OPTN Heart Transplantation Committee
Meeting Summary
March 29, 2023
Richmond, Virginia

Rocky Daly, MD, Chair
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Introduction

The OPTN Heart Transplantation Committee met in Richmond, Virginia on 03/29/2023 to discuss the following agenda items:

1. **Action item:** Review proposed policy changes associated with Modify *Heart Policy for Intended Incompatible (ABOi) Blood Type Offers to Pediatric Candidates* project and Committee vote to accept changes
2. Overview of the cross-organ approach recommended for addressing exception requests in Continuous Distribution
3. Presentation of findings from *4-Year Monitoring Report for 2018 Modifications to Adult Heart Allocation Policy* and member questions
4. **Committee work:** Continuous Distribution of Hearts: Finalize potential attributes not currently in Heart allocation policy for inclusion in Heart CD 1.0
5. Tour of the National Donor Memorial and Organ Center
6. **Committee work:** Overview of Rating Scales and Goal Weights and Member discussion / feedback related to completing Liver Committee's Values Prioritization Exercise (VPE)
7. OPTN Lung Committee: Continuous Distribution best practices and lessons learned
8. Policy Oversight Committee Update
9. Open discussion and closing remarks

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

1. Action item: Review proposed policy changes associated with Modify *Heart Policy for Intended Incompatible (ABOi) Blood Type Offers to Pediatric Candidates* project and Committee vote to accept changes

The Committee reviewed the policy proposal. The proposal's goal is to safely expand access to donor hearts, heart-lungs, and lungs for candidates who are less than 18 years old at the time of registration. Pediatric Committee members who served on the Workgroup that developed the policy proposal participated by phone. Heart Committee members reviewed the general themes from the public comment responses. Among the themes, there was some interest in the Committee considering elimination of the 30-day titer reporting requirement for waitlisted candidates who are two years old or older at the time of the match run. After discussing the proposed changes and the public comment themes, Committee members chose to approve the proposed policy without changes. They also chose not to create a new Workgroup to review the public themes in more detail. The proposed policy will be submitted to the OPTN Board of Directors for consideration in June 2023.

Summary of discussion:

The Committee Vice Chair led the discussion. The purpose of the proposal is to safely expand access to donor hearts, heart-lungs, and lungs for candidates who are less than 18 years old when registered on the waiting list. In addition, the Committee intends that the proposal will reduce the volume of unused donor hearts. The proposal is also intended to permit re-transplant candidates who previously received an ABOi donor heart to receive another one of the same blood type. Improving data collection and outcome reporting about the use of ABOi donor hearts and heart-lungs is another goal.

The proposed changes were well received by the Heart community during public comment. Sentiment received about the proposal was supportive to strongly supportive of the changes, both by OPTN region and by OPTN member type. The Committee considered the general themes from public comment. These included overall support for the proposal and support for transplant programs continuing to be responsible for determining whether ABOi is appropriate for their candidates. Additional considerations suggested by the community included: eliminating the requirement that isohemagglutinin titer cutoff be less than 1:16, increasing the age to "less than two year old" for classification as primary blood type group, and eliminating the 30-day titer reporting requirement for heart and heart-lung candidates to remain eligible to receive ABOi offers.

The Committee was reminded of the actions taken earlier this year by the OPTN Executive Committee. On March 16, 2023, the Executive Committee met, and based on the strength of public comment and with the Committee's support, approved changes permitting pediatric heart and heart-lung candidates who are registered prior to turning 18 years old, and who are listed as status 1A or status 1B to receive ABOi donor offers.[1] The modifications also changed the titer reporting requirements for ABOi heart and heart-lung recipients to require reporting for recipients who were registered prior to turning two years old.

Subsequent to the Executive Committee's actions, the Heart Committee moved forward with the remaining aspects of the original policy proposal for OPTN Board of Directors consideration. The remaining aspects include expanding eligibility to pediatric status 2 heart and heart-lung candidates, and expanding eligibility to lung candidates registered on the waiting list prior to turning 18 years old. As mentioned, several public comment submissions suggested eliminating the requirement that ABOi heart and heart-lung candidates who are at least one year old at the time of the match run must report isohemagglutinin titers to the OPTN every 30 days in order to remain eligible. Some commenters stated that requiring blood to be drawn every 30 days could pose a safety risk to very young candidates with lower blood volumes. Other public comment respondents said it could be difficult for older pediatric candidates to get to their transplant program that frequently to have blood drawn.

The Committee members discussed the options for moving forward. It was pointed out that the themes from public comment were not unexpected when the Workgroup was initially developing the policy. For example, opening access to pediatric status 2 candidates means that the eligibility process becomes a little more cumbersome because they are outpatients who now have to come in for blood testing every 30 days. It was mentioned that while testing is a safety protocol, candidates who are older than two years old who have not previously produced isohemagglutinin titers are unlikely to start producing them later. Therefore, it is reasonable to consider loosening the reporting requirement for certain older patients who are outpatients. It was pointed out that the Workgroup had been somewhat concerned that the policy changes they developed would be considered by the public as being too loose; however, it appears the public comments were suggesting that the policy should consider more openness. It was acknowledged that by expanding eligibility to pediatric status 2 candidates, they get access to additional

[1] Meeting summary for March 16, 2023 meeting, OPTN Executive Committee.

donor hearts, but the change also results in some awkwardness in policy because such candidates are typically outpatient.

