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.”¹ 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.

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). 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. Challenges that may arise from

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3 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.
4 Proposal to substantially revise the national kidney allocation system, OPTN Kidney Transplantation Committee, June 24, 2013.
MOT allocation have been noted in previous reports to the OPTN Board.\(^6\) 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.\(^8\) 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.\(^9\) 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).\(^10\) 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.\(^11\) 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.\(^12\) 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.\(^13\) 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.

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\(^6\) OPTN OPO Report Summary, OPTN OPO Committee, February 26, 2008.

\(^7\) OPTN Policy Oversight Committee Interim Report, OPTN Policy Oversight Committee, October 16, 2007.

\(^8\) OPTN Ethics Report Summary, OPTN Ethics Committee, June 28, 2012.


\(^13\) 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 KT 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. 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”.

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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14 Meeting Summary for November 29, 2018 meeting, OPTN Ethics Committee, available at: https://optn.transplant.hrsa.gov/media/2875/20181129_ethics_committee_minutes.pdf.
15 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 3rd highest overall sentiment score of 4.1 indicating widespread support for the project (Figure 1).

Public comment feedback also showed strong support when broken down by geography (Figure 2). Dark green indicates strong support, while red indicates opposition.
Finally, support was widespread across member type and across region, with most regions and members supporting or strongly supporting the proposal (Figure 3).
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), 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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• 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. 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. 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.

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

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 21st 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 4th. The MOT Work Group reviewed the latest draft along with public comments that came in after the March 21st conference.
call. On April 8th, the full Committee met in Chicago, IL to review public comment that came in after the March 21st 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

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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.”20 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.21

*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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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

Guidance on Multi-Organ Transplant Allocation Policy and Practice

Introduction

Multi-organ transplantation (MOT) refers to the simultaneous transplantation of two or more organs from a single donor into a single recipient, whereas single organ transplantation (SOT) refers to transplantation of one organ. MOT, excluding kidney-pancreas and heart-lung, represented approximately 3% of all transplants in the United States in 2017.22 The prevalence of MOT has increased over the past two decades, with more patients being listed for and undergoing MOT each year.23 The number of MOTs, excluding kidney-pancreas and heart-lung, has nearly doubled in the past six years, from 625 MOT procedures in 2012 to 1,035 in 2017 (Table 1).24 By contrast, kidney-pancreas transplants have remained steady at about 750 per year, as have heart-lung transplants at about 20 per year over this same period.

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

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

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25 42 C.F.R. § 121.8(a)(4)
It is important that any new distribution policies are studied for their effects on SOT and MOT, with the understanding that the outcomes may differ according to organ combination type.

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

Table 1: Combinations of organs involved in MOT and their frequencies

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>1,459</td>
<td>1,508</td>
<td>1,625</td>
<td>1,801</td>
<td>1,853</td>
<td>8,246</td>
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<tr>
<td>Kidney-Pancreas</td>
<td>762</td>
<td>709</td>
<td>719</td>
<td>798</td>
<td>789</td>
<td>3,777</td>
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<tr>
<td>Liver-Kidney</td>
<td>494</td>
<td>558</td>
<td>627</td>
<td>730</td>
<td>739</td>
<td>3,148</td>
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<tr>
<td>Kidney-Heart</td>
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<td>104</td>
<td>141</td>
<td>140</td>
<td>187</td>
<td>657</td>
</tr>
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<td>Liver-Intestines-Pancreas</td>
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<td>69</td>
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<td>299</td>
</tr>
<tr>
<td>Liver-Heart</td>
<td>16</td>
<td>18</td>
<td>28</td>
<td>18</td>
<td>29</td>
<td>109</td>
</tr>
<tr>
<td>Heart-Lung</td>
<td>23</td>
<td>24</td>
<td>15</td>
<td>18</td>
<td>29</td>
<td>109</td>
</tr>
<tr>
<td>Liver-Lung</td>
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<td>9</td>
<td>8</td>
<td>3</td>
<td>39</td>
</tr>
<tr>
<td>Intestines-Pancreas</td>
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<td>9</td>
<td>8</td>
<td>3</td>
<td>33</td>
</tr>
<tr>
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<td>1</td>
<td>4</td>
<td>7</td>
<td>24</td>
</tr>
<tr>
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<td>7</td>
<td>2</td>
<td>20</td>
</tr>
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<td>5</td>
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<td>11</td>
</tr>
<tr>
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<td>3</td>
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<td>6</td>
</tr>
<tr>
<td>Liver-Intestines</td>
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<td>2</td>
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<td>6</td>
</tr>
<tr>
<td>Kidney-Heart-Lung</td>
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<tr>
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<td>0</td>
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</table>

