OPTN POLICY (M COOPER, SECTION EDITOR)



Multi-Organ Allocation: Medical and Ethical Considerations

Mark Aeder¹ · Kenneth A. Andreoni¹

Accepted: 30 November 2021 / Published online: 27 January 2022 © The Author(s), under exclusive licence to Springer Nature Switzerland AG 2022

Abstract

Purpose of Review Since the creation of the Organ Procurement and Transplantation Network (OPTN), the allocation of deceased donated organs for transplantation has been guided by the principles of equity, fairness, and utility. Each individual organ has a well-designed policy which generates a list of eligible potential recipients, with a clearly defined prioritization based on their points. While this system works for single organ transplants, there is an increasing incidence of situations where more than one organ is requested for the recipient.

Recent Findings These multi-organ transplants (MOTs) are being performed with increasing frequency, and now exceed 2000 cases annually, comprising over 4000 of all organs transplanted. Although some organ combinations, heart–lung and pancreas-kidney, have policy-defined listing criteria and others, liver-kidney, have specific medical criteria, there are multiple considerations regarding the ability more urgent or lifesaving organ being able to "pull" the immediately non-lifesaving organ (most frequently the kidney). Currently, the candidates awaiting a kidney transplant alone have limited opportunity to be stratified for a kidney until the MOT candidates are considered, even to the exclusion of the very highly sensitized candidate. In recent analysis, the majority of kidneys utilized in MOT are those with the greatest potential post-transplant lifespan, which should have been primarily prioritized to the pediatric candidates.

Summary We examine the history of MOT and current efforts within the OPTN to address the potential for modification to promote the principles of equity, fairness, and utility. Specific issues were examined, including the prioritization of MOT recipients for the "pulled" organs, the effects on the pediatric kidney waitlist candidates, the data and risk stratification of the MOT recipients as part of the center's Program-Specific Report, and the use of accepted medical criteria, to raise the questions as to how the current policies are comprehensively reevaluated. The need for nationally accepted definitions and criteria within each organ group should be established so as to serve as a common framework for the continuous distribution models currently being proposed. We provide an algorithm for initiating this discussion, with definitions and responsibilities, and the need to encompass all considerations of every organ, including previously OPTN policy–defined combinations, to serve as a discussion template for further dialogue.

 $\label{eq:constraint} \begin{array}{l} \mbox{Keywords} \ \mbox{Multi-organ transplants} \cdot \mbox{Organ allocation} \cdot \mbox{Organ prioritization} \cdot \mbox{Transparency} \cdot \mbox{Policy development} \cdot \mbox{Ethical considerations} \end{array}$

Abbreviations

DSA	Donor service area
EPTS	Estimated Post-Transplant Survival
HRSA	Health Resources and Services Administration
Ht-Lg	Simultaneous heart-lung transplant
KDPI	Kidney Donor Profile Index

This article is part of the Topical Collection on OPTN Policy

Mark Aeder mark.aeder@uhhospitals.org

¹ University Hospitals Cleveland Medical Center, Case Western Reserve University, Cleveland, OH, USA KOT Kidney only transplant MELD Model for end-stage liver disease MO Multi-organ MOT Multi-organ transplant OPO Organ Procurement Organization OPTN Organ Procurement and Transplantation Network PSR Program-specific report SLK Simultaneous liver-kidney transplant SPK Simultaneous pancreas-kidney transplant SRTR Scientific Registry of Transplant Recipients U Units UNOS United Network for Organ Sharing

Introduction

The equitable allocation of deceased donor organs has been a major priority of the Organ Procurement and Transplantation Network (OPTN) since its creation in 1985 and national initiation, under the direction of the contractor, UNOS (United Network for Organ Sharing), in 1988 [1]. Multiple policy modifications of the allocation systems of each donated organ have been implemented over the last 30 plus years to incorporate new technologies, advances in therapies, and review of outcomes. The fundamental goal of each revision has been to balance utility with equity/fairness for all recipient candidates. The OPTN Board of Directors, the body responsible for approving these modifications to send to the HRSA secretary for ultimate implementation, is composed of a diverse membership of medical and lay personnel, transplant experts, patients and their families, and advisory and administrative leaders. The OPTN Committees, which represent the different organs transplanted as well as the operational or social aspects of organ transplantation, report directly to the OPTN Board.

