OPTN Transplant Coordinators Committee
Meeting Minutes
September 9, 2019
Richmond, Virginia

Sharon Klarman, RN-BC, B.S.N., CCTC, Chair
Stacy McKean, RN, B.S.N., CPTC, Vice Chair

Introduction

The OPTN Transplant Coordinators Committee met via in Richmond, Virginia on September 9, 2019 to discuss the following agenda items:

1. Greeting and Welcome to UNOS
2. OPTN Policy Oversight Committee Update and Project Themes
3. Learning Series Development
4. Public Comment Concept Paper Presentation: Continuous Distribution of Lung Concept Paper
5. Public Comment Proposal Presentation: Remove DSA and Region from Kidney Allocation Policy
6. Public Feedback Requested: Data Collection to Evaluate the Logistical Impact of Broader Organ Distribution
7. Committee Charge Discussion
8. Overview of OPTN Data Services Portal
9. Information Technology Update
10. Proposed Changes to U.S. PHS Increased Risk Criteria
11. Further development of public comment feedback
12. Effective Practices Discussion

The following is a summary of the Committee's discussions.

1. Greeting and Welcome to UNOS

The Vice Chair and UNOS staff welcomed committee members to UNOS headquarters in Richmond, Virginia. Members of the UNOS Executive Leadership team shared their welcome message and availability throughout the day.

2. OPTN Policy Oversight Committee Update and Project Themes

The Vice Chair gave a brief update regarding the recent discussions at the OPTN Policy Oversight Committee (POC), including the selected themes: continuous distribution, more efficient donor/recipient matching to increase utilization and improved equity for multi-organ and single organ candidates.

Summary of discussion:

The Vice Chair shared the charge of the POC has evolved over recent months. In addition to their core responsibilities, the POC has asked OPTN committees to consider those potential projects that are aligned with three themes:

- continuous distribution
- more efficient donor/recipient matching to increase utilization, and

- improved equity for multi-organ and single organ candidates

The underpinnings for the evolution of their change due to a change in the OPTN contract that reclassified the POC as an "OPTN operating Committee". This means the POC will have an increased role in strategic planning activities, prioritize OPTN policy development, coordinate policy issues that have broad implications across OPTN committees, and ensure that all OPTN governance groups consider and justify compliance with the requirements of the OPTN Final Rule. The POC will continue to evaluate policy proposals prior to public comment. The goal of these changes are to maximize the benefit of OPTN policy changes to the transplant community.

UNOS staff indicated the "ask" of all OPTN committees was to consider new project ideas during near-term calls and meetings. These will be used by the POC to build the project plan and portfolio. One Committee member shared a current challenge seen with pathologist interpretation of organ biopsies. There would be benefit to the OPTN developing clinical guidance on liver and kidney biopsies to reduce the variability in pathologist interpretation.

Next steps:

UNOS staff and Committee leadership will include new project brainstorming in a future call or meeting.

3. Learning Series Development

UNOS Professional Education staff members facilitated a discussion on the future modules for the Transplant Coordinators Learning Series available in UNOSConnect.

Summary of discussion:

UNOS staff began the discussion by thanking TCC for their contributions to the soft launch testing of UNet^{SM} University. Their feedback was very helpful and will be used to further improve the system.

Staff then profiled the results of the recent survey to identify priorities for future TCC learning series modules. Leading this project would be a module on *How to be Prepared for Site Surveys*. There was substantial interest in this topic outside TCC, but experts from the Committee will be required to make this an impactful offering.

A second module will follow later in 2020 to address OPTN Policy Development. Staff commented there is existing content on this topic use for new committee member orientation. The development of this module may not be as substantial a lift as a result.

Next steps:

Interested Committee members were asked to contact the Transplant Community Administrator with questions or to share their interest in participating on one of the working groups.

4. Public Comment Concept Paper Presentation: Continuous Distribution of Lung Concept Paper

The Vice Chair of the OPTN Thoracic Organ Transplantation Committee (Thoracic Committee) profiled a concept document out for public comment on the continuous distribution of deceased donor lungs. A concept document is s strategy used to solicit public comment on an initiative that may lead to policy development in the future. This concept document is not a proposed policy change or clinical guidance.

