OPTN Organ Procurement Organization Committee
Meeting Summary
June 9, 2022
Conference Call

Kurt Shutterly, RN, CPTC, Committee Chair
PJ Geraghty, MBA, CPTC, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 06/09/2022 to discuss the following agenda items:

1. Recognition of Outgoing Members
2. OPO Education for Implementation of Continuous Distribution of Lungs
3. Kidney-Pancreas Continuous Distribution – Feedback on Dual Kidney and Released Organs
4. Donor and Recipient Information Sharing
5. New Project – Offer Acceptance Limits

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

1. Recognition of Outgoing Members

The Committee recognized outgoing Committee members and thanked them for their service.

Summary of discussion:

The Chair of the Committee thanked outgoing Committee members for their participation.

2. OPO Education for Implementation of Continuous Distribution of Lungs

The Committee received a brief overview of the Continuous Distribution of Lungs project, and provided input on pre-implementation education for OPO members.

Presentation Summary:

The continuous distribution of lungs project converts classification based allocation of lungs, which has hard boundaries, to a continuous system of allocation. In this system, all candidates are ranked continuously based on a composite allocation score. This will include updates to heart-lung, lung-liver, and lung-kidney allocation. The Continuous Distribution of Lungs is slated for implementation in earl 2023.

In the modeling performed by the Scientific Registry of Transplant Recipients (SRTR), the largest impact of the new allocation system was a significant reduction in waitlist deaths. Two-year post-transplant survival was equivalent. While the median distance from donor to recipient is increased, the percent expected to fly (travel more than 75 nautical miles) is slightly less. This is likely because the continuous distribution system does not treat all candidates within 250 nautical miles as equal distance from the donor hospital as the current system does. The modeling would suggest a slight increase in transplants occurring closer to the donor hospital.

The impact of placement efficiency weight on waitlist and post-transplant deaths was also considered. In general, the more weight placed on placement efficiency, the higher the number of combined waiting

list and post-transplant deaths. The impact of lowering the proximity weight diminishes around 10 percent, and there are less gains in terms of survival by lowering the weight on placement efficiency farther. A 10 percent weight was given to placement efficiency.

Heart-lung allocation in continuous distribution will be similar to current heart-lung policy, but will require offering from the lung match run instead of giving an option. The proposed policy requires hearts to be allocated to all Status 1 and 2 candidates within 500 nautical miles of the donor hospital. Following this, the heart must then be offered to any heart-lung candidate with a Lung Composite Allocation Score (CAS) of 28 or higher. This is different from the current system, which is less clear and results in significant variability in how hearts are then offered to heart-lung candidates. Required shares will be indicated on the match run. The new policy will provide clearer direction to OPOs. The Committee chose a Lung Composite Allocation Score cut off of 28 based on how many of the historically performed multi-organ transplants that it would include, specifically 90 percent of currently performed heart-lung transplants.

For other multi-organ combinations, including lung-kidney and lung-liver, similarly the OPO would offer the kidney or liver to any multi-organ candidate with a Lung Composite Allocation Score of 28 or higher. This score encompasses 98 percent of the small number of historically performed lung-kidney and lung-liver transplants.

Summary of discussion:

One member asked what the average patient's CAS was at time of transplant, particularly in terms of how long the match run would be and how to best prioritize multi-organ combinations. The member noted that there are still many questions regarding multi-organ allocations, including when an OPO begins allocation while the lungs are not transplantable, but later are able to heal the lungs and allocate them as transplantable lungs. The member continued that in this scenario, family time constraints must also be considered.

Staff explained that analyses are being performed to help the community understand what currently listed candidates' CAS will look like. Staff continued that the CAS threshold for multi-organ transplant is intended to capture those candidates who are currently receiving multi-organ transplants, which isn't a large volume of patients for lung-kidney and lung-liver. Staff shared that, while policy doesn't currently prescribe allocation order where there are multiple multi-organ combinations and candidates, the OPTN Ad Hoc Multi Organ Transplantation Committee is discussing how to clarify multi-organ allocation and prioritization of multi-organ combinations. Staff noted that, in terms of starting allocation while lungs are not transplantable, member education and policy will be clear that OPOs will not be penalized in the event of late turn downs. If the heart was placed alone and the lungs were placed separately, and then the heart offer is declined and the next candidate is a heart-lung candidate, as long as the lungs are placed elsewhere and thus not available, there is no expectation for the OPO to pull the lung candidate's primary offer.

The member remarked that it can be difficult to make primary offers, particularly for kidneys, with a lot of potential multi-organ candidates further down the match runs.

