**OPTN Living Donor Committee**
**Meeting Summary**
**August 11, 2021**
**Conference Call**

**Heather Hunt, JD, Chair**

## Introduction

The Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 08/11/2021 to discuss the following agenda items:

1. Overview of Vice Chair Process
2. Cross Committee Updates
3. Exclusion Criteria Project

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

## 1. Overview of Vice Chair Process

The Committee was informed of the Vice Chair selection process. There were no questions or comments.

Next steps:

The Committee will receive the Vice Chair application and selection processes.

## 2. Cross Committee Updates

The Committee received updates on their cross committee collaboration efforts.

Summary of discussion:

The Vascularized Composite Allograft (VCA) Committee's proposal regarding membership requirements for genitourinary programs is currently out for public comment. The Kidney Paired Donation (KPD) Workgroup had its initial meeting July 27, 2021, which provided the members of the workgroup with a background of the OPTN KPD program. The KPD Workgroup's initial project will begin with aligning current OPTN KPD Policy with KPD Operational Guidelines. The Living Donor Data Collection Workgroup, a joint workgroup comprised of SRTR and OPTN representatives had its initial meeting on July 30, 2021. This Workgroup will work to determine the future of living donor data collection efforts.

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 evaluated and discussed the exclusion criteria for living liver donors, per *OPTN Policy 14.4.E: Living Donor Exclusion Criteria*.

*Exclusion criterion: HCV RNA positive*

The Living Donor Exclusion Criteria Subcommittee (the Subcommittee) and the Liver & Intestinal Transplantation Committee (Liver Committee) maintained this exclusion criterion is still relevant and protects the safety of living donors. The Ad Hoc Disease Transmission Advisory Committee (DTAC) suggested potential removal because Hepatitis C Virus (HCV) can be adequately treated, but deferred to the Committee due to concerns around potential harm to living donors.

Feedback compiled from Committee members with liver experience prior to this meeting included:

- Overall consensus to keep HCV RNA positive as an exclusion criteria for living liver donors
- No exceptions in which an HCV RNA positive living donor candidate would be accepted for living organ donation transplantation
- Rationale for keeping HCV RNA positive exclusion criterion as is in policy:
    - Medical literature reports decreased regenerative capacity of the liver in the setting of chronic viral infection with HCV
    - Data on loco regional therapy showed that enhanced replication of HCV with resultant hepatitis incidence of 8.2 percent. For living donors, 8.2 percent is too high a risk, especially when it can be cured beforehand.
    - Donor could have liver decompensation after resection if HCV is not treated first
        - Liver decompensation is dependent on the presence of portal hypertension, remnant volume, and liver function. So it could be true if the donor liver has damage from HCV
    - It is in the donor's best interest, from a healthcare perspective, to undergo antiviral therapy to achieve eradication of the virus

A member stated that while DTAC cited that HCV is treatable, the Committee's responsibility is to focus on what is the best interest of living organ donors. The member emphasized the importance of regenerative capacity of living liver donors. The member also added that OPTN deceased donor liver allocation policy prioritizes medial urgency, so it would be unnecessary to allow for HCV RNA positive living donors in medically urgent situations. Another member mentioned that treatment for HCV takes between 8 to 12 weeks, and it is reasonable to have a transplant candidate wait for eradication of HCV in the living donor before undergoing organ transplantation.

HRSA staff asked if there is data regarding the regenerative capacity of livers that have been successfully treated for HCV. A member responded that they were not aware of any literature that specifically analyzed living donors who have been successfully treated for HCV and subsequent regenerative capacity. The member added that there is data related to after eradication of HCV patients can experience significant regression of any existing fibrosis or injury currently within the liver. The member explained it is in the living donor's best interest to eradicate the HCV and allow for recovery of normal liver function.

The Committee agreed to keep the *HCV RNA positive* exclusion criterion as is in OPTN policy.

*Exclusion criterion: HBsAg positive*

The Subcommittee and the Liver Committee maintained this exclusion criterion is still relevant and protects the safety of living donors.

Feedback compiled from Committee members with liver experience prior to this meeting included:

- Overall consensus to keep HBsAg positive as an exclusion criteria for living liver donors
- No exceptions in which an HBsAg positive living donor candidate would be accepted for living organ donation transplantation

- Rationale for keeping HBsAg positive exclusion criterion as is in policy:
    - Similar to HCV, there is medical literature that reports decreased regenerative capacity of the liver in the setting of chronic Hepatitis B Virus (HBV) infection
    - Donor safety issue related to liver resection and risk of HBV flare post resection which can lead to hepatitis and liver failure
    - Risk of post-resection flare is 24 percent

A member stated that literature for HBV and liver regenerative capacity is similar to literature regarding HCV and liver regenerative capacity. The member emphasized that there is no cure for HBV, and there are risks to the living donor. Another member stated that patients with HBV can have a complication in which they develop acute on-chronic HBV which leads to liver failure, post liver resection. The member added that patients with HBV have an increased risk of developing hepatocellular carcinoma (HCC) later in life. The member explained that if a patient had undergone liver resection for living donation, it would make their future treatment for HCC more difficult. Other members agreed.

