

**OPTN Pediatric Transplantation Committee
Meeting Summary
February 2, 2024
Houston, Texas**

**Emily Perito, MD, Chair
Rachel Engen, MD, Vice Chair**

Introduction

The OPTN Pediatric Transplantation Committee (The Committee) met in Houston, Texas, on 02/02/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Public Comment: *Expedited Placement Variance*
3. Public Comment: *OPTN Strategic Plan*
4. SRTR Donation and Transplant System Explorer
5. Data Advisory Committee Pre-waitlist Data Collection Update
6. Pediatric Loss to Follow Up
7. Public Comment: *Concepts for Modifying Multi Organ Policies*
8. Public Comment: *Modify Effect of Acceptance Policy*
9. Data Report: *Assessing the Impact of a Decrease in National Median PELD at Transplant*
10. Public Comment: *Continuous Distribution of Hearts*

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

1. Welcome and Announcements

The Chair welcomed the members of the Committee and the guests of the meeting. Each attendee took a moment to introduce themselves.

Summary of discussion:

The Committee did not make any decisions.

2. Public Comment: *Expedited Placement Variance*

OPTN contractor staff introduced the special public comment item that focuses on expedited placement variance. The Committee had discussed this item during their January meeting but had not yet submitted a public comment.

Presentation summary:

The *Expedited Placement Variance*, originating from the Expeditious Task Force and sponsored by the Executive Committee (ExCom), is currently open for public comment. The purpose of the proposal is to create a variance to test expedited placement protocols.

Structure of Pilot:

- Structure as a variance
 - Board/ExCom approves an open variance
 - Special public comment
 - Time limited study
 - Members opt in
- Protocols
 - Collect protocols from community
 - Task force will develop framework to select protocols to test
 - The protocols would live outside of policy but be accessible to the community
- Test protocols to assess most effective protocols
 - Evaluation plan with objective criteria to measure the variance’s success
 - Members submit information required by variance

Requirements for Protocols:

- Each protocol must include criteria for organs eligible for expedited placement, criteria for candidates eligible to receive expedited placement offer, conditions for the use of expedited placement, and OPO and transplant hospital responsibilities
- Protocols must comply with NOTA and the OPTN Final Rule

Proposed Changes to Variance Governance:

- Clarification regarding the creation of variances
- Remove requirement to solicit agreement prior to public comment
- Change frequency of reporting requirements. Important for short, iterative variances.

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Pediatrics Transplantation Committee would like to thank the OPTN Executive Committee and the Expeditious Task Force for their work on this proposal. Although the Committee supports increasing utilization and decreasing non-use, it is very concerned about unintended consequences. The Committee feels this proposal as written is vague and lacks critical guardrails to ensure that this variance is effective and efficient at achieving its stated goals and preserves equity and access to transplant for children and other hard-to-match populations. Specifically, the Committee is concerned about the impact these protocols will have on access for pediatric candidates and other hard-to-match populations by granting permission for organ procurement organizations to increasingly allocate out of sequence. To accomplish the Task Force’s stated goals, we would recommend the following:

- *Specify that variances are **required** to focus on organs at high-risk for non-use and demonstrate that they are increasing transplants by reducing non-use, not just shifting transplants from one population to another. The proposal as written would allow variances to allocate any organs out-of-sequence for any reason, instead of focusing on organs that the proposing group has identified as likely to be non-used.*

