource is approved, it will be available through the OPTN website. Additionally, this may serve as advice to other committees as they consider policy changes to organ allocation systems.

How will members implement this resource?

Members will not need to take any action to implement this resource. Members could choose to consult this resource on a voluntary basis.

Will this resource require members to submit additional data?

No, this resource does not require additional data collection.

How will members be evaluated for compliance with this resource?

This resource does not affect member compliance. Members could consult this resource on a voluntary basis.

White Paper

All the language in the white paper below is proposed new language; underlines have been omitted for easier reading.

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

Introduction

Due to 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 patients on the waitlist to provide equitable access to life-saving organs.

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 index of disease severity. 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'.

Although ethical principles of equity and justice guide the allocation of organs additional ethical considerations may conflict with these principles.[1] Physicians may be driven to escalate care for patients by different professional obligations. Some physicians may be driven by professional duties to adhere to the Hippocratic Oath or abide by the Rule of Rescue, to give their patient an advantage over other patients. As patient advocates, physicians are expected to do all they can to help their patients receive timely transplants, and some physicians may perceive that raising a patient's waitlist status serves this purpose. But because of this focus, some physicians may lose sight of their professional obligation to serve as stewards of scarce organs to all patients on the waitlist. Competing obligations may compromise physicians' clinical decision-making. While more aggressive therapeutic measures carry increased risks to a patient, these are often outweighed by the advantage of shortening the waiting time for a transplant, during which his/her condition is likely to deteriorate. Further, patients themselves often develop a sophisticated understanding of allocation prioritization, and may ask for interventions (even if medically unnecessary) in order to ascend the waiting list.

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 patients are not disadvantaged as a result of the practices of others.

Due to the organ shortage, the transplant waitlist is functionally a zero-sum game. 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 patient priority can generate complications in patients 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 patient's waitlist priority. OPTN/UNOS 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 waitlisted patients. This white paper examines physicians' dual obligations, including fiduciary obligations to their own patients and 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, 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.[3,4,5] However, OPTN/UNOS has not formalized a position statement on this issue or offered ethical guidance for providers who may be struggling to adhere with OPTN/UNOS policies. Clinical medical ethics entails careful description of questionable ethical 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 patients and highlights the components of the various organ allocation systems that may be at risk for manipulation. 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.[1]

This white paper is not intended to propose new enforcement, monitoring, or policing of any transplant center'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 Waitlist Priority of the Allocation System

For the purposes of this white paper, we will focus on waitlist manipulation related to practices/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 are 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 centers could list a large number of sick patients, some of whom centers 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 UNOS' ethical standards.

Evidence of Manipulation of the Waitlist Priority of the Organ Allocation System

No studies have assessed the prevalence of waitlist manipulation. However, there are numerous well-

publicized reports and editorials highlighting alleged purposeful manipulation of the allocation system.[2-9]

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 wait list.[4] *The hospitals denied any wrongdoing, but did receive financial penalties. This incident generated questions about the integrity and fairness of the liver allocation system based on the alleged events.*[8,9]

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.[2,3] 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.[2] 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.[2] 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. [2,3]

Increasingly, heart transplant candidates are being listed as Status 1A (the highest priority), which is largely based on the intensity/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, Status 1A patients have longer waitlist survival and 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".[2] 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 recipient".[10]

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.[5] 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".[5]

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.[11] A similar analysis of heart transplant centers in the 1990s found that transplant centers in competitive OPOs were most likely to list patients as Status 1.[7] 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.[6] 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%-40% and resulted in a significant decline in the number of overall organ transplants performed.[6]

Ethical Implications of Manipulating the Waitlist Priority of the Organ Allocation System

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.[1] 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.

