OPTN Board Policy Group
Meeting Summary
November 8, 2023

Meg Rogers, Group Leader

Introduction

The Board Policy Group met via Webex on 11/08/2023 to discuss the following agenda items:

1. Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates (Histocompatibility Committee)
2. Update on Continuous Distribution of Livers and Intestines (Liver & Intestinal Organ Transplantation Committee)
3. Continuous Distribution of Hearts (Heart Transplantation Committee)
4. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Test Result (Disease Transmission Advisory Committee)
5. Modify Organ Offer Acceptance Limit (Organ Procurement Organization Committee)

Board Members gathered to discuss select items from 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 in St. Louis. Board Policy Group members were asked to vote on the agenda placement for proposal items (discussion or consent agenda). They were also asked whether they would recommend the Board approve or decline the proposal at the December Board meeting.

1. Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates

John Lunz, Chair of the Histocompatibility Committee presented the proposal to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates on behalf of the committee. Dr. Lunz shared that the purpose of the proposal is to ensure equity for highly sensitized kidney candidates by eliminating additional documentation, which is currently required to gain allocation priority. He shared that the project aligns with the strategic plan goal to improve equity in access to transplants. Dr. Lunz stated that allowing CPRA 99-100% candidates to gain allocation priority immediately will ensure they do not miss a potentially compatible organ offer while waiting for documentation.

Dr. Lunz shared that the proposal suggests removing additional documentation for CPRA 99-100% kidney candidates, and that the policy has not changed since public comment. He shared that public comment feedback showed broad support for the removal of additional documentation for highly sensitized kidney candidates. He noted that there were additional suggestions for the Committee to consider, such as forms to remove, but this was outside of the scope of the current proposal.

Dr. Lunz shared that implementation would no longer require histocompatibility labs and transplant hospital members to sign approval forms for highly sensitized kidney candidates or document approval in the OPTN Waiting List. He shared that there is an expected 700 technical IT implementation hours.

<u>Summary of discussion:</u>

A Board member shared that they were surprised by the amount of technical implementation hours. Dr. Lunz shared that because this information is heavily imbedded in many automated processes, there are more implementation hours allocated. Board members discussed how implementation hours are prioritized compared to other implementation efforts and how these hours are determined.

A Board member stated that they were supportive of the proposal and stated that this would have an immediate impact on highly sensitized patients that would usually have to wait a significant amount of time if these forms were required. A Board member commented that removing this form would not impact patient safety.

Vote:

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

> With a total of 7 votes, the Board Policy Group unanimously voted to recommend approval of the proposal to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates

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

> With a total of 7 votes, the Board Policy Group unanimously voted to place the proposal to Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates on the consent agenda.

2. Update on Continuous Distribution of Livers and Intestines

Contractor staff presented an update on the Continuous Distribution of Livers and Intestines from the Liver and Intestinal Organ Transplantation Committee. Staff presented an overview of public comment feedback. The committee asked for community feedback on the committee's work towards a mathematical optimization analysis, the results of the values prioritization exercise (VPE), and attributes the committee is considering. Contactor staff shared common themes received during public comment: geographic equity and placement efficiency, post-transplant survival, medical urgency, pediatrics, efficiency, and medically complex grafts. Contractor staff shared feedback received on geographic equity and placement efficiency, post-transplant survival, and efficiency.

Contractor staff shared that next, the committee will refine attributes and focus on optimization in collaboration with MIT.

Summary of discussion:

The Board Policy Group discussed the collaboration between the OPTN and MIT on the optimization. They discussed why the Liver and Intestinal Organ Transplantation Committee did not use the SRTR survival models as a starting point to include in the Composite Allocation Score (CAS). Contractor staff explained that the committee believed the models were not strong enough to be predictive in prioritizing candidates. The Board Policy Group discussed long-term post-transplant survival and for the committee to consider this. A Board Policy Group member commented that committees should be encouraged to develop these models because it is information that patients want to see. Board Policy Group members suggested the committee consider not just survival, but the quality of patient survival and the length of survival. A Board Policy Group member commented that long-term post-transplant survival is especially important to consider when it comes to pediatric candidates.

