OPTN Patient Affairs Committee
Meeting Summary
March 11, 2022
Conference Call

Garrett Erdle, M.B.A., Chair
Molly McCarthy, Vice Chair

Introduction

The Patient Affairs Committee (the Committee) met via Citrix GoToMeeting teleconference on 03/11/2022 to discuss the following agenda items:

1. *Public Comment Item*: Continuous Distribution of Kidneys & Pancreata Request for Feedback, and Discussion
2. Kidney/Pancreas Continuous Distribution Focus Group Preparation
3. *Public Comment Item*: Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation, and Discussion

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

1. *Public Comment Item*: Continuous Distribution of Kidneys & Pancreata Request for Feedback, and Discussion

The Committee heard a presentation delivered by the ex officio post-chair of the Pancreas Committee on their request for feedback, *Continuous Distribution of Kidneys & Pancreata Request for Feedback*. The link to the full request for feedback, as well as the public comment feedback, can be found on the OPTN website.

Data summary:

This request for feedback seeks community input on candidate attributes and attribute weightings to be considered for the kidney composite allocation score.

Summary of discussion:

The Committee's review team provided a number of key takeaways from the proposal: first, that there should be no cap to the amount points a candidate can receive for waiting time. It was understood that this may unintentionally incentivize programs not to consider "less than perfect" offers, as wait time would only to increase a candidate's score with no cap, but the review team felt that the increased priority for candidates on dialysis for extended periods of time outweighed this potential downside. Additionally, the team did not have a clear decision on whether a candidate's wait time should be weighted differently if they were on or off dialysis. Members offered feedback that patients on dialysis often are in the greatest need for transplant, voicing support for different weightings, whereas others noted that medical urgency would cover most urgent dialysis patients. In addition, different weightings could negatively impact the timing of a candidate being referred for transplant.

The review team had a number of comments surrounding the use of the post-transplant survival attribute; notably, members questioned whether the attribute was too heavily impacted by other factors to be an attribute in and of itself. Furthermore, there appears to be a lack of clarity of the factors that contribute to the post-transplant survival likelihood – should those factors be considered

independently, rather than conglomerated as a whole? Finally, the team did not have any other attributes they felt should be considered as essential, but supported continued monitoring as the framework evolves.

A member inquired whether factors outside the clinical had been considered in the Kidney & Pancreas Committees' discussions. The presenter responded that the score calculation is extremely multifaceted, as there are multiple factors that play into need, outcome, and post-transplant survival. In addition, there is a level of unpredictability, especially within post-transplant survival, that the scoring attributes have to be ones that are independent and quantifiable. The member also asked whether travel time should have an impact on allocation, as data has started to be gathered surrounding organ usage in comparison to travel duration. The presenter acknowledged that, again, this is difficult to quantify, as travel distance does not always correlate to total cold ischemic time; for example, an organ may wait at a program due to recipient-side delays. Staff added that an OPTN Operations and Safety Committee proposal had been approved at the Board of Directors meeting in December of 2022 to further investigate travel data and the organ GPS tracking pilot project still was ongoing.

A second member wondered whether prior transplant recipients who required a second organ not in the context of a "safety net" kidney would receive priority. The presenter replied that, outside the context of a "safety net" kidney, no points would be granted to previously transplanted patients. They added that the OPTN Multi-Organ Transplantation Committee had a proposal out for public comment on guidelines for the allocation of heart-kidneys and lung-kidneys which would mirror the existing framework for liver-kidney allocation. However, they concluded by noting that the "beauty" of the continuous distribution framework was the flexibility in which these kinds of changes could be included – in the future, the community may decide that candidates should get points for being a previous transplant recipient.

A third member asked how much priority would be granted to prior living donors in the continuous distribution framework, mentioning that, when they received a living donor kidney, they were told the kidney donor would be put at the top of the kidney waitlist if they require a transplant. The presenter answered that, in the current system, being a living donor grants the donor four points, which is equivalent to four years of wait time. However, this no longer puts candidates at the top of some blood group waitlist. They personally hypothesized that a possible solution could be to grant living donation points based off of blood type, to ensure the donor goes to the top of the list, but acknowledged there were a number of factors in play. The Vice-Chair wondered how likely it was that prior donors would require a kidney transplant, to which the presenter responded it was "not that likely". Staff also contributed that the number was not a large population.