Utility

Beneficence

Most situations in which therapeutic measures are manipulated for the sole purpose of raising a patient'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. For transplant providers, beneficence dictates an active effort to advocate for the best medical treatment for a specific patient, which often means timely transplantation. Providers often feel compelled to do whatever is reasonably acceptable to optimize a patient's opportunity to receive a transplant. Manipulation of waitlist priority at times may be in the best interest of the patient, if the benefit (earlier transplantation) outweighs the risk of complications from the therapy.

Non-Maleficence

This principle is premised on the physician commitment to "first, do no harm". Manipulation of waitlist priority may harm individual patients in two ways:

1. Patients who may be harmed are those who received a manipulated medical therapy. Patients who receive medical interventions that are not necessary but serve only to elevate patients' 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 or ventilator-associated pneumonia with prolonged continuous mechanical ventilation.
2. Manipulation of waitlist priority may harm the doctor-patient relationship. If patients hear stories of some physicians showing a willingness to manipulate waitlist priority for other patients, they may lose trust in their own physician who may be unwilling to intentionally manipulate waitlist priority. Additionally, patients might lose faith in their physician if their physician manipulates their therapy to advance waitlist priority because patients may recognize this behavior as dishonest, even if they might benefit.

Autonomy

If physicians were to engage in manipulation 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 maximize health outcomes, preserve the integrity of the organ allocation system and ensure that the system offers equitable access

to transplantation for all patients.[12] Providers must consider competing professional duties of advocating for a particular patient's best interests, while also upholding obligations to society as a whole.[13] 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, physicians may feel compelled to prioritize the principles of beneficence and non-maleficence over justice given their fiduciary obligation to their individual patients.[1] 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, OPTN/UNOS safeguards (see below) can help physicians to mitigate manipulation of waitlist priority, This dilemma arises when clinical discretion crosses a line from patient advocacy to dishonest manipulation.

System-level considerations

The use of standardized organ allocation criteria that are equally accepted and applied, is 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 manipulate care for the sole purpose of helping patients to 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 manipulated. 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).

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 wellbeing of any particular transplant candidate, per se).[1] 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")[14] 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 recipient with equal or lesser disease severity or other allocation priority criteria.

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 reduce organ donation rates.

Justice

Use of the OPTN/UNOS allocation criteria is intended to ensure equity and transparency in access to organ transplantation.[1] 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/or 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 manipulated for the sole purpose of increasing his/her status on the wait list, distributive justice is undermined. Such manipulation may move a patient higher on the wait list at the expense of other patients, who may have equal or more urgent need for the organ, but whose care was not manipulated 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 (an in fact, net benefit to the aggregate waiting list 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 program 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 who the other hospitals serve.

Current OPTN/UNOS policies for organ specific allocation, safeguards to prevent manipulation, and the likelihood of manipulation occurring

The OPTN/UNOS uses organ specific allocation policies for liver, kidney, pancreas, intestine, heart and liver transplantation. In liver, heart, and lung transplantation, priority is generally assigned to patients with the highest risk of death on the waitlist. By contrast, in kidney and pancreas transplantation, priority is generally assigned to patients with the highest waiting time, with additional priority given to highly sensitized patients, pediatric patients, and prior living donors. Below, we review the various allocation

systems, and identify clinical practices, based on a literature review and clinical experience, that may be vulnerable to manipulation. This review of vulnerabilities is not comprehensive. Each organ specific allocation policy has undergone several iterations, with the policies evolving over time. Policies that incorporate primarily objective criteria become increasingly protected from manipulation, whereas policies that incorporate subjective criteria, are more vulnerable to manipulation.

OPTN/UNOS has established several safeguards to mitigate the risk of manipulation of candidates' waitlist priority. The following review includes description of several safeguards. It is important for the transplant community and the public to be aware of these safeguards in order to: a) be mindful of ethical clinical practices, b) assess their effectiveness, and c) foster public trust in the transplant system. This review of safeguards is not comprehensive. As evidence of manipulation of waitlist priority indicates, current safeguards do not sufficiently mitigate this risk. Thus, the OPTN, OPTN/UNOS Committees, and the transplant community should consider refining current and/or developing additional safeguards to mitigate the risk of manipulation of candidates' waitlist priority.