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

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

**Introduction to the Ethical Analysis**

The ethical analysis of MOT allocation largely focuses on the principles of equity and utility, and has been discussed elsewhere.\(^2^9\) The OPTN opines that generally, MOT, if properly performed, is ethically sound. In addition, MOT has become an accepted practice within the transplant community. The frequency of MOT is increasing, which raises questions of distributive justice, as racial/ethnic minorities and those with lower socioeconomic status are not well represented in MOT (Table 2, page 14). Some disparities in organ allocation reflect differences in access to healthcare, limiting the ability of some patient groups to be evaluated and listed for MOT. This white paper highlights specific situations of MOT policies in organ allocation systems that may create additional disparities above and beyond those related to access to MOT. Allocation policies may promulgate disparities and challenge the ethical principles that support our healthcare system. This white paper recommends ways to soundly allocate organs for MOT by minimizing potential disparities. MOT must undergo the same level of data collection, oversight, and scrutiny as SOT to minimize the variability occurring in clinical practice. The need for oversight has become increasingly important as MOT frequency increases.

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

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

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

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\(^{29}\) Reese et al., 2013.
candidates typically have shorter waiting times than isolated kidney candidates, and KP candidates also have higher mortality on the waitlist.\(^{30,31}\)

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

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

The current organ allocation systems for MOT have developed organically out of clinical need, as the use of MOT with new organ combinations has evolved. The current allocation systems for MOT generally maximize the utility at the potential cost of creating disparities in equity. However, each system weighs equity and utility to different degrees.\(^{35}\) The OPTN affirms that optimal allocation policies involving MOT should reflect a balance between equity and utility, with the understanding that no system can maximize both. The main challenge pertains to specifying how to apply ethical principles in the context of each type of MOT allocation.

In the context of MOT allocation policies:

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

a) medical benefit (e.g., years of life, medical urgency)

b) quality of benefit (quality of life years or QALYs, see Appendix C)

c) avoiding futile transplants, a Final Rule requirement\(^{36}\)

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

a) equality of opportunity

b) how the policy inadvertently affects the worse-off (the Maximin principle)

\(^{30}\) 2019 OPTN data (Accessed April 1, 2019).


\(^{32}\) OPTN Policy 8.4, Waiting Time (Accessed March 8, 2019).


\(^{35}\) Reese et al., 2013.

\(^{36}\) 42 C.F.R. §121.8(a)(5).
Ethical Dilemmas Unique to MOT

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

Section A. MOT and Need for Transplant

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

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

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

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

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

**Ethical Principles in Conflict**

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

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38. Reese et al., 2013.
organ distribution (e.g., kidney) are not given an equitable opportunity to access transplantation, and the first-come, first-served doctrine is not respected.

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

**Recommendations**

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

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

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

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

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

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

1. One scenario entails a waitlist that is specific to the MOT organ combination. An example is the heart-lung list, which is different from both the heart and lung allocation separate lists. Heart-lung candidates receive prioritization above the individualized lists if certain criteria are met. In this scenario, policy-induced disparity may arise, depending upon how the priority of a patient on the MOT waitlist (e.g., heart-lung) affects the ability of patients on the individual organ lists (e.g., heart and lung) to receive the needed organ(s). In this situation, the allocation of the multiple organs is based on the status that a candidate receives on the combined list, and how this list is prioritized with the single organ lists. A patient on the heart-lung list may be prioritized for a heart over patients on the heart-only list, and redirect the lungs from those on the lung-only list. Alternatively, organ offers may go to patients on the individual organ lists before going to the person on the heart-lung list, depending on the relative listing status of the potential recipients on each list.

