OPTN Kidney Transplantation Committee
Kidney Paired Donation Workgroup
Meeting Summary
April 4, 2023
Conference Call

Marion Charlton, RN, SRN, CCTC, Chair

Introduction

The Kidney Paired Donation (KPD) Workgroup (the Workgroup) met via teleconference on 04/04/2023 to discuss the following agenda items:

1. Welcome and Introduction
2. Review Post-Public Comment Feedback on *Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements*
3. Discuss Possible Post-Public Comment Changes

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

1. Welcome and Introduction

Staff and the Chair welcomed members to the call and made a few announcements.

2. Review Post-Public Comment Feedback on *Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements*

The Workgroup reviewed feedback on the proposal received during public comment to determine which changes are appropriate to recommend to the OPTN Kidney Committee for approval.

Summary of presentation:

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

1. Are the proposed psychosocial and medical re-evaluation requirements appropriate? Do any of the proposed re-evaluation requirements pose a burden on transplant programs, and if so, which?
2. Are there other additional medical or psychosocial elements that should be included for re-evaluation?
3. Should the infectious disease retesting exception apply to other tests that the donor has previously tested positive for, or just CMV antibodies and EBV antibodies? If so, which?
4. Should the donor's re-evaluation deadline be based on the date the donor was first registered in the OPTN KPDPP system, or the first date that the donor had an active status in the OPTN KPDPP system?
5. Is 60 days prior notice to the donor re-evaluation date sufficient, or should the notification be sent out earlier?
6. Is 90 days between notification and potential donor ineligibility date provide a sufficient amount of time to complete the donor's re-evaluation? Should this timeframe be shortened or extended?

7. Implementation of the donor re-evaluation requirement will include an initial implementation period in which donor eligibility will not be impacted. How long should this initial implementation period be?
8. Do you agree that aligning blood type A, non-A_1 and AB, non-A_1B matching requirements is appropriate?

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.

The Workgroup then reviewed summarized public comment feedback by theme:

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.

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 9- days prior to the date at which the donor would become ineligible
- The date of registration into the OPTN 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 sufficient. 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.
- A suggestion that the initial implementation period where donor eligibility will not be impacted (while programs adjust to the new requirements) should be six months.

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
- The Committee proposes an exception to this requirement such that programs are not required to retest donors for CMV-antibody or EBV-antibody if the donor has previously tested positive, as the donor as already presented the risk of potential CMV transmission

The proposal received the following feedback:

- Support for the requirements as proposed
- A comment that the infectious disease requirements could be confusing for programs, as some centers repeat standard infectious disease panels

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 re-evaluation requirements are reasonable and do not present an undue burden for programs involved with the OPTN KPDPP. One comment mentioned the relatively small size of the program and noted that the requirements would apply to a small patient population.
- Agreement with the discretion given to programs in repeating anatomic assessments and 24-hour urine collection.
- Support for repeating the medical and psychosocial assessments annually as a means of ensuring that the donor has an understanding of the donation process, their rights, and resources available to them.

- A suggestion to align the OPTN KPDPP re-evaluation requirements with the National Kidney Registry's (NKR) KPD requirements. *Note: The Workgroup did discuss this and determined that it was out of scope for this policy proposal, however, could be considered as a future modification.*
- A suggestion to add updating the Independent Living Donor Advocate (ILDA) evaluation as part of this process to demonstrate complete understanding of the evaluation and informed consent process and continued availability of the ILDA. *Note: the proposal states that OPTN 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 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

3. Discuss Possible Post-Public Comment Changes

The Workgroup discussed possible changes to the proposal as a result of public comment to recommend to the OPTN Kidney Transplantation Committee.

Summary of discussion:

Donor Re-Evaluation Requirements: Timeline and Implementation Period

Members discussed whether the donor re-evaluation date should be based on the date that the donor was first registered into the OPTN KPDPP (as originally proposed) or the first active date of the donor in

the system. A member stated that keeping the re-evaluation date from first registered was supported by public comment. The Chair stated that it should be kept at first registered date, but asked for Workgroup members to weigh in. A member asked for clarification on the options, and staff explained. Staff also explained that centers will be able to indicate when the most recent evaluation was completed, if the donor is re-evaluated earlier.. The Workgroup reached consensus to recommend keeping this aspect of the proposal as originally proposed.

