

**OPTN Organ Procurement Organization (OPO) Committee
Meeting Summary
September 8, 2021
Conference Call**

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PJ Geraghty, MBA, CPTC, Vice-Chair**

Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/08/2021 to discuss the following agenda items:

1. Welcome and Icebreaker
2. Continuous Distribution of Lungs
3. Continuous Distribution of Kidneys and Pancreata (Concept Paper)
4. OPTN Regional Review
5. Research Orientation
6. Ad Hoc Multi-Organ Committee Update
7. Technology Tools Workgroup Update
8. OPO Committee Future Projects

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

1. Welcome and Icebreaker

Committee leadership welcomed the Committee members, and the Committee participated in an icebreaker.

Summary of discussion:

The Committee had no comments or questions.

2. Continuous Distribution of Lungs

The Chair of the Lung Transplantation Committee presented the Establish Continuous Distribution of Lungs proposal, which is currently released for public comment.

Presentation summary:

Continuous Distribution of Lungs will move lung allocation from classification groups with hard boundaries to an allocation system that considers individual candidates holistically. This system will align lung allocation with community, ethical, and regulatory goals and medical advancements.

This proposal will replace classification-based allocation with a composite allocation score (CAS) for each candidate. The CAS is composed of the following attributes:

- Waiting list survival – expected 1 year waiting list survival (25%)
- Post-transplant survival – expected 5 year post-transplant survival (25%)
- Candidate biology (15%)
 - ABO – based on percentage of compatible donors by blood type (5%)

- Calculated panel reactive antibodies (CPRA) – based on percentage of compatible donors by cPRA (%5)
- Height – based on percentage of compatible donors by height (5%)
- Patient Access (25%)
 - Pediatric – candidates under 18 years old (20%)
 - Prior living donor – for candidates who donated any organ (5%)
- Placement efficiency (10%)
 - Travel efficiency – based on impact of distance on costs of travel (5%)
 - Proximity efficiency – based on impact of distance on other efficiency such as time, availability, etc. (5%)

The proposed allocation system incorporates community feedback on priorities, and is projected to result in more patients surviving a year on the waiting list, more patients surviving at least 2 years post-transplant, less variation in transplant rates between regions, higher pediatric candidate transplant rate, and less variation in access based on blood type and height. The median donor-recipient distance is currently at 195 nautical miles, and is expected to increase to 353 nautical miles under continuous distribution.

The lung exception system will also change to points-based exceptions for waiting list survival, post-transplant outcomes, candidate biology, patient access or efficiency. The prospective review timeline will be shortened from 7 days to 5 days. Candidates will be able to maintain exceptions indefinitely without extension once granted.

Multi-organ allocation: Heart-lung, lung-liver, and lung-kidney

- Heart-lung offered on heart list first to heart status 1 & 2 within 500 NM, then to the lung list to candidates with a CAS 28 or higher. Once those have been exhausted, the heart-alone may be allocated on the heart list.
- Lung-kidney and lung-liver allocation – OPOs will be required to offer the kidney or liver to Lung candidates CAS 28 or higher that require that second organ before the OPO can offer the kidney alone to the kidney list and liver alone to the liver list.

Summary of discussion:

One member shared that multi-organ allocation policy is confusing, with both OPOs and transplant centers struggling to understand the requirements in every situation. The Chair of the Lung Transplantation Committee confirmed that hearts would be offered to heart-lung candidates at statuses 1 and 2 on the heart list in the 500 nautical mile (NM) category, and then would be offered to heart-lung candidates on the lung list with a CAS of 28 or higher. The Chair of the Lung Transplantation Committee clarified that with liver and kidney as the second organ, the liver or kidney would be offered to any lung-kidney or lung-liver candidate with a CAS of 28 or higher before being offered as a single organ. The member asked if the lung-liver would be offered ahead of status 1 liver candidates, and the Lung Transplantation Committee Chair clarified that it would be, but that there were a very small number of lung-liver transplants performed annually. Another member remarked that there would likely be pushback from liver programs with not allowing status 1 or high model for end-stage liver disease (MELD) score potential recipients to receive offers ahead of lung-liver candidates. The member continued that this is particularly critical with only lung initially moving to a continuous distribution system, with liver still in geographic circle-based distribution. The Chair of the Lung Transplantation Committee noted that the multi-organ allocation policy for lung-liver was designed with the OPTN Liver Committee's input, and was supported by the Liver Committee.

