OPTN Kidney Transplantation Committee
Meeting Summary
April 14, 2021
Conference Call

Vincent Casingal, MD, Chair
Martha Pavlakis, MD, Vice Chair

Introduction

The Kidney Transplantation Committee met via teleconference on 04/14/2021 to discuss the following agenda items:

1. Cross Committee Updates
2. Continuous Distribution Update
3. OPTN Governance Presentation
4. COVID-19 Emergency Policies
5. Biopsy Best Practices Workgroup Recommendations
6. Kidney Paired Donation (KPD) Priority Points Monitoring Report
7. Update Reference Tables for Kidney Donor Profile Index (KDPI) and Estimated Post-Transplant Survival Scores (EPTS)

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

1. Cross Committee Updates

Committee members in Reassess Race in Estimated Glomerular Filtration Rate (eGFR) Calculation, Ad-hoc International Relations KPD, Tech Tools, and Multi-Organ Allocation in Continuous Distribution Workgroups provided updates on their respective projects.

Summary of discussion:

The Reassess Race in eGFR Workgroup has reviewed literature on and discussed the use of the race variable in eGFR calculation and its potential elimination for the purposes of kidney wait listing. A workgroup member expressed support for this project, and requested feedback with workflows and transitions away from race-based eGFR calculation for transplant programs.

The Ad-hoc International Relations' KPD Workgroup has met to discuss the potential for international KPD chains and general organ sharing, and how to tackle the resulting logistical barriers.

The Technology Tools Workgroup updated the Committee that DonorNet® Mobile is now available to all transplant program users. A member suggested the Tech Tools Workgroup consider efforts to update the usability and appearance of the DonorNet interface.

The Multi-Organ Allocation in Continuous Distribution Workgroup is beginning to develop the framework for multi-organ allocation policy, including discussions on organ combination specific eligibility criteria, allocation thresholds between multi- and single-organ candidates, safety net kidneys, and match run prioritization. A member noted that a safety net kidney policy for thoracic candidates would be a major step towards improved kidney utilization and allocation equity. Others agreed that safety nets and eligibility criteria will reduce the current disadvantage to low EPTS and pediatric kidney patients introduced by multi-organ allocation. Another member remarked that some thoracic surgeons

and physicians find that post-thoracic-transplant dialysis can have significant negative impacts on post-transplant survival. Safety net kidneys may not be able to negate these effects. The Vice Chair shared that similar arguments were put forth during the development of simultaneous liver-kidney (SLK) safety net policy. That data showed liver programs were often inappropriately transplanting kidneys into mild chronic kidney disease (CKD) patients, and that those SLK recipients had worse post-transplant outcomes than similar liver recipients who did not receive a kidney. The Vice Chair continued that appropriate data will allow the Multi-Organ Allocation Workgroup to establish appropriate safety net policies to improve kidney utilization and best use. A member agreed that the implications of eligibility criteria and safety net policies will be positive and significant for both renal and thoracic patients.

2. Continuous Distribution Update

Committee Leadership presented an update on the Kidney and Pancreas Continuous Distribution project, including finalized goals, categories, and attributes, as well as the data requests developed by the Kidney and Pancreas Continuous Distribution Workgroup.

Data summary:

The Kidney-Pancreas Continuous Distribution Workgroup (the Workgroup) has identified and categorized attributes, and has begun work developing data requests to create rating scales for some attributes. A concept paper addressing the goals, categories, and attributes will be released for the August 2021 public comment period to collect feedback from the community.

Medical urgency – prioritize those with high mortality due to imminent loss of dialysis

- Medically urgent patients; high mortality due to imminent dialysis loss

Post-transplant survival – increasing graft life and longevity matching

- Human leukocyte antigens (HLA) matching
- EPTS
- Cold ischemic time

Candidate biology – increase transplant opportunities for patients who are medically harder to match

- Blood type
- Calculated panel reactive antibodies (CPRA)

Patient access – appropriate transplant access

- Prior living donors
- Pediatrics
- Simultaneous Liver-Kidney (SLK)
- Waiting time

Placement efficiency – consider resource requirements required to match, transport, and transplant an organ

- Travel (cost) efficiency
- Placement efficiency
- Dual and en-bloc kidneys
- Dual versus single kidneys

The Workgroup has begun work on the second phase of the project, assigning values to attributes. The Workgroup has developed and submitted several attribute-specific data requests, and will begin building rating scales from this data. These rating scales, derived from clinical and operation data, will rank candidates within an attribute. Weights, derived from data on values-based decisions, determine how much each attribute should contribute to a candidate's overall score. Ratings scales and weights together will build a composite allocation score, which will be used to rank-order candidates on match

runs. The weights for each attribute will be analyzed and collected via pairwise decision-making processes by the community.