3. Continuous Distribution of Hearts

Contractor staff presented on the Continuous Distribution of Hearts Concept Paper. Contactor staff shared that during the summer 2023 public comment cycle, the Heart Transplantation Committee submitted a concept paper for community feedback. The concept paper detailed progress on developing the continuous distribution allocation framework for heart, and the committee identified initial

attributes to consider. Contractor staff shared the number of comments received from different membership groups and an analysis of public comments. Key themes from public comment include general support for continuous distribution, considerations of post-transplant survival attributes, considerations for additional attributes, and other considerations for improving heart allocation. Next, the committee will finalize a list of initial attributes and distribute a community values prioritization exercise (VPE).

Summary of discussion:

The Board Policy Group discussed the importance of post-transplant survival. A Board member suggested that when considering efficiency, the committee consider all the dimensions that contribute to measuring efficiency. The Board member commented that they believed efficiency was more complicated than the committee has considered.

4. Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Test Results

Contractor staff presented on the Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with HIV Positive Test Results Concept Paper from the Disease Transmission Advisory Committee (DTAC). Contractor staff shared that the purpose of the concept paper is to request feedback from the community to determine whether a future policy proposal and/or algorithm is warranted. This concept paper developed out of a suggestion from the Membership and Professional Standards Committee (MPSC), for the DTAC to develop an algorithm that clearly delineates when a donor with a positive HIV test is not infected with HIV. The concept paper aligns with the strategic plan goal to promote living donor and recipient safety by standardizing this practice among OPOs, and reducing the risk of HIV transmission through organ transplantation.

Contractor staff shared the considerations the community was asked to ponder during public comment. Staff shared the key themes during public comment included support for an algorithm, request for clear guidelines for testing, concern around turnaround time and the availability of confirmatory testing, and concern about utilization of HIV-positive organs. Contractor staff stated that there was limited feedback received from OPOs because they encounter this situation so infrequently.

Contractor staff shared that the Centers for Disease Control and Prevention (CDC) does not support creating an algorithm. The CDC does not support creating an algorithm because they stated HIV tests are highly sensitive and specific, and data gathered does not justify an algorithm. The CDC also commented that this could result in HIV transmission through organ transplantation. The DTAC acknowledged that developing an algorithm would be challenging due to confirmatory testing turnaround time and availability. Contractor staff shared that the DTAC will reevaluate the need for an algorithm if the HHS Secretary recommends removing the HOPE Act variance for kidneys and livers. There is no Board action requested at this time.

Summary of discussion:

A Board Policy Group member asked if the DTAC considered creating an algorithm on the utility of creating an algorithm, so the committee can gain more clarity on what may be required of the algorithm. Contractor staff explained that the committee did discuss defining what an HIV infection is instead of developing an algorithm on whether an organ is HIV positive or not. The CDC was reluctant to follow this pathway and believes the MPSC should be the body reviewing cases with HIV positive test cases.

A Board Policy Group member asked if it was possible to construct an algorithm that could provide additional data to inform the future of HIV positive tests. The Board Policy Group member commented

that when the DTAC looked at this information retrospectively, they can potentially understand whether an algorithm measuring the impact on allocation decisions would be effective. Contractor staff agreed to take this suggestion back to the committee.

5. Modify Organ Offer Acceptance Limit

PJ Geraghty, Chair of the Organ Procurement Organization Committee, presented the proposal to Modify Organ Offer Acceptance Limit on behalf of the committee. Mr. Geraghty explained that the proposal aims to eliminate the scenario where allocation efficiency is diminished when a transplant program holds two primary acceptances for one candidate. The OPO Committee proposes modifying OPTN Policy 5.6.C: *Organ Offer Acceptance Limit* to only allow a transplant hospital to have one primary organ offer acceptance for each organ type for any one candidate.

Mr. Geraghty shared that the proposal aligns with the strategic plan goal of providing equity in access to transplants, especially for higher status candidates who could miss out on offers when OPOs are forced to reallocate organs due to a late turndown. He shared that reducing the number of organ offer acceptances also aligns with the strategic plan goal to increase the number of transplants by creating efficiency in the organ placement process.