Next steps:

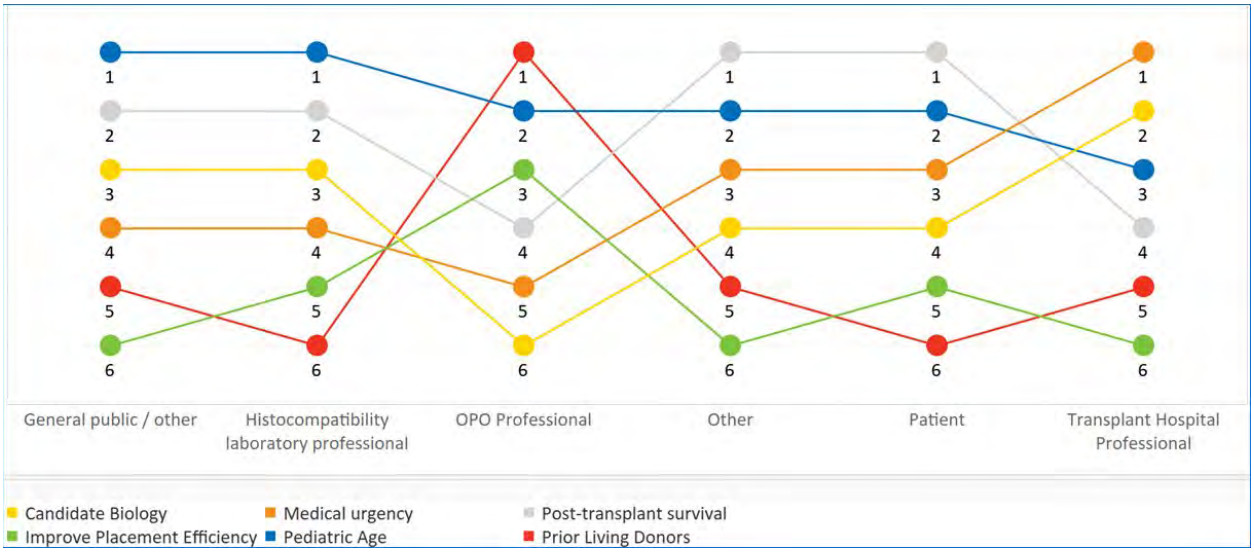
The Kidney & Pancreas Committees will consider the feedback from the Patient Affairs Committee.

2. Kidney/Pancreas Continuous Distribution Focus Group Preparation

UNOS Staff briefed the committee on the upcoming patient focus group where they will break down the patient perspective regarding results from the analytic hierarchy process (AHP) exercise.

Data summary:

The Committee considered the following breakdown of AHP feedback gathered from the lung exercise.



The goal of the patient focus group is to isolate the patient perspective, which may not be as well represented across committees, but could be a large source of responses. Similar to how OPO Professionals responded significantly differently than other groups represented on the graphic, the Committee could help break down the reasoning behind any drastically different responses. This would help the Kidney & Pancreas Committees gain an informed opinion that represents patients.

Summary of discussion:

A member wondered what the response would be from the Committee if there were a significant portion of conflicting responses. Additionally, does this survey bind the sponsoring committee to any specific action? The presenter acknowledged that the AHP exercise comprises only one piece of information among many. While it can be used to help determine the direction the sponsoring committee should consider, it does not bind that committee to any response.

A second member speculated that there could be inconsistency amongst organs, noting that in the lung AHP exercise graphic, Post-Transplant Survival rated most highly among the patient population, but likely would not share a similar position in the kidney and pancreas framework. The presenter responded that this was absolutely true, and could be used as an indicator of where to study for updates to organ-specific frameworks; for example, if all organs except for one highly prioritize post-transplant survival, it could indicate that the one organ where it is not prioritized needs better modeling. The member contributed that they felt that post-transplant survival rate would likely be very highly ranked among members of the general public since it serves as a "utility function" – recipients do better with an organ that will function well than either remaining without one, or being transplanted with a marginal organ. The Vice Chair agreed with this perspective, noting that when donors decide to become a donor, they imagine the continued use of their organs improving the long-term quality of a recipient's life.