Multi-organ transplantation (MOT) has been performed with increasing frequency for more than a decade and now exceeds 2000 cases annually (2,026 (2020)) [2], encompassing over 4000 of all organs transplanted. From the initial combinations of heart-lung (Ht-Lg) and simultaneous pancreas-kidney (SPK), the visceral and thoraco-visceral combinations have grown as surgical techniques, experience and supportive care have expanded the potential recipient population. Currently, Ht-Lg and SPK are the only MOT combinations with an OPTN-defined waitlist. Simultaneous liver-kidney (SLK) allocation requires a policy-defined set of medical criteria and has an incorporated Safety Net for kidney prioritization. The other MOT combinations have no specified medical criteria and, in general, have a second (or third) organ allocated, or "pulled," with the primarily allocated organ. Although the issue has been raised over the last decade regarding the justifications [3] for this practice, and has been extensively discussed by various OPTN/ UNOS Committees, MO allocation has only recently been addressed by the Policy Oversight Committee in an effort to establish allocation guidelines. Additionally, the OPTN Ethics Committee published a white paper in 2019 addressing MOT and issues of equity and utility [4••]. The specific dynamics surrounding the allocation of a second (or third) organ in a MOT have become complicated especially considering the OPTN's focus to prioritize equity in organ distribution and maximize utilization of all donated organs.

History of MOT and Current Status

Over the last 30 years, MOT has advanced from a relatively rare event to a common occurrence, averaging over 5 a day, about 6% of all deceased donor transplants. The most frequent combination of transplanted organs, SPK transplants (40.8%), spent over 2 decades with no firm national guidance as to the prioritization of candidates for organ distribution. There were different allocation algorithms established by each local distribution service area (DSA), which, more often than not, depended on the presence of more than one significant volume SPK transplant center to prioritize the double listing for their patients. The overwhelming majority of all MOTs involve the use of a kidney, frequently as the desired but non-essential organ, that is carried or "pulled" by the primary organ [5]. As the MOTs were historically governed on a local level within the individual DSA, a local transplant center would identify a recipient or recipients who would require a second organ to be carried with the primarily allocated one [6]. The center would make the request and the local OPO would usually ask the other local transplant centers to approve this combined allocation. Thus, candidates were treated unequally around the country as this MOT allocation was a local approval occurrence.

Most commonly in the past, a recipient waiting for a pancreas would have had that organ allocated and the pancreas would pull the kidney from the same donor, removing that organ from the kidney only transplant (KOT) list. As the frequency of pancreas programs increased, many DSAs developed a modified kidney waitlist, allocating the SPK combination only when the recipient reached an agreed upon priority on the kidney list, such as a minimum amount of waiting time. This priority was a local DSA agreement among the local kidney transplant centers. The OPTN, after long deliberations and discussions, adopted defined medical criteria for SPK candidates in 1998 and established SPK allocation as a distinct waitlist entity in 2010 [7].

As transplant success improved through the 1990s, patients with more acute liver, heart, and lung disease were considered for transplantation. As the severity of their clinical illness increased, it was recognized that the recipient was often in need of a kidney allograft, having poor native renal function due to the manifestations of the primary disease process added to the anticipated nephrotoxic effects of the immunosuppressive and other medications. The number of these combinations subsequently grew to almost 1000 combined transplants a year by the mid-2010s. For most of these organ combinations, there was no requirement to show the medical necessity for the second organ. After SPK, the most frequent MOT was simultaneous liver-kidney (SLK). In 2014, an ad hoc Committee of the OPTN comprising members of the kidney, liver, patient affairs, pediatrics, and OPO Committees met to address this issue, which resulted in the passage of a defined SLK allocation policy in 2018 [5, 8, 9]. For the first time, medical necessity criteria were attached to MOTs beyond SPK, and a new concept, the medically indicated Safety Net, was established. The Safety Net was a compromise that allowed acceptance of reasonable medical necessity for primary SLK allocation while allowing for kidney only allocation priority to post-liver transplant recipients who did not recover or lost native renal function. The Safety Net would only apply to those candidates who did not receive a kidney at the time of their liver transplant. Since most patients recover native renal function after successful liver transplant, this policy was expected to decrease the number of kidney allografts going unnecessarily to liver failure patients [8].

