

OPTN Transplant Coordinators Committee

Meeting Summary

August 2, 2023

Detroit, Michigan

Stacy McKean, RN, BSN, MHA, CPTC, Chair
Christine Brenner, RN, BSN, CPTC, CCTC, Vice Chair

Introduction

The OPTN Transplant Coordinators Committee met in Detroit, MI and via Citrix GoToMeeting teleconference on 08/02/2023 to discuss the following agenda items:

1. Board of Directors Meeting Update
2. Ethical Analysis of Normothermic Regional Perfusion
3. Modify Organ Offer Acceptance Limits
4. Concepts for a Collaborative Approach to Living Donor Collection
5. Remove 99-100% CPRA Form
6. Open Discussion
7. Efficiency and Utilization in Kidney and Pancreas Distribution
8. Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results
9. Improve Deceased Donor Evaluation for Endemic Diseases Guidance Documents
10. Continuous Distribution of Liver Update
11. Continuous Distribution of Heart Update
12. Amend Adult Heart Status 2 Mechanical Device Requirements

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

1. Board of Directors Meeting Update

The Committee received an update on the OPTN Board of Directors meeting that took place on June 26, 2023. The update included the following:

- Approved default filters for adult kidney transplant programs, identified because of modeling analysis of the program's organ acceptance patterns.
- Approved measures that increase the security of the OPTN computer system and OPTN data by placing additional security requirements on OPTN members.
- Accepted additional policy updates to increase access to intended incompatible blood type organ offers for pediatric heart and heart-lung candidates.
- Endorsed measures to improve evaluation of deceased donors for potentially transmissible diseases endemic to certain areas of the world.
- Approved a set of new data and program requirements to improve efficiency of the OPTN Kidney Paired Donation Pilot Program.
- Endorsed policy changes to expand transplant candidate access to simultaneous liver-kidney allocation.
- Approved revisions to National Liver Review Board guidance to clarify consideration of exception status for

- candidates needing transplants of multiple abdominal organs.
- Endorsed the appointment of incoming OPTN committee chairs whose term begins July 1, 2023.
- Approved a fiscal year 2024 OPTN budget and registration fee, subject to fee review and approval by the U.S. Department of Health and Human Services (HHS).
- Declined, after discussion, to approve a proposed white paper addressing the ethics of transplant candidate listings at multiple hospitals.
- Aspects and goals of developing enhanced organ procurement organization (OPO) performance monitoring by the OPTN, including expected outcomes, the standardized processes that could support performance improvement, and the differences between the Centers for Medicare and Medicaid Services (CMS) and OPTN monitoring.
- Potential goals, objectives, and initiatives to include in the next iteration of the OPTN strategic plan.

2. Ethical Analysis of Normothermic Regional Perfusion

The Committee reviewed the OPTN Ethics Committee’s *Ethical Analysis of Normothermic Regional Perfusion* (NRP) white paper.

Summary of discussion:

Decision: The Committee supported the white paper, with an emphasis on consideration for donor families to be included.

The Chair informed the Committee that each transplant center handles NRP differently and thus there is no clear standard. A member whose center utilizes NRP says they have seen positive impacts from the incorporation of the practice. The member also urged the OPTN Ethics Committee to keep science at the forefront of the recommendations being made, as this is a controversial topic. When looking at what information should be disclosed to potential donors and next of kin regarding NRP, a member recommended providing as much information as the family wants to know to feel comfortable deciding, as this can negatively impact donors’ perceptions of donation. They recommended setting a minimal guideline for disclosing information, however organ procurement organization (OPO) staff is experienced with having difficult conversations, which may include NRP. The Chair emphasized what the previous member said, highlighting that providing too much information may overwhelm donor families, thus giving them a negative perception of donation, and therefore leading to families opting to not donate. They recommended having standard language about NRP, saying it would be helpful and then allowing room for donor and family questions. They also advised considering donor hospitals, as they often struggle more understanding the concept of NRP, especially amongst donor hospitals that are not familiar with NRP. Another member agreed, saying if the donor hospital is not engaged, it would be challenging going forward.

A member recommended also involving transplant programs when determining what information about NRP should be shared with donor families, because having such a partnership will promote providing accurate information to families. The Chair agreed, adding that OPOs should also be included to understand the transplant center’s NRP process so they are able to share the information with operating room staff and other important stakeholders. The Vice Chair cautioned that providing detailed information to donor families about NRP may deter them from donation, and recommended providing

high-level information will help families in making their decision. They advised that a nationwide standard to approach these conversations would be ideal.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Ethical Considerations of Normothermic Regional Perfusion* white paper on the OPTN public comment website.