It was also discussed that maintaining the 30-day reporting requirement is still in accord with the proposal's goal of increased access overall, while maintaining an existing patient safety guardrail. The Vice Chair stated there are still some concerns that the very youngest children, even if outpatient, may start producing isohemagglutinin titers. Therefore, the current policy is a good safety net against such circumstances. If a patient, the patient's caregivers, and the transplant program decide not to submit a blood sample, the candidate is not eligible for ABOi donor offers, but they are still eligible for ABO compatible donor organs.

The Chair stated that if changes are needed, then the policy must go back for public comment; whereas, if the Committee approves the policy as it is, then it can be moved forward towards implementation and be that much closer to increasing patient access to needed organs. In addition, if the policy is not approved now, the manual process for registering candidates that was implemented to accommodate the changes approved by the Executive Committee would remain in place. Approving the current proposal would allow for implementation of an automated process to register and monitor ABOi eligible candidates.

A member of the OPTN Pediatrics Transplantation Committee who also participated on the Workgroup that developed the initial policy proposal encouraged the Heart Committee members to approve the remaining aspects of policy as draft. The Pediatric Committee member added that the Committee should take the opportunity to develop a new policy modification that would address some of the general themes that came through public comment. The Pediatric Committee member brought up that HLA policy, which is similarly designed to protect patients safety, handles these circumstances a little differently, and could serve as an example. Another member of the Pediatric Committee said she concurred with all of the suggestions.

The Committee reviewed the version of draft language that would be submitted to the OPTN Board of Directors. The members considered two options related to the proposal. First, whether to approve the aspects of the policy proposal. A motion was made and seconded to approve the draft policy language. A voice vote was taken, and there was no opposition to the proposed policy language, nor did any members abstain from voting. The motion to approve the policy language was passed.

A second motion was made to form a workgroup tasked with initiating a policy project addressing the public comment suggestions. The members discussed the project process such, including POC approval, development of IT estimates, public comment, and ultimately OPTN Board of Directors approval. They also talked about how some of the public comment suggestions would result in a 'loosening' of existing criteria. And while less frequent testing might be appropriate for older candidates who previously have not produced isohemagglutinin titers, that may not be the case for young candidates. Less reporting could become a safety issue for young candidates if they start producing new isohemagglutinin titers later in life.

Alternative reporting approaches were discussed. For instance, the members talked about whether to establish a 30-day reporting requirement for pediatric status 1A and 1B candidates, and a longer reporting interval for other candidates. Extending the reporting interval for all pediatric heart and heart-lung candidates was also discussed. Several Committee members expressed their concern that it was too early in the process to remove the reporting requirements because they serve as guardrails and will allow others to see how the policy changes are being used. A Heart Committee member recommended allowing time for data collection and using future monitoring reports to assess how transplant programs use the changes before making additional policy modifications, because there are unknowns associated

with increasing access to ABOi donor hearts. The Committee decided to move forward with data collection that would allow them to review potential changes in the future.

The Committee voted to table formation of a new workgroup.

Next Steps:

The Committee will submit the policy proposal to the OPTN Board of Directors for consideration during the June 2023 meeting. A new project form will be created to potentially address the themes submitted through public comment.

2. Overview of the cross-organ approach recommended for addressing exception requests in Continuous Distribution

The Committee received a presentation about ways that adult and pediatric status exception requests may be reviewed in the future as part of a continuous distribution allocation framework.

Summary of discussion:

As part of a continuous distribution allocation framework, exception requests will not seek to assign a candidate to a particular status. In fact, the statuses in current Heart policy will not exist in Heart continuous distribution. Instead, transplant programs will submit exception requests to obtain a certain percentage of the points available for a particular attribute. It is expected that within Heart continuous distribution, there will still be instances where the prioritization available through a specific attribute does not match with an individual candidate's unique situation. An important question is what should the allocation framework allow exceptions be applied to? The decision was to apply exceptions at the attribute level. As part of continuous distribution, transplant programs will not request an exception because the candidate is most similar to a status 3 candidate, for example. Instead, transplant program staff will consider the amount of points a candidate is being assigned within an attribute. If the program staff believe that is not the correct amount given the candidate's circumstances, then an exception request can be submitted. The request will ask for the additional amount points needed to reflect what the program believes is the correct amount. New resources are being prepared to help the community (patients as well as programs) better understand how the exception process will work. Some of the resources can be found on the OPTN website. In addition, a new review board framework will be introduced with continuous distribution to manage the exception requests.

A member asked about how this change, and other changes related to continuous distribution, will be communicated to patients. For example, will it be easier, harder, or will there be no change for patients to understand their priority in terms of obtaining a transplant? The Committee members said that candidates may not know exactly where the stand on the list. However, tools are being developed to help members have a sense of where they are on the list.

Next steps:

The Committee agreed that some of the questions related to exceptions would be addressed in presentations scheduled for later in the meeting and decided to move forward.

3. Presentation of findings from 4-Year Monitoring Report for 2018 Modifications to Adult Heart Allocation Policy and member questions

UNOS Research staff presented the findings from the 4-Year Monitoring Report for the 2018 Modifications to Adult Heart Allocation policy. The presentation compared the outcomes between the previous allocation policy with the current heart allocation policy. The Committee found the results to be useful in considering how to develop the continuous distribution allocation framework.

