

## Briefing Paper

# Ethical Implications of Multi-Organ Transplants

*OPTN Ethics Committee*

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# Ethical Implications of Multi-Organ Transplants

*Affected Policies:* N/A  
*Sponsoring Committee:* Ethics Committee  
*Public Comment Period:* January 22, 2019 – March 22, 2019  
*Board of Director's Date:* June 10-11, 2019

## Executive Summary

The allocation policies for multi-organ transplant (MOT) have the potential to create inequity in the organ distribution process, either in the rate of transplantation or in the time that candidates wait to receive transplants. Such potential inconsistencies may affect the patients who are awaiting MOT as well as those who are awaiting single organ transplant (SOT) because both groups depend upon available organs from the same limited donor pool. Prioritization of MOT candidates and the allocation rules for each combination have not been standardized across the different organs. As a result, the current allocation system has generated confusion in the transplant community about the rationale for differences in MOT allocation systems between different organ combinations.

The OPTN Ethics Committee (hereafter “The Committee”) performed an analysis of policy and relevant literature focusing on the potential conflicts in the principles of equity and utility in the allocation of multi-organ transplants. Ultimately the Committee affirmed that MOT should reflect a balance between equity and utility, with the understanding that no system can maximize both. Because the ethical issues of equity and utility that MOT raises are common with all organ combinations, the ethical principles must be carefully considered and weighed in the development and modification of MOT policy. This white paper details the ethical dilemmas that arise from conflicts between equity and utility and the recommendations of the Committee regarding the allocation of multi-organ transplants.

The 2018 OPTN Strategic Plan called for the OPTN to “measure equity in allocation, including geographic disparities and multi-organ disparities.”<sup>1</sup> This white paper lays the foundation for other committees to clarify or modify existing multi-organ allocation policy and to do so in a consistent, principled manner, which aligns with the OPTN strategic goal to provide equity in access to transplant.

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<sup>1</sup> OPTN Strategic Plan 2018-2021, available at: <https://optn.transplant.hrsa.gov/governance/strategic-plan>.

## What problem will this resource address?

Prioritization of multi-organ transplant (MOT) candidates and the allocation rules for each combination have not been standardized across the different organs. The allocation policies for MOT have the potential to create inequity in the organ distribution process, either in the rate of transplantation or in the time to transplantation. Such potential inconsistencies may affect the patients who are awaiting MOT as well as those who are awaiting single organ transplantation because both groups depend upon available organs from the same limited donor pool. The prevalence of MOT has increased over the past two decades, with more patients being listed for, and undergoing, MOT each year (see *Table 1: Combinations of organs involved in MOT and their frequencies* on page 10).<sup>2</sup> This increase underscores the importance of addressing conflicts between equity and utility that may exist in the current multi-organ allocation policies.

The white paper identifies the following ethical dilemmas that indicate an impact on equity, utility or both:

- MOT and need for transplant
- MOT and the redirecting of organs from single organ transplant (SOT) waitlists
- MOT and organ quality
- MOT and alternative support treatments
- Prioritization of MOT over SOT
- MOT and protected subgroups
- Monitoring MOT
- MOT and fairness to patients awaiting SOT
- MOT and standardized criteria
- MOT and relative futility
- Impact of adult MOT on pediatric SOT

A full discussion of each of these ethical dilemmas and the recommendations of the Committee can be found in the white paper itself, attached to this document.

## Why should you support this resource?

This white paper provides an ethical framework for approaching policy changes to MOT allocation. It identifies the ethical dilemmas that could arise in developing policy solutions for MOT, and provides recommendations that would represent an important foundation for the OPTN to use in determining potential MOT policy modifications.

The analysis provides a careful examination of the ethical implications of MOT transplant, especially regarding the ethical principles of equity and utility. Apart from its usefulness in providing guidance for any future changes to MOT policy, the white paper helps inform and empower members of the transplant community to consider MOT as a transplant option for appropriate candidates.

## How was this resource developed?

### *Initial Development of Project*

MOT transplant policies across different allocation systems have been developed piecemeal and have not been addressed systematically to ensure equity and consistency.<sup>3,4,5</sup> Challenges that may arise from

<sup>2</sup> 2018 OPTN data, available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>, (accessed December 15, 2018).

<sup>3</sup> *Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list*, OPTN Pancreas Transplantation Committee, March 3, 2009.

<sup>4</sup> *Proposal to substantially revise the national kidney allocation system*, OPTN Kidney Transplantation Committee, June 24, 2013.

<sup>5</sup> *OPTN Thoracic Report Summary*, OPTN Thoracic Transplantation Committee, June 24, 2010.

MOT allocation have been noted in previous reports to the OPTN Board.<sup>6,7</sup> To address these concerns, the Policy Oversight Committee (POC) submitted a memorandum to the Committee in 2012 to consider the ethical implications of MOT allocation.<sup>8</sup> The Committee considered the POC's questions and issued a response highlighting the need to consider equity and utility, in accordance with the Final Rule, when addressing challenges related to MOT allocation.<sup>9</sup> In 2016, the Committee began work on a document regarding MOT policies and the potential ethical principles impacted. However, the project was never approved by the Executive Committee due to conflicts with strategic plan alignment and was later placed on hold. In February 2018, the project was taken off hold due to changes in OPTN strategic priorities and recognition of the importance of addressing MOT allocation.

The Committee focused on the general ethical principles related to MOT allocation instead of the challenges inherent in individual allocation systems. Committee members were in agreement that focusing on the ethical implications for both adult and pediatric populations would add too much complexity to the current project and favored addressing pediatrics in a separate and future project.

#### *Data Request*

The Committee submitted a data request regarding MOT and kidney-alone transplantation to provide evidence on the utility of MOT compared to SOT. This descriptive data analysis used a cohort from 2015 to 2017 and compared MOT recipients (with kidney as one of the organs transplanted, excluding kidney-pancreas) and kidney-alone recipients across a number of different factors, including: geography, age, sex, race, blood type, kidney donor profile index (KDPI), post-transplant patient and graft survival, waitlist removal, glomerular filtration rate (GFR), and calculated panel reactive antibodies (CPRA).<sup>10</sup> The Committee excluded kidney-pancreas (KP) from the data analysis because it considered KP as a single organ transplant from an ethical point of view, the reasons for which are discussed in the section "Was this resource changed in response to public comment?" (pages 7-8). The Committee focused its request on kidney transplants because most MOT performed are in combination with a kidney.<sup>11</sup> The request focused on adult candidates as the issues with pediatric MOT may significantly differ.

Overall, this analysis found that, compared to kidney alone (KI), recipients of MOT were significantly more likely to be white.<sup>12</sup> The analysis also found MOT recipients were more likely to come from zip codes with higher median incomes. MOT recipients overall were more likely to have a CPRA of 0% compared to KI recipients, who were more likely to have an elevated CPRA. MOT recipients tended to be older than KI recipients. MOT recipients also had significantly higher median and mean estimated GFR compared to KI. Finally, death rates on the wait list for MOT were significantly higher than KI and time to transplant for KI recipients was significantly longer than for MOT recipients.<sup>13</sup> These factors were considered in the development of ethical discussions in the white paper and incorporated when appropriate (see "Development of MOT White Paper," below, for the sections that were modified).

#### *Development of MOT White Paper*

The Work Group within the Committee tasked with developing the white paper was comprised of transplant professionals and bioethicists whose expertise is especially pertinent in evaluating ethical implications of MOT. The Work Group's discussion and evaluation of the balance of equity and utility in MOT and SOT allocation helped develop the substance of the white paper. Additionally, the Work Group evaluated relevant literature that discussed the ethical implications of MOT, which informed the ethical discussions in the white paper and which are cited when applicable.

<sup>6</sup> *OPTN OPO Report Summary*, OPTN OPO Committee, February 26, 2008.

<sup>7</sup> *OPTN Policy Oversight Committee Interim Report*, OPTN Policy Oversight Committee, October 16, 2007.

<sup>8</sup> *OPTN Ethics Report Summary*, OPTN Ethics Committee, June 28, 2012.

<sup>9</sup> *OPTN Ethics Report Summary*, OPTN Ethics Committee, August 22, 2012.

<sup>10</sup> *OPTN Descriptive Data Request. An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>11</sup> 2019 OPTN data, available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>, (accessed January 3, 2019).

<sup>12</sup> *OPTN Descriptive Data Request. An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>13</sup> *Ibid.*

The Committee reviewed the data analysis at its in-person meeting in Chicago, IL on October 29, 2018. The Committee agreed the data was supplementary to the ethical analysis, not the main focus of the white paper. The data helped the Committee strengthen and enhance certain portions of the draft white paper. Specifically, the data analysis supplemented sections regarding protected subgroups and potential disparities in socioeconomic status (SES) and race for SOT candidates compared with MOT candidates. The Work Group also highlighted the results regarding organ quality and waitlist mortality for MOT compared to SOT patients. The Committee agreed to add two appendices to highlight the geographic differences and similarities between KI transplants and MOT.

MOT ethical issues touch all OPTN committees in some capacity. Recognizing the importance of stakeholder feedback prior to public comment, the Committee distributed a draft white paper, updated with relevant information from the data analysis, to all committees for a chance to review and provide feedback. On November 29, 2018, the Committee held a one hour conference call to allow the opportunity for other committees to discuss their questions and comments. Members of the OPTN Pediatrics, Minority Affairs, and Pancreas Committees participated.<sup>14</sup> Feedback was also obtained from an Operations and Safety Committee member, the Patient Affairs Committee (PAC) and stakeholders with liver transplantation experience.

Members of the Pediatric and Patient Affairs Committees expressed concern that the paper does not focus extensively on pediatric patients, and KP should be considered as it relates to prioritization for pediatric patients. In contrast, the Pancreas Committee felt that the paper adequately addressed why KP was not included in MOT and found it appropriate that KP be considered differently than other MOT. Pre-public comment feedback also focused on clarifying what “life-saving” organs are, and when organs may be “life-saving” or “life-enhancing”.<sup>15</sup>

In response to these comments, the Committee added a section to the paper titled **Section L: Impact of Adult MOT on Pediatric SOT** and clarified the scope of the paper as it relates to pediatric and adult MOT in the introduction. Additionally, the Committee modified the introduction to clarify the use of the term “life-saving” throughout the paper.

Generally, pre-public comment feedback was positive, indicating the paper was clear, well written and easy to understand. The Committee voted to send the white paper out for public comment on December 20, 2018. Through email by January 8, 2019, all Committee members unanimously voted that the Committee incorporate language clarifying the impact on pediatric patients with MOT.

## How well does this resource address the problem statement?

The white paper identifies several potential ethical conflicts between equity and utility in the allocation of multi-organ transplants. The Committee provides an overview of the ethical dilemmas, the resulting impact on equity and utility, and recommendations based on the ethical discussion. These recommendations and discussions of the ethical consequences of MOT directly address the problems of lack of clarity and inconsistency with current MOT allocation. This is accomplished by clearly describing the relevant ethical implications of MOT and providing guidance to the transplant community and public.

## Was this resource changed in response to public comment?

Yes, this proposal was changed in response to public comment. Below is a summary of public comment feedback and themes; Committee discussion and response to public comment; and additional changes made to the white paper.

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<sup>14</sup> Meeting Summary for November 29, 2018 meeting, OPTN Ethics Committee, available at: [https://optn.transplant.hrsa.gov/media/2875/20181129\\_ethics\\_committee\\_minutes.pdf](https://optn.transplant.hrsa.gov/media/2875/20181129_ethics_committee_minutes.pdf).

<sup>15</sup> Ibid.

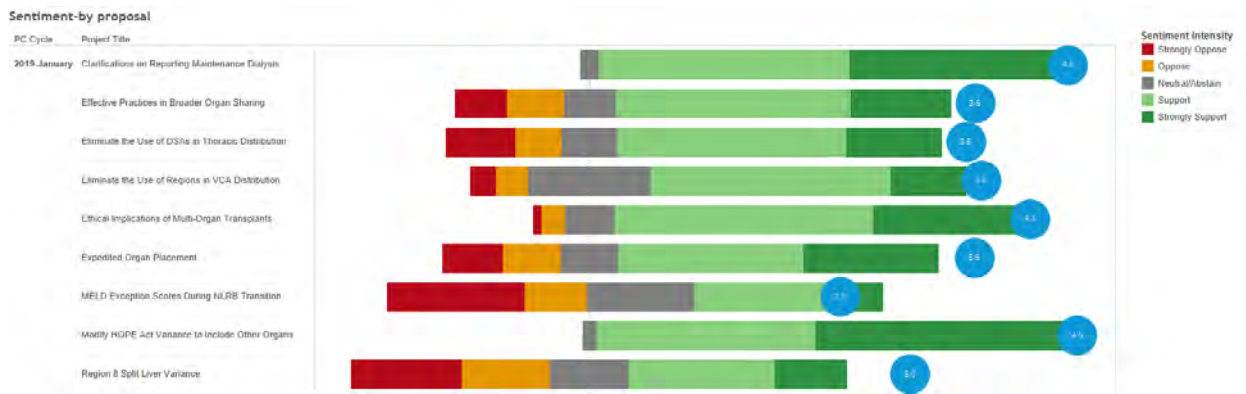
### Public Comment Feedback and Themes

The white paper was received positively during public comment, supported by all 11 regions and the American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), American Society for Histocompatibility and Immunogenetics (ASHI) and American Nephrology Nurses Association (ANNA). The Committee received feedback from:

- 11 regions
- 4 organizations (AST, ASTS, ASHI, ANNA)
- 8 OPTN Committees (Thoracic, Minority Affairs, Transplant Coordinators, Patient Affairs, Pediatric, Liver, Pancreas, OPO)
- 5 individuals
- 2 transplant programs

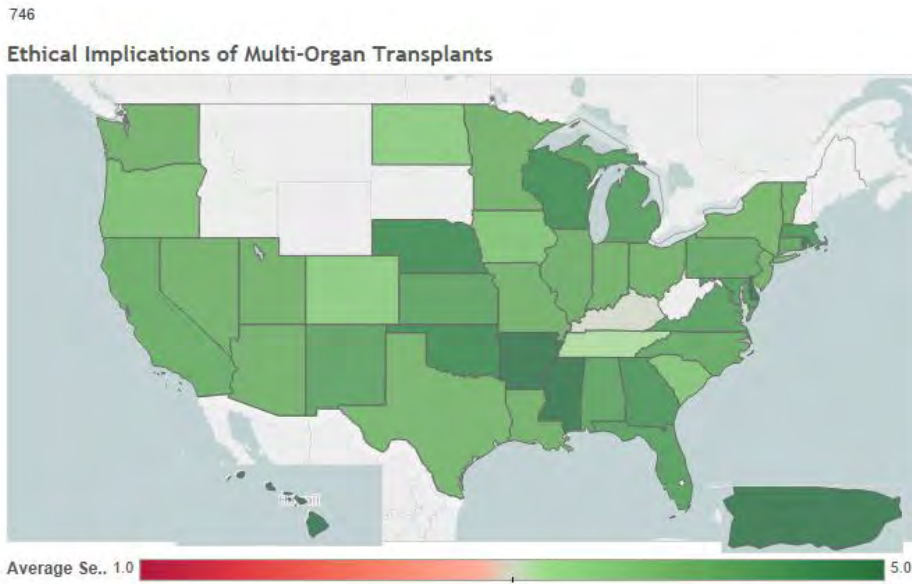
Of the proposals out for Spring 2019 public comment, the MOT white paper received the 3<sup>rd</sup> highest overall sentiment score of 4.1 indicating widespread support for the project (Figure 1).