- *Ensure that all protocols are data driven. All proposals should include a background section providing data showing that the organs included in the protocol are at high risk of non-use and that the included population is equitable and appropriate.*
- *Ensure that all proposed protocols are feasible, having a reasonable chance of showing meaningful results. This would require a sample size calculation for each protocol, demonstrating how many centers/transplants/candidates would need to be involved to demonstrate statistically meaningful improvements. This could also include stopping rules, which could include early identification of both benefits as well as harms.*
- *Add specific safeguards to protect the pediatric population from losing access to organs. Children and other hard-to-match populations often rely on broader geographic sharing, which can be “less efficient” because it requires communication between OPOs and transplant centers less used to working together, more travel and logistics. However, data repeatedly shows that this broader geographic sharing has been essential to prevent pediatric waitlist deaths and increasing transplant rates. It is critical that variances not undermine this sharing. Therefore, the variance should explicitly exclude kidneys with a KDPI of 0-35% and pediatric donor livers, hearts, and lungs from any proposed protocols. **Allowing allocation out-of-sequence for these organs would back pedal on important policy changes made in the last 2-3 years to direct particularly pediatric donors to pediatric candidates.***
- *Ensure expedited placement does not result in worse patient outcomes by tracking the outcomes. Patients who receive transplants under a variance protocol should have their outcomes tracked even after the variance has ended to provide important information for future policy development.*
- *Increase transparency for this variance by making all protocols that are submitted publicly available; this includes approved and non-approved submissions. It would be particularly helpful to include at least an assessment of why the Executive Committee did/did not approve each protocol; this would help future submitting entities understand how to make their protocols.*

The Committee reiterates its recommendation to add safeguards to the policy for pediatric and consider other hard-to-match candidates, as well as provide a mechanism for members of the community to report any observed adverse outcomes as a result of protocols approved under the variance.

3. Public Comment: OPTN Strategic Plan 2024-2027

The OPTN President provided a brief presentation on the proposal to the Committee, which was followed by discussion.

Presentation summary:

The OPTN Board of Directors adopts a new strategic plan every 3 years to align resources with significant opportunities. The current plan expires June 2024, and a new one will go into effect July 2024. The strategic plan creates a high-level framework to guide OPTN priorities and focus over the next 3 years. It contains goals, objectives and metrics but does not detail every initiative or project since flexibility is needed over time. The vision is to promote long, healthy, and productive lives for people with organ failure by promoting maximized organ supply, ensuring effective and safe care, and equitable allocation, while balancing competing goals transparently. The OPTN is committed to achieving the goals outlined

in the Strategic Plan while continuing a dedication to increase the number of successful transplants, honor the selfless gift of life given by organ donors, safeguard the well-being of patients and living donors, and continuously improve the outcomes of patients on the waiting list, living donors, and transplant recipients.

The Strategic Plan goals are:

- 1) Improve organ offer acceptance rates
- 2) Optimize organ use
- 3) Enhance OPTN efficiency.

The first goal, improve offer acceptance rate, seeks to increase opportunities for transplants by enhancing offer acceptance. The first objective for the goal is to develop, implement, and effectively promote education programs for patients and transplant programs focused on understanding offer acceptance. The second objective seeks to collaborate with stakeholders to improve offer and acceptance processes to increase consistency. The metrics for this goal include increase in offer acceptance rates overall, percentage of completed learnings, percentage of programs utilizing education offerings, decreased time from first offer to offer acceptance, decreased variation in time from first offer to offer acceptance, and decreased number of offer declines.

The second goal, optimize organ use, seeks to maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains. The first objective of this goal is to collaborate with stakeholders to identify and reduce key barriers influencing organ non-use. The second objective is to disseminate and promote best practices and effective strategies for reducing organ non-use across the transplantation community. The third objective is to explore and evaluate alternative allocation strategies for organs at high risk of non-use. The metric for this goal includes an overall decrease in the percentage of organs recovered and not transplanted, an overall decrease in percentage of organs not recovered for transplant from deceased organ donors, maintaining or improving equity, achievement of milestones in identifying and addressing key barriers to organ non-use, decreased variation of risk adjust non-use rate by organ procurement organizations (OPOs), and decreased high risk organ non-use rate.

The third goal in the proposal is to enhance OPTN efficiency through improvement and innovation. The first objective of this goal is to refine the policy development and implementation process to be more efficient and strategically aligned. The second objective is to enhance OPTN data collection, increasing the availability of actionable data while reducing member burden. The metrics for this goal include a decrease in policy development time, a decrease in policy implementation time, policy alignment with the strategic plan, stakeholder satisfaction in the policy development process, and milestone achievement in data optimization.

