OPTN Board Policy Group
Meeting Summary
November 15, 2023

Nicole Hayde, Group Leader

Introduction

The Board Policy Group met via Webex on 11/15/2023 to discuss the following agenda items:

1. Update HLA Equivalency Tables, 2023 (Histocompatibility Committee)
2. Require Reporting of Patient Safety Events (Membership & Professional Standards Committee)
3. Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation (Disease Transmission Advisory Committee)
4. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback (Kidney Transplantation Committee; Pancreas Transplantation Committee)
5. Concepts for a Collaborative Approach to Living Donor Data Collection (Living Donor Committee)

Board Members gathered to discuss select items from the Summer 2023 Public Comment cycle to prepare for the December Board of Directors Meeting. The following is a summary of the group's discussions.

Contractor staff presented the purpose of Board Policy Groups and explained what the next steps are for the policy process ahead of the December Board Meeting. Board Policy Group members were asked to vote on the agenda placement, and were also asked whether they recommend the Board approve or decline the proposal at the December Board meeting.

1. Update HLA Equivalency Tables, 2023

Contractor staff presented an update on HLA Equivalency Tables, 2023. Contractor staff explained that the purpose of the report is to update HLA equivalency tables to better support safety, equity, and accuracy in matching potential donors with transplant candidates. They noted that the proposal aligns with the strategic plan goal to increase the number of transplants and to improve equity in access to transplants.

Contractor staff noted that the proposal includes adding all HLA P-groups with more than a single two-field allele for all loci, adding P-groups equivalences to allele-level acceptable antigens, updating HLA matching equivalences to make all within a serologic antigen group match each other, and updating HLA-DPB1 tables to IPD-IMGT/HLA version 3.52.0.

Contractor staff noted that the proposal would be implemented using the expedited actions pathway and is being presented to the Board for awareness and not as an action item. Contractor staff noted that during public comment there was overall support for the proposal and support for using the expedited actions pathway. They shared that the committee also received recommendations for updates to HLA equivalency tables outside of the scope of current efforts, including the transition to full molecular nomenclature.

Contractor staff shared the implementation actions associated with the proposal. They shared that histocompatibility labs may need to update their Application Programming Interfaces (APIs) to incorporate additional unacceptable antigen options. They noted that histocompatibility labs and

transplant hospitals may need to evaluate their transplant agreements. Contractor staff stated that there would be a technical implementation component for the OPTN.

Summary of discussion:

There was no further discussion from the Board Policy Group.

2. Require Reporting of Patient Safety Events

Scott Lindberg, Vice Chair of the Membership and Professional Standards Committee (MPSC), presented on Require Reporting of Patient Safety Events on behalf of the MPSC. Dr. Lindberg explained that the purpose of the proposal is to align OPTN members' reporting requirements with the requirement for the OPTN to notify MPSC leadership and HRSA of certain patient safety events. Dr. Lindberg explained that OPTN policy does not specifically require members to report some specific patient safety events, including "near misses". He also noted that the proposal aligns with the strategic plan goal to promote living donor and transplant recipient safety.

Dr. Lindberg explained that the proposal is seeking to include new patient safety reports for transplant hospitals in Policy 18. Dr. Lindberg shared the events that would be reported by transplant hospitals. He shared that the policy would broaden reporting instances where a living donor is placed on a waiting list for transplant to any organ waiting list. Dr. Lindberg then shared events that would need to be reported by organ procurement organizations (OPOs).

Dr. Lindberg presented feedback that was incorporated by the MPSC after public comment. He shared that this feedback included extending the required reporting timeframe to 72 hours after members become aware of the event. After public comment, the MPSC also removed the proposed required reporting of transportation events for organs that did not arrive when expected, sanctions against a transplant professional, and attempts to deceive the OPTN or Health and Human Services (HHS).

Dr. Lindberg explained that public comment showed broad support for the proposal and the proposal was particularly supported by patients. He shared that the MPSC received feedback that the 24-hour reporting timeframe should be extended, and the committee incorporated this feedback to extend the reporting timeframe to 72 hours. Dr. Lindberg shared that the community was supportive of the "near miss" definition and asked to clarify whether incorrect organ also means incorrect laterality, and to consider near miss events identified outside of standard processes. Dr. Lindberg shared that there was also support for including transportation events but to clarify "did not arrive when expected". Other public comment feedback included recommendations to include the timeframe "after allocation has begun" for the OPO ABO typing error or discrepancy event, clarify the definitions for "sanction" and "other professional body", and evidence discovered of an attempt to deceive the OPTN or Department of HHS should be related to transplant. Dr. Lindberg explained the proposal saw support to include additional events including HLA discrepancies and that events directly resulting in non-use of transplantable organs should also be collected beyond transportation errors, such as late declines.