Figure 1: Sentiment by proposal



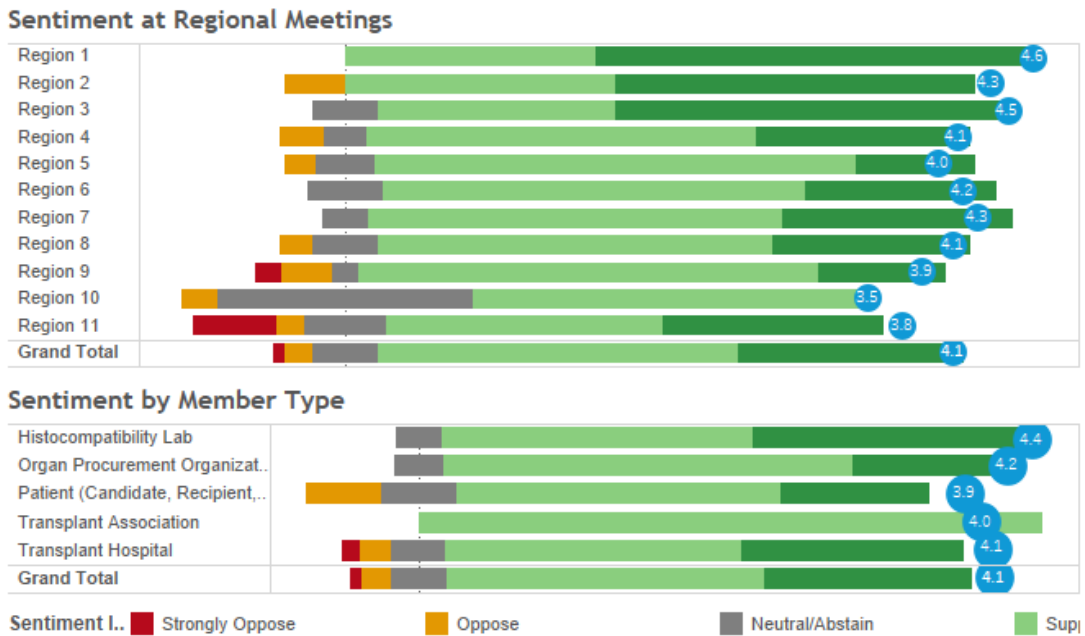
Public comment feedback also showed strong support when broken down by geography (Figure 2). Dark green indicates strong support, while red indicates opposition.

Figure 2: Sentiment by geography



Finally, support was widespread across member type and across region, with most regions and members supporting or strongly supporting the proposal (Figure 3).

Figure 3: Sentiment by region and member type



### *Themes of Public Comment*

The Committee reviewed public comment feedback organized by four themes: impact on pediatric populations, evaluation of kidney-pancreas (KP) transplants, impact on MOT by geography, and clarification of how simultaneous liver-kidney (SLK) allocation accords with MOT recommendations.

#### 1. Discussion of Impact on Pediatric Populations

Several comments focused on the potential impact of MOT on pediatric populations: specifically, pediatric kidney-alone access to low KDPI kidneys that may be diverted at the local level to simultaneous pancreas-kidney (SPK) and other MOT candidates. MOT candidates generally receive priority above pediatric candidates in allocation at the local level, which could impact pediatric candidate access to low KDPI (higher quality) kidneys. American Society of Transplantation (AST) indicated overall support for the paper, but noted the paper should include discussion of the “dedicated needs and potential impact” on pediatric populations.

As noted in the “how was this proposal developed?” section, the Committee modified the paper to include a section on impact of adult MOT on pediatric populations prior to public comment. However, the MOT white paper overall focuses on adult populations because the Committee agreed that encompassing a detailed review of all the implications for both adult and pediatric populations would prove too complex, and the issues related to pediatric populations should be addressed in a separate MOT white paper.

In post-public comment discussions, the Committee reiterated this position that the impact on pediatrics should be discussed in the paper to a limited extent, but a more thorough review of pediatric MOT may need to be discussed separately and as a future project. The Committee added more discussion of the impact of KP on pediatrics in the introduction of the white paper, which notes the need for future research to assess the implication of KP redirecting of low KDPI organs to pediatric populations. The Committee also reviewed **Section F: MOT and Protected Subgroups** and **Section K: Impact of Adult MOT on Pediatric SOT** to ensure they clearly identify the potential impact of MOT on pediatric populations. Section G outlines how the OPTN should seriously consider pediatrics as a vulnerable population that may be negatively impacted by MOT over-prioritization. Section L addresses the impact of adult MOT on pediatric SOT and highlights how local prioritization of MOT can impact pediatric candidates.

In post-public comment discussions, Committee members noted that pediatric SOT candidates sometimes receive more priority than MOT candidates depending on the organ type (specifically, pediatric liver candidates may receive priority access to pediatric donor livers above any adult candidates),<sup>16</sup> which highlights that the issues facing pediatric MOT candidates may be complex and vary between individual organ allocation systems. This reconfirmed for Committee members not only that it is appropriate to include the potential impact of MOT on pediatric populations, but also that the topic may need further addressing in a future white paper.

#### 2. Role of KP as MOT

Feedback from public comment highlighted how consideration of KP transplants could be clarified in the white paper. Certain commenters expressed support for KP as a separate ethical consideration than the rest of MOT. Others criticized it because KP can still impact kidney-alone candidates by receiving priority at the local level, or found it unclear why KP was considered separately from other MOT combinations.

The paper treats KP as a single organ transplant from an ethical point of view for several reasons:

- It is less common to implant a pancreas without a kidney because both are required to treat single disease process (Type 1 diabetes)

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<sup>16</sup> OPTN Policy 9.8.F, *Allocation of Livers from Non-DCD Deceased Donors 11 to 17 Years Old*. OPTN Policy 9.8.G, *Allocation of Livers from Non-DCD Deceased Donors Less than 11 Years Old*, available at: [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf), (accessed April 12, 2019).



- Both kidney and pancreas are based on waiting time, unlike other MOT combinations which have one organ based on waiting time (kidney) and one on medical urgency (e.g. heart)
- KP candidates need to meet kidney waitlist criteria
- The pancreas is not usually utilized if not in a KP transplant (unlike other MOT)

The Committee clarified in the white paper how KP can impact SOT (including pediatric candidates) by redirecting kidneys from SOT kidney candidates at the local level. As noted in the pediatrics section, the Committee also clarified how low KDPI kidneys may be redirected to KP candidates instead of high-priority kidney-alone candidates, including pediatric patients. The Committee agreed to keep its focus on MOT combinations that are not clearly delineated in policy in terms of their prioritization relative to single organ transplant options. Certain recommendations from the MOT paper (such as collecting data on outcomes and identifying how to prioritize the specific organ combination in relation to other SOT alternatives) would not apply to the MOT combinations of KP, heart-lung and SLK because these combinations are already addressed in OPTN policy. The Committee added an appendix clarifying how these MOT combinations are not the focus of the paper and why they were excluded – specifically, because these allocation systems have already implemented changes to address MOT prioritization and ethical distribution.

### 3. Impact on Geography

Several commenters questioned whether MOT candidates may be negatively or positively impacted by changes to geographic distribution. According to policy now, MOT combinations are prioritized above SOT at the local level if one of the organs in the MOT combinations is a heart, liver or lung, or if the combination is a kidney-pancreas.<sup>17</sup> What “local” means is subject to change as donation service area (DSA) and region are removed from allocation policies as units of distribution. Instead, MOT combinations may be prioritized based on the distance from the donor hospital and depending on the organ combinations. For example, liver has an initial circle of 150 nautical miles (NM) and heart one of 250 NM, so a kidney could be redirected to go with an SLK out to 150 NM from the donor hospital, or out to 250 NM for a heart-kidney combination.

While questions of geographic priority are pertinent to the discussion of MOT generally, the Committee agreed in post-public comment discussions that these questions are separate from the ethical dilemmas related to MOT allocation and it is difficult to weigh in on the ethical implications while changes to geographic distribution are ongoing. The Committee did add language noting that removal of DSA and region may make challenges with MOT allocation and standardization more pronounced.

### 4. Overlap with SLK allocation policy

Public comment feedback also included questions about how SLK policy did or did not address issues with MOT allocation. The MOT white paper that went out for public comment did include discussion of SLK, but the Committee agreed that further discussion was warranted. The Committee added substantive discussion of the changes in SLK policy to **Section I. MOT and Standardized Criteria**.<sup>18</sup> The Committee also added language indicating how SLK policy addressed certain recommendations that were included in the MOT white paper – organ prioritization, listing criteria, and having a safety net. Finally, the Committee clarified how the MOT white paper goes beyond the SLK policy change in discussion of the ethical dilemmas that arise from MOT allocation to provide a broad overview of the ethical challenges inherent in allocating multiple organs to individual recipients.

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<sup>17</sup> OPTN Policy 5.10.C, *Other Multi-Organ Combinations*. OPTN Policy 11.4.A, *Kidney-Pancreas Allocation Order*, available at: [https://optn.transplant.hrsa.gov/media/1200/optn\\_policies.pdf](https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf), (accessed April 12, 2019).

<sup>18</sup> Simultaneous Liver Kidney (SLK) Allocation. OPTN Kidney Transplantation Committee, June 2016, available at: [https://optn.transplant.hrsa.gov/media/1871/kidney\\_briefingpaper\\_slk\\_201606.pdf](https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf).

### *Other Public Comment Changes*

While certain comments did not qualify as themes, the Committee still seriously considered their implications and reviewed all suggested changes or modifications to the white paper. The MOT Work Group also reviewed the paper and provided suggestions or modifications for better flow, clarity, and discussion of the ethical implications of MOT.

#### 1. Review of Recommendations

The Committee reviewed feedback from the Houston Methodist Hospital that disputed the basis for certain recommendations in the MOT white paper. The Committee agreed with the comment that the term “cherry-picking” is not neutral and changed the term to MOT “redirecting” organs from SOT candidates. However, the Committee disagreed with the commenter’s suggestion that there is no adverse impact associated with redirecting organs (recommendation 3 recommends considering this impact), because even though MOT candidates may need both organs, SOT candidates can still be negatively impacted by having a smaller pool of lesser quality organs from which to obtain a transplant.

The Committee confirmed their support for recommending a national review board for MOT exceptions to address issues with MOT access to alternative supportive treatment options (recommendation 4). Many MOT candidates are not eligible for supportive treatments because of the second organ’s dysfunction and must appeal through a review board. Uniformity through a national review board could help ensure fair treatment of these candidates.

While not every MOT combination may result in a negative impact on a vulnerable population, and in fact there may be organ combinations (liver, specifically) in which MOT candidates are more disadvantaged than SOT candidates, the Committee still felt that the impact of MOT prioritization on SOT should be considered in changes to MOT allocation regardless whether that impact is negative or positive (recommendations 6 and 7). Because recommendations 6 and 7 were substantively similar in recommendation the potential impact on vulnerable populations, the Committee combined them. Finally, the Committee reiterated its support for establishing additional standards for centers performing MOT (recommendation 9). No substantive evidence of a negative impact on establishing standards was presented to the Committee, and the Committee considers it imperative to provide patients with adequate information to make informed decisions and to ensure accountability of transplant programs that perform MOT.

#### 2. Glossary of Terms

The Patient Affairs Committee recommended that a glossary of terms be added to clarify the technical, ethical terms used in the paper. The Committee agreed with this suggestion and added a glossary as an appendix to the paper.

#### 3. Figures in **Section B. MOT and the Redirecting of Organs from SOT Waitlists** Removed

The Committee initially updated two figures that illustrated how organs may be redirected to MOT candidates from SOT candidates because staff and Work Group members identified these figures as confusing and not intuitive to understand. The Committee reviewed the language in the section and found it sufficiently clear in discussing the ethical implications of redirecting organs. Ultimately the Committee supported removing these figures because they did not add clarity to the section.

### *Incorporation of Post-Public Comment Changes and Vote*

The Committee reviewed public comment feedback on a March 21<sup>st</sup> conference call, the day before public comment ended. The Committee discussed themes from public comment detailed above, regional votes, and feedback from committees, individuals, and organizations. The Chair of the Ethics Committee worked with UNOS staff and the Chair of the MOT Work Group to update the paper based on public comment feedback and provide this draft to the MOT Work Group for a teleconference on April 4<sup>th</sup>. The MOT Work Group reviewed the latest draft along with public comments that came in after the March 21<sup>st</sup> conference

call. On April 8<sup>th</sup>, the full Committee met in Chicago, IL to review public comment that came in after the March 21<sup>st</sup> call, as well as changes to the paper that were made post public comment.

After review and incorporation of edits, the Committee voted unanimously to send the updated MOT white paper to the OPTN Board of Directors for approval at their June 2019 meeting in Richmond, VA.

## Which populations are impacted by this resource?

Both MOT and SOT candidates are impacted by how OPTN Policy allocates organs for multi-organ transplants (see Table 1). This white paper does not directly impact allocation policies, but provides the ethical framework for the OPTN to do so. The white paper identified several subpopulations of candidates that could be impacted depending on how MOT are allocated: pediatrics, highly-sensitized, low SES, and racial minorities.