Summary of discussion:

The reporting timeframes used in the monitoring report consisted of a pre-implementation period from October 18, 2014 through October 17, 2018 and a post-implementation period from October 18, 2018 through October 17, 2022. The Committee reviewed the findings related to Deaths Per 100 Active Patient Years Waiting by Medical Urgency and Era. The members agreed that the results appear to indicate that the 2018 policy modifications achieved the goal of better classifying candidates based on their medical urgency. The graphic on slide 43 demonstrates that as part of the six-tier classification system, candidates are better prioritized based on their medical urgency than they were under the three-tier system. Slide 44 reflected waitlist mortality by criteria within medication urgency status. Some considerations need to be given to small population sizes, but overall, the information on slide 44 can be used for future decision-making with continuous distribution. The transplant rates were similar to the waitlist mortality rates in the sense that higher statuses had better transplants rates than lower statuses. Considering three-year post-transplant survival rates by era, there were no significant differences between survival during the pre-implementation and post-implementation periods. There were no substantial differences when comparing the findings reported in the three-year monitoring report and the four-year monitoring report.

In summary, findings related to the policy modifications implemented in October 2018 included:

- Donor hearts are traveling greater distances to be transplanted
- Candidates experienced a reduced median waiting time spent waiting before a transplant
- Transplant rates increased
- There was no substantial impact on the number of waiting list registrations or heart utilization
- There was not significant change in three-year patient survival
- Adult status 2 represents the largest number of forms submitted to the Regional Review Boards for review

The Chair discussed the post-transplant outcome-related information in the monitoring report. As of now, post-transplant survival is not one of the attributes the Committee identified for inclusion in the initial version of Heart CD. When the previous policy modifications were developed and implemented, there were concerns that having the ECMO criterion in adult status 1 would lead to a lot of futile transplants among those who had been on ECMO. However, that did not occur. Transplant programs responded to the policy changes as necessary, and were able to maintain their transplant outcome metrics.

Another take-away involves the adult status 2 – IABP criterion. The post-implementation waitlist mortality rates for candidates listed using the IABP criterion are more similar to the overall adult status 3 waitlist mortality rates, than adult heart status 2. Additionally, the highest volume of exceptions requests are for assignment at status 2. The Committee intends to address some of the concerns through continuous distribution, and at the same time, recognizes a need to address the issues more rapidly. In fact, there is interest in starting a new project soon that would be very focused on ensuring

that IABP as a therapy is appropriately aligned with other criterion that have similar waitlist mortality rates.

A Committee member asked about the potential to analyze the information submitted in the clinical narratives of the adult status 2 exception requests? Knowing the reasons transplant programs are submitting such exceptions could help the Committee improve policy in the short-term, and in the long-term as part of continuous distribution. The narratives could make it easier for the Committee to identify exactly what the 'problem' is. Another member stated that there are challenges to reviewing the narratives, in part because the submission are in the form of free text. Before they could be reviewed, the narratives would have to be de-identified and/or redacted. Because the information is free text, classifying the reasons or factors being provided becomes difficult. The resources needed to perform such reviews are also high. For example, the Committee produced a guidance document to assist transplant programs with understanding the information and level of detail that should be included in the narrative of an exception request for adult heart status 2 assignment. As part of that project, a limited review of narratives was performed, and even that small effort required a lot of time and effort on the part of the reviewers. A Committee member involved with creating the guidance document said that it appears that the document has not had the desired impact because anecdotally, the information currently provided in the narratives does not follow what was recommended.

Another Committee member asked about how the COVID pandemic might have affected the information presented in the monitoring report? The member was interested to know how, if at all, transplant program behavior changed after the pandemic. The findings were what the community would likely expect, such as dramatic reductions in listings and increased mortality due to the impact of COVID. However, this report does not address that period specifically. It was pointed out that some of the previous monitoring reports did call out the COVID time periods.

Next steps:

The Committee members will use the findings in developing the continuous distribution allocation framework, and also as part of any short-term projects they may initiate.

4. Committee work: Continuous Distribution of Hearts: Finalize potential attributes not currently in Heart allocation policy for inclusion in Heart CD 1.0

The Committee reviewed the attributes they previously identified for inclusion in Heart CD that are not currently in Heart allocation policy. The additional attributes will be included as part of the initial version of Heart CD. Members were asked to confirm that they still want to include the new attributes in Heart CD.

Summary of discussion:

The Committee was reminded that as part of Heart CD, they have the opportunity to add new attributes that affect how donor hearts are allocated, and to do so in ways that provide some degree of fairness and equity. Members were shown the attributes in current policy and reminded that these would be included in Heart CD. They were also shown the new attributes that were considered, and provided an overview of each. The new attributes consisted of:

- Time on LVAD
- Re-transplant
- Congenital heart disease
- Restrictive and hypertrophic cardiomyopathy

- Sensitization
- Pediatric medical urgency

Members were also reminded that during previous Committee meeting they had voted to include the attributes.

The Time on LVAD attribute is intended to ensure patients with the durable devices have a realistic chance to receive a transplant. Currently, such patients are assigned to status 4 and tend to stay at status 4 because of the success of the devices. Unfortunately, such candidates' clinical conditions can deteriorate rapidly several years after receiving the device and the patients may become too sick for transplant. It also intended that the attribute will reassure transplant programs that they can implant LVADs with the expectation that the candidates have a realistic opportunity for a future transplant.

