OPTN Board of Directors
Meeting Summary
March 20th, 2023
Conference Call

Jerry McCauley, MD, President
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Introduction

The Board of Directors met via Webex on 03/20/2023 to discuss the following agenda items and public comment items:

1. Welcome
2. Post Public Comment Feedback
    a. Ethical Evaluation of Multiple Listing (Ethics Committee)
    b. Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors (Histocompatibility Committee)
    c. Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements (Network Operations Oversight Committee (NOOC))
3. OPTN FY23 Budget and Fee*

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

1. Welcome

Jerry McCauley, President of the OPTN Board of Directors welcomed everyone to the meeting.

2. Post Public Comment Feedback

The OPTN Board of Directors heard feedback about the three proposals from the winter 2023 public comment cycle:

- Ethical Evaluation of Multiple Listing White Paper (Ethics Committee)
- Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors (Histocompatibility Committee)
- Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements (Network Operations Oversight Committee).

<u>Ethical Evaluation of Multiple Listing</u>

Dr. Keren Ladin, Chair of the Ethics Committee, presented the Ethics White Paper on behalf of the committee and explained that the purpose of the white paper was to conduct an ethical analysis of multiple listing and to consider how the practice fares against the ethical principles of transplant. The committee specifically evaluated equity (including distributive justice and procedural justice) autonomy, and utility. The Ethics Committee welcomed the community's feedback on how to encourage multiple listing for patients who are exceptionally difficult to match, how to better direct patients who are seeking multiple evaluations, and sentiment about the proposal in general. During the committee's initial research, they found that utilization of multiple listing is patterned in a way that aligns with sociodemographic disparities. Dr. Ladin explained that for kidney and liver patients, their education level

and whether they are single and multiple listed aligns with existing sociodemographic disparities in access to health care. Thus, patients who are more wealthy are more likely to be multiple listed than patients who are disadvantaged financially.

Dr. Ladin shared sentiment by region, member type, and by participation by state. Dr. Ladin also shared a summary of the public comments from the community, these comments supported the findings that there is more advantage for socioeconomically advantaged and health literate individuals. Public comment feedback also showed agreement that efforts to address equity disparities are critical. The community expressed concern on how to define "medically complex" and whether there would be unintended impacts of the white paper. The community also noted how continuous distribution may impact the paper's conclusions or whether the paper should be delayed or revisited because of this, and whether multiple listing infringed on a patient's autonomy or impacted their access to care.

Summary of discussion:

A Board member asked Dr. Ladin what the difference is for a patient that does not multiply list. They also asked that if a patient multiply lists, does their benefit translate into a detriment to someone else, and they also mentioned that geography can impact waitlist status. Dr. Ladin responded that from a population health ethicist perspective, there are bedside rationing decisions, which are decisions made for a specific patient, and then there are systemic decisions, which are decisions made for the system at large. A patient relocating and meeting listing criteria at a center is not the harm, the potential harm is that patients can have the ability to have multiple offers simultaneously while many other patients only have one. Dr. Ladin commented that the harm in multiple listing is that a patient could potentially jump the line or violate a procedure in place that aims to establish equity and transparency for everyone. Dr. Ladin explained that according to literature, there is a benefit to multiply listing and those who are multiply listed are more likely to receive an organ transplant. Therefore, because a patient is more likely to receive a transplant if they are able to multiply list, then many of the patients who are unable to multiply list are at a disadvantage and perhaps perpetuating a disparity. The Board member then asked if the disparity is enough to restrict access to individuals with a lower educational level that are still benefitting from current multiple listing practices. Dr. Ladin explained that the white paper asks the Board to consider why the OPTN would have a policy that does not improve utility and may also disadvantage some patients. Dr. Ladin concluded that there is justification for maintaining the practice, but there could be potential harm.