Past equity gains have been incorporated into the proposed plan's strategic goals recognizing that as advances in efficiency occur, equity must be maintained or improved. The desire is to increase donors, both living and eligible. The Living Donor Committee has been charged with generating specific tactics to enhance living donation.

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The Pediatric Committee has some very serious concerns about this strategic plan and the direction it would take the OPTN. The proposed strategic plan does not take equity into account in any of the proposed goals or objectives. In recent years the transplant system in this country has made progress in equity, and excluding equity from the new strategic plan puts that progress at risk. The policy evaluation process needs to be clearly defined. The current evaluation model used by the OPTN Policy Oversight Committee accounts for proposals that do not have impact across the transplant system but will greatly impact smaller population of candidates. This is critical to patient populations like pediatrics whose raw numbers may be small when compared to adult patient populations, but every policy change that increases adult access to organs limits pediatric access to organs. Pediatric policy proposals are often related to equity and not efficiency. Will proposals that increase the pediatric population's access to organs be allowed under this plan, or would those proposals not be approved for public comment because they do not neatly fit into this strategic plan? Projects that would increase the likelihood of pediatric candidates being matched to pediatric donors have already been delayed in favor of proposals focusing on efficiency. The Committee feels strongly that a performance metric that is based on successful transplant outcomes should be included. While reducing non-use and increasing utilization is important, ensuring that patients who receive lifesaving transplants are able to live longer, healthier lives is equally important but is entirely left out of this strategic plan. The goals and objectives listed within this plan overlap, and the plan is ambiguous in informing the transplant community what policies or proposals would not fit within its parameters. Moving forward, the Committee asks the Executive Committee to assign a pediatric specialist, not a physician who treats both adults and children, to all committees to ensure pediatric candidates are not left behind in over the next three years.

4. SRTR Donation and Transplant System Explorer

An Analyst at the Scientific Registry of Transplant Recipients (SRTR) presented the Donation and Transplant System Explorer. This is a new tool that aims to understand the impact of policy and other changes on transplant metrics.

Presentation summary:

- The Donation and Transplant System Explorer is a public application that had recently launched and helps users understand the different aspects of the transplant system from a data driven view
- Motivating recommendations behind the creation of this tool was the SRTR Task 5, Recommendation 6.4, and the National Academies of Science, Engineering, and Medicine (NASEM) Recommendation 12
- Data will be updated on a monthly cadence and new trends can be added to fill gaps and meet needs
- This tool:
 - Can be accessed through the SRTR.org website
 - Includes specific data fields such as time, organ type, and transplant metric type
 - Can be used to understand how policies have influenced changes in transplant metrics over time
 - Can be used to download data and produced plots

Summary of discussion:

The Committee did not make any decisions.

A member noted the Donation and Transplant System Explorer tool's capacity to present both pediatric and adult-related data. However, she raised a concern regarding the absence of comprehensive pediatric data in certain areas, such as graft survival statistics. She inquired about potential plans to integrate more pediatric-specific information into these sections. In response, the SRTR Analyst acknowledged the existing gaps and emphasized ongoing efforts to address them. He encouraged the group to utilize the tool and provide feedback on areas where pediatric data is lacking, as this input would greatly assist in refining and enhancing the tool's functionality.

In addition, a member inquired about the potential inclusion of multi-organ transplant (MOT) data in the tool. In response, the SRTR Analyst expressed the need for further consideration, noting that the current structure of the tool aligns closely with the organization of data within the OPTN. He explained that integrating MOT data would require further evaluation to determine how such information could be incorporated into the existing tool. Acknowledging the complexity of the subject matter, another member suggested the possibility of leveraging national data available from the OPTN to inform this endeavor.

