

## **OPTN Board of Directors**

### **Meeting Summary**

**January 23, 2024**

**Webex**

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

**Richard Formica, MD, Vice President**

### **Introduction**

The Board of Directors met via Webex on 01/23/2024 to discuss the following agenda items and public comment items:

1. Welcome & Announcements
2. Modify Effect of Acceptance Policy (Multi-Organ Transplantation Committee)
3. Refit Kidney Donor Profile Index without Race and Hepatitis C Virus (Minority Affairs Committee)
4. Standardize the Patient Safety Contact and Reduce Duplicate Reporting (Disease Transmission Advisory Committee)
5. OPTN Strategic Plan 2024-2027 (Executive Committee)
6. Winter 2024 Public Comment Items

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

#### **1. Welcome & Announcements**

Dianne LaPointe Rudow, OPTN President, welcomed the Board to the meeting. Contractor staff explained that Winter 2024 Public Comment is currently open and will close on March 19, and special public comment is currently open for Expedited Placement Variances until February 4. Contractor staff presented the schedule for Winter 2024 regional meetings, the draft agenda for the meetings, and shared expectations with Board members for regional meetings, including the expectation for OPTN Board Members to attend at least one regional meeting per policy cycle. Contractor staff shared the next steps Board members can anticipate during public comment and how Board members can engage in the process. Contractor staff presented the full list of items out for Winter 2024 Public Comment.

#### **2. Modify Effect of Acceptance Policy**

Lisa Stocks, Chair of the Multi-Organ Transplantation (MOT) Committee, presented the committee's proposal to Modify Effect of Acceptance Policy. Ms. Stocks shared that the purpose of the policy is to clarify that organ offer acceptance takes priority over requirements to offer more than one organ to a single candidate if the second organ has already been accepted by a transplant program. She shared that the proposal allows organ procurement organizations (OPOs) to move forward with placing single organs without holding back offers in case there is a late organ offer refusal of a previously accepted organ and multi-organ candidates are on the match run. Ms. Stocks noted that the proposed policy would clarify that OPOs are not expected to offer the kidney along with the heart to the next qualifying heart-kidney candidate since the kidneys have already been allocated with a primary acceptance.

Ms. Stocks explained that the rationale for the proposal is that due to the increase in multi-organ transplants, it is imperative that policies be developed to allow OPOs to efficiently place organs and that previous public comments on multi-organ policy proposals expressed concern that policies requiring multi-organ shares may conflict with policy on the binding nature of organ offer acceptance. Ms. Stocks

shared the implementation considerations and the key questions for the community to consider during public comment.

Summary of discussion:

Multiple Board members asked about potential scenarios they may experience and how this policy could impact their work. Ms. Stocks encouraged Board members to provide these scenarios as public comments for the MOT Committee and the entire community to consider during public comment.

**3. Refit Kidney Donor Profile Index without Race and Hepatitis C Virus**

Oscar Serrano, Vice Chair of the Minority Affairs Committee (MAC), presented the proposal to Refit Kidney Donor Profile Index without Race and Hepatitis C Virus. Dr. Serrano shared that the purpose of the proposal is to remove race and Hepatitis C Virus (HCV) from the Kidney Donor Profile Index (KDPI) and to better reflect the likelihood of graft failure for kidneys from African American/Black and HCV-positive deceased donors.

Dr. Serrano shared that the proposal would refit the Kidney Donor Risk Index (KDRI) model without race and HCV and remap it to KDPI. Dr. Serrano explained that transplant professionals use KDPI to help make informed decisions about donor organ suitability for their candidates. He shared that KDRI is an estimate of the relative risk of post-transplant kidney graft failure and is translated into a KDPI percentile from 0-100% for OPTN allocation process. He noted that lower KDPI scores are associated with longer estimated function, while higher KDPI scores are associated with shorter estimated function.

