

OPTN Kidney Transplantation Committee

Meeting Summary

January 9, 2023

Conference Call

Martha Pavlakis, MD, Chair

Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 1/9/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Predictive Analytics
3. National Academy of Sciences, Engineering, and Medicine (NASEM) Recommendations
4. New Organ Allocation Simulation (OASIM) Metrics

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

1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members, and Staff provided an update on the implementation of the estimated Glomerular Filtration Rate (eGFR) Wait Time Modification Policy. Staff provided details on the upcoming in-person Committee meeting in Houston and introduced new Committee support staff.

Summary of discussion:

There were no questions or comments.

2. Predictive Analytics

Staff presented the Predictive Analytics tool, which will be nationally rolled out in the OPTN Donor Data and Matching System.

Presentation summary:

The predictive analytics tool is intended to aid clinicians in decision making. The tool will show, based on the Kidney Donor Profile Index (KDPI) of a kidney offer and the particular candidate receiving the offer, the predicted time for the next KDPI less than 30 percent offer for this patient and the predicted probability of death for this particular patient before that next offer.

The predictive analytics tool is the result of an intensive collaboration between Accenture Federal Services and the OPTN. Accenture specializes in working with clients to translate complex processes into solutions using a human centered design approach, and has been engaged with the transplant community since 2018, conducting work on behalf of CMS and HRSA, focusing largely on root causes of kidney discards and potential improvements to the offer acceptance process. Accenture has conducted in-depth interviews with patients, transplant surgeons, nephrologists, transplant coordinators, and other stakeholders and in doing so, they've developed some level of expertise in transplantation and have also identified a number of ideas for improving the system. The predictive analytics project

continues to be a highly cross-functional endeavor, involving behavioral science, data science, and software technology expertise.

This project took a phased approach:

- Phase I was focused on developing our approach, and I'll talk more about the concept testing and behavioral testing that was done in a moment.
 - Resonance testing interviews included kidney transplant surgeons, a nephrologist, and an administrator
 - Behavioral study utilized 16 simulated offers, and was designed to estimate the impact of various predictive analytics to guide the project, detect unintended consequences, and increase confidence before launching the pilot
- Phase II focused on refining the analytics and user interface design, and built out the computational infrastructure needed to support this new feature
 - Design included: time to next offer of KDPI less than 30 percent and less than 50 percent, probability of death before next offer (KDPI less than 30 percent and less than 50 percent), and the survival curve candidate without transplant
 - Indicator for when next offer is predicted
 - Designed to convey information in a way that is understandable, trusted, and preserves the autonomy of clinicians
- Phase III included ongoing Beta testing, as well as upcoming Pilot testing of new predictive analytics to evaluate how well they support decision making on real offers
 - Pilot involved approximately 15 kidney programs and more formal analysis of the impact of predictive analytics on decision making
 - Participating programs were matched 1 to 1 into pairs on geographic location, racial diversity of waiting list, and transplant volume
 - The Predictive analytics group received predictive analytics, while the control did not
 - Pilot data showed that the Predictive Analytics group had an increased offer acceptance rate, while the control did not

Monitoring results are consistent with previous reports, and suggests a need for models to be living and continuously updated. The modeling team is continuing to improve methodology, including revising the definition of next offer and leveraging improved calibration measures. The Human-Centered Design Team is continuing to refine user display to improve the clarity of analytics shown and encourage ease of understanding. A national scale predictive analytics tool will utilize a customer feedback loop for continuous improvement.

A national roll out for the predictive analytics tool for adult kidney offers is expected in mid-January 2023.

Summary of discussion:

One member expressed support and excitement for this tool, and asked if this will show up on every offer the programs receive. Staff explained that the tool will be available in the mobile application of the OPTN Donor Data and Matching System, but that the tool itself will be a website and can be accessed from a phone, tablet, or a computer. The goal for the national rollout is to focus on getting the tool to decision makers, which will allow for feedback to be collected on a national level and be incorporated continually.

A member asked if the tool will include any other KDPI cut offs. Staff shared that this was some of the feedback collected early on as well, particularly to look at KDPI less than 85 percent. The advisory panel built for the predictive analytics tool determined that it may not be necessary to include that cut off at this time. Staff shared that this could change later if it is determined that this would help improve utilization of kidneys.

The Chair remarked that this tool is a great step forward for the system, and recalled discussing this tool with a surgeon who noted that it's less about the time to next amazing offer, and more about the time to the next reasonable offer. The Chair noted that utilizing a low KDPI level as the next best offer will make time to transplant look significantly worse than if it was time to next middle or higher range KDPI kidney. The Chair noted that the more important question is whether it would be time to next similar or better kidney. Staff appreciated this feedback, and noted that this aligns with earlier feedback. Staff shared that the predictive analytics tool was particularly helpful in the scenarios for hard to place kidneys and making some of those decisions. Staff shared that a lot of times decision makers felt that this analytic allowed them to visually connect with their decision.

