OPTN Transplant Administrators Committee
Meeting Summary
October 12, 2022
Richmond, Virginia

Susan Zylicz, MHA, BSN, CCTC, Chair
Jason Huff, MSN, RN, FNKF, Vice-Chair

Introduction

The Transplant Coordinators Committee (the Committee) met in Richmond, Virginia on 10/12/2022 to discuss the following agenda items:

1. Welcome and Icebreaker
2. National Academics of Science, Engineering, and Medicine (NASEM) Report Overview
3. Potential project recommendations to align with NASEM Report
4. Patient & Donor Affairs Engagement
5. Introductory Normothermic Regional Perfusion (NRP) Discussion
6. Regulatory changes – Impact on Transplant Centers and Organ Procurement Organizations (OPOs)

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

1. Welcome and Icebreaker

Staff presented the agenda for the day and introduced the icebreaker. Committee members introduced themselves.

2. National Academics of Science, Engineering, and Medicine (NASEM) Report Overview

Staff gave an overview of the National Academies of Sciences, Engineering, and Medicine (NASEM) Report, stating, the NASEM Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution issued a report "Realizing the Promise of Equity in the Organ Transplantation System" in February 2022.[1] The OPTN Board of Directors responded to the NASEM report in April 2022, and the NASEM committee leadership presented the report's recommendations to the Board of Directors in June 2022.

The recommendations fell into the categories of improving equity, using more donated organs, and improving the system and system performance. Staff explained how the OPTN has worked to incorporate these recommendations

Improving equity:

- Kidney
  - Implemented policy requiring use of race-neutral eGFR calculations in July 2022
  - KDPI and EPTS mapping tables updated annually
- Liver
  - Approved changes to MELD to address sex-based disparity in June 2022

[1] https://www.ncbi.nlm.nih.gov/books/NBK578320/

    - MMaT updated quarterly
- Lung
    - Implemented updates to prediction models in 2021
- Heart
    - Updating adult status qualifications
- All organs: Ongoing Social Determinants of Health Special Study Projects
- Multi-organ: Approved changes to balance access between kidney-alone and multi-organ transplant (MOT) candidates in June 2022

Use more donated organs:

- Improve use of organs
    - Donation after cardiac death (DCD) Collaborative increased recovery and transplant of DCD organs
    - Ethical considerations of normothermic regional perfusion (NRP) in DCD
- Make it easier for transplant centers to say "yes" to organ offers
    - Kidney Offer Filters – national rollout Jan '22; concept paper on optimizing use out for public comment
    - Redefining Provisional Yes and the Approach to Organ Offer and Acceptance concept paper out for public comment
    - OPTN predictive analytics pilot project
    - Approved Standardize Kidney Biopsy Requirements and Reporting in June 2022
    - Enhancements to OPTN Donor Data Collection out for public comment
    - Deceased Donor HIV Positive Test Result Clarification - new project

Improve the system and system performance:

- Standardized metrics to track performance – new MPSC metrics approved
    - Pre-transplant mortality rate ratio
    - Offer acceptance rate ratio
    - 90-day graft survival hazard ratio
    - 1-year conditional graft survival hazard ratio
- Embed continuous quality improvement efforts in system
    - OPTN Individual Member Focused Improvement – IMFI
    - OPTN Collaborative Improvement Projects
- Improve the OPTN policy-making process
    - Pursuing resources from the National Quality Forum

Other recommendations

- Allocate kidneys based on time spent on dialysis
- Allocate kidneys based on survival benefit scores
- Evaluate the use of race as a weighting factor in clinical equations
- Incorporate Cystatin C testing into kidney disease evaluation

3. Potential project recommendations to align with NASEM Report

The Committee responded with their thoughts and potential project ideas based on the recommendations.

Summary of Discussion:

A member expressed concern about the impact that insurance companies and their quality metrics have on the work the transplant centers do to utilize more organs and increase equity. The member asked if something was being done to engage insurance companies during these discussions. They commented how some centers, particularly small kidney centers, are not able to do as much pre-transplant care for their patients, which in turn means they are not listed as a "center of excellence" which severely impacts their ability to receive payments from insurance companies. This member expressed concern that the whole system does not seem to work together, and they wondered if there were opportunities to address this. Members discussed how to hold the insurance companies accountable for the increased expenses that would improve access and equity, as they currently are attempting to cut rates. The members conversed about whether continuous distribution can be put on a faster timeline, though it was expressed that many OPTN committees working on those projects feel they are already working at a fast pace.

