

OPTN Heart Transplantation Committee

Meeting Summary

April 19, 2022

Chicago, IL

Shelley Hall, MD, Chair

Rocky Daly, MD, Vice Chair

Introduction

The Heart Transplantation Committee met in Chicago, Illinois on 04/19/2022 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Feedback Request: Member Experience with Normothermic Regional Perfusion (NRP)
3. Quarterly Review of RRB Activities
4. Update on Heart Committee Activities
5. Farewells to Departing Members
6. Discussion: Kidney and Pancreas Committees' Continuous Distribution
7. Overview: Considerations When Developing a Heart Continuous Distribution Allocation Framework
8. Discussion: OPO Tech Tools Project – Feedback Regarding Heart-related Donor Data Elements
9. Miscellaneous Topics of Discussion

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

1. Policy Oversight Committee Update

The Vice Chair shared an update from the OPTN Policy Oversight Committee (POC). The POC is comprised of all OPTN Committee Vice Chairs and is tasked with approving all Committee projects and guiding the portfolio of OPTN work. The POC prioritizes the OPTN strategic plan¹ and strategic policy priorities when allocating resources for Committee projects. Additionally, the Vice Chair discussed the POC's current efforts to define project benefit and develop a method to rate various attributes similar to all projects. The POC's objective is to create a more objective measure to evaluate potential impacts to help guide project prioritization. The Vice Chair said that the changes will result in the Heart Committee spending more time initially developing project proposals and addressing questions about the resources associate with different solutions.

Summary of discussion:

A member inquired where the resource limitation was. UNOS staff clarified that the limitations exist with finances and staffing. The goal is to increase funding to hire more IT staff to increase the speed for programming continuous distribution and other policies. As more continuous distribution frameworks are built out, the implementation become easier but the first iteration will require extensive IT resources. A member inquired if there were types of programming that are easier than others, such as

¹ Organ Procurement and Transplantation Network, "2021-2024 Strategic Plan," June 2021, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/2021-2024-optn-strategic-plan/>.

adding a data field. UNOS staff noted that adding a data field tends to be an easier task, but complexity is added when those data fields are linked to other forms or autofill into later iterations of the form.

A member inquired if there is a way to screen potential projects to determine if the resources needed are reasonable. UNOS staff responded that there is not a threshold for resources at this time, but that the Committee will dedicate more time to the first phase of the project to make the case for why this project ought to be prioritized against others. The Vice Chair noted that the POC could ask for clarification on a project or for the Committee to consider something not mentioned in their project form before moving forward with approval.

Members discussed ways to better understand community challenges in order to be proactive, as opposed to reactive, in their policy development. The Chair suggested regional representatives communicate directly with the program leads in their region. These communications could occur on a small scale, sharing a summary of the Heart Committee meetings, or on a larger scale of asking for feedback and policy issues that programs want to be remedied. The Chair emphasized the weight and value of the heart community's voice in pursuing a project for approval through the POC.

Next steps:

Members have asked for contact lists for the adult and pediatric heart programs in their regions. UNOS staff will follow up directly to members on this information.

2. Feedback Requested: Member Experience with Normothermic Regional Perfusion (NRP)

Members were asked to share their experience of NRP being performed at their transplant programs. Members were specifically asked to share how they have witnessed this process impact organ utilization and what monitoring and evaluation practices have been developed.

Summary of discussion:

A member shared their institution's experience, notably that they met with a local organ procurement organization (OPO) and regional transplant team in order to develop a protocol for NRP before approaching their internal ethics review team. This center worked closely with its transplant coordinators to educate them about the process in order to provide comprehensive informed consent to donor families. The member added that their institution has closely regulated NRP and maintained continuous discussions with their ethics team about the practice. Since NRP was occurring under a research protocol, the NRP hearts were transplanted into status 4 patients with Left Ventricular Assist Devices (LVAD) who are less likely to receive a transplant. It was highly urged for the OPTN to develop standardization of NRP practice but underscored that an ethical analysis is essential before progressing into standardization. UNOS staff responded that the OPTN Ethics Committee has begun undertaking an ethical analysis of NRP and will present this project to the POC in the coming months. Their goal is to develop a white paper for public comment in January 2023.