Summary of discussion:

The Vice Chair of the Thoracic Committee thanked the Transplant Coordinators Committee for the opportunity to present the concept document on the continuous distribution of deceased donor lungs. This is the first OPTN initiative that is following the OPTN Board of Directors framework for future organ distribution. The speaker described how the OPTN could move from a classification-based system to a

points-based system that considers multiple factors (e.g.: ABO compatibility between a donor and potential recipient, medical priority, ischemia time, placement efficiency, waiting time, candidate sensitization, and candidate age). The speaker then provided a synopsis challenges of organ distribution within the current system, an overview of the concept of a "composite allocation score" that was derived from the factors above, an example of how match run priority may look like using a composite allocation score, and the Thoracic Committee's plan of work in the months ahead.

The Vice Chair thanked the speaker for the insightful presentation and opened the floor for questions. Members shared the field experience following the most recent lung allocation policy changes was that both organ offers and subsequent declines of these offers have increased. The Committee expressed wider distribution may not correlate with increase in offer acceptances; this may mean that lungs are coming from donors at other locations as compared to today. There was agreement that elements of a composite allocation score cannot be equally weighted and members supported evidence-based approach to deriving these weights. The was broad interested in future monitoring metrics that would show program acceptance rates, cold ischemia times, transplant outcomes, and distances between donor hospitals and accepting transplant programs. They asserted that post-implementation monitoring include attention to transplant equity to ensure this is not decreased as a result of policy changes.

At the conclusion of the discussion, the Committee members were in agreement that the concepts profiled represented a good solution as compared to the current OPTN policy. Sentiment polling on the proposal reflected: 3 Strongly Support, 8 Support, 2 Neutral/Abstain, 0 Oppose, 0 Strongly Oppose.

Next steps:

UNOS staff will compile a summary of the Committee's feedback. A review by the Chair and Vice Chair will precede sharing this feedback with the sponsoring committee. The feedback will also be posted on the OPTN website.

5. Public Comment Proposal Presentation: Remove DSA and Region from Kidney Allocation Policy

UNOS staff members who support the OPTN Kidney Transplantation Committee thanked the Transplant Coordinators Committee for the opportunity to present the proposal to replace the use of donation service areas (DSAs) and regions in kidney distribution policy with a 500 nautical mile (NM) concentric circle.

Summary of discussion:

UNOS staff described how the proposal intends to solve two key problems:

1) DSAs and regions were never optimized for organ distribution. Because DSA and region weren't optimized for organ distribution, they may not fully comply with the Final Rule requirement that geography not impact access to transplant.
2) Disparity in equitable access to transplant for pancreas candidates. DSA is the largest factor related to disparity in pancreas allocation. This is significant because a majority of pancreas transplants are simultaneous pancreas kidneys (SPKs).

The speaker described a solution that was developed by the Kidney Committee. This "hybrid framework" for kidney distribution uses fixed distance circles with proximity points. The fixed distance circle and the proximity points awarded are based on the distance from the donor hospital to the candidate's place of listing. This solution was previously informed by public comment received on a concept document in the spring of 2019.

The speaker continued by providing a synopsis of the data illustrating the scope of the problem, elements of the proposed solution to the problem:

- the slide scale of proximity points,
- central point of a circle,
- compliance with the OPTN Final Rule,
- how medical urgency and import match runs would be addressed
- results seen in Kidney-Pancreas Simulation Modeling (KPSAM) from the Scientific Registry of Transplant Recipients (SRTR), and
- prioritization of pediatric kidney transplant candidates and prior living donors.

The Vice Chair thanked the speaker for the insightful presentation and opened the floor for questions. Members share their general understanding of the concept, adding greater clarity in points and circles would be beneficial (e.g.: simulated match run lists). Several members suggested the use of different sized circles influenced by the kidney donor profile index (KDPI) with several member supporting larger distribution circles for low KDPI donor kidneys. Other members expressed concern that that frequent use of a donor recovery center as the center of the circle could concentrate kidneys. To better support equity in access to transplantation, members suggested consistently using the donor hospital where the donor was identified rather than an OPO's recovery center. Members also mentioned managing import back-up is an added administrative responsibility for an OPO. This translates to the use of staff and financial resources that are unpredictable in nature. They suggested the UNOS Organ Center manage import offers to mitigate the potential for an importing OPO with low vested interest in allocating organs from a donor outside their DSA.