The Committee conversed about concerns of turning down offers on behalf of patients, and whether that process needs to be more transparent along with factors that go into turning down or accepting offers. Some members expressed their worry that physicians might have some level of medical autonomy taken away from them when they are tied to constantly referring to patients for organ acceptance. Members agree that getting more feedback from patients is crucial, however they expressed concern about including patients in the organ offer evaluation process. This could be overwhelming for both transplant programs and patients.

Members expressed a desire to have other OPTN Committees speak about projects that align with changes from the NASEM Report. They want to collaborate with the Committees and help work with them on either deciding policy language or work on implementation.

4. Patient & Donor Affairs Engagement

Staff presented on efforts for improving patient and donor affairs and how to develop representative engagement with the OPTN. She explained that increased patient and donor affairs representation has been implemented on OPTN policy making committees (two representatives on all OPTN committees). Enhanced patient and donor affairs onboarding is conducted by UNOS staff. There is added patient and donor affairs representation as a minimum requirement for regional nominating committees and increased focus on patient and donor affairs participation in regional meetings.

The OPTN Patient Affairs Committee participates in public comment every cycle. They are currently working on updating the OPTN required Patient Information Letter. They help with advocacy for patient-centric policies, accessible information, and opportunities for engagement. There is representation on cross-committee projects.

UNOS staff requested feedback from the Committee on:

- Suggestions for increasing patient and donor affairs engagement?
- Suggestions for additional ways to capture the patient and donor affairs perspective?
- From a transplant administrator's perspective, what area/process/issue would be recommended for the OPTN Patient Affairs Committee's expertise?
- What can the Committee gain from increased patient and donor affairs perspective?

<u>Summary of Discussion:</u>

Members discussed what efforts were being made at their own institutions to engage patients more, and gather more feedback beyond the regional representatives. However, they expressed concern on how to connect the regional representatives with a larger group of patients so that the sentiments expressed are more representative of the typical patient. A member spoke up about the importance of

getting that patient involvement beyond the regional meetings, and perhaps giving them the ability to provide feedback more regularly. Members also spoke about the variation of patients and the variation of communities, stating there is a larger amount of diversity of patients in the urban areas than rural areas and the question of how to gather all those voices is still a large one. One member brought up the concern that medical terminology often alienates patients and patient representatives on the committees, and meeting the patients where they are as well as providing guidance and education for the representatives is critical.

Members agree that there are many areas where improvements can be made. They discussed different opportunities at their own centers, such as developing volunteer groups, providing QR codes at clinics, or checking in on Facebook groups where patients can share their feedback and opinions.

5. Introductory Normothermic Regional Perfusion (NRP) Discussion

A member of the NRP workgroup presented on heart transplantation from donation after circulatory death (DCD) using normothermic regional perfusion. The presenter explained the process of DCD has not changed much in the last twenty years. There is a withdrawal of support, ideally 30 minutes or less of functional warm ischemic time, circulatory arrest and finally the declaration of death following an observation period of two to five minutes. There is a proposal of adding hearts to this donation after brain death (DBD) protocol.

The major development that allowed a resurgent interest in DCD heart transplant was the availability of the ex-vivo perfusion systems for hearts. Successful DCD heart transplant programs were established in Australia initially (July 2014) and the United Kingdom following that experience (2015).

The presenter gave an overview of NRP. NRP was used initially in Europe and sporadically in the US for abdominal transplantation. NRP is the cannulation of venous system for drainage and the arterial system for return of normal temperature oxygenated blood. NRP uses an extracorporeal membrane oxygenation (ECMO) machine to accomplish this (a pump-oxygenator). There is required cannulation of the femoral vessels in the leg and invariably the aorta must be occluded at the level of the diaphragm to prevent retrograde perfusion of the heart and the brain.

The presenter explained the procedure of NRP. He noted when applied for the heart it involves the opening of the chest through standard sternotomy, ligation of the three aortic arch vessels to prevent antegrade blood flow to the brain, aortic cannulation, cannulation of the right atrium, and placement on circulatory support. If accepted, cardiac re-arrest ensues under controlled condition cardioplegia. Procurement is done using standard techniques like DBD. Organ transport involves cold storage and ex-vivo perfusion machine perfusion.