Table 1: Combinations of organs involved in MOT and their frequencies<sup>19</sup>

Multi-Organ Transplants Performed in the US from 2013-2017						
	2013	2014	2015	2016	2017	Total
<b>Total</b>	1,459	1,508	1,625	1,801	1,853	8,246
Kidney-Pancreas	762	709	719	798	789	3,777
Liver-Kidney	494	558	627	730	739	3,148
Kidney-Heart	85	104	141	140	187	657
Liver-Intestines-Pancreas	50	69	67	58	55	299
Liver-Heart	16	18	28	18	29	109
Heart-Lung	23	24	15	18	29	109
Liver-Lung	7	6	9	9	8	39
Intestines-Pancreas	5	8	9	8	3	33
Kidney-Lung	7	5	1	4	7	24
Liver-Kidney-Intestines-Pancreas	6	3	2	7	2	20
Kidney-Intestines	1	2	2	5	1	11
Liver-Pancreas	0	0	2	3	1	6
Liver-Intestines	2	0	2	2	0	6
Kidney-Heart-Lung	0	1	0	0	2	3
Liver-Kidney-Heart	1	0	0	1	0	2
Liver-Heart-Lung	0	0	0	0	1	1
Liver-Kidney-Pancreas	0	1	0	0	0	1
Liver-Pancreas-Lung	0	0	1	0	0	1

<sup>19</sup> 2018 OPTN data, available at: <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>, (accessed December 15, 2018).

## How does this resource impact the OPTN Strategic Plan?

*Increase the number of transplants:* No expected impact on this goal.

*Improve equity in access to transplants:* The 2018 OPTN Strategic Plan called for the OPTN to “measure equity in allocation, including geographic disparities and multi-organ disparities.”<sup>20</sup> This white paper lays the foundation for the OPTN to clarify or modify existing multi-organ allocation policy and to do so in a consistent, principled manner, which aligns with the OPTN strategic goal to provide equity in access to transplant.<sup>21</sup>

*Improve waitlisted patient, living donor, and transplant recipient outcomes:* No expected impact on this goal. The ethical analysis could lead to future policy changes that could impact this goal.

*Promote living donor and transplant recipient safety:* No expected impact on this goal.

*Promote the efficient management of the OPTN:* No expected impact on this goal. The ethical analysis could lead to future policy changes that could impact this goal.

## What are the costs associated with this resource?

### Member

No anticipated costs.

### UNOS:

Significant time is attributed to the Policy and Community Relations department in the development of the paper in Committee, work to compose and modify the paper, and to respond to input from community stakeholders. Approximately 300 hours is estimated in development.

## 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 a guide to other committees and the OPTN Board of Directors 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. However, the resource recommends that the OPTN consider additional data collection related to MOT outcomes.

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<sup>20</sup> OPTN Strategic Plan 2018-2021, *available at:*  
[https://optn.transplant.hrsa.gov/media/2546/optn\\_unos\\_strategic\\_plan.pdf](https://optn.transplant.hrsa.gov/media/2546/optn_unos_strategic_plan.pdf).

<sup>21</sup> OPTN Strategic Plan 2018-2021, *available at:*  
[https://optn.transplant.hrsa.gov/media/2546/optn\\_unos\\_strategic\\_plan.pdf](https://optn.transplant.hrsa.gov/media/2546/optn_unos_strategic_plan.pdf).

## **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

## 1 Guidance on Multi-Organ Transplant Allocation Policy and Practice

### 2 Introduction

3 Multi-organ transplantation (MOT) refers to the simultaneous transplantation of two or more organs from a  
4 single donor into a single recipient, whereas single organ transplantation (SOT) refers to transplantation  
5 of one organ. MOT, excluding kidney-pancreas and heart-lung, represented approximately 3% of all  
6 transplants in the United States in 2017.<sup>22</sup> The prevalence of MOT has increased over the past two  
7 decades, with more patients being listed for and undergoing MOT each year.<sup>23</sup> The number of MOTs,  
8 excluding kidney-pancreas and heart-lung, has nearly doubled in the past six years, from 625 MOT  
9 procedures in 2012 to 1,035 in 2017 (**Table 1**).<sup>24</sup> By contrast, kidney-pancreas transplants have remained  
10 steady at about 750 per year, as have heart-lung transplants at about 20 per year over this same period.  
11

12 The Organ Procurement and Transplantation Network (OPTN) Final Rule requires that the OPTN develop  
13 allocation policies “specific for each organ type or combination of organ types to be transplanted into a  
14 transplant candidate.”<sup>25</sup> Yet organ allocation policies governing MOT have not been developed  
15 consistently, and ethical principles determining prioritization of MOT have not been systematically  
16 evaluated. There are many different combinations of organs involved in MOT (**Table 1**), and additional  
17 combinations may arise in the future as medical care evolves.  
18

19 Each organ combination has its own allocation strategy.<sup>26</sup> Prioritization of MOT candidates and the  
20 allocation rules for each combination have not been standardized across the different organs. Some  
21 multi-organ combinations (e.g., kidney-pancreas and heart-lung) have a single, combined MOT waitlist,  
22 while other multi-organ combinations (e.g., liver-kidney, heart-kidney, heart-liver, and others) require  
23 patients to be listed on multiple, separate single-organ lists. The combined MOT lists (e.g., kidney-  
24 pancreas and heart-lung) were developed to treat specific diseases that affect multiple organs, such as  
25 Type 1 diabetes with renal failure, and combined heart-lung disease, respectively.<sup>27</sup> At the local level,  
26 Organ Procurement Organizations (OPOs) have the discretion to choose which MOT combination gets  
27 allocated if there are multiple MOT combinations possible from the same donor. Such OPO discretion  
28 reflects that OPTN policies do not currently specify which particular MOT combinations are prioritized  
29 above others. As a result, the current allocation system has generated confusion in the transplant  
30 community about the rationale for differences in MOT allocation plans between different organ  
31 combinations. MOT is also generally prioritized above SOT at the local level according to *Policy 5.10:*  
32 *Allocation of Multi-Organ Combinations*. This prioritization may impact areas of the country differently  
33 depending on whether a high volume MOT program is near the donor hospital. With the removal of  
34 donation service area (DSA) and region from organ allocation policies, and subsequent increases in  
35 broader distribution of organs, the challenges of MOT allocation might become more pronounced. The  
36 revisions in distribution policies align with the OPTN strategic goal to improve equity in access to

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<sup>22</sup> 2018 OPTN data (Accessed December 11, 2018).

<sup>23</sup> Wolf, J. H., M. E. Sulewski, J. R. Cassuto, M. H. Levine, A. Naji, K. M. Olthoff, A. Shaked, and P. L. Abt. "Simultaneous Thoracic and Abdominal Transplantation: Can We Justify Two Organs for One Recipient?" *American Journal of Transplantation* 13, no. 7 (2013): 1806-816. doi:10.1111/ajt.12291.

<sup>24</sup> 2018 OPTN data (Accessed December 11, 2018).

<sup>25</sup> 42 C.F.R. § 121.8(a)(4)

<sup>26</sup> Reese, P. P., R. M. Veatch, P. L. Abt, and S. Amaral. "Revisiting Multi-Organ Transplantation in the Setting of Scarcity." *American Journal of Transplantation* 14, no. 1 (2013): 21-26. doi:10.1111/ajt.12557.

<sup>27</sup> *Proposal to Develop an Efficient, Uniform National Pancreas Allocation System*, OPTN Pancreas Committee, November 2010, <https://bodandcommittees.unos.org/archive/Documents/Proposal%20to%20Develop%20an%20Efficient.%20Uniform%20National%20Pancreas%20Allocation%20System%20-BP.pdf> (accessed December 17, 2018).

37 transplant. It is important that any new distribution policies are studied for their effects on SOT and MOT,  
 38 with the understanding that the outcomes may differ according to organ combination type.

39  
 40 This white paper provides recommendations to the transplant community to ensure that MOT proceeds in  
 41 an ethically responsible manner. These recommendations are for the OPTN organ-specific committees to  
 42 consider when developing their own policies for multi-organ transplantation, which may help to ensure the  
 43 optimal use of scarce national resources. This white paper does not prescribe specific policy solutions.  
 44 Instead, it aims to foster transparency and accountability within transplant allocation policies and  
 45 processes by outlining a broad overview of the ethical dilemmas that arise from current MOT policy and  
 46 providing recommendations for the Board to consider in improving the balance of equity and utility in MOT  
 47 allocation.

48 **Table 1: Combinations of organs involved in MOT and their frequencies<sup>28</sup>**

49  
 50

<b>Multi-Organ Transplants Performed in the US from 2013-2017</b>						
	<b>2013</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>Total</b>
<b>Total</b>	1,459	1,508	1,625	1,801	1,853	8,246
Kidney-Pancreas	762	709	719	798	789	3,777
Liver-Kidney	494	558	627	730	739	3,148
Kidney-Heart	85	104	141	140	187	657
Liver-Intestines-Pancreas	50	69	67	58	55	299
Liver-Heart	16	18	28	18	29	109
Heart-Lung	23	24	15	18	29	109
Liver-Lung	7	6	9	9	8	39
Intestines-Pancreas	5	8	9	8	3	33
Kidney-Lung	7	5	1	4	7	24
Liver-Kidney-Intestines-Pancreas	6	3	2	7	2	20
Kidney-Intestines	1	2	2	5	1	11
Liver-Pancreas	0	0	2	3	1	6
Liver-Intestines	2	0	2	2	0	6
Kidney-Heart-Lung	0	1	0	0	2	3
Liver-Kidney-Heart	1	0	0	1	0	2
Liver-Heart-Lung	0	0	0	0	1	1
Liver-Kidney-Pancreas	0	1	0	0	0	1
Liver-Pancreas-Lung	0	0	1	0	0	1

51  
 52 The allocation systems for MOT may create potentially inequitable differences in organ distribution, either  
 53 in the rate of transplantation or in the time to transplantation. Potential inconsistencies in MOT  
 54 prioritization at the local level, and in medical urgency in MOT qualifying criteria may affect the patients  
 55 who are awaiting MOT as well as patients who are awaiting SOT because both groups depend upon  
 56 available organs from the same limited organ pool. Accordingly, allocation policies should generally

<sup>28</sup> 2018 OPTN data (Accessed December 11, 2018).

57 consider and attempt to mitigate disparities to disadvantaged groups to the extent possible while  
58 balancing the ethical principle of equity with the ethical principle of utility.

59

## 60 **Introduction to the Ethical Analysis**

61 The ethical analysis of MOT allocation largely focuses on the principles of equity and utility, and has been  
62 discussed elsewhere.<sup>29</sup> The OPTN opines that generally, MOT, if properly performed, is ethically sound.  
63 In addition, MOT has become an accepted practice within the transplant community. The frequency of  
64 MOT is increasing, which raises questions of distributive justice, as racial/ethnic minorities and those with  
65 lower socioeconomic status are not well represented in MOT (**Table 2**, page 14). Some disparities in  
66 organ allocation reflect differences in access to healthcare, limiting the ability of some patient groups to  
67 be evaluated and listed for MOT. This white paper highlights specific situations of MOT policies in organ  
68 allocation systems that may create additional disparities above and beyond those related to access to  
69 MOT. Allocation policies may promulgate disparities and challenge the ethical principles that support our  
70 healthcare system. This white paper recommends ways to soundly allocate organs for MOT by minimizing  
71 potential disparities. MOT must undergo the same level of data collection, oversight, and scrutiny as SOT  
72 to minimize the variability occurring in clinical practice. The need for oversight has become increasingly  
73 important as MOT frequency increases.

74

75 A key term in the ethical analyses of MOT organ allocation is 'life-saving' (or medical urgency). Defining  
76 the term 'life-saving' is challenging. The OPTN recognizes that all organ transplants have the potential to  
77 be life-saving, depending on the waitlist candidate's condition and risk of mortality. However, the OPTN  
78 differentiates organs that are *immediately* life-saving at the time of transplantation for which candidates  
79 have an urgent medical claim to them, from organs that are life-enhancing at the time of transplantation  
80 yet may potentially be life-saving at a future time. For example, hearts, lungs, and livers are organs that  
81 are more likely to be life-saving. Kidneys are organs that are traditionally categorized as not immediately  
82 life-saving, although in certain circumstances, kidneys may become immediately life-saving if all access  
83 options close and preclude further dialysis. In this paper, 'life-saving' refers to transplants that are  
84 immediately life-saving. The OPTN differentiates between MOT transplants in which the organ pair  
85 includes two life-saving organs, and MOT transplants in which the organ pair includes one life-saving  
86 organ and one organ that is not immediately life-saving, but could maximize the health outcomes for the  
87 recipient.

88

89 Since the kidney is the most common organ involved in MOT, most available data pertain to kidney  
90 allocation, and an analysis of OPTN data requested by the OPTN Ethics Committee was restricted to  
91 MOTs involving a kidney. The principles outlined in this white paper are broadly applicable to kidneys and  
92 to other organs involved in MOT, and provide general ethical considerations of MOT to guide future  
93 analysis and inform specific MOT policies. This white paper focuses on issues associated with MOT in the  
94 adult population. This white paper addresses preliminary considerations of pediatric populations in  
95 **Section K: Adult MOT Impact on Pediatric SOT** and **Section F: Protected Subgroups** to inform future  
96 analysis. The ethics of pediatric access to organs including MOT will need to be thoroughly addressed as  
97 a separate topic.

98

99 From an ethics standpoint, kidney-pancreas (KP) transplants can be viewed as a single organ transplant.  
100 It is less common to implant a pancreas without a kidney as both are usually required to treat a single  
101 disease process, and unlike other organs the pancreas may be more likely to be discarded if not used in  
102 a multi organ transplant. In addition, kidney and pancreas allocation are both allocated primarily on  
103 waiting time. By contrast, other MOT combinations generally have one organ allocated on waiting time  
104 (kidney) and the other organ based on urgency/need (e.g., heart). Although kidney and pancreas patients  
105 are prioritized by time and not urgency, it is possible for a patient awaiting a KP to redirect a kidney from  
106 someone waiting for a SOT kidney because KP are prioritized above SOT at the local level. KP

---

<sup>29</sup> Reese et al., 2013.



