

OPTN Board of Directors

Meeting Summary

July 31st, 2023

Webex

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, President

Richard Formica, MD, Vice President

Introduction

The Board of Directors met via Webex on 07/31/2023 to discuss the following agenda items and public comment items:

1. Welcome & Announcements
2. Summer Public Comment 2023 Information
3. Require Reporting of Patient Safety Events
4. Modify Organ Offer Acceptance Limit
5. Ethical Considerations of Normothermic Regional Perfusion (NRP)
6. Summer 2023 Public Comment Items

The following is a summary of the Board of Directors discussions.

1. Welcome & Announcements

Dianne LaPointe Rudow, Board President, welcomed the Board to their first meeting of the year.

2. Summer Public Comment 2023 Information

The Board received a briefing on the future creation of the OPTN Task Force on Efficiency. Dr. LaPointe Rudow shared that the priority areas of focus for the Task Force are decreasing non-use, scalability and replication of member processes, and consistency in allocation practices. OPTN contractor staff presented information about the Summer 2023 public comment cycle and upcoming regional meetings.

Regional meeting dates and agendas were shared with the Board. All Board members are required to attend one regional meeting each public comment cycle to stay informed and engaged in the policy making process. Next steps for Board member engagement throughout the public comment process include a post-public comment Board meeting, Board policy group meetings, and finally the Board meeting in December 2023. Board members were encouraged to engage with the proposals outside of the formal meetings, and to contact staff, committee leadership, or other Board members with their questions and ideas.

The Summer 2023 Public Comment items were shared with the Board, along with each item's sponsoring committee.

Summary of discussion:

There were no questions or comments from the Board.

3. Require Reporting of Patient Safety Events

Scott Lindberg, Vice Chair of the Membership and Professional Standards Committee (MPSC), presented a proposal on behalf of committee to Require Reporting of Patient Safety Events. The purpose of the

proposal is to align OPTN member reporting requirements with the requirement for the OPTN to notify MPSC leadership and HRSA of certain patient safety events. The proposal would add specific patient safety reporting requirements to Policy 18 and would update the OPTN Improving Patient Safety Portal Safety Situation and Living Donor Event form instructions. In changing the form instructions, the MPSC aims to streamline the reporting process for members and create a single reference point when submitting a report. The rationale behind the project is that if these patient safety events are considered important enough for the purpose of notification to MPSC leadership and HRSA, then these events should specifically be required by OPTN Policy to be reported to the OPTN.

Dr. Lindberg presented the proposed safety events each member type should report, including requirements for transplant hospitals, recovery hospitals, and organ procurement organizations (OPOs).

Dr. Lindberg shared the key questions that the MPSC is asking the community to consider during public comment.

Summary of discussion:

A Board member asked if the project plans to collect only specific types of events that the MPSC has outlined or if the MPSC is working to gain insight on any event that may lead to organ non-use. Dr. Lindberg explained that there are additional projects the MPSC is looking to work on that explore all causes of non-utilization, and this project is the first of these projects. Dr. Lindberg noted that another area the MPSC is currently exploring focuses on allocations out of sequence because the committee is looking to explore how these two relate to one another.

A Board member asked how the MPSC plans to ensure that near misses are reported and how the MPSC plans to operationalize the proposal. Dr. Lindberg responded that there are many policies that rely on voluntary reporting by members. There are no punitive actions against members for near misses, so there is no reason members should not report near misses. A Board member asked if this is something site surveyors would investigate during site visits. Dr. Lindberg confirmed he would discuss with the MPSC to see whether this information is attainable during site surveys. A Board member commented that transportation events that lead to near misses should be clearly defined so members track these situations correctly.

4. Modify Organ Offer Acceptance Limit

Lori Markham, Vice Chair of the Organ Procurement Organization (OPO) Committee, presented to Modify Organ Offer Acceptance Limit on behalf of the committee. The purpose of the proposal is to eliminate the scenario where allocation efficiency is diminished when a transplant program holds two primary acceptances for one candidate. The proposal would modify OPTN Policy 5.6.C to only allow a transplant hospital to have one organ offer acceptance for each organ type for any one candidate. The rationale behind the proposal is that concurrent acceptances often lead to late turndowns. On average, concurrently accepted recovered livers are declined 1.5 hours before cross clamp, and lungs 5 hours before cross clamp when an organ is declined late in the process due to acceptance of another organ.

Ms. Markham explained that the other options the OPO Committee considered include reducing the offer acceptance limit from two to one, creating exceptions for higher status liver and lung candidates, creating exceptions for DCD donors, and creating timeframes prior to scheduled donor recovery.