Heart transplantation

Currently, organ allocation in heart transplantation assigns priority based on the amount of time on the waitlist and attempts to determine disease severity (and therefore medical urgency) based on the intensity of the therapeutic measures a patient is receiving. Patients are assigned to Status 1A (the highest priority), Status 1B, or Status 2 (lowest priority). This system relies on the assumption that the decision to institute a medical intervention accurately reflects the severity of the disease and waitlist mortality. As discussed previously, much publicity has been given to the belief that disease severity is being inflated by the unnecessary escalation of medical therapy, which has led to a dramatic rise in the number of patients listed as Status 1A.[2,3,5]

In response, a new cardiac allocation system was proposed and approved in 2016.[15] The new system aims to better stratify potential candidates based on medical severity with the stated goal of improving waitlist survival. By changing from a three-tier system to a six-tier system, the transplant community envisions that patients with the most critical need for a timely transplant will be better identified. However, this newly proposed system continues to rely predominantly on the aggressiveness of the intervention as the surrogate for disease severity. For example, in order to qualify for Status 1 listing (the highest priority), one of the following criteria must be met:

- Patient must be receiving extracorporeal membrane oxygenation (ECMO)
- Patient must be receiving continuous mechanical ventilation
- Patient must have a non-dischargeable left ventricular assist device (LVAD)
- Patient must have a mechanical circulatory support device (MCSD) with life threatening ventricular arrhythmias

Just as the prior system was vulnerable to manipulation through the aggressive use of medical interventions, the new heart allocation system continues to rely predominantly on the aggressiveness of the intervention, and is thus at risk of manipulation. In 2016, these concerns were expressed by various OPTN/UNOS regions, transplant hospitals, organizations, and the overall transplant community during the public comment period.[16] Recurring concerns have centered on the following ideas:

- Continued reliance on treatment interventions and stratification based on therapeutic aggressiveness will lead to widespread changes in clinical practice (clinicians will adapt to the new policy and treat to the priority).
- Concerns that the allocation system can be manipulated and that allocation could incentivize excessive use of specific mechanical support systems.[16]

By incentivizing its use, ECMO and other assist devices which have high complication rates (and possibly lower post-transplant outcomes) will be utilized more liberally in order to advance a patient's waitlist

priority.
The new cardiac allocation policy attempts to address some of these concerns by instituting qualifying criteria for specific interventions and placing time limits on the duration a candidate can remain on certain therapies. However, the transplant community continues to express concerns that the practice of escalating medical interventions to fit the allocation criteria was not fully addressed by the new allocation system.[5,17]

Liver transplantation

Liver grafts are allocated based on the model for end-stage liver disease (MELD) or pediatric model for end-stage liver disease (PELD) score, which have been in place since 2002[18]. A MELD score is derived from a scoring system comprised of objective laboratory values: serum bilirubin, International normalized ratio (INR), serum creatinine, and it may also incorporate serum sodium. This scoring system predicts 3-month mortality, and thus, prioritizes patients with the highest MELD scores (urgent medical need) to receive liver transplants.

Previous generations of liver allocation policies had prioritized patients who were admitted to an ICU. However, at many centers, patients on the transplant wait list were routinely admitted to the ICU for the sole purpose of gaining an advantage on the wait list.[19] When the Child-Turcotte-Pugh allocation system was introduced, it incorporated new objective criteria, but it too continued to utilize "subjective" criteria that were susceptible to manipulation, including the presence of ascites and encephalopathy, which were reported at the discretion of the treating provider.

