OPTN Living Donor Committee
Exclusion Criteria Subcommittee
Meeting Summary
April 2, 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 04/02/2021 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 exclusion criteria for living donation.

Summary of discussion:

Uncontrollable hypertension or history of hypertension with evidence of end organ damage

The Chair suggested that the Living Donor Committee submit a data request to analyze 1) whether this exclusion criteria has been misused by transplant programs, and 2) donors with history of hypertension subsequently listed for a kidney transplant. Members agreed. A member stated that in addition to analyzing data related to outcomes, the data request should include donor characteristics. The member added that donor characteristics are more important to analyze than solely the combination of comorbidities and hypertension.

Liver-specific exclusion criteria

OPTN Liver and Intestinal Transplantation Committee leadership provided feedback that the liver-specific exclusion criteria were appropriate and should not be any more restrictive.

Disease-related exclusion criteria

OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) leadership provided feedback that there could be potential to remove *HCV RNA positive* and *HBsAg positive* exclusion criteria for living donation. DTAC leadership stated that both of these can be adequately treated within the recipient, but will discuss further with members who have expertise in order to ensure the safety of the living donor.

The Subcommittee requested that DTAC leadership be reminded that the exclusion criteria for living donation in OPTN Policy is there to protect the safety of living donors.

HCV RNA positive

A member stated that hepatitis C virus (HCV) can be cured, and about 2,000 HCV antibody positive deceased donor organ transplants have occurred. The member added that over half of these are

ribonucleic acid (RNA) positive, with intent that the recipient will be cured afterwards because the therapy is very effective. The member stated that while there is an effective cure, the safety of the donor is paramount while considering changes to exclusion criteria for living donation. The member stated that in situations where a living donor is HCV RNA positive, then the living donor should be treated before undergoing organ donation. The member cited a case report, from Europe, in which a mother who was HCV RNA positive donated to her daughter.

The Chair asked if a patient would be excluded from being a living donor if they were HCV RNA negative and HCV antibody positive. A member confirmed that a patient that is HCV RNA negative and HCV antibody positive would be allowed to be a living donor because they have been treated and cured.

HBsAg positive

A member stated that the hepatitis B surface antigen (*HBsAg*) *positive* exclusion criteria is a different clinical situation than *HCV RNA positive* because hepatitis B virus (HBV) does not have a cure. The member stated there is treatment for HBV but since there is no cure, there are different concerns for recipients and donors.

Donors with ZZ, Z-null, null-null, and S-null alpha-1-antitrpsinphenotypes and untype-able phenotypes

A member stated that alpha-1-antitrpsin deficiency has no cure. The member stated that an individual who has this deficiency and donates a liver could be compromised. The member agreed with OPTN Liver and Intestinal Transplantation Committee leadership feedback that this exclusion criteria should remain as is in order to protect the living donor.

Expected donor remnant volumes less than 30% of native liver volume

The Subcommittee discussed feedback given during the 2014 Summer Public Comment cycle, "'expected donor remnant volume less than 30% of native liver volume' should be stricken and replaced with 'ratio between expected donor remnant volume and weight of donor' ". A member stated that the ratio of liver volume to total volume weight is established in the recipients, not the donors. The member stated that there are criteria for transplanted liver, and if that is less than 0.8% of total volume weight for the recipient then there is risk for small for size. A member stated that 30% as an expected donor remnant volume is reasonable. Members agreed with OPTN Liver and Intestinal Transplantation Committee leadership feedback that this exclusion criteria should remain as is in order to protect the living donor.

Prior living liver donor

A member agreed with OPTN Liver and Intestinal Transplantation Committee leadership feedback that this exclusion criteria should remain as is in order to protect the living donor.

Stakeholder organizations

The Subcommittee identified potential stakeholder organizations to seek feedback from during the development of this project.

- American Society of Transplantation
- American Society of Nephrology
- American Diabetes Association
- American Society of Transplant Surgeons
- American Association for the Study of Liver Diseases
- American Cancer Society
- American Society of Hypertension

The Subcommittee identified potential stakeholder organizations to educate potential changes to exclusion criteria for living donation.

- American College of Physicians
- Society for General Internal Medicine

2. Next steps

The Subcommittee will present their recommendations to the Living Donor Committee during their meeting on April 19, 2021.

Attendance

- **Subcommittee Members**
  - Nahel Elias
  - Pooja Singh
  - Stevan Gonzalez
  - Vineeta Kumar
- **SRTR Staff**
  - Bertram Kasiske
- **UNOS Staff**
  - Lauren Motley
  - Lindsay Larkin
  - Meghan McDermott
  - Nicole Benjamin
  - Sarah Booker
  - Tina Rhoades