OPTN Kidney Transplantation Committee
Meeting Summary
February 22, 2021
Conference Call

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

Introduction

The Kidney Transplantation Committee met via teleconference on 02/22/2021 to discuss the following agenda items:

1. Welcome & Announcements
2. Calculated Panel Reactive Antibodies (CPRA) Project: Update and Data Request
3. Clarification of Multi-Organ Allocation Policy Proposal
4. Refusal Codes: Request for Feedback

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

1. Welcome & Announcements

Committee Leadership presented updates on the kidney allocation policy implementation.

Summary of discussion:

There were no comments or questions.

2. Calculated Panel Reactive Antibodies (CPRA) Project: Update and Data Request

The Histocompatibility ex-officio Chair presented an update on the CPRA Revision Project and related data request. The Committee provided feedback on the project and data request.

Data summary:

CPRA is currently used to prioritize highly sensitized candidates in kidney and pancreas allocation, in order to improve patient access. Current CPRA calculation does not factor in sensitization at three major loci, only utilizes low-level specificities, and is based on Organ Procurement and Transplant Network (OPTN) frequency data and ethnic proportions are based on a 14-year-old cohort. Some candidates also receive lower CPRA scores when certain unacceptable antigens are added.

This project proposes several changes:

- Addition of Human Leukocyte Antigens (HLA)-DQA, DPB, and DPA
- Use of National Marrow Donor Program (NMDP) HLA typing data to create a more comprehensive list of HLA frequencies
- Use of a genotype calculation instead of a haplotype calculation to better approximate rate of incompatible donors.

Once implemented, that anticipated impact of this project includes a calculation that more accurately depicts a candidate's likelihood of compatibility with potential deceased donors. Preliminary modelling from 2017 indicates that the addition of DQA and DPB most significantly impact the African American candidate population.

Proposed analyses for public comment include:

- Size of Impact – count and percent of kidney waiting list with CPRA change and allocation category change under proposed CPRA and the distribution of change in CPRA for kidney waitlist candidates
- Degree of Improvement – Correlation between offer rate and CPRA, correlation between transplant rate and CPRA, and the proportion of compatible donors
- Stratifications on race and ethnicity, region, pediatric and adult, and candidates with unacceptable antigens lacking frequencies and those without said antigens

Summary of discussion:

The Vice Chair of the Committee expressed approval for the project and asked for clarification between genotype and haplotype calculations. It was explained that genotype calculations utilize the number of donors in a population that have that particular allele or antigen, while haplotypes stratify A, B, and DR loci all together. Genotypes focus on specific antigens.

The Vice Chair of the Committee asked if the Histocompatibility Committee will examine regional differences in the donor population, whether that had been analyzed before, and how these differences would be addressed. The ex-officio Chair of the Histocompatibility Committee noted that regional differences had not been looked at previously, and that this project will not likely have unintended consequences on equity with kidney allocation moving to continuous distribution. The Histocompatibility ex-officio Chair agreed that it will be important for this project to examine any potential differences, particularly as there are known regional differences in racial populations.

A Scientific Registry of Transplant Recipients (SRTR) representative asked if DPA and DPB typing is done ubiquitously, and it was confirmed that the methods predominately used for HLA typing also type for DPA, although DPA typing is not mandatory and not currently input into UNet^{SM}. The SRTR representative expressed concern about adding points based on DPA and DPB if some hospitals did not have access to necessary typing methods. The Histocompatibility ex-officio Chair agreed, and noted that all labs type DPA and DPB at this point, and that the addition of DPA to required typing will not be onerous for histocompatibility labs.

The Histocompatibility ex-officio Chair and staff clarified that the modeling for this project is being done through a contract with Tulane, due to compatibility issues with the kidney-pancreas simulated allocation model (KPSAM) program typically used by SRTR.

3. Clarification of Multi-Organ Allocation Policy Proposal

The Chair of the Organ Procurement Organization (OPO) Committee presented the Clarification of Multi-Organ Allocation Policy proposal currently out for public comment and received feedback from the Committee.

Data Summary:

This proposal is the initial phase to address multi-organ allocation policy, and aims to provide OPOs with clearer direction when offering certain multi-organ combinations. Addressing the multi-organ combinations in this proposal will provide policies for 97 percent of multi-organ transplants. The clear thresholds established in this proposal limit OPO discretion and improve consistency in multi-organ allocation.

This proposal establishes medical criteria for when the OPO must offer the second organ to the same candidate when allocating according to the heart or lung match run.

- Heart Adult Statuses 1, 2, and 3
- Heart Pediatric Status 1A and 1B
- Lung candidates with a lung allocation score (LAS) greater than 35

This proposal expands the size of the nautical mile circle for required sharing to 500 NM, and specifies the required second organ as either the liver or the kidney. This proposal does not address which match run OPOs use to allocate multi-organ combinations.