A Board member asked if the Ethics Committee could allow multiple listing for a specific group of truly hard to transplant patients or whether this could create a new disparity. Dr. Ladin explained that the Ethics Committee considered who this policy is helping and that it is important in equalizing their chances, therefore they determined that multiple listing is valuable for patients who are difficult to match. Dr. Ladin concluded that the question of whether multiple listing would create a new disparity is not ethically concerning for all noted reasons.

A Board member asked how this white paper works in connection with the white paper to increase Transparency in Program Selection. The Board member commented that the committee's white paper on Transparency in Program Selection did not require transparency about all issues to all patients. They commented that because patients don't have full knowledge of the system before they're listed, they may not know where it is in their best interest to list. If a patient initially lists at one program and then learns of a different program that better suits their needs, they should not lose the advantage of where they listed first. The Board member noted that it is important to not only consider patients who are difficult to match but to also consider patients who may have difficult anatomical issues or issues that may require program expertise. They asked that the committee consider patients who decided to multiply list after some time of not being transplanted, who were then transplanted shortly after being

multiply listed. Dr. Ladin responded that the Transparency in Program Selection white paper characterized what areas were needed as examples for transparency. The overall premise of the paper states that there is an ethical imperative to give greater transparency to patients to allow them to make decisions and find the center that best meets their medical needs. The Ethics Committee sees the two white papers working in synergy and supporting a systems level ethics approach. The paper recommends multiple evaluations and once a patient finds the right center for them, there is no ethical justification for retaining priority at the prior center. A patient should be able to move to a new center if it is in their best interest. Dr. Ladin continued that she does not think transplant and OPTN Policy can level all the disparities seen across the healthcare system, but what the OPTN can do is ensure that the policies in place do not make the system worse for any patients.

A Board member stated that they believe the white paper did not account for transplant complexity or difficulty matching and thought that the paper does not provide full transparency on the transplant center side and that there are more that goes on behind the scenes at a transplant center than the paper accounts for. The Board member asked why the committee chose to answer the question of multiply listing now as they believe there are other poignant ethical questions that the committee could analyze first.

A Board member asked if multiple listing is something that is helpful to patients and whether the committee considered ways to help educate patients on resources on how to help them multiple list. Dr. Ladin explained that there already is a policy in place that requires transplant centers to notify patients on how to multiply list. She agreed that there could be better education developed for patients but does not think this is an area that can be addressed easily.

A Board member commented that whether patients should be allowed to multiple list is a minor issue, and if the ability to multiple list is taken away, there will still be patients who will travel to centers with lower waiting times and gain advantages because they are have the means to do so. They noted that they white paper may not accomplish what the Ethics Committee intended it to.

A Board member commented that they would not be comfortable removing a patient option until other areas were identified and measures of equity were taken. Dr. Ladin responded that the committee was also concerned about the potential of taking away a patient option and that the advantage some patients may receive from multiple listing is not well justified and contributes to disparities amongst patients. The Ethics Committee thought it was important to note that patients who are disadvantaged by multiple listing may not be participating in public comment. The committee thought it was important to recognize the potential limitations of the public comment process.

A Board member stated that the biggest challenge with this project is capturing one-off situations. Dr. Ladin agreed that implementation could be a challenge, but the scope of the Ethics Committee is to determine whether something is ethically justified.

Next Steps:

Post public comment changes are currently under consideration. The committee plans to finalize the paper during their April meeting.

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

Dr. John Lunz, Chair of the Histocompatibility Committee, presented the post public comment analysis on the proposal to Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors to the Board. The purpose of the proposal is to increase the safeguards for deceased donor typings. The committee asked the community whether labs would be able to run these tests in parallel or whether they anticipate an increase in time for HLA typing, whether a potential increase in turnaround time for

initial HLA typing would be worth the increased confidence in the results and the ability to confidently use virtual crossmatching, whether potential increased costs for confirmatory typing would be prohibitive, and whether the use of two different testing methods should be a requirement.