The Workgroup has developed data requests for ABO blood type, cPRA, pediatrics, and HLA matching, in order to help convert attributes to points via weights and rating scales.

- The ABO blood type data request seeks to build a rating scale based in historical data on volume of kidney candidates and donors by blood type, as well as the ratio of ABO compatible kidney donors to kidney candidates by candidate blood type
- The cPRA data request seeks data to build a rating scale based on the scale developed by the Lung Continuous Distribution project
- The pediatric data request seeks descriptive data, as well as data on pediatric donation to pediatric candidates, living donation and pediatric priority, and adolescent pediatric to adult candidate transition
- The HLA matching data request focuses on five year outcomes for patient and graft survival, and will examine 0-ABDR mismatch, 0-ABDRDQ mismatch, and degree of matching at class II loci (DR and DQ)

Summary of discussion:

One member commented the continuous distribution project was somewhat like data-driven subjectivity, particularly with values decisions about attribute prioritization. The Committee Chair noted that this subjectivity plays out in the current allocation system, but with less transparency and flexibility.

The Committee Chair remarked that adolescent candidates experience a hard barrier as they age out of pediatric priority, and that it will be important for this project to carefully consider these patients. An SRTR representative agreed, noting that a 17-year old patient is clinically very similar to a 19-year old patient, but have vastly different transplant and allocation experiences. The Chair reflected that the flexibility of a continuous distribution system will allow current and future allocation work to dial in appropriate priority for developing adolescent candidates. Another SRTR representative noted that the legal definition of pediatric presents a hard boundary that continuous distribution may not be able to remove, and that the project will need to justify treating an 18-year old listed a day before their 18th birthday differently than an 18-year old registered a day after the 18th birthday. One SRTR representative noted that the disadvantage for the latter patient exists in the current allocation system as well, and that the pediatric transplant community has adapted by trying to list patients before their 18th birthday. The Chair agreed, remarking that the current system attempts to account for this through low EPTS priority, but that the continuous distribution system will hopefully be capable of better addressing pediatric boundaries.

A member noted that the literature around HLA matching has focused mostly on Class II matching, as Class I matching has historically shown little preference for long term graft survival. The member continued that 5-year outcomes will allow the Continuous Distribution Workgroup to analyze long term graft survival while still capturing robust data for DQ locus matching.

One member remarked that the continuous distribution system will be incredibly complex, and may be difficult to explain to patients, who may feel disadvantaged in some way if they don't fully understand it. The Chair agreed, noting that a predictive analytics tool would likely help patients figure out where they stand and how the composite allocation score is built. Donor factors, recipient factors, and center acceptance criteria make prediction and communication about patient opportunity and access difficult to communicate transparently. Staff shared that communications and education are being developed to help ensure patient awareness and understanding. The Vice Chair responded that wait time will still be critical to allocation in continuous distribution, an impression that most patients and non-transplant

clinical professionals have about the current allocation system. Patients will need to understand, but so will many other constituencies, including referring nephrologists and nurse coordinators.

One member asked how antibodies affect wait time, and how that will change in the current allocation system. The Vice Chair answered that high antibodies, or high cPRA, narrow the population of potential donors from which a candidate can safely receive a transplant. The Chair remarked that the current allocation system tries to give extra points to higher cPRA patients who will wait longer, but that trying to dial in the appropriate level of priority for these patients can be difficult.

3. OPTN Governance Presentation

The Committee reviewed the governing structures of the OPTN and authority and compliance analysis processes.

Data Summary:

OPTN policy development is governed by the National Organ Transplant Act (NOTA), the Final Rule, the OPTN contract, and OPTN policies and bylaws

All committee project work must be authorized by NOTA, the Final Rule, or the OPTN contract. The work must also comply with NOTA, the Final Rule, the OPTN contract, and OPTN policies and bylaws.

Summary of discussion:

The Committee had no questions or comments.

4. COVID-19 Emergency Policies

The Committee reviewed the use of Covid-19 emergency waitlist policies currently in place for kidney waitlist registration, and discussed continuation and eventual termination of the emergency policy.

Data summary:

The Applications for Modifications of Kidney Waiting Time during COVID-19 Emergency policy allows programs to request waiting time modification for non-dialysis kidney candidates who meet waiting time GFR or creatinine clearance criteria, but are unable to obtain additional labs required for listing.

The policy is currently still widely utilized as of March 2021, and submissions may increase as programs bring patients in at later dates.