Members next discussed whether the 60 days prior notice to the donor re-evaluation date should be left as proposed, or extended to 90 days. The Chair stated that 60 days seemed sufficient to complete the proposed requirements. A member agreed. The Workgroup reached consensus that the 60 days as originally proposed was sufficient, given that there is a 90-day window already proposed between this notification and potential donor ineligibility date. The Workgroup also confirmed that they would like to keep the 90-day window between notification and potential donor ineligibility date, as was supported in public comment.

Members discussed the public comment feedback on the initial implementation period, where donor eligibility will not be impacted (while programs adjust to the new requirements). Staff reminded members that one comment suggested an implementation period of six months. The Chair stated that six months seemed too long, and suggested three months. Staff noted that there aren't very many centers that would be re-evaluating a large number of people all at once when these requirements would go into effect, and that significant effort would be devoted to education and program preparation before the requirements would go into effect. A member asked if this would apply to someone who was just registered three months prior to the new requirements going into effect, and staff clarified that because the first re-evaluation date would be based on one year from their registration date, it would not apply to them. This member also asked what would happen if a donor is not re-evaluated by the deadline, and staff noted that they would be ineligible for to participate in match runs until they complete the re-evaluation requirements and report date of re-evaluation in the system. This member noted that ian implementation "grace period" of three months seems sufficient. The Workgroup reached a consensus to recommend an initial implementation period of 90 days between implementation of the re-evaluation requirements and when donors with overdue re-evaluations would become eligible.

Infectious Disease Re-Evaluation Requirements

Staff asked the Workgroup if they would like to keep the requirements as proposed or add additional serologies to the re-test exception that would fall in line with the goal of reducing burden on the donor and center by not retesting for serologies that would always remain positive. A member stated that it seemed reasonable not to require re-testing for Hepatitis B core antibody and Hepatitis C antibody (anti-HCV) if the donor had a previously positive result. However, this member noted that most centers would just order the testing as a standard panel, so it may not make sense for them to exclude these specifically; however, it could always be included as an option for centers. Staff explained that this question was brought to the OPTN Disease Transmission and Advisory Committee (DTAC) leadership, who advised that it would be reasonable to include Hepatitis B core antibody (total anti-HBc) testing and Hepatitis C antibody (anti-HCV) testing to the retest exception. Staff noted that DTAC leadership noted that the other Hepatitis B and C testing may yield important information for treatment and matching of the potential donor, such as viral load. Members agreed with this assessment and reached consensus to recommend adding Hepatitis B core antibody (total anti-HBc) testing and Hepatitis C antibody (anti-HCV) testing to the retest exception.

Donor Re-Evaluation Requirements: Obtaining Donor Signature

Staff reminded members that as proposed, 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. The options that the Workgroup has would be to modify the requirement, eliminate the requirement, or leave the requirement as proposed. The Workgroup discussed several options for modification, including requiring that the transplant hospital maintain documentation in the donor's medical record that they had been re-informed, requiring that the transplant hospital confirm that the donor has been re-informed, or requiring only that the transplant hospital re-inform the donor. A member stated that requiring that the transplant hospital confirm that the donor has been reinformed made sense, because it could take the form of a note in their chart. The Chair agreed with this. Staff pointed out that this will probably not be included in the audit. No members wished to eliminate the requirement. The Chair stated that it would be preferable to modify it, but that the Workgroup could also recommend leaving it as proposed. A member asked about the difference between some of the modification options, and staff clarified. Maintaining documentation may require a signature from someone (but not necessarily the donor), while confirming may mean simply a note in the donor's chart. Members reached consensus to recommend requiring that the transplant hospital confirm that the donor has been reinformed that they may withdraw from the OPTN KPDPP at any time, for any reason, and to remove the requirement for the transplant hospital to obtain the donor's signature confirming they have been re-informed.

Next steps:

The OPTN Kidney Transplantation Committee will receive a presentation on these recommended changes and vote on them on April 17, 2023.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
  - Marian Charlton
  - Stephen Gray
  - Sanjeev Akkina
  - Vineeta Kumar
- **HRSA Staff**
  - Arjun Naik
- **SRTR Staff**
  - Jonathan Miller
- **UNOS Staff**
  - Kayla Temple
  - Lindsay Larkin
  - Alina Martinez
  - Kieran McMahon
  - Megan Oley
  - Steve Wendt
  - Ruthanne Leishman