Dr. Lunz provided a summary of the public comment sentiment from each region, by each member type, and participation by state. Public comment showed that members were concerned about the burden this proposal this would put on members. There was also concern that the amount of supporting data felt insufficient to institute the requirement, which led to multiple recommendations for additional data to evaluate alternative measures. The Histocompatibility Committee is recommending the policy be withdrawn from Board consideration.

Summary of discussion:

A Board member commented that they understand the apprehension from the community because of the high cost associated with testing, but that they also think it is important to consider due to the transcription errors that could be minimized by the policy. They explained that these tests could help reduce organ non utilization. They encouraged the committee to continue their work and bring a more centralized message to the Board in June.

A Board member stated that they thought this was consistent with OPTN policy that already requires two donor blood typing tests and two recipient candidate blood typing tests. They commented that this is a policy that increases safety and is not only in the candidate's best interest, but it is also in the transplant system's best interest. They also suggested the committee consider how this is messaged to the community; noting that they attributed some of the negative feedback from the community to messaging.

A Board member stated that the main criticism around the policy is the lack of evidence that the 0.3% of cases these errors occur in are due to sample switches or sample issues. They agree that the OPTN should do everything it can to increase confidence in data integrity and patient safety, but there is no way to guarantee that this would fix the issue. They recommended that if the Histocompatibility Committee is going to continue this project, then they need to collect data to see if this policy could actually fix the issue. They recommended the committee determine what the errors were and the root cause of these errors to determine whether confirmatory typing is the appropriate route to follow.

A Board member agreed with others that the messaging of the project was an issue. They thought that because this was a situation around data errors and not around patient outcomes, that the committee must determine the patient risk and consider what the negative consequences could be with this extra step. They asked whether this extra step could increase the time of allocation or cause an increase in cold ischemic time.

A Board member commented that a concern from their Region was that the policy only seemed to fix a small number of cases without relevant data on patient outcomes. They suggested the committee provide more clarity in the data provided, to better exemplify and understand outcomes of multiple listing. As a Board, they think it is important that the Board sees how much the second test would cost in order to see if it is fiscally responsible, especially if it is not clear whether the second test twice will produce the results the committee is hoping for.

Another Board member commented on the feedback they heard from their region and said that their region thought that mandating the testing was an overreaction for what the committee is trying to resolve. Their region was also concerned whether there was any clinical relevance to the proposal because there was no evidence of this in the proposal. They were also concerned that the cost of performing these tests would be astronomical. The Board member concluded their statement by saying

that it is hard to see the patient safety benefit given what has been presented on this proposal, and that there is additional work for the committee to do.

A Board member commented that even though this policy would only impact a small percentage of patients, they asked whether the community is waiting for a big event to happen and affect a large percentage of patients for them to act. They agreed that this would be an expensive practice to implement but that is not a reason for the Board to not approve the proposal.

Next Steps:

The Histocompatibility Committee will meet in April to discuss alternative safety measures to propose for a future public comment cycle, and to discuss withdrawing the proposal from consideration for June 2023.

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

Dr. Edward Hollinger, Chair of the Network Operations Oversight Committee (NOOC), presented the committee's proposal to Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements. The purpose of the proposal is to increase the security of a broader OPTN Computer System ecosystem by increasing member security and establishing incident response requirements. The NOOC discussed who within their institutions should be engaged in the development of the proposal, whether the proposed phased implementation is feasible for members, what plans member institutions have to maintain operations in the case of a breach, and how transplant fits into this plan. Dr. Hollinger shared a summary of public comment feedback that was organized by region, member type, and participation by state.

Themes in the feedback highlighted the importance in securing of patient data, concern about access to the OPTN Computer System, concern and recommendations for end-user burden, concern about the timing of the proposed implementation timeline being too quick, and recommendations for alternative measures or considerations.

Summary of discussion:

There were no comments or questions from the Board on the proposal.

Next Steps:

Post-public comment changes are currently under consideration. The NOOC is considering potentially including training requirements in member's attestations instead of requiring duplicate training. The committee is also evaluating the scope of incident response planning and increasing the timeframe for the proposed phased implementation.