107 candidates typically have shorter waiting times than isolated kidney candidates, and KP candidates also  
108 have higher mortality on the waitlist.<sup>30,31</sup>

109  
110 To accrue waiting time, KP candidates must meet the same criteria that SOT kidney candidates meet:  
111 dialysis dependent end-stage renal disease (ESRD) or glomerular filtration rate (GFR) < 20.<sup>32</sup> No other  
112 MOT combinations rely upon SOT kidney criteria for waiting time accrual. Both KP candidates and SOT  
113 kidney candidates rely heavily on waiting time to receive offers, because there is no medical urgency  
114 score for kidney or pancreas allocation.<sup>33</sup> In fact, liver-kidney MOT is the only other combination that  
115 relies on kidney-related criteria, but the criteria are less strict than for kidney alone.<sup>34</sup> The distribution of  
116 the kidney as part of KP transplantation can potentially affect the outcome of other patients on the waitlist.  
117 For example, low KDPI kidneys go to KP candidates, who are usually adults, before they go to pediatric  
118 candidates. Future research is needed to assess the number of low KDPI kidneys that go to KP  
119 candidates rather than to pediatric candidates and thereby evaluate the implications of this allocation  
120 system on pediatric patients.

121  
122 The OPTN recognizes that the ethical framework presented in this white paper may require adaptation to  
123 new or unanticipated situations related to transplantation. For example, there may be different ethical  
124 considerations concerning organs that are: a) not scarce (such as intestines), and/or b) “marginal” in  
125 quality – in that they would not otherwise be accepted by other transplant candidates. Recent advances  
126 in vascularized composite allotransplantation such as face and hand transplants may also require  
127 adaptation of this ethical framework. Moreover, future changes to the organ allocation systems may also  
128 affect MOT allocation.

129  
130 The current organ allocation systems for MOT have developed organically out of clinical need, as the use  
131 of MOT with new organ combinations has evolved. The current allocation systems for MOT generally  
132 maximize the utility at the potential cost of creating disparities in equity. However, each system weighs  
133 equity and utility to different degrees.<sup>35</sup> The OPTN affirms that optimal allocation policies involving MOT  
134 should reflect a balance between equity and utility, with the understanding that no system can maximize  
135 both. The main challenge pertains to specifying how to apply ethical principles in the context of each type  
136 of MOT allocation.

137  
138 In the context of MOT allocation policies:

139  
140 The principle of **utility** requires that an MOT allocation system maximizes the benefit experienced by the  
141 population of potential recipients of these organs. Benefit can be interpreted in terms of the greatest  
142 likelihood of:

- 143 a) medical benefit (e.g., years of life, medical urgency)  
144 b) quality of benefit (quality of life years or QALYs, see Appendix C)  
145 c) avoiding futile transplants, a Final Rule requirement<sup>36</sup>

146  
147 The principle of **equity** requires that an MOT allocation system maximizes fairness for patients’ access to  
148 organs in terms of:

- 149 a) equality of opportunity  
150 b) how the policy inadvertently affects the worse-off (the Maximin principle)

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<sup>30</sup> 2019 OPTN data (Accessed April 1, 2019).

<sup>31</sup> Wolfe, R.A., McCullough, K.P., Schaubel, D.E., Kalbfleisch, J.D., Murray, S., Stegall, M.D., Leichtman, A.B.,  
“Calculating Life Years from Transplant (LYFT): Methods for Kidney and Kidney-Pancreas Candidates.” *American  
Journal of Transplantation*, 8, no. 4 (2008): 997-1011. doi: 10.1111/j.1600-6143.2008.02177.x.

<sup>32</sup> OPTN Policy 8.4, *Waiting Time* (Accessed March 8, 2019).

<sup>33</sup> OPTN Policy 8: *Allocation of Kidneys* & OPTN Policy 11: *Allocation of Pancreas, Kidney-Pancreas, and Islets*  
(Accessed March 8, 2019).

<sup>34</sup> *Simultaneous Liver Kidney (SLK) Allocation*. OPTN Kidney Transplantation Committee, June 2016,  
[https://optn.transplant.hrsa.gov/media/1871/kidney\\_briefingpaper\\_slk\\_201606.pdf](https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf).

<sup>35</sup> Reese et al., 2013.

<sup>36</sup> 42 C.F.R. §121.8(a)(5).

- 151 c) “fair innings” concept  
152 d) those who are near death or the “Rule of Rescue”  
153 e) first-come, first-served  
154

155 These principles are discussed in the Principles of Organ Allocation White Paper and the Pediatric Ethics  
156 White Paper and defined in Appendix E of this paper.<sup>37</sup>  
157

## 158 **Ethical Dilemmas Unique to MOT**

159 The OPTN identified ethical dilemmas unique to MOT. Each section below details the ethical dilemma,  
160 the conflict between ethical principles, and the recommendations of the OPTN. Discussion of conflicting  
161 ethical principles allows the OPTN to identify and strive to achieve the optimal balance between equity  
162 and utility in relation to MOT policy.  
163

### 164 **Section A. MOT and Need for Transplant**

#### 165 *MOT is Ethically Justified when Both Organs are Life-Saving*

166 Transplant candidates have varying levels of need for MOT. “Need” can be expressed in different ways:

- 167 • MOT is needed as an urgent measure to save a patient’s life (e.g., heart-liver)
- 168 • MOT is needed to improve the quality of the patient’s life and extend their length of life even  
169 though death from that disease is not imminent (e.g., KP)
- 170 • MOT is needed because the second organ makes some organ transplant combinations more  
171 successful in the short term post-transplant<sup>38</sup> (e.g., heart-lung when the heart is not end-stage but  
172 would increase the operative risk)
- 173 • MOT is needed because the long-term post-transplant outcomes may improve with the additional  
174 organ, but patient survival with a single organ is still possible (e.g., liver-kidney)

175 In diseases in which both organs are necessary for survival (e.g., heart/-lung transplantation in cor  
176 pulmonale), both organs should be considered as a single organ for the purposes of ethical analysis; the  
177 transplantation of only one organ (only the heart or only the lungs, in this example) will fail and the patient  
178 will die (see **Appendix D: MOT combinations not addressed in white paper**). In diseases that pose an  
179 imminent threat to life from the first organ, and the second organ is either critical to success or will  
180 significantly improve the outcomes, redirecting of the second organ is ethically sound. Redirecting,  
181 otherwise known as “pulling,” refers to redirecting that organ to someone of lower priority on that organ’s  
182 allocation list.  
183

184 In MOT situations where the candidate is reasonably stable from the standpoint of the first organ (e.g.  
185 lower model for end-stage liver disease (MELD) score or lung allocation score (LAS), or lower status on  
186 the heart list), redirecting of the second organ (e.g., kidney) from those SOT candidates whose waitlist  
187 time is a critical factor in allocation is harder to justify. When the first organ is less urgent (e.g., lower  
188 MELD score), and the second organ is not mandatory for immediate survival, SOT candidates’ need for  
189 the MOT’s second organ is comparable to that of the MOT candidate at that time. If the MOT candidate’s  
190 condition later deteriorates to the point where organ transplantation becomes a more medically urgent  
191 matter, then redirecting of the second organ from the SOT candidate becomes ethically justifiable. For  
192 candidates awaiting organs that are not for immediately life-threatening illnesses, a balance is required  
193 between the needs of the patient for MOT and those awaiting SOT.  
194

#### 195 **Ethical Principles in Conflict**

- 196 • Equity: When organs are redirected from a SOT candidate for transplantation in a MOT candidate  
197 for whom death is not imminent, then SOT candidates for whom waitlist time is a major factor in

<sup>37</sup> *Ethical principles in the allocation of human organs*, OPTN Ethics Committee, June 2015,  
<https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>. *Ethical*  
*principles of pediatric organ allocation*, OPTN Ethics Committee, November 2014,  
<https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-of-pediatric-organ-allocation/>.

<sup>38</sup> Reese et al., 2013.

198 organ distribution (e.g., kidney) are not given an equitable opportunity to access transplantation,  
199 and the first-come, first-served doctrine is not respected.

200

- 201 • Utility: Benefit in MOT is maximized when a patient with a medically urgent need for multiple  
202 organs receives these organs. When candidates do not have a medically urgent need for the  
203 additional organ, candidates can still benefit from getting that second organ from the same donor  
204 as the first organ. Receiving both organs can reduce complications from a second surgery and  
205 reduce the likelihood of greater risk of rejection from a second transplant. However, benefit may  
206 not be maximized when candidates do not have a medically urgent need for the additional  
207 organs, especially when the need for the first organ is not life-saving. Also, if a kidney is the  
208 second organ, sometimes the recipient's native kidney function can recover when the other life-  
209 saving organ starts to function well after transplantation.

## 210 Recommendations

211 There should be a distinction between MOT situations when the second organ is life-saving and situations  
212 when the second organ is non-life saving, but aids in maximizing the outcomes for that patient.

213 Organ allocation policies should consider the difference in outcomes between MOT pairs of two life-  
214 saving organs and MOT pairs of one life-saving organ and one life-enhancing organ. In the case of two  
215 life-saving organs, the ethical argument is stronger for the MOT candidate redirecting the second life-  
216 saving organ from a candidate who has been waiting a long time for a transplant than in the situation  
217 where one of the organs is life-enhancing. While both situations may be ethically justified in certain  
218 circumstances, the second situation will require greater ethical justification than the first.

219 Policies such as those included in OPTN Policy 6.6.F.1: *Allocation of Heart-Lungs* may serve as a useful  
220 guide to other organ combinations. However, Policy 6.6.F.1 pertains to priorities for lung allocation when  
221 heart-lung candidates are competing with heart candidates for the same organ. Policy 6.6.F.1 illustrates  
222 how the risk of mortality changes with the listing status of the patient. Additionally, Policy 6.6.F.1 shows  
223 how the organ is sometimes better used for SOT, whereas at other times it is better used for MOT,  
224 depending on the relative degrees of need of the individual patients involved.

225

### 226 **Section B. MOT and the Redirecting of Organs from SOT Waitlists**

227 *MOT allocation should be consistent and transparent when redirecting organs becomes*  
228 *ethically acceptable*

229 There are two mechanisms by which MOT candidates may secure multiple organs:

- 230 a. One scenario entails a waitlist that is specific to the MOT organ combination. An example is the heart-  
231 lung list, which is different from both the heart and lung allocation separate lists. Heart-lung  
232 candidates receive prioritization above the individualized lists if certain criteria are met. In this  
233 scenario, policy-induced disparity may arise, depending upon how the priority of a patient on the MOT  
234 waitlist (e.g., heart-lung) affects the ability of patients on the individual organ lists (e.g., heart and  
235 lung) to receive the needed organ(s). In this situation, the allocation of the multiple organs is based  
236 on the status that a candidate receives on the combined list, and how this list is prioritized with the  
237 single organ lists. A patient on the heart-lung list may be prioritized for a heart over patients on the  
238 heart-only list, and redirect the lungs from those on the lung-only list. Alternatively, organ offers may  
239 go to patients on the individual organ lists before going to the person on the heart-lung list, depending  
240 on the relative listing status of the potential recipients on each list.
- 241
- 242 2. Another scenario entails placing a patient awaiting MOT on separate waiting lists for each organ.  
243 When the candidate matches for one organ (typically one necessary to sustain life e.g., a liver or  
244 heart), the patient is immediately given priority for the other organ (e.g., a kidney), redirecting the  
245 other organ (kidney) from other potential SOT recipients, regardless of the position of the MOT  
246 recipient on the other (kidney) list. When this occurs, the MOT candidate bypasses those candidates  
247 who are otherwise prioritized for that other organ (kidney) based on the other candidates' waitlist

248 duration, sensitization, longevity matching, or other factors.<sup>39</sup> These issues are discussed in greater  
 249 detail in **Section G: Protected subgroups**. In the situation where a MOT candidate is listed on the  
 250 separate organ lists, the allocation of the multiple organs is made based on the status of the  
 251 candidate for one of the organs, and prioritization for the second organ generally follows. A candidate  
 252 on the heart-only list and a candidate waiting for a heart-kidney are competing equally for the same  
 253 heart based on their priority on the heart list. However the candidate awaiting a heart-kidney will have  
 254 priority over a potential SOT kidney recipient.

255

#### 256 Ethical Principles in Conflict

- 257 • Equity: Patients with multi-organ failure are worse-off compared to patients with single organ  
 258 disease, even when both patients have the same degree of dysfunction of the organ that they  
 259 both commonly need. Need-based allocation systems (e.g., heart, lung, and liver) do not respect  
 260 the principle of first-come, first-served that applies to kidney transplantation.
- 261
- 262 • Utility: In most situations, the degree of medical benefit that one individual patient gains by MOT  
 263 is less than the total collective medical benefit that two, three, or even four individual patients gain  
 264 by undergoing SOT. However, the length of benefit to the MOT recipient may be less than that to  
 265 the SOT candidate due to the lower rate of patient survival in some MOT recipients compared to  
 266 SOT recipients receiving the same organ.<sup>40</sup>

#### 267 Recommendations

268 To ensure fair and equitable distribution of organs for MOT, a system of organ allocation for MOT should  
 269 be adopted and used for all organ combinations, unless there are clinically valid and ethically justifiable  
 270 reasons why separate systems should exist. One system, rather than the current piecemeal arrangement,  
 271 would foster transparency and more clearly predict the effects of organ allocation decisions across the  
 272 different organ combinations and among those waiting for a single organ. When separate lists are  
 273 deemed appropriate (for example, continuing to maintain separate lists for the combinations of heart-lung  
 274 and kidney-pancreas), the impact of allocation decisions on access to and outcomes of transplantation  
 275 among those waiting for the separate organs needs to be evaluated and justified. Since organ declines  
 276 near the top of the list may adversely affect perception of that organ by those with candidates lower on  
 277 the list, ways to minimize organ rejection by MOT candidates could be considered.

278

### 279 **Section C. MOT and Organ Quality**

#### 280 *MOT organs are of higher quality organs than SOT organs*

281 The quality of organs used for MOT is commonly better than the quality of similar organs used for SOT  
 282 (Figure 1). For example, the average KDPI in various MOT combinations is 18% to 36% versus an  
 283 average KDPI of 46% in isolated kidney transplantation.<sup>41</sup> MOT kidney recipients have a significantly  
 284 lower Calculated Panel Reactive Antibodies (CPRA) (difference of means=21.5, p=0.001), and receive  
 285 kidneys with a significantly lower Kidney Donor Profile Index (KDPI) than recipients of isolated kidneys  
 286 (difference of means=12%, p<0.001).<sup>42</sup> Since organs used for MOT tend to be, on average, higher quality  
 287 organs than organs used for SOT, MOT has the potential to concentrate the best organs into fewer,  
 288 typically higher risk,<sup>43</sup> recipients, magnifying the overall effect of any potential disparities between MOT

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<sup>39</sup> Reese et al., 2013.