Another member added their institutional experience, emphasizing that their local OPO already has experience working with other institutions conducting NRP. This institution polled its cardiologists and surgeons to gain a better understanding of the cardiac team's willingness to accept and implement the practice. The cardiac team engaged in an open conversation about NRP and when they all felt comfortable the group presented the topic to their institution's Ethics Committee. The primary question from their internal Ethics Committee was regarding the process for informed consent and education for the donor families, noting the need for transparency at all stages in the process. Once the institution felt comfortable with proceeding with NRP, the largest challenge they faced was in staffing the NRP team, adding that not all surgeons may want to participate but the perfusionist was the most important role to fill. Once the on call team was developed, the group presented the proposed NRP protocol to their

institution for financial approval and found this method to be less expensive than the Organ Care System™ (OCS™).

Another member's experience started with presenting NRP to their ethics review board and discussing the topic until everyone felt comfortable. There were two cardiologists at this program who did not feel comfortable participating in NRP and the department honored those concerns by providing them a space to voice those opinions and ensuring that participation was voluntary. The department proceeded in working through the logistics of creating a travel team and laying the ground work of practice and protocol for them. The member emphasized continuing to have those ethics discussions and honoring the team members who may still be uncomfortable with NRP.

Members highlighted the importance of informed consent for recipients and an opt-in system for receiving a NRP donor heart. A member shared the role their center took to fully educate transplant coordinators about the NRP process and protocol, in order to thoroughly proceed with informed consent for the donor family. The member emphasized the importance for informed consent for donor families and expressed concern that OPOs may not be fully explaining the transplant process, which would be an issue of program transparency.

A member from an OPO that participates in NRP shared the feedback from their center, agreeing with the importance of consent. The member noted the challenge of informed consent for the donor family insofar as it could limit the donor's autonomy if the family is able to decide against proceeding with organ procurement. Regardless, the OPO decided that full transparency is the best practice.

A member inquired how other transplant teams, like abdominal, for example, react when they are informed that procurement is occurring through NRP. Members shared common experiences of consistently positive feedback from transplant professionals involved in procurement. They commented that the other organ transplant teams have been very supportive of NRP as it provides them with more time to proceed with procurement and preserves the quality of the organs.

Member discussed the variance in practices due to the lack of standardization, specifically the number of minutes that the transplant team must wait to proceed with procurement after death is declared. A member added that standardization will be essential to ensure equity across the country. A member inquired which types of patients are receiving the NRP organs. A member responded that their center provides NRP hearts to status 4 patients on LVADs who are less likely to receive a transplant from a deceased donor because they were perceived as more stable on the device.

A member inquired if NRP resulted in improved organ quality compared to OCS™. Those who responded were clear that their comments were anecdotal only, and not based on results from formal studies. One Committee member noted that NRP allows for procurement to occur without the blood removal that is part of the OCS™ process. Members responded that while the organs were of good quality, it was too early to tell if they were of better quality. The member added that their center's NRP heart recipients have had no primary graft disease (PGD) and experienced overall improved outcomes. The member emphasized that training for the full team was essential to ensure that protocol was followed appropriately and with respect to all involved.

A member noted that some of the challenges discussed exist for DCD as well since the same protocol is followed up to procurement. Members had noted the importance of having these discussions within the International Society for Heart and Lung Transplantation (ISHLT). The Vice-Chair added that the OPTN is not a regulatory body, but instead an allocation organization, so there will be limitations to the ability to address some of the challenges noted today.

Members noted that their experiences in NRP led to an increase in donor availability. However, without the OPTN collecting data on the centers performing NRP and their outcomes, the centers would have to rely on their own results and the published findings of other institutions. Members were in agreement that collecting data on NRP would be essential to better understanding the outcomes.