One member asked if the pilot saw any major differences between large transplant programs and small transplant programs. Staff explained that this information is in the monitoring report for the pilot, and that they will follow up with the member to connect them with research liaisons who can answer that question. The member noted that it would be useful to see comparisons between large and small volume transplant programs in six-month post-implementation monitoring. Staff agreed, and noted that national release will also provide more data, which will help to improve modeling and create feedback loops, providing insight in how this tool can increase utilization.

Staff thanked the Committee members for their time and feedback.

3. NASEM Recommendations

The Committee reviewed the NASEM Report and project recommendations.

Presentation summary:

NASEM Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution issued a report "Realizing the Promise of Equity in the Organ Transplantation System" in February 2022. The OPTN Executive Committee responded to the report in April 2022, highlighting ongoing OPTN work aligning with the recommendations and offering corrections.

NASEM recognized that there are multiple entities with different roles in the transplant community, including:

- Department of Health and Human Services (HHS)
- Centers for Medicare and Medicaid Services (CMS) which falls under HHS
- Health Resources and Services Administration (HRSA) which falls under HHS
- OPTN

The NASEM Recommendations fell into three categories: improving equity, using more donated organs, and improving the system and system performance. These align with the OPTN's strategic goals, which include increasing the number of transplants, providing equity in access to transplants, improving waitlisted patient, living donor and transplant recipient outcomes, and promoting living donor and transplant recipient safety. Staff also outlined several OPTN projects and efforts that align with NASEM's categorical goals.

The OPTN Committees will each review these recommendations and discuss project ideas based on these recommendations. The Policy Oversight Committee (POC) will prioritize potential committee projects.

Current active Committee projects include:

- Continuous Distribution of Kidneys
- Modify eGFR Waiting Time for Candidates Affected by the use of the Race Variable
- KPD Policy Updates
- Collaborating on:
 - Offer Filters
 - Organ Offer Acceptance Limit
 - Discard Reasons Field in OPTN Computer System
 - Ad Hoc MOT Committee projects

Kidney sponsored Workgroups include the Medical Urgency Review Subcommittee, Kidney Paired Donation Workgroup, Kidney-Pancreas Continuous Distribution, Utilization Considerations of Kidney-Pancreas Continuous Distribution, and the Kidney Pancreas Review Boards Workgroup. Other collaborations include the POC, the ad hoc Multi Organ Transplantations Committee, the Offer Filters Workgroup, the Organ Offer Acceptance Limits Workgroup, the Discard Reasons Field Workgroup, and the Simultaneous Liver Kidney Allocation Circles Workgroup.

Summary of discussion:

The Chair remarked that this report is comprehensive, and remarked that it was odd for the NASEM report to not stress living donation, particularly with the recommendation to not give pre-dialysis waiting time. The Chair shared that, before the Kidney Allocation System (KAS) which utilized donor service area (DSA), candidates were not granted waiting time until they were on dialysis, at least in Region 1. The natural progression of kidney failure management was chronic kidney disease stage 5, options counseling, access placement, dialysis initiation, and then transplant referral. The opportunity for living donor transplant was dramatically dis-incentivized. The Chair remarked that they understand the concern that pre-emptive listing should not count as much as dialysis waiting time, but the suggestion to completely eliminate pre-dialysis waiting time was a surprise.

The Chair pointed out that the yearly KDPI and EPTS updates don't really relate to increasing equity, and fall more in line with maintaining accuracy based on the current policy definition of these calculations. The Chair remarked that removing the race variable and the hepatitis C variable from KDPI would really increase equity in organ allocation. The Chair noted that the race factor in KDPI arises from mutations in the APOL-1 gene, and that this mutation only affects 13 percent of the black population, and thus there is no justification to apply it to all black donors. Staff noted that the Committee has previously expressed interest in revisiting the KDPI and EPTS calculations. Other members agreed.

One member asked if providing equity in access to transplant is meant to include patients who are facing barriers and obstacles to getting on the waitlist. The member shared that there is currently a research project attempting to help patients overcome barriers to access the transplant waiting list. The member pointed out that these barriers are an issue all over the country, especially when evaluating the impact of social determinants of health, which can hinder the transplant process. The member added that none of these recommendations include behavior health during the transplant process. The member explained that once someone is on the waitlist, there are a whole host of other things to consider – going from active to inactive because of a medical abnormality, or the impact of guilt for transplant recipients, the impact of waiting for a transplant and kidney failure management on

relationships and families, and the impact of waiting for a transplant while watching peers and friends receive transplants ahead of them. All of these factors can impact the mental health of a patient and cause issues when it comes to management of their transplant, particularly in the first year post-transplant. Staff asked if this suggestion would focus on access to the waitlist as a potential project, and the member agreed.