3. Modify Organ Offer Acceptance Limits

The Committee reviewed the OPTN Organ Procurement Organization (OPO) Committee's *Modify Organ Offer Acceptance Limits*.

Summary of discussion:

Decision: The Committee supported the proposal.

The Chair asked if transplant programs are only allowed one organ offer acceptance, will the timeframe and parameters around holding the provisional yes on the other offers be strengthened? The OPTN OPO Committee Vice Chair said that the timeframes are established by policy and OPOs and transplant centers will have to work through that part of a process. They do not think that will impact how they work through the system. The Vice Chair said once operating room times are set, transplant centers should be required to decide on an offer and commit to it to ensure fairness to other transplant centers. A member suggested having an exception to encourage centers to take donation after circulatory death (DCD) organs, so they are not waiting for donation after brain death (DBD) cases. A member suggested that there be an exception pathway for DCD donors; however, they recognize that DCD donors make up a relatively small proportion of these donors. The member also recommended that during data review of this policy, the OPO Committee should be prepared to take emergent action if there are unintended consequences when it comes to DCD donors, specifically waitlist deaths. The member said overall the proposal helps address logistical issues with rapid organ placement and is asking transplant centers to remain accountable to their decisions.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Modify Organ Offer Acceptance Limits* proposal on the OPTN public comment website.

4. Concepts for a Collaborative Approach to Living Donor Collection

The Committee reviewed the OPTN Living Donor Committee's *Concept for a Collaborative Approach to Living Donor Collection* proposal.

Summary of discussion:

Decision: The Committee supported the proposal and provided points for the OPTN Living Donor Committee to consider.

A member said they support this effort and emphasized the need for long-term follow-up, especially for living donors who donated with preexisting comorbidities. They said that most health issues donors experience do not occur until after two years post-donation, when the donor is no longer being monitored by the transplant program. Some of these issues include increases in weight, high blood pressure, resuming smoking, and other factors that can increase other comorbidities. The member said they agree with the definition and terminology used in this proposal. They also said that being upfront

with what the Living Donor Collective is can be very important, as donors often receive lots of information and surveys that can be confusing and overwhelming. The member said that regarding moving the data collection upstream, their program has data interface software which allows them to enter information that can be transferred into the OPTN living donor registration (LDR) forms. Another member agreed that long-term follow-up is extremely important and can be useful in determining future donation criteria. The member then said having a universal resource where donors can assess their risk would be beneficial, as there currently is a variance in the information provided. They said that it is important to determine what the term “evaluation” means. The member asked how payment would work for donors who engage in life-long studies and testing and how engaging with donors long-term would work.

Another member supported the proposal as well as the importance of long-term follow up but is unsure how to get good engagement from potential donors who were turned down for donation. They also said it would be difficult for transplant hospitals to bear the costs of lifetime lab tests for living donors. Another member pointed out that although the Centers for Medicare and Medicaid Services (CMS) does not directly define the medical components for a living donor evaluation, the regulations generally define the phases of living donor care.¹ The member urged the OPTN Living Donor Committee to consider whether a patient traveled to the transplant hospital for testing, as this can be vital information. The member continued to say that there may be some unintended consequences in the relationship between the transplant centers and donors if data reporting is transitioned to SRTR and having a transition period would be extremely important. They also urged the OPTN Living Donor Committee to submit responses to staff for a request for information (RFI) for recipient selection and evaluation, which can be used in understanding the variation that occurs in each transplant center. A member echoed the importance of education as to why it’s important to engage in long-term follow-up to donors.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Concepts for a Collaborative Approach to Living Donor Collection* proposal to the OPTN public comment website.

5. Remove 99-100% CPRA Form

The Committee reviewed the OPTN Histocompatibility’s *Remove 99-100% CPRA Form* Proposal.

Summary of discussion:

Decision: The Committee supported the proposal.

The Vice Chair said they agree with the proposal and believes it will remove an unnecessary extra step. A member said they agree with the proposal and these forms cause unnecessary delays. Another member said they agree, and that this paperwork may delay a candidate’s opportunity for transplant, especially smaller centers with less resources and staff to complete the form in a timely manner

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Remove 99-100% CPRA Form* proposal to the OPTN public comment website.

¹ 42 CFR § 482.94

6. Open Discussion

The Committee brought up relevant issues in the transplant community.