Summary of discussion

The Vice Chair remarked that the emergency waitlist policy had a huge positive impact, allowing centers to serve non-dialysis patients fairly and without putting them at risk. The Vice Chair continued that regional differences in COVID-19 incidence over time make it difficult to pin down whether or not the policy is still needed, and that centers should be given a few months' notice at least between announcement and termination of the policy. However, barriers in some regions have decreased, though some programs are still only recently returning to full staffing, as nurse coordinators return from redeployment. The Chair agreed, noting that frequent re-evaluation has been critical to understanding use of this policy, as planning and preparation for the future is particularly unpredictable in regards to the COVID-19 pandemic.

One member shared that the southwest was currently experiencing a surge, and was still utilizing the emergency waitlist policy necessarily. It would be best not to terminate the policy just to reinstate it later if more surges occurred. The member asked if there were negative impacts from the implementation and continued use of the policy, and it was confirmed that there were no immediately known negative consequences of the emergency kidney waitlist policy.

Another member agreed that the policy is still needed, noting that other programs in the southwest have only just begun returning to in-person evaluation after more than a year. These programs are finding huge wait times for other services, such as cardiology and colonoscopy, that are experiencing a huge backlog of patients in need of procedures and testing. Extending the policy would allow programs to continue servicing non-dialysis patients fairly and appropriately.

A member agreed that any elimination of the policy should happen over a few months, particularly with regional variation in COVID-19 prevalence and patient populations. Another member concurred, suggesting that the emergency policy be re-evaluated in September, as greater populations have access to vaccines. Several Committee members agreed.

The Vice Chair commented that there was a small possibility some transplant programs may use the emergency policy for reasons beyond COVID-19, and that the number of programs utilizing the policy on an ongoing basis may not be justification enough for continuation. However, programs now still need the emergency waitlist policy, and it should be continued with further evaluation.

5. Biopsy Best Practices Workgroup Recommendations

The Committee reviewed recommendations for standardization of biopsy practices and reporting developed by the Biopsy Best Practices Workgroup, and provided feedback.

Data summary:

Currently, there is an absence of standardization in biopsy practices, both in the criteria appropriate to initiate a kidney biopsy and in the reporting and performance of biopsies themselves. As a result, many kidneys are likely biopsied unnecessarily, and the quality of biopsies performed vary considerably. The Biopsy Best Practices Workgroup has developed a set of minimum donor criteria appropriate for biopsy and a standardized pathology report, and is seeking Kidney Committee feedback before bringing this project to the Policy Oversight Committee for approval.

Literature is not consistently supportive of the use of biopsy in kidney evaluation, but with more than 50 percent of kidneys being biopsied, there is a strong need for standardization of biopsies that are done. These biopsies should be performed to determine which patient will receive the most benefit from the organ, valuing recipient-organ matching over determination of overall organ usability.

The minimum criteria proposed by the Biopsy Best Practices Workgroup follows:

- Anuria
- Renal Replacement Therapy
- Diabetes – any history, including diagnosis or elevated Hemoglobin A1C (HbA1C) during donor evaluation
- KDPI ≥ 85 percent, excluding pediatric donors
- Donor age 60 or older
- Donor age 50-59 and at least two risk factors:
    - Hypertension
    - Manner of death: Cerebrovascular Accident (CVA)
    - Terminal creatinine

Inconsistencies in the quality of biopsy analysis is a major hurdle to allocation efficiency. The proposed standardized report focuses on information necessary to evaluate both critical organ information and biopsy quality. The report is also designed to be useable for non-renal pathologists, while still providing useful clinical information. The report includes the following fields:

- Biopsy type (wedge or core needle)

- Tissue preparation technique (frozen section or formalin-fixed paraffin-embedded (FFPE))
- Number of glomeruli and number of sclerosed glomeruli
- Percent globally sclerotic glomeruli (less than 5 percent, 5-10 percent, 11-25 percent, or greater than 25 percent)
- Nodular sclerosis (present or absent)
- Interstitial fibrosis / tubular atrophy (less than 5 percent, 5-10 percent, 11-25 percent, 26-50 percent, and greater than 50 percent)
- Vascular disease, also known as percent luminal narrowing (none, mild, moderate, and severe)
- Cortical necrosis (none, focal or less than 10 percent, diffuse or greater than 50 percent)
- Fibrin thrombi (none, focal or less than 10 percent, diffuse or greater than 50 percent)

The Biopsy Best Practices Workgroup is also seeking feedback on whether these recommendations best serve as a guidance document or incorporated into policy.