Although the numbers of SLK transplants initially decreased, they have recently returned to pre-policy levels and the numbers of MOTs presently continue to rise [2]. The current increase in the medical acuity of candidates presenting to transplant centers with multi-organ failure is driving a new need for multi-organ replacement therapy, especially when the secondary organ has either failed or is irreparably damaged. In 2017, the OPTN Ethics Committee was charged with creating a white paper on MOTs. Presented with comments in 2019, it provided extensive insight into the multiple aspects of MOTs, addressing the equity and utility considerations for each of the issues raised [4••]. By design, this paper did not make any attempt to include the specific effects of MOT on the pediatric kidney allocation or SPK transplants. Although the SPK candidates must fulfill standard criteria for kidney listing, the Ethics Committee did not address the utility/fairness of SPK recipients, nearly 43% of all MOTs (2018–2020), that have preferential access to higher quality kidneys ahead of the KOT waitlist population.

Another contribution to the consideration for and listing of patients for MOTs is the lack of data available for the completed transplants. In discussion for almost a decade, the HRSA statistical contractor, the Scientific Registry for Transplant Recipients (SRTR), has not implemented calculations for assessing the appropriately risk-adjusted outcomes of these MOTs. Although a high MELD recipient of a liver organ alone has an expected risk-adjusted outcome and is incorporated into the transplant center's program-specific report (PSR), once a kidney is added to the transplant, there is no national database reporting of the expected outcome of either of the individual organs or that of patient survival. Although the actual outcomes are reported and there is a national outcome average, there are no risk-adjusted expectations calculated and the outcomes of the center's MOTs do not affect the public outcome grading for any of the organs transplanted. Interestingly, with the institution of the kidney Safety Net in the SLK allocation policy, each organ transplant is now followed as a unique follow-up event in the program's national data, their PSR. By not having risk-adjusted outcome metrics, the true utility of the MOT cannot be assessed. Of the abdominal MOTs, only SPK is reported by the SRTR; however, these numbers can be clouded by organ failure definition inconsistencies. While the OPTN defines pancreas failure as removal, registered for a pancreas, received subsequent islets or insulin > 0.5U/kg for 90 days [10], there is considerable debate ongoing as to using those metrics in addition to HgA1c and differing definitions for Type I and Type II diabetic recipients. Some patients consider the necessity of any insulin to be a failure while others may accept an insulin dosage reduction of 50% a success.

Questions of Equity and Utility in Kidney Allocation

How should considerations for pediatric candidates waiting for transplant affect priority for MOTs?

This is a fundamental question partially addressed by the Ethics Committee white paper of 2019. The specific exclusion of the considerations of pediatric candidates and the failure to consider the impact of prioritizing the SPK candidate are, by the Committee's admission, a marked weakness rendering the summarization incomplete. Clearly the entire scope of organ prioritization requires an evaluation to assess the impact on equity, fairness, and utility and, for that, all organs retrieved for transplant must be considered [4••].

An accepted premise is that not every allocated organ will achieve maximal equity and utility. The Kidney Allocation System (KAS) instituted in 2014 tried to move the bar in that direction by creating a scoring system which identified the Kidney Donor Profile Index (KDPI) and the Estimated Post-Transplant Survival (EPTS). The aim was to match those organs with the most favorable potential outcomes (low KDPI, < 20%) with those candidates who would have the longest projected lifespan after transplant (EPTS < 20%). This would maximize the utility and, in an eligible pool of recipients, address equity. Earlier versions of KAS used the term LYFT (Life Years from Transplant) with inclusion of all KDPI and EPTS values and strategies to align the potential function of the organ with the potential survival/need of the recipient, but LYFT was considered too restrictive to higher EPTS candidates and difficult to understand by many transplant professionals and patients [11].

