OPTN Kidney Transplantation Committee
Meeting Summary
November 7, 2022
Conference Call

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

Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 11/07/2022 to discuss the following agenda items:

1. Welcome and Announcements
2. Proposal: *Modify Waiting Time for Candidates Affected by Race-Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations*
3. Proposal: *Update Kidney Paired Donation Policy*
4. Continuous Distribution of Kidneys Organ Allocation Simulator (OASIM) Modeling Results

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

1. Welcome and Announcements

Staff and Committee Leadership welcomed the Committee members.

Summary of discussion:

There were no questions or comments.

2. Proposal: *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations*

The Committee reviewed previous discussion on the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* and voted on finalized policy language to send to the OPTN Board of Directors in December.

Presentation summary:

Previously, the Kidney Committee agreed on several key aspects of the proposal:

- Optional vs. Mandatory: mandate eGFR waiting time modifications
- Monitor: documentation and attestation
- Scope: pre-emptively registered and dialysis candidates
    - Must span from above 20 to below 20 mL/min with re-calculation
- Timeframe: 365 days
- Patient notification: pre-review notification to all listed candidates and post-review notification to listed Black and African American candidates informing them of their eligibility

Key points:

- Notification requirements:
    - Programs must notify every candidate registered at the program of the responsibilities of the program related to waiting time modifications for kidney candidates affected by race-inclusive eGFR calculations

- Determination of eligibility:
    - Programs must determine eligibility for each candidate registered at the program
    - An eligible candidate is:
        - Registered as Black or African American in the OPTN Computer System
        - Has documentation establishing that the candidate had an eGFR that was over 20 mL/min and would have been 20 mL/min or less if a race-neutral calculation had been used
- Application for waiting time modification:
    - Programs must submit an eGFR waiting time modification for each eligible candidate
    - Application must include:
        - Documentation of eGFR values for black and non-black candidates or
        - Estimation of GFR with a race inclusive calculation and a re-estimation of GFR with a race-neutral calculation
        - Name and signature of physician or surgeon
- Reporting requirements:
    - Programs must submit an attestation that they have completed:
        - Notification to all candidates registered as Black or African American of their eligibility
        - Submission of eGFR waiting time modification for all eligible candidates registered at their program

Summary of discussion:

One member asked from what time point the new qualifying eGFR date should occur, asking if the new calculation has to be from time of registration or if it can be earlier. The member noted that most candidates will have a qualifying eGFR at some time or another prior to registration. The Chair responded that there would not be a specific time requirement for the requested calculation to have been taken during, and that there would be no reference to the new calculation date to be within listing or referral to the transplant program. The member asked if there would be confusion about this for transplant programs. The Chair noted that it may be easier to find if the candidate has been in the same healthcare system prior to referral as a patient, but that it would be more difficult if they had only been seen at that system for transplant referral. The Chair continued that there will not be a timeframe for the qualifying eGFR date, and that this will be explained in the frequently asked questions (FAQ) document. The member agreed that this makes sense, as long as it is explained in an FAQ or resource document.

A member asked if the candidate was referred a year ago, but was found to have a race neutral qualifying eGFR a year and a half ago, that the older qualifying eGFR date could be submitted. The Chair responded that, yes, the year and a half old race-neutral qualifying eGFR can be submitted under the proposed modification process. The Chair explained that the argument is that, had a race-neutral calculation been used, that person might have been referred earlier. Thus, referral date is not referenced in this policy. The member agreed this makes sense.

One member asked if the "Application for Waiting Time Modification" section should specify modifications should be submitted for each qualifying candidate, since modifications can't be submitted without appropriate documentation. The Chair explained that the term "eligibility" in this section refers back to the "determination of eligibility" section, and so that reference is not necessary. The member agreed. Staff pointed out that, since documentation is part of the defined eligibility, this is carried along into the following sections and subsections. The member agreed, remarking that it must be clear that a center does not need to submit a modification for a candidate with no previous applicable

documentation, as there is nothing for that program to submit. Staff continued that, because eligibility includes documentation, a candidate who has no documented earlier race-neutral qualifying eGFR date is not eligible.

A member asked how this should work for candidates listed at more than one center, and if each program would need to submit a modification. Staff explained that, as written, the proposed policy language would require each program to submit a modification for an affected candidate. The policy language relates to candidates registered with a program. Staff added that this would be made clear in an FAQ and in member education.

VOTE: The Committee voted unanimously in favor of sending the proposed policy language for the *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations* proposal to the Board of Directors for approval.

3. Proposal: *Update Kidney Paired Donation Policy*

The Committee reviewed public comment analysis and proposed post-public comment changes on the *Update Kidney Paired Donation Policy* proposal, and voted to send the updated proposal to the Board of Directors in December.

