

OPTN Ad Hoc Multi-Organ Transplantation Committee Meeting Summary February 26, 2025 Conference Call

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Introduction

The OPTN Ad Hoc Multi-Organ Transplantation Committee (the Committee) met via WebEx teleconference on 02/26/2025 to discuss the following agenda items:

- 1. Welcome and updates
- 2. Eligibility criteria for multi-organ offers
- 3. Open forum

The following is a summary of the Committee's discussions.

1. Welcome and updates

The Co-Chair reminded members to respond to an email about extending their committee terms.

OPTN Contractor staff also reminded attendees about regional meetings, which are now virtual, and invited feedback from those who had presented. The Co-Chair shared their experience presenting at the Region 5 meeting, where they received feedback on kidney allocation and pediatric prioritization, including concerns that pediatric patients should receive higher priority. Another member shared that no concerns were reported at their regional meeting and that transplant administrators and coordinators seemed generally supportive.

Additionally, members were reminded to hold their calendars for April 4th for an in-person meeting in Detroit, with a possible transition to virtual. OPTN Contractor Staff thanked the small group members working on an additional allocation table for DCD donors, which will be discussed in an upcoming meeting before being reviewed by the full committee.

No decisions were made.

2. Eligibility criteria for multi-organ offers

The Committee reviewed the current eligibility criteria policy and discussed potential revisions. The Committee focused on heart-lung, heart-liver, heart-kidney, lung-liver, lung-kidney, liver-kidney.

Summary of presentation:

The discussion focused on medical eligibility criteria for multi-organ offers, specifically for heart, lung, liver, and kidney combinations, with plans to address additional combinations in a future meeting. Eligibility criteria determines whether a candidate can receive a multi-organ offer but does not affect priority, which is based on match run position and allocation tables.

OPTN Contractor Staff provided an overview of current policies, outlining the minimum requirements for various organ combinations:

- Heart-lung, heart-liver, and lung-liver offers have specific criteria based on status and score.
- Kidney eligibility requires candidates to meet criteria for chronic kidney disease, acute kidney injury, or metabolic disease.
- Pediatric candidates are exempt from the kidney criteria applied to adults.

Potential approaches for refining eligibility criteria were introduced. One approach is to keep the existing criteria for adult heart-kidney, lung-kidney, and liver-kidney combinations, allowing these organs to pull kidneys if the candidate meets kidney criteria.

Staff presented another potential option to streamline policy by setting up a single eligibility standard: candidates who meet criteria would receive offers based on match order, while those who do not would be excluded from multi-organ offers. Staff also noted that current policy is silent on livers "pulling" the heart or lungs.

Summary of discussion:

The Committee agreed to further discuss this topic.

A member noted that eligibility criteria for listing combined heart-kidney transplants was already in place, with the safety net providing an acceptable option for those not meeting eligibility criteria. They saw no need to alter this approach after policy implementation, as patients would only be listed if they met the existing criteria. A Co-Chair agreed with incorporating existing eligibility criteria into the policy proposal. The member acknowledged that eligibility criteria has been accepted by the community, as a measure to protect solitary kidney candidates.

A Co-Chair then raised the question of whether pediatric patients needed different considerations. A member pointed out that there are currently no listing criteria for some single kidney transplants, making it difficult to impose specific criteria on multi-organ transplants unless the OPTN Kidney Committee addressed the issue separately.

Another member questioned whether hearts or lungs would still be available for allocation by the time most liver candidates who need them are considered. A Co-Chair acknowledged this concern, noting that the OPTN Heart Committee had raised similar issues during public comment. Many heart-liver candidates are not in Status 1 or 2, often limiting their access to a heart when needed. However, they pointed out that this challenge is not a departure from current policy.

OPTN Contractor staff added that the current allocation process typically prioritizes heart and lung match runs before liver allocations. However, under the proposed allocation tables, liver allocation could occur earlier in some cases—for example, when a MELD/PELD 37 liver candidate is considered before an Adult Status 3 heart candidate. They emphasized that as policies evolve, these practices may shift over time.

A Co-Chair raised concerns about the complexity of these cases, suggesting that a rigid, one-size-fits-all policy might not be effective. They proposed that rare clinical scenarios could be better addressed through exception pathways decided by the relevant organ-specific committees. Additionally, they questioned whether pediatric patients might be disadvantaged by the current policy silence on livers pulling hearts and lungs.