For sensitization, the concept is that the transplant program will list specific unacceptable antigens that will result in limiting the availability of donor hearts for which a candidate is eligible. As part of the sensitization attribute, the actual amount of sensitization that the candidate would get credit for would be based on the actual listed unacceptable antigens. This puts the onus on the program to determine how many or how few unacceptable antigens they want to list the candidate for, which in turn determines the number of donor organs the candidate will be eligible for. Based on the information, the candidate will get some level of priority for being sensitized. The Committee will need to determine how to capture it within a rating scale, and then what weight to apply to the attribute.

Candidates needing re-transplant are already addressed in current policy, but the Committee has discussed providing such candidates with a little higher priority. The main reason candidates need a re-transplant is due to cardiac allograft vasculopathy (CAV). As a result of their condition, it is hard for such candidates to be prioritized at one of the high priority statuses, even though they are at a very high risk of death in some circumstances. The priority would be based on the level of CAV, which is based on the definition associated with the ISHLT criteria.

For CHD and the cardiomyopathies, the attribute would essentially use the information in the existing guidelines and transition the criteria into policy. With this change, it won't be necessary to go through the exception process for such candidates.

The Committee also developed an attribute for taking the five criteria within existing pediatric heart status 1 and transitioning them to a medical urgency rating scale. The Committee received a presentation about what the scale might look like and how the five criteria might be aligned on the scale, relative to where the adult heart statuses are assigned to the scale.

A member also stated that it is also important for the Committee to explain why they chose not to include some attributes. The member said that explaining to the community why some attributes were considered, but not addressed is important information to share and it will help increase transparency around the Committee's work. Some of these potential attributes include socioeconomic disparity, population density, post-transplant survival, and equity in transplant outcomes.

It was in this light, that the Committee discussed two of the other potential attributes: post-transplant survival and equity in transplant outcomes. The two subjects were previously identified by the Committee for consideration along with the other potential attributes for the first version of Heart CD. At the time, the Committee identified several factors that led them to classify both topics for consideration as components within a future iteration of Heart CD. For instance, the lack of heart-specific data made the Committee members somewhat reluctant to move forward with developing either subject for inclusion as part of the initial continuous distribution allocation framework. The complexity associated with how to integrate them as in CD also contributed to the Committee

suggesting they be addressed in the future. At the same time, the members thought it important to discuss the topics as part of their review of the attributes that would be included to reaffirm to the Heart community that the Committee is aware of the importance of the topics and to document the reasons for not including them as part of the initial version of Heart CD.

It was highlighted that current heart allocation policy does not include a model for post-transplant survival. It is difficult to create such a model because of the roles devices play when it comes to transplant. It was pointed out that the Lung Committee was able to rely on the post-transplant outcome model that existed as part of the Lung Allocation Score when they created their CD allocation framework. It was also mentioned that the Liver policy did does not have a post-transplant survival model, and the Liver Committee was initially thinking they would not address outcomes as part of their initial CD effort. Subsequent to those discussions a post-transplant model for Liver has been published that the Committee will likely consider. Another reason the Heart Committee suggested addressing post-transplant survival as part of a future version of CD is that transplant programs are already held accountable for their outcomes through the performance metrics. Members were reminded that the monitoring report findings indicate that transplant programs already manage outcomes well. Moreover, rushing to include post-transplant survival in this version of CD could have unintended consequences, such that some candidates might experience reduced access if programs feel that their program-wide score is going to be based on post-transplant survival. Committee members suggested that the Committee could make a commitment to reviewing data that is considered associated with post-transplant survival on a regular timeframe. The Committee could also consider if the outcome information provided in the monitoring report is sufficient, or if more data elements should be collected. The Risk Stratification Data collected on the justification forms was intended to inform a Heart Allocation Score, and includes data fields associated with post-transplant survival.

Another member asked if the Committee is aware of any models that are currently being developed that could be considered for inclusion? A SRTR representative stated that it isn't that a model could not be fit for post-transplant survival. Rather, the question is whether the Heart Committee believes it has all of the data elements they would want to consider when developing a rating scale for post-transplant survival. There is data available that could be used to create a post-transplant model for heart, and that could be a data request the Committee makes of the SRTR, although such scale might not be available for this first version of CD.

A patient member on the Committee said that negatively impacting access is his biggest concern. He was worried about the unintended consequences on access if the Committee moved forward with introducing a post-transplant survival model.

The Visiting Board Member told the Committee that the OPTN Board of Directors has had a number of conversations about attributes like post-transplant survival, and outcomes generally. He said that among Board members who are transplant recipients or who are family members of donors and/or recipients, the consensus is that outcomes need to be addressed for all of the continuous distribution allocation frameworks being developed.

The Committee also discussed equity in transplant outcomes. There is some data available from the SRTR that shows differences in transplant rates based on race, and differences based on where people live in the country, on physical location. According to the SRTR database, women have a lower transplant rate when compared to men. However, it could be challenging to discern whether gender is the appropriate factor for consideration, or whether it might be something else, like size.

A member stated that some of the attributes that the Committee has focused on do address equity-related issues. For example, prioritizing sensitized candidates has the benefit of improving equity for

women candidates, because women are more sensitized, generally, than men are. Time on LVAD is another example. Some patient populations who receive a LVAD because of access to care issues, and then the candidates remain stuck with the device. The Committee made attempts through a number of the attributes to address equity.