Transplant Coordinators Committee members expressed their support for a broader policy revision using the continuous distribution framework approved by the Board in December 2018. Such an approach may make more inroads to reducing lengthy candidate waiting times. The speaker acknowledged this sentiment and shared it was mentioned by many others in the past several weeks. In short, the current proposal to replace DSAs and regions with a 500 NM concentric circle centered on the donor hospital was a step in that direction. The speaker reminded the Committee the current proposal was intended to achieve greater compliance with the OPTN Final Rule and make what gains could be possible at this time. Future efforts, including the use of the continuous distribution framework, will be pursued. This could include opportunities to consider a "KDPI-circle size ratio" and factoring population density in organ distribution.

At the conclusion of the discussion, the Committee members participated in the sentiment polling for the proposal: 1 Strongly Support, 8 Support, 4 Neutral/Abstain, 0 Oppose, 1 Strongly Oppose.

The Committee then considered the concepts in the Pancreas Committee's proposal to also replace the use of donation service areas (DSAs) and regions in pancreas distribution policy with a 500 nautical mile (NM) concentric circle. Members were in agreement that pancreata are less resilient to ischemic time than kidneys. They disagreed with the mileage distance of 500 NM in the proposal. Alternatives of 100 or 250 NM were suggested.

The Committee was asked to consider two elements of the Pancreas Committee's proposal, 1) changes to facilitated pancreas placement, and 2) managing pancreas import back-up offers.

Members discussed the facilitated pancreas placement concept and agreed that the number of pancreata allocated through the facilitated placement mechanism is low. There was general agreement with the framework outlined for facilitated placement. Further clarification was requested whether this policy would apply to solitary pancreata allocated by the host OPO, for imported pancreata, or for pancreata included in a multivisceral graft. There was also general agreement with the changed proposed for pancreas import back-up.

One member supported post-implementation monitoring of pancreas transplant programs to assess for low case volume and meeting requirements of participation in the facilitated pancreas allocation program.

Next steps:

UNOS staff will compile a summary of the Committee's feedback. A review by the Chair and Vice Chair will precede sharing this feedback with the sponsoring committee. The feedback will also be posted on the OPTN website.

6. Public Feedback Requested: Data Collection to Evaluate the Logistical Impact of Broader Organ Distribution

The Chair of the OPTN Operations and Safety Committee profiled a request for feedback on possible changes to OPTN data collection. These changes would allow the OPTN to evaluate the impact of broad organ distribution in the U.S., and guide future policy making. This initiative is not a proposed policy change or clinical guidance.

Summary of discussion:

The Chair of the Operations and Safety Committee thanked the Transplant Coordinators Committee for the opportunity to profile this initiative. He provided a synopsis of the origins to this initiative, the recently approved guidance document, and a solution to address a gap in data collection that hampers the OPTN's understanding of the issue. This feedback request allows for the identification of data that will help with future analysis of broader distribution and ultimately help in the optimization of future allocation policies. The data collection changes may include:

- Transportation mode
- Organ transport time
- Who recovered the organ

The Vice Chair thanked the speaker for the insightful presentation and opened the floor for questions. Members shared two strategies that have been used successfully:

- The use of local recovery teams more frequently
- Training OPO staff to perform donor nephrectomies

The Committee shared that the increase frequency of traveling procurement teams adds complexity to scheduling and coordinating procurement procedures. Real world experience has seen an increase in operating room delays as a result.

