OPTN Pediatric Transplantation Committee
Meeting Summary
January 30, 2023
In-Person and Conference Call
Emily Perito, MD, Chair
Rachel Engen, MD, Vice Chair

Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met in-person in Chicago, IL and via Citrix GoToMeeting teleconference, on 01/30/2023 to discuss the following agenda items:

1. Welcome, housekeeping, and icebreaker
2. Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates
3. Heart Continuous Distribution Update
4. One Year Monitoring Report for Pediatric National Heart Review Board
5. Continuous Distribution Updates: Liver and Intestine, Kidney-Pancreas, and Lung
6. Pediatric Data in OPTN Monitoring Report Discussion
7. Multi-Organ Transplantation (MOT) Update
8. Pediatric Emergency Exception Pathway Bylaws Discussion
9. Ethical Evaluation of Multiple Listing
10. Adjourn

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

1. Welcome, housekeeping, and icebreaker

Committee leadership welcomed the Committee, gave a few announcements, and led an icebreaker activity.

2. Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates

The Committee heard a presentation on the OPTN Heart Transplantation Committee's *Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates* proposal out for public comment and provided feedback.

Presentation Summary:

Pediatric heart candidates continue to experience high waitlist mortality rates when compared to adult heart candidates. The OPTN Heart Transplantation Committee proposed taking another incremental step to improve waitlist mortality rates by allowing candidates registered prior to turning 18 years old to receive offers of intended incompatible blood type (ABOi) donor hearts, lungs, and heart-lungs. In addition, eligibility for ABOi donor organs would be extended to pediatric Status 2 heart candidates, as well as all pediatric lung candidates under the proposal, essentially removing status as an eligibility consideration. This proposal has expected positive outcomes for pediatric candidates but may mean that histocompatibility labs see increased demand for analyses. Transplant hospitals may want to re-examine the appropriateness of candidates for ABOi offers and train staff concerning updated requirements.

Summary of Discussion:

The Chair thanked everyone involved in bringing this proposal and issue to the forefront. A member stated that there is a subset of children who are eligible for ABOi transplant who are never listed for these transplants, and more information is needed as to why this is. This member suggested it may have something to do with center volume and clinician experience. A member explained that for a center with a lower transplant volume, there may be barriers to keeping up with ABOi listings. This member suggested considering whether to disclose the option for an ABOi transplant to families as part of the listing process.

A member expressed support for the proposal, noting that high volume transplant centers will likely take advantage of this more quickly than centers with lower volumes. This member asked the presenter why a 30-day repeat bloodwork requirement was decided upon. The presenter explained that this was to ensure that programs are checking titers regularly in infants but may be less relevant for older patients. A member asked if there should be particular titer requirements, and the Committee discussed the relative imprecision and variability of these tests. The Chair noted that the frequency of titer testing could present a barrier to centers and may pose a safety risk to very young children.

The Chair noted that while the Committee supports this idea, eligibility does not always lead changes in practice, and this should be closely monitored in post implementation data. The Chair also suggested a need for educational materials for centers. A member suggested obtaining more practical clinical information about ABOi transplants in Canada and the UK to help inform policy decision making for the Committee.

3. Heart Continuous Distribution Update

The Committee received an update on heart continuous distribution.

Presentation Summary:

A general overview of the goals and steps of transitioning to continuous distribution was presented. The OPTN Heart Transplantation Committee is in the process of identifying the appropriate attributes and developing a concept paper. Current heart statuses will be converted into medical urgency points. The following additional attributes in current policy will be transitioned into continuous distribution: donor-recipient age, blood type, waiting time, and distance from donor to transplant hospital. Also, priority for prior living donors and pediatric candidates will be included. The Heart Committee has identified the following additional attributes for consideration of inclusion within continuous distribution: sensitization, time on Ventricular Assist Device (VAD), size matching, population density, prospective cross matching, socioeconomic characteristics, congenital heart disease, re-transplant, hypertrophic and restrictive cardiomyopathy, and pediatric medical urgency.

Specific consideration for medical urgency, especially Pediatric Status 1A, is being discussed for the transition to continuous distribution. The Heart Committee is looking for feedback and guidance for how to transition specific clinical conditions to the medical urgency priority framework in continuous distribution.

Summary of Discussion:

A member shared their experience participating in the Heart Pediatric Medical Urgency Workgroup. The Chair recommended using age-adjusted mortality rates to provide better consideration for pediatric patients. The presenter explained that pediatric waiting time will also be considered in pediatric urgency. Members discussed specific clinical conditions that would point to the need for higher medical urgency.