2. Another scenario entails placing a patient awaiting MOT on separate waiting lists for each organ. When the candidate matches for one organ (typically one necessary to sustain life e.g., a liver or heart), the patient is immediately given priority for the other organ (e.g., a kidney), redirecting the other organ (kidney) from other potential SOT recipients, regardless of the position of the MOT recipient on the other (kidney) list. When this occurs, the MOT candidate bypasses those candidates who are otherwise prioritized for that other organ (kidney) based on the other candidates’ waitlist.
duration, sensitization, longevity matching, or other factors. These issues are discussed in greater detail in Section G: Protected subgroups. In the situation where a MOT candidate is listed on the separate organ lists, the allocation of the multiple organs is made based on the status of the candidate for one of the organs, and prioritization for the second organ generally follows. A candidate on the heart-only list and a candidate waiting for a heart-kidney are competing equally for the same heart based on their priority on the heart list. However the candidate awaiting a heart-kidney will have priority over a potential SOT kidney recipient.

Ethical Principles in Conflict

- Equity: Patients with multi-organ failure are worse-off compared to patients with single organ disease, even when both patients have the same degree of dysfunction of the organ that they both commonly need. Need-based allocation systems (e.g., heart, lung, and liver) do not respect the principle of first-come, first-served that applies to kidney transplantation.

- Utility: In most situations, the degree of medical benefit that one individual patient gains by MOT is less than the total collective medical benefit that two, three, or even four individual patients gain by undergoing SOT. However, the length of benefit to the MOT recipient may be less than that to the SOT candidate due to the lower rate of patient survival in some MOT recipients compared to SOT recipients receiving the same organ.

Recommendations

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

Section C. MOT and Organ Quality

MOT organs are of higher quality organs than SOT organs

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

39 Reese et al., 2013.
41 Reese et al., 2013.
42 Ibid.

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

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.

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

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45 Reese et al., 2013.


47 Ibid.

48 Reese et al., 2013, p. 9.
heart-kidney combination from a donor when there is moderate dysfunction of either organ, resulting in higher quality organs being used for MOT.

Ethical Principles in Conflict

- Equity: When higher-quality organs are removed from the pool before a group has had an opportunity to be considered for those organs, candidates lack a fair opportunity to receive them. Additionally, MOT can violate the principle of first-come, first-served when kidneys are allocated to MOT recipients who have been waiting for shorter periods, than to kidney candidates who have been waiting for longer periods. However, MOT does follow the principle of the rule of rescue, because candidates closest to death are given priority.

- Utility: MOT recipients usually derive the most benefit from the life-saving organ (heart, lung, liver), with less overall benefit coming from the kidney, and this benefit declines with decreasing kidney organ quality. In one analysis, simultaneous liver-kidney transplantation only provided a survival benefit compared to an isolated liver transplant if the kidney donor risk index was ≤1.10.49 However, while MOT patients do derive a benefit from higher quality organs, in general, recipients of some MOT combinations have lower overall survival than isolated organ recipients.50 Thus, overall SOT recipients receive a greater net utility in terms of years of graft function from the kidney than do heart-kidney or liver-kidney recipients.

Recommendations

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

Section D. MOT and Alternative Supportive Treatments

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

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

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

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

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

Ethical Principles in conflict

- Equity: Heart MOT candidates who are not eligible for support therapies that would appropriately
elevate their status experience a lack of equality of opportunity to receive the organs in need.
While this situation may be addressed by an RRB, the inconsistent manner in which different
RRBs deliberate about candidates may not resolve this inequality. In addition, decisions by the
RRB for one organ affect patients waiting for the other organ(s) even though that RRB does not
oversee the other organs. In other words, if the heart RRB approves a status upgrade for a
candidate on the heart list who also needs a kidney, then the heart RRB has essentially
prioritized that kidney since the heart will redirect the kidney, even though the RRB does not
oversee allocation of kidneys.

- Utility: none.

Recommendations

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

52 OPTN Policy 6.1.E, Adult Heart Status 5 Requirements (accessed March 18, 2019).
53 OPTN Briefing Paper Proposal to Establish a National Liver Review Board, OPTN Liver and Intestinal Organ
54 Bittermann, Therese, George Makar, and David Goldberg, "Exception Point Applications for 15 Points: An
Section E. Prioritization of MOT over SOT

MOT allocation strategies should take into account candidates’ degree of need of each organ for transplantation

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

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

Ethical Principles in Conflict

- **Equity:** Under the Maximin principle, the candidate who needs a MOT is worse off than the SOT candidate with a similar dysfunction of the single organ because more than one organ system has failed. Policies that unduly favor SOT violate the Maximin principle by directing organs to those who are less ill.

