OPTN Board of Directors
Meeting Summary
January 18th, 2023
Conference Call

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Introduction

The Board of Directors met via Webex on 01/18/2023 to discuss the following agenda items and public comment items:

1. Welcome
2. Ethical Evaluation of Multiple Listing
3. Identify Priority Shares in Kidney Multi-Organ Policies
4. Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors
5. Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements
6. Optimizing Usage of Offer Filters

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

1. Welcome

Board Manager, Susie Sprinson, started the meeting with updates and announcements. The Board was reminded that public comment opens tomorrow, January 19th and runs through March 15th. Board members were reminded of their regional meeting dates and were given a preview of the agendas for the meetings. Susan Tlusty, Policy Manager, presented an overview of the items that were not on the discussion agenda for today's meeting. Items not on the discussion agenda:

- Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates
- Continuous Distribution of Kidneys and Pancreata Committee Update
- Update on Continuous Distribution of Livers and Intestines
- Improve Deceased Donor Evaluation for Endemic Diseases
- Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements
- Expand Required Simultaneous Liver-Kidney Allocation
- National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates

2. Ethical Evaluation of Multiple Listing

Keren Ladin, Chair of the Ethics Committee, presented the white paper on the Ethical Evaluation of Multiple Listing. The white paper conducts an ethical analysis of multiple listing while applying the ethical principles of equity, autonomy, and utility. The paper hopes to address the impact of multiple listing on patients and the transplant system and to promote equitable access for everyone in need of an organ transplant. The implementation considerations were shared with the Board as well as the questions the committee has posed for public comment.

Summary of discussion:

The Board asked about the proposal and what benefits the proposal would create for candidates on the waiting list. A Board member asked if once a candidate is listed at a transplant center, they can leave that program if they find another program instead. Dr. Ladin responded that the Ethics Committee encourages patients to find a transplant center that aligns with their goals. A patient is welcome to leave a transplant center and may seek as many evaluations as they wish. A Board member asked if this white paper is based on behavior from a limited number of patients and asked why it was necessary. Dr. Ladin explained that patients with the financials means may list themselves at multiple centers, which means that other patients should have the opportunity to list at multiple centers as well. Patients are typically informed of their right to list at multiple centers but not all patients are told this nor do all patients have the means to do so; this then creates an inequality in access to transplantation.

A Board member commented that the patients who may not have access to multiple list due to their circumstances may also be the people that are unable to respond to public comment and thought the committee should take this into consideration. Dr. Ladin agreed that the committee will hear from individuals that are more likely to utilize multiple listings during public comment. Dr. Ladin stated that the committee supports transplant centers education to patients about their options eand supports patient autonomy to list at multiple centers.

A Board member commented that the language of the white paper could be more specific to explain that patients should have the autonomy and freedom to go wherever they please. The Board member hoped this paper will close the loophole that some patients are using to potentially gain an advantage in listing at multiple centers. Dr. Ladin commented that she will take this comment back to the Ethics Committee. A Board member expressed that this proposal would be hard for them to support due to the recommendations from the National Academics of Sciences, Engineering, and Medicine (NASEM)report on organ nonuse. They thought that multiple listing could have adverse effects and increase the number of nonutilized organs. Dr. Ladin explained that the white paper does not speak to the potential for organ nonuse, but it does mention a waste of resources in terms of multiple evaluations. The white paper does address that this would not promote utility except for very hard to match candidates.

A Board member asked if the committee gave any consideration to patients who may reside in multiple places throughout the year or have support systems in multiple states. Dr. Ladin commented that geography is a complex issue when it comes to listing and multiple listing. Dr. Ladin continued that the white paper does not suggest limiting patients autonomy to list at multiple places and instead says that they should be able to have as many opinions as they choose. The committee's concern is that some patients may have an advantage in receiving a transplant sooner if they multiple list.

3. Identify Priority Shares in Kidney Multi-Organ Policies

Lisa Stocks, Chair of the Multi-Organ Transplantation (MOT) Committee, presented the concept paper on behalf of the committee. The purpose of the concept paper is to request feedback from the community to inform the future policy proposal and establish an updated framework for kidney multi-organ allocation. The concept paper hopes to address concerns from transplant programs about the impact that multi-organ allocation may have on kidney-alone candidates. The MOT Committee aims to address when kidneys should be offered to kidney-alone candidates prior to kidney multi-organ candidates, determine which kidney should be offered to multi-organ candidates with equal priority, what to do when organ offer acceptance conflicts with a required multi-organ offer, and to provide more direction on multi-organ allocation while still allowing flexibility in allocation.