One member noted that the "placement efficiency" attribute wasn't highly weighted, and the median nautical miles is expected to increase from 190 to 350 nautical miles. The member explained that this is an impact on OPOs, particularly on case time, or the amount of time it takes from donor consent to recovery of the organs. The member continued that aircraft availability is severely limited, and the expanded median distance from donor hospital to transplant program will strain already limited access to air transportation.

A member agreed, and expressed concern that travel logistics have not been appropriately considered. The member shared there have been several instances where their program has had difficulty accessing air transportation, even contacting several vendors. The member remarked that transportation issues often make it difficult for OPOs to coordinate donor care and finalize allocation, leading to late declines and expedited placement.

Another member agreed, noting that there are finite aircraft and few thoracic recovery surgeons, and so transplant teams themselves will need to fly out to the donor hospital, extending case times. The member noted that this could be a burden on OPOs and transplant programs. Another member agreed, adding that it is an increased burden on all resources for staffing.

The member commented that donor families' wishes are the biggest concern when considering impact on case time. Another member agreed, adding that many times authorization isn't given or is rescinded because of the extended case time, particularly if there is inefficiency in placement. The member continued that inefficiency in placement and recovery can create barriers for donation. The member explained that, if the case timeline can't be guaranteed and the families' wishes respected, the donation won't happen. The member added that lung donors are often lost simply because the OPO can't efficiently allocate lungs in a sufficient amount of time to honor a family's wishes.

Another member asked if there seem to be more families withdrawing consent due to extended allocation time, or if this trend is more anecdotal. Several members agreed that they have seen an increase in families withdrawing consent.

One member remarked that transplantable lungs and livers aren't being recovered because they can't be placed in the appropriate timeframe for the family. The member noted that the more inefficient placement becomes, the more common this could become. The member expressed support for the Continuous Distribution of Lungs, but noted that there should be a mechanism in policy for OPOs to make aggressive offers, in order to place and recovery a transplantable organ. Another member agreed, but noted that many bigger institutions have access to their own private aircraft, and such a process could disadvantage smaller programs. The member shared that typically, they evaluate and make a decision on organ offers quickly, but struggle to find aircraft in a rapid timeframe. The member expressed concern that smaller programs would be bypassed because of logistical challenges, as this would be unfair to the patients listed at the smaller programs. Another member agreed.

A member added that OPOs are also struggling to access operating rooms for recovery with local hospitals operating at capacity, which is also leading to increased case times and loss of authorization. The member noted that this is not unusual for donation after circulatory death (DCD) donors in particular, as these donors can't be moved to an independent recovery center.

One member remarked that issues with access to air transportation have become significant, and appreciated that this feedback will be taken back to the OPTN Lung Transplant Committee.

A member recommended the OPTN create relationships with the aviation industry as a whole to solve transportation challenges. The member remarked that allocation has placed too much emphasis on equity, to the detriment of utility considerations.

3. Kidney-Pancreas Continuous Distribution – Feedback on Dual Kidney and Released Organs

The Committee discussed dual kidney and released organ allocation policies and how to appropriately and effectively transition these policies into a continuous distribution framework.

<u>Dual Kidney Presentation Summary:</u>

The Kidney Committee has reviewed monitoring data on OPTN Policy 8.6.A: Allocation of Dual Kidneys, and noticed that many dual kidneys are allocated out of sequence. The Kidney Committee has begun discussions on this policy in the context of ongoing discussions in the development of continuous distribution.

Before the current Dual Kidney Allocation policy was implemented in 2020, previous policy required an OPO to offer kidneys individually before offering both kidneys to a single candidate, unless the deceased donor met at least two of the following criteria:

- Age is greater than 60 years
- Estimated creatinine clearance is less than 65 mL/min based on serum creatinine at admission
- Rising serum creatinine (greater than 3.5 mg/dL) at time of organ recovery
- History of longstanding hypertension or diabetes mellitus
- Glomerulosclerosis greater than 15 percent and less than 50 percent.

Summary of discussion:

One member remarked there are significant challenges with allocating dual kidneys, explaining that, by the time allocation reaches the dual kidney classifications on the match run, the kidney is too cold and is declined by evaluating programs. The member noted many of these programs would have accepted those organs as dual if they had lower cold ischemic times. The member commented that the current dual kidney allocation policy isn't efficient, and doesn't accommodate allocating to dual kidney recipients fast enough. The member added that there is an onus on the transplant program side as well, as some programs accept dual kidneys and then determine that the kidneys should be split and transplanted singly. In this case, the transplant program should have accepted the single kidney to begin with. The member noted that the inefficiencies of the current dual allocation policy most heavily impact hard to place and high KDPI kidneys. Another member agreed.