A participant questioned the possibility of extending the timeframe beyond one to three years to analyze transplant outcomes. In response, the SRTR Analyst affirmed that such an opportunity exists. However, he explained that there are technical considerations that need to be addressed to facilitate this extension.

A member wondered about the potential use of alternative data sources to supplement the primary data from the OPTN within the tool. In response, the SRTR Analyst explained that while they are already incorporating additional data sources for post-graft survival analysis, they have not extensively explored other avenues for supplemental data. However, he expressed openness to the idea, stating that if there are opportunities to integrate additional sources that could enhance both the quality of the data and the functionality of the tool, it would be a worthwhile consideration.

Overall, members voiced their unanimous support and satisfaction with the tool during the meeting. They enjoyed its interactivity, appreciating the ability to engage with the data dynamically. Furthermore, they appreciated the granularity of information available at each time point, highlighting the tool's capacity to provide detailed insights into transplant outcomes.

5. Data Advisory Committee Pre-waitlist Data Collection Update

The Chair presented on the Pre-Waitlist Data Collection project that the Data Advisory Committee (DAC) has been working on.

Presentation summary:

The process of data collection within the OPTN commences at the point of listing for transplant, resulting in a lack of data regarding patients who undergo referral or evaluation but are ultimately not listed. This gap in information was highlighted in the NASEM report titled "Realizing the Promise of Equity in the Organ Transplantation System," where one of the six key action items emphasized the need to bridge gaps in standardized and publicly reported measurement concerning patient referral, evaluation, and wait-listing at transplant centers. In response to the NASEM report, the Health Resources and Services Administration (HRSA) solicited feedback from the OPTN Data Advisory Committee (DAC) regarding two drafted data collection forms: ventilated referral notification and

referral evaluation registration. The DAC's input is crucial for finalizing the HHS Secretarial Directive and for HRSA's plans to incorporate these new data collection forms into the 2023 OPTN Data System Package.

Two main types of pre-waitlist events include referral, and evaluation, each with start and end triggers. Once event closure takes place, transplant programs will not be able to edit the data. For the referral event, the Workgroup identified 27 elements for collection, while for the evaluation event, there were 32. Nearly half of these identified data elements are currently collected on the Transplant Candidate Recipient (TCR) form. Additionally, five of the 12 new elements identified are collected at both referral and evaluation stages. An important addition to data collection was the data field that identifies reasons for referral closure or a turn down for listing following evaluation. Some of the reasons for closure will include active or recent malignancy, inadequate care giver support, metabolic issues, substance use, and more.

Summary of discussion:

The Committee did not make any decisions.

A concern was raised regarding the potential workload for users, questioning whether the information collected at this stage would automatically populate in later phases or if manual entry would be necessary at each subsequent step. In response, the OPTN contractor staff acknowledged that this aspect had not yet been finalized. However, they indicated that the most probable option would involve having the collected information automatically populate for later phases.

A member emphasized the importance of noting the deferment date when a potential recipient is deferred at the end of the evaluation process. They highlighted that this information would add to the patient's evaluation time and could aid in identifying reasons for prolonged evaluation processes. In addition, a participant suggested implementing a closed or deferred designation within the evaluation process. She emphasized that if a valid reason for deferment is provided, transplant centers should not be penalized for a prolonged evaluation period.

A member expressed concern that if there is a metric for evaluating the duration of evaluations, patients might be declined, or the center could face penalties. However, the Chair responded by stating that the DAC prioritized simplicity in data fields for feasibility reasons and preferred not to delve into the nuances of different designations or dates.

It was pointed out that the reasons for referral closure, as presented, could potentially shape or serve as metrics for evaluating transplant candidacy. A member expressed concern that this approach might inadvertently lead to certain patient populations being overlooked or avoided during the referral or evaluation process, which could ultimately be detrimental to patients. In response, the Chair acknowledged the concern and explained that listing a reason for referral closure, even if a patient is referred to a provider but turned down prior to evaluation, will be a requirement. This requirement would provide transplant centers with a sense of accountability throughout this process.