Summary of discussion:

A member recommended that the percent sclerotic categories should have greater granularity between 11-25 percent sclerosed and greater than 25 percent sclerosed. Another member agreed, and pointed out that the proposed form also provides the total number of glomeruli and glomeruli sclerosed, meaning that surgeons could calculate exact percentage outside of these categories. The total number of glomeruli was also important in evaluating general biopsy quality. The member continued that percent sclerosis was a critical consideration in evaluating a biopsied kidney, and more detail in this area will be beneficial for evaluating surgeons.

One member commended the Biopsy Standards Workgroup for their efforts, noting that a standardized minimum process for when biopsies are conducted will help decrease discard rates and increase transplantation. The member expressed that many patients feel that even a more marginal kidney giving them 2 or 3 years of freedom from hemodialysis would be extremely valuable, and that processes that decrease discard rate are critical. Another member agreed, noting that more universal education around procurement biopsies will be critical to reducing biopsy-related discard. Providing standardization about when a biopsy should be done can reduce pressure on transplant centers who want to see biopsy results before accepting a kidney for certain patients, who may otherwise decline the organ without a biopsy.

A member suggested biopsy results could be linked to allocation in the future, which would increase allocation efficiency for more marginal kidneys. This would be critical, as the appropriate patients for these kidneys are often further down the match run, meaning that the kidney already has a lot of cold time when they receive the offer, making the organ less viable for its appropriate recipient. The Chair agreed, noting that biopsy results can be utilized to identify organs that may need to be expedited for placement in order to reduce chances for discard. The member continued that a standard reporting pathway for biopsies will also allow for standardized biopsy data collection, which can be used to guide kidney allocation. Reducing cold time for kidneys with more marginal biopsy results will decrease organ discards. Another member agreed, but noted that the quality and accuracy of some biopsies would mean that any biopsy-influenced allocation would need to be carefully planned.

One member remarked that biopsy standardization will be valuable, and recommended the Biopsy Standards Workgroup examine data from previous kidney donors to see how many biopsied kidney donors would have met the proposed criteria. The member continued that reproducibility will likely remain a concern, even with standardized reporting. Another member noted that this has come up, and that in an ideal state, organ procurement organizations (OPOs) and transplant programs could utilize remote interpretative services via biopsy imaging through UNet℠. These services would increase access to nephro-pathologists, and improve the accuracy and reproducibility of biopsies performed.

6. KPD Priority Points Monitoring Report

The Committee reviewed the one-year post-implementation monitoring report for the Kidney Paired Donation Priority Points policy.

Data summary:

The Priority Points policy aimed to increase the likelihood of finding matches for highly sensitized candidates and pairs with difficult to match blood types, as well as add a remedy for orphan candidates who are part of a failed exchange.

Over the first year post-implementation, there were no failed exchanges resulting in an orphan candidate

The first 14 months of data suggest that the policy is having the intended effect of increasing matches and match rates for type O candidates and pairs with AB donors, though more time and data are needed to assess whether these increases are sustained over time. More time and data are needed to assess the policy's impact on matches and match rates for highly sensitized candidates, pediatric candidates, and prior living donors.

Summary of discussion:

The Vice Chair of the Committee remarked that the policy change seemed to be producing its intended effects. The Workgroup had no other questions or comments.

7. Update Reference Tables for KDPI and EPTS

The Committee reviewed changes in the reference donor and recipient populations in the last year, and voted to update the reference tables for KDPI and EPTS with data from the updated reference donor and recipient populations.

Data summary:

Kidney Donor Risk Index (KDRI) for each donor is converted to a KDPI percentage using a KDRI-KDPI mapping table, which is based on data from all kidney donors recovered in the previously calendar year. EPTS is similarly updated.

KDRI to KDPI mapping has changed significantly over time. A KDPI 50 percent donor in 2019 has a slightly higher KDRI than a KDPI 50 percent donor in 2015. The updated KDPI cohort from 2020 follows this trend, with a small and steady increase in the KDRI distribution over time. This is essentially a steady decrease in donor quality as measured by KDRI over time. This shift is driven by a number of factors:

- Kidney donors have become slightly older on average
- Donor creatinine has increased, particularly the upper levels
- Proportion of kidney donors with a history of hypertension, as well as history of diabetes
- Donor height has remained unchanged
- Donor weight has increased over time, though KDRI increases as weight increases
- The proportion of donation after cardiac death (DCD) donors has increased over time
- Proportion of donors recovered with Hepatitis C (HCV) has increased

Other factors used to measure KDRI that did not contribute to this trend include:

- Average donor race and ethnicity has not changed significantly over time
- Donors who die of a Cerebrovascular Accident (CVA) or stroke have higher KDRI; however, the donor population with CVA as the cause of death has decreased over time.
- Donor height has remained unchanged

- Donor weight has increased over time, though KDRI increases as weight increases

These changes in KDRI to KDPI mapping is still relatively small year to year. The proposed new KDRI-to-KDPI mapping table follows these trends.