4. One Year Monitoring Report for Pediatric Heart National Review Board

The Committee heard the results from the One Year Monitoring Report for the Pediatric National Heart Review Board and discussed.

Presentation Summary:

Before the implementation of the pediatric National Heart Review Board (NHRB) on June 15, 2021, Regional Review Boards (RRBs) handled and reviewed exception cases for pediatric candidates listed before their 18th birthday. The purpose of the NHRB was to improve quality and consistency in evaluating exceptions for heart candidates listed before their 18th birthday. Pediatric heart candidates can be listed as Status 1A, Status 1B, Status 2 or Inactive. Active pediatric candidates not meeting the criteria for Statuses 1A and 1B are put in Status 2 by default. The NHRB is comprised of representatives from pediatric heart programs from across the country. Reviewers are randomly assigned to review exception requests.

There was an increase in pediatric status 1A waitlist additions and a decrease in pediatric status 1B waitlist additions from the pre-policy era to the post-policy era. Age and exceptions were similarly distributed across eras in both waitlist additions and transplants. Transplants by medical urgency status were also similarly distributed across eras. There was an increase in exception denials from 1 in the pre-policy era to a total of 33 in the post-policy era. Overall post-transplant patient survival increased, especially for pediatric status 1A patients. The transplant rate increased across eras for pediatric status 1A patients with an exception, but decreased for pediatric status 1B patients with an exception. Mortality increased from the pre-policy era to the post-policy era in all categories except pediatric status 1A candidates without an exception and pediatric status 2 candidates with an exception.

Summary of Discussion:

The Chair noted difficulty interpreting the data due to extremely small numbers and overlapping confidence intervals, suggesting that the data is not statistically significant. The presenter explained that this is true and that the two-year monitoring report may have larger numbers. A member suggested looking into the denials and reasons for the denials as this will be helpful in informing choices regarding the move to continuous distribution. Another member suggested looking at the narratives for both approvals and denials to see patterns. The Chair noted that this may be best handled by an outside research program instead of a formal data request.

The Committee discussed that an increase in denials may not be a bad thing, as there was a feeling that before the pediatric specific review process, most cases were approved simply because the case involved a pediatric patient. A member also suggested reviewing discard rates. Members discussed updating the guidance document for pediatric exception requests with some conclusions from this report.

5. Continuous Distribution Updates: Liver and Intestine, Kidney-Pancreas, and Lung

The Committee received updates on the continuous distribution of liver and intestine, kidney-pancreas, and lung.

Presentation Summary:

Liver and Intestine

In December 2021, the OPTN Liver and Intestinal Organ Transplantation Committee began their work to convert the current classification-based allocation system for livers and intestines to a point-based framework, otherwise known as continuous distribution. Continuous distribution will replace the

current classification-based approach, which draws hard boundaries between types of candidates (for example, blood type compatible vs. identical; inside vs. outside a circle), with a composite score that simultaneously takes into account donor and candidate attributes. This points-based framework will create a more equitable and transparent allocation system.

This request for feedback builds upon the previous concept paper on the continuous distribution of livers and intestines that was released for public comment in August 2022. The purpose of this request for feedback is to supplement the values prioritization exercise (VPE) that is currently available for members of the transplant community to complete. The values prioritization exercise asks community members to compare the relative importance of the different factors that will be included in the new allocation system. The results of the values prioritization exercise will provide valuable feedback to the Committee on how to weight the different factors in continuous distribution.

Kidney-Pancreas

A brief update on the progress of the OPTN Kidney and Pancreas Committees in continuous distribution was provided to the Committee. The Kidney and Pancreas Committees are working to make final decisions about rating scales and weights for the second Organ Allocation Simulation (OASim) modeling request. Both Committees have decided that pediatric candidates should receive high priority.

Additionally, some members of the Committee will be sitting in on Kidney Committee calls moving forward.

Lung

Lung continuous distribution will be implemented on March 3, 2023. Starting on February 9, 2023, transplant programs may submit lung composite allocation scores (CAS) exceptions to ensure their candidates have the exceptions transferred into the new system. The exception approval process includes pediatric reviewers.

Next, the Committee received a presentation on the Lung Continuous Distribution CAS Rankings Data Request. In general, pediatric candidates showed increased priority for transplant in the CAS rankings as compared to the current allocation scheme.