There has been a marked difference in allocating organs that are considered immediately lifesaving versus those that are not. Should the urgency to receive one organ pull the allocation of a second organ which is desirable but not urgent? In reality, this second organ is usually a kidney allograft. The SLK policy was instituted with the understanding that the initial parameters would be followed and assessed by outcomes. Given the lack of detailed SRTR reporting of SLK recipient outcomes, it is difficult to deduce meaningful comparative data of these MOTs. Initial follow-up of kidney allograft survival in SLK recipients collected by the OPTN shows that there is a 5.5% decrease in 1-year kidney graft survival in SLK vs KOT (kidney graft survival 89.08 vs 94.64%) [12•]. Having such a marked difference (approximately twice the rate of kidney loss at 1 year) should necessitate the re-evaluation of allocation of non-immediate lifesaving organs. This is especially true considering that kidney graft survival in prior liver transplant recipients, when implanted after liver transplant, has identical outcomes to KOT, thus favoring the use of the Safety Net [8, 9, 12•].

SPK transplantation allocation prioritization is more complex since the Type I diabetic patients with renal disease have a higher death rate on the kidney waiting list compared to the rest of the KOT population (see below). The creation of a separate waiting list, which gives these patients access to kidney allografts years ahead of KOT, was considered a fairness in access. As the overall kidney survival of the SPK recipients similar to the KOT recipients, the utility of organ use is also fulfilled. The ongoing debate is whether this outcome justifies bypass of the very highly sensitized and pediatric KOT recipients in favor of the SPK, especially as this primarily involves the utilization of the "best" kidneys available. This aspect will be further discussed below.

To summarize allocation, the equity considerations are not maintained between MOT and KOT, and the utility appears to be valid only in the select Type 1 diabetic SPK population, but at a cost of utilizing the best donated kidneys (predominantly low KDPI) in this MOT.

KDPI of MOT

As noted above, a significant factor in the allocation of kidneys is the KDPI or quality of the donor allograft. This value drives the allocation sequences, which in turn prioritizes the differing patient groups on the match run list. To briefly review, the 0–20% KDPI donor kidneys are expected to have the best chance to function for the longest possible time and by policy have been prioritized to the pediatric and the 20% of the candidate list with the longest Estimated Post-Transplant Survival (EPTS). Examining all MOTs performed in 2017, the MOT recipients received 22.8% of the KDPI 0–20% and 12.7% of the KDPI 21–35% kidneys (kidney allocation sequences A and B). Breaking this down further, 86.7% of SPK transplants, 46.4% of SLK transplants, and 67.8% of the remaining MOTs utilizing a kidney were from the 2 most favorable sequences, the 35% of all donor organs that would have the best overall function and the ones prioritized to the pediatric and younger adult KOT recipients. Interestingly, only 32.8% of all MOT recipients received a kidney with a KDPI > 35 [13]. Although only 5.3% of all kidney transplants in 2017 went to SPK recipients, nearly 87% of these kidneys were from the "best" (the top 35%) of all deceased donors. The Ethics Committee, in association with other OPTN/UNOS stakeholder committees, should discuss these MOTs so that the principles of utility and equity, with regard to the intent of the KDPI sequence prioritization, can be maintained. These principles should apply to all potential recipients without any disadvantage (or conversely any advantage) to any recipient group.

In the situation of an "ideal" donor, one with a low KDPI, and who would potentially be able to donate multiple organs, the heart, two lungs, the liver, the pancreas, and two kidneys and potentially even the small intestines, the OPO will run the recipient lists with attention to maximally placing the organs. There are certain prioritizations that need to be considered, with an "unofficial" order of allocation of usually the heart, then lung, then liver, then pancreas, and then the kidneys (small bowel transplantation is rare). Any extrarenal recipients on the list are examined to see if they are to be considered for a "pulled" kidney (heart-kidney listing, lung-kidney listing, medical criteria for the SLK, or SPK list) to travel with the extra-renal organ. If both kidneys are allocated to these extra-renal recipients, then there would not be a kidney for a KOT candidate, a category which would certainly include the highly sensitized and possibly the pediatric recipients.