The Committee suggested the following:

- Transplant programs would benefit from analysis of their STAR file data in order to see if the respective transplant programs acceptance practices (including ischemic time limits) are helping achieve desired recipient and graft survival outcomes
- OPTN gather and analyze the impact of organ preservation pumps on organ acceptance practices and outcomes
- Careful examination of actual organ departure and check-in times, to include an "out of ice" time for organs
- Carefully consider the impact of expedited procurements in the setting of donor decompensation, and that organ allocation may not start until *after* procurement

At the conclusion of the discussion, the Committee members shared their support for this initiative, that Deceased Donor Registration (DDR) forms may be the most intuitive, but not the only mechanism, to

collect this important data. TransNet[SM] may be another OPTN-based source for data. For transplant program-related data, the Transplant Recipient Registration (TRR) form may be a useful approach for perioperative data on "out of ice" or "back table" times.

Next steps:

UNOS staff will compile a summary of the Committee's feedback. A review by the Chair and Vice Chair will precede sharing this feedback with the sponsoring committee. The feedback will also be posted on the OPTN website.

7. Committee Charge Discussion

All OPTN committees have been asked to review their respective committee charges and provide feedback to the OPTN Executive Committee.

Summary of discussion:

One of the requirements of the new OPTN Contract is to re-examine the charges of the respective OPTN committees. Committees were asked to take a "first pass" to assess for currency of their work and offer updated member felt were appropriate. The Committee review the current charge and agreed that improvements could be made for clarity. Members felt it was important to reflect the diversity of their assignments. Additionally, there would be benefit to additional specifically regarding donors and families. Members were cognizant of balance being reflected in the charge and the need to avoid the appearance some element of their work was of lower priority or an "add on". They also expressed the need for the charge to reflect the Committee's central role to examine the impact of policy or bylaw changes, how to reflect these changes in the Learning Series, and the "value add" of collaborating with those who provide inpatient and outpatient care. UNOS staff appreciated these ideas and recommended reworking for the sake of read-ability. Members were in favor of seeing these types of improvements.

UNOS staff made modifications to a working draft of the change and the Committee viewed these modifications positively.

> *The OPTN Transplant Coordinators Committee provides recommendations to OPTN Committees and the OPTN Board of Directors to improve the quality, efficiency, and effectiveness of procurement and transplant coordination. With an expertise in operational efficiency, the Transplant Coordinators Committee offers feedback on proposed policies and bylaws, including the impact on implementation, the development of education for transplant coordinators, and the care of candidates, recipients, living donors, and their families.*

The Committee supported sharing this draft with the OPTN Executive Committee for their review later in the month.

Next steps:

UNOS staff will update the Committee on feedback from the Executive Committee. Further discussions on the Committee's charge will occur in the coming months. The OPTN Board of Directors will consider all committee changes during their December 2019 meeting.

8. Overview of OPTN Data Services Portal

UNOS Research staff members profiled the capabilities of the OPTN Data Services Portal.

Summary of discussion:

UNOS Research staff were asked to share a profile of services and reports available on the OPTN Data Services Portal. The goal of this presentation was to better inform members to the resources available

and enable use at their respective institutions. This included overviews of data analytics, data files and documentation, and a custom report builder.

In addition to the introduction to the Data Services Portal, a series of Tableau dashboards were shared that were openly available to OPTN members. Examples of the capabilities of the Tableau dashboards included a hypothetical liver kidney donor programs' donor follow-up, a waitlist management tool for kidney transplant programs, and the OPTN Recovery and Usage Maps.

A third series of data files tools were profiled that included the Kidney Offer Potential Tool, KAS Points at Transplant, a data validation report, expected follow-up forms report, and a report summarizing data fields that are used in a transplant programs' Program Specific Report (PSR).

The Committee was very appreciative of this information and thanked UNOS staff for their work.

Next steps:

UNOS staff will be available throughout the year for assistance with the Data Services Portal or other questions regarding OPTN data.

9. Information Technology Update

UNOS Information Technology staff members profiled two pilot programs that are currently underway.

Summary of discussion:

UNOS staff from the Information Technology (IT) department were invited to provide update on a pilot programs for DonorNet℠ Mobile for transplant programs. Staff described the role of the working group testing enhancements to a mobile device compatible environment that will allow transplant programs to view and respond to organ offers from deceased donors. A total of 17 transplant hospitals and third parties will be involved in the pilot program. Their feedback will be instrumental to enhancing organization of new offer notifications, the presentation of donor medical information, improvements to the offer and notification lifecycle, and user interface (UI)/user experience (UX) and its impact on behavior.