Summary of discussion:

The Vice Chair remarked that high KDPI kidneys were gradually representing worse kidneys over time, with the donor pool showing increased rates of DCD, diabetes, hypertension, and high creatinine. The Committee Chair noted that this trend in KDPI reflected the kidney transplant community's growth and improvement in more marginal kidney utilization.

The Chair expressed concern that these trends in KDPI would impact risk adjustment in transplant data, and an SRTR representative responded that KDRI is used for risk adjustment, not KDPI.

The Vice Chair and other Committee members agreed that there are aspects of the KDPI and KDRI formulas that will need to be reworked, particularly medical advances over the last decade. In particular, one member noted that race and hepatitis C may be less relevant, with results from the Apollo study forthcoming and HCV treatments becoming more effective. Staff shared that the group who developed KDRI performed a ten-year review of KDRI, and found very minimal changes in the coefficients, but that these pieces should still be addressed.

Vote:

The Committee voted unanimously to approve the new KDRI-to-KDPI mapping table based on the year 2020 reference population.

Data summary:

A candidate's EPTS score indicates the percentage of adult kidney candidates on the waiting list with a higher estimated post-transplant longevity, based on data from December 31 of the previous year. The EPTS score is used to confer priority on the waiting list.

There has been an increase in raw EPTS over time, meaning that patients on the waiting list have a slightly lower expected post-transplant survival on average, compared to patients in 2014. The threshold for the EPTS 20 percent or less priority has become slightly easier to meet. This shift is driven by:

- Candidates are older on average, with higher raw EPTS scores
- More candidates on the waiting list have diabetes

Center factors influencing raw EPTS calculation have opposed this trend

- The proportion of candidates who have received prior transplant has decreased
    - Prior recipients have a higher raw EPTS
- The average amount of time that candidates are dialyzed has decreased
    - Patient with more dialysis time have higher raw EPTS

Year to year, there is a small increase in the average raw EPTS. The 2020 data follows this trend, and adopting the new EPTS reference population will have implications for patients. Slightly more candidates would qualify for top 20 percent EPTS priority due to recalibration, as the raw EPTS score needed would increase from 1.5226 to 1.5329. Some candidates with an EPTS of 21 percent would see their score drop to 20 percent, giving them additional priority.

Summary of discussion:

A member noted that approving the new EPTS mapping tables would not result in a disadvantage to either pool of candidates, those above and below EPTS of 20 percent. A minority of candidates will become EPTS 20 percent or less and receive priority in allocation. This understanding was confirmed by staff.

The Vice Chair confirmed that there were no limits on the total population of patients in the 0-20 percent EPTS cohort, and asked if non-pediatric adolescents (over age 18) would be crowded out in the data remapping. Staff confirmed that this process could alter access slightly, and that a scenario such as that makes a strong case for a continuous distribution allocation system, which removes hard boundaries and smooth patient experiences and access.

Vote:

The Committee voted unanimously to adopt the new EPTS mapping table based on the reference population snapshot of all adult kidney candidates on the waiting list on December 31, 2020.

Upcoming Meetings

- May 17, 2021
- June 21, 2021

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Vincent Casingal
  - Andrew Weiss
  - Arpita Basu
  - Asif Sharfuddin
  - Alejandro Diez
  - Amy Evenson
  - Bea Concepcion
  - Cathi Murphey
  - Deirdre Sawinski
  - Elliot Grodstein
  - Jim Kim
  - Marilee Clites
  - Peter Kennealey
  - Precious McCowan
  - Erica Simonich
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Jon Miller
  - Nick Salkowski
  - Jodi Smith
- **UNOS Staff**
  - Tina Rhoades
  - Kayla Temple
  - Amanda Robinson
  - Chelsea Haynes
  - Darren Stewart
  - James Nicholson
  - Joann White
  - Julia Chipko
  - Kaitlin Swanner
  - Lauren Motley
  - Matt Prentice
  - Meghan McDermott
  - Melissa Lane
  - Mohamed Abbas Roshanali
  - Nicole Benjamin
  - Rebecca Murdock
  - Ross Walton
  - Ruthanne Leishman
  - Sara Moriarty
  - Beth Coe