A member shared that their OPO could not place a medically suitable pair of pediatric kidneys due to size. The member explained that transplant programs need to not opt in candidates to receive dual or en bloc offers if the program does not actually want to accept those organs for those candidates.

One member explained that OPOs want control over when the switch from single kidney allocation to dual kidney allocation occurs. The member noted that some transplant programs are eager to accept a dual kidney offer early on in allocation, when there is still potential opportunity place the kidneys singly and achieve two transplants instead of just one. The member continued that many programs declining for a single organ have candidates at a dual classification further down the match run, and that proactive, pre-recovery communication on the part of the transplant program in terms of declining single offers and remaining open to dual kidney offers is critical to effective allocation of these hard to place organs. The member explained that time is critical for hard to place kidneys, and that dual allocation could be an effective method to placing these organs. The member shared that their OPO allocates very few dual kidneys each year, and they are relatively few and far between. The member added that those centers who are interested in accepting dual kidney offers are typically only interested for organs that can be placed and transplanted singly and separately. The Chair agreed, noting that time is a critical factor. The Chair shared that it is a common experience for centers to decline dual kidney offers and point to cold ischemic time as the biggest factor in their decline.

The Vice Chair agreed that proactive communication is critical in considering dual kidney allocation. The Vice Chair explained that their OPO proactively asks evaluating programs if they would accept the kidneys as a dual offer later one, and encourages programs to be proactive in expressing their interest in receiving a dual kidney offers. The Vice Chair recommended that dual kidney sequences should placed

higher up on the match run, to increase the efficiency of allocation overall. The Vice Chair noted that allocation time isn't well spent offering to single kidney classification candidates for whom it's known the transplant program will not accept the single organ.

Released Organ Presentation Summary:

OPTN *Policy 8.8: Allocation of Released Kidneys* allows the OPO to continue allocation of the released kidney according to the original match run, allocate the kidney using a new released match run, or contact the OPTN for assistance allocating the kidney.

OPTN *Policy 11.8: Allocation of Released Kidney-Pancreas, Pancreas, or Islets* allows the OPO to continue allocation according to the match run, contact the OPTN for assistance allocating the organs, or allocate the kidney-pancreas, pancreas, or islets to a potential transplant recipient at the transplant program that originally accepted the organs. If allocating a pancreas alone potential transplant recipient at the same program, the kidney must allocated according to *Policy 8.8: Allocation of Released Kidneys*.

Summary of discussion:

One member shared that their OPO requires accepting programs to identify a back-up candidate at their program, should their intended recipient become unsuitable for whatever reason. The member continued that their OPO ensures there is an understanding of the accepting program's intent for preservation, pump, and re-biopsy of the kidney. The member explained that it's rare, likely less 5 percent of the time, that an accepting program ends up transplanting their back-up candidate, but that it's helpful to utilization in these rare cases. The member remarked that the current released kidney allocation policy is inefficient, and can contribute to increased cold ischemic time and likely more hard-to-place kidneys. The member pointed out that there is no time requirement on the program to notify the OPO that they can't or won't transplant the kidney, limiting the transplant programs' accountability in the utilization of an organ. The member shared a recent example, where an accepting program declined a kidney at 44 hours cold ischemic time because of a recipient issue.

Another member agreed, sharing a similar situation where a transplant program declined a kidney at 22 hours of cold time for a positive crossmatch, after back-tabling the kidney. The member expressed support for an accountability timeframe for transplant programs. The member shared that their OPO is conservative with open offers or local back up, unless the distance and cold time preclude the organ from being effectively reallocated. The member emphasized that their OPO tries to follow the match run as closely as possible, as there could be a suitable candidate in between the originally accepting candidate and the accepting transplant program's back up candidate.

One member agreed that late declines from transplant programs for recipient issues are problematic and too common, sharing that their OPO often experiences transplant programs declining at high cold ischemic times for a positive crossmatch. The member commented that local back up is important to reallocating released kidneys. The member added that lack of tissue typing material is difficult, and that there is little the OPO can do to be proactive about tissue typing. An OPO can send material to the first four transplant programs on the match run, but those programs are crossmatching for highly sensitized candidates and could be very far away. The member remarked that maximization is critical to consider with allocation of hard to place kidneys, as cold ischemic time makes allocation of medically complex kidneys even more difficult.