Some equity issues are not going to be addressable right away in CD, like socioeconomic status, as other organ committees working on CD have found, the OPTN may need to weigh in to describe why a particular equity issues needs to included in CD. Addressing socioeconomic concerns in allocation will probably require data collection from members. It was explained that a few cycles ago, the Minority Affairs Committee submitted a public comment proposal to start collecting such data, and the transplant community was very much against the idea. Still, the Heart Committee can look for opportunities to create metrics that might address equity issues, and then those can be developed in the system even though a specific attribute for equity isn't included.

Next steps:

The Committee will consider all of the comments as they continue developing continuous distribution as an organ allocation framework.

5. Tour of the National Donor Memorial and Organ Center

Committee members toured the Memorial and observed the activities of the Organ Center.

6. Committee work: Overview of Rating Scales and Goal Weights and Member discussion / feedback related to completing Liver Committee's Values Prioritization Exercise (VPE)

Summary of discussion:

The Committee Chair began the discussion by showing the Committee a timeline on the development of the continuous distribution framework. The Chair highlighted the overall timeline starting in August 2022 and continuing through January 2027, including a projected target date of December 2025 for OPTN Board approval. The Chair reminded the Committee they are still early in the process. At this time, the Committee is at the point of developing priority rating scales for each attribute. A future Committee effort will involve weighting the attributes against each other.

The Chair briefly reviewed current heart policy to demonstrate how it is classification based. The Committee needs to determine how to incorporate the factors in current policy into the five attributes (medical urgency, post-transplant survival, candidate biology, patient access, and placement efficiency), along with the newly identified attributes into continuous distribution. Some of the current heart allocation practices fit into the five continuous distribution attributes easily, some do not, and some attributes will need to be created and defined specifically for heart. The Chair reminded the committee, that just for the time being, the Committee will not be considering post-transplant survival.

The next step will be developing a rating scale for each attribute, followed by determining the weight of each attribute against the others. This will be achieved through discussion, research, and value prioritization exercises similar to one recently released by the OPTN Liver and Intestines Committee. Once this is completed, the framework should fall into place.

The Chair explained there are different options for assigning scales to each attribute. The Chair showed how the OPTN Lung Transplantation Committee was able to achieve this and developed their own continuous distribution composite score. The rating scales can be binary yes or no, linear, or

exponential. The chair reviewed the tools for determining attribute priority and rating scales. These include values prioritization exercise (VPE), optimization analysis, and sensitivity tools.

As part of CD, a committee needs to decide what the goals are for the system. There are multiple goals within CD and some of them are in contention with each other. For example, broader distribution helps address geographic inequities but might exacerbate inefficiencies in the system. VPE is a way to gather information about the tradeoffs members of the community are willing to make with regard to values-laden decisions.

Staff took a moment to review VPE, previously referred to as analytical hierarch process (AHP). The exercise is structured in a pair-wise comparison survey asking respondent to rank attributes or goals against each other to determine the importance of each one. The exercise is values driven, and the results are not binding but are used to inform a committee when making decisions. Each committee developing a continuous distribution allocation framework will develop its own attributes and then those will be compared to each other, for example a medically urgent candidate versus an extremely difficult to match candidate. The comparisons can show how different groups or demographics value certain attributes more than others. This should provide a better understanding of what should be used for modeling when a committee reaches that point.

A Committee member commented they completed the Values Prioritization Exercises for both the Lung Committee and the Liver Committee and found the Liver VPE to be much more simplistic compared to the sophistication of the Lung VPE. Almost as if Liver did not want as many components to be involved. The member added that the practice itself is fantastic, and you start to analyze things differently to try to remove any biases you may have. The member encouraged everyone to do the exercise.

Another member commented they completed the Liver VPE and thought it was very brief and simplistic. The member continued they believe the Heart Committee has an opportunity to incorporate more comparisons and increase the value of the exercise. The member did point out that because it is so accessible patients should be able to complete it, and there are ways to get the exercise in front of patients and allow more of them to participate. The Chair pointed out that this is the point, to get input from a broad spectrum within the community.

Another member agreed that the Liver VPE seemed simplistic. They added that they continued to think about the exercise after completing it and questioning if their initial selections had been accurate versus what they would believe if it was their patient.

The Vice Chair explained they completed the Kidney and Pancreas VPE exercise and the Liver VPE, and felt the Kidney and Pancreas was far more in depth. They believe the Heart VPE will be much more similar to Kidney and Pancreas than to Liver.

A member stated they believe that communicating the availability of the exercise to the community is important. They don't believe changing the name helped in this regard, but reaching out to patient groups would be far more beneficial.

Another member stated that many patients don't like the term "continuous distribution" because it sounds like they are addressing a supply chain issue, suggesting the fewer the syllables the better.

Staff assured the committee they have experience in reaching out to the broader transplant community so that should not be an issue when the Committee releases their exercise. Staff stated that the liver exercise received more participation then all other organs combined, due to the staff reaching out to partner organizations to encourage participation. This included reaching out to transplant hospitals and OPOs asking them to reach out to their patient networks. Another staff member shared a few lessons

learned during the lung exercise that some patients did not feel qualified to participate, and so making the liver exercise easier helped increase patient participation.

A member suggested having two VPEs, one clearly labeled for patients or non-medical professionals and the other labeled for medical professionals. This might help patients feel more comfortable participating even if the exercises are the same. Staff pointed out that this might be a possibility because you do not need any expertise to determine your values; later in the process there will be exercises where you do need a certain level of expertise but not for VPE.