The Committee agreed to keep the *HBsAg positive* exclusion criterion as is in OPTN policy.

*Exclusion criterion: Donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes*

The Subcommittee and the Liver Committee maintained this exclusion criterion is still relevant and protects the safety of living donors.

Feedback compiled from Committee members with liver experience prior to this meeting included:

- Overall consensus to keep donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes as an exclusion criteria for living liver donors
- No exceptions in which an individual with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes would be accepted to be a living organ donor
- Rationale for keeping donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes exclusion criterion as is in policy:
    - Alpha-1-antitrypsin deficiency has no cure, so an individual with this deficiency who donates a liver could be compromised
    - This criterion protects the living donor
    - Alpha-1 antitrypsin deficiency phenotypes define the disease states with the highest risk of chronic liver disease and pulmonary disease, therefore it would be in the best interest of the donor to not proceed with donation under these circumstances
    - Unsure of long term outcomes of donors when transplanting these phenotypes

A member stated that alpha-1-antitrypsin is associated with both chronic liver disease and lung disease. The member explained that some patients develop the chronic liver disease because they accumulate abnormal protein within the liver, which leads to cirrhosis and liver failure. The member added that the phenotypes listed within the exclusion criterion are the ones that are associated with the highest risk of chronic disease. The member emphasized that if an individual undergoes liver resection with one of these phenotypes, it may compromise their survival and future outcomes.

The Committee agreed to keep the *donors with ZZ, Z-null, null-null and S-null alpha-1-antitrypsinphenotypes and untype-able phenotypes* exclusion criterion as is in OPTN policy.

*Exclusion criterion: Expected donor remnant volume less than 30% of native liver volume*

The Subcommittee and the Liver Committee maintained this exclusion criterion is still relevant and protects the safety of living donors.

Feedback compiled from Committee members with liver experience prior to this meeting included:

- Overall consensus to keep expected donor remnant volume less than 30 percent of native liver volume as an exclusion criteria for living liver donors
- No exceptions in which an individual who would have an expected donor remnant volume less than 30 percent of native liver volume would be accepted for living organ donation transplantation
- Rationale for keeping expected donor remnant volume less than 30% of native liver volume exclusion criterion as is in policy:
    - This criterion protects the living donor
    - It is well established that the limit for safe hepatic resection has a range up to 30% future remnant liver volume – a lower remnant volume would be unsafe for the donor and could result in post-hepatectomy liver failure
    - Consequences for living donor with liver failure, requiring a transplant, and the possibility of death
    - Research reviewing transplant program practices show that most currently favor a minimum remnant of 30 percent

A member stated that literature shows, as well as common practice nationally, that 30 percent native liver volume is a safe threshold. The member added that the 30 percent ratio is used for liver resection in non-transplant patients as well. The Committee agreed to keep *expected donor remnant volume less than 30% of native liver volume* exclusion criterion as is in OPTN policy.

*Exclusion criterion: Prior living liver donor*

The Subcommittee and the Liver Committee maintained this exclusion criterion is still relevant and protects the safety of living donors.

Feedback compiled from Committee members with liver experience prior to this meeting included:

- Overall consensus to keep prior living liver donor as an exclusion criteria for living liver donors
- No exceptions in which an individual who had been a prior living liver donor be accepted for living organ donation transplantation
- Rationale for keeping prior living liver donor exclusion criterion as is in policy:
    - This criterion protects the living donor
    - Living donors should not take a higher risk of what is the standard
    - Vessel/bile duct issue
    - From an ethical standpoint, a person who proceeds with living liver donation is taking on a substantial risk, and taking on that risk a second time may be excessive for an otherwise healthy person

The Committee agreed to keep *prior living liver donor* as is in OPTN policy.

Next steps:

The Committee will continue discussions during their September 8, 2021 meeting.

**Upcoming Meetings**

- September 8, 2021 (teleconference)

- September 13, 2021 (virtual “in-person”)
- October 13, 2021 (teleconference)

**Attendance**

- **Committee Members**
  - Aneesha Shetty
  - Camille Rockett
  - Carol Hay
  - Heather Hunt
  - Mark Payson
  - Mary Beth Stephens
  - Omar Garriott
  - Roberto Hernandez
  - Stevan Gonzalez
  - Tyler Baldes
  - Yee Lee Cheah
- **HRSA Representatives**
  - Jim Bowman
  - Marliyn Levi
  - Vanessa Arriola
- **SRTR Staff**
  - Christian Folken
  - Krista Lentine
- **UNOS Staff**
  - Anne McPherson
  - Keighly Bradbrook
  - Lauren Motley
  - Lindsay Larkin
  - Matt Prentice
  - Meghan McDermott
  - Supraja Malladi
- **Visiting Board Member**
  - Brad Kornfeld