Summary of discussion:

Members expressed concerns about information in the news and offered support to ensure accurate information is being displayed in the community. Members also highlighted some of the positive milestones that have been seen in the transplant community, such as advancements in technology and more transplants being performed.

A member recommended making information technology platforms more user friendly. Another member suggested creating a workgroup to give feedback about usability of technology platforms.

Next steps:

Members will continue to find ways to support the OPTN.

7. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

The Committee reviewed the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee's *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution* proposal.

Summary of discussion:

Decision: The Committee supported the proposal with suggestions.

A member recommended that the OPTN Kidney and Pancreas Transplantation Committees consider applying the kidney minimum acceptance criteria (KiMAC) automatically to all match runs and advised starting at 0% in comparison to 8%. The Chair voiced concern with having two separate lists regarding dual kidneys and advised that they use one list. This can be done like how split livers are allocated, where transplant centers can select if they prefer dual kidney offers. A member suggested creating donor criteria for when potential dual kidneys could be offered, as opposed to creating programming into the match run or the creation of another match run. They said this would eliminate the back and forth between donor hospitals and accepting transplant centers, as they would know immediately if the potential accepting center would take the kidney if it is offered as a dual. The Chair said that the goal of this should be to make the process of procurement overall more efficient and running multiple match runs will make that more difficult. The Vice Chair recommended that dual kidneys should be allocated first and be placed at the top of the match run.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution* proposal to the OPTN public comment website.

8. Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results

The Committee reviewed the OPTN Disease Transmission Advisory Committee's (DTAC) *Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results* proposal.

Summary of discussion:

Decision: The Committee supported this proposal.

A member said they would like to have a standardized algorithm to address donors who have at least one HIV positive test but are not thought to be infected, as this would allow for a uniform process as long as it was done in a timely fashion. The member said if time was a concern, then the organ could be reallocated to a candidate who is on the HIV Organ Policy Equity (HOPE) Act match run. The member suggested that the Final Rule stating “infected with HIV” and the OPTN policy that says “HIV positive” needs to be more consistent and clearer, as these are two different things. A member said that pediatric surgeons would be cautious to take an HIV-positive organ, but if there was an algorithm in place to get repeat testing done in a cost-effective and timely manner to prevent significant delays in going to the operating room, there would be no downsides in repeat testing. The Vice Chair said an algorithm is a great idea, as this would create a standardized process. The Chair said they have seen a handful of donors that come back with an unexpected HIV-positive test that they suspected was a false positive. They said an algorithm would be extremely helpful and consulting with an infectious disease transplant physician was incredibly helpful and should be included when developing an algorithm.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Clarification of OPO Requirements for Deceased Organ Donors with HIV Positive Test Results* proposal to the OPTN public comment website.

9. Improve Deceased Donor Evaluation for Endemic Diseases Guidance Documents Revisions

The Committee reviewed the OPTN Disease Transmission Advisory Committee’s (DTAC) *Improve Deceased Donor Evaluation for Endemic Disease Guidance Documents Revisions* proposal.

Summary of discussion:

Decision: The Committee supported the proposal with additional items for the OPTN Disease Transmission Advisory Committee to consider.

A member said that screening living donors and including information as specific as possible would be extremely valuable. The member said the maps included in the guidance document were helpful in providing education to patients, specifically to explain why they are being tested for certain diseases. The Chair recommended having a standardized approach for ancillary testing as well as guidance on what to test for.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Improved Deceased Donor Evaluation for Endemic Diseases Guidance Documents Revisions* proposal to the OPTN public comment website.

10. Continuous Distribution of Liver and Intestines

The Committee reviewed the OPTN Liver and Intestinal Transplantation Committee’s *Continuous Distribution of Liver and Intestines* proposal.

Summary of discussion:

Decision: The Committee provided feedback in support of the concept paper.

The Chair asked if there was any consideration on how machine perfusion will impact geographic equity, and if not, recommended it be considered in how it will affect the continuous distribution system. The Vice Chair of the OPTN Liver and Intestinal Transplantation Committee said that it has not been considered yet, as machine perfusion is so new, and it is difficult to understand what the future holds with this technology. Regarding post-transplant survival, a member said they strongly agreed with the Liver and Intestinal Transplantation's position, as there is no supported model to help predict this outcome, therefore they feel that they are on the right track. The member asked why liver and intestine transplants were prioritized over all multi-organ transplants. The Vice Chair of the Liver and Intestinal Organ Transplantation Committee said that there are not many liver and intestine candidates on the waitlist, but we must give them priority compared to liver alone candidates because they have limited options in organs they can receive. A member said that they also agree with the Liver and Intestinal Transplantation's position regarding post-transplant survival.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Continuous Distribution of Liver and Intestines* paper on the OPTN public comment website.