Mr. Geraghty shared key themes during public comment. During public comment, the proposal saw support for improving efficiency in organ allocation, maximizing organ utilization and preventing the non-use of organs, reducing out of sequence allocations, and reducing late turndowns, which impacts OPOs, donor hospitals, families and other transplant programs and recovery teams. During public comment, the proposal received recommendations to document and publish data on late turndowns, establish a timeframe to acceptance, increase the use of pre-donation biopsies, improve communication and information sharing, encourage machine perfusion, and improve “backup” process. Public comment feedback reflected a concern for the impact on higher status candidates, pediatrics, and DCDs.

Mr. Geraghty shared that the committee did not make any changes after public comment. Mr. Geraghty shared the rationale for not making post-public comment changes by addressing the perceived impacts to each group, including higher status candidates, pediatrics, and DCDs.

Mr. Geraghty shared the implementation efforts for both OPOs and transplant hospitals. He shared that OPO implementation will include spreading awareness of policy changes and developing communication strategies with transplant programs. Implementation for transplant hospitals will include spreading awareness that to accept another organ offer, centers will need to decline the current primary organ offer acceptance. Mr. Geraghty shared that an IT effort of approximately 530 hours is necessary for the OPTN to implement the reduction in primary organ offer acceptance allowed from two to one.

Summary of discussion:

A Board Policy Group member asked about the number of pediatric cases that were represented in the study. The Board Policy Group member asked Mr. Geraghty if the percentage that 2% of concurrent acceptance events involved pediatric candidates was calculated from all donor offers, or if the percentage was calculated specifically within pediatric offers. Mr. Geraghty explained that of the 860 concurrent acceptance events that the committee analyzed, only 2% (or 18 cases) were pediatric cases. The Board Policy Group member was concerned that the pediatric community was underrepresented and although the change may look insignificant, it is hard to know if the potential impact is insignificant or not. The Board Policy Group member encouraged the committee to analyze what percentage of pediatric donor offers are implicated within the change.

A Board Policy Group member noted their concern about cases where DCDs are involved in the primary offer in case the offers do not progress to the sickest patients. Mr. Geraghty explained that there are

comparatively fewer high-status patients that were involved in the test cohort, and the committee does not believe this group of patients will be significantly impacted.

A Board Policy Group member commented that with the expansion of continuous distribution, it is even more important to increase efficiencies within the transplant community. They comment that this policy is one way to help increase efficiency.

The Board Policy Group discussed if there were situations where it would be reasonable for transplant hospitals to accept two offers. A Board Policy Group member suggested that if there are situations were this would be reasonable, then the committee should include this in the policy. The Board Policy Group member encouraged the committee to include an example of a situation that would warrant accepting two offers.

A Board Policy Group member encouraged the committee to analyze the system more holistically and to potentially stratify patients, so organs are utilized more frequently.

Vote:

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

> The Board Policy Group voted 4 approve, 3 undecided, 0 decline, on the proposal to Modify Organ Offer Acceptance Limit.

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

> The Board Policy Group voted 6 discussion and 2 consent on agenda placement for the proposal to Modify Organ Offer Acceptance Limit.

Attendance

- **Group Members**
  - Alan Langnas
  - Andrea Tietjen
  - Erika Demars
  - Jim Sharrock
  - Kelley Hitchman
  - Laura Butler
  - Luis Hidalgo
  - Meg Rogers
  - Melissa McQueen
  - Stuart Sweet
- **HRSA Representatives**
  - Chris McLaughlin
  - Frank Holloman
  - Mesmin Germain
- **UNOS Staff**
  - Anna Messmer
  - Cole Fox
  - Courtney Jett
  - Eric Messick
  - James Alcorn
  - Jacqui O'Keefe
  - Kaitlin Swanner
  - Lauren Mauk
  - Morgan Jupe
  - Robert Hunter
  - Ross Walton
  - Susan Tlusty
  - Susie Sprinson
- **Other Attendees**
  - John Lunz
  - PJ Geraghty