- **Utility:** The benefit to a single MOT recipient may be greater than the benefit to a single SOT recipient. However, the benefit to a single MOT recipient may not be as great as the combined benefit to all SOT recipients who could have received the multiple organs in consideration if the MOT recipient had not received them.

Recommendations

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

Section F. MOT and Protected Subgroups

Consider revising MOT allocation to minimize harm to protected subgroups

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

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

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

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

<table>
<thead>
<tr>
<th>Organ</th>
<th>White</th>
<th>Black</th>
<th>Hispanic</th>
<th>Asian</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOT</td>
<td>1,540 (60.8%)</td>
<td>463</td>
<td>402 (15.9%)</td>
<td>93</td>
<td>35</td>
<td>2,533 (100.0%)</td>
</tr>
<tr>
<td>KI Alone</td>
<td>12,949 (36.3%)</td>
<td>12,590</td>
<td>6746 (18.9%)</td>
<td>2,572</td>
<td>864</td>
<td>35,721 (100.0%)</td>
</tr>
<tr>
<td>Total</td>
<td>14,489 (37.9%)</td>
<td>13,053</td>
<td>7,148 (18.7%)</td>
<td>2,665</td>
<td>899</td>
<td>38,254 (100.0%)</td>
</tr>
</tbody>
</table>

**Ethical Principles in conflict**

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

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57 2019 OPTN data (accessed March 18, 2019).
59 NOTA, 42 U.S.C. § 274n
60 OPTN Policy 5.10, Allocation of Multi-Organ Combinations (Accessed April 8, 2019)
may potentially violate the “fair innings” principle because pediatric patients have, by definition, not been able to reach the major life milestones that adult patients have been able to reach.

- Utility: Allocation decisions that favor adult recipients may potentially lead to fewer years of life gained when compared to the same organ that is provided to a pediatric patient.

Recommendations

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

Section G. Monitoring MOT

MOT Should be Monitored in Transplant Programs

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

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

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

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

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63 Reese et al., 2013, p. 24.
64 Reese et al., 2013, p. 23.
65 Reese et al., 2013, p. 24.
66 Ibid.
67 Ibid.
Ethical Principles in Conflict

- Equity: Centralized data collection, analysis, and reporting will provide transparency to MOT outcomes. Data monitoring will likely enable the creation of standards expected for transplant programs to follow, outcomes to achieve, and more conscientious use of organs. As the outcomes become better known, minimum standard criteria can be developed for MOT to decrease the variability in patient selection for MOT and results. This will improve outcomes and minimize unnecessary or futile MOT procedures, allowing increased access to organs by SOT candidates. Data collection, analysis, and reporting may deprive those candidates who are worse off from the chance of undergoing a high-risk MOT procedure (and thus violate the Maximin principle). However, this possibility will not differ from the current situation for SOT candidates in which monitoring and reporting are routinely practiced. Data analysis for MOTs may be difficult due to the low number of MOTs performed.

- Utility: In situations where high-risk MOT is only enabled by the lack of accountability, poor outcomes may result in futile transplants. With a futile transplant, there is no benefit to the MOT recipient, and there is additional harm to the potential SOT recipients who were denied the potential benefit of the organs.

Recommendations

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

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

Section H. MOT and Fairness to patients awaiting SOT

Policies should account for quality of life for SOT candidates

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

Candidates who are awaiting a kidney also have a lower overall expected waitlist mortality than those

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69 Reese et al., 2013, p. 24.
70 Ibid.
71 Ibid.
waiting for many other organs, and are thus considered by many to be less needy for their organ than the 
MOT candidates.\textsuperscript{74} This does not take into account the effect of dialysis on their quality of life, or the slow, 
insidious decline in life expectancy associated with renal failure and dialysis. Although kidney SOT 
candidates are not at high risk of imminent death, their need for transplantation is real and might be life-
saving. Thus, patients awaiting SOT should not be unfairly penalized for having a lower degree of illness 
(i.e., single organ involvement compared to multi-organ involvement).

