OPTN Kidney Transplantation Committee
Meeting Summary
April 17, 2023
Teleconference

Martha Pavlakis, MD, Chair
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Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 4/17/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Estimated Post Transplant Survival (EPTS) and Kidney Donor Profile Index (KDPI) Mapping Tables
3. *Align OPTN Kidney Paired Donation (KPD) Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* Proposal Public Comment Review and Vote
4. Offer Acceptance Limits
5. Policy Oversight Committee (POC) Update

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

1. Welcome and Announcements

Committee Leadership welcomed the Committee members. Staff announced the May 23 Committee call will be an extended virtual meeting.

Summary of discussion:

There were no questions or comments.

2. Estimated Post Transplant Survival (EPTS) and Kidney Donor Profile Index (KDPI) Mapping Tables

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. Kidney allocation policy requires committee review and annual update of KDPI and EPTS mapping tables. 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.

KDPI Data summary:

The updated KDPI cohort from 2022 is similar to 2021, 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 steadily increased, with a slight dip between 2020 and 2022
- Proportion of kidney donors with a history of hypertension has been increasing, as well as history of diabetes
- The proportion of donation after cardiac death (DCD) donors has steadily increased over time
- Proportion of donors recovered with Hepatitis C (HCV) has increased, with a slight dip in 2021

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

- Proportion of Black kidney donors has fluctuated over time but remain fairly consistent
- 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 decreases 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:

There were no questions or comments.

Vote:

The Committee voted unanimously to approve the new KDRI-to-KDPI mapping table based on the year 2022 reference population.

EPTS 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, however from 2021 to 2022 there was a slight decrease meaning in the past year there was a slight shift to lower scores, meaning in general candidates had longer estimated longevity. This shift is driven by:

- Over time there has been a slight increase in age, but from 2021 to 2022 there was not much change in average age
- There was a small increase in candidates with diabetes from 2021 to 2022
- The proportion of candidates who have received prior transplant has decreased over time
- The average amount of time that candidates are dialyzed has decreased over time

Adopting the new EPTS reference population will have implications for patients. Upon implementation, it is possible slightly less candidates would qualify for top 20 percent EPTS priority due to the recalibration of the mapping table, as the raw EPTS score needed would decrease from 1.535142 to 1.535102, a difference of 0.000041. Any candidates with a raw EPTS greater than 1.535102 and less than 1.535142 would have their EPTS increase from 20 to 21 percent.

Summary of discussion:

There were no questions or comments.

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, 2022.

3. *Align OPTN Kidney Paired Donation (KPD) Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* Proposal Public Comment Review and Vote

The Committee reviewed submitted public comment feedback and KPD Workgroup recommendations for potential post-public comment changes for the *Align OPTN Kidney Paired Donation (KPD) Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* Proposal.

Public Comment Feedback Summary:

The community was asked to consider the following during public comment:

- Burden and appropriateness of proposed requirements
- Additional medical or psychosocial elements that should be required
- Exceptions to infectious disease testing requirements
- Calculation of the donor re-evaluation deadline, based on date of registration
- Notification, re-evaluation, and eligibility timeframes
- Implementation considerations

The proposal received 245 comments, with 19 written responses. The greatest participation came from transplant hospitals and organ procurement organizations (OPOs). There was participation from at least 43 states and all member types. The proposal received an overall sentiment score of 4.0 from all respondents, and a score of 4.0 from regional meetings. Some opposition was noted in regions 2, 8, and 10. Most opposition fell in the category of medical and psychosocial re-evaluation requirements.

The Committee then reviewed summarized public comment feedback by theme:

Donor Re-evaluation Requirements: Timeline

As originally proposed:

- An automated notification is sent to transplant programs' point of contact 60 days prior to a donor's upcoming re-evaluation date
- An automated notification is sent to transplant programs' point of contact 90 days prior to the date at which the donor would become ineligible
- The date of registration into the OPTN KPD Pilot Program (KPDPP) is the date from which the re-evaluation date is calculated or the date of the most recent re-evaluation, whichever is most recent

In public comment, the following feedback was received:

- Support for the 60 days prior notice to donor re-evaluation date as reasonable. However, one comment did state that extending this to 90 days may help better accommodate donor schedules and benefit programs with fewer resources.
- Support for 90 days between notification and potential donor ineligibility date as sufficient for programs and potential donors.
- A suggestion that the re-evaluation deadline be based from the time of registration because there can be significant periods of time between registration and activation, which may lead to many initial evaluation components being out of date. *Note: as originally proposed, re-evaluation date is already based on registration date.*
- A suggestion that the anniversary of the last re-evaluation be considered such that donors are not ever re-evaluated more than once per year unless there is a medically supported reason for more frequent evaluations. *Note: This is specified in the original proposal.*
- A suggestion that the due date for re-evaluation be more specifically defined.

