OPTN Living Donor Committee
Meeting Summary
September 14, 2022
Conference Call

Nahel Elias, MD, Chair
Steve Gonzalez, MD, Vice Chair

Introduction

The OPTN Living Donor Committee (the Committee) met via Citrix GoTo Meeting teleconference on 09/14/2022 to discuss the following agenda items:

1. Public Comment Presentation: Transparency in Program Selection
2. Discussion: Living Donor Data Collection

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

1. Public Comment Presentation: Transparency in Program Selection

The Committee received a presentation on the OPTN Ethics Committee's public comment paper, *Transparency in Program Selection.*

<u>Summary of discussion:</u>

A member suggested that potential living donors would benefit from transparency in transplant program's exclusion criteria for living donation. The member also suggested to use a different word than "paternalism". The member expressed concern that some data transparency which shows past inequalities may further inequalities.

Another member stated that transparency in living donor programs is important for transplant candidates. The member explained that a transplant candidate may be accepted for living donation at different programs and knowing where that opportunity is available may determine which transplant program to select. The member added that they have experienced nephrologists in their area only refer to one transplant program. The member explained that then transplant candidates are not aware of the other transplant programs in the area and therefore may miss opportunities that the other transplant programs may offer. The presenter responded that transplant programs need to provide basic information so that transplant candidates are not reliant on the referring physicians.

A member stated that transplant candidates should be informed that there is the ability to self-refer to transplant programs and multi-list at transplant programs. The member suggested that the Centers for Medicare & Medicaid Services (CMS) end stage renal disease (ESRD) education program include these components and teach patients how to find information to help with transplant program selection. The Chair agreed and suggested that the program be expanded to include individuals with chronic kidney disease (CKD).

<u>Next steps:</u>

The Committee's feedback will be summarized and submitted to the OPTN Ethics Committee for consideration.

2. Discussion: Living Donor Data Collection

The Committee continued discussing living donor data collection.

Summary of discussion:

The Committee affirmed that living donors should be followed for a lifetime to help support the health of the living donor and empower potential living donors to understand the risks associated with the procedure.

The Chair stated that while understanding the risk of the procedure, it is also important for potential living donors to be able to make an informed decision.

Another member emphasized that long-term living donor follow-up has been discussed for decades and lifetime follow-up of living donors is needed. The member emphasized that the transplant community owes it to living donors. The member stated that potential living donors often have a lot of questions, and medical professionals may only be able to speculate what the answer may be due to lack of data.

The Committee affirmed that there are real and significant challenges with transplant programs collection of longer-term follow-up on living donors. The Committee affirmed that these challenges and costs become more significant as time progresses and some other entity, such as a registry, may be better situated to connect directly with living donors for long-term data collection.

A member stated that prospective data collection of living donors will take decades to have meaningful data. The member wondered whether a retrospective data collection on living donors may be a beneficial approach. The Vice Chair stated that retrospective data collection has many challenges and may not achieve the goals of understanding long-term outcomes of living donors. The Vice Chair stated that this highlights the importance of having a solid foundation of prospective data collection.

Members noted support for a control group. The Chair stated that the Living Donor Collective follows potential living donors who did not go on to donate as a control group. SRTR staff stated that the Living Donor Collective is funded through HRSA, which would remove the burden from transplant programs. The Chair noted that long-term follow-up also places burden on living donors themselves. SRTR staff responded that survey engagement helps alleviate some of that burden. SRTR staff stated that one of the main objectives of the Living Donor Collective is to establish data collection upstream in order to have a control group. SRTR staff explained that the Living Donor Collective collects data on individuals who were evaluated at a transplant program, but do not move forward with donation, and seeks to engage these individuals in order to have a comparison group for living donors.

Another member mentioned the Committee may need to consider the differences between long-term data collection and long-term medical follow-up. The Vice Chair stated that medical care may be beyond the scope, and the focus may need to be on data collection. The member added that the Committee may also need to consider long-term data collection and the impact it may have on insurance coverage for potential living donors and living donors. The member explained that long-term data collection may potentially show significant outcomes that were not previously predicted.

The Vice Chair stated that while a registry may be voluntary participation, it remains a good opportunity to collect longer-term data. The Vice Chair stated that the future may afford more opportunities to enhance the data collection through technological efficiencies.

The Committee affirmed that OPTN data collection has improved significantly in its time and is an important part of living donor follow-up. The Committee affirmed that the OPTN should continue follow-up for living donors for the currently mandated six, twelve, and twenty-four month follow-up periods.

A member noted that the twenty-four month follow-up may be an opportune time to advocate for the living donor to participate in a registry for longer-term follow-up.

The Committee affirmed that there are opportunities for increased efficiencies and better integration of data across organizations that support the transplant community. The Committee affirmed support for improved technological efficiencies to support better health and follow-up care for all living donors.

<u>Next steps:</u>

The Committee will continue discussions in order to finalize a report to the OPTN Board of Directors.

Upcoming Meetings

- October 17, 2022 (Chicago, Illinois)
- November 9, 2022 (teleconference)
- December 14, 2022 (teleconference)

Attendance

- **Committee Members**
    - Alexandra Shingina
    - Aneesha Shetty
    - Doug Penrod
    - Henkie Tan
    - Hoylan Fernandez
    - Katey Hellickson
    - Mark Payson
    - Mary Beth Stephens
    - Nahel Elias
    - Nancy Marlin
    - Stevan Gonzalez
    - Tyler Baldes
- **HRSA Staff**
    - Adriana Martinez
    - Arjun Naik
    - Jim Bowman
    - Mesmin Germain
    - Marilyn Levi
    - Vanessa Arriola
- **SRTR Staff**
    - Bert Kasiske
    - Katie Siegert
    - Krista Lentine
- **UNOS Staff**
    - Carol Covington
    - Cole Fox
    - Jen Wainright
    - Kim Uccellini
    - Krissy Laurie
    - Laura Schmitt
    - Lauren Motley
    - Lindsay Larkin
    - Meghan McDermott
    - Rachel Hippchen
    - Sam Weiss