A member advocated for a breakdown or subdivision of the "Inadequate Patient Caregiver Support" referral closure reason. She pointed out that older pediatric patients, particularly those aged 16-17, may lack support systems, which could prevent them from being listed for transplant. Additionally, she highlighted the potential long-term consequences, noting that when these patients turn 18, they lose their pediatric points, effectively penalizing them for a situation that could harm them in the future. The member suggested that there might be other social issues at play, such as a parent who is unable to reliably bring the child to appointments.

A participant proposed expanding the definition of the "Patient Unable to Adhere" referral closure reason to encompass instances where patients fail to attend or complete specific parts of the evaluation process. She suggested that this addition would more accurately capture cases where patients or their families neglect referral events, such as obtaining a cardiac clearance. Another participant recommended creating a metric or data field specifically for out-of-state evaluations. He explained that when a patient is referred from out-of-state and is covered by state insurance that does not permit evaluation or referral, providers are forced to decline the patient. He noted that the existing "Financial/Insurance Issues" referral closure option doesn't address this scenario.

Members collectively acknowledged that the definitions provided for the reasons for refusal were somewhat narrow and might not encompass all relevant scenarios. For instance, the category "Too Sick for Transplant" was deemed too restrictive and failed to adequately address instances of medical complexity. They suggested that broadening this definition or modifying the title to include medical complexity would be advantageous. Additionally, one member highlighted that infectious issues and malignancies are commonly cited as contraindications in transplant selection criteria, yet there was no specific category for infectious issues in the list of reasons for referral closure.

6. Pediatric Loss to Follow Up

The Committee reviewed their previous "Loss to Follow Up" (LTF) conversation and engaged in continued discussion on the matter.

Presentation summary:

Review:

- This topic was last discussed on December 13, 2023
- Approximately 12% of kidney recipients ages 0-17 transferred to non-OPTN programs within 5 years post-transplant between years 2000-2010
- LTF occurred in 50% of kidney recipients who transferred institutions
- Approximately 17% of pediatric liver transplant recipients were LTF between the years 1990 and 2018
- There is no standard definition for "Loss to Follow Up"

Previous Discussion:

- "Drop-down" option on TRF for "transfer to non-OPTN center"
- More granular data collection for LTF
- Formal definition for "Loss to Follow Up"
- Issues that could be impact LTF:
 - Change to non-OPTN centers (no access to OPTN Computer System)
 - Change to insurance status
 - Geographic issues

Summary of discussion:

The Committee will be reaching out to other OPTN committees to determine if there is a future project they could pursue regarding Loss to Follow Up situations.

A member proposed the idea of granting access to the OPTN Computer System data for patients, parents, or caregivers to monitor patient information. While acknowledging potential legal constraints, the member argued that such access could empower caregivers or patients to track and manage their own data, fostering a sense of accountability. The Chair recognized the significant undertaking of providing access to information for all patients and caregivers.

A member raised the possibility of creating a separate website for patients in non-OPTN centers to input their data, though concerns were voiced about the accuracy of such data given that patients may lack medical expertise. To mitigate this issue, members suggested simplifying input questions to focus on essential information such as graft functionality and demographic details.

During the meeting, the Vice Chair proposed a minor adjustment to the drop-down options regarding patient transitions from transplant centers, suggesting that providing more specific destination choices could enhance the granularity of research and data collection. Specifically delineating where patients go or to whom they are referred could offer valuable insights. In response, a member highlighted that transplant centers no longer have the option to select "transfer to non-OPTN center" in data collection forms. Both the Chair and Vice Chair expressed agreement that it would be prudent to inquire with the Data Advisory Committee (DAC) about the removal of this option, aiming to gain a better understanding of the rationale behind the change.

During the discussion, a member raised the question of whether transplant centers would exhibit greater diligence in patient referrals and data collection if official reporting extended to include 5 or 7-year survival rates to SRTR. Several members concurred, suggesting that integrating longer-term outcome reporting could indeed incentivize centers to be more conscientious in their practices.

