

OPTN Living Donor Committee

Meeting Summary

October 29, 2021

Conference Call

Heather Hunt, JD, Chair
Nahel Elias, MD, Vice Chair

Introduction

The OPTN Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 10/29/2021 to discuss the following agenda items:

1. Exclusion Criteria Project
2. Exclusion Criteria Project Review
3. Discussion: Long-Term Data on Living Donors

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

1. Exclusion Criteria Project

The Committee discussed their project regarding living donor exclusion criteria.

Summary of discussion:

Exclusion criterion: Diabetes

The Committee reviewed guidelines from Kidney Disease: Improving Global Outcomes (KDIGO), European Renal Best Practice, and British Transplantation Society. The Committee further discussed their intent to modify this exclusion criterion, and potential policy language. The Committee agreed that type 1 diabetes should remain an absolute contraindication to living kidney donation. The Committee agreed there are select type 2 diabetic individuals that may be allowable for living kidney donation.

A member asked whether policy language modifications should explicitly reference age or whether reference to individualized assessment of donor demographics is acceptable. The member explained that explicitly referencing age will help indicate that a main aspect of the individualized assessment is to determine a person's expected lifespan compared to time until developing potential kidney disease related to their type 2 diabetes, which is the Committee's intent in modifying.

The Chair asked whether specific age cut offs are included in other OPTN policy. Staff responded that in OPTN living donor policy, the only other age reference is the exclusion criterion, *is less than 18 years of age and mentally incapable of making an informed decision*. The Vice Chair added that it is clinically difficult to determine such a threshold related to this exclusion criterion. The Committee agreed that a defined age threshold did not need to be specified within the diabetes exclusion criterion modification. A member stated the modification to the diabetes exclusion criterion should address that age is an important factor which transplant programs should be reviewing during the evaluation of select type 2 diabetic living kidney donor candidates. The Committee agreed that the term "donor demographics" encompasses evaluation of age.

The Vice Chair suggested that the modification to the diabetes exclusion criterion should address the risk to the donor's long-term health rather than the transplant program's acceptable risk threshold.

Members agreed with this modification intent. The Vice Chair suggested policy language to state “type 2 diabetes with potential risk, long-term, post-donation”.

A member expressed caution in modifying the diabetes exclusion criterion to be too prescriptive. Another member stated that it is difficult to gather data on long-term health outcomes of living donors. The member explained that, due to the lack of substantial data, the language used in these modifications should allow trust in the transplant programs to make their own decisions in the best interest of living donors. Another member agreed and stated that adding multiple exclusion criteria that are vague in nature contradicts the concept of exclusion criteria.

A member stated that they would argue that a 65-year-old donor, with well controlled type 2 diabetes, who has a suggestion of neuropathy that has been attributed to diabetes, but no retinopathy, no kidney disease, and no heart disease, and good kidney function could be an acceptable living kidney donor. The member explained that if “type 2 diabetes with evidence of end organ damage” was added into exclusion criteria, this donor would be excluded because neuropathy is end organ damage. The member stated that modifying the diabetes exclusion criterion in this way is too strict. The member added that consideration to comorbidities is important for diabetes evaluation, as comorbidities will accelerate the effect of diabetes on an individual’s health.

Another member suggested the diabetes exclusion criterion modification include “individualized assessment of the donor’s lifetime risk of progressing to end stage organ failure”. The member stated that unmanaged type 2 diabetes should be an absolute exclusion by itself, and type 2 diabetes with evidence of end organ damage should be another separate absolute contraindication. The member explained that those select type 2 diabetics that are being considered for living kidney donation should be assessed on their lifetime risk based on their age and a transplant program’s acceptable risk threshold. A member responded that it may be redundant to address transplant program’s acceptable risk threshold in policy language as it is understood that every transplant program must meet their risk threshold.

2. Exclusion Criteria Project Review

The Committee reviewed their evaluations of living donor exclusion criteria.

Summary of discussion:

A member requested the Committee seek feedback from the transplant community regarding current literature and research on any of the living donor exclusion criteria and proposed modifications for the Committee to consider in the future.

The Committee reviewed their previous decisions regarding keeping or modifying living donor exclusion criteria. The Committee agreed with their previous decisions.

Next steps:

The proposed policy language modifications will be finalized, and the Committee will vote to submit this project as a proposal for winter 2022 Public Comment, during the November 10, 2021 meeting.

3. Discussion: Long-Term Data on Living Donors

The Committee discussed long-term data collection on living organ donors.

Summary of discussion:

Staff informed the Committee that the OPTN collects follow-up data on living donors via the Living Donor Follow-up (LDF) form at the 6-month, 12-month, and 24-month intervals post-donation. Additionally, the Scientific Registry of Transplant Recipients (SRTR) runs the Living Donor Collective,

currently a voluntary initiative, which aims to collect follow-up data past the two-year interval post-donation, as well as data on potential living donors that did not go forward with donation. SRTR staff added that the Living Donor Collective looks to analyze access to living donation, as well as assess the attributable risk to donation for the lifetime of the living donor.

The Chair emphasized that long-term data collection on living donors is needed to appropriately advise living donor candidates on the potential risk of donation. The Chair added that living donors are required to give informed consent on their agreement to become a live organ donor, however living donors are not provided long-term data to inform the consent given. The Chair stated that it is important to collect long-term data on living donors while recognizing the concern regarding data burden on transplant programs. The Chair questioned whether the data collected on the LDF is the correct and relevant data needed to evaluate living donor health post-donation. A member agreed that an important consideration is determining a solution that is cognizant of data burden on transplant programs.

A member asked for the reason why the specific timeframes for data collection on LDF were determined. SRTR staff responded that the one-year and two-year time frames for data collection were identified to maintain contact with the living donor. A member added that the creation of the LDF also was an initial point to start collecting data as there was very minimal data on living donors only a couple decades ago, and the hope was to expand on that in the future. The member stated that the patient community advocated for more data in order to have the ability to understand the risk they were undertaking.

Upcoming Meetings

- November 10, 2021 (teleconference)
- December 8, 2021 (teleconference)

Attendance

- **Committee Members**
 - Aneesha Shetty
 - Heather Hunt
 - Henkie Tan
 - Mark Payson
 - Mary Beth Stephens
 - Nahel Elias
 - Stevan Gonzalez
 - Tyler Baldes
 - Yee Lee Cheah
- **HRSA Representatives**
 - Adriana Martinez
 - Arjun Naik
 - Raelene Skerda
 - Vanessa Arriola
- **SRTR Staff**
 - Bert Kasiske
 - Christian Folken
- **UNOS Staff**
 - Anne McPherson
 - Lauren Motley
 - Lindsay Larkin
 - Rebecca Goff
- **Other Attendees**
 - Brad Kornfeld