<u>Summary of discussion:</u>

A Board member asked for the committees' consideration when it comes to placing extra renals when placing multiple organs. They commented that the process has become complex over the years and

hope that the MOT gives consideration on interweaving lists. Ms. Stocks commented that the MOT Committee did discuss this topic and have included this in the concept paper. Another Board member asked what happens when a kidney is offered to a multi-organ candidate, is the kidney offered to single-organ recipients as a back-up plan if the multi-organ candidate does not accept? They wanted to know what then happens to the multi-organ candidate and at what point are organs offered to multi-organ candidates released. Ms. Stocks explained that the committee did briefly discuss this and the importance this has because of the added cold time to the kidney. The committee has included when the kidney should be released in the proposed concept paper.

A Board member commented that there needs to be a lot of attention given to the issue of access. They have seen this become an increased issue and people who need another organ have received priority for the kidney. They commented that there should be constant work to find the balance between equity and utility; they are concerned with the number of kidneys that are discarded because they are held up with multiple organs and are then released late. They suggested that when there is a late turn down for multiple organs and the OPO is trying to place the kidney, then there needs to be a clear determination on what OPOs should do next to ensure the kidney is utilized. They commented that there needs to be a happy medium to maximize utilization and the committee should be clear on when not to prioritize multi-organ candidates.

Another Board member commented that children and highly sensitized patients should have priority over multi-organ candidates and that multi-organ candidates should look for potential living donors for kidneys. Ms. Stocks commented that the committee had discussed PRA candidates extensively. Another Board member commented that there is an opportunity to better match liver-kidney transplants with older patients. Another Board member commented that for the purpose of public comment, the committee should ask people to comment on efficiency and to clarify the paper as much as possible. Ms. Stocks commented that she would take these comments back to the committee. A Board member stated that they did not think kidney-pancreas should be involved in this because it is a different situation compared to other multi-organ transplants.

4. Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors

John Lunz, Chair of the Histocompatibility Committee, presented the proposal on behalf of the committee. The purpose of the proposal is to increase safeguards for deceased donor HLA typings to reduce the risk of unintended immunologically incompatible transplants, increase confidence in HLA typing and confidence in using virtual crossmatching, and to address technical laboratory errors. The proposal suggests two HLA typings be performed for deceased donors when HLA typing is required and that specimens must be drawn at two separate times. Dr. Lunz also shared the committee rationale, implementation estimates, and key questions posed during public comment.

Summary of discussion:

A Board member commented that the cost of double testing would be significant when this error only occurs in 0.3% of cases. Another Board member asked how far apart in time must the drawings take place. Dr. Lunz commented that the committee recommends using the same rule as ABO typings, which is usually within five minutes of each other, but still technically are two independent draws. The Board member also commented on the volume of work this would take when this affects a very small number of cases. Dr. Lunz commented that this proposal is part of an over overarching goal of the committee to reduce critical discrepancies.

A Board member asked if the discrepancies in data were likely from incorrect data entries or transcription errors that could be corrected with API usage or are these technical problems due to machinery. Dr. Lunz commented that they do not have a way to determine this. He also mentioned that

this project was based on a letter the OPTN received from a concerned lab director that had experienced this situation for mistaken typing. He commented that the committee is also looking to utilize APIs to import the data more readily.

A Board member suggested that the committee present in a clear manner how much this will cost to implement and the average cost associated with this testing. The Board member also suggested the committee rethink how they present their data when explaining how many candidates could be affected by this. Another Board member asked who would be responsible to pay for the extra testing. Dr. Lunz responded that this would be an understanding between the OPO and histocompatibility labs to decide. The Board member continued that this is another situation where OPOs are being requested to perform a test that would increase costs for OPOs for a situation that affects a very small percentage. A Board member asked how many of the discrepancies were due to a lack of universal use of high-resolution molecular typing. Dr. Lunz explained that they have eliminated from their calculations any type of high versus low resolution discrepancies because they are considered non-critical.

5. Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements

Ed Hollinger, Chair of the Network Operations Oversight Committee (NOOC), presented the proposal on behalf of the NOOC. The project aims to enhance the security of the OPTN Computer System by reducing the risk of member security incidents could have on the OPTN Computer System by establishing concrete expectations for member notification to the OPTN in the event of a security incident. This project is in response to a new OPTN contract requirement. Dr. Hollinger shared the topics the committee has focused on and the implementation efforts they predict will be necessary for the project. Dr. Hollinger also shared some questions the committee is posing to the community during public comment.

Summary of discussion:

A Board member asked what the cost associated with this proposal will be for member organizations. Dr. Hollinger explained that the variation between member organizations is dramatically different. He explained that the goal of the proposal is provide some guidance to member organizations on what their framework should look like and for the OPTN to act as a resource to members to help develop their frameworks. A Board member asked if there were other models of a similar system within any governmental agencies that the OPTN could use as a model for their approach to the project. Dr. Hollinger explained that the NOOC has considered analyzing what works well for other systems, but it is difficult to do this across different member types within the OPTN. He explained that for right now, he believes the OPTN will utilize multiple different frameworks to ensure the framework meets the need of the member organization.

6. Optimizing Usage of Offer Filters

Alden Doyle, Chair of the Operations and Safety Committee (OSC) presented the proposal on optimizing usage of offer filters on behalf of the committee. Currently, offer filters are voluntary but this proposal would change the default setting of offer filters from “off” to “on”, as well as update the available filter options. Offer filters would be applied automatically for all adult programs and would be reapplied every three months. The proposal would also allow programs to turn off any or all filters, but certain patient groups will not have any offers filtered. The committee plans to use the data from this proposal to inform whether a future mandatory proposal is necessary.

The committee chose the default usage of offer filters for the proposal based on the feedback they received from their concept paper during summer 2022 public comment. The proposal will require the

creation of a new field in the OPTN Waiting List system but will require no effort from OPTN members. Dr. Doyle also presented the committee's key questions they will be posing to the public during public comment.

Summary of discussion:

A Board member asked about the filters and clarified that these are program level filters, which means that they will be applied to the program at large. Dr. Doyle confirmed this to be correct and explained that there are also individual patient level filters. Dr. Doyle commented that part of this project was implementing better filters, while the other half was about figuring out where there is an intersection between program level and patient level filters. He explained that most programs don't use filters. The Board member also suggested the committee make it possible for programs to save filters so they can apply them to individual patients when they are listed and to increase the usage of filters. Dr. Doyle thought this was a great suggestion and explained that the committee was trying to address the big steps of the project first.

Another Board member commented that the biggest challenge the committee was going to face is that many programs do not know how to use filters. They suggested the committee make filter adoption easy upfront and then make a generic filter that programs could customize for their individual programs. They suggested the OSC educate programs on this so they are comfortable using the filters and to encourage adoption.

Next Steps:

Public comment will run from January 19th to March 15th. The Board will meet again at the end of public comment to review the proposals and feedback received from the community.

Upcoming Meeting

- March 20th, 2023

Attendance

- **Board Members**
  - Adam Frank
  - Barry Massa
  - Clifford Miles
  - Daniel Yip
  - Dianne Lapointe Rudow
  - Earnest Davis
  - Edward Hollinger
  - Evelyn Hsu
  - Ginny McBride
  - Jeffrey Orlowski
  - Jerry McCauley
  - Jim Sharrock
  - Jonathan Fridell
  - Kelley Hitchman
  - Laurel Avery
  - Linda Cendales
  - Lloyd Ratner
  - Manish Gandhi
  - Mark Barr
  - Maryjane Farr
  - Matthew Cooper
  - Meg Rogers
  - Melissa McQueen
  - Nicole Hayde
  - Richard Formica
  - Robert Goodman
  - Stuart Sweet
  - Valinda Jones
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Shannon Taitt
- **UNOS Staff**
  - Alex Carmack
  - Anna Messmer
  - Courtney Jett
  - Isaac Hager
  - Jacqui O'Keefe
  - Joann White
  - Kaitlin Swanner
  - Kristine Althaus
  - Kim Uccellini
  - Laura Schmitt
  - Lauren Mauk
  - Liz Robbins Callahan
  - Mary Beth Murphy

    - Maureen McBride
    - Morgan Jupe
    - Roger Brown
    - Susan Tlusty
    - Susie Sprinson
    - Terri Helfrich
    - Tina Rhoades
    - Taylor Livelli
- **Other Attendees**
    - Alden Doyle
    - Andrew Flescher
    - John Lunz
    - Keren Ladin
    - Lisa Stocks