A member responded, noting that such cases in pediatrics are extremely rare. They highlighted that the primary concern in pediatric multi-organ transplants involves Fontan patients needing a heart-liver transplant. However, they clarified that most of these patients are late teens or young adults rather than

young children. Another member agreed, adding that these transplants are more common among teenage patients.

The member discussed the complexities of heart-lung and heart-liver policies, noting the current priority for higher heart statuses before allocation from the lung match. They found it unclear why a similar structure did not exist for livers pulling hearts or lungs.

Staff clarified that under current policy, heart-liver offers must first go to heart candidates in Adult Status 1 through 3 or any active pediatric status within 500 nautical miles. However, organ procurement organizations (OPOs) are allowed—but not required—to offer heart-liver transplants to candidates outside those requirements.

The member acknowledged this and emphasized their primary concern: how the proposed new allocation system might affect multi-organ transplants. Under the proposed framework, a liver Classification 1 (Status 1A) candidate could be prioritized above heart Status 1 and 2 candidates. They questioned whether such a candidate should receive a heart-liver offer at that stage or if that priority should apply only to liver-alone candidates.

Staff confirmed that, under the proposed system, a liver Classification 1 candidate whould receive a heart-liver offer, even if that heart would otherwise be allocated to a Status 1 heart candidate. The member then clarified that this issue was distinct from kidney listing criteria, as the key concern here was the ability of a primary organ (such as a liver) to "pull" another organ (such as a heart) under the new allocation framework.

A major concern among members was whether allowing livers to pull hearts and lungs could disadvantage heart-alone and lung-alone candidates, potentially disrupting established allocation priorities. To address this, some committee members suggested introducing eligibility criteria to ensure that only candidates with a high medical urgency for the additional organ would qualify.

Staff then sought clarification on whether these criteria should set a minimum classification for the organ being claimed—meaning that a liver candidate could only pull a heart if the heart met a specific severity threshold. Members also questioned whether the new allocation model, which already prioritizes candidates based on severity, might naturally address this issue, making added criteria unnecessary. Specifically, for liver-lung allocation, they suggested that the minimum threshold could be based on a lung Composite Allocation Score (CAS) to ensure that only high-priority lung candidates receive the organ.

Another member shifted the discussion to the proposed allocation table, which determines the sequencing of multi-organ offers. They pointed out that under the new model, a candidate listed as liver Classification 1 (Status 1A) would receive offers for any additional organs they were listed for ahead of other candidates. The key concern, they noted, was that while kidneys have clear listing criteria—such as requiring a creatinine clearance below 25—no equivalent criteria exist for hearts and lungs when they follow livers. They questioned whether sufficient safeguards were in place to ensure that the most urgent heart- or lung-alone candidates would receive transplants before lower-priority multi-organ candidates.

A member clarified that there were two distinct issues at play: (1) the criteria for listing a candidate for a multi-organ transplant and (2) the rules governing when a secondary organ can be allocated. They explained that setting listing criteria for heart-liver transplants is particularly complex, as transplant centers have differing opinions on when liver disease is severe enough to justify a combined transplant. Currently, centers have full discretion to list a candidate for heart-liver or lung-liver based on their own assessments, which can lead to inconsistencies.

To illustrate the issue, they provided an example: A liver Status 1A patient is listed for a heart due to coronary disease, but that candidate is only Status 6 on the heart waitlist. If the allocation system allows the liver candidate to claim the heart before higher-priority heart-alone candidates, it raises fairness concerns. However, they also noted that current policies already include safeguards—such as preventing livers from pulling a heart if a higher-priority heart candidate is available within a certain distance.

A Co-Chair cautioned against overcomplicating the discussion by attempting to address every possible clinical scenario, rather than focusing on real-world practice. They questioned whether Status 1A liver patients frequently list for a heart at all and argued that the primary goal should be to ensure access to transplants for patients with the highest medical urgency. They also expressed concern that the proposed policy changes might disadvantage certain patient groups—such as high-MELD liver candidates with moderate heart disease—by increasing competition from heart Status 1 and 2 candidates.

Another member highlighted that the heart allocation system is structured so that most hearts go to Status 1 and 2 patients, making it difficult for lower-priority heart candidates—even those with severe liver disease—to receive a heart in a multi-organ allocation. They also raised concerns about potential use of ventricular assist devices (VADs) to elevate a patient's heart urgency status.