Ethical Principles in Conflict

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

- Utility: None

Recommendations

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

Section I. MOT and Standardized Criteria

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

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

Simultaneous transplantation presents several advantages over isolated transplantation. Patients with a 
diminished GFR who are not on dialysis and who undergo simultaneous heart-kidney transplantation 
generally fair better than those who undergo heart transplantation alone.\textsuperscript{80} However, there is a need to

\textsuperscript{74} Ibid.
\textsuperscript{75} Ibid.
\textsuperscript{76} Ibid.
\textsuperscript{77} Ibid.
\textsuperscript{78} Reese et al., 2013.
\textsuperscript{79} OPTN Descriptive Data Request. \textit{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.
\textsuperscript{80} 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 
balance the improved results seen in these studies with efficient use of organs, which does not occur when kidneys are transplanted prophylactically.

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

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

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

**Ethical Principles in Conflict**

- **Equity:** Equity is threatened when a patient undergoing MOT who could benefit but does not require the second organ (e.g., heart-lung where the heart function is good enough that the recipient has a reasonable chance of surviving a lung transplant without the heart) takes that organ from a SOT candidate who requires the same organ (e.g., heart). This is particularly ethically problematic since the current allocation system for some organ combinations (e.g., heart-kidney) allows the MOT candidate to get priority for the second organ, even though the need for the second organ is less critical or clear.

- **Utility:** Benefit to the transplant community as a whole is not maximized when an organ is transplanted into any recipient, when such transplantation is, in retrospect, not necessary. In addition, there is no significant difference between the transplantation of an organ that is not

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83 Reese et al., 2013.
necessary and the transplantation of an organ in which the recipient does not survive for an extended period of quality life. In both cases, these may be seen as futile cases from the perspective of the organ and in terms of those who are awaiting an available organ. Another potential issue with utility is that for organ combinations like a heart-kidney, the need for a kidney may come later, meaning that not getting that second organ from the same donor could lead to increased risk from a second surgery and greater risk of immunological incompatibility.

Recommendations

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

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

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

Section J. MOT and Relative Futility

MOT Should Not be Performed if Relatively Fute

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

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

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

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

However, in the case of the heart-liver candidate, greater overall benefit may be achieved by giving the
heart to an equally sick isolated heart candidate and the liver to a candidate with a high MELD score,
because both SOT candidates would have a significantly greater chance of survival than the heart-liver
candidate on ECMO\(^{89}\). Without a transplant, the heart-liver candidate will die. However, MOT
transplantation may not be justified if the chance of survival with transplantation is sufficiently small. The
heart-kidney candidate could still undergo heart transplantation with post-operative dialysis, and
potentially be listed for kidney transplantation later if the candidate survives the heart-only transplant
operation.

**Ethical Principles in Conflict**

- **Equity:** A policy that is too restrictive on MOT allocation will violate the Maximin principle by
denying the worse-off candidates access to transplantation. Such a policy will also violate the
Rule of Rescue because patients close to death will not have the chance to undergo a life-saving
transplantation.\(^{90}\)

- **Utility:** A policy that is too liberal on MOT allocation will minimize the medical benefits because
non-survivors gain no benefit from MOT. In these cases, there is neither length nor quality of
benefit, and the end result is a futile transplant procedure.

**Recommendations**

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

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\(^{87}\) OPTN Policy 6: *Allocation of Hearts and Heart-Lungs* (Accessed April 7, 2019).

\(^{88}\) 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

\(^{89}\) Ibid

\(^{90}\) Reese et al., 2013.
Section K. Impact of Adult MOT on Pediatric SOT

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

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

Ethical Principles in Conflict

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

Recommendations

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

Conclusions:

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

Recommendations:

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

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91 NOTA, 42 U.S.C. § 274n
770  7) Establish data reporting and accountability mechanisms to ensure that MOT is transparently performed.
771  8) Hold transplant centers accountable for MOT results to minimize futility in organ transplantation.
772  9) Consider establishing minimum requirements for centers to perform MOT that are above and beyond the requirements for the SOT organs.
773 10) Establish organ allocation policies that consider the potential effects of MOT organ failure on recipients’ quality of life, and the impact of MOT on long-term survival even when death is not imminent.
774 11) Establish allocation policies that do not disadvantage patients who undergo SOT instead of MOT when the second organ subsequently fails, and when the need for a simultaneous second organ transplant is questionable.
775 12) Review MOT policies to ensure that these policies do not adversely affect the number or quality of organs available to pediatric candidates without ethical justification.
Appendix A: Number of kidney transplants performed in 2015-2017 by multi-organ transplant (MOT) status\(^1\) and geographic distribution\(^2\)