The member explained that it would be worthwhile to examine and identify these barriers, especially as it relates to different kinds of minority groups. The member added that rural patients in particular faces challenges, particularly if they are trying to multi-list, as not all transplant programs follow the same onboarding processes. Transport issues, affordability, lack of insurance – all of these things can hinder people who have qualified for a transplant to actually access the waitlist. Another member agreed, noting it is critical to address the barriers in order to increase the number of transplant. The member asked what resources are available to the Kidney Committee to begin a project like that. The member also noted that a project addressing mental health of candidates and recipients could fall under the goal of promoting living donor and recipient safety. The member added that there seems to be relevant project ideas for each goal. The member agreed that these barriers need to be addressed to increase the number of transplants and provide equity in access. The Chair agreed, adding that the entire report could have been dedicated to improving equity in access and supporting patients on the waitlist.

A member explained that they bring up these ideas because the OPTN has a wealth of data and information that other organizations do not have. The member noted that the more this data is shared, the more attention will be brought to these topics in the kidney community. The member noted that a lot of this information can be used to build educational tools for patients, so that patients can advocate on behalf of themselves and have real conversations with their care partners and care givers. The member added that equity needs to be greater than just race, and needs to include people with disabilities, older people, and members of the LGBTQ community. The member added that the transplant community should be diversified across many types of people.

One member asked if these recommendations were shared with the other regulatory agencies, including CMS or other end stage renal disease (ESRD) networks. The member noted that there is data that some of these organizations can access and use to determine gaps in referrals and deficiency in access, and that the OPTN may not have jurisdiction over these things. Staff noted that the OPTN does not have purview prior to a candidate's registration on the waiting list. The member added that it is helpful to know this when considering where to go with these recommendations. The member agreed that sharing information with different organizations can help, and added that in some parts of the country, ESRD advocacy networks are making efforts to improve equity in access across financial and other social determinants of health.

A member shared that they and another Committee member are part of the Kidney Patient Advisory Council, which represents all 18 national ESRD networks. The member noted that it would be advantageous to share this information, particularly as it could educate those currently on dialysis who are trying to access the waitlist. This information will do justice to these patients and would better empower patients to share their opinions and particular needs, in order to identify barriers and dismantle those barriers. The member recommended sharing information with the Kidney Health Initiative Patient Family Partnership Council. Another member agreed.

Staff summarized the suggestions, including ideas to re-evaluate the KDPI and EPTS calculations; interest in addressing barriers to transplant and the waitlist, particularly for sub-populations; and interest in enhanced information and data sharing with other organizations to provide more information and education to patients.

4. New OASIM Metrics

Staff presented supplemental OASIM metrics.

Presentation summary:

Several scenarios were modeled in the OASIM, including:

- Scenario 1: Combined Analytical Hierarchy Process (AHP) weights
- Scenario 2: Increased Longevity Weight
- Scenario 3: All Donor Efficiency Weights
- Scenario 4: High Kidney Donor Profile Index (KDPI) Efficiency Weights

Supplemental results include:

- Median travel distance by KDPI
 - Median travel distance by KDPI differs between the high KDPI efficiency scenario and the combined AHP scenario, showing that the donor modifiers the former is working as intended
- Travel distance distribution by calculated Panel Reactive Antibody (CPRA)
 - For CPRA 0 percent to 99.5 percent, kidneys are travelling farther except for the all donor efficiency scenario
 - For CPRA 99.5 percent and above, kidneys are traveling similar distances to current policy except for the all donor efficiency scenario
- Transplant rates by CPRA
 - For 99.5 percent to 99.9 percent, transplant rates are going down

Summary of discussion:

Staff noted that the modeling shows that donor modifiers are having an effect, and that the Committee will need to decide to keep or adjust that donor modifier going forward. The Committee will discuss these results at their next meeting.

Upcoming Meetings

- January 17, 2023 – Teleconference
- January 27, 2023 – Houston, TX
- February 6, 2023 - Teleconference

Attendance

- **Committee Members**
 - Martha Pavlakis
 - Asif Sharfuddin
 - Bea Concepcion
 - Tania Houle
 - Caroline Jadlowiec
 - Jesse Cox
 - Kristen Adams
 - Marilee Clites
 - Oscar Serrano
 - Patrick Gee
 - Precious McCowan
 - Sanjeev Akkina
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Caitlin Peterson
 - Jon Miller
- **UNOS Staff**
 - Lindsay Larkin
 - Kayla Temple
 - Keighly Bradbrook
 - Thomas Dolan
 - Kieran McMahon
 - Ruthanne Leishman
 - Lauren Motley
 - Michael Ghaffari
 - Ben Welford
 - James Alcorn