Another consideration is the utilization effect that the availability of a kidney has on the placement of the other organs, particularly the pancreas. If both kidneys are used as a MOT with the heart, the lung, or the SLK, then the pancreas has a greater likelihood of not being used as a single organ transplant (compared to SPK). If the potential heart and liver recipients each requested or were eligible for a simultaneous kidney, then in all likelihood, the pancreas would not be utilized as a single organ, with the OPO receiving credit for 6 organs transplanted (organs per donor). If, instead, either the liver or the heart was placed as a single organ, then there would be the opportunity to offer one of the kidneys with the pancreas, with the OPO then placing 7 organs (the pancreas is now transplanted as well). In both scenarios, the KOT candidates would not have an opportunity to receive a kidney.

To summarize, the lack of a nationally defined order within the allocation process for all organs needs to be addressed. Currently, there is no direction as to which list the OPO should prioritize for each individual donor, and this decision will then likely drive MOT allocation. Currently, there are different priorities driving each organ list with medical urgency being the key factor for the liver, heart, and lung and waiting time for the kidney and pancreas. Having an established algorithm would assist in mitigating the potential differences in prioritization, and possibly improve the fairness in distribution of organs to candidates on the list.

The Concept of "Lifesaving" Versus "Non-lifesaving" Organ Transplant

Although transplants such as the heart, lung, and liver are traditionally considered "immediately lifesaving" transplants, some Type I diabetics receiving SPK transplants as well as patients who medically qualify for a KOT transplant gain many years of life lived after transplant compared to standard of care medical treatment.

The average adult who receives a kidney transplant is expected to live twice as long with their transplant as they would on traditional dialysis. Children gain even more years from transplantation. In many cases, these kidney alone recipients will gain more years of life than a patient is expected to live after a lung transplant [14]. Over 30% of patients listed for a pancreas transplant die before they are offered a transplant with the SPK waitlist candidates' mortality at 5.6 per 100 waitlist years and only 0.9 per 100 waitlist years for pancreas after kidney (PAK) transplant (2019). This latter value clearly demonstrates the life extending effect of a kidney alone transplant into a diabetic patient. This knowledge of a very high relative death rate of the Type I diabetic candidate on the kidney transplant list compared to non-Type I diabetics is what led to the local DSA prioritization of SPK recipients over KOT more than 20 years ago. The results and outcomes have been favorable in this select group but at the expense of disadvantaging the very highly sensitized KOT and the pediatric populations from lifesaving opportunities. With years of outcomes data, this should be carefully evaluated. In the discussion of SLK allocation, the lower long-term survival of both the liver and kidney allograft in these SLK patients led to much discussion in the field. The likely advantage of the liver failure patient with concomitant kidney failure also receiving a kidney allograft from the same deceased donor resulted in the final medical criteria for SLK listing and the creation of the Safety Net for those liver recipients who did not recover native renal function.

In kidney alone transplantation, Schold et al. [15] demonstrated the life extending benefit of KOT. Considering only patients who were healthy enough to be listed for kidney transplantation (the healthiest patients on dialysis), actually receiving the transplant compared to remaining on the waiting list resulted in a 26% greater chance of survival at 5 years after transplant or being placed on the waiting list. For all dialysis patients, this life extending benefit doubles life expectation [16]. Therefore, we would suggest that all transplants are significantly life extending. Not all recipients of heart, lung, or liver allografts are expected to die within the next several days, so even for these organs, most of recipients have profound extension of their life expectancy as opposed to immediate lifesaving procedures. This may appear to be word play, but as the transplant community moves to increasing access to older and sicker candidates, more candidates are likely to be in need of multiple organs-usually with the need for a kidney allograft-with the non-renal transplant often being in a state of less medically urgency. The patients who have Stage 4 or 5 CKD, or perhaps even starting dialysis, and cirrhosis with otherwise compensated liver function are a prime example. They truly need a kidney transplant, but their portal hypertension often precludes a safe kidney alone transplantation. If these patients are fortunate enough to have access to a combined liver-kidney allocation, they may draw a kidney allograft with much less waiting time than other similar ESRD patients. Their longterm survival, the organ utility, will be less than a kidney only recipient due to their liver transplant procedure. How to balance utility, equity, and fairness in this situation is a Solomon-like task.