3. Quarterly Review of Regional Review Boards (RRB) Activities

Keighly Bradbrook, from UNOS Research, reviewed the data trends for RRB and what potential next steps the committee could take in response to these trends. The use of exception requests was highlighted, specifically for Status 2.

Summary of discussion:

A member inquired about overall approval rates, which are currently 90-95% across all regions with little variation. A member opined that the current statuses have created issues in the allocation system where patients must be listed as status 1 or 2 in order to receive a transplant. A member identified LVADs as a barrier to transplant because they allow the patient to be more stable and less medically urgent. The member suggested removing exceptions for status 2 and requiring patients to meet the requirements as they are outlined in policy.

The Vice-Chair countered that center practice will not change until RRBs begin to deny appeals and that will require national consistency. The Heart Committee can make adjustments to the RRB process during the development of continuous distribution, but it is unlikely that they will be able to make any changes until then.

The Chair reminded the Committee that the adult heart policies were modified in 2018, but as the policies changed so did center behavior. The Committee is now faced with either accepting how the statuses have impacted appeals and review boards, or find a remedy without policy changes. The Committee has issued guidance on this issue in the past and is in the process of developing an educational email for heart programs, but ultimately center behavior needs to change. Members also noted that the high volume of exceptions may be unmanageable, and RRBs may just be 'rubber-stamping' the results.

A member inquired if there was a way to determine what criteria was being missed on the exception form. The Chair noted that the majority of analysis occurs from the narratives and the process to deidentify and analyze that information is grueling. A previous qualitative analysis was conducted and found 'not a Ventricular Assist Device (VAD) patient' and 'patient does not want VAD' to be two recurring themes. A member inquired about the possibility to include more specific data points, as opposed to open text boxes, to provide a more quantified understanding of the exceptions. That process would require public comment and IT programming, which is not currently an option that the Committee is looking at. Alternatively, there may be some options for text mining and reviewing natural language patterns to identify existing themes.

A member inquired about the potential to provide an explicit format for status exceptions that would result in an automatic denial if it is not followed. The Committee developed a guidance document informing programs on how they ought to submit exceptions, but without a policy requirement that could not be fully adopted. The Chair added that the Heart Committee is not supposed to dictate practices to the RRBs.

Members highlighted the issue of prospectively increasing the patient's status while the exception request is under review. Members expressed the desire to manually hold their patient at the initial status until the exception was approved, but that is not an option. Members supported changing this to not allow a patient's status to change until the exception was approved. This decision was made out of

concern to not harm the patient while their exception was pending. A member suggested that this practice may harm other patients, though. A member suggested this practice for the status 2 exception requests to start out.

Members inquired about submitting programs where transplants are occurring at a denied status to the Membership and Professional Standards Committee (MPSC). The Chair informed the Committee that route was pursued, but the MPSC responded that policy does not identify any actions to be taken in such cases. UNOS staff added that the MPSC's concern was whether a patient was harmed and if there were centers who were consistently transplanting patients at denied statuses. A member suggested having the transplant centers that transplanted at a denied status be required to present to the Heart Committee why they transplanted the patient. A member noted that the Heart Committee reviews those cases. Another member pushed back that the center should not be punished for transplanting their patient when the system automatically upgrades them.

Members provided a range of suggestions for how review boards could be improved:

First, a member suggested going back to the former local exception request process. The member noted that the programs were able to discuss the case over a video chat to better understand the issue and integrity of the program. A member opined that the opportunity to discuss the case together allowed for reviewers to consider points they may not have thought of individually and suggested that a better outcome was ultimately found. The member favored more direct conversations over anonymous reviewers. It was also considered that the regions reviewing each other's cases are not close in proximity, so approving a center's request does not have direct implications on you, thus the local reviewers had more scrutiny when considering an exception request. A member inquired about a potential change in approval rates from local to regional review. UNOS research staff is going to look into including this information in the next monitoring report. A representative from SRTR reminded the group that the local system was not perfect and revised for a reason.