Dr. Serrano explained that the rationale for the proposal is because both race and HCV variables equivocally increase the KDPI from kidneys from African American/Black and HCV-positive deceased donors, making these kidneys appear less suitable for transplant. He explained that race is a poor proxy for human genetic variation since it is a social construct that lacks biological meaning and excluding race from the KDPI has no impact on the calculation's predictive ability. Dr. Serrano explained that the rationale for removing HCV from KDPI is because contemporary HCV treatments are highly effective.

Dr. Serrano concluded the presentation by noting the implementation considerations for the policy proposal and shared questions for the community to consider during public comment.

Summary of discussion:

A Board member also asked if the organ non-utilization rate will decrease because of this policy, and how the transplant community may react to this policy change. Dr. Serrano explained that programs that tend to be risk averse may turn down more offers than before because a kidney may have a higher KDPI.

A Board member asked if the overall quality of kidneys will improve because organs will be discarded that were formerly thought to be negative, but all kidneys will still be evaluated over a 100% scale. Dr. Serrano explained that the policy is intended to transplant more kidneys that are of a higher KDPI into the appropriate recipient. He noted that the goal of the proposal is to be accurate with post-transplant survival, to ensure the appropriate kidneys are utilized, and not have a disproportionate amount of African American kidneys or HCV positive kidneys in the 85% and above group.

**4. Standardize the Patient Safety Contact and Reduce Duplicate Reporting**

Lara Danziger-Isakov, Chair of the Disease Transmission Advisory Committee (DTAC), presented the proposal to Standardize the Patient Safety Contact and Reduce Duplicate Reporting. Dr. Danziger-Isakov shared that the purpose of the proposal is to improve functionality of the Patient Safety Contact (PSC)

and infectious disease reporting process, and to eliminate duplicate reporting of recipient illness to the OPTN Patient Safety Reporting Portal. Dr. Danziger-Isakov shared that elements of the proposal include:

- Require OPOs and transplant programs to list a secondary PSC
- Require that PSCs work at the OPO or transplant program for which they are listed
- Require that PSCs have a valid phone number and email address listed
- Require OPOs and transplant programs to review PSCs every six months for currency
- Require use of OPTN Donor Data and Matching System enhancement to communicate and acknowledge donor results received post-procurement
- Eliminate requirement for OPOs to report recipient illness to the OPTN Improving Patient Safety Portal.

Dr. Danziger-Isakov shared that the rationale for the proposal is that PSCs listed may be out of date or have invalid contact information, with no confirmation of recipient required of potential disease transmission events, and OPTN Policies require both OPOs and transplant programs to report donor-derived recipient illness to the OPTN. Dr. Danziger-Isakov shared implementation considerations for both OPOs and transplant programs, and shared the questions posed to the community for their feedback during the public comment period.

#### Summary of discussion:

A Board member commented that this project is essential and that the policy needs to provide clarity to centers on how to track recipient illness. They suggested that the portal to input this information be mobile phone friendly. A Board member asked the committee to provide members with the capability to select a primary and secondary PSC.

A Board member asked about the member burden expected with this change. Dr. Danziger-Isakov explained that the committee is working to reduce the burden on members by adding a second contact. She stated that the committee expects that members are already auditing their PSCs during their routine self-audits, so this should not cause a heavy burden on members. Dr. Danziger-Isakov also noted that the policy does not specify who the PSC contact should be or what role they should play within a member organization. She explained that the only requirement is PSCs must work for the member organization and cannot work for a third-party contractor.

