

**OPTN Living Donor Committee  
Exclusion Criteria Subcommittee  
Meeting Summary  
March 5, 2021  
Conference Call**

**Pooja Singh, MD, Chair**

## **Introduction**

The Living Donor Committee's Exclusion Criteria Subcommittee (the Subcommittee) met via Citrix GoTo Meeting teleconference on 03/05/2021 to discuss the following agenda items:

1. Discussion
2. Next steps

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

### **1. Discussion**

The Subcommittee reviewed and discussed research and guidelines related to diabetes and malignancies.

#### Summary of discussion:

##### *Exclusion criteria for living donation: Active malignancy, or incompletely treated malignancy*

A member stated the members should examine the exclusion criteria for living donation considering potential harm to donor versus recipient. The member stated that, as a living donor representative, the Subcommittee should work towards regulations that protect donors. The member asked how donating an organ with a malignancy is harmful for the donor (e.g. is treating this malignancy in the future harmful to the donor if they have one kidney versus two kidneys). Another member agreed and suggested that if any exclusion criteria for living donation is changed to be a relative exclusion, rather than absolute exclusion, the Living Donor Committee should educate the community on risk to the donor's long term health and risk of transmission to the recipient.

The Chair stated that the Kidney Disease: Improving Global Outcomes (KDIGO) Guidelines state donor candidates may be considered in some cases of "active malignancy with low transmission risk, clear management plan, and minimal risk to the donor". The Chair noted that the guidelines do not address minimal risk to the donor at time of donation and long term treatment options.

A member stated that a potential policy change which would allow programs to make an exception to the rule would be beneficial. Another member agreed and stated that policy could create tier levels of types of permissible malignancies.

The Subcommittee agreed to recommend the Living Donor Committee further evaluate this exclusion criteria for living donation for a potential policy modification.

##### *Exclusion criteria for living donation: Diabetes*

The Chair referenced that the language used in some of the guidelines which the Subcommittee reviewed leaves room for potential use of Type 2 diabetic living donors.

- KDIGO Guidelines: “The decision to approve donor candidates with prediabetes or type 2 diabetes should be individualized based on demographic and health profile in relation to the transplant program’s acceptable risk threshold.”
- British Transplantation Society Guidelines: “In the absence of evidence of target organ damage and having ensured that other cardiovascular risk factors...are optimally managed, diabetics can be considered for kidney donation after a thorough assessment of the lifetime risk of cardiovascular and progressive renal disease in the presence of a single kidney.”

A member expressed concern in creating a policy that is protective enough to ensure a program’s judgement is in the best interest of the living donor. The member stated that if a policy is not carefully crafted it could result in subjective application by different programs, which would result in lower living donor protections.

The Chair asked the Subcommittee whether there were any diabetic donors that, under their clinical judgement, could be considered as living donors. A member responded that Type 1 diabetes should stay an absolute contraindication for living donation. The member added that there are certain Type 2 diabetic patients that they would consider for living donation. Another member stated the Subcommittee will need to define what criteria should be considered when approving or denying a potential diabetic living donor. A member suggested reviewing outcomes of varying subsets of diabetic patients.

The Subcommittee agreed to recommend the Living Donor Committee further evaluate this exclusion criteria for living donation for a potential policy modification.

*Exclusion criteria for living donation: Uncontrollable hypertension or history of hypertension with evidence of end organ damage*

A member stated that some research articles have reviewed the combination of multiple comorbidities and hypertension. The member stated that this should be discussed further and that the exclusion criteria should potentially be changed to be dependent on comorbidities. Members agreed and stated policy could define specific clinical criteria for when hypertensive patients would be approved or denied as potential living donors.

Another member suggested that a potential policy change could allow for programs to create their own protocols in order to not create prescriptive policy but still have oversight.

The Subcommittee agreed to recommend the Living Donor Committee further evaluate this exclusion criteria for living donation for a potential policy modification.

The Subcommittee expressed interest in collaborating with medical societies while developing policy changes to these criteria.

## **2. Next steps**

The Subcommittee will continue discussions on exclusion criteria for living donation. The Subcommittee will present their recommendations to the Living Donor Committee during their meeting on April 19, 2021.

### **Upcoming Meeting**

- April 2, 2021

## Attendance

- **Subcommittee Members**
  - Angie Nishio Lucar
  - Nahel Elias
  - Pooja Singh
  - Randy Schaffer
  - Stevan Gonzalez
  - Vineeta Kumar
- **HRSA Representatives**
  - Arjun Naik
  - Raelene Skerda
  - Vanessa Arriola
- **SRTR Staff**
  - Bertram Kasiske
  - Melissa Skeans
- **UNOS Staff**
  - Leah Slife
  - Lindsay Larkin
  - Meghan McDermott
  - Nicole Benjamin
  - Sarah Booker