

**OPTN Living Donor Committee  
Meeting Summary  
October 13, 2021  
Conference Call**

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

## **Introduction**

The Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 10/13/2021 to discuss the following agenda items:

1. Welcome & Announcements
2. Exclusion Criteria Project Work
3. Exclusion Criteria Project Review

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

### **1. Welcome & Announcements**

The Committee welcomed Dr. Nahel Elias as the new Vice Chair of the Committee. The Chair updated the Committee on the recent prior living donor recommendations presentation to the OPTN Vascularized Composite Allograft (VCA) Committee.

### **2. Exclusion Criteria Project Work**

The Committee discussed their project regarding living donor exclusion criteria.

#### Summary of discussion:

##### *Exclusion criterion: Diabetes*

Feedback compiled from Committee members prior to this meeting included:

- No consensus
- A few exceptions in which a living donor candidate with diabetes would be allowed to proceed with living donation were noted:
  - Older diabetics with no evidence of kidney disease during workup
  - Well controlled new onset type II diabetes, not on insulin with no end organ injury in a candidate with expected life expectancy for a normal healthy U.S. adult
- Rationale for keeping exclusion criterion as is:
  - Diabetes is one of the leading causes of kidney failure
  - Detrimental to donors with type I and type II diabetes
  - May lead to increase post donation chronic kidney disease (CKD)/end stage renal disease (ESRD) rates
  - More diabetics needing dialysis and a kidney transplant in the future
- Rationale for modifying the exclusion criterion:
  - It takes a long time to progress from diabetes to microalbuminuria to CKD to ESRD
  - Many but not all diabetics progress from microalbuminuria to CKD to ESRD

- Allow donor centers some autonomy much like the hypertension criteria and not make it a blanket statement
- Increase pool of living donors, specifically the older donor pool

The Chair reminded the Committee that there was community feedback about modifying the diabetes exclusion criterion to be less restrictive.

The Vice Chair suggested a modification to the diabetes exclusion criterion could be based on the number of years since an individual was diagnosed with diabetes. However, the Vice Chair added that it would be difficult to define time of diagnosis because there are individuals who are diagnosed late.

Another member stated that transplant programs appear to be thoughtful and careful in their selection of living donors with hypertension, given their autonomy for hypertensive living donors. The member added that this may give precedence to allow for a similar pathway for diabetic living donors. The member stated that type I diabetics should be an absolute exclusion to living donation. The member stated that they would allow select type II diabetics, with an age where the time to ESRD or time to CKD from the diagnosis of type II diabetes is longer than their expected life expectancy, to become living donors. The member added that there should be no known clinically detectable diabetic related kidney disease in these select individuals. The member explained that a spousal donation, in which a 70 year old spouse, with newly diagnosed diabetes, could fit this model.

Staff clarified that the Committee could request feedback from the transplant community regarding the diabetes exclusion criterion. Staff added that any decision made on a potential modification would be able to be revised by the Committee based on public comment feedback.

A member expressed interest in reviewing international outcomes of living donors with diabetes. The Committee reviewed the European Renal Best Practices, British Transplant Society Best Practices, and Kidney Disease Improving Global Outcomes (KDIGO) Guidelines. Another member noted that two of the three guidelines allow for living donor with diabetes selection based on individualized assessment and transplant program acceptable risk thresholds. While the European Renal Best Practices recommends diabetes as a contraindication, it does indicate donation is allowable in exceptional circumstances.

The Committee discussed whether there was a specific medical marker to distinguish acceptable living kidney donors with diabetes. A member stated that performing a kidney biopsy is the only way to determine if there is diabetes related kidney disease.

