OPTN Kidney Transplantation Committee
Meeting Summary
February 14, 2022
Conference Call

Martha Pavlakis, MD, Chair
Jim Kim, MD, Vice Chair

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 2/14/2022 to discuss the following agenda items:

1. Modify Living Donor Exclusion Criteria
2. Change Calculated Panel Reactive Antibody (cPRA) Calculation
3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

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

1. Modify Living Donor Exclusion Criteria

A representative from the OPTN Living Donor Committee presented an overview of the *Modify Living Donor Exclusion Criteria* proposal.

Data summary:

The purpose of the proposal is to ensure the relevancy of living donor exclusion criteria within OPTN policy. The proposed modifications intend to broaden individuals' opportunities to become living organ donors while maintaining living donor and transplant recipient safety.

The Living Donor Committee proposed four modifications to living donor exclusion criteria, related to malignancy, donor coercion, illegal exchange, and diabetes.

- Malignancy – currently, any individual with any type of malignancy is excluded from the ability to be evaluated as a living donor
    - Literature, data, and clinical experience show that individuals who have low-grade malignancies, that do not require current or future treatment, other than surveillance, or have a minimal risk of transmission may be acceptable as living donors
    - Updated language includes mention of treatment and risk of transmission
- Donor coercion and illegal exchange – the Living Donor Committee proposes modifications to align language with other OPTN policy references
    - "High suspicion of donor coercion" is proposed to be modified to align with other OPTN policy references to donor coercion, which include language related to inducement and other undue pressure
    - "High suspicion of financial exchange between donor and recipient" is proposed to be modified to align with other OPTN policy references, which use broader language. The proposed modification will encompass any type of exchange, for any human organ, not just financial.
- Diabetes – current policy excludes any individual with diabetes from becoming a living kidney donor

- Literature, data, and clinical experience show that diabetes living donor exclusion criterion is outdated
- The proposed modification will distinguish between types of diabetes, with type 1 remaining an absolute contraindication to living donation. The proposed modifications for individuals with type 2 diabetes allows for the ability for transplant programs to perform individualized assessments and use clinical judgment.
    - Should a program choose to evaluate an individual with type 2 diabetes, it should assess donor demographics, such as age, and any comorbidities. If any evidence of end organ damage or unacceptable lifetime risk of complications is found, the individual may not be acceptable as a living donor

The proposed modifications will not require transplant programs to change their living donor evaluation and acceptance practices. Should a transplant program choose to expand their living donor evaluation and acceptance practices based on the proposed modifications, there may be additional administrative burden for programs to adapt evaluation protocols.

Summary of discussion:

One member pointed out that type 2 diabetic patients accepted as living donors will have a long disease process, if at all, if it will affect the remaining kidney. The member asked if the Living Donor Committee will propose a modification to living donor follow up requirements for this type of donor, in order to have longer term data available for living donor safety evaluation. The member also asked if there will be an age limit for diabetic living donors, pointing out that there are different risk levels for a 41 year old diabetic living donor versus a 61 year old living donor. The presenter shared that age thresholds for diabetic donors were discussed, but that the Living Donor Committee ultimately decided not to set one and instead allow transplant programs to make their own individualized evaluation. The presenter noted that there is limited long term data to provide grounding for a specific age threshold, but that the Living Donor Committee is interested in finding ways to obtain and collect that longer term living donor data.

A member asked if this proposal could result in more living donor biopsy, with more diabetic living donors and the onus falling on transplant centers to make that determination. The member noted that biopsies are crucial in determining the microvascular changes. The presenter shared that the Committee didn't go in depth when discussing biopsies, but that requiring a biopsy could provide additional challenges, and potentially limit transplant centers. The Living Donor Committee decided to leave that determination to a transplant center, as to whether they feel a potential donor candidate is appropriate based on their individualized assessment. The Living Donor Committee wanted to allow transplant programs autonomy in evaluating potential living donors, while allowing for the evaluation of diabetic individuals.

The Kidney Committee Chair expressed support for the proposed modifications, particularly where the proposal broadens transplant center autonomy. The Chair pointed out that intention is to open the door for more living donors while maintaining donor safety, and leave it up to transplant programs to determine how they will implement the policy. Some programs may not change their practices, while others might accept a potential living donor with a short, controlled history of diabetes and record of normal hemoglobin a1C levels five years ago, for example. The Chair remarked that many programs can agree that a diabetic living donor under 30 likely would not be a good candidate, and that a diabetic 60 year old donor could be a good donor candidate. The Chair noted that the grey area in between shouldn't necessarily be addressed by policy, and that it should be up to transplant programs to loosen their own criteria as they see fit and are allowed by policy.

