

Meeting Summary

OPTN Living Donor Committee
Meeting Summary
July 14, 2021
Conference Call

Heather Hunt, JD, Chair Titte Srinivas, MD, Vice Chair

Introduction

The Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 07/14/2021 to discuss the following agenda items:

- 1. Welcome New Members
- 2. Cross Committee Updates
- 3. Exclusion Criteria Project
- 4. Committee Orientation

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

1. Welcome New Members

The Committee welcomed new members.

2. Cross Committee Updates

The Committee received updates on their cross committee collaboration efforts.

Summary of discussion:

There were no new updates regarding the Policy Oversight Committee or Vascularized Composite Allograft (VCA) Genitourinary Workgroup. The Kidney Paired Donation Workgroup will have its initial meeting July 27, 2021. The Living Donor Data Collection Workgroup is a joint workgroup comprised of SRTR and OPTN representatives. The initial meeting for this workgroup will occur on July 30, 2021.

There were no questions or comments.

3. Exclusion Criteria Project

The Committee discussed their project regarding living donor exclusion criteria.

Summary of discussion:

The Committee discussed data that would be helpful for their evaluation of living donor exclusion criteria. A member suggested reviewing data regarding prior living donors who experienced kidney failure, broken down by whether they were on one anti-hypertensive medication, or two or more anti-hypertensive medications. Staff responded that the Living Donor Registration (LDR) form collects history of hypertension, and if yes, method of control (diet, diuretics, other hypertensive medication), therefore this would not be available data to request as there is not specification of how many medications a patient is on. The member also suggested reviewing international data on diabetic living donors and whether there is progression to end stage kidney disease. Staff responded that international data is not available through an OPTN data request, but a review of literature would be helpful in this instance.

Another member suggested data to review the number and percentage of living donors with history of hypertension pre and post implementation of living donor exclusion criteria. A member responded that the Exclusion Criteria Subcommittee (the Subcommittee) reviewed number and percent of living kidney donors with history of hypertension by year of donation, which helps address this request. The member specified that data which shows the number of living donors with history of hypertension, normalized to the total number of living donors will help add context to the usage of living donors with history of hypertension.

A member suggested reviewing available follow-up data through the Living Donor Follow-up (LDF) form for diabetic living donors. Another member responded that the Subcommittee reviewed data on the diabetes status for living kidney donors indicated on the LDR. The member noted that there were 29 living kidney donors that were indicated as diabetic prior to 2013, and 5 post-2013. Staff added that when the transplant programs of those 5 living kidney donors were contacted, they reported that these data had been inaccurately reported, and the living kidney donors had developed diabetes after donation. The member suggested reviewing characteristic data on the 29 living kidney donors indicated as diabetic on the LDR, prior to 2013.

A member suggested requesting stakeholders, such as American Diabetes Association, to educate the Committee on risk progression with the diagnosis of diabetes. Staff responded that subject matter experts can be included during those specific discussions.

A member suggested reviewing data on hepatitis C virus (HCV) and hepatitis B virus (HBV). Another member summarized the Subcommittee's conversation regarding HCV RNA positive and HBsAg positive, and Ad Hoc Disease Transmission Advisory Committee's (DTAC) input. The member stated that the exclusion criteria is in place for the protection of the donor. The member added that DTAC's input originated from a recipient perspective, using the example of a candidate in need of an urgent, lifesaving liver transplant, and the only organ available is through an HCV RNA positive living donor. The member stated the liver allocation system prioritizes urgency, so there is a mechanism in place to address a situation such as this without relying on a HCV RNA positive living donor. The member stated there was a case study in Europe regarding the use of an HCV RNA positive living donor, but due to their unfamiliarity with Europe's organ allocation system, they feel this case study is not necessarily applicable to the U.S. The member stated that the Subcommittee's consensus was to keep HCV RNA positive and HBsAg positive criteria as is in OPTN policy.

The Committee discussed additional data to review in regards to the malignancy exclusion criteria. Staff informed the Committee that the Subcommittee reviewed data on number and percent of living kidney donors, and living liver donors, with history of cancer by year of donation, as well as cancer-free interval. Staff added that there would not be additional available data to request from the LDR related to malignancy.

Another member suggested reviewing data on living donor age and mental capacity. Staff stated that living donor age could be requested, but the LDR does not capture anything related to mental capacity.

Additionally, the Committee agreed with the Subcommittee's following data requests:

- Number and percent of living kidney donors with hypertension at donation (based on preoperative blood pressure on LDR)
- Demographic characteristics of living kidney donors with hypertension at donation (race, sex, age group, etc.)
- Pre-donation blood pressure and history of hypertension for living kidney donors subsequently listed for a kidney transplant

The Committee reviewed their assignments for evaluating living donor exclusion criteria, and the worksheet to aid in this evaluation.

Next steps:

A data request will be submitted. The Committee will complete their assigned living donor exclusion criteria review. The Committee will continue discussions during their August 11, 2021 meeting.

4. Committee Orientation

New committee members were informed of the policy development process, committee structure, committee purpose, and committee member expectations.

Upcoming Meetings

- August 11, 2021 (teleconference)
- September 8, 2021 (teleconference)
- September 13, 2021 (virtual "in-person")

Attendance

• Committee Members

- o Aneesha Shetty
- o Angie Nishio Lucar
- o Camille Rockett
- o Carol Hay
- o Heather Hunt
- o Henkie Tan
- o Katey Hellickson
- o Mark Payson
- o Mary Beth Stephens
- o Roberto Hernandez
- o Stevan Gonzalez
- o Titte Srinivas
- o Tyler Baldes
- o Vineeta Kumar
- Yee Lee Cheah

• HRSA Representatives

- o Raelene Skerda
- o Vanessa Arriola

SRTR Staff

- o Christian Folken
- o Nick Salkowski

UNOS Staff

- o Anne McPherson
- o Kelsi Lindblad
- o Lauren Motley
- o Leah Slife
- o Lindsay Larkin
- o Meghan McDermott
- o Supraja Malladi