Second, members suggested requiring a super-majority of RRB votes to approve or deny as opposed to just a simple majority. A member considered that an individual review board member may have a 75-80% approval rate but when the group votes are combined the approval rate jumps to 90-95%. A member suggested that if a supermajority is not reached, there could be a subcommittee of three who would have to make the final decision to approve or deny. It was also suggested that a final decision could not be reached until every member voted, however, the Committee had previously decided against that to reduce wait times. UNOS staff noted that as the organ systems move to continuous distribution, there is a hope to develop some consistency for review boards. The other organs types have decided against pursuing a supermajority system.

Third, members suggested increasing feedback on why the reviewer approved the exception and providing reviewers with feedback on how they voted in comparison to their colleagues. Members suggested additional training to review board members. A member suggested that members of the Committee could mentor review board members and provide feedback on their cases. A member cautioned that providing information on how a reviewer voted in comparison to other RRB members could lead to changes in behavior by the review board members.

Fourth, a member noted that center behavior will not change until exceptions are denied. A member opined that centers accept others' exceptions because the center wants their own exception's approved. Transplant centers may be acting in their own self-interest by accepting others' exceptions in the hopes that their exceptions will continue to be accepted. It was urged that the Heart Committee ought to set the expectation for the RRBs.

Fifth, a member suggested reviewing donor acceptance practices to promote transparency. There was a concern that centers may be too selective in their donors and submitting exception requests to receive more preferred patients. A member emphasized that the onus should be on transplant programs to prove why their patient needs a status exception.

4. Update on Heart Committee Activities

The Vice Chair provided an update on the progress of the workgroup revising *OPTN Policy 6.6.B: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Hearts*. This policy revision is slated to go out for public comment in August 2022.

Summary of discussion:

A member added that expanding the age group is an important step to increasing access for pediatric patients. The workgroup is discussing where the titer cut off should be for older pediatric patients. The workgroup generally feels that until there is data on high titer transplants being safe and efficient, they should be prioritized fairly low. The goal of this policy proposal is to allow for safe transplants to medically urgent pediatric patients occur without disadvantaging other groups. The workgroup is also discussing how to consider patients who have received treatment to artificially lower their titer score. A member noted the importance of having the most accurate titer information as possible.

Next steps:

The workgroup will be finalizing the policy language in the next month or so. The full Committee will vote on the policy language before it goes to public comment.

5. Farewells to Departing Members

The Chair thanked the departing members, whose terms end on June 30, 2022, for their service and contributions to the Committee.

6. Discussion: Kidney and Pancreas Committees' Continuous Distribution

Joann White, the UNOS point of contact for the OPTN Pancreas Transplantation Committee, presented to the committee on the progress to date of developing Kidney-Pancreas continuous distribution frameworks. The purpose of this presentation was to provide an introduction to the Heart Committee on considerations necessary when developing the heart continuous distribution framework and share best practices and lessons learned.

Summary of discussion:

A member inquired about the implementation of multi-organ transplants (MOT) and whether all MOT patients will receive a set number of points to reflect their MOT status or if it will vary by organ combination. The presenter responded that the workgroup will be working closely with the Ad Hoc Multi-Organ Transplantation Committee to determine how to proceed. In reference to the development of continuous distribution, UNOS staff noted that each Committee has their core support staff working on the project as well as staff that have worked on all continuous distribution projects to promote consistency.