Summary of discussion:

One member noted that heart status 4 was not included in the required multi-organ share eligibility criteria, though the number of multi-organ heart status 3 transplants was very similar. The member asked about the rationale behind heart status 4 exclusion, and if modelling was done to set the lung candidate eligibility at an LAS of 35 or higher. The OPO Committee Chair acknowledged that there have been many recommendations to include heart status 4. The OPO Committee Chair explained that both the heart and lung multi-organ eligibility criteria were established based on previous years' multi-organ transplant data, and that those scores and status were chosen as appropriate thresholds by representatives of the thoracic committees at the time.

Another member asked how a heart status 4 patient would receive a kidney if they were a multi-organ candidate, and if that candidate could only receive a kidney from the kidney waitlist. The Chair of the OPO Committee clarified that sharing a second organ with a status 4 multi-organ heart candidate would be a permissible share for the OPO. The member questioned the rationale behind allowing the status 4 heart-kidney share instead of then requiring the kidney to be allocated from the kidney match run or other required multi-organ share. The OPO Committee Chair remarked that this proposal is the first phase in clarifying multi-organ allocation, and aims to provide further clarity, while later phases can produce more consistency in multi-organ sharing. The member noted that too many high quality kidneys were allocated with multi-organ combinations, and that more emphasis is needed to ensure pediatric and low estimated post-transplant survival score (EPTS) patients aren't inappropriately disadvantaged by multi-organ allocation.

A member noted that the kidneys used in multi-organ transplants tend to be the highest quality kidneys, which puts kidney alone candidates at a disadvantage. The member asked how many kidneys would have been allocated as a single organ instead of as part of a multi-visceral over the last year if the proposed required multi-organ share criteria had been in place. The OPO Committee Chair shared that more than 80 percent of 232 multi-organ transplants performed in 2019 would meet the proposed criteria.

The Committee Chair expressed support of improved clarity around required and permissible multi-organ kidney shares. The Chair recommended that the thoracic committees follow a similar process used to develop SLK, and work with the Kidney Committee to establish multi-organ eligibility criteria in later phases of multi-organ allocation policy development. The Chair noted that some heart-kidney and lung-kidney candidates may not necessarily need a kidney, as receiving the heart or lung transplant alone can often vastly improve renal function.

The Committee Chair asked if the OPO Committee planned to include or release any guidance to limit allocating one kidney as part of a multi-organ combination, so the other could be allocated from the kidney match run. The OPO Committee Chair shared that the Data Advisory Committee had a similar comment, and that the OPO Committee will consider this feedback. The Committee Chair noted that the Kidney-Pancreas candidate populations and disease processes are very similar, and could potentially be considered an exception to this limit if implemented.

One member asked how a released kidney would be allocated if it had been placed and transported as part of a multi-organ share, but later had to be declined. The OPO Committee Chair explained that the kidney would be reallocated according to the board-approved released kidney policy, once implemented.

4. Refusal Codes: Request for Feedback

Staff presented the list of refusal codes and categories developed by the Refusal Codes and Late Turndowns Workgroup and requested feedback from the Committee.

Data Summary:

The Refusal Codes and Late Turndowns Workgroup has developed 40 refusal codes across 8 categories in order to improve data quality on organ refusals to reflect real-time offer decision making. The current refusal codes in use are outdated and vague.

Summary of discussion:

The Committee Chair noted that the current codes do not provide enough granularity, which hinders analysis of why potential useable kidneys are refused and discarded. The Chair continued that the granularity within the categories will be critical to evaluation.

The Committee Chair remarked that for pediatric patients, organs are typically turned down because they are a poor match for that particular candidate, not because they are not useable organs. The Chair added that the proposed codes may not get to the heart of that kind of refusal. Another Committee member agreed, explaining that a 65 year old donor kidney is not a good match for a 25 year old candidate, and that there needed to be a refusal code to reflect that. An SRTR representative agreed. Another member noted in that scenario, that specific refusal codes would be input for specific candidates, so that donor age could be used for younger candidates, but wouldn't be necessary for an older recipient. A member agreed, and noted that adding the word "mismatch" to codes such as donor age. The Vice Chair agreed, adding that calling it "donor age mismatch" is clarifying.

Upcoming Meetings

- March 15, 2021
- April 14, 2021 – Virtual "In-Person" Committee Meeting

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Vincent Casingal
  - Jim Kim
  - Any Evenson
  - Andrew Weiss
  - Arpita Basu
  - Precious McCowan
  - Deirdre Sawinski
  - Elliot Grodstein
  - Erica Simonich
  - Marilee Clites
  - Peter Kennealey
  - Asif Sharfuddin
  - Cathi Murphey
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Nick Salkowski
  - Peter Stock
- **UNOS Staff**
  - Adel Husayni
  - Amanda Robinson
  - Ben Wolford
  - Courtney Jett
  - James Alcorn
  - Joel Newman
  - Kayla Temple
  - Kelsi Lindblad
  - Lauren Motley
  - Lindsay Larkin
  - Meghan McDermott
  - Melissa Lane
  - Robert Hunter
  - Ruthanne Leishman
  - Sara Moriarty
  - Sarah Konigsburg
  - Tina Rhoades
- **Additional Attendees**
  - John Lunz
  - Peter Lalli
  - Loren Gragert
  - Diane Brockmeier