A different member acknowledged this concern but pointed out that upcoming policy changes in heart allocation aim to distribute more hearts to Status 3 candidates by tightening the criteria for Status 1 and 2. They argued that if a liver candidate has a sufficiently high MELD score and a heart remains available after being offered to nearby high-status heart candidates, it should be permissible to allocate the heart to that liver candidate without imposing additional restrictions. They suggested that the current policy might already allow for this scenario and questioned whether further limitations were necessary.

Members discussed the implications of maintaining minimal eligibility criteria for heart, lung, and liver combinations. Without such requirements, the policy would remain aligned with current allocation rules, allowing high-MELD liver patients to pull hearts or lungs without restrictions based on the severity of their secondary organ disease.

A Co-Chair expressed concern about the potential impact of this policy, particularly for liver-heart and liver-lung candidates. Under the proposed model, patients with severe liver disease (MELD 35 or higher) but a lower heart status, such as Status 4, might struggle to receive a heart. Since Status 1 and 2 heart candidates would almost always take priority, lower-status patients could be left without access. The Co-Chair worried that while these patients currently had some opportunities for transplants, the new approach might unintentionally push them further down the list, limiting their chances of receiving life-saving treatment.

Another member, however, saw the proposed system as an opportunity to expand access. They pointed out that under the current policy, these candidates must wait for a heart to become available before they can pull a liver, leading to delays or missed opportunities. The proposed model, by contrast, would allow a liver-qualified candidate to pull a heart—even with a lower heart status. However, another member challenged this perspective, arguing that in practice, high-quality hearts would likely already be claimed by higher-status heart candidates before a lower-priority patient became eligible.

A Co-Chair then called for greater clarity regarding the lung Composite Allocation Score (CAS) threshold. Staff clarified that the proposed CAS thresholds for these transplants differed from the current minimum of 25. They noted that while it was possible to set higher CAS thresholds in the allocation tables while keeping CAS 25 as a baseline, doing so raised additional questions about how heart-lung and lung-heart allocations would be affected. The Co-Chair emphasized the importance of ensuring that any new system did not inadvertently disrupt existing priority structures. A member then introduced a key distinction: the difference between *listing criteria* and *pulling rules*. Listing criteria determine whether a patient is even eligible to be placed on the transplant list for a multi-organ transplant—for example, a heart-lung candidate must meet a minimum lung CAS score before being considered. Pulling rules, on the other hand, dictate whether an organ can be allocated as part of a multi-organ transplant once the patient is already listed. The committee needed to decide whether minimum criteria should apply differently to these two processes.

Members agreed that setting universal minimum criteria for multi-organ transplants would be especially difficult beyond kidney transplants. Deciding when a combined heart-liver or lung-liver transplant is truly necessary remains highly controversial, with practices varying across transplant centers. Establishing a single standard for all centers would be challenging.

A Co-Chair suggested pausing the discussion and revisiting it in a future meeting. Another Co-Chair agreed, proposing that the next step should be gathering more data. They requested information on heart-liver and lung-liver transplants, including details on organ allocation, statuses and scores involved, and which organs had pulled others. They believed this data would help the Committee focus on actual patterns rather than hypothetical concerns. Staff acknowledged the request and confirmed that their team would explore the feasibility of collecting this information.

Next steps:

The Committee concluded with an agreement to discuss at the next meeting.

3. Open forum

There were no open forum requests from the public for this meeting. A Co-Chair asked if committee members had any other topics to discuss.

Summary of discussion:

There were no other topics to discuss.

Upcoming Meetings

- March 12, 2025
- March 26, 2025

Attendance

- Committee Members
 - Lisa Stocks, Co-Chair
 - o Zoe Stewart Lewis, Co-Chair
 - Vincent Casingal
 - o Rocky Daly
 - o Rachel Engen
 - o Jonathan Fridell
 - o Jim Kim
 - o Deanna Santana
 - 0
- SRTR Staff
 - o Avery Cook
 - o Jon Miller
- UNOS Staff
 - Houlder Hudgins
 - o Sara Langham
 - o Kelsi Lindblad
 - o Sarah Roache
 - o Erin Schnellinger
 - o Susan Tlusty
 - o Stryker-Ann Vosteen
 - o Ross Walton
 - o Ben Wolford