One member asked if the Living Donor Committee had an idea of the number of donors that were previously excluded for malignancy criteria. The member expressed support for the modifications, and recommended expanding data collection in order to better understand the effects of these modifications. The member also asked if there will be some mechanism for collecting malignancy risk for potential living donors in the living donor form. The presenter agreed that monitoring will be important, and noted that the Disease Transmission Advisory Committee (DTAC) published a framework regarding risk of transmission, qualifying minimal risk as less than 0.1 percent. Cohorts with low-grade prostate cancers or certain skin cancers were found to have no transmission. The presenter shared that the Living Donor Committee decided not to include 0.1 percent in the language, since that is difficult to determine. Staff commented that it is difficult to determine how many donors were excluded for any reason, as the OPTN data only tracks living donors that go on to donate. Staff noted that there is limited data collected regarding living donor malignancy in UNet℠. The member remarked that, since the scope of the issue is not clear, it would be helpful to increase relevant data collection to improve monitoring capability.

A member recommended increasing the duration of living donor monitoring for diabetic donors, in order to monitor the safety of these living donors post-donation.

2. Change Calculated Panel Reactive Antibody (cPRA) Calculation

The Chair of the Histocompatibility Committee presented the *Change cPRA Calculation* proposal.

Data summary:

The Histocompatibility Committee proposes a revision of the cPRA calculation, to better reflect actual sensitization and improve access to transplant for the highly sensitized and minority OPTN candidates.

The Histocompatibility Committee proposes the following:

- Add the following human leukoctye antigens (HLA) loci: HLA-DQA1, DPB1, DPA1, and allele-level antibodies to calculation
    - These loci are not currently in the cPRA calculation, disadvantaging eight percent of kidney and kidney-pancreas candidates reporting unacceptable antigens for DQA and DPB
    - Some candidates also receive lower cPRA scores when certain unacceptable antigens are added
- National Merit Donor Program expands the data cohort 100 times, and includes much higher typing resolution than most OPTN deceased donors
    - Current calculation only uses low resolution HLA typing, and allelic antibodies do not receive allocation benefits. Most deceased donor HLA typing is reported at a low resolution
- Use genotype instead of haplotype calculation to better approximate rate of incompatible donors
- Expand from four to seven groups for deceased donor ethnicity, and expand from kidney-specific donor ethnicities to all organs
    - Frequency data needs updating from the 2007-2008 donor populations. OPTN race and ethnicity data is limited for smaller minority groups and needs expanding

This proposal will not change required testing or data collection. There will be a week transition period to obtain documentation for candidates with 99-100 percent cPRA prior to implementation, to allow those candidates to receive the higher allocation priority.

Summary of discussion:

The Kidney Committee Chair asked for clarification on the one week transition period. The Chair of the Histocompatibility Committee explained that once the updated calculation goes live, some patients will jump over night from 60 percent cPRA to 99 percent cPRA. In order to get the allocation priority, the system requires confirmatory documentation. The one week transition period intends to give transplant programs appropriate time to get that documentation and ensure those patients get priority when the updated calculation goes live. The Histocompatibility Chair noted that transplant programs will be notified one week prior to the activation of the new algorithm of any patients who will change classifications due to updated cPRAs. The Kidney Committee Chair remarked that two weeks would be better, to allow programs more time to prepare, but acknowledged that there are challenges and downsides to sending out too many notifications. The Vice Chair agreed, noting that one week seems arbitrary and that a longer transition period will be more beneficial. The Chair of the Histocompatibility Committee explained that the transition time frame can be easily changed, and shared that this is expected to impact about 500 candidates in total, across the country. The Chair of the Histocompatibility Committee added that a potential transplant recipient whose cPRA jumps from 70 percent to 99 percent with the new calculation can still receive similar priority offers as they were receiving before without the documentation, but will not be eligible for the national priority offers based on their cPRA.

One member asked if cPRA is currently viewable in Waitlist℠ for extra-renal multi-organ candidates. The Histocompatibility Committee Chair responded that a multi-organ candidate's cPRA is only viewable in their kidney listing. The member asked why the Histocompatibility Committee wanted to make a candidate's cPRA viewable for all organ types. The Histocompatibility Committee Chair explained that this would make that information available, and added that, as more organs move into continuous distribution frameworks, cPRA will likely factor into more organ's allocation systems. A member agreed, noting that more information is always better. The member continued that the only potential down side would be administrative burden or high programming costs, but otherwise the increased information will be beneficial. The Histocompatibility Committee Chair shared that there will be a programming effort to update Waitlist, but should not be overly burdensome.

3. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

The Kidney Committee representative from the Ad Hoc Multi-Organ Transplantation (MOT) Committee presented the *Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation* proposal.

Data Summary:

The Ad Hoc Multi-Organ Transplantation Committee includes representation from the following OPTN Committees: Ethics, Heart, Kidney, Liver, Lung, Minority Affairs, Operations and Safety, OPO, Pancreas, Patient Affairs, Pediatric, Policy Oversight, Transplant Coordinator, and Vascularized Composite Allograft Committees.

The Ad Hoc Multi-Organ Transplantation Committee is charged with developing and proposing allocation policies addressing multiple organ groups and the practice of multi-organ allocation in alignment with the Final Rule and the transition of organ allocation to continuous distribution. The project map follows the timeline for continuous distribution, so the initial work is focused on kidney multi-organ combinations, which account for 92 percent of all multi-organ transplant in recent years.