### **5. OPTN Strategic Plan 2024-2027**

Dianne LaPointe Rudow, Chair of the Executive Committee, presented the public comment proposal for the OPTN Strategic Plan 2024-2027. Dr. LaPointe Rudow reminded the Board that the OPTN Board of Directors adopts a new strategic plan every three years, and that the strategic plan aligns OPTN resources with specific, significant opportunities within the transplant community. She noted that the strategic plan is not an exhaustive list of the OPTN's work, but rather a high-level framework to guide the OPTN's strategic focus. The proposed plan contains goals, objectives, and metrics, but does not detail every OPTN initiative or project. She shared that engagement with OPTN members, committees, task force(s), and professional societies within the community will shape the formation and implementation of specific initiatives, noting that a collaborative effort will be required to achieve the outlined goals of the plan. Dr. LaPointe Rudow explained that the Executive Committee intentionally selected goals with specificity to allow for a focusing of resources on key opportunities to drive action to ultimately benefit patients. Dr. LaPointe Rudow noted the Executive Committee's continued dedication to the OPTN's Vision when drafting the strategic plan. Dr. LaPointe Rudow shared the three proposed goals are to improve offer acceptance rate, optimize organ use, and enhance OPTN efficiency.

Dr. LaPointe Rudow explained that during the development of the plan, the Executive Committee considered alternative goals, and that the committee ensured past equity gains have been incorporated into the proposed plan's strategic goal, recognizing that as advances in efficiency occur, equity must be maintained or improved. Dr. LaPointe Rudow noted that the community recognized that all goals focus on benefiting patients and the committee intentionally wrote each goal to emphasize its impact on patients, and the committee included an introduction focusing on patients and donors.

#### Summary of discussion:

A Board member asked why increasing the number of organ donors is not included in the strategic plan. Dr. LaPointe Rudow explained that increasing the number of organ donors is more of a general initiative, rather than a focused goal that needed to be explicitly stated in the strategic plan. The Board member suggested that the strategic goal on organ non-use be reworked to include donors that are eligible for transplant but do not end up donating.

A Board member asked about the inclusion of living donors in the strategic plan and asked about the initiatives intended to address living donation throughout transplant.

### **6. Winter 2024 Public Comment Items**

Contractor staff presented the remaining winter 2024 public comment items:

- Clarify Requirements for Pronouncement of Death (Organ Procurement Organization Committee)
- Standardize Six Minute Walk for Lung Allocation (Lung Transplantation Committee)
- National Liver Review Board (NLRB) Updates Related to Transplant Oncology (Liver and Intestinal Organ Transplantation Committee)
- Promote Efficiency of Lung Allocation (Lung Transplantation Committee)
- Update Post-Transplant Histocompatibility Data Collection (Histocompatibility Committee)
- Concepts for Modifying Multi-Organ Policies (Multi-Organ Transplantation Committee)
- Update on Continuous Distribution of Hearts (Heart Transplantation Committee)

Contractor staff explained that the proposal from the OPO Committee to Clarify Requirements for Pronouncement of Death would update current policies for consistency and ensure a valid and unbiased pronouncement of death, and the policy would clearly outline responsibilities of individuals that may be employed at a donor hospital and an OPO.

Contractor staff shared the proposal from the Lung Transplantation Committee to Standardize the Six Minute Walk for Lung Allocation and explained both the purpose of the policy and guidance included in the proposal. It was noted that the policy would require a titration test ahead of an initial six-minute walk test for lung candidates twelve years or older. Contractor staff explained that the guidance would complement existing clinical standards with recommendations for lung transplant programs on the provision of supplemental oxygen and safety considerations during six-minute walk test.

Contractor staff presented on the National Liver Review Board (NLRB) Updates Related to Transplant Oncology from the Liver and Intestinal Organ Transplantation Committee. They noted that the proposal would expand the scope for one adult review board from Hepatocellular (HCC) to Transplant Oncology, create NLRB guidance for colorectal liver metastases and intrahepatic cholangiocarcinoma, and would update Policy 9.5.A: *Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions* for clarity. Contractor staff shared that this project will be on the discussion agenda during the Winter 2024 Regional Meetings.

Contractor staff presented the data collection proposal from the Lung Transplantation Committee to Promote Efficiency of Lung Allocation. Contractor staff noted that this item would add new data collection to aid evaluation of lung offers, provide an overview of lung offer filters that are slated to be released in early 2024, and request feedback on other potential system enhancements.