The same member noted that there may be factors that could drive medical decisions that were not based off of clinical needs. For example, they considered, end stage renal disease patients' treatment is paid for by the government, which could incentivize some programs to list more kidney candidates

earlier. As a counterpoint, they considered heart transplant candidates "who aren't even listed until they're within a year of death". The presenter reiterated this was a further reason for why, in this version of continuous distribution, weights and attributes would not be the same across organ types. They further speculated that it may not ever make sense in the future to align weights and attributes, as each organ has specific needs.

The Chair wondered what the review process for the allocation system would look like moving into the future. The presenter responded that, similar to how the current allocation policies change through proposals approximately every 3-5 years, continuous distribution would likely have approximately the same update cadence. They went on to add that each organ has a table in which all the attributes and weightings can be updated relatively easily. The Vice Chair then asked if there was ongoing monitoring of the impact of this proposal, similar to a dashboard. The presenter replied that there were both short term reports available, as to the specific numbers of organs transplanted daily, as well as long term reports, which would report the overall effect of the policy on that organ. The Vice Chair advocated for close monitoring, considering that lots of patients can be impacted even within a short review period.

The Chair also asked if the presenter could give a preview of what would be asked of the Committee following the conclusion of public comment. The presenter stated that, once the AHP exercise has been concluded, they will approach the Committee and discuss where patient responses differed from other demographics. Additionally, they added that it would be in the context of a discussion, in which members may be asked to argue a point contrary to what they reported on the survey. In this manner, the sponsoring committee hopes to isolate why patients feel a certain way about specific attributes and garner a unified opinion.

Next steps:

The Committee will take the AHP exercise and prepare to discuss their responses.

3. *Public Comment Item*: Establish Eligibility and Safety Net Criteria for Heart-Kidney and Lung-Kidney Allocation, and Discussion

Data summary:

This proposal will determine specific eligibility criteria for candidates to qualify for a "safety net" kidney when receiving a heart or a lung transplant. This ensures there is clinical justification for allocating multiple organs to one candidate. Furthermore, this will help protect kidney-alone candidates who would otherwise not receive an isolated kidney if a heart or lung-kidney would take it. The link to the full proposal, as well as the public comment feedback, can be found on the OPTN website.

Summary of discussion:

The Committee review group agreed that a key purpose of the proposal should be to ensure single organ transplant candidates feel confident that multi-organ transplant candidates are not unfairly being prioritized. This, again, returns to the need for clinical justification when performing multi-organ transplants. The review group did feel that the criteria outlined by the proposal were clear and the framework made sense, as there were instances where patients needed another organ following an initial transplant; additionally, the wait time for this second organ should be shorter due to the chance of the initial transplant becoming worse during that period. They had general support for the proposal provided there is ongoing review of post-transplant outcomes for multi-organ transplants to determine if the policy is functioning as intended.

The Chair noted that they had also sat in on the Multi-Organ Transplantation Committee meetings, and felt much more comfortable with the proposal once they realized that the "safety net" kidneys were not

allowed to be the best kidneys available. They also supported the unification of rules for heart, lung, and liver to ensure consistency across multi-organ transplants. Additionally, they felt that the patient community will be more supportive of multi-organ transplants once they see specific guidelines outlined for "safety net" kidneys; anecdotally, they noted there was a possible misconception currently that multi-organ transplants would take kidneys from single organ transplants in instances when it was not required. They concluded by asking what the review process will be to ensure that multi-organ candidates have clinical justification for their transplants. The presenter responded that, first, the OPTN has audits to ensure that transplants are performed with clinical justification, and, second, every 3-5 years, each program has a site survey to review all of the transplants performed.

A member inquired how programs will be able to innovate, noting the presence of triple organ transplants, with these new policies. The presenter answered that, at present, there are no guidelines for heart-kidney and lung-kidney transplants outside of clinical judgement; at this point, the community is past the point of innovation and needs to start considering standardization. Furthermore, the policy was developed to ensure fairness in organ distribution, and it does not disallow innovation. They noted that there were always possibilities for innovation, anecdotally mentioning the recent investigations into xenotransplant that had occurred. To conclude, they said they personally felt that the rules were not so stringent as to stifle innovation.