Data Follow-up

A major issue is the data follow-up associated with the MOT. Although this deficit has been recognized for over a decade, there is still no Scientific Registry for Transplant Recipients (SRTR) report for many MOT outcomes [17]. Additionally, if there is a MOT, an SLK for example, the entire transplant is not included on the transplant center's Program-Specific Report (PSR) for the liver outcome. Only the SPK and Ht-Lg have complete risk-adjusted SRTR follow-up data as MOT, leaving over 3% of all organ transplant recipients and 6% of all organs without any risk-adjusted outcome measures. For the SPK, we do have reliable data showing that the longterm survival of the kidney allograft is excellent in these MOT recipients with 10-year death censored renal allograft failure at only 21.4%, close to the 18.5% rate for living donor recipients who received a pancreas after kidney transplant. In comparison, 5-year heart allograft only failure is nearly 40% and just over 40% patient death for lung recipients with 10-year lung graft recipient death over 60%. Scientific and best practices should emphasize the necessity to not only follow the outcome of each organ into every recipient but to use the data to further define future modifications to the allocation priorities. This is a situation where we have limited data to even assess utility or equity. Balancing the utility of the MOT transplant which utilized a kidney allograft should be the focal point of MOT allocation prioritization discussions.

Path Forward (Table 1)

The growth of MOT has become a major issue for consideration and has propelled current discussion within the OPTN. A structured allocation algorithm is necessary to maintain the goals of utility and equity/fairness and to protect the integrity of the organ allocation system. This needs to occur on multiple levels [18–21].

First, on the OPO/DSA level, a prioritization stratification should be employed that, at the first level, will categorize the potential need for each organ as immediately or urgently lifesaving, with a critical time frame for transplantation that differentiates these candidates from those that are not as urgent, for instance a liver candidate with a MELD of 38 versus a MELD of 15. Both are benefitted and should receive the liver but for the first patient, there is likely a more critical time–based urgency. This could also be extended to the kidney candidate who is out of potential access sites and is in the critical need for a kidney.

Once these considerations have been prioritized, the process of assessing a medical criteria-based allocation of a second organ to be pulled with the first can begin. The need to establish a stratification prioritization that promotes and enhances the utility and equity of all organs must be maintained. Although the current practice is to permit kidneys to be pulled with other organs regardless of the needs of the kidney alone recipients, this group has its own internal critical and vulnerable recipient population $[22\bullet]$.

The third aspect of this distribution paradigm is to incorporate the donor KDPI into the process. As at least twothirds of all kidneys pulled onto MOTs are within sequences A and B, those with the potential for maximal utility, these kidneys must be prioritized according to their excellent potential for all recipients. The Safety Net policy for prior liver recipients meeting kidney allocation criteria within the first year after liver transplant alone recognizes this demarcation as only kidneys with a KDPI of greater than 35 are included in the distribution (sequences C and D). The science behind that policy development must be incorporated into the final distribution of all pulled kidneys (Table 1).

Finally there has to be transparent reporting of the outcomes of all organs transplanted. Programs need to report and be accountable for the decisions of patient and organ selection and review their data regularly on their PSR. Currently, there is variability within the system to which combinations are risk adjusted reported (SPK is and SLK is not) as well as the definition of what constitutes the failure of the transplanted organ (any insulin requirement versus less