The group expressed shared concern regarding the lack of clear definition and standardization surrounding the designation of LTF status within transplant data. Currently, the absence of guidelines means that individual centers have the discretion to determine this status, leading to potential inconsistencies in reporting. Moreover, the data collection process does not account for the time elapsed between the last known follow-up and the point at which a patient is labeled as LTF, further complicating data interpretation.

To address these issues, the Chair proposed collaboration with the Patient Affairs Committee to explore avenues for addressing concerns related to LTF designation, recognizing the importance of establishing clearer guidelines in this regard. There was discussion around the idea of establishing a registry where living donors and recipients could input their own data regarding post-donation outcomes, reflecting a proactive approach to addressing concerns surrounding LTF and enhancing data collection efforts.

Members predominantly supported pursuing the project related to addressing Lost to Follow-up concerns and enhancing data collection. They emphasized that such a project aligns closely with the strategic goals of the OPTN, particularly in its focus on improving long-term outcomes for transplant recipients and donors.

7. Public Comment: *Concepts for Modifying Multi Organ Policies*

The Chair of the OPTN Ad Hoc Multi-Organ Transplantation Committee joined the meeting to present the concept paper *Concepts for Modifying Multi Organ Policies*.

Presentation summary:

The purpose of this concept paper is to request feedback on concepts for updating the kidney multi-organ allocation system. The MOT Committee is not proposing any policy changes, but does want the

feedback collected with this concept paper to inform future policy proposals. This is a follow up to a January 2023 concept paper that requested community input on a variety of kidney multi-organ topics. The feedback received from that concept paper suggested prioritizing pediatric, high CPRA, medically urgent candidates, and prior living donors over some multi-organ candidates. The MOT Committee is now seeing feedback on prioritizing kidney alone vs kidney with another organ candidates when allocating kidneys, whether kidney-pancreas should be considered multi-organ, policy guidance around required organ offer acceptance and sequence when allocating from a multi-organ donor, and allocating one kidney to a kidney-alone candidate and the other kidney to an MOT candidate when both kidneys are available from the same donor.

Data collected between March 15, 2021, and December 31, 2022, shows a kidney with KDPI between 0-34% was allocated to a kidney-alone candidate 41% of the time. Additionally, 82% of donors whom both kidneys were transplanted, both kidneys went to kidney-alone recipients. For 0-34% KDPI donors, both kidneys went to kidney-alone recipients 70% of the time. For 35-85% KDPI donors, both kidneys went to kidney alone candidates 91% of the time. Finally, for 86-100% KDPI donors, both kidneys went to kidney-alone recipients 99% of the time.

The MOT Committee is seeking feedback on: How MOT candidates should be prioritized when only one kidney is available? Should kidney-pancreas candidates be considered multi-organ candidates and be prioritized among other multi-organ combinations? When both kidneys are available from a donor with a KDPI between 0-34%, should one kidney be allocated to an MOT candidate and the second to a kidney-alone? What are the potential impacts to kidney-pancreas and pediatric candidates?

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Pediatrics Committee would like to thank the MOT Committee for the opportunity to provide feedback on this concept paper. The Committee agrees with the idea that when both kidneys from a donor are available for transplant, one kidney should go to a multi-organ candidate and the other should go to a kidney-alone candidate. If the kidney that is being allocated to kidney-alone candidates has a KDPI less than 35%, pediatric candidates should be given priority over kidney-pancreas candidates. Reviewing the available data, the Committee believes a policy like this could greatly reduce, if not eliminate, the pediatric kidney waiting list. The Committee discussed at length the placement of kidney-pancreas candidates with kidney-alone candidates for allocation. As long as kidney-pancreas candidates are offered the kidney after the pediatric list has been exhausted for kidneys less than 35% KDPI, the Committee is comfortable with the inclusion of kidney-pancreas candidates with kidney-alone candidates. The Committee also feels that living donors, 100% CPRA, and medically urgent candidates should also be given priority over kidney-pancreas candidates and other kidney-alone candidates for kidneys with a KDPI less than 35%. As for the specific order of allocation for MOT combinations, the Committee does believe this process should be dictated by policy and should be consistent. The order should be dictated by data including waitlist survival and mortality rates but should still prioritize pediatric candidates.