Staff explained that once the VPE is complete (generally after public comment ends), the results are provided to a group at the Massachusetts Institute of Technology (MIT) who perform a mathematical optimization. MIT performed the same analysis using the results of the Lung and Kidney and Pancreas VPE. MIT starts with the public simulators built by SRTR and then changes policy scenarios to determine the changes. While SRTR is still going to perform simulation modeling in the future, MIT can perform more policy scenarios faster. These can then be used to determine weights. The MIT group starts with what the Committee will want for the outcome and MIT will see what needs to be adopted to make those a reality. At the end, those results are reviewed by SRTR staff to ensure their accuracy. Based on their work with previous organs, it appears the MIT group's work is accurate. Allowing MIT to do this speeds up the process greatly instead of asking SRTR to do everything.

Next, staff explained the purpose of the sensitivity tool. The sensitivity tool allows transplant community members to simulate various scenarios by changing the weights, rating scales, and donor multipliers for each attribute. This helps to visualize the impact those changes could have on the overall match run. This is helpful when determining the weights and ratings in CD because at a certain point the numbers become too small to manipulate in modeling and the difference in scores is better understood in this type of simulation. The sensitivity tool can also show a simulated mock match run that would allow the user to change the scores by changing the weights of the attributes. This tool is already available for committee members to use for lung, kidney, and pancreas within the tableau site on the public continuous distribution website.[2]

Staff then reviewed the basics of building a rating scale. These include binary rating scales, where a candidate either gets all or none of the available points (such as pediatrics or prior living donor); also, linear, and non-linear, linear gradually decreases or increases whereas non-linear increases or decreases on a curve exponentially. Linear and non-linear scales are useful for attributes like travel efficiency and medical urgency. The Chair reminded the members that these are not the only options, scales can plateau or be in a bell curve, but the next step is for working groups to determine these scales for attributes. Also, some attributes will provide more points than others, each attribute will be on a scale of zero to 100 percent. As an example, the Chair used proximity efficiency, which factors in transportation and coordination costs, cold ischemic time, offer refusal, and non-utilization. The goal with this attribute is to account for inefficiencies generally associated with transporting organs, which will be weighted with medical urgency in some way. The Chair reminded the Committee they will need to have similar conversations for each attribute, and they will build off the work of other organs as much as possible. There will be some easier binary scales, but also rating scales that will be more complicated like medical urgency, waiting time and time on LVAD. For each rating scale there will need to be a document created outlining the description of the rating scale, the current policy, how other organ committees developed their rating scale, data that supports the rating scale, and the proposed rating scale. During meetings the proposed options and relevant data will be reviewed, and a consensus will

[2]https://public.tableau.com/app/profile/optn.committees

eventually be reached on the rating scale. Staff pointed out that initial decisions by the working groups are not final the committee will continue to work on details as heart CD framework gets developed.

Staff informed the committee that prior to making their final decisions there should be monitoring report data available from Lung CD to examine and compare.

A committee member asked if they, as a committee, would have to have the same weighted categories as the Lung Committee used since some of the Lung attributes are not the same for Heart. The Chair responded that the Committee does not have to use the same since Lung started with a Lung Allocation Score (LAS) they were able to build their CD framework in a different way.

Next steps:

Workgroups and subcommittees will begin considering rating scales in future meetings to be determined.

7. OPTN Lung Committee: Continuous Distribution best practices and lessons learned

The immediate past Chair of the OPTN Lung Committee joined the meeting to share their experience in developing CD.

Summary of discussion:

The past Lung Chair began by demonstrating how the former Lung Allocation Score (LAS) worked, and how that score was then able to be translated into a Composite Allocation Score for Lung CD. This was done by using existing LAS factors and fitting them into the CD attributes before assigning weights to the CD attributes. The Lung Committee did use this as an opportunity to examine post-transplant survival and expand that from one year out to five years. The Lung Committee also decided to incorporate pediatrics into patient access rather than having three separate categories as were used in previous policy, using a binary scale pediatric candidates so to provide some advantage to these candidates on a match run. The same was done for prior living donors. For placement efficiency, the Lung Committee based their decision on the modeling and determined that a scale of ten possible points was best for this attribute in CD.

The past Lung Chair spoke about using the SRTR modeling support for developing a rating scale. The Lung Committee was able to use the modeling provided to compare travel efficiency and ischemic time by distance, also waitlist and post-transplant survival for pediatric priority 1 and 2, and 1-year versus 5-year post-transplant survival model. In the first round of modeling the Lung Committee was able to look at the more extreme options for comparisons. In round two, they were able to refine the proposed weights. Round two also initially included insurance status as proxy for socioeconomic positions in an attempt to address some social determents of health. However, Lung Committee members decided to withhold on addressing these issues in their allocation process knowing the OPTN was looking at these factors throughout the transplant process.

The key metrics from round two of modeling showed a decrease in one year waitlist mortality between the LAS system and CD. The modeling also showed a slight decrease in death two years post-transplant, a slight decrease in the percent of organs expected to fly further than 75 nautical miles, and an increase in the median donor recipient distance. The past Lung Chair noted that in the LAS system any recipient within 250 nautical miles is considered to be equal distance which skews that number slightly, but the modeling also showed an increase in lungs allocated within 150 nautical miles under CD than LAS. Modeling also showed less variation in transplant rates between regions, higher pediatric candidate transplant rate, and less variation in access based on blood type and height.