A member inquired if all organ systems will be transitioning to continuous distribution simultaneously or sequentially. Each organ committee has been tasked with developing continuous distribution in a sequential order. The Lung Committee was selected to go first because Lung policy already includes a Lung Allocation Score (LAS) which was easier to transition to a continuous model. A member noted that this was inefficient, but the Chair countered that it would allow for the Heart Committee to learn more from the other organs experiences. The Vice Chair noted that developing continuous distribution will

require a lot of process understanding and buy in from the community and going later in the process will allow trust to build. UNOS staff added that other OPTN committees, like Ethics, Minority Affairs, and Pediatrics, are included in the committee discussions. A member inquired about the OPTN wide shift to continuous distribution. UNOS staff clarified that the OPTN Board of Director's has identified moving to continuous distribution organ allocation system as a policy priority, emphasizing the elimination of hard geographic boundaries.

7. Overview: Considerations when Developing a Heart Continuous Distribution Framework

The Committee discussed various ideas and considerations that would be important as heart allocation policy transitions from the existing statuses to a continuous distribution framework. As part of continuous distribution, the Heart Committee will sponsor an Analytic Hierarchy Process (AHP) exercise for the community to participate in. This exercise will inform the attribute weights for modeling by the Scientific Registry of Transplant Recipients (SRTR).

Summary of discussion:

A member inquired if this would remove exceptions. The Chair responded that this is something the other organ systems will have to figure out first through their developments of continuous distribution. There will always be situations where the care team does not believe the patient's score accurately reflects his or her medical condition so there will need to be some method for obtaining extra points.

If the Committee chose to keep the heart statuses, they would become an attribute that receives a tiered weight. Alternatively, it was suggested that the Committee could eliminate statuses and use disease elements. A member noted the challenge of modeling all disease elements and quantifying how sick a patient is.

Members suggested a variety of potential attributes:

- Devices with points given by device
- Time on VAD and time on temporary devices
- Sensitization
- Blood type O
- Donor recipient matching
- Donor recipient matching by age
- Population density
- Comorbidities

A member suggested considering extreme height as an attribute. The Vice-Chair added that the Lung Committee included this in their continuous distribution framework, but it will be essential to first review the data and identify if those patients wait longer. A member noted that for situations like this the points do not need to be provided on a sliding scale; patients could be eligible to receive a set number of points if they are over or under a certain height.

A member inquired about polling the heart community regarding what attributes ought to be considered prior to the AHP exercise to ensure that the AHP exercise accounts for what the heart community has identified to be important. A member suggested using an educational email to communicate with the heart community about what they think the attributes should be. A member inquired about the possibility of receiving a list of the attributes that other organ committees considered to ensure that the Heart Committee does not forget any potential attribute.

Members discussed population density as an attribute and the possibility of providing points to patients in sparsely populated areas. The Vice-Chair referenced the discussion that occurred within the Lung

Transplantation Committee and emphasized how travel times vary geographically. UNOS staff informed the Committee that the Research department will assist them in developing a range of linear and nonlinear scales to show the ways in which the Committee can consider travel proximity.

As the conversation progressed, the Chair clarified that it will be unlikely for the Committee to be able to develop a Heart Allocation Score during the first iteration of continuous distribution. That inclusion will likely occur after continuous distribution has been implemented. A member noted that there is a disagreement between what the upper cap of age for transplant should be within the heart community. A member responded that centers have the autonomy to determine who they will list and policy should not dictate an age cut off. The Vice Chair referenced the ethical perspective of 'innings played' and providing younger people with the opportunity for access comparatively.

The Vice Chair informed the Committee that UNOS is developing offer filters for kidney transplant programs that allow programs to filter out characteristics of donors that they will not accept. Members expressed interest in having this technology available for heart transplant programs. A member suggested that this information could be helpful to better understand center practices, specifically the number of times a center was listed as primary on an organ offer but turned it down to wait for the perfect available heart. A member pushed back that this scenario was a clinical decision by the transplant team and ought not to be governed by policy.