Presentation summary:

The Update KPD Policy proposal will:

- Condense match offer and exchange deadlines in the OPTN KPDPP
- Establish new deadlines from match offer to recovery and transplant
- Modify the OPTN KPDPP extension request policy
- Clarify informed consent requirements are applicable to any KPD program
- Align KPD donor informed consent requirements with Living Donation policy
- Update the definition of bridge donor
- Modify informed consent requirements for bridge donor, to emphasize donor autonomy
- Update informed consent documentation requirements
- Additional minor language alignments

The rationale behind these changes includes:

- Establish more efficient timeframe for OPTN KPD exchanges
- Increase fairness to patients
    - Reduce risk of an exchange breaking due to candidate illness, donor unavailability, etc.
    - Prevent termination of an exchange due to non-response
- Ensure holistic informed consent for participants in any KPD program
- Emphasize donor autonomy and ensure transplant programs have explicit conversations regarding expectations
- Align policy language with other OPTN Policies to provide clarity

Public comment sentiment was largely supportive, with support across regions and member types. In particular, the National Kidney Foundation, the National Association of Transplant Coordinators Organization, The American Society for Transplant, the American Nephrology Nurses Association, Kidney Donor Conversations, the OPTN Transplant Coordinators Committee (TCC) and the OPTN Living Donor Committee supported this proposal. Comments submitted to the OPTN site included:

- General support for reduced timeframes and increased efficiency, as well as reduction to potential for and number of delays to an exchange

- Support for maintaining the 2-business day preliminary response deadline
- General support for the 60 day deadline from match offer to transplant and recovery, and benefits to efficiency
- Support for expanded language regarding financial risk and improved clarity in informed consent policies
- Support for increased emphasis on donor and bridge donor autonomy, as well as increased communication and patient understanding
- Support for tighter deadlines, noting this will improve efficiency and make the KPD program more aggressive
- Support for updates to extension request policy to default to granting an extension in the case of non-response from participating centers
- Concern for KPDPP policies to not be overly prescriptive, at the risk of disincentivizing programs to participate
- Support for standardizing clinical kidney paired donor information necessary for evaluation

The OPTN KPD Workgroup recently met and reviewed public comment feedback. After this review and discussion, the OPTN KPD Workgroup is recommending several specific post-public comment changes:

- Deadline from match offer to scheduled recovery and transplant
    - Allows programs to account for increased donor autonomy in when surgery occurs
- Additional language to clearly state all of a bridge donor's options for donation, and the option to decline to donate
    - Increased transparency in patient communication
- Informed consent clarifications and clarifications to policy language related to match offer response deadlines
- Additional deadline: agree upon date and time for recovery of matched kidneys within 15 business days of receiving the match offer
    - Encourages efficiency within the OPTN KPDPP

Recommended updates also include the following, based on policy language conventions and clarity:

- Remove proposed cross reference to *13.4.D: Additional Requirements for Non-Directed Donors* from *14.6.B: Placement of Non-directed Living Donor Organs*
    - Concerns for authority, particularly in the wording of the cross reference
    - Cross reference may be more confusing, as the intentions of these polices are misaligned
- Minor updates to definition for Bridge Donor
    - Improved clarity and accuracy, aligns with the use of Bridge Donor in OPTN Policy
    - Increased emphasis on donor autonomy

<u>Summary of discussion:</u>

One member expressed support for the post-public comment changes recommended and the proposal, remarking on the benefits to the efficiency of the OPTN KPD pilot program. The member noted that most constraints for KPD come from the administrative side, particularly relative to contracts between the donor and recipient hospitals. The member recommended having a sample contract that can be modified and utilized by hospitals in the program. The member continued that clinical exchange of details has worked well, but that contractual discussion, particularly related to donor complication coverage, can be more difficult. Staff shared that there is a sample template contract available to members in the OPTN KPD System, but that this contract is not required.

The Chair remarked that the proposal is reasonable and likely overdue.

VOTE: The Committee voted unanimously in favor of sending the proposed policy language for the *Update Kidney Paired Donation Policy* proposal to the Board of Directors for approval.

4. Continuous Distribution of Kidneys: OASIM Modeling Results

The Committee reviewed an initial overview of the Kidney Continuous Distribution OASIM modeling results.

Presentation summary:

Background and request:

- The Kidney and Pancreas Continuous Distribution Workgroup requested simulation results for 4 continuous allocation scenarios
- The Workgroup set attribute weights and modifiers for each of these scenarios for Kidney and Pancreas, Kidney-Pancreas, and Pancreas Islet Allocation
- The continuous distribution framework for kidney transplant includes 5 components: medical urgency, post-transplant outcomes, candidate biology, patient access, and placement efficiency
- Uses OASIM software, which is a modern, more flexible update of the Kidney-Pancreas Simulated Allocation Model (KPSAM)

Why Simulate Organ Allocation?