<sup>40</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>41</sup> Reese et al., 2013.

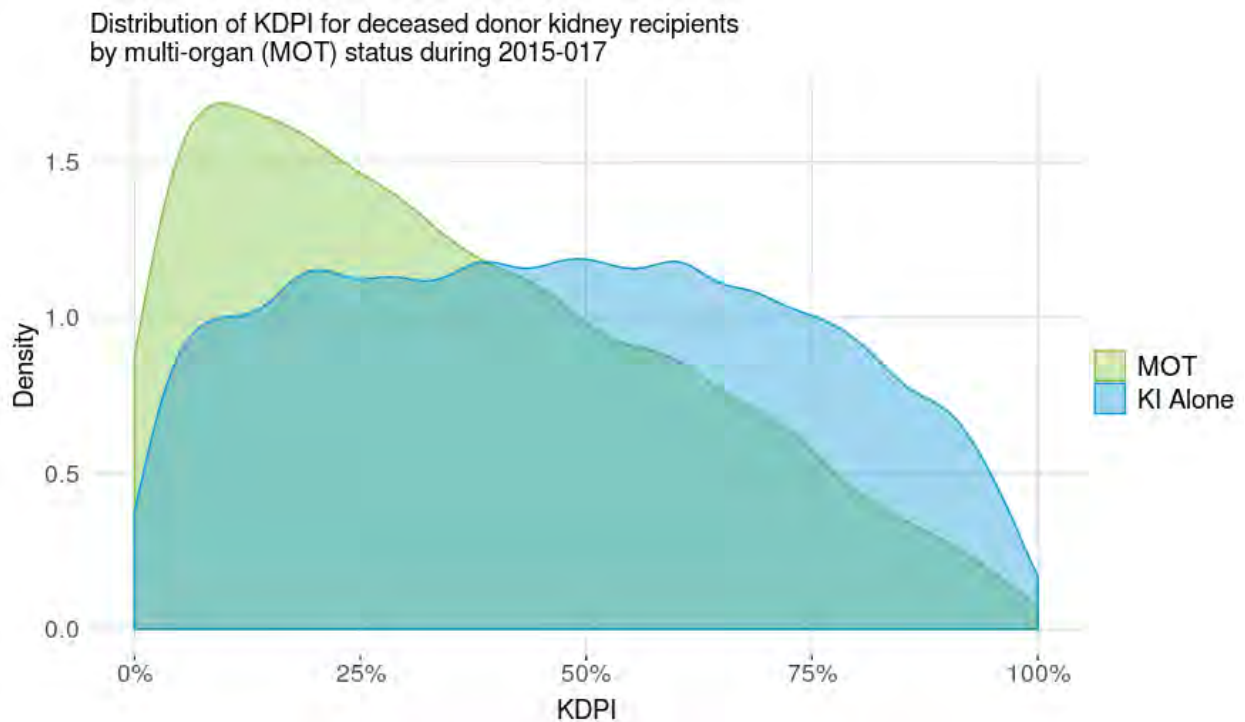
<sup>42</sup> Ibid.

<sup>43</sup> Lunsford, Keri E., Adam S. Bodzin, Daniela Markovic, Ali Zarrinpar, Fady M. Kaldas, Hans Albin Gritsch, Victor Xia, Douglas G. Farmer, Gabriel M. Danovitch, Jonathan R. Hiatt, Ronald W. Busuttil, and Vatche G. Agopian. "Avoiding Futility in Simultaneous Liver-kidney Transplantation." *Annals of Surgery*, 265, no. 5 (2017): 1016-024. doi:10.1097/sla.0000000000001801.

289 and SOT candidates that exist.<sup>44,45</sup> Furthermore, the recipients of MOT involving a kidney tend to be  
 290 significantly older (difference of means=3.6 years,  $p<0.001$ ), reducing the utility of these “ideal” organs as  
 291 the lifespan of older transplant recipients is generally shorter than younger recipients.<sup>46</sup> The age disparity  
 292 of older MOT recipients redirecting better-quality organs from younger candidates may disproportionately  
 293 affect pediatric recipients because pediatric recipients typically have longer graft survival than older  
 294 recipients.

295  
 296

Figure 1: KDPI by MOT status, 2015-2017



297  
 298  
 299  
 300  
 301  
 302  
 303

Currently, the Estimated Post Transplant Survival (EPTS) score is used to allocate the best kidneys (KDPI of 20% or less) to candidates who have the longest life expectancy (thus maximizing benefit). Redirecting these kidneys from the isolated kidney transplant list for MOT candidates does not maximize benefit through the use of EPTS because the graft survival of the kidney in MOT recipients is lower compared to the graft survival in an isolated kidney transplant recipient.<sup>47</sup>

304 Focused distribution of higher quality organs for MOT allocation can occur either by the inherent nature of  
 305 the allocation system, or through program behavior. For heart-kidney transplantation, the kidneys that are  
 306 available for MOT are from donors with a heart suitable for allocation. These tend to be younger, healthier  
 307 donors and the kidneys tend to be higher quality kidneys as a result.<sup>48</sup> Thus, the allocation system allows  
 308 a heart candidate access to kidneys that tend to be, on average, higher quality than those available to the  
 309 isolated kidney recipients. Program behavior can also lead to focused distribution of higher quality organs  
 310 to MOT candidates. A program with a patient who is waiting for a heart-kidney is less likely to take a

<sup>44</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>45</sup> Reese et al., 2013.

<sup>46</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018 (50-51).

<sup>47</sup> Ibid.

<sup>48</sup> Reese et al., 2013, p. 9.

311 heart-kidney combination from a donor when there is moderate dysfunction of either organ, resulting in  
312 higher quality organs being used for MOT.

### 313 Ethical Principles in Conflict

- 314 • Equity: When higher-quality organs are removed from the pool before a group has had an  
315 opportunity to be considered for those organs, candidates lack a fair opportunity to receive them.  
316 Additionally, MOT can violate the principle of first-come, first-served when kidneys are allocated  
317 to MOT recipients who have been waiting for shorter periods, than to kidney candidates who have  
318 been waiting for longer periods. However, MOT does follow the principle of the rule of rescue,  
319 because candidates closest to death are given priority.  
320
- 321 • Utility: MOT recipients usually derive the most benefit from the life-saving organ (heart, lung,  
322 liver), with less overall benefit coming from the kidney, and this benefit declines with decreasing  
323 kidney organ quality. In one analysis, simultaneous liver-kidney transplantation only provided a  
324 survival benefit compared to an isolated liver transplant if the kidney donor risk index was  $\leq 1$ .<sup>49</sup>  
325 However, while MOT patients do derive a benefit from higher quality organs, in general, recipients  
326 of some MOT combinations have lower overall survival than isolated organ recipients.<sup>50</sup> Thus,  
327 overall SOT recipients receive a greater net utility in terms of years of graft function from the  
328 kidney than do heart-kidney or liver-kidney recipients.

### 329 Recommendations

330 The impact of higher quality organs distributed to MOT candidates and removed from the pool for SOT  
331 candidates must be considered in organ allocation so as to not disadvantage SOT candidates. SOT  
332 candidates (most often the kidney) are often denied access to the organs of highest quality because  
333 these are redirected out of the system for MOT patients before SOT patients have had a chance to  
334 accept them.  
335

### 336 **Section D. MOT and Alternative Supportive Treatments**

337 *MOT should be prioritized for candidates who have no alternative supportive treatments options*

338 Some transplant candidates can receive life-sustaining therapy through alternative supportive treatments  
339 while they await transplantation. Examples include dialysis (for kidney), left ventricular assist devices  
340 (LVADs) (for heart), and extracorporeal membrane oxygenation (ECMO) (for lung and/or heart). These  
341 supportive treatments allow a patient who would otherwise die from their organ dysfunction to remain  
342 alive to await transplantation. For many of these organs, these supportive treatments also change the  
343 candidate's allocation priority.

344 Many patients awaiting MOT are not eligible for supportive treatments because of the second organ's  
345 dysfunction. For example, placing an LVAD in a heart failure patient who also has severe liver disease is  
346 associated with a significant risk of morbidity and mortality.<sup>51</sup> Thus, such patients are usually not provided  
347 an LVAD. Accordingly, MOT candidates are placed at a survival disadvantage prior to transplant because  
348 they are not deemed candidates for these supportive therapies due to their multi-organ failure, compared  
349 to heart failure patients who need a SOT for whom an LVAD is an option. Further, when the listing status

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<sup>49</sup> Sharma, Pratima, Xu Shu, Douglas E. Schaubel, Randall S. Sung, and John C. Magee. "Propensity Score-Based Survival Benefit of Simultaneous Liver-Kidney Transplant Over Liver Transplant Alone for Recipients with Pretransplant Renal Dysfunction." *Liver Transplantation* 22, no. 1 (2015): 71-79. doi:10.1002/lt.24189.

<sup>50</sup> Cheng, Xingxing S., Margaret R. Stedman, Glenn M. Chertow, W. Ray Kim, and Jane C. Tan. "Utility in Treating Kidney Failure in End-Stage Liver Disease With Simultaneous Liver-Kidney Transplantation." *Transplantation* 101, no. 5 (May 2017): 1111-119. doi:10.1097/tp.0000000000001491.

<sup>51</sup> Kato, Tomoko S., P. Christian Schulze, Jonathan Yang, Ernest Chan, Khurram Shahzad, Hiroo Takayama, Nir Uriel, Ulrich Jorde, Maryjane Farr, Yoshifumi Naka, and Donna Mancini. "Pre-operative and Post-operative Risk Factors Associated with Neurologic Complications in Patients with Advanced Heart Failure Supported by a Left Ventricular Assist Device." *The Journal of Heart and Lung Transplantation* 31, no. 1 (January 2012): 1-8. doi:10.1016/j.healun.2011.08.014.

350 is based on the utilization of these therapies, the inability to be treated with these therapies prevents their  
351 listing status from reflecting their true degree of illness.

352 For heart MOT candidates who could benefit from supportive treatments, but who are not good  
353 candidates for them, the Regional Review Board (RRB) provides a mechanism of appeal so that the  
354 patient's listing status can more appropriately match their degree of need (in general, MOT candidates  
355 are status 5 in the new heart allocation system, unless they meet criteria for a higher status).<sup>52</sup> One major  
356 problem with RRBs is that they lack standardization and hold great potential for inconsistency in the  
357 granting of exceptions.<sup>53</sup> Not all patients who could be eligible for an exception are granted one by an  
358 RRB.<sup>54</sup> Inconsistency can occur between regions, or even in the same region when members of the RRB  
359 rotate off and are replaced by a new group of representatives. While RRBs may review exceptions for  
360 candidates in other regions to avoid this problem, inconsistencies may remain in practice: if the RRB in  
361 one region is relatively strict in granting exceptions for heart MOT candidates, then there may be a net  
362 efflux (e.g., flowing out) of organs out of that region into other regions that are more liberal in granting  
363 exceptions. This is particularly harmful to the SOT candidates in the first region whose priority is based on  
364 time on the waitlist, because organs that may have otherwise gone to them are redirected with the organ  
365 that is allocated by degree of need. Thus, the RRB for heart allocation will have an effect on SOT  
366 candidates for other organs in their area, even though they have no direct role in the allocation order of  
367 these organs. A national review system with a consistent method of granting exceptions to MOT  
368 candidates would largely negate this issue. In addition, a candidate in a region with a strict RRB who is  
369 not granted an exception will not compete on even footing for the needed organs with an identical  
370 candidate under the auspices of a less strict RRB.

#### 371 Ethical Principles in conflict

- 372 • Equity: Heart MOT candidates who are not eligible for support therapies that would appropriately  
373 elevate their status experience a lack of equality of opportunity to receive the organs in need.  
374 While this situation may be addressed by an RRB, the inconsistent manner in which different  
375 RRBs deliberate about candidates may not resolve this inequality. In addition, decisions by the  
376 RRB for one organ affect patients waiting for the other organ(s) even though that RRB does not  
377 oversee the other organs. In other words, if the heart RRB approves a status upgrade for a  
378 candidate on the heart list who also needs a kidney, then the heart RRB has essentially  
379 prioritized that kidney since the heart will redirect the kidney, even though the RRB does not  
380 oversee allocation of kidneys.
- 381 • Utility: none.

#### 383 Recommendations

384 Consideration should be given to a national board to review exceptions for MOT listing priority in order to  
385 develop and maintain a consistent approach to assessing MOT candidates for listing exceptions. Unlike  
386 SOT candidates, exception requests for MOT candidates are likely to be infrequent because listing for  
387 MOT is less common and the current listing mechanisms are appropriate for most listed patients. In  
388 addition, MOT exceptions affect more patients per decision because in MOT, secondary organs are often  
389 redirected by the needs of the first organ. A national review board may help to ensure consistency in the  
390 way that exception requests are handled given that regional variations in the granting of exceptions will  
391 disappear, allowing candidates from different regions to have similar access to available organs. A  
392 national review board for MOT may also be applicable to any situation in the future if there are changes in  
393 the allocation system by geography, because the review system will not need to be adjusted if there are

<sup>52</sup> OPTN Policy 6.1.E, *Adult Heart Status 5 Requirements* (accessed March 18, 2019).

<sup>53</sup> OPTN Briefing Paper *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017,

[https://bodandcommittees.unos.org/archive/Documents/Liver\\_Establish\\_National\\_Liver\\_Review\\_Board\\_201706.pdf](https://bodandcommittees.unos.org/archive/Documents/Liver_Establish_National_Liver_Review_Board_201706.pdf)

<sup>54</sup> Bittermann, Therese, George Makar, and David Goldberg. "Exception Point Applications for 15 Points: An Unintended Consequence of the Share 15 Policy." *Liver Transplantation* 18, no. 11 (2012): 1302-309. doi:10.1002/lt.23537.

394 changes in allocation. Better standardization of the exceptions granted may also lead to more valid data,  
395 which can help to refine future modifications of policies affecting MOT.