8. Public Comment: *Modify Effect of Acceptance Policy*

The Committee Vice Chair, who also serves on the OPTN Ad Hoc Multi Organ Transplant Committee, gave a brief presentation on the proposal *Modify Effect of Acceptance Policy*.

Presentation summary:

The purpose of this proposal is to clarify when single organ offer acceptance takes priority over required MOT shares. This proposal will clarify that when a primary single organ is declined after an organ has been accepted, the organ procurement organization (OPO) is not required to allocate to required MOT shares since a second organ is no longer available.

OPTN Policy 5.6.D: Effect of Acceptance states that when a transplant hospital accepts an OPO's organ offer without conditions, this acceptance binds the transplant hospital and OPO unless they mutually agree on an alternative allocation of the organ. Some OPOs will not finalize acceptance of organs in case there is a late organ offer refusal and an MOT candidate is on the match run. This policy change will allow OPOs to move forward with placing single organs. The OPO will not be required to allocate to required MOT shares if a second organ is no longer available. It is important to note that OPOs are still required to place multi-organ combinations according to current OPTN policies.

For example, an OPO may place a heart, liver, and lung with individual candidates and the kidneys with other candidates, but then receive notification that the heart candidate can no longer accept the organ. If the next candidate on the match is a qualifying heart-kidney candidate, policy says that the OPO must offer the kidney along with the heart, but the OPO no longer has a kidney to offer since the kidneys were accepted by other candidates. This proposed policy would clarify that the OPO is not expected to offer the kidney along with the heart to the next qualifying heart-kidney candidate since the kidneys have already been allocated with a primary acceptance.

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Pediatrics Committee supports this proposal. The Committee discussed this proposal, and the devastation families have when an organ offer is pulled, which can also be traumatizing for physicians as well. The Committee welcomes this policy change, and thanks the OPTN MOT Committee for developing this proposal.

9. Data Report: *Assessing the Impact of a Decrease in National Median PELD at Transplant*

OPTN Contractor staff provided the Committee with an overview of the main findings in the *Assessing the Impact of a Decrease in the National Median PELD at Transplant* report.

Presentation summary:

- Most transplants that occurred during the observation period had an MMaT value between 30 and 32. Regions 1, 2, and 9 had several transplants conducted where the MMaT value was 33.

This data reveals the potential for kids aged zero to eleven to be affected by the decrease in median PELD at transplant.

- Approximately 3% of deceased liver donors between the ages of 18 and 40 were allocated to a pediatric recipient. In the past, transplants from those between 18 and 40 made up approximately 10-25% of transplants conducted monthly for pediatric recipients zero to eleven.
- Pre to post decrease, there was a decrease in transplants where the PELD or MELD score was 37 or greater and an increase in transplants where the PELD or MELD score was 33 to 36.
- In the post era, there was a decrease in the proportion of transplants to pediatric recipients where the distance between donor hospital to transplant center was 0-150 NM
- There was a substantial increase in the proportion of pediatric recipients transplanted with a PELD score of 33-36. There was a decrease in the proportion of pediatric recipients transplanted with a PELD score of 37 or greater.
- Post era data shows that pediatric patients spent eight days longer on the OPTN Waiting List
- In the post era, pediatric patients with or without exceptions experienced longer wait list times. However, medically urgent pediatric patients experienced a shorter wait list time.

Summary of discussion:

The Committee did not make any decisions.