Table 1 Proposed clarification algorithm for MOT and SOT

- 1 Classify donor organs as immediately lifesaving (ILSO), urgently lifesaving (ULSO), or life-enhancing (LEOT)
 - 1a ILSO recipient candidates should be clearly defined (i.e., MELD, heart status, etc.) with absolute values to define status, or have an anticipated candidate survival of 1 week without transplant
 - 1b ULSO recipient candidates should be those who do not meet ILSO criteria but have clearly defined medical criteria (i.e., MELD, cardiac status, true 100% sensitization, etc.) that would pre-emptively increase chances of avoiding ILSO status or severely limit future opportunity
 - 1c LEOT candidates should include those who do not qualify for an ILSO or ULSO organ and who have a stable mechanism for addressing their organ failure
- 2 Establish a national review board, or regionally adjudicated review boards, which subscribe to a national standard for MOT that can direct oversight of the above classifications and can make exceptions on a case by case basis
 - 2a Board will approve candidates for MOT by nationally defined patient medical criteria for the second (or third) organ
 - 2b Board will re-review candidate status for MOT as requested with clinically relevant change in medical condition
- 3 Establish transparency in MOT
 - 3a Require submission of all data and follow-up to the OPTN Data Contractor
 - 3b National reporting of the program-specific outcomes of all MOT by center
- 4 Develop defined allocation stratification sequences for each organ that would be considered "secondary" to the primary transplanted organ addressing equity and utility while protecting disadvantaged recipient populations
- 5 Develop defined prioritization sequences for OPO distribution of ILSO and ULSO so that the offers maintain a national standard for equity and utility across all recipient lists
- 6 Establish a "Safety Net" policy for all patients who would have been either (1) medically eligible for a MOT and receive a single organ transplant (SOT), or (2) did not have an ILSO necessity for the second organ and received a SOT, or (3) developed irreversible failure of the second organ following the SOT of the primary organ, with a defined time limit for prioritization for the second (or third) organ
- 7 Policy(s) will be reviewed biannually by representative MOT workgroup for assessment of impact on disadvantaged populations (i.e., pediatric, true highly sensitized, racial and ethnic minorities) and overall outcomes
 - 7a Ethics Committee to focus on transparency in allocation of organs adhering to principles of utility and equity
 - 7b OPTN Board of Directors will review data for recommendations for policy modifications

than half the pre-transplant insulin requirement versus any reduction in insulin for the pancreas or dialysis for 3 months or 4 months and so on for the kidney). Nationally accepted definitions should be adopted and the data for all organ outcomes should be nationally reported.

Once these four components can be adjudicated, no small task especially considering the proposed continuous distribution models, then the primary principles of equity, fairness, and utility be achieved [4••, 18, 20]. It will require the cooperation of all stakeholders, who, in addition to advocating for their populations, are to also be sensitive to the needs of their colleagues within the national system.

Declarations

The authors (MA and KA) do not have any conflicts of interest with regard to the contents of this manuscript. They have no financial relationships to disclose. The above review does not contain any unique studies involving human or animals and represents a summary of the current literature and potential for future directions.

References

Papers of particular interest, published recently, have been highlighted as:

- Of importance
- •• Of major importance
- National Organ Transplant Act (NOTA; P.L. 98–507). 1984. https://www.congress.gov/bill/98th-congress/senate-bill/2048. Last Accessed 11/5/2021.
- OPTN/UNOS Data. Organ Procurement and Transplantation Network Website. https://optn.transplant.hrsa.gov/data/. Last accessed 11/5/2021.
- Wolf JH, Sulewski JR, Cassuto MH, et al. Simultaneous thoracic and abdominal transplantation: can we justify two organs for one recipient. Am J Transplant. 2013;13(7):1806–16. https://doi.org/ 10.1111/ajt.12291.
- 4.•• Ethics implications of multi-organ transplants: OPTN Ethics Committee White Paper. 2019. This paper is a well-referenced resource of the ethical considerations for the multi-organ process, divided into distinct sections to examine specific characteristics of the current policy. It avoids addressing the issues of pediatric and SPK transplant.https://optn.trans plant.hrsa.gov/media/2989/ethics_boardreport_201906.pdf. Last Accessed 11/1/2021.
- Westphal SG, Langewisch ED, Robinson AM, et al. The impact of multi-organ transplantation allocation priority on wait-listed kidney candidates. Am J Transplant. 2021;21(6):2161–74. https://doi.org/10.1111/ajt.16390.
- OPTN Allocation Policies: 5.10.c: Allocation of multiorgan combinations. https://optn.transplant.hrsa.gov/media/eavh5 bf3/optn_policies.pdf. Last accessed 11–1–21.
- OPTN Allocation Policies: Policy 11: Allocation of Pancreas, Kidney-Pancreas and Islets. https://optn.transplant.hrsa.gov/ media/eavh5bf3/optn_policies.pdf. Last accessed 11–1–21.
- 8. Aeder MI. Simultaneous liver-kidney transplantation: policy update and the road ahead. Curr Transpl Rep. 2018;5:130–8. https://doi.org/10.1007/s40472-018-0190-0.