Ms. Markham shared the key questions that the committee is asking the community to consider during public comment.

Summary of discussion:

A Board member asked when a transplant center can decline the organ acceptance that they have. The Board member asked if this policy would be effective if there is not a timeframe on the front end of the organ acceptance. Ms. Markham explained that the committee did not consider a particular timeframe but would like to determine what next steps may be when an event like this occurs.

A Board member commented that the Board should consider how OPOs may have been impacted by policy changes that allow transplant centers to accept multiple organs, and the change in broader geographic sharing of livers. Ms. Markham explained that the committee collected data and found that out of sequence allocation doubled when a transplant center declined an organ for the purpose of accepting another. Ms. Markham agreed that there is a need for more work in this area. Another Board member agreed that it is important to remember the impact non-utilized organs have on patients.

A Board member asked if the OPTN should track DCDs to ensure the OPTN is not analyzing exceptions in the future. Ms. Markham agreed that with changes in policy transplant centers will be accepting more DCD organs so is important to monitor moving forward. A Board member commented that this can be challenging for patients that are highly sensitized. Ms. Markham responded that she would share this feedback with the committee.

A Board member asked if OPOs have visibility on whether a transplant center has accepted more than one organ. Ms. Markham responded that OPOs can only see if a transplant center has accepted more than two offers. The Board member commented that OPOs should have visibility on whether a recipient has accepted another offer. They also commented that sensitized patients and acceptances should be included in the proposal. Markham emphasized the importance of transparency and communication between transplant centers and OPOs to best serve these patients. The Board member encouraged the OPO Committee to analyze current barriers in place and how to serve the community more efficiently.

5. Ethical Considerations of Normothermic Regional Perfusion (NRP)

Andrew Flescher, Chair of the Ethics Committee, presented the white paper proposal on the Ethical Considerations of Normothermic Regional Perfusion (NRP) from the Ethics Committee. The purpose of the white paper is for the committee to examine the ethical implications of NRP according to the ethical principles of nonmaleficence (do no harm), respect for persons (autonomy), and utility. These principles are established in the OPTN white paper “Ethical Principles in the Allocation of Human Organs” and states that abiding by these ethical principles supports trust in the organ donation and transplantation system and seeks to balance the ethical principles to which the Committee is bound.

Dr. Flescher presented on the Uniform Declaration of Death Act (UDDA), which states that 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. A determination of death must be made in accordance with accepted medical standards. The UDDA is not federal law, but it provides guidance and acts as a model for enacting state laws. The Committee’s analysis of NRP considers the UDDA as it is currently written.

NRP was presented as a unique approach to organ procurement because it involves the restoration of circulation regionally in the donor body before the organs are removed and after circulatory death is declared. Standard donation after circulatory death (DCD) does not entail blood circulation within the body after death is declared owing to cessation of circulation. With NRP, methods such as ligation of vessels are used to prevent circulation from reaching the brain, with the purpose of preventing cerebral blood flow.

When discussing the implications of nonmaleficence for NRP, the Ethics Committee found that it was unclear whether NRP violated the Dead Donor Rule. The Dead Donor Rule states that donors must be

dead at the time of organ procurement, meet criteria for brain or circulatory death, and that organ donation must not cause death. With NRP, circulation is restored after circulatory death has been declared, raising meaningful questions about whether the person continues to meet criteria required for a determination of death. The Ethics Committee concluded that more research is potentially needed to confirm there is no blood flow to the brain or brainstem during NRP. The paper states that specifically, more robust evidence could address potential collateral flow through the spinal cord. The committee wondered whether there is a possibility of potential harm if inadvertent cerebral blood flow occurs.

When discussing the implications of respect for persons in the context of NRP, respect for persons requires transparency and informed decision-making. The Ethics Committee acknowledged the balance between adequately informing donor families and the challenge of explaining components needed for informed decision making. The committee considered the possible promotion of respect for persons by honoring first-person authorization for donation as a way of maximizing the gift. The committee stressed the importance of upholding informed decision-making for donor families, given that perspectives on NRP vary compared to more established forms of transplant.

Implications of utility for NRP saw a great potential for increasing the number and quality of solid organs procured from DCD donors. The committee suggested there may be an increase in the average number of organs transplanted per donor with NRP and decreased rate of allograft failure post-transplant. The committee determined that more data are needed to compare NRP to other machine perfusion techniques. The Ethics Committee also determined that utility is a great benefit but must always be held in balance with other principles.