A member asked about the difference between placement and travel efficiency, and remarked that a combined 10 percent weight didn't seem sufficient. The member asked what consideration was given to the infrastructure available to facilitate and transport broader sharing, as well as to the impact on getting donors to the operating room, total recovery time, and teams' ability to travel. The Chair of the Lung Transplantation Committee noted that broader sharing impacted different parts of the country differently across both OPOs and transplant centers, and pointed out that the OPTN does not collect data on travel and logistics. The Lung Committee Chair continued that splitting efficiency into travel efficiency, the number of miles between candidate and donor hospitals, and placement efficiency allows allocation to capture all the ways allocation can be inefficient. Efficiency and travel will be monitored closely, and the Lung Committee has already begun discussions on how to capture that data in a more objective way. Another member expressed concern that monitoring transportation following a policy change instead of providing data on potential impacts to efficiency is insufficient. The member remarked that travel and transport systems are already stressed, and that it has become very difficult to get flights to procure livers or even have livers shipped. The member continued, asking why this data isn't currently being collected. The Chair of the Lung Transplantation Committee agreed, noting that it is difficult to develop that aspect of the proposal with so little data. The Lung Committee Chair shared that this particular feedback has been heard, and that the transportation system should be improved, not necessarily incorporated into allocation. The member commented that it is inadequate to create policy without sufficient data, and that it creates an unfair burden on OPOs and transplant centers when there isn't transportation available. Another member agreed, sharing that the charter service organizing organ transport had to call eighteen independent services to find an airplane. The member expressed concern that the current infrastructure may not be able to support further broader sharing.

A member asked if the policy language allowing the OPO to determine organ recovery time with transplant centers will remain in policy, and the Lung Committee Chair confirmed that will not change.

3. Continuous Distribution of Kidneys and Pancreata (Concept Paper)

The Chair of the Pancreas Transplantation Committee presented an Update on the Continuous Distribution of Kidneys and Pancreata, which is currently out for public comment as a concept paper.

Presentation summary:

The Continuous Distribution of Kidneys and Pancreata concept paper aims to introduce the kidney and pancreas transplantation communities to the project, update the community on progress to date, and seek community feedback to inform the new allocation framework.

Continuous distribution will replace the current classification-based allocation system with a points-based allocation system. Continuous distribution will rank waiting list candidates in a points-based framework based on various attributes, providing a more equitable approach to matching kidney and pancreas candidates and donors and removing hard boundaries that prevent candidates from being prioritized further on the match run.

The Kidney and Pancreas Continuous Distribution Workgroup has identified a number of attributes, and is currently working to convert attributes into points.

Kidney Attributes

- Medical Urgency
- Post-transplant survival – human leukocyte antigen (HLA) matching, estimated post-transplant survival score (EPTS), ischemic time
- Candidate biology – blood type,* cPRA*

- Patient access – prior living donors,* pediatrics*, simultaneous liver-kidney (SLK) safety net, waiting time*
- Placement efficiency – travel efficiency, proximity efficiency, dual vs. single, en-bloc

Pancreas Attributes

- Medical Urgency – Kidney-pancreas (KP) vs. Pancreas vs. Islets
- Post-transplant survival – HLA matching, ischemic time
- Candidate biology – blood type,* cPRA*
- Patient access – prior living donors,* pediatrics,* pancreas after kidney (PAK), waiting time*
- Placement efficiency – travel efficiency, proximity efficiency

*Also identified as a KP attribute

In order to convert attributes into points, the Workgroup will develop a rating scale and determine a weight for each attribute. The rating scales are derived from clinical and operational data and describes how much preference is provided to candidates within each attribute. The weights reflect the relative importance of each attribute toward the overall goal of allocation, and are derived from values-based decisions.

Summary of discussion:

One member recommended utilizing longer term outcomes than one-year post-transplant survival, particularly in terms of optimizing allocation for kidney and pancreas recipients.

A member remarked that there should be a way to factor in hard to place kidneys, such as a prioritization that takes into consideration the centers accepting and transplanting these organs so that utilization can be improved would be impactful. The member added this is not only helpful to recipients, but to donor families as well, particularly for very young pediatric donors. The Chair of the Pancreas Committee agreed.