The past Lung Chair shared some lessons learned during their experience with building a CD framework. First is to think big in terms of the goal of CD, but keep in mind that the initial version is not the final version. Consider easy fixes to allocation that can be incorporated now. Keep ideas of bigger fixes in front of mind, and how the work to fix big problems can start being addressed even if it cannot be solved right now. Request a variety of modeling scenarios, this will provide the most information when building the framework.

The past Lung Chair mentioned that in the process of building CD for Lung other proposals and guidance came up the committee chose to address after CD. The Lung Committee chose to revise lung review board guidelines, guidance, and policy for continuous distribution. They also needed to update multi-organ allocation for CD of lungs. More recent data suggested the original CAS threshold for multi-organ offers may have been too high. The Lung committee chose to change the threshold to a lower CAS to preserve access to lung multi-organ transplant in CD.

The Chair mentioned that the Committee had discussed whether to give points for willingness to accept DCD, but in doing so you exclude yourself on that listing criteria and you change your patient's access, and so it did not make sense to add that complexity to heart CD at this stage. The Chair then asked how the Lung Committee approached building scales for attributes, was any modeling data used, and were there any comparisons of linear versus exponential? The past Lung chair said the Lung Committee had some difficulty doing this because they only had a moderate sense of what the new composite allocation score and they were examining the factors independently. The past Lung Chair said they started that process by talking it through. Using CPRA as an example, the past Lung Chair explained the Lung Committee wanted to make sure highly sensitized candidates had more access and not less, and so an exponential rating scale made sense. Height was another example, the past Lung Chair explained the committee looked at whether or not the rating curve should be the same for all candidates regardless of their disease; they quickly realized that someone short in stature with a restrictive lung disease is harder to match than someone who is larger. Talking through the possibilities is very helpful, prior to modeling, and then using the modeling to make the determination. For CPRA, lung has not historically collected that data so the Lung Committee used kidney data and made the determination to have the exponential curve for the highly sensitized rather than the mildly sensitized, the lung committee used this to inform their modeling request.

8. Policy Oversight Committee Update

The Vice Chair presented an update from the Policy Oversight Committee.

Summary of discussion:

The Policy Oversight Committee (POC) is made up of all the vice chairs of OPTN committees. It is the responsibility of POC to review OPTN committee projects and proposals, assess the impact of implemented projects, and develop and support progress on policy priorities. The POC is also responsible for project approval, public comment approval, and post-implementation review. The POC reviews how new projects align with the strategic plan and policy priorities, while assessing the level of collaboration and effort required for the project, identify benefit score, and a quantifiable element to measure success known as key metrics. POC votes whether to recommend a policy move forward in the cycle. The POC Chair presents the committee vote and comments from their discussion to the Executive Committee, which votes whether to approve the new project.

POC has an initial review of proposals several months prior to public comment, and another review of the same proposal before public comment starts. The review focuses on whether the proposal is ready

for public comment and not whether there is agreement with the solution in the proposal. Proposals should show due diligence in developing solution and gathering evidence. POC votes to recommend to Executive Committee, which approves proposals for public comment.

The OPTN Board hands down policy priorities to the committees for POC to gauge proposals on. For 2021-2024 those priorities include continuous distribution, efficient matching, and multi-organ allocation.[3] These are used when POC reviews a project and factor into the benefit score.

POC is working on developing a Benefit Score to improve efficiency by standardizing review of new projects. This would support, and more consistently measure, a project's benefit. The benefit score was implemented in June 2022, and evaluation and refinement of the score is ongoing. Currently the score components are:

- Policy priority (yes/no) 30%
- Vulnerable populations (yes/no) 30%
- Measurable (yes/no) 17%
- Patient population size number (greater than 10,00/3,000-9,999/1-2,999/no impact) 11.5%
- Patient population size by percentage (greater than 50%/25-49%/1-25%/no impact) 11.5%

The Vice Chair noted that even if a proposal does not score well, it can still move forward in the cycle. The Benefit Score is currently being used in a pilot program. Measurability has become an important component, and it is critical for the Committee to have a measurability component to its proposals to show what success is post-implementation. The key metric in a proposal will be used to determine its measurability. Most proposals that have been reviewed using the Benefit Score are within the 50 to 70% range, some projects score lower which is not a bad thing. There is no low score-threshold for not moving a proposal forward, POC recognizes there are too many factors that go into a proposal to judge them on the Benefit Score alone.

Post-implementation monitoring has become more important. POC's goal is consistency and oversight in assessing the impact of implemented projects. POC formed a subcommittee on the subject in the fall of 2022. That subcommittee determined there is a need for more consistency that should include measurement of success based on a key metric (successful, maybe/undecided, concerns, no analysis performed), any unintended consequences, and any limitations. There will also be a post-implementation review of a policy by POC. The success assessment by POC is based on the key metric. If the key metric was to increase transplant rate for a subpopulation by 10% and the monitoring report shows an increased rate of 12% the project is deemed successful. The limitations of this include data that is not for research but to facilitate organ allocation, this may impact interpretation or there could be unintended consequences.

The Vice Chair shared the key takeaways should be to think through the benefit of new projects, who it impacts, how much, and policy priority alignment and measurability. It is very important to identify a key metric that is specific as possible and tied to the goal of the project. When reviewing post-implementation monitoring reports, measure success and identify any unintended consequences or limitations.

