OPTN Living Donor Committee
Meeting Summary
April 19, 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 04/19/2021 to discuss the following agenda items:

1. Prior Living Donor Priority Discussion
2. Exclusion Criteria Subcommittee Recommendation
3. Update on post COVID-19 Emergency Policy Data
4. Living Donor Education Discussion

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

1. Prior Living Donor Priority Discussion

The Committee continued their discussion regarding prior living donor priority.

Summary of discussion:

Overview of Ethics Committee Feedback

The Ethics Committee discussed the following:

- Ethical principles of heroism, reciprocity, and making one whole
- Recognizing the commitment and efforts taken by living donors to help others
- Humanitarian approaches and what that would suggest in terms of inherent values for people to donate and voluntarily contribute to a system as a societal resource
- Concern regarding determining causal connection, citing the complexity between putting a linear line between two outcomes and the difficulty in developing a framework for clinicians
- The majority of the Ethics Committee members supported *prior living donor priority for any organ needed*

Overview of Living Donor Committee Feedback

Before the Committee meeting, members completed worksheets to document their opinions and rationale related to prior living donor priority.

Some members supported *prior living donor priority only for organ donated* but it was not an exclusive choice by any member. Other members opposed this option, citing that organ systems are interconnected and donation of one may impact function or structure of another.

Some members, although none exclusively, supported *prior living donor priority for organ if causal connection to organ donated*, citing that priority should absolutely be given for causal connections. Other members opposed this option citing that causal connection would be too difficult to define.

The majority of the Committee members supported *prior living donor priority for any organ needed*. Members cited several reasons for support:

- Valuing living donors
- Prior living donor need for transplant is low
- Value of reciprocity
- Unknown risks associated with donation
- Cannot place value on different organ types

Other recommendations:

- Limit priority to prior living donor of non-vascularized composite allografts (VCA) (to be addressed subsequently)
- Prior living donor choice on whether or not to receive priority
- Providing a higher level of priority for donated organ, lower level for other organs
- Education and reinforcement for prior living donors to connect them with potential living donors
- Prior living donor priority for kidney paired donation (KPD) chains or bridge donors

Members who did not complete the worksheet provided their opinion and rationale, and the Committee continued their discussions surrounding prior living donor priority.

The Chair stated that, as a donor, the *prior living donor priority for organ if causal connection to organ donated* option is of preference. The Chair stated that if it is not a viable option, then their preference is *prior living donor priority for any organ needed*. The Chair cited two reasons for this preference; 1) that the system should support donors for a lifetime, and 2) potential living donor families need the reassurance that the system will protect their living donor family member.

A member stated preference for *prior living donor priority for any organ needed*, but remains conflicted whether to include VCA living donors. The member cited life-saving versus life-enhancing transplants but also recognizes that the risk of complication is the same for non-VCA and VCA living donors.

Another member echoed the sentiments expressed by the Chair and previous member. The member stated that giving prior living donors priority for all organs needed is the least the transplant community could provide for living donors.

A member agreed with the previous points and stated support for *prior living donor priority for any organ needed.* The member stated that if the transplant community is seeking to increase living donation, then living donors need this reciprocity. The member stated they have not decided whether VCA living donors should be included within the priority or not. The member stated VCA living donor transplants are currently experimental, and as such, priority for them could wait to be addressed until it becomes more mainstream.

Another member stated that the best way to honor reciprocity is to provide living donors as much opportunity to access organs as possible. The member stated that *prior living donor priority for organ if causal connection to organ donated* would be subjective, difficult to pursue, and does not honor the value of reciprocity. The member stated that while VCA living donation is currently experimental, they are still living donors and they should be advocated for and treated as such. The member stated the Committee should be cautious in placing judgment on what type of donation is more or less valuable. The member stated that the act of donation needs to be honored and those who choose to be live donors should be provided support.

A member agreed with the previous member's statements that VCA living donors should be included in prior living donor priority. The member reminded the Committee that the transplant society determined that VCA living donors will be covered under the same regulatory processes as all other live donors. The member also agreed and emphasized that the Committee should not place a value judgement on the decision to be a certain type of living donor. The member did not support the option of offering living donors the choice to receive priority, citing that it would take advantage of the selfless, giving nature of live donors. The member stated that it is the Committee's responsibility to ensure the safety and wellbeing of living donors, which should be offered unconditionally.

Another member stated their support for *prior living donor priority for any organ needed*. The member stated that when considering *prior living donor priority for organ if causal connection to organ donated,* they could not conceptualize a medical process that did not have holes, and given the lack of clarity able to be provided for a consistent and consensus-driven approach, it did not seem like an appropriate option. The member stated there is an emotional component of needing to safeguard the living donors for their noble act. Additionally, the member stated they are not opposed to allowing living donors the choice of priority, but if it is given, then it should be ensured that the living donors do not have to justify their decision.