One member shared that the recently implemented circles-based kidney allocation system has exponentially increased transactions with transplant centers and significantly stressed transportation systems. Transplant centers are increasingly using third party services to receive organ offers, leading to increased inefficiency. The member continued, noting that under broader sharing, there have been upwards of 6000 candidates in the 250 nautical mile (NM) circle on the match run. It is almost impossible to get through that many candidates in an equitable manner efficiently. The member concluded that OPOs need support from transplant centers to more efficiently allocate kidneys, and that DonorNet is inefficient. The Chair of the Pancreas Committee agreed that these were legitimate concerns, and remarked that community sentiment about inefficiencies in transportation and broader sharing would be reflected in the weighting of placement and transportation efficiency attributes. The Pancreas Committee Chair continued that there should be legitimate reasoning behind the weights of each attribute. The member expressed concern that transportation and placement inefficiencies have been ignored through broader sharing and continuous distribution conversations.

A member shared that their center has seen significantly reduced kidney offers since implementation of the circles-based distribution, and recommended adding some kind of recognition for veterans as an attribute. The member also noted that their military education is not appropriately considered in the demographic data collection for waitlist, and suggested including demographic questions for military service. The member explained that there should be some kind recognition for veterans with exposure to agent orange and other warfare chemicals, so there is some recognition of why these patients need transplant. The Chair of the Pancreas Committee thanked the member, and noted that the 3-month

post-implementation monitoring report showed very positive outcomes, with increased transplant and placement of kidneys.

One member commented that the hard boundaries aren't serving patient populations well, particularly the use of nautical miles and the 250NM then national placement boundary. The member continued that education would be critical for patients, and added that there are barriers to broader sharing in differences in practices between transplant centers and inefficient courier systems. The member provided cross-matching as one such example of differing transplant center practices creating inefficiencies. Some centers will do retroactive and virtual cross matching, while others ask for blood samples. As an OPO, only so many donor blood samples can be taken and shared. The member remarked that these kinds of practices should be considered when potential recipients are from so many different transplant centers. Another member agreed that the blood sample issue is an obstacle to efficiency, particularly with unpredictable couriers. The new policy could build something in that would set a limit on the number of blood samples OPOs would be required to send. The member agreed, that prioritizing virtual crossmatch could be impactful, particularly investing in the knowledge and research required for virtual crossmatching on the transplant program side.

A member shared that for efficient management of kidneys, pre-recovery focus in allocation is on equity and fairness, and following the match run. Transplant center behavior varies in terms of serious offer evaluation. Post-recovery, however, the member shared that after 5 or 6 transplant centers decline a kidney for all their candidates, the kidney can become difficult to place. The member continued that these allocation policies will increasingly push OPOs to expedite allocation post-recovery, simply because the volume of patients on the match run is too large. Particularly, transplant centers waiting until they're primary and taking the full hour to evaluate, and then declining, increases the cold ischemia time on marginal kidneys, reducing their chances of placement. Another member commented that the idea of building in a way to prioritize centers that accept marginal kidneys would be very helpful. The Chair of the Pancreas Committee agreed, noting that pancreas allocation has facilitated placement, which could be a similar model. The Pancreas Committee Chair also noted that most of the continuous distribution discussion has focused on pre-procurement, and that the feedback to acknowledge and discuss post-procurement is very helpful. One member recommended a dynamic match run that adapts and prioritizes as an organ approaches cross clamp time or as cold time increases, so that there is more weight towards efficiency at a critical point to avoid organ discard. The member also noted that pancreas allocation has become more like liver allocation in terms of transportation timeframes, and recommended thinking about proximity points differently with pancreas and kidney-pancreas versus kidney alone.

A member shared that circles-based geography presents its own inequities – the Pacific Northwest has a quarter of a circle and a sparse population, while Nashville has a complete circle in the middle of the country. The member continued that their centers have lost a large geographic area in the circles-based distribution, and that geography is not appropriately weighted. The member recommended that geography be considered as an area, rather than a line or a circle.

One member recommended that the need for more air transportation, from a systems perspective, needs to be considered in broader allocation of kidney and pancreas in order to avoid increased discards.

4. OPTN Regional Review

Staff presented an update on the OPTN Regional Review Project, currently out for public comment, and the Committee provided feedback.

Presentation summary:

The purpose of the regional review project is to re-evaluate regions, the governance structure associated with regions, and effectiveness of regions, considering the current and future needs of the nation's donation and transplant community.