Summary of Discussion:

Liver and Intestine

A member asked if pediatric priority is taken into account specifically, and the presenter answered that pediatric candidates are taken into account. Members advocated for pediatric priority to be specifically called out (now called candidate age) on the attributes and for inclusion of patient advocacy organizations throughout the policy development process.

A member stated that split liver may not belong in the identified attributes because it is a center attribute, not a candidate attribute. This member explained that candidates should not be disadvantaged for things that are out of their control or not technically feasible.

Members filled out the VPE.

Kidney-Pancreas

There was no additional discussion. Staff will draft a public comment for the Committee to review.

Lung

A member asked if clarification would be provided as to what high flow oxygen is defined as and noted that high flow for a baby will be different for an adolescent patient. Staff will follow up with more information. Members discussed how pediatric patients will sort among other pediatric patients.

6. Pediatric Data in OPTN Monitoring Report Discussion

The Committee discussed OPTN monitoring reports in small, organ-specific groups and reported out to the larger group.

Presentation Summary:

The Chair explained some background information and the goal of the project to create an internal reference document for UNOS research staff to include or not include specific metrics on monitoring reports. The Vice-Chair introduced recent efforts by the OPTN Policy Oversight Committee to standardize and improve data monitoring for policies. The Committee split out into organ-specific small groups to discuss the variables included in recent monitoring reports and any additions or edits for the eventual reference document.

Summary of Discussion:

Some questions about the role of the OPTN monitoring reports versus Scientific Registry of Transplant Recipient (SRTR) reports were clarified.

Each organ-specific group recapped their discussion.

Heart

Members discussed the following recommendations to include in heart monitoring reports:

- Include 0-1 age group as its own category
- Report weight in addition to age
- Include ABO compatible versus incompatible
- Specific diagnostic categories

Kidney and Pancreas

Members discussed the following recommendations to include in kidney and pancreas monitoring reports:

- Age groups as 0-5, 6-11, and 12-17
- Transplant rate reported as actual number of transplants
- Active wait time instead of total wait time
- Data stratified by age and race
- Clarification on statistical significance of figures

Liver and Intestine

Members discussed the following recommendations to include in liver and intestine monitoring reports:

- 0-2 year old as its own age category
- ABO compatible versus incompatible
- Data about multi-organ transplants
- Data about exceptions
- Waitlist mortality specific to pediatric candidates

Lung

Members discussed the following recommendations to include in lung monitoring reports:

- Split out 0-11 and 12-17 age grouping
- Show extreme outliers and note specifically in report
- Quality of life metrics specific to pediatrics

Next Steps:

Staff will compile and organize these recommendations and the Committee will continue to discuss in future meetings.

7. Multi-Organ Transplantation (MOT) Update

The Committee heard public comment presentations for the following two items presented by the OPTN Ad-Hoc MOT Committee: Identify Priority Shares in Kidney Multi-Organ Allocation and Expand Required Liver-Kidney Allocation.

Presentation Summary:

Identify Priority Shares in Kidney Multi-Organ Allocation

The Ad Hoc Multi-Organ Transplantation Committee aims to establish an updated framework for kidney multi-organ allocation to improve equity in access to transplant between single organ and multi-organ candidates, and to improve efficiency in allocating multiple organ types from one donor. This framework will consider if and when kidneys should be offered to kidney-alone candidates prior to kidney multi-organ candidates, how to determine which kidney (including laterality) should be offered to various kidney multiorgan and single organ candidates, how to handle situations in which organ offer acceptance conflicts with a multi-organ offer required by policy, and providing more direction for multi-organ allocation while leaving flexibility for the dynamics of the allocation process.

Expand Required Simultaneous Liver-Kidney Allocation

OPTN liver-kidney allocation policy requires organ procurement organizations (OPOs) to offer the kidney with the liver to candidates who are registered at a transplant program within specified distances from the donor hospital and who meet certain clinical criteria, including medical urgency for liver transplant and kidney dysfunction. Beyond the specified distance thresholds for required shares, the OPO may then either offer the kidney and liver to any liver-kidney candidates who meet the clinical criteria for kidney dysfunction, or offer the liver to liver-alone candidates and offer the kidney to kidney-alone candidates. As a result, there is variation in whether an OPO opts to allocate a kidney with a liver to candidates who meet the clinical criteria for both organs but fall outside the distance threshold for required shares.