A member stated that every organ recipient, if they were a prior living donor has a choice to receive priority or not. The member cautioned against adding this into policy as it takes advantage of the selfless nature of prior living donors. The member stated that if it is the Committee's view that living donors deserve priority, then they should be given priority but they will always have the right to refuse the priority. Another member agreed and added that there is no other instance where candidates are given the option to refuse certain allocation measures in determining their place on the waitlist, as it puts an unwarranted pressure on the prior living donor. Other members agreed.

A member stated, from a donor perspective, that it seems unfair to put a time limit on prior living donor priority. The member explained if one donated in their 20s but did not develop symptoms until their 60s, it seems unfair to not receive advantage because they were too young and healthy at the time of donation. Another member agreed and added that from a medical perspective, the lifetime risk is higher for the younger donor population because they have more years to live. The member stated another reason to not limit the time frame is because something could be missed during living donor evaluation processes.

Another member asked if the Committee was determining whether prior living donors receive priority multiple times. Staff responded that the Kidney Transplantation Committee discussed this previously, so the Committee could reference this decision making. Staff added that this decision may be up to each organ-specific committee.

A member stated that while they considered counter arguments, they found themselves firmly in the *prior living donor priority for any organ needed* option. The member explained that the factors in favor of this option outweigh any potential negatives. The member agreed with previous points made regarding placing judgement on types of donation. The member addressed the counter argument of individuals taking advantage of the system. The member stated that this is not a valid argument to differentiate between VCA and non-VCA living donors given the processes to become a living donor.

Another member stated that they would prefer not to include VCA living donors in prior living donor priority. The member suggested the Committee consider the transplant community's perception of prioritizing VCA living donors for any organ needed.

A member stated that it is difficult for them to support prioritizing VCA living donors, given it is not a lifesaving organ transplant. Additionally, the member cited concerns regarding public perception and taking advantage of the system as reasons for nonsupport.

The Chair suggested requesting the Ethics Committee give input on prioritizing VCA living donors for any organ donated. A member requested the Committee receive the updated list of defined VCA transplants.

The majority of the Committee supports the option *prior living donor priority for any organ* needed. A summary of the primary rationale for their recommendation is as follows:

- Medical rationale
    - Intrinsic risk of donation
    - Unknown risks associated with donation
    - Prior living donor need for transplant has historically is very low
- Ethical rationale
    - Sends message to the public that the system values living donors
    - Offers support and assurance for the donor and the donor's family
    - Societal value of reciprocity
- System efficiency

Additionally, primary counter arguments for other options are as follows:

- Priority for organ donated
    - Organ systems are interconnected and donation of one may impact function or structures of another
- Priority for organ with causal relationship to organ donated
    - Casual connection too difficult to define and determine
- Priority for organ needed
    - Primary concern is priority for VCA donation
    - Values should not be place on what kind of organ is donated

The Chair explained that system efficiency results from giving potential donors more confidence to donate which increases rates of living donation, therefore freeing up deceased donor organs to transplant.

A member noted that while the prior living donor need for transplant is low, the only data available is historic. The member explained that it may take up to five decades to understand the implications for younger living donors. The member stated that while it is expected that the need for transplant after being a live donor will remain low, it is still unknown.

A member expressed concern prioritizing VCA living donors because it might allow medical teams to perform riskier surgeries than the necessary risk for altruistic donation because there is a safety net. The member stated that VCA procedures are complicated and have large learning curves, so the likelihood of risk is higher. Another member responded that no surgeon wants to depend on transplant as a safety net and that concern does not encompass the mentality of the surgical community. The member added that VCA living donors should not be excluded based on their placement in an evolving field.

Another member stated that living donation is encouraged to make up for the gap in the supply of deceased donor organs and the demand of patients in need of an organ transplant. The member asked if that gap is the same for VCA organs. A member responded that beyond the perspective of supply and

demand, there are inherent outcome advantages of utilizing a living organ donor. The member added that outcomes of living donor uterus transplant are better than those of deceased donor uterus.

A member stated that most VCA organ transplants are novel concepts, and since the incidence of these transplants are so low it makes sense to provide protection for all living donors. Another member added that the Committee could evaluate this recommendation and potential policy changes in the future if it is deemed that the decided prioritization of prior living donors is no longer advantageous to the system and community.

Another member stated a counter argument would be to wait and see how the VCA transplantation field develops because undoing policy takes time. A member agreed that the Committee should wait and see how the VCA living donor transplantation field evolves. Other members suggested adding types of VCA transplants that have occurred and leave the hypothetical VCA transplant out until it evolves. Another member responded by asking what the harm of including all types of living donor, if the likelihood of them needing a transplant is so exceptionally low. The member added that parsing out and placing judgement on different living organ donations, is creating more unnecessary work for the Committee. The member cited the Committee's previous projects regarding creating living donor policy and whether or not to include VCA. The member stated that because of the lack of initial inclusion of VCA in living donor policy, there were no guardrails to protect those living VCA donors during the several years the Committee waited to see how it evolved. The member added that maybe no living donors will take advantage of the system if they are included in prioritization, but at least no one will miss out, and the Committee can reevaluate it in the future. A member agreed.