The presenter proposed advantages of using NRP over machine perfusion. NRP involves the perfusion of all organs with oxygenated blood. It corrects all metabolic abnormalities on a pump (severe acidosis, electrolytes). It involves in situ evaluation of the heat under normal physiologic conditions. It is cheaper in cost and allows time for multi-organ retrieval without delaying the other transplant teams or creating potential conflicts during procurement. There is also the potential for improved preservation of all organs with longer ischemic times. He noted the assessment of the heart and internal protocols on withdrawing support must be extensive. He explained a mobile ECMO system is used by Vanderbilt to handle DCD procurement.

The presenter summarized that DCD heart donation is possible and has the potential to significantly increase the number of hearts available for transplantation. The NRP model offers the best methodology for preservation of all organs. Survival results to date have been excellent with worldwide experience.

The presenter highlighted some hurdles to NRP. He noted there are non-uniform policies for DCD despite more than twenty years of this practice. He explained that mobile ECMO has limited availability and high cost of staffing. He suggested the standardization and development of specific donor hospital centers in a co-operative model to allow for the best outcomes.

The presenter explained that there are ethical concerns regarding the Uniform Determination of Death Act that states "an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead." There is also ethical concern with the Death Donor Role that essentially states that retrieval of vital organs can not cause death. He asked if ligations of the arch vessels induce death.

Data Summary:

The growth of DCD organ donation has increased. Utilization of the DCD pool for transplantation could increase heart transplants by 20-30%. The Australian programs published data that DCD mortality rates compared to DBD donations showing the favorable outcomes of DCD transplantation.[2] The hemodynamics of a beating heart after NRP results in normal heart rates, electrocardiograms (EKGs), cryopreserved allograft veins (CPVs), etc.

A study that examined five-year outcomes of patients on NRP showed out of 128 DCD donors, 25 were procured using NRP and 75 with machine perfusions. The presenter explained the five-year survival with NRP was 100% and with normal machine perfusion survival rates went down to 98%.[3] He stated that 19 NRP transplants have been done at New York University Hospital and have published data on eight patients with 100% survival rates. Vanderbilt Hospital has published data on 15 patients that show 100% survival rates. This has allowed for increased use of the NRP technique by programs.

Summary of Discussion:

The Chair noted that her center has a conservative legal team that is not onboard with NRP. She noted they have the mobile ECMO already set up. She asked if the OPTN Ethics Committee is working on a white paper to persuade centers to practice NRP transplant. The presenter responded that many organizations will not take a position, like the OPTN. He predicts the white paper will discuss pros and cons without saying whether the OPTN endorses NRP. He explained that the NRP Workgroup is made up of those who are for NRP and some who are ethically against NRP. He noted that many do not understand what heart recipients face while waiting for an organ. He emphasized the need for transparency with donor families.

The Ex-officio asked what donor families are told when NRP is used. The presenter responded that he does not relay every step completed to do the NRP recovery. He stated providing every step can be anxiety provoking. His program met with his OPO representatives to explain the NRP process in detail to help them inform the families. He asked what OPOs relay to families and they explained they convey that they use a perfusion machine to restart circulation to allow the heart to beat again. He emphasized that the heart is an organ that evokes a lot of emotion and families are more willing to donate the heart.

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[2] Chew H, Iyer A, Connellan M, et al. Outcomes of Donation After Circulatory Death Heart Transplantation in Australia. *J Am Coll Cardiol.* 2019 Apr, 73 (12) 1447–1459.**https://doi.org/10.1016/j.jacc.2018.12.067**

[3] Messer S, Cernic S, Page A, Berman M, Kaul P, Colah S, Ali J, Pavlushkov E, Baxter J, Quigley R, Osman M, Nachum E, Parameshwar J, Abu-Omar Y, Dunning J, Goddard M, Bhagra S, Pettit S, Cheshire C, Lewis C, Kydd A, Ali A, Sudarshan C, Jenkins D, Tsui S, Hall R, Catarino P, Large SR. A 5-year single-center early experience of heart transplantation from donation after circulatory-determined death donors. J Heart Lung Transplant. 2020 Dec;39(12):1463-1475. doi: 10.1016/j.healun.2020.10.001. Epub 2020 Oct 3. PMID: 33248525.

The presenter explained that when families want to donate an organ, the family will do a lot to make that happen.

A member asked if in the United Kingdom data all those patients were co-located. The presenter stated there are three hospitals in the country who do this using the same type of device. One member asked if a clinical assessment can be conducted on brain death to address ethical concerns. The presenter explained there are an extensive number of evaluations to determine brain death, but in the operating room there is not enough time to do all these assessments. 15 minutes are allowed for the lack of perfusion, but that is not adequate time to determine brain stem death.