Several members agreed that local back up is an important option to consider in reallocation. The Chair agreed that local back up, though not currently in policy, is important to utilization of kidneys that may otherwise not be utilized for transplant at high cold ischemic times. Another member pointed out that currently, local back up requires a lot of administrative resources in terms of the OPTN developing a

request for a response regarding out of sequence allocation and the OPO having to develop that response. The member continued that this requires a significant amount of man hours that could be avoided, particularly when the organ was more than likely re-allocated to the most appropriate recipient given cold ischemic time and logistic considerations. Another member agreed.

A member emphasized the importance of accepting program accountability in terms of confirming or releasing an accepted kidney once it's been shipped to the program.

4. Donor and Recipient Information Sharing

The Committee discussed current challenges and potential solutions to gathering and sharing recipient information with donor families.

Summary of discussion:

Staff explained that one Committee member asked to discuss information sharing between OPOs and transplant programs, in order to share the status of a donor family's gift, and wanted to know if other OPOs are encountering problems attempting to gather graft status and recipient information from transplant programs.

One member shared that their OPO is encountering similar issues.

The Chair noted that their OPO can typically get the recipients' demographic information, but less on the status of the recipient. The Chair continued that some OPOs send an 18 month follow up letter. Another member remarked that many programs are protective of their patient information, and won't share it unless mandated. Another member agreed, sharing that there is a lot of variation in practice by both OPOs and transplant centers. The member noted that many programs are protective of sharing clinical or psychosocial details, and many want to receive direct consent from the patient to share that information. The member pointed out that it can take months to answer basic questions a donor family may have about their loved ones' gift.

The Vice Chair shared that their OPO will pull the information available in the OPO report in the OPTN Computer System, such as the state the organ was transplanted in and whether the graft is functioning, and share that information with the donor family. Another member commented that their OPO will request information from a transplant program once, and then will only pull and share the information available in the OPTN Computer System. Another member agreed that their OPO does the same thing.

The member explained that this is complicated for both transplant programs and OPOs. The member explained that transplant program coordinators have other work and patient management, and managing these requests can be difficult. The member noted that standardization of how to manage these requests and type of information sharing would be helpful, as it can be time consuming to determine what legally can be shared and what is available. The member shared that their OPO will share the minimal information available with the donor families, but that this is often not necessarily what the recipients or donor families wants. The member noted that there is a time commitment aspect to this information sharing that is difficult for both OPOs and transplant programs. Another member agreed that this is a time consuming process, and there is a lot of room for improvement.

One member pointed out that it has become easier to triangulate with even limited patient information, and this typing of information sharing can be tricky. Another member agreed.

The Chair remarked that it would be helpful to have the OPTN release some kind of guidance or standardization. The Chair noted that, unless there is a directive to do it, these problems will persist.

One member recommended the creation of a website where donor families and recipients could be linked via an ID and determine themselves if they want to connect. Otherwise, there is just basic information. The member commented that this would give people who want to interact the opportunity to do so. The member noted that having OPOs and transplant programs between the donor families and recipients is difficult. Another member agreed with the recommendation. Another member agreed, but noted that there may not be enough impetus to build such a website.

Staff noted that there is a guidance document from 2012 on the OPTN site, which the Committee could review to determine if the guidance is still relevant and appropriate, and then determine potential next steps. One member remarked that the guidance is old and likely outdated, and should be reviewed. Other members agreed, and volunteered to participate in a review of the guidance document.

5. New Project – Offer Acceptance Limits

The Committee discussed a potential new Committee project to limit the number of offers accepted for a candidate to one, reduced from the current offer acceptance limit of two.

Presentation Summary:

OPTN Policy 5.6.C: Organ Offer Acceptance Limit:

For any one candidate, the transplant hospital can only have two organ offer acceptances for each organ type. The host OPO must immediately report transplant hospital organ offer acceptances to the OPTN.

Summary of discussion:

One member expressed support for this project idea, but noted there could be information technology (IT) implementation costs associated with this project. Staff shared that the OPTN Policy Oversight Committee considers the resource costs of each project in context with the other in-progress projects.

The Committee achieved consensus in support of a new project to reduce the offer acceptance limit.

Upcoming Meeting

- July 20, 2022 – Teleconference

Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Catherine Kling
  - Chad Ezzell
  - Chad Trahan
  - David Marshman
  - Deb Cooper
  - Erin Halpin
  - Jennifer Muriett
  - John Stallbaum
  - Larry Suplee
  - Malay Shah
  - Mary Zeker
  - Meg Rogers
  - Sue McClung
  - Valerie Chipman
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Ajay Israni
  - Katie Audette
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Darby Harris
  - Heather Carlson-Jaquez
  - Joann White
  - Katrina Gauntt
  - Kaitlin Swanner
  - Lindsay Larkin
  - Elizabeth Suskind
  - Lloyd Board
  - Susan Tlusty