Another member stated that VCA and non-VCA living donations are both the act of giving an organ so that someone else can benefit. The member expressed concern over why the Committee felt the need to place different values on those acts. A member responded that as the living VCA donation field grows, it will impact the patients on the waitlist as those who receive priority will be taking lifesaving organ transplants away from those who need them. Another member stated that they view VCA and non-VCA living donations differently, as they are life-enhancing versus life-saving. The member stated that perhaps more data would help with these conversations, but that requires the Committee to wait to understand how the field evolves as data become available. A member reminded the Committee that prior living pancreas donors currently receive priority for kidney, and pancreas transplant is not considered to be a life-saving transplant.

The Chair requested the data on the number of living donor VCA organs.

A member stated support for *prior living donor priority for any organ needed.* The member suggested that the Committee could recommend the organ-specific committees to consider global priority and then allow them to filter their decisions within their perimeters rather than guessing how each committee would judge what is valuable. Other members agreed a broad recommendation may be an appropriate approach.

Another member stated that the Committee should consider why it is important to give priority to prior living donors. The member stated that it is important because it recognizes the selfless behavior that benefits the recipient and the society by removing another patient from the waitlist. The member concluded this is why all living donors should be included within the priority.

<u>Next steps:</u>

The Committee will continue discussions and finalize recommendations regarding prior living donor priority.

2. Exclusion Criteria Subcommittee Recommendation

The Committee reviewed the Exclusion Subcommittee's previous discussions and recommendations.

Summary of discussion:

The Exclusion Criteria Subcommittee recommended that the Committee continue forward with this project by seeking project approval from the Policy Oversight Committee (POC) to further evaluate exclusion criteria for living donation and propose policy changes. The Exclusion Criteria Subcommittee recommended that the Committee continue to seek feedback from OPTN committees as well as stakeholder organizations and societies during the development of this project.

The Committee agreed with the Exclusion Criteria Subcommittee's recommendations and will move forward with this project.

Next Steps:

The Committee will seek project approval from POC during their meeting on May 12, 2021.

3. Update on post COVID-19 Emergency Policy Data

The Committee reviewed updated data on Living Donor Follow-up (LDF) forms submission for forms impacted by COVID-19 emergency policy.

Data summary:

Data showed the number and percent of LDF forms in 'expected' status by week due from January 2020 to March 2021. Data showed in December 2020, there were about 22 percent of LDF forms in 'expected' status, 13 percent in February 2021, and about 6 percent of forms in March 2021.

Summary of discussion:

There were no questions or comments.

4. Living Donor Education Discussion

The Committee discussed topics for living donor member education.

Summary of discussion:

Members brainstormed several ideas for living donor member education

- The need for donor follow-up after donation and specific risks concerning prior living donors
- Landscape of living donor risk and how to present data to patients
- Options to help if an individual is deemed not a candidate to donate
- Advantages of living donation over decease donation
- Complex donors, and how to choose a donor
- Linguistic and cultural competence
- Kidney paired donation for matching pairs
- Living donor collective through the SRTR, and their role with long-term donor follow-up
- Follow-up after donation

A member suggested reviewing other organization's education in order to share resources as well as brainstorm other topics and optimize on the resources already available.

Next steps:

The Committee will review current living donor member education materials and brainstorm additional topics.

Upcoming Meetings

- May 12, 2021 (teleconference)
- June 9, 2021 (teleconference)

Attendance

- **Committee Members**
  - Aneesha Shetty
  - Angie Nishio Lucar
  - Carol Hay
  - Carolyn Light
  - Heather Hunt
  - Jessica Spiers
  - Katey Hellickson
  - Mark Payson
  - Mary Beth Stephens
  - Nahel Elias
  - Omar Garriot
  - Pooja Singh
  - Randy Schaffer
  - Roberto Hernandez
  - Stevan Gonzalez
  - Titte Srinivas
  - Vineeta Kumar
- **HRSA Representatives**
  - Adriana Martinez
  - Arjun Naik
  - Jim Bowman
  - Vanessa Arriola
- **SRTR Staff**
  - Bert Kasiske
  - Krista Lentine
- **UNOS Staff**
  - Lauren Motley
  - Lindsay Larkin
  - Matthew Prentice
  - Meghan McDermott
  - Melissa Koch
  - Nicole Benjamin
  - Rebecca Murdock
  - Sarah Booker
  - Tina Rhoades
- **Other Attendees**
  - Mahwish Ahmad