MELD-based liver allocation considerably decreased the potential for manipulation of a patient's waitlist status by removing subjective variables (e.g., presence of ascites, encephalopathy). However, the risk for manipulation has still not been eliminated entirely. Opportunities exist for patients to receive additional MELD exception points for hepatocellular carcinoma (HCC) (the most common MELD exception), hepatopulmonary syndrome, and portopulmonary syndrome, among others. The number of applications and the approval rate for exception points varies widely by OPTN/UNOS region[20] which may contribute in part to ethnic/racial disparities in access to liver transplantation.[21] Further, determining the degree and severity of HCC remains somewhat subjective. Efforts are underway to transition to a national liver review board in an attempt to mitigate the variation that exists in the rewarding of exception points.
It is also plausible that some physicians develop strategies that deviate from sound medical norms, for the sole purpose of escalating a patient's standing on the waitlist. Examples include starting a patient on diuretics without medical indication in order to increase the patient's serum creatinine and achieve a higher MELD score. Similarly, a patient with mild to moderate renal impairment could be started on dialysis without an actual indication, which allows the patient to receive the maximum number of MELD points from their renal dysfunction. While it is not anticipated that this is common practice, these are potential areas where even an objective scoring system could be manipulated.

Lung transplantation

Lung allocation score (LAS) utilizes a comprehensive allocation scoring system that includes the need for supplemental oxygen or assisted ventilation, etiology of lung disease, functional status, diabetes, 6-minute walk distance, kidney/liver function, and a number of cardiopulmonary hemodynamic indicators.[18] Priority for a given organ is then assigned based on LAS score and time on the waitlist.

LAS uses mostly objective variables (e.g., lab results, hemodynamic parameters) that protect this organ allocation system from the risk of manipulation. However, subjective considerations are included in LAS, such as functional status. Either the physician or the patient could inaccurately suggest a functional status that is reported as more impaired than what is actually true. As a result, the patient would receive additional priority for a lung transplant. The same subjective consideration could also be true for the 6-minute walk test. If the physician informs the patient that a worse performance on the 6-minute walk test will lead to a higher placement on the transplant list, a patient is incentivized to perform poorly on the test in an attempt to exaggerate disease severity.

Kidney and/or pancreas transplantation

The Kidney Allocation System (KAS) was modified in December, 2014.[18] Allocation for kidney and/or pancreas transplantation is based predominantly on waitlist duration, with additional priority given to highly sensitized patients, pediatric patients, prior living donors, and highly immunologically matched donor-recipient pairs.

KAS is based primarily on objective criteria for determining organ allocation, and is therefore largely protected from manipulation. Unlike the other organ allocation systems, medical urgency is not necessarily considered in the standard kidney or pancreas match run and escalation of medical care has almost no impact on waitlist priority. Patients are eligible to accrue waiting time when glomerular filtration rate (GFR) reaches 20 ml/min or at the start of maintenance dialysis.

In KAS, allocation priority for the highest quality donor organs, those with a kidney donor profile index (KDPI) less than 20%, is given to candidates with an estimated post-transplant survival (EPTS) score that is less than or equal to 20%. EPTS is calculated based on four candidate factors: age, diabetes status, history of prior organ transplantation, and dialysis duration. Generally, increasing age, increasing dialysis vintage, the presence of diabetes, and prior transplantation, leads to a higher EPTS score. Due to the long kidney national waiting time, many patients who were once prioritized for these high quality kidneys may lose their priority while they are on the waitlist, typically due to increasing age or accumulating additional time on dialysis.

However, there is a subtle loophole in the EPTS determination that is largely a product of the design and structure of the formula used to calculate EPTS, and impacts non-diabetic candidates who are listed pre-emptively for a kidney transplant.[22] These patients counterintuitively have a small improvement in their EPTS score when they are started on dialysis. This EPTS benefit lasts for approximately the first five months after dialysis initiation.[22] While on the waitlist, a non-diabetic pre-dialysis patient may lose priority to the highest quality organs if their EPTS score increases above the 20% cutoff. The patient's nephrologist could choose to start dialysis even if there is no indication to do so, for the purpose of potentially lowering the EPTS back below 20%, which extends the patient's priority access to the highest quality organs for another five months.