3. OPTN FY23 Budget and Fee*

Bob Goodman, member of the OPTN Finance Committee, and Dale Smith, UNOS Chief Financial Officer, presented the proposed budget and fee to the Board of Directors. Mr. Goodman presented the background on the budget and detailed the process to-date. He explained that the OPTN has continued to work with HRSA to develop the FY2023 budget and that this will be the third time the Board has submitted a budget proposal for FY23. He explained that the Board revisited the proposed budget after it was denied the first time in mid-September 2022. The Board then met in mid-October to reaffirm their original budget and fee proposal to be resubmitted to HRSA for the FY23 budget. The proposal was sent to HRSA on November 11, 2022. In February of 2023 HRSA denied the proposed budget from the OPTN for a second time. He noted that the OPTN is not working under a currently approved budget, but have been operating on the FY22 registration fee. After the budget was denied a second time, the Finance

Committee met on March 9 to consider budget reforecasts and voted to recommend that the OPTN maintain the OPTN Operating Budget amount of $72,482,500, excluding the $4.6 million dollars of PPP funds, and that the OPTN maintain the registration fee proposal of $944. He noted that the OPTN is currently billing the FY22 registration fee of $868; $76 lower than the budgeted and Board approved FY23 fee of $944.

Mr. Smith presented the reforecasts that were presented to the Finance Committee as potential options and explained what the reforecasts could mean across the OPTN. He noted that as of January, personnel expenses are under budget by $356K, purchased services are under budget by $1.8M, meetings and travel are under budget by $322K, and IT and telecommunications is over budget by $178K. He noted that staff went through an in-depth analysis with leaders in each department and asked what was causing the underruns, what they forecast for the rest of the fiscal year, and shared the results with the Board.

Mr. Goodman explained the Finance Committee's recommendation to the Board. The Finance Committee recommended that the OPTN maintain the previously submitted budget of $72.4 million so the organization can continue to uphold its commitment to support and improve the donation and transplantation system. After detailed review and discussion, the committee chose not to apply the $4.6 million PPP loan credit amount to the available funding in the OPTN budget. This decision resulted in a need for the committee to recommend the use of excess OPTN operating funds to compensate for the gap in available funding. Based on the reforecast, the areas that are under budget will have a reduction in budget, while categories with a forecasted increase in spending will receive an increased budget, which leads to a total proposed budget of $72.4 million. The committee's recommendation to adopt an OPTN registration fee of $944 aligns with previous proposals from June 2022 and October 2022. Once this fee is approved by the OPTN Board of Directors and HRSA, the $944 registration fee would be applicable for the remainder of the 2023 OPTN Fiscal Year.

Mr. Smith presented the proposed revised budget and illustrated how the committee voted on this proposal, and how the Board has voted on the budget the past two times. He noted that with four months of actual expenses in the reforecast, the committee was able to shift some money where necessary. One highlighted area was that at the beginning of fiscal year 2023, HRSA made a unilateral contract modification, so where there may have been room in the budget before (one to two million dollars), this amount will now be absorbed in the budget to account for the modification. The OPTN continues to work with HRSA to determine the best approach on how to handle the $4.6 million dollar PPP loan and how to return the money. The money may either be returned to HRSA or to the Small Business Administration (SBA). Ultimately, Mr. Smith shared that the recommendation from the Finance Committee was to not change the budget.

Mr. Smith explained the OPTN Reserve Fund and showed the bylaws that set the parameters for using this funding. He wanted to show the entire Board why the Finance Committee is not using these funds and what the bylaws state these funds may be used for. He informed the Board that the committee plans to create the Fiscal Year 2024 budget soon and the OPTN Reserve Funds will be analyzed then on whether the committee agrees with the use of the reserve funds.