A national consulting firm with no previous affiliation with transplant stakeholders, developed three potential models to replace the current administrative regions, incorporating OPTN member input:

- Communities of common interest – organize members into like-interested communities, maintaining policy debate and sentiment, and elect councilors to serve on the Board as community representatives
- Repurposed regions – resize and redraw geographic regions grouped by population size, number of transplant centers, geographic proximity, with policy debate and discussion moved from regions to national forums
- Hybrid cohorts – organize members into cohorts in a hybrid approach, including geographic proximity for procurement and transplant organizations and like-interests for other stakeholders, with a Policy Council built from cohort representatives to replace the Policy Oversight Committee

Summary of discussion:

One member remarked that regional meetings vary region to region, and that it would be nice to be able to maintain current regional relationships, and maximize relationships with new key partners (OPOs and transplant centers) in broader sharing, who are outside of the administrative region. Another member agreed, sharing that many OPOs have already begun to reach out to transplant centers that they have begun to share more organs with in broader sharing. The member added that a hybrid model built to optimize these allocation relationships in a more formal way would work best. One member agreed, noting that there has been a fundamental change in how procurement and allocation are organized, and redistributing those relationships within the broader sharing boundaries would be worthwhile.

5. Research Orientation

OPTN Research Staff presented an orientation to the research department and processes, as well as publicly available data.

Presentation summary:

One of the key roles of the OPTN is to collect and maintain data for all solid organ transplants in the United States (US), as well as to publish and report data in order to advance the field of transplantation. The United Network for Organ Sharing (UNOS) as the OPTN Contractor collects and maintains waiting list and transplant related data, augments that data with additional sources, and provides the data to the Scientific Registry of Transplant Recipients (SRTR) contractor. The SRTR Contractor augments that data with additional sources based on their own analytical conventions, and maintains the SRTR data.

The Research Department has a number of responsibilities, including committee support, data analytics, clinical data and registries, and data products. This provides advanced analytical support for members, community, and internal departments, as well as management for data sites. We work with data governance and information technology to provide support for examining accuracy and completeness of data. Data analytics delivers analytical support to organ-specific and clinical committees to enhance policymaking and to conduct scientific research to improve the knowledge of transplantation.

Research provides analysis to support policy change initiatives and for monitoring the change in post-implementation. When a committee is working on policy development, this generally includes the need

to review data in order to generate sufficient evidence that the policy action is required. Research support helps the committee develop a data request addressing a specific research hypothesis aligned with committee project, determines the type of analysis needed to address the question, and supplementing OPTN data. The committee data requests follow from discussion by the full committee, subcommittee, or workgroup.

Non-committee or independent data requests can be submitted through the OPTN website or in the service portal, where users can also obtain data tables and build custom reports. The data on the OPTN site is refreshed weekly. The service portal provides a multitude of tool kits, including organ offers reports, kidney waitlist managements tools, and the run report.

Research staff also performs several self-initiated research and data visualization products to further the science of transplantation. Examples of such projects include the equity in access report, which measures and monitors equity in access to deceased donor transplants for lung, liver, kidney, and heart. Research staff also collaborates with professionals in the transplant community, and presents at national and international transplant conferences.

Summary of discussion:

The Chair asked if these kinds of research orientations were ever given or available to OPO quality analysis personnel, similar to data and reports, as a training. Staff responded that research orientations are given to each OPTN committee annually, and that the information presented is publicly available on the OPTN site.

6. Ad Hoc Multi-Organ Committee Update

The Chair presented an update on the work and progress of the OPTN Ad Hoc Multi-Organ Committee, and the committee provided feedback.

Presentation summary:

The Ad Hoc Multi-Organ Committee has representation from many committees, including all organ-specific, operations and safety, OPO, patient affairs, minority affairs, ethics, pediatric, histocompatibility, transplant coordinators, and policy oversight.

Simplified sequencing shows when lung allocation is projected to move into continuous distribution, as well as project implementation dates for upcoming multi-organ projects, including heart-kidney and lung-kidney eligibility criteria and safety-net, prioritization between kidney multi- and single organ candidates, eligibility criteria and safety net for heart-lung, lung-liver, and liver heart, and match run prioritization for OPOs.