### 396 **Section E. Prioritization of MOT over SOT**

397 *MOT allocation strategies should take into account candidates' degree of need of each organ*  
398 *for transplantation*

399 A major concern with MOT is that one patient is given potentially life-prolonging treatment with two or  
400 more organs that could provide the same treatment to two or more patients awaiting SOT. Given the  
401 position of this paper that MOT is ethically appropriate in some instances, there needs to be a balance in  
402 the need of one patient versus the needs of two patients. While there are many situations in which the  
403 waitlist mortality of the MOT candidate exceeds the waitlist mortality of SOT candidates, the relative  
404 mortality rates depend upon the specifics involved.

405 For example, candidates for simultaneous heart-kidney transplantation have a 1-year waitlist mortality  
406 rate of 32.6% compared to 25.4% for heart alone candidates.<sup>55</sup> Conversely, there is no statistically  
407 significant difference between liver-kidney candidates with a MELD or PELD (pediatric end-stage liver  
408 disease score) of 15-19 who have a waitlist mortality of 6.9% (95% CI: 5.06%; 9.28%) compared to those  
409 awaiting a kidney-alone who have a waitlist mortality of 8.8% (95% CI: 8.65%, 8.77%).<sup>56</sup> In the absence  
410 of a survival difference on the waitlist, there needs to be ethical justification if the allocation system is to  
411 prioritize one of these groups over the other for the kidney.

### 412 Ethical Principles in Conflict

- 413 • Equity: Under the Maximin principle, the candidate who needs a MOT is worse off than the SOT  
414 candidate with a similar dysfunction of the single organ because more than one organ system has  
415 failed. Policies that unduly favor SOT violate the Maximin principle by directing organs to those  
416 who are less ill.
- 417 • Utility: The benefit to a single MOT recipient may be greater than the benefit to a single SOT  
418 recipient. However, the benefit to a single MOT recipient may not be as great as the *combined*  
419 benefit to all SOT recipients who could have received the multiple organs in consideration if the  
420 MOT recipient had not received them.

### 422 Recommendations

423 Allocation strategies for organs and organ combinations should take into account the degree of benefit to  
424 the individual(s) transplanted (and potential benefit to be lost by those not transplanted) under each  
425 allocation system. While waitlist mortality is an important factor in organ allocation systems, it is not the  
426 only factor in consideration, and differences in mortality (including the degrees of difference) need to be  
427 considered, along with other factors, including wait time and racial and socioeconomic disparities, when  
428 making allocation decisions. Transplant candidates who do not have a claim to medical urgency or are  
429 not expected to have a lasting benefit from the second organ should not be prioritized to receive that  
430 organ until others with greater need for and/or better outcome with that isolated organ have had the  
431 opportunity to accept that organ.

### 432 **Section F. MOT and Protected Subgroups**

433 *Consider revising MOT allocation to minimize harm to protected subgroups*

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<sup>55</sup> Wolf, J. H., M. E. Sulewski, J. R. Cassuto, M. H. Levine, A. Naji, K. M. Olthoff, A. Shaked, and P. L. Abt.  
"Simultaneous Thoracic and Abdominal Transplantation: Can We Justify Two Organs for One Recipient?" *American  
Journal of Transplantation* 13, no. 7 (2013): 1806-816. doi:10.1111/ajt.12291.

<sup>56</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor  
adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.



434 Given the organ shortage, not all transplant candidates will receive an organ transplant.<sup>57</sup> It is incumbent  
 435 upon the transplant community to ensure that groups of patients are not doubly-disadvantaged through  
 436 the process of organ allocation (policy-induced disparities). African Americans are over-represented as  
 437 SOT recipients and under-represented as MOT recipients, and therefore could be doubly disadvantaged  
 438 by policies that prioritize MOT over SOT.<sup>58</sup> For another example, patients who are highly sensitized (have  
 439 antibodies against many common antigens and thus are unable to accept organs with those antigens) are  
 440 less likely to be offered a compatible organ. To grant MOT candidates without extenuating circumstances  
 441 even greater prioritization would magnify the disadvantage to highly sensitized SOT candidates by  
 442 redirecting organs out of the system before highly sensitized candidates have the opportunity to be  
 443 matched to that organ. The National Organ Transplantation Act (NOTA) specifically requires the OPTN to  
 444 consider “populations with special needs” such as highly sensitized candidates.<sup>59</sup>

445 Pediatric patients (less than 18 years of age) awaiting transplantation may be disadvantaged by the  
 446 prioritization of MOT at the local level. Pediatric candidates are commonly prioritized in organ allocation  
 447 policies, but MOT candidates generally receive priority above pediatric candidates at the local level which  
 448 may reduce pediatric candidates’ access.<sup>60</sup> Redirecting organs that would have been offered to pediatric  
 449 isolated-organ candidates to MOT candidates may reduce the available organs for pediatric candidates.  
 450 Future research should assess whether OPOs vary in their distribution of MOTs for pediatric candidates.

451 Differences also exist in the current MOT allocation systems that appear to disadvantage racial/ethnic  
 452 minority candidates awaiting isolated kidney transplantation. Black patients are underrepresented among  
 453 those who receive MOT involving a kidney, comprising about 18% of the recipients, compared to isolated  
 454 kidney transplantation, where they comprise about 35% of the recipients. **Table 2** shows that there is a  
 455 significant difference by race/ethnicity between MOT and kidney (KI) alone transplants ( $p < 0.001$ ).<sup>61</sup>  
 456 Similar patterns occur by socioeconomic status, whereby those receiving a kidney as part of MOT live in  
 457 zip codes with a significantly higher than average socioeconomic status (SES) than those who receive an  
 458 isolated kidney transplant (difference of mean SES = \$5,717,  $p = 0.001$ , where SES is median annual  
 459 income of the recipient’s zip code). Further research is needed to ascertain whether these differences  
 460 comprise disparities in the sense of significantly disproportionately placing underserved groups at a  
 461 disadvantage.  
 462  
 463  
 464

Table 2. Kidney transplants 2015-17 by MOT Status and Race/Ethnicity

Organ	White	Black	Hispanic	Asian	Other	Total
MOT	1,540 (60.8%)	463 (18.3%)	402 (15.9%)	93 (3.7%)	35 (1.4%)	2,533 (100.0%)
KI Alone	12,949 (36.3%)	12,590 (35.2%)	6746 (18.9%)	2,572 (7.2%)	864 (2.4%)	35,721 (100.0%)
Total	14,489 (37.9%)	13,053 (34.1%)	7,148 (18.7%)	2,665 (7.0%)	899 (2.4%)	38,254 (100.0%)

465

#### 466 Ethical Principles in conflict

- 467
- Equity: Policy-induced disparities create inequality of opportunity. In addition, prioritizing MOT  
 468 over SOT in policy may violate the Maximin principle, because pediatric or racial/ethnic minority  
 469 or low SES candidates who are already disadvantaged in the organ allocation process are made  
 470 “worse-off” in terms of long-term prognosis even with a similar degree of illness at the present  
 471 time. Allocation decisions that favor providing an organ to adult recipients over pediatric recipients

<sup>57</sup> 2019 OPTN data (accessed March 18, 2019).

<sup>58</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>59</sup> NOTA, 42 U.S.C. § 274n

<sup>60</sup> OPTN Policy 5.10, *Allocation of Multi-Organ Combinations* (Accessed April 8, 2019)

<sup>61</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

- 472 may potentially-violate the “fair innings” principle because pediatric patients have, by definition,  
473 not been able to reach the major life milestones that adult patients have been able to reach.  
474
- 475 • Utility: Allocation decisions that favor adult recipients may potentially lead to fewer years of life  
476 gained when compared to the same organ that is provided to a pediatric patient.

#### 477 Recommendations

478 Each organ committee should consider candidate groups that may be already disadvantaged by the  
479 organ allocation process. If modeling with MOT suggests that additional harms from MOT may  
480 disproportionately affect subgroups compared to the general population awaiting transplantation, then  
481 MOT allocation systems should be revised to minimize the additional harm. To prevent organ allocation  
482 systems involving MOT from disproportionately disadvantaging pediatric recipients, further research should  
483 assess how MOT allocation algorithms affect the distribution of organs between adult and pediatric  
484 patients. Future research should also assess whether MOT and SOT discard rates differ, and what  
485 causes may contribute to potential differences in these discard rates. Such a difference would raise  
486 concern about finding back-up recipients in a timely manner who could accept the organs if the MOT falls  
487 through.

#### 488 **Section G. Monitoring MOT** 489 *MOT Should be Monitored in Transplant Programs*

490 As described in the Principles of Organ Allocation, scarce organs must be allocated in an equitable  
491 manner while also maximizing their utility.<sup>62</sup> Data and transparency can help determine whether organs  
492 are being allocated accordingly.<sup>63</sup> Data provide benchmarks for standards of care that transplant centers  
493 are expected to share.

494  
495 However, there are few published data on the allocation and outcomes of MOT, which may be related to  
496 a relative paucity of data available at the national level. Consequently, no robust statistical models are  
497 used to compare the observed outcomes of MOT to the expected outcomes.<sup>64</sup> Therefore, to a large  
498 extent, transplant centers are not held accountable for the results of MOT outcomes.

499 The absence of standards can open the door for transplant centers to manipulate transplant outcomes in  
500 several ways. First, in many cases, requalifying a potential high-risk SOT candidate as an MOT candidate  
501 effectively removes the candidate from the center’s publicly reported data.<sup>65</sup> Second, centers may be  
502 inclined to waitlist a candidate for MOT who would not ordinarily meet the acceptance criteria for SOT at  
503 that center.<sup>66</sup> In either of these scenarios, a bad clinical outcome in a MOT recipient is not likely to  
504 jeopardize a center’s standing, thus making these behaviors risk-free from the perspective of the center.<sup>67</sup>

505 It is well documented that the outcomes of many surgical procedures in general, and some organ  
506 transplantations specifically, are tied to the volume of the procedures at a given center, with volume  
507 acting as a surrogate for experience.<sup>68</sup> Greater experience is associated with better outcomes. Since  
508 outcomes for one organ may not reflect the outcomes for other organs at that same center, monitoring of  
509 SOT only may not be an adequate surrogate for MOT quality and outcomes.

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<sup>62</sup> *Ethical principles in the allocation of human organs*, OPTN Ethics Committee, June 2015,  
<https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/> (accessed  
December 17, 2018).

<sup>63</sup> Reese et al., 2013, p. 24.

<sup>64</sup> Reese et al., 2013, p. 23.

<sup>65</sup> Reese et al., 2013, p. 24.

<sup>66</sup> *Ibid.*

<sup>67</sup> *Ibid.*

<sup>68</sup> Shuhaiber, Jeffrey H., MD, Jeff Moore, MS, and David B. Dyke, MD. "The Effect of Transplant Center Volume on Survival After Heart Transplantation: A Multicenter Study." *The Journal of Thoracic and Cardiovascular Surgery* 139, no. 4 (April 2010): 1064-069. doi:10.1016/j.jtcvs.2009.11.040.

510 Ethical Principles in Conflict

- 511 • Equity: Centralized data collection, analysis, and reporting will provide transparency to MOT  
512 outcomes.<sup>69</sup> Data monitoring will likely enable the creation of standards expected for transplant  
513 programs to follow, outcomes to achieve, and more conscientious use of organs. As the  
514 outcomes become better known, minimum standard criteria can be developed for MOT to  
515 decrease the variability in patient selection for MOT and results.<sup>70</sup> This will improve outcomes and  
516 minimize unnecessary or futile MOT procedures, allowing increased access to organs by SOT  
517 candidates. Data collection, analysis, and reporting may deprive those candidates who are worse  
518 off from the chance of undergoing a high-risk MOT procedure (and thus violate the Maximin  
519 principle). However, this possibility will not differ from the current situation for SOT candidates in  
520 which monitoring and reporting are routinely practiced. Data analysis for MOTs may be difficult  
521 due to the low number of MOTs performed.<sup>71</sup>  
522
- 523 • Utility: In situations where high-risk MOT is only enabled by the lack of accountability, poor  
524 outcomes may result in futile transplants. With a futile transplant, there is no benefit to the MOT  
525 recipient, and there is additional harm to the potential SOT recipients who were denied the  
526 potential benefit of the organs.

527 Recommendations

528 Organ stewardship requires systematic data collection, analysis, and public reporting.<sup>72</sup> Data for each  
529 MOT combination should be made publicly available to foster transparency while protecting patient  
530 confidentiality. When possible, center-specific data should also be made available to help patients select  
531 transplant centers for MOT based on experience and outcomes. If sufficient data do not yet exist to create  
532 risk-adjustment models for a given organ combination, then the data on a MOT case should be attributed  
533 to the organ of that specific combination with the highest risk of graft failure or posttransplant mortality,  
534 and let the transplanting center decide if it is willing to accept the risk of failure for that patient. Transplant  
535 centers that perform MOT should be held to standards of excellence, just as they are for SOT.

536 Consideration should be given to the Membership and Professional Standards Committee (MPSC)  
537 approving transplant centers to perform MOT in order to ensure that there are optimal outcomes for  
538 individual recipients and good stewardship of the available organs. As local expertise will vary, it may be  
539 best to approve MOT for specific combinations (e.g., heart-kidney or lung-liver) or similar combinations  
540 (heart-abdominal or abdominal solid organ-intestine). An assessment of the impact upon patients in the  
541 region who may need MOT is reasonable, especially in regions where there is low availability of  
542 transplant centers capable of performing MOT.

543 **Section H. MOT and Fairness to patients awaiting SOT**  
544 *Policies should account for quality of life for SOT candidates*  
545

546 Some organs are more commonly involved in MOT than others. For example, kidneys are over-  
547 represented in MOT. Excluding kidney-pancreas transplantation, kidneys were utilized in 91% of MOT  
548 cases in 2017 (Table 1), redirecting nearly 1,000 kidneys from the isolated kidney waitlist. This represents  
549 6.7% of the deceased donor kidneys transplanted that year, not an insignificant number for someone who  
550 is waiting for an isolated kidney.<sup>73</sup> Patients waiting for a kidney are prioritized by time with renal failure  
551 and other factors, but not degree of illness, unlike those awaiting heart, liver, and lung transplants.  
552 Candidates who are awaiting a kidney also have a lower overall expected waitlist mortality than those

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<sup>69</sup> Reese et al., 2013, p. 24.

<sup>70</sup> Ibid.

<sup>71</sup> Ibid.