11. Continuous Distribution of Hearts

The Committee reviewed the OPTN Heart Transplantation Committee's *Continuous Distribution* proposal.

Summary of discussion:

Decision: The Committee supported this proposal with some concerns.

A member of the Committee said that they agreed with the updated diagnoses but want growth parameters to be added to the listing status. Another member of the Committee agreed with what the previous member said but mentioned that the proposal seemed to realign pediatric statuses to be more like the adult statuses. However, the member feels that pediatric durable ventricular assist devices (VADs) are at a much higher advantage than other pediatric VADs that are not dischargeable and is unsure if pediatric wait time for durable VAD is as relevant. The member also said that candidates who are non-dischargeable from the hospital should get some priority in the status. The member said the Committee should consider giving extra points to members who are transplanted as a pediatric patient but need to be re-transplanted as an adult.

A member said size matches are an important consideration when looking at donors at their center and was curious if that would be applied as an attribute. The Chair of the OPTN Heart Transplantation Committee said it will likely not be an attribute. A member asked how portable perfusion machines factor into geography. The Chair of the OPTN Heart Transplantation Committee said that it depends on how highly the distance attribute is weighted, which will determine the significance of travel and how perfusion machines can impact that.

The Vice Chair said they were surprised with the length of the continuous distribution project. A member said it was important to be as transparent as possible to the transplant community and the general public about the details of the continuous distribution project and why it has a longer timeline compared to other projects. A member said there is benefit in not being the first organ system to move to the continuous distribution model of allocation, as this allows the committee to learn from previous committees. A member voiced their concern with the timeline, specifically that there will be no changes to the pediatric statuses in the meantime. A member agreed, saying that pediatric candidates need changes sooner and not in four years.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Continuous Distribution of Hearts: Concept Paper* on the OPTN public comment website.

12. Amend Adult Heart Status 2 Mechanical Device Requirements

The Committee reviewed the OPTN Heart Transplantation Committee's *Amend Adult Heart Status 2 Mechanical Device Requirements* proposal.

Summary of discussion:

Decision: The Committee strongly supported this proposal.

The Vice Chair said that this proposal is encouraging and sufficiently addresses the issue. A member of the Committee said that this proposal is thoughtful and will address the issues seen in their transplant center, specifically for pediatric and adolescent candidates. A member commended the OPTN Heart Transplantation Committee, saying that this proposal was readable, especially for the patient population and applauded the patient education video that was paired with the proposal. The member said they hope that other OPTN Committees will do something like this to assist patients in understanding proposals. The member continued saying that data supports this change and the OPTN Heart Transplantation Committee is doing their due diligence to follow up on the implementation, specifically addressing intended and unintended consequences and making appropriate changes.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Amend Adult Heart Status 2 Mechanical Device Requirements* proposal on the OPTN public comment website.

Upcoming Meeting

- August 17, 2023 @ 2pm ET
- September 21, 2023 @ 2pm ET

Attendance

- **Committee Members**
 - Amy Olsen
 - Anne O'Boye
 - Ashley Cardenas
 - Ashley Hamby
 - Brandy Baldwin
 - Christine Brenner
 - Gertrude Okelezo
 - Heather Bastardi
 - Heather Miller-Webb
 - Karl Neumann
 - Kelsey McCauley
 - Kenny Laferriere
 - Rachel White
 - Robin Petersen-Webster
 - Stacy McKean
 - Stacy Sexton
- **HRSA Representatives**
 - Kala Rochelle
 - Shelley Grant
- **SRTR Staff**
 - Katherine Audette
- **UNOS Staff**
 - Cole Fox
 - Courtney Jett
 - Dave Roberts
 - Elena Liberatore
 - Eric Messick
 - Kayla Balfour
 - Kayla Temple
 - Kieran McMahan
 - Kevin Daub
 - Krissy Laurie
 - Laura Schmitt
 - Lauren Mauk
 - Lindsay Larkin
 - Meghan McDermott
 - Robert Hunter
 - Tamika Watkins
 - Taylor Livelli
- **Other Attendees**
 - Arpita Basu
 - Gerald Morris
 - Keren Ladin
 - Lara Danziger-Isakov
 - Lori Markham

- Rocky Daly
- Shimul Shah
- Stevan Gonzalez