The Ethics Committee presented some conclusions and considerations for the community. The committee suggested that people may proceed with performing NRP, but to proceed cautiously. Dr. Flescher concluded that the ethical concerns that the community must consider and determine a resolution, include:

- Assurance that NRP adheres to the Dead Donor Rule
- Nonmaleficence must not be violated in the pursuit of NRP, even if positive utility outcomes could result,
- Standardized and transparent protocols are necessary pre-conditions for any ethical pursuit of NRP, and
- Uncontrolled scenarios for any form of NRP should not be performed at this time because of added concern regarding nonmaleficence and respect for persons.

The Board was reminded that white papers are developed to analyze a complex issue and they do not change policy or dictate practice. The charge of the Ethics Committee is to help guide the policies and practices of the OPTN to be consistent with ethical principles. The white paper is not a referendum on clinicians, centers, or OPOs that engage in NRP and does not preclude a future of ethically practicing NRP in the United States.

Dr. Flescher shared the key questions that the committee is asking the community to consider during public comment.

Summary of discussion:

A Board member commented that donor families are excellent at asking for the information that they need during the donation process and stated that they struggled with the notion of deciding what information donor families should or should not be given during the donation process. Dr. Flescher responded that the committee plans to take feedback received during public comment into great

consideration, especially in regard to the weight given to different principles and what information should be disclosed to donor families.

A Board member commented that intent to donate is something that is important to consider and asked if the OPTN plans to take a stance on this issue. The Board member expressed that the question of intent should be considered when discussing NRP. Dr. Flescher agreed to share this feedback with the committee, and explained that the intent of donation does not have a large effect on the analysis of do no harm, because of it being an independent analysis.

A Board member stated that it is important to present donor families with an appropriate level of information when they are deciding whether to donate, and thought it was important to weigh the options between the organs that could be procured without NRP and the organs that could be procured when utilizing NRP. Dr. Flescher encouraged the Board member to submit their insight as public comment as this is something the committee should consider.

A Board member asked about the Dead Donor Rule and how different interpretations may alter this understanding. Dr. Flescher responded that this is the most discussed portion of NRP and what some people have identified as the biggest issue when it comes to the ethical principles of NRP.

A Board member explained that in Europe recently, it has been claimed that there are physiological benefits to ligate the head vessels so they do not travel into other regions of the body. They asked if the committee considered this as the decision to ligate head vessels decreases the risk for cytokine release and negative impact on the heart (stress cardiomyopathy). They explained that ligation increases utility and this could be used for patients that have already been declared dead.

6. Summer 2023 Public Comment Items

Susan Tlusty, Policy Manager, presented the remaining items going out for summer 2023 public comment.

The proposal from the Heart Transplantation Committee to Amend Adult Heart Status 2 Mechanical Device Requirements proposes adding eligibility requirements to two adult status 2 criteria to better align with the medical urgency of the other status 2 criteria. Transplant programs will have to demonstrate failure of inotropic therapy prior to implanting intra-aortic balloon pumps or a percutaneous endovascular mechanical circulatory support device, and failure to wean from device while on inotropic therapy to extend status assignment.

A proposal from the Histocompatibility Committee to Update HLA Equivalency Tables 2023 would incorporate proposed policy revisions, including to incorporate higher resolution HLA typing into HLA matching more equitably, add more higher resolution typing options, and to update the HLA-DPB1 tables to be current with the international standard. The Histocompatibility Committee has another proposal out for public comment to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates. The policy proposes to remove requiring histocompatibility lab director and transplant program signatures when a kidney candidate has a 99-100% CPRA, as eliminating this documentation would decrease time for highly sensitized kidney candidates to gain allocation priority.

The proposal from the Operations and Safety Committee (OSC) on Deceased Donor Support Therapy Data Collection proposes to create a multi-option field within the OPTN Donor Data and Matching System on standardizing donor support therapy data collection of continuous renal replacement therapy (CRRT), dialysis, and extra-corporeal membrane oxygenation (ECMO). Data will provide granular information to complement ongoing offer filter efforts, to promote efficiency in organ offer review, and to allow for the evaluation of post-transplant outcomes.

The proposal from the Vascularized Composite Allograft (VCA) Transplantation Committee to Update Guidance on Optimizing VCA Recovery aims to increase VCA recovery and transplantation. The guidance seeks to inform the community of VCA graft recovery recommendations, provide guidance to OPOs and transplant programs pursuing VCA transplantation, and to increase VCA visibility in the transplant community.