The Chair directed the OPTN contractor staff to condense information for the upcoming report, suggesting a focus on data by region as it appeared to be most beneficial and important based on initial findings. Regarding the data's implications, members deliberated on whether policy changes within the OPTN were effectively mitigating the impact of reduced PELD scores on pediatric recipients. While acknowledging the data's limited sample size for drawing statistical conclusions, the group agreed to monitor trends closely, particularly to assess if a further decline in the MPaT would disadvantage recipients. In response to the Vice Chair's inquiry about revisiting the data if the MPaT increased within the next 12 months, members unanimously concurred that such a review would be prudent.

10. Public Comment: *Continuous Distribution of Hearts*

The OPTN Heart Transplantation Committee Vice Chair gave an update on the Heart Committee's work on developing a new continuous distribution system for allocating donor hearts. The purpose of this update is to get feedback on developments since last year's concept paper and encourage ongoing community engagement.

Presentation summary:

Key goals for continuous distribution are to establish more equitable and transparent distribution based on current values, while considering multiple candidate attributes by using a composite allocation score. Proposed attributes include medical urgency, post-transplant survival, reducing biological disadvantages, patient access, and placement efficiency. Some of these attributes can be found in the current system, others are new additions. Weights and rating scales for each attribute will be determined based on clinical data, operational data, and community input through a publicly available survey. This allows quantifying preferences on weights for the allocation framework.

The values prioritization exercise for continuous distribution of hearts is currently available. This is a pairwise comparison survey to provide input on preferences between attributes and relative

importance. The Heart Committee Vice Chair encouraged participation from physicians, coordinators, patients, and caregivers to make sure the pediatric voice is heard in policy development.

The Heart Committee will use the survey results when developing an updated policy proposal. The goal is to improve transparency, equity and outcomes in the continuous distribution system for allocating scarce pediatric donor hearts.

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Pediatrics Committee would like to thank the Heart Committee for the work they have done on Continuous Distribution, and for including members of the Pediatrics Committee in their discussions while developing the continuous distribution framework. The Committee supports and agrees with many of the components provided in this update, particularly the binary scale for all pediatric candidates that is being proposed. However, the Committee is concerned about certain attributes that were not included in this update.

While providing all pediatric candidates with a certain amount of points to ensure some level of priority is a good thing, there are certain attributes within heart policy that are unique to pediatric candidates that should be considered by the Heart Committee. Many pediatric candidates end up spending more time on the waiting list than their adult counterparts, so the Committee would like to see waiting time included as an attribute.

Pediatric candidates are often unable to benefit from many mechanical support devices because they weigh too little. This creates a scenario where the pediatric candidate's urgency drastically increases and their options for care decreases. However, this is not accounted for in continuous distribution. The Pediatrics Committee recommends this be discussed by the Heart Committee for inclusion in the next continuous distribution update as a biological disadvantage.

In current heart allocation policy, pediatric candidates receive priority during allocation of pediatric donor organs. The Committee feels strongly this policy should be included in continuous distribution.

11. Adjournment

The Chair thanked members for their participation and adjourned the meeting.

Upcoming Meeting

- March 13, 2024

Attendance

- **Committee Members**
 - Emily Perito
 - Rachel Engen
 - Joe Brownlee
 - Namrata Jain
 - JoAnn Morey
 - Geoffry Kurland
 - Carol Wittlieb-Weber
 - Reem Raafat
 - Aaron Wightman
 - Katrina Fields
 - Ryan Fischer
 - Melissa McQueen
 - Meelie DebRoy
 - Gonzalo Wallis
 - Sonya Kirmani
 - Neha Bansal
 - Caitlin Peterson
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **SRTR Staff**
 - Avery Cook
 - Jodi Smith
 - Nick Wood
- **UNOS Staff**
 - Alex Carmack
 - Kaitlin Swanner
 - Susan Tlusty
 - Eric Messick
 - Sharon Shepherd
 - Dzhulivana Handarova
 - Robert Hunter
 - Betsy Gans
 - Sarah Roache
 - Laura Schmitt
- **Other Attendees**
 - Lisa Stocks
 - Roshan George
 - Dianne LaPointe Rudow
 - JD Menteer