- To generate data that does not exist
    - No data exists for *potential* allocation policies, only for historical allocation policies
- We use simulation to generate data about "possible worlds"
    - Through assumptions, statistical modeling, and running the simulation over a historical period with different allocation rules we create match runs that did not happen in reality
- The data produced from the simulation "looks like" the historical data
- This creates comparisons of the type "what would have happened under different allocation policies"
    - Counterfactual comparisons, not predictions of future events

Organ allocation simulation includes several sub-models to predict:

- What would happen once a match run is generated:
- How patients accept or decline those offers
- Once identified patients transplanted in the simulation, what would their post-transplant outcomes look like?

Scenarios modeled include:

- Scenario 1: Current policy
- Scenario 2: Combined analytical hierarchy process (AHP) weights
- Scenario 3: Increased longevity weights (more weight to post-transplant outcomes)
- Scenario 4: All donor efficiency weights (more weight to placement efficiency)
- Scenario 5: High Kidney Donor Profile Index (KDPI) efficiency weights (use of donor modifiers)

Summary of Results

- OASIM has modeled a continuous distribution system that has eliminated hard boundaries of previous systems

    - Increased travel distance for all kidneys
    - Particular increase in travel distance for pediatric kidneys, whose priority for national kidneys was greater under the continuous distribution scenarios
    - Can manage travel distances by increasing the weight on proximity efficiency
- Longevity matching of kidney is more precise under all continuous distribution scenarios compared to current policies
    - Higher KDPI kidneys go to older recipients
    - Longevity matching trend is strongest under the increased longevity scenario
    - Side-effect of more precise longevity matching is lower transplant rates in kidney candidates age 18-35
    - The continuous distribution longevity matching score gives priority for high estimated post-transplant survival (EPTS) score candidates, generally older recipients for high KDPI kidneys
    - Difference from current policy under which there is no specific mechanism that pushes high EPTS candidates higher on the high KDPI match runs
- The "increased longevity" scenario has increased weight on "post-transplant outcomes" and lower weight on "qualifying time" score
- The "all donor efficiency" scenario has increased weight on "placement efficiency" and lower weight on "qualifying time"
- The lower weight on "qualifying time" for each of these scenarios:
    - May explain lower transplant rates for patients on dialysis for greater than 5 years
    - Unintended consequence of slightly lower rates for Black candidates, who tend to have longer dialysis time
    - Continuous distribution can be adjusted – transplant rates for Black candidates and candidates on hemodialysis greater than 5 years are higher in scenarios with higher weight on "qualifying time"
- The continuous distribution scenarios showed lower transplant rates in some OPTN regions – but this was in regions with already high transplant rates, which brought these regions closer to the transplant rates in many other OPTN regions

Summary of discussion:

One member asked if pre-transplant waitlist mortality could be modeled. An SRTR representative explained that the report does include some metrics on pre-transplant mortality, but that this metric requires a higher level of assumptions.

The Chair and Vice Chair thanked the SRTR representatives for their presentations.

The Committee tabled discussion due to time constraints, and will continue discussion at their next meeting.

Upcoming Meetings

- November 14, 2022 - Teleconference
- November 21, 2022 - Teleconference

Attendance

- **Committee Members**
  - Martha Pavlakis
  - Jim Kim
  - Arpita Basu
  - Bea Concepcion
  - Chandrasekar Santhanakrishnan
  - Elliot Grodstein
  - Tania Houle
  - Carrie Jadlowiec
  - Jason Rolls
  - Jesse Cox
  - Kristen Adams
  - Marian Charlton
  - Marilee Clites
  - Patrick Gee
  - Peter Lalli
  - Precious McCowan
  - Sanjeev Akkina
  - Nidyanandh Vadivel
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Caitlyn Nystedt
  - Grace Lyden
  - Jon Snyder
  - Jon Miller
  - Josh Pyke
  - Nick Wood
  - Raja Kandaswamy
  - Ryan Follmer
  - Tim Weaver
- **UNOS Staff**
  - Lindsay Larkin
  - Kayla Temple
  - Keighly Bradbrook
  - Ben Wolford
  - Beth Coe
  - Kaitlin Swanner
  - Kelley Poff
  - Kim Uccellini
  - Krissy Laurie
  - Lauren Motley

    - Matt Belton
    - Rebecca Murdock
    - Roger Brown
    - Ross Walton
    - Ruthanne Leishman
    - Sara Moriarty
    - Sarah Booker
    - Susan Tlusty
    - Tamika Qualls
    - Tomas Dolan
    - Tina Rhoades
- **Other**
    - Lisa Stocks