Contractor staff presented the data collection proposal from the Histocompatibility Committee to Update Post-Transplant Histocompatibility Data Collection. The proposal would update post-transplant histocompatibility data collection instruments with current testing methods, add data collection for virtual crossmatching, and generate discrepant HLA typings reports for all potential HLA critical discrepancies.

Contractor staff presented the request for feedback from the Multi-Organ Transplantation (MOT) Committee on Concepts for Modifying Multi-Organ Policies. The proposal asks for community feedback to inform future policy decisions regarding multi-organ versus single organ offers as well as policy guidance for organ procurement organizations (OPOs).

Contractor staff presented the request for feedback from the Heart Transplantation Committee on the Continuous Distribution of Hearts. Contractor staff shared that the request for feedback will include a prioritization exercise which will ask the community to weigh one attribute against another. They shared that the committee included an option for post-transplant outcomes in the exercise based on prior feedback from the Board of Directors.

Contractor staff also presented a proposal from the Membership and Professional Standards Committee (MPSC) that was not approved to be sent to Winter 2024 Public Comment by the Executive Committee. The project from the MPSC was on Concepts for Organ Procurement Organization Referral Evaluation Process Data Collection. Contractor staff shared that the intended goal of the proposal was to improve the collection of reliable and accurate data on portions of the donation process that precede donor registration. Contractor staff shared that the project is currently on pause pending the imminent Health and Human Services' (HHS) Secretary data collection directive regarding referral data. Contractor staff noted that the Executive Committee agreed to revisit the concept paper upon directive receipt or by March 1, 2024. Dr. LaPointe Rudow shared that the Executive Committee was concerned that the overlap between the data directive and the concept paper would cause confusion in the community.

#### Summary of discussion:

When discussing the project on pause from the MPSC, a Board member asked if the OPTN expects the data being collected in the secretarial data directive to be similar to the data in the concept paper. A representative from HRSA shared that the data directive from HHS will not include as much data as the concept paper was suggesting. The representative from HRSA explained that HHS plans for the data in the secretarial directive to be collected more quickly. They shared that the goal behind the directive is to start the data collection process sooner than the OPTN policy development process would allow. A Board member asked if once the secretarial data directive has undergone the Office of Management and Budget (OMB) public comment period, whether the data collection becomes enforceable. A representative from HRSA explained that HHS is permitted to implement the directive based on the Final Rule.

The meeting adjourned.

#### **Upcoming Meetings**

- February 27, 2024
- March 26, 2024

## Attendance

- **Board Members**
  - Alan Langnas
  - Andrea Tietjen
  - Andrew Kao
  - Barry Massa
  - Christopher Jones
  - Christopher Woody
  - Daniel Yip
  - Dianne LaPointe Rudow
  - Emily Blumberg
  - Erika Demars
  - Evelyn Hsu
  - George Surrat
  - Ginny McBride
  - Jen Lau
  - Jerry McCauley
  - Jim Sharrock
  - Julie Spear
  - Kelley Hitchman
  - Laura Butler
  - Laurel Avery
  - Linda Cendales
  - Lloyd Ratner
  - Manish Gandhi
  - Mark Barr
  - Maryjane Farr
  - Michael Kwan
  - Nicole Hayde
  - Reg Rogers
  - Melissa McQueen
  - Silas Norman
  - Stuart Sweet
  - Wendy Garrison
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Chris McLaughlin
  - Frank Holloman
  - Shannon Dunne
- **UNOS Staff**
  - Anna Messmer
  - Jacqui O'Keefe
  - Julie Nolan
  - Kelley Poff
  - Maureen McBride
  - Morgan Jupe
  - Robert Hunter

- Roger Brown
- Ryan Ehrensberger
- Sharon Shepherd
- Susan Tlusty
- Susie Sprinson
- Tony Ponsiglione
- Trish Jasion
- **Other Attendees**
  - Lara Danziger-Isakov
  - Lisa Stocks
  - Oscar Serrano