This proposal will set eligibility criteria and safety net for heart-kidney and lung-kidney allocation based on kidney function. The eligibility criteria and safety net work hand-in-hand to balance access to transplant for multi-organ candidates and single-organ candidates.

- Eligibility criteria ensures there is a clinical justification for allocating multiple organs to one candidate, while safety nets protects access to kidneys for heart-alone and lung-alone recipients with pre-transplant kidney failure.
- Patients who don't meet the eligibility criteria for simultaneous transplant but need a kidney within a year of their heart or lung transplant would receive priority in kidney allocation through the safety net.

Eligibility criteria for simultaneous heart-kidney and lung-kidney allocation

- Uses the same medical criteria as simultaneous liver-kidney (SLK) allocation for chronic kidney disease and sustained acute kidney injury diagnoses
- Retains 500 nautical mile (NM) distance threshold established in recently approved policy
- Does not apply to pediatric candidates – they are eligible if registered for both organs

Safety net for kidney-after-heart and kidney-after-lung allocation

- Uses the same criteria as kidney-after-liver safety net
- Gives the same priority in kidney allocation to qualifying heart recipients and lung recipients as prior liver recipients

Proposed eligibility criteria:

- If the candidate's transplant nephrologist confirms a diagnosis of Chronic Kidney Disease (CKD), with a measured or estimated glomerular filtration rate (GFR) less than or equal to 60 mL/min for greater than 90 consecutive days, then the transplant program must report at least one of the following:
    - That the candidate has begun regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital-based, independent non-hospital based, or home setting
    - At the time of registration on the kidney waiting list, that the candidate's most recent measured or estimated creatinine clearance (CrCl) or GFR is less than or equal to 30 mL/min
    - On a date after registration on the kidney waiting list, that the candidates measured or estimated CrCl or GFR is less than or equal to 30 mL/min
- If the candidate's transplant nephrologist confirms a diagnosis of sustained acute kidney injury, then the transplant program must report and document at least one of the following:
    - The candidate has been on dialysis at least once every seven days
    - That the candidate has a measured or estimated CrCl or GFR less than or equal to 25 mL/min at least once every seven days
    - If the candidate's eligibility is not confirmed at least once every seven days for the last six weeks, the candidate is not eligible to receive a heart or lung and a kidney from the same donor

Prior heart and lung recipients registered for a kidney would receive safety net priority if:

- The candidate is registered on the kidney waiting list prior to the one-year anniversary of the candidate's most recent heart or lung transplant date

- On a date that is at least 60 days but not more than 365 days after the candidate's heart or lung transplant date, at least one of the following criteria is met:
    - The candidate has a measured or estimated CrCl or GFR less than or equal to 20 mL/min
    - The candidate is on dialysis

Safety net candidates would not receive priority for the highest quality kidneys, only those kidneys with a kidney donor profile index (KDPI) above 20 percent.

Eligibility criteria based on kidney function that is consistent across multi-organ combinations is clinically appropriate and equitable.

- Data on heart-kidney and lung-kidney transplantation support following the approach used for liver-kidney transplantation
- Safety net will prioritize patients who don't meet eligibility criteria but need a kidney shortly after transplant
- Criteria can be adjusted as more data are gathered

Summary of discussion:

One member asked how the MOT Committee developed these criteria, working through concerns about multi-organ candidates and single organ candidates, such as pediatric kidney candidates. The presenting member responded, pointing out that there is no specific guidance for when there are multiple multi-organ shares, such as when one donor has heart-kidney, lung-kidney, simultaneous liver-kidney (SLK), and kidney-pancreas. The presenting member continued, noting that the Kidney Committee has previously discussed the issue of low kidney donor profile index (KDPI) kidneys being offered to multi-organ candidates before single-organ pediatric kidney candidates, which could disadvantage pediatric candidates. The presenting member noted that this proposal is a first step in trying to give guidance to OPOs regarding multi-organ candidates, and what extra-renal shares should be prioritized. The presenting member added that current MOT allocation practices vary between OPOs, and that the decision is often made at an OPO level.

Upcoming Meetings

- March 21, 2022 – Teleconference
- April 1, 2022 – In Person

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Vincent Casingal
  - Amy Evenson
  - Arpita Basu
  - Asif Sharfuddin
  - Caroline Jadlowiec
  - Dierdre Sawinski
  - Elliot Grodstein
  - Marian Charlton
  - Marilee Clites
  - Peter Lalli
  - Precious McCowan
  - Sanjeev Akkina
  - Erica Simonich
  - Stephen Almond
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Lindsay Larkin
  - Ross Walton
  - Kayla Temple
  - Amanda Robinson
  - Lauren Motley
  - Tina Rhoades
  - James Alcorn
  - Jennifer Musick
  - Joel Newman
  - Kaitlin Swanner
  - Laura Schmitt
  - Leah Slife
  - Meghan McDermott
  - Melissa Lane
  - Rebecca Marino
- **Other Attendees**
  - Stevan Gonzalez