The Ad Hoc Multi-Organ Transplantation Committee proposes expanding the distance threshold for required liver-kidney allocation. This change is expected to improve equity in access to simultaneous liver-kidney transplantation across the nation. Based on current OPO practice, this change is not expected to greatly increase liver-kidney transplants, and is not expected to have a large impact on access to kidney-alone or pancreas-kidney transplantation. However, this change would make it more likely that candidates requiring a simultaneous liver-kidney transplant receive offers for the organs they need. This proposal would also update liver-kidney policy so that the OPO may offer the liver and kidney in accordance with other multi-organ policies once the OPO completes all required liver-kidney offers. Finally, the proposal includes other non-substantive changes to liver-kidney policy for clarity and to further align liver-kidney policy with other multi-organ policies.

Summary of Discussion:

Identify Priority Shares in Kidney Multi-Organ Allocation

A member described concern with prioritizing highly sensitized kidney candidates over pediatric candidates as the highly sensitized candidates already receive priority. This member stated that they agreed with prioritizing kidney offers for medically urgent candidates, candidates needing more than two organs, and pediatric candidates, however. Additionally, there may be a consideration to reduce the priority that kidney-pancreas candidates get with respect to other multi-organ candidates because the mortality risk has been reduced with advances in treatment for diabetes.

A member stated that pediatric candidates should be separated from discussion of the other groups that may warrant priority such that other groups do not compete for kidneys for children. The Committee discussed if only certain or all pediatric candidates should be prioritized over multi-organ candidates. The Vice-Chair explained that some people feel as though because the general pediatric population has lower waitlist mortality, other groups may be prioritized over some pediatric candidates. A member disagreed with only prioritizing some candidates, noting that pediatric candidates need longer graft outcomes and are restricted by other factors, such as size. Members described concerning poor outcome trends when pediatric patients are passed over for multi-organ candidates or other population groups.

A member stated that decision-making based on pediatric kidney waitlist mortality is flawed, because although waitlist mortality is low, the growth and developmental problems children face are severe.

The Committee was in favor of requiring offering the second kidney to a kidney alone candidate when one kidney is offered to a multi-organ candidate as this will help increase offers to pediatric patients. The Committee was also in favor of policy dictating an allocation order across heart-kidney, liver-kidney, lung-kidney, and pancreas-kidney based on medical urgency, mortality, and safety net eligibility and suggested that these could be handled by review boards.

Regarding clarifying binding organ offer acceptance, members suggested using the primary offer mechanism. Regarding how the OPTN can provide more direction in policy without impinging on an organ procurement organization's (OPO's) ability to place organs efficiently, members suggested clarifying what OPOs can and cannot do once an offer is sent to a program.

Expand Required Simultaneous Liver-Kidney Allocation

A member shared that they are concerned that expanding SLK shares may have unanticipated negative consequences for pediatric candidates. A member stated that they are in favor of aligning policy, however, that the policy will have a net zero effect overall or that specific regions will end up exporting more organs than the offers they will receive. Another member explained the importance of making transparent, very clear policies for OPOs to follow. The Chair stated that pediatric liver candidates need to be closely tracked for this policy.

8. Pediatric Emergency Exception Pathway Bylaws Discussion

The Committee discussed the pediatric emergency exception pathway project.

Presentation Summary:

The Chair recapped prior discussion on the pediatric emergency exception pathway and showed the bylaws. Leadership met with the OPTN Membership and Professional Standards Committee (MPSC) and received additional information about the cases that were sent to them for review. The Chair went over these cases with the Committee. Several options were presented for how to move forward on this project, including continued monitoring before action, reviewing bylaw language and modifying if necessary, and creating a review board to help adjudicate cases as they arise.

Summary of Discussion:

Members discussed the clinical specifics of the cases and challenges associated with the exception pathway and each option presented. A member suggested having the Committee review the cases instead of the MPSC. The MPSC has limited pediatric experience, so they may not be the best group to review these cases. Members discussed adding pediatric representatives to the MPSC. A member suggested adding additional text boxes in the OPTN computer systems to help reduce the caseload.

A member asked if there was any way to determine if the center that is requesting the exception was previously denied from having a pediatric component, as this could present a patient safety issue. The Committee was in favor of reviewing the cases every six months before deciding on any one modification after a vote.

9. Ethical Evaluation of Multiple Listing

The Committee received a presentation on the OPTN Ethics Committee's white paper.

