

OPTN Living Donor Committee

Meeting Summary

August 9, 2023

Conference Call

Nahel Elias, MD, Chair

Stevan Gonzalez, MD, Vice Chair

Introduction

The OPTN Living Donor Committee (the Committee) met in via WebEx teleconference on 08/09/2023 to discuss the following agenda items:

1. Public Comment Presentation: Require Patient Safety Events
2. Monitoring Report: Modify Living Donor Exclusion Criteria
3. Public Comment Updates

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

1. Public Comment Presentation: Require Patient Safety Events

The OPTN Membership & Professional Standards Committee (MPSC) presented their public comment proposal, *Require Patient Safety Events*.

Summary of Discussion:

The Vice Chair asked whether the MPSC considered requiring a timeframe longer than two years for reporting living donation related safety events. The Chair of the MPSC stated that the two-year timeframe was modelled off of the current living donor follow-up requirements in policy. The Chair stated that if living donor follow-up is extended, then they would be supportive of a longer time frame for required reporting of living donation related safety events.

The Chair supported the proposal to require reporting for whether any prior living donor was placed on the wait list regardless of the previous organ donation.

A member asked whether there was data to analyze how many living donors developed organ failure within 2 years of the donation. The MPSC Chair stated they did not have this data, but it is an exceedingly rare event. The Chair noted that the Committee has previously reviewed data regarding the number of prior living donors that are subsequently added to the waitlist and suggested redistributing the data to the Committee for review. A member noted it is also important to understand whether any prior living donor received dialysis.

The Chair asked if the MPSC develops policy based on patient safety reported data. The MPSC Chair stated a Subcommittee reviews cases and determines the appropriate next steps. The MPSC Chair stated that a solution may be education. The MPSC Chair noted that if policy change is necessary the MPSC will refer the project to OPTN Policy Oversight Committee and other appropriate OPTN policy making committee.

Another member supported the inclusion of requiring reporting of transportation events.

Next steps:

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

2. Monitoring Report: Modify Living Donor Exclusion Criteria

The Committee reviewed the six-month monitoring report for the implementation of *Modify Living Donor Exclusion Criteria*.

Data Summary:

The six-month monitoring report examined data from six months pre and post policy implementation.

The overall volume of living kidney donors was 3,004 pre policy era and 3,043 post policy era. The overall volume of living liver donors was 308 pre policy era and 306 post policy era.

The number and percent of living kidney donors with diabetes was 6 (0.2%) in the pre policy era and 3 (0.1%) in the post policy era. While the number and percentage of living kidney donors indicated to have diabetes in the pre policy era was higher, a previous data request for the Committee during the project development process showed that some living donors were indicated as having diabetes due to data entry errors, diabetes that was resolved with weight loss, and gestational diabetes.

The number and percent of living kidney donors with history of cancer was 86 (2.9%) in the pre policy era and 103 (3.4%) in the post policy era. The number and percent of living liver donors with history of cancer was 2 (0.6) in the pre policy era and 4 (1.3%) in the post policy era.

Summary of Discussion:

A member noted that six months may be too short of an interval to monitor the impact. Another member agreed. Staff added that future monitoring reports will incorporate follow-up data as well.

A member stated that the progression of diabetes and chronic kidney disease may differ for individuals with one kidney compared to individuals with two kidneys. The member stated the living donor with pre-diabetes should be followed-up twice a year.

Another member stated that this emphasized the need for longer-term follow-up for all living donors, not just those with diabetes. The member added that it will be interesting to continue to monitor the impact of the proposal and analyze whether this policy change increases the numbers of living donors.

Next Steps:

The Committee will receive a one-year monitoring report and continue to review the impact of the proposal.

3. Public Comment Update

Members discussed public comment feedback received to date on their concept paper, *Concepts for a Collaborative Approach to Living Donor Data Collection*.

Summary of Discussion:

A member stated that feedback received during a regional meeting noted concern for following up with living donors long-term due to the current issues with two-year follow-up. The member stated they emphasized the benefits of the Living Donor Collective performing long-term follow-up rather than transplant programs. The member added there was other feedback noting concern regarding data security. The member stated they informed the region that the OPTN and SRTR have protections due to their statuses as public health authorities. The member stated there was other feedback which sought more information regarding potential consent processes. The member stated that they informed the region that living donor candidates and living donors are always able to opt out of the follow-up. The

member stated that additional feedback received was concern regarding following living donor candidates who do not proceed to donation.

The Vice Chair noted that their region also had concerns regarding consent. The Vice Chair added that new consent processes would add burden to transplant programs. The Vice Chair stated that SRTR representative clarified that consent processes would not need to be changed but noted that it is important for the community to understand how processes may or may not change in order for members to understand potential impact.

The Vice Chair noted that the OPTN Transplant Coordinators Committee (TCC) provided supportive sentiment as well as useful feedback, specifically on the definitions. The Vice Chair noted that TCC members also suggested the Committee consider unintended consequences such as living donors feeling abandoned by their transplant programs.

Another member asked for more information on why living donor candidates who are not approved for living donation are an appropriate comparator group to living donors long-term. An SRTR representative stated that within the group of living donor candidates, there are individuals who are approved and do not proceed with donation, and that smaller sub-population is an ideal comparator group. The SRTR representative explained that living donor candidates who are not approved for living donation allow for analyses on current acceptance practices. The SRTR representative added that this type of analysis could positively influence living donor acceptance practices based on data and evidence.

Next Steps:

The Committee will continue to review and discuss public comment feedback.

Upcoming Meetings

- September 13, 2023 (teleconference)
- October 3, 2023 (in-person)

Attendance

- **Committee Members**
 - Alexandra Shingina
 - Anita Patel
 - Annie Doyle
 - Ashtar Chami
 - Camille Rockett
 - Catherine Huynh
 - Danielle Reuss
 - Dylan Adamson
 - Henkie Tan
 - Karen Ormiston
 - Kelley Hitchman
 - Laura Butler
 - Nahel Elias
 - Nancy Marlin
 - Stevan Gonzalez
 - Tyler Baldes
- **HRSA Representatives**
 - Arjun Naik
 - Lauren Darensbourg
 - Kala Rochelle
 - Mesmin Germain
- **SRTR Staff**
 - Avery Cook
 - Caitlyn Nystedt
 - Katie Siegert
 - Krista Lentine
- **UNOS Staff**
 - Elena Liberatore
 - Jennifer Wainright
 - Kim Uccellini
 - Meghan McDermott
 - Rebecca Brookman
 - Sally Aungier
 - Samantha Weiss
 - Sara Langham
 - Sara Rose Wells