A member asked if the Benefit Scores are published, if so are they public or remain in the OPTN? The Vice Chair responded that are currently there is not an answer to that question since the Benefit Score is

[3] https://optn.transplant.hrsa.gov/media/4355/2021_2024_optn_strategic_plan_proposal.pdf

still in the trial period. The Benefit Score is not being used as a decision maker in the POC process at the moment, but that could change moving forward.

A member asked if there is a patient or donor representative on POC. Staff responded that POC is made up of vice chairs from all OPTN committees, this includes the OPTN Patient Affairs Committee Vice Chair, a kidney recipient, who serves as the patient representative for POC.

The Vice Chair was asked if POC sees a high volume of projects coming to them on a monthly basis. The Vice Chair responded that a fair amount of projects are reviewed monthly, and POC meets monthly and typically has at least two or three projects to review every time they meet. That adds up to several dozen projects a year, most of which are approved to move forward. The goal is for a committee to have data that supports a project, and most committees do a good job of screening projects before they come to POC.

9. Open discussion and closing remarks

The Chair began open discussion by reminding the Committee the next items they will need to address for continuous distribution are the rating scales for each attribute. The Chair noted that three of the attributes (proximity efficiency, medical urgency, and sensitization) are going to take more discussion than the others, suggesting that smaller groups approach these three attributes to work on separate from the full committee and then provide recommendations to the full committee. Proximity efficiency will need to discuss the rating scale shape that is most appropriate with all factors considered. The Chair mentioned that part of the medical urgency discussion will involve examining the current statuses, waitlist mortality data, and moving that into continuous distribution. Once the statuses are transferred to a continuous distribution framework then rearranging within and between the status can occur. Sensitization should be slightly easier to determine and might be a smaller portion of the composite allocations score, and may not need to be modeled at length.

A member asked the Chair if the expectation to have the groups meet before the next meeting or will they be assigned at the next meeting. The Chair responded that the hope is the small groups could meet prior to the next meeting to determine what data they might need in order to make informed decisions.

Another member asked staff if a ranking pool could be sent out to the Committee so members could select their top three small groups, and then staff could make those small group the assignments based on those choices.

The Chair hypothesized that the other attributes would be fairly straightforward. For example, ABO would require data on transplant rates for the different blood groups and assign points based on the data and the disadvantaged groups.

Staff stated they would gather resources regarding the development of scales for similar attributes from the organ groups that have completed this process. Staff reminded the Committee there is always potential for unintended topics that could arise during discussion that might need to be address. Additionally, if needed, more meetings can be added to the calendar to address data request needs.

A member asked if all this work will be happening as the public comment concept paper is being drafted. Staff confirmed. Another staff member shared that the other organ groups have issued a CD update following the initial concept paper that highlights the work that has been done for CD, this is to keep the community informed on the work that has happened and what the committee hopes to accomplish in the immediate and intermediate future.

A member asked about the anticipated turnaround time for data analyses. Staff responded that it is based on the complexity of the data request.

The Chair stated that medical urgency is going to be a big topic to undertake. Other organ groups already had some kind of framework to operate off of, like the lung allocation score, but heart having discreet statuses that have to be moved into the framework could become complicated. This might require more modeling and justification.

A member asked what the next milestones are for CD. Staff responded that scheduling the group meetings and their report out to the full committee, plus the concept paper are the next milestones to hit. After that it would be gathering the feedback from public comment and making potential changes to the rating scales. Additionally, the plan is to approach the rating scales by starting with the binary attributes so members get an understanding of how those conversations work before moving on to the more complex attributes. The Chair pointed out that the small groups do not have to solve everything regarding their attribute, it is ok to bring items to the full committee for discussion. Staff reminded the Committee that the small groups will need to create summary documents doe the committee to review. These should be detailed and address what data the committee needs to create the scale and what a proposed scale might look like.

The Chair thanked the Committee for their hard work and adjourned the meeting.

Upcoming Meeting(s)

- April 25, 2023
- May 16, 2023
- June 20, 2023

Attendance

- **Committee Members**
  - Rocky Daly, Chair
  - J.D. Menteer, Vice Chair
  - Shelley Hall, Immediate Past Chair
  - Tamas Alexy
  - Amrut Ambardekar
  - Jennifer Carapellucci (phone)
  - Hannah Copeland (phone)
  - Jen Cowger (phone)
  - Timothy Gong
  - Glen Kelley
  - Earl Lovell
  - Kelly Newlin
  - John Nigro (phone)
  - Jonah Odim
  - Adam Schneider (phone)
  - Fawwaz Shaw
  - Cristy Smith, (phone)
  - Martha Tankersley (phone)
  - Dmitry Yaranov
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - James Alcorn
  - Alex Carmack
  - Mariah Huber
  - Krissy Laurie
  - Kelsi Lindblad
  - Alina Martinez
  - Kieran McMahon (phone)
  - Eric Messick
  - Holly Sobczak
  - Laura Schmidt
  - Kaitlin Swanner (phone)
  - Kim Uccellini
  - Tamika Watkins
  - Sara Rose Wells
- **Other Attendees**
  - Neha Bansal, OPTN Pediatric Committee member
  - Brian Feingold, OPTN Pediatric Committee member
  - Robert Goodman, Visiting Board Member
  - Erika Lease

- Shellie Mason, OPTN Pediatric Committee member
- Daniel Yip, OPTN Board of Directors