Dr. Lindberg explained that the American Society of Transplant Surgeons (ASTS) strongly opposed the proposal. He shared that ASTS was concerned that the proposal: markedly broadens the type and number of events to reported to the OPTN within the specified timeframe, required reporting of near miss events, requires reporting of transportation events, requires reporting of sanctions against transplant professionals, and creates duplication of reporting to the OPTN and to the Centers for Medicare & Medicaid Services (CMS). Dr. Lindberg noted that ASTS was supportive of reporting ABO typing errors or discrepancies and modifying living donor reporting requirements.

Dr. Lindberg explained that implementation would be required by members and the OPTN, and that all members would need to be familiar with the patient safety reporting requirements. He shared that

OPOs and transplant hospital members will be required to report events within 72 hours of becoming aware of the event.

Summary of discussion:

A Board Policy Group member asked about the source of the initial recommendation for the MPSC to include sanctions against a transplant professional or attempts to deceive the OPTN or HHS. Dr. Lindberg and contractor staff shared that these recommendations were initially included in the Wakefield letter, and although these recommendations were not included in the final proposal from the MPSC, the committee will continue to revisit these proposed required reporting events. Contractor staff explained that required sanctions were difficult to include because there are different regulations by state and each state uses different language. After the suggestion during public comment on the language differing by state, the MSPC did not think it had adequate time to craft language on the two requirements, so it is encompassing of all states.

Dr. Lindberg commented that most of the time, reports of sanctions against a transplant professional or reports of an attempt to deceive the OPTN or HHS have been reported through anonymous reporting sources.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 6 discussion votes and 1 consent vote, the Board Policy Group voted to recommend placement on the discussion agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 7 approve, 0 abstain/undecided, 0 decline, the Board Policy Group voted to recommend approval of the proposal.

3. Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation

Lara Danziger-Isakov, Chair of the Disease Transmission and Advisory Committee (DTAC), presented on Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation on behalf of the DTAC. Dr. Danziger-Isakov explained that the guidance document aims to decrease donor-derived disease transmission from organ transplantation. She explained that endemic diseases have a high potential for morbidity and possible mortality if transmitted to recipients. Dr. Danziger-Isakov explained that as organ offer patterns continue to change, increased awareness and communication for potential endemic diseases across regions is necessary to mitigate risk. She noted that the guidance document aligns with the strategic plan goal to promote living donor and recipient safety by reducing transmission of endemic infections through organ transplantation.

Dr. Danziger-Isakov explained that the guidance document combines and modifies four existing guidance documents on endemic disease screening for living donors, incorporates guidance for screening for endemic disease for deceased and living donors, advises transplant hospitals on recipient and living donor management after transplanting organs from donors with endemic diseases, and includes updated epidemiology and added sections on testing turnaround time.

Dr. Danziger-Isakov shared feedback received during public comment. She shared the themes from public comment focused on support for an updated guidance document, cost and availability of recommended testing, lack of medical and social history to inform screening, system enhancements

needed for endemic disease screening, and turnaround time of testing and organ utilization. Dr. Danziger-Isakov specifically noted that the American Society of Transplantation (AST) recommended modification to the histoplasmosis donor screening section to highlight urine histoplasma antigen as the optimal screening method. She explained that the DTAC agreed with the suggestion.

Dr. Danziger-Isakov noted that there is no implementation needed by members or the OPTN for the guidance document. Next steps include: posting the guidance document on the OPTN Website, DTAC will continue to monitor donor-derived transmission events for endemic diseases, and DTAC will consider additional guidance or policy if necessary.

Summary of discussion:

There was no further discussion from the Board Policy Group.

Vote:

Do you recommend placement of this proposal on the consent or discussion agenda?

> With a total of 6 consent and 1 discussion vote, the Board Policy Group voted to recommend placement on the consent agenda.

Does the group recommend the Board approve or decline this policy proposal?

> With a total of 7 approve, 1 abstain/undecided, and 0 decline, the Board Policy Group voted to recommend approval of the guidance document.

4. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback

Contractor staff presented on the Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback. Contractor staff shared that the goal of the Kidney and Pancreas Committees is to transition the current classification system into a continuous distribution framework. Contractor staff noted that the scope of the project has changed over the past few months due to the Board's creation of the Task Force on Efficiency.

Contractor staff shared that the committees started by identifying the goals of the community. Identifying these goals helps the committees understand what they are trying to achieve in the continuous distribution framework. Contractor staff shared that there were 5 goals identified, and these 5 goals are the same across all organ types. Contractor staff explained that next the committees established a rating scale and then held a community wide values prioritization exercise with OPO and patient focus groups. This exercise was to help the committees determine the weights of each attribute. The committees then submitted their first modeling requests and tested extreme scenarios to test the limits of the system and to ensure that the system was responsive to the attributes and the rating scales that the committees had developed. The committees then collaborated with partners at MIT on optimization work with the priorities, and completed another modeling request and took this information back to MIT to continue optimization work.