The eligibility criteria and safety net for heart-kidney and lung-kidney allocation project has a number of goals, including:

- Ensure clinical justification for allocating multiple organs to one candidate while protecting access for heart and lung recipients who do not regain kidney function
- Address concern about rising numbers of kidney multi-organ transplants (MOT)
- Align with Final Rule requirements to develop allocation policies “specific for each organ type or combination of organ types to be transplanted into a transplant candidate”
- Align with the Ethics white paper recommendations for MOT allocation

Most members of the Multi-Organ Committee supported keeping criteria consistent with liver-kidney, keeping the glomerular filtration rate (GFR) threshold at 25 mg/dl for sustained acute kidney injury diagnosis. That Workgroup also discussed not including “metabolic disease” as a diagnosis category in

lung-kidney and heart-kidney allocation. Safety net criteria will be kept consistent across all organ systems.

Summary of discussion:

One member asked if the OPTN Ad Hoc Multi-Organ Committee will develop any policy or guidance on which multi-organ combinations take priority over others, or if that will remain at OPO discretion. Staff responded that match run prioritization is one of the projects the Multi-Organ Committee plans to address, but that it will not be part of the project currently in development. However, the Multi-Organ Committee will discuss how to incorporate heart-kidney and lung-kidney eligibility criteria into the OPO Committee's updated multi-organ allocation policy, which was approved by the OPTN Board of Directors in June 2021. Another member asked for clarification on the timeline, specifically when match run prioritization would go to public comment. Staff noted that while it is currently planned for August 2023, it's a high priority for the Chair of the Multi-Organ Committee, and other things could influence the project timeline, including the progress of the continuous distribution projects. The member remarked that the OPO discretion in match run prioritization is confusing, and that thoughtful, defined operationalization policy will enhance the multi-organ eligibility criteria policies as well. The Chair agreed.

7. Technology Tools Workgroup Update

Staff provided an update on the work and progress of the Technology Tools Workgroup.

Presentation summary:

The Technology Tools Workgroup has two main charges:

- Provide subject matter expertise on current IT projects such as DonorNet Mobile, Image Sharing, Chat Capabilities, and In-App Notifications
- Identify additional projects that improve the efficient matching of donors and recipients

The Workgroup determined that updating the clinical data reported in DonorNet would better capture information used by transplant centers during donor and organ evaluation. The Workgroup will finalize the project form, compile resource estimates, and submit the project for review by the Policy Oversight Committee.

Summary of discussion:

The Committee had no questions or comments.

8. OPO Committee Future Projects

Staff presented a request for future project ideas from the Committee, to be submitted over the next few weeks.

Presentation summary:

When going to the Policy Oversight Committee (POC) for approval, a project idea must provide a problem statement and potential solution, address a target population, have plans for collaboration, name relevant stakeholders and potential controversy and barriers, lay out a timeline with anticipated milestones, align with strategic goals and provide rationale, and explain the impact of the potential solution on transplant programs, OPOs, histocompatibility labs, and the OPTN.

Staff will email the committee requesting potential ideas, including a problem and proposed solution.

Summary of discussion:

The Committee had no questions or comments.

Upcoming Meetings

- October 20, 2021 – Teleconference
- November 10, 2021 – Teleconference
- December 15, 2021 – Teleconference

Attendance

- **Committee Members**
 - Kurt Shutterly
 - PJ Geraghty
 - Bruce Nicely
 - Catherine Kling
 - Chad Ezzell
 - Chad Trahan
 - David Marshman
 - Debra Cooper
 - Diane Brockmeier
 - Erin Halpin
 - Jeffrey Trageser
 - Jennifer Murriett
 - Jill Grandas
 - John Stallbaum
 - Kevin Koomalsingh
 - Lawrence Suplee
 - Malay B Shah
 - Mary Zeker
 - Meg Rogers
 - Merry Smith
 - Samantha Endicott
 - Susan McClung
 - Valerie Chipman
- **HRSA Representatives**
 - Adriana Martinez
 - Jim Bowman
 - Vanessa Arriola
- **SRTR Representatives**
 - Jon Snyder
 - Katie Audette
 - Matthew Tabaka
- **UNOS Staff**
 - Robert Hunter
 - Darby Harris
 - Elizabeth Miller
 - Joann White
 - Kaitlin Swanner
 - Katrina Gauntt
 - Kayla Temple
 - Krissy Laurie
 - Kristine Althaus
 - Leah Slife
 - Matthew Prentice
 - Nicole Benjamin
 - Sara Moriarty

- Sara Rose Wells
- **Other Attendees**
 - Rachel Forbes
 - Erika Lease