<sup>72</sup> *Manipulation of the Organ Allocation System Waitlist Priority through the Escalation of Medical Therapies*, OPTN Ethics Committee, June 2018, [https://optn.transplant.hrsa.gov/media/2500/ethics\\_whitepaper\\_201806.pdf](https://optn.transplant.hrsa.gov/media/2500/ethics_whitepaper_201806.pdf) (accessed December 17, 2018).

<sup>73</sup> 2018 OPTN data (accessed December 11, 2018).

553 waiting for many other organs, and are thus considered by many to be less needy for their organ than the  
554 MOT candidates.<sup>74</sup> This does not take into account the effect of dialysis on their quality of life, or the slow,  
555 insidious decline in life expectancy associated with renal failure and dialysis. Although kidney SOT  
556 candidates are not at high risk of imminent death, their need for transplantation is real and might be life-  
557 saving. Thus, patients awaiting SOT should not be unfairly penalized for having a lower degree of illness  
558 (i.e., single organ involvement compared to multi-organ involvement).

559 Ethical Principles in Conflict

560 • Equity: Patients awaiting SOT are denied an equitable access to transplantation if the organ that  
561 they are waiting for is redirected from the organ pool available for SOT at a disproportionately  
562 high rate.

563  
564 • Utility: None

565 Recommendations

566 To address this inequity, policies should be modified to account for the impact of organ dysfunction on the  
567 quality of life for SOT candidates. Policies should also limit the ability of MOT candidates who are at low-  
568 risk for death on the waitlist to redirect secondary organs.

569 **Section I. MOT and Standardized Criteria**

570 *Standardized criteria would bring transparency and clarity to MOT policy*

571 The OPTN does not set standard listing criteria across all MOT combinations in policy, and the resulting  
572 discretion of transplant programs may lead to inconsistency in the medical urgency of the MOT  
573 candidates listed for transplant. Variations in the criteria used for MOT may lead to patients receiving  
574 MOT who may not require this therapy and removing organs from the allocation system that may not  
575 need to be removed.<sup>75</sup> For example, a heart transplant candidate with a diminished creatinine clearance  
576 may be listed for heart transplantation alone and then be listed later for kidney transplantation if the  
577 kidney fails after heart transplantation. That same candidate may also be listed for heart-kidney  
578 transplantation without first determining whether the patient's native kidney function would have improved  
579 following heart transplantation.<sup>76,77</sup>

580 Some MOT candidates who receive a kidney as part of the MOT are not eligible as a candidate for  
581 isolated kidney transplantation because the kidney disease is not that severe to be waitlisted for a kidney  
582 transplant.<sup>78</sup> Under current allocation policy an MOT candidate could be eligible for a kidney with an  
583 eGFR greater than 20 mL/min whereas this would not be allowed for an isolated kidney.<sup>79</sup> This  
584 demonstrates that the waitlist criteria are less strict for MOT candidates than they are for SOT candidates.

585 Simultaneous transplantation presents several advantages over isolated transplantation. Patients with a  
586 diminished GFR who are not on dialysis and who undergo simultaneous heart-kidney transplantation  
587 generally fair better than those who undergo heart transplantation alone.<sup>80</sup> However, there is a need to

---

<sup>74</sup> Ibid.

<sup>75</sup> Levitsky, J., T. Baker, S. N. Ahya, M. L. Levin, J. Friedewald, L. Gallon, B. Ho, A. Skaro, J. Krupp, E. Wang, S. M. Spies, D. R. Salomon, and M. M. Abecassis. "Outcomes and Native Renal Recovery Following Simultaneous Liver-Kidney Transplantation." *American Journal of Transplantation* 12, no. 11 (2012): 2949-957. doi:10.1111/j.1600-6143.2012.04182.x.

<sup>76</sup> Ibid.

<sup>77</sup> Reese et al., 2013.

<sup>78</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.

<sup>79</sup> OPTN Policy 8.4.A, *Waiting Time for Candidates Registered at Age 18 Years or Older* (accessed April 7, 2019).

<sup>80</sup> Kilic, Arman, Joshua C. Grimm, Glenn J.r. Whitman, Ashish S. Shah, Kaushik Mandal, John V. Conte, and Christopher M. Sciortino. "The Survival Benefit of Simultaneous Heart-Kidney Transplantation Extends Beyond Dialysis-Dependent Patients." *The Annals of Thoracic Surgery* 99, no. 4 (2015): 1321-327. doi:10.1016/j.athoracsur.2014.09.026.

588 balance the improved results seen in these studies with efficient use of organs, which does not occur  
589 when kidneys are transplanted prophylactically.

590  
591 For example, in the area of heart-kidney transplantation, there are currently no standardized criteria to  
592 determine which heart transplant candidates should receive a simultaneous kidney. One heart-kidney  
593 candidate may have established end-stage renal disease with long-standing dialysis dependence. This  
594 patient would not be expected to have renal recovery after an isolated heart transplant, and as such, this  
595 patient will clearly require a kidney transplant in order to come off dialysis. On the other hand, another  
596 patient may need a heart transplant and have relatively recent acute kidney injury due to cardiorenal  
597 syndrome with a glomerular filtration rate of 30 ml/min. Without standardized criteria, this patient can also  
598 be listed for a heart-kidney transplant. Unlike the prior patient, this patient has at least a reasonable  
599 chance of renal recovery and freedom from dialysis. However, this patient receiving a kidney may prevent  
600 the opportunity to observe for native renal recovery, and potentially redirects the kidney away from other  
601 MOT candidates with more clear need for a kidney transplant, or from SOT isolated kidney candidates  
602 with demonstrated need for a kidney transplant.

603  
604 While the SLK policy addressed certain ethical dilemmas associated with MOT including organ  
605 prioritization, listing criteria, and a safety net, this MOT white paper addresses those and other ethical  
606 dilemmas beyond the scope of the SLK policy change to provide a broad overview of the ethical  
607 challenges inherent in allocating multiple organs to individual recipients.

608  
609 In the absence of standardized criteria, there is significant variability in the listing practices for patients  
610 who could be considered for MOT. In the case of simultaneous liver-kidney transplantation (SLK), prior to  
611 the establishment of standardized eligibility criteria, there was significant variation in the listing practice  
612 and utilization of SLK versus isolated liver transplantation.<sup>81</sup> These variations may be attributed to many  
613 factors, including a center's assertiveness in being willing to undertake MOT or the willingness to take the  
614 risk that the results of an isolated liver transplant will not be diminished by forgoing the additional  
615 organ(s). In 2017, the OPTN Board of Directors passed an SLK policy that sought to minimize variability  
616 in practice, improve outcomes and decrease the transplantation of unnecessary organs.<sup>82</sup> The SLK policy  
617 proposal did raise ethical issues specific to liver-kidney allocation including the risk of creating inequity  
618 due to a lack of standardized criteria and the need to create medical criteria in order to be compliant with  
619 the Final Rule. With the adoption of this policy, minimal medical eligibility criteria were established in  
620 order for an individual to receive a liver and kidney from the same donor. A safety net was also  
621 established in order to prioritize isolated liver recipients for a kidney after liver transplant if they have  
622 persistent renal failure following an isolated liver transplantation.

#### 623 624 Ethical Principles in Conflict

- 625 • Equity: Equity is threatened when a patient undergoing MOT who could benefit but does not  
626 require the second organ (e.g., heart-lung where the heart function is good enough that the  
627 recipient has a reasonable chance of surviving a lung transplant without the heart) takes that  
628 organ from a SOT candidate who requires the same organ (e.g., heart).<sup>83</sup> This is particularly  
629 ethically problematic since the current allocation system for some organ combinations (e.g.,  
630 heart-kidney) allows the MOT candidate to get priority for the second organ, even though the  
631 need for the second organ is less critical or clear.
- 632  
633 • Utility: Benefit to the transplant community as a whole is not maximized when an organ is  
634 transplanted into any recipient, when such transplantation is, in retrospect, not necessary. In  
635 addition, there is no significant difference between the transplantation of an organ that is not

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<sup>81</sup> Eason, J. D., T. A. Gonwa, C. L. Davis, R. S. Sung, D. Gerber, and R. D. Bloom. "Proceedings of Consensus Conference on Simultaneous Liver Kidney Transplantation (SLK)." *American Journal of Transplantation* 8, no. 11 (August 2008): 2243-251. doi:10.1111/j.1600-6143.2008.02416.x.

<sup>82</sup> Simultaneous Liver Kidney (SLK) Allocation. OPTN Kidney Transplantation Committee, June 2016, [https://optn.transplant.hrsa.gov/media/1871/kidney\\_briefingpaper\\_slk\\_201606.pdf](https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf) (accessed December 11, 2018).

<sup>83</sup> Reese et al., 2013.

636 necessary and the transplantation of an organ in which the recipient does not survive for an  
637 extended period of quality life. In both cases, these may be seen as futile cases from the  
638 perspective of the organ and in terms of those who are awaiting an available organ. Another  
639 potential issue with utility is that for organ combinations like a heart-kidney, the need for a kidney  
640 may come later, meaning that not getting that second organ from the same donor could lead to  
641 increased risk from a second surgery and greater risk of immunological incompatibility.

## 642 Recommendations

643 Organ committees should examine their isolated organ-specific data in conjunction with other organ data  
644 to determine if the need for a second, not immediately life-saving organ is demonstrable, and if so, set  
645 appropriate criteria for listing the second organ, similar to that which is done for SLK.<sup>84</sup> These actions  
646 demonstrate a respect for the needs of SOT candidates by not unnecessarily removing organs from their  
647 potential donor pool. Making redirection of organs more difficult to accomplish when the organ need is  
648 debatable may help reduce the chances of an unnecessary transplant occurring.

649 Policies should not disincentivize single organ transplantation if the second organ will likely recover  
650 function. This requirement has already been established as part of the liver-kidney transplantation policy  
651 in which a safety net provides allocation priority for a kidney transplant if an isolated liver transplant  
652 recipient has non-recovery or persistent renal failure following liver transplant (Policy 8.5.G: *Prioritization*  
653 *for Liver Recipients on the Kidney Waiting List*).<sup>85</sup> Applying a safety net for other organ combinations may  
654 decrease some potentially unnecessary MOTs, particularly in situations when the second organ (i.e.,  
655 kidney) has a chance for recovery.

656 For example, a heart transplant candidate with borderline renal function may do just as well with an  
657 isolated heart transplant if the renal function improves thereafter. The candidate may be willing to  
658 undergo this sequential approach if the candidate may potentially receive a kidney transplant thereafter if  
659 needed. Policies similar to Policy 8.5.G: *Prioritization for Liver Recipients on the Kidney Waiting List* could  
660 alleviate the pressure to perform prophylactic MOT. Policy 8.5.G acts as a safety net and allows liver-  
661 kidney MOT candidates to undergo liver transplantation, yet maintain priority for subsequent kidney  
662 transplantation in the event that the native kidneys do not recover after liver transplantation. While there  
663 may be benefits to receiving multiple organs from the same donor as opposed to receiving different  
664 organs from different donors, this benefit needs to be balanced by the net benefit to the transplant  
665 community when MOT can be avoided with a reasonable degree of safety.

## 666 **Section J. MOT and Relative Futility** 667 *MOT Should Not be Performed if Relatively Futile* 668

669 The short- and long-term outcomes of organ transplantation depend on many factors, including the  
670 candidate's degree of illness at the time of transplantation. The risks of MOT are typically higher than the  
671 risks of SOT because the MOT recipient is more ill with multi-organ failure, the combined MOT operations  
672 are longer and require more technical skill than SOT, and complications with one or both MOT organ(s)  
673 can be life-threatening.<sup>86</sup> When a recipient dies during or soon after the transplant surgery or when one of  
674 the MOT organs fails, there is a double insult to the allocation system – the loss of life and organ function  
675 despite the successful transplant, and the loss of an organ that another patient could have used  
676 successfully.

677 MOT can be life-saving to someone who is critically ill with multi-organ failure. Since more donated  
678 organs are lost when a MOT recipient dies than when a SOT recipient dies, it is imperative that MOT  
679 candidates be healthy enough to survive post-transplant. For MOT candidates whose expected likelihood

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<sup>84</sup> Simultaneous Liver Kidney (SLK) Allocation. OPTN Kidney Transplantation Committee, June 2016, [https://optn.transplant.hrsa.gov/media/1871/kidney\\_briefingpaper\\_slk\\_201606.pdf](https://optn.transplant.hrsa.gov/media/1871/kidney_briefingpaper_slk_201606.pdf) (accessed December 11, 2018).

<sup>85</sup> OPTN Policy 8.5.G: *Prioritization for Liver Recipients on the Kidney Waiting List*. Accessed December 12, 2018.

<sup>86</sup> Lunsford, Keri E., Adam S. Bodzin, Daniela Markovic, Ali Zarrinpar, Fady M. Kaldas, Hans Albin Gritsch, Victor Xia, Douglas G. Farmer, Gabriel M. Danovitch, Jonathan R. Hiatt, Ronald W. Busuttil, and Vatche G. Agopian. "Avoiding Futility in Simultaneous Liver-kidney Transplantation." *Annals of Surgery* 265, no. 5 (2017): 1016-024. doi:10.1097/sla.0000000000001801.

680 of survival is significantly lower than that for SOT candidates, “relative futility” exists. “Relative futility”  
681 means that the expected outcomes of the several candidates who could have received the individual  
682 organs would far exceed the expected outcome of the single MOT recipient. Thus, caution should be  
683 exercised before proceeding with MOT when a poor outcome is likely because the MOT will not maximize  
684 lives saved or life-years added.

685 An example of relative futility arises in two MOT candidates awaiting heart-liver and heart-kidney  
686 transplantation. If both candidates are hospitalized and are on inotropes (e.g., medicines that increase the  
687 heart’s strength to contract for moving blood in the body), they would both qualify for a high listing status  
688 for the heart which would reflect their elevated risk for death, and both would have a reasonable chance  
689 of survival with the dual organ transplant. As an aside, both candidates would have to meet other  
690 stringent criteria to be listed at higher statuses, whereas normally they would be at status 5.<sup>87</sup> If both  
691 candidates’ health deteriorates, they could be placed on ECMO and justify an even higher listing status  
692 that would reflect the imminent death that they both face. However, their risk of death from the transplant  
693 procedure would increase significantly. Studies show that patients awaiting heart transplantation on  
694 ECMO have a much higher mortality risk from the transplant while on ECMO than those who are not on  
695 ECMO.<sup>88</sup> Both candidates could be viewed as justifying this increased risk under the Maximin principle or  
696 the Rule of Rescue, because both candidates have increased need for the MOT.