A member asked if it is possible to give pain control prior to organ recovery when NRP is used. The presenter noted this is the issue with the lack of standardization in protocols. He believes this is not the job of the NRP Workgroup. The Chair suggested the OPTN OPO Committee address this issue. The presenter emphasized the need for regulation and policy on how withdrawal of life support should be done. The Chair agreed. Staff explained that internal policy is required by OPOs on how to withdrawal life support.

A member asked if any of these cases have been done in pediatric hearts. The presenter responded that none have been done in pediatric hearts, but it can be done.

6. Regulatory changes – Impact on Transplant Centers and Organ Procurement Organizations (OPOs)

The president of the Association of Organ Procurement Organizations (AOPO) presented on the Centers for Medicare and Medicaid Services (CMS) Final Rule regulatory changes. He explained the purpose is to create new metrics to evaluate OPO performance using verifiable and independent data. This became effective in August 2022. He explained that CMS will review this during the 2026 Certification Cycle based on 2024 results only. New metrics will be enforced such as donation rate and transplantation rate. Performance tiers will be set in place. 2026 recertification will be determined by which tier each OPO falls into.

The presenter explained that OPOs are taking steps to achieve higher donation and transplant rates. They are expanding criteria for a potential donor. There is change of age criteria for brain dead and DCD donors to increase potential donors. OPOs are pursuing more medically complex donors. Discussions with families when withdraw of care is first mentioned is occurring to inform of donation possibility earlier in the process. OPOs are utilizing data and expediting placement to transplant more organs through:

- Utilization of data from the OPTN, SRTR, etc. on historic acceptance practices
- Expediting placement with transplant centers in which the OPO has a relationship

OPOs are looking to place pancreata for islet cell research and are developing relationships with transplant centers outside of the OPO's Donation Service Areas (DSA). OPOs are establishing Donor Care Units within OPOs or dedicated space in donor hospitals.

The presenter highlighted the impact to transplant centers/donor hospitals. OPO staff are on-site more frequently and are pursuing donation on an expanded population of patients. There is a greater number of DCD donors, which means:

- Physicians are needed for withdrawal/pronouncement of death
- Organs that are viewed as "less optimal" than organs from brain dead donors have an impact on acceptance rates
- DCD livers are being transplanted in patients with lower MELD/PELD scores

Transplant centers are inundated with organ offers and OPOs are calling for expedited placement and this can impact acceptance practices.

Transplant centers are expanding relationships with OPOs, which may do things differently than the local OPO. There are higher costs of transplant because of transportation, staff, import fees, etc. These changes have resulted in staffing challenges.

The presenter recommended navigating the CMS Final Rule through collaboration, communication, incorporating the recommendations of the NASEM report, and focusing on the mission of donation and transplantation.

Summary of Discussion:

A member asked if any conversations have been had on if other OPOs take on additional territories. The presenter explained there is no guidance from CMS on how that will take place. Tier three OPOs will be decertified by 2026, but there is an appeal process for these OPOs. He explained there is no guidance on how to handle this.

Upcoming Meeting

- November 16, 2022, 4pm EST, teleconference

Attendance

- **Committee Members**
  - Susan Zylicz
  - Nancy Metzler
  - Denise Neal
  - Michelle James
  - Joshua Gossett
  - John Gutowski
  - Christopher Wood
  - Rachel Detwiler
  - Brian Roe (Virtual)
  - Erica Seasor (Virtual)
  - Kavita Devairakkam (Virtual)
  - Laura O'Melia (Virtual)
  - Melissa Roberts (Virtual)
  - Sara Geatrakas (Virtual)
  - Sarah Madgwick (Virtual)
  - Stephanie Johnson (Virtual)
- **HRSA Representatives**
  - Megan Hayden (Virtual)
  - Shiree Southerland (Virtual)
  - Vanessa Arriola (Virtual)
- **UNOS Staff**
  - Taylor Livelli
  - Robert Hunter
  - Angel Carroll
  - Lauren Mauk
  - Susan Tlusty
  - Cole Fox (Virtual)
  - Kaitlin Swanner (Virtual)
  - James Alcorn (Virtual)
  - Kristina Hogan (Virtual)
  - Laura Schmitt (Virtual)
  - Tina Rhoades (Virtual)
- **Other Attendees**
  - Barry Massa (Virtual)
  - Nader Moazami (Virtual)