Presentation Summary:

The purpose of the OPTN Ethics Committee's white paper is to conduct an ethical analysis of multiple listing, and understand how the practice fares against the ethical principles of transplant. This white paper will serve to concretely conclude the decades-old debate surrounding multiple listing, which is a process that permits patients to be listed at multiple transplant programs and accept organ offers from more than one transplant program simultaneously. Ultimately, this white paper answers the question "What are the ethical implications of permitting patients to be listed at multiple transplant programs?"

To address this question, the Ethics Committee considers the ethical principles of equity (including distributive justice and procedural justice), autonomy, and utility, which are the foundation of an ethical transplant system. In addition to the ethical analysis, the Ethics Committee conducted two data requests to examine the prevalence of multiple listing, whether it confers an advantage in likelihood of transplant and examined the sociodemographic patterns of utilization of multiple listing.

The Ethics Committee recommends that multiple listing be retained as an option only for patients who are exceptionally difficult to match, and that transplant programs should underscore the value of multiple listing to patients who meet the agreed-upon criteria. This would apply to sensitized patients or patients exhibiting other agreed-upon characteristics that represent medical complexity. Furthermore, the Ethics Committee recommends prohibiting transplant programs from refusing multiple listed patients, in support of patient autonomy over transplant program autonomy. Lastly, to increase patient autonomy, transplant hospitals are encouraged to increase transparency in evaluation, listing, and organ acceptance practices to help patients choose a primary transplant program that is an optimal fit for their needs. The Ethics Committee acknowledges the challenges defining this medically complex group and defers the identification of these individuals and modification of the relevant policies to other OPTN committees.

Although the transplant community cannot resolve all public health disparities, it must strongly consider revising policies that entrench them and continue efforts to rectify these.

Summary of Discussion:

A member asked who would determine which patients are medically complex and asserted that insurance often limits patients from seeking multiple evaluations. Another member asked if race was evaluated, and the presenter answered that there were not significant differences among races for single and multiple listing.

A member stated that transparency for families is extremely important, and families should be allowed to do what they see fit for their child, including multiple listing. This member explained that multiple listing should be allowed for pediatric candidates. A member stated that from a parent perspective, it may limit autonomy if decision-making is taken out of families' and parents' hands. Another member explained that multiple listing makes sense for some organs more than others when accounting for travel distance.

A member explained that while the desire to multiple list for a child is noble, it clearly expands disparities in access to transplantation and explained that this should not be an option for children more so than adults. A member stated that the Committee should separate personal opinions from moral and ethical decision making as a policy-making Committee and explained that reserving multiple listing for pediatric patients but disallowing it for adults is hard to morally justify. Another member expressed that disparities among children are the least tolerable and that elimination of disparities such as this should be a top priority. A member stated that one option may be advocating for requiring multiple evaluations (with the goal that a candidate would be listed at a center appropriate to their needs) instead of artificially leveling the playing field by disallowing multiple listing for everyone. The Chair stated that effort should be devoted to reducing disparity without taking away access to multiple listing, such as providing more resources to allow for multiple evaluations and utilizing telehealth. The Vice Chair stated that more education, policies, and elimination of barriers around multiple evaluation are needed as a companion to this proposal.

The Chair advocated for inclusion of more information about which patients benefit from multiple listing in the proposal and in educational materials for families to better inform decision making on who multiple listing should be reserved for. A member explained that rural patients may benefit.

10. Adjourn

Presentation Summary:

The Chair and Vice Chair thanked members for their attendance and participation and reminded them about the upcoming meeting on February 15th.

Upcoming Meeting

- February 15th, 2023

Attendance

- **Committee Members**
  - Abigail Martin
  - Neha Bansal
  - Danny Ranch
  - Emily Perito
  - Evelyn Hsu
  - Gonzalo Wallis
  - Jennifer Lau
  - Johanna Mishra
  - Meelie Debroy
  - Kara Ventura
  - Namrata Jain
  - Rachel Engen
  - Reem Raafat
  - Shellie Mason
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Simon Horslen
  - Jodi Smith
  - Katherine Audette
- **UNOS Staff**
  - Austin Chapple
  - Matt Cafarella
  - Kieran McMahon
  - Dzhuliyana Handarova
  - Krissy Laurie
  - Samantha Weiss
  - Susan Tlusty
- **Other Attendees**
  - Melissa McQueen