Another potential loophole that allows for manipulation arises when patients with mild chronic kidney disease (CKD) (e.g., a GFR of 50 ml/min) develop acute kidney injury (AKI) leading to a transient GFR decline to 20 ml/min or less. If such patients fully recover renal function back to their baseline, depending on the etiology of the CKD, patients may be decades away from developing progressive CKD, and they may never require a kidney transplant. Yet, such patients do technically qualify for waiting time accrual, given the one-time GFR reading of 20 ml/min or less. This could allow such patients to accumulate years (or potentially even decades) of waiting time. While pre-emptive listing and transplantation of potential kidney transplant candidates are encouraged and associated with improved outcomes, patients with transient AKI and mild CKD are not necessarily the candidates for whom this practice was originally intended.

Summary

While physicians' fiduciary duty to "do all they can" for their patients is understandable, 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/UNOS'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 manipulation 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 OPTN/UNOS 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 OPTN/UNOS and the transplant community to ensure that providers understand expectations for upholding the principles of organ allocation.

References

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. Warmbir, Steve. “UIC hospital sued for Medicare fraud” Chicago Sun-Times, July 29, 2003.
5. 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
6. Shaw D. “Lessons from the German Organ Scandal”. The Intensive Care Society 14(3), 2013: 200-203.
7. Scanion 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.
8. Burton TM, Merrick A. “U.S. Alleges Liver-Transplant Fraud”. Wall Street Journal, July 29, 2003.
9. O’Connor M. “Transplant scandal hits 3 hospitals”. Chicago Tribune, July 29, 2003.
10. 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.
11. Snyder, J. Gaming the Liver Transplant Market. The Journal of Law, Economics, and Organization 26(3), 2010: 546-568.
12. Griffin L. Retransplantation of multiple organs: how many organs should one individual receive? Progress in transplantation. Jun 2002;12(2):92-96
13. 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.
14. Identified Versus Statistical Lives: An Interdisciplinary Perspective. I.Cohen, Oxford Press 2015
15. OPTN/UNOS Policy Notice: Proposal to Modify the Heart Allocation System (2017 December) The Organ Procurement and Transplant Network. Retrieved from https://optn.transplant.hrsa.gov/media/2028/thoracic_policynotice_201612.pdf

16. Modify Heart Allocation 2016 Second Round. The Organ Procurement and Transplant Network. Retrieved from https://optn.transplant.hrsa.gov/governance/public-comment/modify-adult-heart-allocation-2016-2nd-round/
17. Fudim M. (2017, February 9). The future of the adult heart allocation system in the United States. American College of Cardiology. Retrieved from http://www.acc.org/latest-in-cardiology/articles/2017/02/09/07/24/the-future-of-the-adult-heart-allocation-system-in-the-us
18. Policies. (2017 December) The Organ Procurement and Transplant Network. Retrieved from https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_09
19. Freeman RB, Wiesner RH, Roberts JP, McDiarmid S, Dykstra DM, Merion RM. Improving liver allocation: MELD and PELD. American Journal of Transplantation. 4(S9), 2004: 114-131.
20. Bitterman T, Maker G, Goldberg D. Exception point applications for 15 points: An unintended consequence of the Share 15 policy. Liver Transplantation, 18(11), 2012, 1302-1309.
21. Wong, RJ, Devaki P, Nguyen L, Cheung R, Nguyen MH. Ethnic disparities and liver transplantation rates in hepatocellular carcinoma patients in the Recent Era: Results from the Surveillance, Epidemiology, and End Results Registry. Liver Transplantation 20:528-535, 2014.
22. Schold JD, Buccini LD, Reese PP, Poggio ED, Goldfarb DA. Effect of dialysis initiation for preemptively listed candidates in the revised kidney allocation policy. American Journal of Transplantation. XX, 2014: 1-6.

#