Members proposed the following language as a starting point for the Committee to discuss potential modifications:

- Potential living donor with known type II diabetes of short duration with no evidence of diabetes related end organ kidney or heart disease with optimal management of any co-morbid conditions (like obesity and hyperlipdemia), with expected life expectancy that does not exceed the time to develop diabetes related kidney disease and meets the individual transplant program's acceptable risk threshold for kidney donation
- Select type II diabetic patients without evidence of microvascular disease

The Vice Chair asked if other types of end organ damage should be included along with heart and kidney. A member responded that evidence of microvascular end organ diabetic disease should be included. The member added that for type I diabetes individuals may develop both eye disease and kidney disease, but that type II diabetics may develop kidney disease without eye disease.

The Committee discussed removing diabetes from living donor exclusion criteria entirely. The Committee agreed that while they believe transplant programs do their best to protect living donors,

they still agree some type of modified exclusion criteria for diabetes should be included in OPTN policy. The Committee agreed it is too risky to remove diabetes completely from exclusion criteria due to diabetes being an important risk factor for kidney disease combined with limited long term outcome data on diabetic living donors.

### **3. Exclusion Criteria Project: Discussion**

The Committee reviewed their evaluations of living donor exclusion criteria.

#### Summary of discussion:

*Exclusion criterion: Active malignancy, or incompletely treated malignancy*

The Committee discussed their proposed modification: *Known active malignancy, and incompletely treated malignancies that do not require current or future treatment (other than active surveillance) and considered as minimal risk of transmission*

Specifically, the Committee discussed whether “minimal risk” would be interpretable by the transplant community. Staff reminded the Committee that during public comment, they can seek specific feedback regarding minimal risk language.

A member stated that based on the article, *Donor-transmitted malignancies in organ transplantation: Assessment of clinical risk* (Nalesnik et al, 2011), minimal risk was defined as less than 0.1 percent. A member asked if a 0.1 percent risk of transmission is the same for various cancers.

Another member stated that the exclusion criterion should clarify that, in addition to minimal risk of transmission, that minimal risk of progression in the donor should also be included. A member agreed that the purpose of the exclusion criteria is to focus on the safety of the living donor.

The Chair asked if a percent of risk of transmission was added into policy, would it become a hard cut-off. Staff confirmed that if policy included a specific percentage, then it would be interpreted as a hard cut off.

A member stated that it is important to allow transplant programs the autonomy to define minimal risk themselves. The member added that it would be difficult to hold transplant accountable if there is a defined percentage of risk, due to how to determine that risk percentage. Another member agreed.

A member stated that the term minimal risk is difficult to understand, and is too subjective. The member stated that language should include a percentage of risk of transmission in order for transplant programs to have a uniform practice. Another member responded that transplant programs will often consult with oncology teams, as well as reference guidelines, when deciding whether to accept a living donor candidate that has a certain malignancy. The member added that transplant programs have individual risk thresholds for kidney donation, and including language referencing minimal risk of transmission would align with this.

Another member asked whether there is language from oncology evaluations that may be helpful for the Committee to reference. Members agreed that the risk tolerance of oncology evaluations compared to transplant evaluations are different.

A member asked if it will be a problem for transplant programs and assessing compliance with minimal risk of transmission.

#### Next steps:

The Committee will continue to evaluate living donor exclusion criteria.

**Upcoming Meetings**

- October 29, 2021 (teleconference)
- November 10, 2021 (teleconference)
- December 8, 2021 (teleconference)

## Attendance

- **Committee Members**
  - Angie Nishio Lucar
  - Camille Rockett
  - Heather Hunt
  - Henkie Tan
  - Katey Hellickson
  - Mark Payson
  - Mary Beth Stephens
  - Nahel Elias
  - Roberto Hernandez-Alejandro
  - Stevan Gonzalez
  - Tyler Baldes
  - Vineeta Kumar
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Bert Kasiske
  - Christian Folken
- **UNOS Staff**
  - Anne McPherson
  - Lauren Motley
  - Leah Slife
  - Lindsay Larkin
  - Matt Prentice
  - Meghan McDermott
  - Nicole Benjamin
  - Rebecca Goff