A list of questions was provided by the review team, which the presenter addressed:

- Why has there been a two times increase in heart-kidney transplants since 2016?
  The presenter responded that this is likely due to an increased level of intensive care unit (ICU) capability, which enables programs to consider sicker patients for transplant. However, they also pointed to the overall percentage of multi-organ transplants as a part of the whole number of kidney transplants: since 2016, the ratio has remained constant around approximately 11%.
- Who reviews multi-organ transplants, to make certain all rules were followed?
  The presenter noted they had answered this question earlier in the presentation.
- What is the sample size for the review? What does the data show for multi-organ transplants from 2011-2015?
  The presenter replied that there is an ongoing review process for all policy changes that tracks the changes in a six-month, 1 year, and 2 year monitoring report. The data for multi-organ transplants shows that kidney-pancreas rates decreased, whereas liver-kidney, heart-kidney, and lung-kidney all increased over the four years. However, they did refer to their answer to the first question that the overall rate of kidney transplants has also increased, so part of the increase is due to the availability of more kidneys.
- Tell us more about the safety net protections where transplant program is late in reporting and/or did not register in 365-day window?
  The presenter clarified that a "safety net" kidney is when a patient requires a kidney transplant following an initial transplant because their kidney function suffers as a result of the initial transplant. This helps preserve the function of the original graft and exists as a way to encourage programs not to transplant kidneys simultaneously with a second organ for patients whose glomerular filtration rate (GFR) is borderline for the initial transplant. Programs have 60 days to review the function of the kidney, and, if after 60 days the candidate's GFR is below 20 or the candidate is on dialysis, then the candidate meets the criteria to register for a "safety net" kidney. "Safety net" allocation does receive priority on the kidney waitlist. However, if a transplant program does not register the candidate for the kidney and report qualifying criteria between 60 and 365 days following the heart or lung transplant, then the patient does not get "safety net" priority.

The Chair followed up on the last question, asking why this policy accounted for programs failing to meet policy requirements. The presenter noted that, at the heart of many policies, is a patient's medical treatment, and their committee did not feel that patients should be penalized for a program's lack of oversight. They added this was similar to how waiting time can be backdated if it is shown that there were lab values to support their listing, but not if the only indicator is the intent to list five years prior.

The Chair had a second question and inquired why the specific GFR thresholds were chosen for the "safety net" criteria. It was noted that the policy was built off framework taken from liver-kidney allocation, and from the sponsoring committee, there was consensus that a candidate who has either been on dialysis once a week for a period of six weeks or had a GFR lower than 25 mL/min has a sustained acute kidney injury. A member contributed that frequently kidneys will take approximately 40 days to recover from an injury. Staff also noted that the thresholds in the proposal were also based off a consensus conference on sustained acute kidney injuries in the context of multi organ transplant.

Next steps:

The Multi Organ Transplantation Committee will consider the feedback received.

Upcoming Meetings

- March 30, 2022
- April 19, 2022

Attendance

- **Committee Members**
  - Garrett Erdle
  - Molly McCarthy
  - Diego Acero
  - Katherine Audette
  - Julie Ice
  - Sarah Koohmaraie
  - Kenny Laferriere
  - Earl Lovell
  - Anita Patel
  - Kristen Ramsay
  - James Sharrock
  - Julie Spear
  - Sejal Patel
  - Justine Van Der Pool
  - Justin Wilkerson
  - Christopher Yanakos
- **HRSA Representatives**
  - James Bowman
  - Laura Darensbourg
  - Raelene Skerda
- **UNOS Staff**
  - James Alcorn
  - Isaac Hager
  - Lindsay Larkin
  - Meghan McDermott
  - Laura Schmitt
  - Kaitlin Swanner
  - Kim Uccellini
  - Sara Rose Wells
  - Joann White
- **Other Attendees**
  - Dolamu Olaitan
  - Silke Niederhaus