Summary of discussion:

A representative from HRSA commented that HRSA told the committee the loan could not be applied to the OPTN budget line items based on HRSA's legal interpretation. They concurred that UNOS and HRSA are working together to return the loan and are trying to determine how this money may be applied in contract activities in the future but not by the OPTN itself. Mr. Smith commented that the committee decided to remove it from the budget and replace it with other funds. He stated that although UNOS

applied for the PPP loan, they applied due to the 40% drop in registrations during COVID-19. UNOS applied for the PPP loan to ensure employees had salaries, kept their jobs, and continued their work for the transplant community.

A Board member asked HRSA what they thought of the proposal for a $944 dollar registration fee. A representative from HRSA commented that they initially do not have an issue with the $944 fee, that their main concern was about the $4.6 million dollar line item.

A Board member asked for clarification on whether the proposal was to use the reserve or operating funds to balance the $4.6 million dollar PPP loan. Mr. Smith explained that they were proposing to use the OPTN Operating Funds. The Board member cautioned that the OPTN be careful about using reserve funds and staying true to the original intention behind a reserve fund. Mr. Smith agreed with the Board member that the reserve funds should be hard to access and should require specific circumstances to trigger access. Mr. Smith explained that in mentioning the OPTN Reserve Funds, he wanted to provide the Board with a preview of some of the conversations the Finance Committee will have when preparing the 2024 Fiscal Year Budget.

Another Board member asked for clarification on the difference in the budget now and the budget that was previously denied. They asked if the main concern was around the PPP loan because this is the only area where the funding in the budget has changed. Mr. Smith explained that the first time the budget was denied, HRSA did not think the OPTN had done a thorough enough job in explaining the budget to the Board, and HRSA was not comfortable with approving the budget. The second time the Board revisited the budget, they voted to send the same budget back to HRSA because the Board felt it necessary to continue to meet the promises to the community. The second time the budget was denied by HRSA, HRSA noted that their concern was about the $4.6 million dollar PPP loan. Thus, the third proposed budget removes the use of the $4.6 million dollar PPP loan, but still commits to the Board's original commitment of the $72.4 million dollar budget. A representative from HRSA commented that they expected an expedited review by HRSA because there were no changes to the overall budget and the line item concern of the $4.6 million dollar PPP loan has been addressed.

Vote:

> RESOLVED, that the OPTN Board of Directors approves the revised FY2023 OPTN budget and associated registration fee as recommended by the Finance Committee and directs the OPTN Executive Director to re-submit a statement of the OPTN's proposed registration fee to the Secretary.

Next Steps:

The Executive Director will organize the proposed budget packet and submit the proposed budget to HRSA.

Attendance

- **Board Members**
  - Adam Frank
  - Andrea Tietjen
  - Barry Massa
  - Bryan Whitson
  - Christopher Woody
  - Clifford Miles
  - Earnest Davis
  - Edward Hollinger
  - Dianne LaPointe Rudow
  - Heather Hunt
  - Irene Kim
  - Jeffrey Orlowski
  - Jerry McCauley
  - Jim Sharrock
  - Jonathan Fridell
  - Kelley Hitchman
  - Laurel Avery
  - Linda Cendales
  - Lloyd Ratner
  - Manish Gandhi
  - Maryjane Farr
  - Matt Cooper
  - Meg Rogers
  - Melissa McQueen
  - Nicole Hayde
  - Richard Formica
  - Robert Goodman
  - Stuart Sweet
  - Valinda Jones
  - Virginia (Ginny) McBride
  - Wendy Garrison
  - Willscott Naugler
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Frank Holloman
  - Shannon Taitt
- **UNOS Staff**
  - Alex Tulchinsky
  - Anna Messmer
  - Cole Fox
  - Courtney Jett
  - Dale Smith
  - Jacqui O'Keefe
  - James Alcorn
  - Jason Livingston

    - Liz Robbins Callahan
    - Maureen McBride
    - Morgan Jupe
    - Rebecca Murdock
    - Roger Brown
    - Susie Sprinson
    - Tony Ponsiglione
- **Other Attendees**
    - John Lunz
    - Keren Ladin