Contractor staff shared that the committees have developed and discussed how review boards may operate in a continuous distribution framework. The committees have also developed and discussed solutions to several significant operational components, including release organs, en bloc kidney allocation, dual kidney allocation, mandatory kidney-pancreas allocation, Kidney Minimum Acceptance Criteria (KiMAC), and national kidney offers. Contractor staff shared that the committees are continuing discussions regarding definitions for Kidney and Medical Urgency.

Contractor staff discussed the initial optimized policies from the committees. They shared that MIT optimized the polices in January 2023 while the Scientific Registry for Transplant Recipients (SRTR)

simulated the policies. They explained that the committees continue to explore how to improve each metric and goals that the community has for the allocation system. Contractor staff shared areas of concern following the review of modeling results but noted that the committee's goals were largely met by optimized policies. Contractor staff shared that the committees have continued optimization with MIT partners and have begun preliminary discussions related to efficiency, non-use, and expediated placement.

Contractor staff shared that next the committees will consider areas for improvement, including pediatric travel distance and pediatric access, equalizing access across CPRA groups, and efficiency and utilization.

Summary of discussion:

The Board Policy Group discussed how the creation of the Task Force on Efficiency may impact the continuous distribution timeline.

5. Concepts for a Collaborative Approach to Living Donor Data Collection

Contractor staff presented the Concepts of a Collaborative Approach to Living Donor Data Collection on behalf of the Living Donor Committee. Contractor staff stated that the purpose of the presentation was to engage the Board on what a potential future state could look like between the OPTN and the SRTR collaborating on collecting living donor data. Contractor staff shared that the Living Donor Committee submitted a concept paper for public comment that detailed a collaborative approach to living donor data collection by the OPTN and the SRTR Living Donor Collective. The concept paper detailed support on data collection that fills the current gaps in knowledge related to the long-term outcomes of living donors and barriers to living donation. Contractor staff shared that the concept paper provided an update on the progress of the OPTN's living donor data element granular review.

Contractor staff detailed the relationship between the OPTN and SRTR. The Living Donor Committee determined that extending follow up for transplant programs past two years may not be the best approach and that there might be a better option to have another entity that can directly interface with living donors. Contractor staff noted that the SRTR runs the Living Donor Collective, which acts as a living donor candidate and living donor registry. In the concept paper, the committee is looking to have the OPTN collect data on living donor candidates, their donation decisions, and to continue collecting data on the donation. The SRTR would then be able to analyze the barriers to living donation. Contractor staff shared that the Living Donor Committee has identified the importance of registering living donor candidates in a more systematic way at a national level.

Contractor staff shared feedback the concept paper received during public comment. They shared that public comment showed general support of the goals of the concepts. Contractor staff noted that there was concern regarding burden, long-term follow up, and privacy of data.

Contractor staff shared that one of the key themes during public comment feedback was around terminology and definitions. There was concern that a difference in definition could lead to data collection disparities due to variations in screening and evaluation processes. Contractor staff shared that another theme in feedback was around a concern for long-term follow up of living donor candidates. They shared that there was concern that living donor candidates may not wish to be followed long-term, and long-term follow up of living donor candidates may not provide meaningful or reliable data. Another theme was around donation decision and analyzing barriers to living donation. Contractor staff shared that while there was support for understanding barriers to living donation, there was a concern for collecting donation decisions due to confidentiality.

It was noted that the Living Donor Committee proposed potentially removing the 12 and 24 month follow up requirements to allow transplant programs to alter those resources to collect living donor candidate data, however during public comment the committee saw a mix of support and opposition for removing these two points of follow up. Contractor staff explained that there was concern expressed during public comment regarding the privacy of data related to living donor candidates and their donation decision. Contractor staff then noted the concern expressed during public comment surrounding burden. They explained that based on public comment feedback, there was concern that the conceptual future state of living donor data collection will add burden on transplant programs and living donors. They noted that there was recognition that the Living Donor Collective's role may help reduce burden. The committee received suggestions during public comment on how to further ease burden, particularly highlighting the importance of data interfaces.

Next, the committee will consider the feedback received during public comment to inform the development of the project.

Summary of discussion:

The Board Policy Group discussed the committee's work on developing a definitions.

Attendance

- **Group Members**
  - Andrew Kao
  - George Surratt
  - Julie Spear
  - Kelley Hitchman
  - Lloyd Ratner
  - Manish Gandhi
  - Michael Kwan
  - Nicole Hayde
  - Silas Norman
  - Wendy Garrison
- **HRSA Representatives**
  - Daniel Thompson
- **UNOS Staff**
  - Anna Messmer
  - Cole Fox
  - Courtney Jett
  - Jacqui O'Keefe
  - James Alcorn
  - Kaitlin Swanner
  - Kayla Temple
  - Kieran McMahon
  - Krissy Laurie
  - Leah Nunez
  - Meghan McDermott
  - Morgan Jupe
  - Ross Walton
  - Sally Aungier
  - Sharon Shepherd
  - Susan Tlusty
  - Susie Sprinson
  - Tamika Watkins
- **Other Attendees**
  - Lara Danziger-Isakov
  - Scott Lindberg