697 However, in the case of the heart-liver candidate, greater overall benefit may be achieved by giving the  
698 heart to an equally sick isolated heart candidate and the liver to a candidate with a high MELD score,  
699 because both SOT candidates would have a significantly greater chance of survival than the heart-liver  
700 candidate on ECMO<sup>89</sup>. Without a transplant, the heart-liver candidate will die. However, MOT  
701 transplantation may not be justified if the chance of survival with transplantation is sufficiently small. The  
702 heart-kidney candidate could still undergo heart transplantation with post-operative dialysis, and  
703 potentially be listed for kidney transplantation later if the candidate survives the heart-only transplant  
704 operation.

#### 705 Ethical Principles in Conflict

- 706 • Equity: A policy that is too restrictive on MOT allocation will violate the Maximin principle by  
707 denying the worse-off candidates access to transplantation. Such a policy will also violate the  
708 Rule of Rescue because patients close to death will not have the chance to undergo a life-saving  
709 transplantation.<sup>90</sup>  
710
- 711 • Utility: A policy that is too liberal on MOT allocation will minimize the medical benefits because  
712 non-survivors gain no benefit from MOT. In these cases, there is neither length nor quality of  
713 benefit, and the end result is a futile transplant procedure.

#### 714 Recommendations

715 Holding transplant centers accountable for their MOT outcomes will help to minimize the effects of relative  
716 futility. However, a risk-stratification system should prevent transplant centers from performing transplants  
717 on potentially futile cases without stopping to consider the effects of these decisions. For example, a risk  
718 stratification system that caps the maximum predicted mortality at, say, 20% would require a program to  
719 seriously reconsider listing patients with a higher estimated mortality. Establishing a risk stratification  
720 system with MOT is especially important since the death of a single MOT recipient affects the transplant  
721 community at least twice that of the death of a SOT recipient.

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<sup>87</sup> OPTN Policy 6: *Allocation of Hearts and Heart-Lungs* (Accessed April 7, 2019).

<sup>88</sup> Fukuhara, Shinichi, Koji Takeda, Paul A. Kurlansky, Yoshifumi Naka, and Hiroo Takayama. "Extracorporeal Membrane Oxygenation as a Direct Bridge to Heart Transplantation in Adults." *The Journal of Thoracic and Cardiovascular Surgery* 155, no. 4 (2018). doi:10.1016/j.jtcvs.2017.10.152.

<sup>89</sup> Ibid

<sup>90</sup> Reese et al., 2013.

722 **Section K. Impact of Adult MOT on Pediatric SOT**

723 *MOT allocation policy should avoid adverse impact on pediatric candidates whenever possible*

724 Any changes to the allocation system for adult organs has the potential to directly or indirectly affect the  
725 allocation of organs among the pediatric candidates who may also be candidates for those same organs.  
726 The National Organ Transplantation Act requires the OPTN to consider pediatric transplant candidates by  
727 “improving procedures for organ donation procurement and allocation” for children.<sup>91</sup> Between 2015 and  
728 2017, the mean KDPI for MOT recipients aged 50 and above was 36%, even though kidneys with a KDPI  
729 < 35 are prioritized to pediatric patients.<sup>92</sup>

730

731 Ethical Principles in Conflict

- 732 • Equity: Pediatric patients, by the nature of their age, have not had the opportunity to lead a full life  
733 as described by the “fair innings” concept. Policies that disadvantage pediatric transplant  
734 candidates at the expense of adult MOT recipients would violate the principle of equity.  
735
- 736 • Utility: Pediatric recipients have the potential to derive greater length of benefit and quality of  
737 benefit (in QALYs) than older adult recipients with a similar degree of illness. Thus, policies that  
738 disadvantage pediatric transplant candidates at the expense of adult MOT recipients would  
739 violate the principle of utility.

740 Recommendations

741 All policies that involve MOT allocation should be reviewed to ensure that they do not adversely affect the  
742 number or quality of organs available to pediatric candidates, without ethical justification.

743

744 **Conclusions:**

745 The OPTN strongly supports the concept and practice of MOT because MOT has been proven to be a  
746 life-saving therapy for patients who do not have any other treatment alternative. However, there are  
747 situations where MOT is less defensible and may even be inappropriate. These situations occur when the  
748 expected survival of the MOT recipient or organs is poor, and when the need for the second organ is  
749 unclear. When the chance of survival is low, a transplant center should not proceed with MOT. When the  
750 need for the second organ is unclear, a transplant center should only proceed after a thorough review of  
751 the candidate’s condition and available data regarding whether the second organ is deemed necessary.

752

753 **Recommendations:**

- 754 1) Establish a system for allocation of organs for MOT candidates based on the ethical principles of  
755 equity and utility, is transparent, and is consistent across the different organ combinations unless  
756 there is an ethical justification for a different system.
- 757 2) Establish allocation policies that distinguish between organs that are immediately life-saving and  
758 those organs that are not immediately life-saving.
- 759 3) Consider the potential adverse effects of MOT allocation redirecting high-quality organs that are  
760 consequently unavailable to SOT candidates.
- 761 4) Consider establishing a national review board specific for MOT candidates that provides clear  
762 guidance on the granting of exceptions for MOT candidates. This board may help to account for  
763 patients awaiting MOT who are disadvantaged by needing MOT, and may bring consistency to the  
764 implications for SOT candidates that may be impacted by how MOT exceptions are granted.
- 765 5) Establish allocation policies that prioritize MOT candidates who have medical urgency in both  
766 organs, but generally do not prioritize MOT candidates who do not have medical urgency in one  
767 organ.
- 768 6) Ensure that organ allocation policies minimize the additional harm to disadvantaged subgroups  
769 e.g., children, racial/ethnic minorities, and highly sensitized patients (for kidney patients).

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<sup>91</sup> NOTA, 42 U.S.C. § 274n

<sup>92</sup> OPTN Descriptive Data Request. *An analysis of multi-organ transplants during 2015-2017 for deceased donor adult kidney recipients*. Prepared for OPTN Ethics Committee In-Person Meeting, October 29, 2018.



- 770 7) Establish data reporting and accountability mechanisms to ensure that MOT is transparently  
771 performed.  
772 8) Hold transplant centers accountable for MOT results to minimize futility in organ transplantation.  
773 9) Consider establishing minimum requirements for centers to perform MOT that are above and  
774 beyond the requirements for the SOT organs.  
775 10) Establish organ allocation policies that consider the potential effects of MOT organ failure on  
776 recipients' quality of life, and the impact of MOT on long-term survival even when death is not  
777 imminent.  
778 11) Establish allocation policies that do not disadvantage patients who undergo SOT instead of MOT  
779 when the second organ subsequently fails, and when the need for a simultaneous second organ  
780 transplant is questionable.  
781 12) Review MOT policies to ensure that these policies do not adversely affect the number or quality of  
782 organs available to pediatric candidates without ethical justification.  
783

784 **Appendix A: Number of kidney transplants performed in 2015-2017 by multi-organ transplant**  
 785 **(MOT) status<sup>1</sup> and geographic distribution<sup>2</sup>**

Organ	Local	Regional	National	International
MOT	1,736 (68.5%)	692 (27.3%)	105 (4.1%)	0 (0.0%)
Kidney Alone	24,677 (69.1%)	4,715 (13.2%)	6,327 (17.7%)	2 (0.0%)

786  
 787 1. 'MOT' is any deceased donor multi-organ kidney transplant, excluding kidney-pancreas. 'KI' is any single-organ  
 788 kidney transplant (kidney only).

789 2. Local distribution means that organs that were shared within the same donor service area (DSA). Regional  
 790 distribution means that organs were shared outside of the DSA but within the same OPTN region. National  
 791 distribution refers to organs that were shared beyond the regional level.

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**Appendix B: Number of and percent multi-organ transplants by recipient region and geographic distribution**

Region	MOT Status	Local	Regional	National	International	Total
Region 1	MOT	55 (75.3%)	13 (17.8%)	5 (6.8%)	0 (0.0%)	73 (100.0%)
	KI	1064 (82.7%)	52 (4.0%)	171 (13.3%)	0 (0.0%)	1287 (100.0%)
Region 2	MOT	201 (67.7%)	89 (30.0%)	7 (2.4%)	0 (0.0%)	297 (100.0%)
	KI	3051 (67.0%)	530 (11.6%)	968 (21.3%)	2 (0.0%)	4551 (100.0%)
Region 3	MOT	301 (68.9%)	124 (28.4%)	12 (2.7%)	0 (0.0%)	437 (100.0%)
	KI	3453 (71.8%)	862 (17.9%)	494 (10.3%)	0 (0.0%)	4809 (100.0%)
Region 4	MOT	202 (70.6%)	79 (27.6%)	5 (1.7%)	0 (0.0%)	286 (100.0%)
	KI	2733 (76.1%)	431 (12.0%)	428 (11.9%)	0 (0.0%)	3592 (100.0%)
Region 5	MOT	281 (60.8%)	173 (37.4%)	8 (1.7%)	0 (0.0%)	462 (100.0%)
	KI	3718 (59.0%)	1155 (18.3%)	1430 (22.7%)	0 (0.0%)	6303 (100.0%)
Region 6	MOT	42 (77.8%)	12 (22.2%)	0 (0.0%)	0 (0.0%)	54 (100.0%)
	KI	1205 (90.0%)	51 (3.8%)	83 (6.2%)	0 (0.0%)	1339 (100.0%)
Region 7	MOT	162 (64.8%)	75 (30.0%)	13 (5.2%)	0 (0.0%)	250 (100.0%)
	KI	1931 (76.0%)	195 (7.7%)	416 (16.4%)	0 (0.0%)	2542 (100.0%)
Region 8	MOT	106 (85.5%)	14 (11.3%)	4 (3.2%)	0 (0.0%)	124 (100.0%)
	KI	1814 (78.8%)	299 (13.0%)	190 (8.3%)	0 (0.0%)	2303 (100.0%)
Region 9	MOT	81 (61.4%)	22 (16.7%)	29 (22.0%)	0 (0.0%)	132 (100.0%)
	KI	1176 (46.6%)	167 (6.6%)	1183 (46.8%)	0 (0.0%)	2526 (100.0%)
Region 10	MOT	152 (74.1%)	41 (20.0%)	12 (5.9%)	0 (0.0%)	205 (100.0%)
	KI	2039 (77.5%)	280 (10.6%)	311 (11.8%)	0 (0.0%)	2630 (100.0%)
Region 11	MOT	153 (71.8%)	50 (23.5%)	10 (4.7%)	0 (0.0%)	213 (100.0%)
	KI	2493 (64.9%)	693 (18.1%)	653 (17.0%)	0 (0.0%)	3839 (100.0%)

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799	<b>Appendix C: List of Acronyms</b>
800	CPRA: Calculated Panel Reactive Antibodies
801	DSA: donor service area
802	ECMO: extracorporeal membrane oxygenation
803	EPTS: Estimated Post Transplant Survival
804	ESRD: End-stage renal disease
805	GFR: glomerular filtration rate
806	KDPI: Kidney Donor Profile Index
807	KP: Kidney-Pancreas
808	LAS: lung allocation score
809	LVAD: left ventricular assist devices
810	MELD: model for end-stage liver disease
811	MOT: Multi-organ transplantation
812	NOTA: National Organ Transplantation Act
813	OPO: Organ Procurement Organization
814	OPTN: Organ Procurement and Transplantation Network
815	PELD: pediatric end-stage liver disease score
816	QALY: Quality of life years
817	RRB: Regional Review Board
818	SLK: Simultaneous liver-kidney transplantation
819	SOT: Single organ transplantation
820	UNOS: United Network for Organ Sharing

821 **Appendix D: MOT combinations not addressed in white paper**  
 822

<b>Organ combinations not addressed</b>	<b>Rationale for exclusion</b>
Kidney-Pancreas	The policy has already been clearly delineated and we collect relevant outcomes data, so the issues with confusion and lack of clarity don't exist the way they do for other MOT combinations. Also, KPs address single disease (T1 diabetes), have to meet kidney waiting time criteria other MOTs do not, and would likely not get transplanted if not for MOT (most pancreata are transplanted as simultaneous pancreas-kidneys)
Liver-Kidney	The policy has already been clearly delineated and we collect relevant outcomes data, so the issues with confusion and lack of clarity don't exist the way they do for other MOT combinations
Heart-Lung	Combined heart-lung transplant is the only option for patients with both end stage lung failure and end stage heart failure. The policy has already been clearly delineated and we collect relevant outcomes data, so the issues with confusion and lack of clarity don't exist the way they do for other MOT combinations

823

824 **Appendix E: Glossary of terms**

825 **Equity:** fairness in the pattern of distribution of the benefits and burdens of an organ procurement and  
826 allocation program.

827 **Equality of Opportunity:** equivalent access to potential recipients to receive an organ when they are in  
828 need<sup>93</sup>

829 **Fair Innings:** an ethical principle that maintains that every individual deserves to experience a full life and  
830 that the allocation of society's resources should try to maximize the opportunity for each person to reach  
831 a full lifespan.

832 **First-come, first-served:** an impersonal form of equity, in which patients who queue up sooner have  
833 priority in receiving treatment over patients who queue up later<sup>94</sup>

834 **Medical Benefit:** prioritizing the medically sickest patients even if it is predictable that other patients who  
835 are not as sick will have better outcomes

836 **Maximin Principle:** an ethical principle developed by philosopher John Rawls that maintains that society  
837 should only tolerate inequality in our system when those inequalities are arranged so that they are the  
838 greatest benefit to the least-advantaged members of society

839 **OPTN Final Rule:** Health and Human Services (HHS)-implemented regulatory framework for the  
840 structures and operations of the OPTN

841 **Rule of Rescue:** a perceived duty to save endangered life where possible<sup>95</sup>

842 **Utility:** refers to the maximization of net benefit to the community while taking into account both the  
843 amount of benefit and harm and the probability of such benefit and harm

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<sup>93</sup> *Ethical principles in the allocation of human organs*, OPTN Ethics Committee, June 2015,  
<https://optn.transplant.hrsa.gov/resources/ethics/ethical-principles-in-the-allocation-of-human-organs/>.

<sup>94</sup> Beauchamp, Tom L., Childress, James F., *Principles of Biomedical Ethics*. New York: Oxford University Press, 2016.

<sup>95</sup> Bochner et al., 1994, p. 90.