<table>
<thead>
<tr>
<th>Organ</th>
<th>Local</th>
<th>Regional</th>
<th>National</th>
<th>International</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOT</td>
<td>1,736 (68.5%)</td>
<td>692 (27.3%)</td>
<td>105 (4.1%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>Kidney Alone</td>
<td>24,677 (69.1%)</td>
<td>4,715 (13.2%)</td>
<td>6,327 (17.7%)</td>
<td>2 (0.0%)</td>
</tr>
</tbody>
</table>

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

2. Local distribution means that organs that were shared within the same donor service area (DSA). Regional distribution means that organs were shared outside of the DSA but within the same OPTN region. National distribution refers to organs that were shared beyond the regional level.
## Appendix B: Number of and percent multi-organ transplants by recipient region and geographic distribution

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

<table>
<thead>
<tr>
<th>Page</th>
<th>Acronym</th>
<th>Definition</th>
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</thead>
<tbody>
<tr>
<td>799</td>
<td>CPRA</td>
<td>Calculated Panel Reactive Antibodies</td>
</tr>
<tr>
<td>800</td>
<td>DSA</td>
<td>donor service area</td>
</tr>
<tr>
<td>801</td>
<td>ECMO</td>
<td>extracorporeal membrane oxygenation</td>
</tr>
<tr>
<td>802</td>
<td>EPTS</td>
<td>Estimated Post Transplant Survival</td>
</tr>
<tr>
<td>803</td>
<td>ESRD</td>
<td>End-stage renal disease</td>
</tr>
<tr>
<td>804</td>
<td>GFR</td>
<td>glomerular filtration rate</td>
</tr>
<tr>
<td>805</td>
<td>KDPI</td>
<td>Kidney Donor Profile Index</td>
</tr>
<tr>
<td>806</td>
<td>KP</td>
<td>Kidney-Pancreas</td>
</tr>
<tr>
<td>807</td>
<td>LAS</td>
<td>lung allocation score</td>
</tr>
<tr>
<td>808</td>
<td>LVAD</td>
<td>left ventricular assist devices</td>
</tr>
<tr>
<td>809</td>
<td>MELD</td>
<td>model for end-stage liver disease</td>
</tr>
<tr>
<td>810</td>
<td>MOT</td>
<td>Multi-organ transplantation</td>
</tr>
<tr>
<td>811</td>
<td>NOTA</td>
<td>National Organ Transplantation Act</td>
</tr>
<tr>
<td>812</td>
<td>OPO</td>
<td>Organ Procurement Organization</td>
</tr>
<tr>
<td>813</td>
<td>OPTN</td>
<td>Organ Procurement and Transplantation Network</td>
</tr>
<tr>
<td>814</td>
<td>PELD</td>
<td>pediatric end-stage liver disease score</td>
</tr>
<tr>
<td>815</td>
<td>QALY</td>
<td>Quality of life years</td>
</tr>
<tr>
<td>816</td>
<td>RRB</td>
<td>Regional Review Board</td>
</tr>
<tr>
<td>817</td>
<td>SLK</td>
<td>Simultaneous liver-kidney transplantation</td>
</tr>
<tr>
<td>818</td>
<td>SOT</td>
<td>Single organ transplantation</td>
</tr>
<tr>
<td>819</td>
<td>UNOS</td>
<td>United Network for Organ Sharing</td>
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### Appendix D: MOT combinations not addressed in white paper

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

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

Equality of Opportunity: equivalent access to potential recipients to receive an organ when they are in need.

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

First-come, first-served: an impersonal form of equity, in which patients who queue up sooner have priority in receiving treatment over patients who queue up later.

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

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

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

Rule of Rescue: a perceived duty to save endangered life where possible.

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

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95 Bochner et al., 1994, p. 90.