- Simultaneous Liver Kidney Allocation Policy. OPTN/UNOS Kidney Transplantation Committee. https://optn.transplant. hrsa.gov/media/1192/0815-12_slk_allocation.pdf. Last accessed 11/1/2021.
- Definition of Pancreas Graft Failure. Pancreas Transplantation Committee, OPTN. 2014. https://optn.transplant.hrsa.gov/media/ 1572/policynotice_20150701_pancreas.pdf, Last accessed 11/5/2021.
- Stegall MD, Stock PG, Andreoni K, Friedewald JJ, Leichtman AB. Why do we have the kidney allocation system we have today? A history of the 2014 kidney allocation system. Hum Immunol. 2017;78(1):4–8. https://doi.org/10.1016/j.humimm.2016.08.008.
- 12. Altshuler PJ, Shah AP, Frank AM, Glorioso J, Dang H, Shaheen O, Patel K, Ramirez CB, Maley WR, Bodzin AS. Simultaneous liver kidney allocation policy and the Safety Net: an early examination of utilization and outcomes in the United States. Transpl Int. 2021;34(6):1052–1064. Published online 2021 May 19. https://doi.org/10.1111/tri.13891. As the first multi-organ combination to have a policy directive defining medical necessity, liver-kidney, this is a review of the early outcomes, gaps, and successes of the policy.
- Aeder M, Turgeon N. Multi-organ (M-O) prioritization of kidneys: time for policy modification? [abstract]. https://atcmeeting abstracts.com/abstract/multi-organ-m-o-prioritization-of-kidne ys-time-for-policy-modification/. Last accessed 11/5/2021.
- 2019 Annual Data Report. Scientific Registry of Transplant Recipients. http://srtr.transplant.hrsa.gov/annual_reports/2019_ ADR_Preview.aspx. Last accessed 11/5/2021.
- Schold JD, Buccini LD, Goldfarb DA, Flechner SM, Poggio ED, Sehgal AR. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. Clin J Am Soc Nephrol. 2014;9(10):1773–80. https:// doi.org/10.2215/CJN.02380314.
- Kaballo MA, Canney M, O'Kelly P, Williams Y, O'Seaghdha CM, Conlon PJ. A comparative analysis of survival of patients on dialysis and after kidney transplantation. Clin Kidney J. 2018;11(3):389–93. https://doi.org/10.1093/ckj/sfx117.
- Scientific Registry of Transplant Recipients. https://www.srtr. org/. Last accessed 11/5/21.
- Reese PP, Veach RM, Abt PL, Amaral S. Revisiting multiorgan transplantation in the setting of scarcity. Am J Transplant. 2014;14(1):21–6.
- OPTN/UNOS Clarify Multi-Organ Allocation Policy Public Comment Proposal January 2021. https://optn.transplant.hrsa. gov/media/4354/2021_pc_opo_clarify_multi_organ_allocation_ policy.pdf. Last Accessed 11.1.2021.
- OPTN/UNOS White Paper, Ethical Considerations of Continuous Distribution in Organ Allocation, submitted August 2021. https://optn.transplant.hrsa.gov/media/4778/ethical_considerat ions_of_continuous_distribution_in_organ_allocation.pdf. Last accessed 11.1.2021.
- Stites E, Wiseman AC. Multiorgan transplantation. Transplant Rev. 2016;30(4):253–60. https://doi.org/10.1016/j.trre.2016.04.002.
- 22• Cheng XS, Reese PP. Incorporating kidney related multi-organ transplants into the kidney allocation sequence. Am J Transplant. 2021;21:2614–5. https://doi.org/10.1111/ajt.16542 In this relatively short comment, the authors raise key issues for the consideration of the multi-organ stratification process. This is well outlined in the table.

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.