The ad hoc Diseases Transmission Advisory Committee (DTAC) submitted a guidance document on Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations During Deceased and Living Donor Evaluation. The purpose of the document is to assist transplant programs and OPOs in screening deceased and living donors for endemic diseases. The guidance covers Histoplasmosis, Coccidioidomycosis, Strongyloidiasis, Chagas disease, Tuberculosis, and West Nile Virus. The document also provides guidance to the community on recipient management. The DTAC also submitted a concept paper on the Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with Positive HIV Test Results. The purpose of the concept paper is to gather relevant data and feedback regarding Human Immunodeficiency Virus (HIV) testing and results. The DTAC is considering creating an algorithm to guide situations where a donor may have a positive Human Immunodeficiency Virus (HIV) test but does not have HIV infection.

The Living Donor Committee submitted a concept paper on Concepts for a Collaborative Approach to Living Donor Data Collection that details the potential future state of living donor data collection. The concept is based on an OPTN and SRTR collaboration to obtain long-term living donor follow-up. This follow-up could include the OPTN collecting living donor candidate and donation decision data, having these data be shared with the SRTR Living Donor Collective, and establishing a foundation to perform national long-term follow-up with living donor candidates and living donors.

The Heart Transplantation Committee submitted a concept paper on the Continuous Distribution of Hearts, with the purpose of introducing the heart transplantation community to continuous distribution and to seek feedback regarding the development of allocation framework and attributes.

The Kidney Transplantation Committee and the Pancreas Transplantation Committee submitted a request for feedback on Efficiency and Utilization in Kidney and Pancreas Continuous Distribution. The request for feedback details operational components on Kidney and Pancreas Continuous Distribution. Operational components include screening and alternate allocation pathways for medically complex kidneys and pancreata. A few examples shared with the Board include released organs, national kidney offers, kidney minimum acceptance criteria screening tool, dual kidneys, en bloc kidneys, facilitated pancreas, mandatory kidney-pancreas offers, and pancreas medical urgency.

The Liver and Intestinal Organ Transplantation Committee submitted a request for feedback on an Update on the Continuous Distribution of Liver and Intestines. Updates include results from the Value Prioritization Exercise (VPE), an overview of mathematical optimization analysis and policy development next steps, information on ongoing committee deliberations related to post-transplant survival, medical urgency scoring (MELD/PED vs. OPOM) and geographic equity.

Each public comment item was classified into the respective strategic plan goals they address.

Maureen McBride, Executive Director of the OPTN, shared an update on the three-month monitoring report on the continuous distribution of lungs. Dr. McBride shared that the monitoring report showed an unexpected decrease in transplants for blood type O. This has led the Lung Transplantation Committee to further examine the situation and have found an issue in the modeling used to develop the policy. Updates will be provided to the Board as they become available.

Summary of discussion:

There were no questions or comments from the Board.

Upcoming Meetings

- September 22, 2023
- October 25, 2023
- November 29, 2023
- December 4, 2023

Attendance

- **Board Members**
 - Andrea Tietjen
 - Andrew Kao
 - Barry Massa
 - Bhargav Mistry
 - Christopher Jones
 - Colleen McCarthy
 - Dianne LaPointe Rudow
 - Emily Blumberg
 - Erika Demars
 - Evelyn Hsu
 - George Surratt
 - Ginny McBride
 - Jennifer Lau
 - Jim Sharrock
 - Julie Spear
 - Kelley Hitchman
 - Kenneth McCurry
 - Laura Butler
 - Laurel Avery
 - Lloyd Ratner
 - Luis Hidalgo
 - Manish Gandhi
 - Maryjane Farr
 - Meg Rogers
 - Melissa McQueen
 - Michael Kwan
 - Reginald Gohh
 - Richard Formica
 - Silas Norman
 - Stuart Sweet
 - Valinda Jones
 - Wendy Garrison
 - Willscott Naugler
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Daniel Thompson
 - Frank Holloman
 - Shannon Taitt
- **UNOS Staff**
 - Ann-Marie Leary
 - Anna Messmer
 - Cole Fox
 - David Klassen
 - Jacqui O'Keefe
 - James Alcorn

- Jason Livingston
- Julie Nolan
- Liz Robbins Callahan
- Maureen McBride
- Morgan Jupe
- Rebecca Brookman
- Robert Hunter
- Roger Brown
- Salt Aungier
- Susan Tlusty
- Tony Ponsiglione
- Tynisha Smith
- **Other Attendees**
 - Andrew Flescher
 - Lori Markham
 - Scott Lindberg