Donor Re-evaluation

- There was general support for the concept of donor re-evaluation to keep potential donor information updated, improve ongoing candidacy, decrease the number of swap failures, and increase the number of successful KPD transplants.
- Some commenters noted that additional requirements will increase administrative and patient burden and costs and may present barriers.

- There was a note that these changes may have limited impact to the overall KPD patient population, because the OPTN KPDPP is relatively small.

Infectious Disease Re-Evaluation Requirements:

Staff recapped that the following testing is currently proposed as infectious disease re-evaluation requirements:

- Cytomegalovirus (CMV) antibody
- Epstein Barr Virus (EBV) antibody
- Human Immunodeficiency Virus (HIV) antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination
- HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
- Hepatitis B surface antigen (HbsAg)
- Hepatitis B core antibody (total anti-HBc) testing
- Hepatitis B Virus (HBV) deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
- Hepatitis C antibody (anti-HCV) testing
- Hepatitis C Virus (HCV) ribonucleic acid (RNA) by nucleic acid test (NAT)
- Syphilis testing
- Donor does not need to retest for CMV-antibody or EBV-antibody if they have previously tested positive

The proposal received the following feedback:

- Support for repeating all infectious disease testing, keeping the re-test exception only for previously positive CMV and EBV antibodies
- Comment that the infectious disease requirements could be confusing for programs, as some centers repeat standard infectious disease panels
- Suggestion to limit the infectious disease retesting to conditions that could be treated prior to donor surgery, such as positive RPR (syphilis) or TB, and conditions relevant to matching, such as CMV serostatus.
- An alternative suggestion to the one above is to require only testing for serologies that were previously negative
- A suggestion to add Hepatitis B and Hepatitis C virus as additional infectious disease retesting exceptions for living donors who have previously tested positive for these diseases

In public comment, the public was asked if any additional tests should be included in the re-test exception currently proposed for EBV and CMV antibody testing. The community offered the following suggestions:

- Suggestion to limit the infectious disease retesting to conditions that could be treated prior to donor surgery, such as positive syphilis (RPR) or Tuberculosis (TB) and conditions relevant to matching, such as CMV serostatus. This comment noted that other serological testing could be updated at the time of the preoperative visit.
- An alternative to the above suggestion is to require only testing for serologies that were previously negative. *Note: this was discussed by the Workgroup previously and determined to be inadequate to achieve the goals of the re-evaluation.*
- A suggestion to add Hepatitis B and Hepatitis C viruses as additional infectious disease retesting exceptions for living donors who have previously tested positive.

Donor Re-Evaluation Requirements: Medical and Psychosocial

The medical and psychosocial requirements received the following feedback in public comment:

- The medical and psychosocial re-evaluation requirements are reasonable and do not present an undue burden for programs involved in the OPTN KPDPP
- Support for repeating the medical and psychosocial assessments annually
- Suggestion to align KPDPP re-evaluation requirements with the National Kidney Registry's (NKR) KPD requirements to reduce burden on programs and reduce potential unintentional non-compliance from members attempting to keep up with different requirements
- Suggestion to add updating the Independent Living Donor Advocate (ILDA) evaluation as part of this process as a way to demonstrate complete understanding of the evaluation and informed consent process and the continued availability of the ILDA. Note: the proposal states that *Policy 14.2* encompasses re-evaluation of the ILDA

Donor Re-Evaluation Requirements: Obtaining Donor Signature

The original proposal stated that programs will be required to obtain the donor's signature confirming that the donor has been re-informed that they may withdraw from participation in the OPTN KPDPP program at any time, for any reason. There were some comments received specific to this requirement:

- Disagreement with the proposed requirement to re-consent donors annually as evidenced by the donor's signature. Commenters pointed out that informed consent is an evolving process documented over many visits and that requiring an additional written signature is beyond the minimum necessary standards for safe and effective practices. Another commenter suggested that ensuring re-education is documented would be sufficient for the purposes the Committee is trying to serve.
- Concern that this requirement may conflict with existing living donor policy.
- Concern that the requirement for a written signature would be difficult and impractical to obtain, especially from donors outside of the local area of the transplant center, which may lead to losing donors from the system if they do not wish to travel.
- A note that a written signature is not sufficient for ensuring that a patient has read or understands a document.
- A note that the requirements should allow for telehealth options for donors.
- A suggestion to align the signature and consent process with the listing requirements, which currently requires signatures for consent to blood type and for high KDPI kidneys.