UNOS staff provided the members with a test environment to use on their respective mobile devices. Members viewed these enhancements very positively and enthusiastically supported wider use. The pilot is targeted to run through Q1 of 2020. Nationwide use is later in 2020.

Next steps:

UNOS staff will provide updates on these pilot programs during future calls or meetings.

10. Proposed Changes to U.S. PHS Increased Risk Criteria

The Committee was provided advance materials pertaining to the proposed changes to U.S. Public Health Service (PHS) increased risk criteria. The Committee shared feedback to aid in the development of a response from the OPTN.

Summary of discussion:

The Committee discussed the proposed modifications to the U.S. PHS *Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation*. The Committee is supportive of the proposed modifications as these will help identify those potential deceased and living organ donors with risk factors for HIV, HBV, or HCV infection. The Committee supports the reduction in risk period from 12 months to 30 days, and removing the identified elements as risk factors. The Committee understands the intent of the narrower testing period for potential living donors (from 28 days to 7 days) is to assess for new infection more proximate

to the donation procedure, thus reducing the risk of disease transmission. However, this shorter testing period requirement present substantial logistical challenges for transplant hospitals:

- It is imperative for transplant hospitals to identify potential donor comorbidities, or absolute or relative contraindications to living donation to weigh the risks/benefits of proceeding to donation. This requires substantial coordination to ensure comprehensive donor evaluation is performed in compliance with OPTN and institutional requirements. Inclusive of this process are screening and diagnostic testing for HIV, HBV, and HCV. Further, the testing period for HCV at many hospitals is 72 hours for final results to be reported, thus very close to the surgery date. It is simply not practical to condense components of this evaluation process so close to a potential surgery date.
  The Committee did discuss the use of other laboratories (e.g.: those used by Organ Procurement Organizations-OPOs) that may have testing ability with shorter turn-around time or those closer to out-of-town donors. While possible, the Committee felt this would present administrative, logistical, and financial challenges.
  - There is the logistical dilemma of locating another laboratory or hospital that would be willing to draw these blood samples from a patient that are not commonly drawn at facilities outside of the transplant community. If any of these were completed incorrectly, the process may need to be repeated. In addition, if these tests could not be completed in the time frame recommended, it would result in the inability of the donor to proceed and the transplant program losing the potential scheduled surgery date.
  - Billing and inclusion on a transplant hospital's Medicare Part A cost reports may also be challenging. The reimbursement of those laboratory tests through a third party at the organ acquisition rate already stand to be difficult and are commonly turned down when requested in less time sensitive events (e.g.: screening labs to begin a donor evaluation).
- Many living donors travel to a transplant hospital for donor evaluation and subsequent donation. It is unrealistic to require a potential living donor to travel to a transplant hospital for the aforementioned testing within 7 days of the donation procedure, then either stay in the local area or travel again to the transplant program. This would be additional strain emotional and financial to the donor and their family.

The Committee requested clarifying what types of HIV, HBV, and HCV testing is required within the 7 day period prior to donation.

The Committee appreciated the opportunity to provide feedback to the OPTN Disease Transmission Advisory Committee. While outside the scope of the federal regulation and more appropriate for an OPTN initiative, the Committee feels there is a need in the transplant community for guidance how to appropriately and effectively communicate the risk with transplant patients. The Committee remains ready to assist with developing guidance or contributing to policy work as a result of changes to these federal regulations.

Next steps:

UNOS staff will compile a summary of the Committee's feedback. A review by the Chair and Vice Chair will precede sharing this feedback with the Disease Transmission Advisory Committee.

11. Further development of public comment feedback

This agenda item was deferred due to meeting time constraints.

12. Effective Practices Discussion

This agenda item was deferred due to meeting time constraints.

The Vice Chair thanked the attendees for making the trip to UNOS headquarters and for contributing to this engaging event. With no further business to discuss, the meeting was adjourned.

Upcoming Meetings

- Conference calls Third Wednesday of each month from 2-3 PM (Eastern)
- Winter/Spring In-person meeting – TBD, Chicago, IL