A member suggested that the heart community should not be penalized for offer turn downs, as per the recent MPSC policy, until they have offer filters that will allow them to customize donor characteristics. A member suggested that as the heart waitlist becomes closer to reaching an equitable number of patients listed and transplanted each year, the OPTN ought to provide pathways for increased organ utilization. The Chair countered that balance could only be possible if centers continue to be extremely restrictive in their listing practices (ie not listing patients who are too sick to transplant or may die on the waitlist). The Vice-Chair added that the waitlist depends on the rules that are applied to it, noting that if wait time is a consideration for transplant then the number of listings would increase. The member urged that there should be more flexibility for programs to use more marginal hearts without penalty. The Chair acknowledged that this challenge is unlikely to be resolved with continuous distribution, but agreed that there ought to be a way to incentivize programs to use more marginal hearts. However, the Chair added that as more transplants are occurring, more patients will be listed for transplant.

8. Discussion: OPO Tech Tools Project – Feedback Regarding Heart-related Donor Data Elements

Robert Hunter, the UNOS staff point of contact for the Organ Procurement Organization (OPO) Committee, requested feedback on the donor data elements project.

Summary of discussion:

Members suggested including the tracing for hemodynamics and including the output and index for right heart catheters. Members suggested including how the outputs are measured to provide clarity for those reviewing information. Members noted that the proposed new data elements may not provide as much value as is intended. Some of the information may encourage or discourage centers to review the records, but emphasized that many centers will receive the ECHO regardless and in some cases repeat the tests when they receive the organ. Members expressed concern about how the measurements are conducted, whether done through an automatic system or through a medical professional reviewing it.

The group decided that the most helpful information would be the image from the ECHO, the hemodynamics tracing, the method for obtaining the data, and the scanned PDF of records. A member suggested against including end-diastolic measures due to concerns of inaccuracy.

9. Miscellaneous Topics of Discussion

The Committee used the last few minutes of the meeting to bring up any miscellaneous topics they wanted to share with the Committee.

Summary of discussion:

The Chair noted that issues have been raised on whether procurement will occur through NRP or using the Organ Care System™. Members noted that some organ procurement organizations (OPO) will not do NRP; a member added that some states are against the practice.

A member expressed concern about the issue with the Medtronic HVAD population, which the Committee discussed during their March meeting. A member added that consideration is needed regarding whether status 3 exemption requests need to be modified so that hospitalization is no longer a requirement. This modification is necessary to allow the patients that have received mechanical devices that are included in the recall from Medtronic to receive a higher status.

A member also expressed concern about the exclusion of heart status 4 and 5 patients from the Ad Hoc Multi-Organ Transplantation's (MOT) public comment proposal *Eligibility Criteria and Safety Net for Simultaneous Heart-Kidney and Lung-Kidney*. The Chair, who is also a member of the MOT Committee, informed the Committee that the prolific feedback from the thoracic community was consistent and well heart by the MOT Committee. The MOT Committee will be voting on the revised policy next week which will likely include the heart status 4 and 5 patients. A member inquired about outcomes for multi-organ transplants (MOT) on transplant center metrics. Currently, MOT-specific statistics are not included in center outcomes.

Upcoming Meetings

- May 17, 2022
- June 21, 2022

Attendance

- **Committee Members**
 - Adam Schneider
 - Amrut Abardekar
 - Arun Krishnamoorthy
 - Cindy Martin
 - Cristy Smith
 - David Baran
 - Fawwaz Shaw
 - Hannah Copeland
 - JD Menteer
 - Jennifer Carapellucci
 - Jose Garcia
 - Michael Kwan
 - Nader Moazami
 - Rocky Daly
 - Shelley Hall
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Grace Lyden
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Carson Yost
 - Eric Messick
 - James Alcorn
 - Janis Rosenberg
 - Joann White
 - Keighly Bradbrook
 - Kristin Cuff
 - Laura Schmitt
 - Robert Hunter
 - Sara Rose Wells
 - Susan Tlusty
 - Tamika Qualls
- **Other Attendees**
 - Kurt Shutterly
 - Martha Tankersley
 - PJ Geraghty
 - Timothy Gong