Align Blood Type Matching

In public comment, feedback showed that the community thought the blood type alignment requirements were appropriate and were supported. No comments demonstrated opposition to the proposed requirements.

Living Donation

Two comments were received during the public comment period from the general public on the importance of living donation in general. The feedback included the following:

- The importance of keeping living donors at the top of the priority list for organ transplants
- Consideration for the sacrifice and gift from living donors and their families

<u>Post-Public Comment Changes for Consideration:</u>

The KPD Workgroup met on April 4, 2023 to review public comment feedback and determine changes to recommend to the Kidney Committee. The Workgroup offers the following post-public comment changes for consideration:

Timeline and Implementation Period

- Donor re-evaluation date: the Workgroup recommends keeping the donor re-evaluation date from first registered date
- The proposed 60 days prior notice to donor re-evaluation date supported in public comment: The Workgroup recommends keeping this at 60 days
- 90 days between notification and potential donor ineligibility date: The Workgroup recommends keeping this as proposed at 90 days
- Initial implementation period: The Workgroup recommends an initial implementation period of 90 days (3 months)

Infectious Disease Requirements

- The Workgroup recommends adding Hepatitis B core antibody (total anti-HBc) testing and Hepatitis C antibody (anti-HCV) testing to the re-test exception, for donors who have prior positive results for these tests
- As recommended by the Workgroup: Donor will be retested for the following during the re-evaluation:
    - Cytomegalovirus (CMV) antibody
    - Epstein Barr Virus (EBV) antibody
    - Human Immunodeficiency Virus (HIV) antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination
    - HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
    - Hepatitis B surface antigen (HbsAg)
    - Hepatitis B core antibody (total anti-HBc) testing
    - Hepatitis B Virus (HBV) deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
    - Hepatitis C antibody (anti-HCV) testing
    - Hepatitis C Virus (HCV) ribonucleic acid (RNA) by nucleic acid test (NAT)
    - Syphilis testing
- Donor does not need to retest for CMV-antibody, EBV-antibody, Hepatitis B core antibody (total anti-HBc) testing, and Hepatitis C antibody (anti-HCV) testing, if they have previously tested positive

Obtaining Donor Signature

- Workgroup recommendation: modify this to require that the transplant hospital confirm that the donor has been re-informed. Requiring a signature was not supported in public comment, but the Workgroup wants to ensure that the informed consent piece is still being accomplished.

Summary of discussion:

There were no questions or comments.

Vote:

The Committee unanimously approved sending the *Align OPTN Kidney Paired Donation (KPD) Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* proposal with recommended modifications to the Board of Directors in June, 2023.

4. Offer Acceptance Limits

An OPTN Organ Procurement Organization (OPO) Committee member presented an update on the *Organ Offer Acceptance Limit* project and options the Offer Acceptance Limit Workgroup is exploring. The Workgroup is requesting feedback from stakeholder committees to inform a proposal to go out in Summer of 2023.

Summary of discussion:

The Vice Chair commented there may be concern for missing out on another potential donor offer if there's only the choice of one acceptance. The Vice Chair further commented there is variability in OPO practice so some standardization would be helpful.

Next Steps:

The OPO Committee will be meeting to discuss all committee feedback on Friday, April 21, 2023.

5. Policy Oversight Committee (POC) Update

The Vice Chair presented an update on the Policy Oversight Committee's (POC) continual improvement efforts related to benefit scoring and post-implementation monitoring.

Summary of discussion:

There were no questions or comments.

Upcoming Meetings

- May 23, 2023 – Conference Call

Attendance

- **Committee Members**
  - Jim Kim
  - Arpita Basu
  - Asif Sharfuddin
  - Patrick Gee
  - Precious McCowan
  - Carrie Jadlowiec
  - Jason Rolls
  - Jesse Cox
  - Peter Lalli
  - Steve Almond
  - Tania Houle
- **HRSA Representatives**
  - Shelley Grant
- **SRTR Staff**
  - Ajay Israni
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
  - Ryo Hirose
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Kieran McMahon
  - James Alcorn
  - Lauren Motley
  - Thomas Dolan
  - Carly Layman
  - Katrina Gauntt
  - Keighly Bradbrook
  - Kimberly Uccellini
  - Krissy Laurie
  - Mariah Huber
  - Robert Hunter
  - Ross Walton
  - Sara Moriarty
  - Tina Rhoades
- **Other**
  - Kurt Shutterly
  - Caitlin Peterson
  - John Lunz
  - Reza Saidi
  - Leigh Burgess