

**OPTN Living Donor Committee  
Meeting Summary  
November 8, 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 11/08/2023 to discuss the following agenda items:

1. Review of Health Resources and Services Administration (HRSA), OPTN, Scientific Registry of Transplant Recipients (SRTR), and Centers for Medicare and Medicaid Services (CMS) Roles
2. Refine Scope: Concepts for a Collaborative Approach to Living Donor Data Collection

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

**1. Review of Health Resources and Services Administration (HRSA), OPTN, Scientific Registry of Transplant Recipients (SRTR), and Centers for Medicare and Medicaid Services (CMS) Roles**

The Committee heard a presentation about the roles of HRSA, the OPTN, the SRTR, and CMS and asked questions.

### Presentation Summary:

CMS:

- Is responsible for Medicare reimbursement and conditions for participation
- Issues regulations for organ procurement organizations (OPOs), transplant programs, donor hospitals, and histocompatibility laboratories
- A condition of participation in the Medicare program for transplant programs is membership in the OPTN

HRSA:

- Is responsible for awarding, managing, and overseeing the OPTN and SRTR contractors

SRTR:

- Responsible for providing statistical and other analytic support to the OPTN for purposes including the formulation and evaluation of organ allocation and other OPTN policies.
- Provides analytic support to HHS in a variety of areas including: policy formulation and evaluation, system performance metrics, economic analysis, and preparation of recurring and special reports to Congress.
- Under contract with HRSA, established and manages the Living Donor Collective which has two primary goals:
  - Study the long term health effects of living organ donation, and
  - Understand potential barriers to living donation

OPTN:

- National Organ Transplant Act (NOTA) established the OPTN to maintain a national registry for organ matching
- The OPTN acts through its Board of Directors and Committees
  - The Board establishes and maintains transplant policies (operational rules) and bylaws (membership requirements) that govern the OPTN
  - OPTN has authority to develop policies and bylaws for requirements related to transplant programs, organ procurement organizations, and histocompatibility laboratories

Staff also presented a recap of the OPTN governance structure and the charge of the OPTN Living Donor Committee.

Summary of Discussion:

A member asked how the governance structure of the OPTN would change when the OPTN Board of Directors becomes separate from the Board of Directors for the Contractor. Staff responded that any OPTN Committee sponsored proposal would remain to be reviewed and approved by the OPTN Board of Directors. The Vice Chair stated that in the context of the Committee’s work, it is very important to understand the role of each agency.

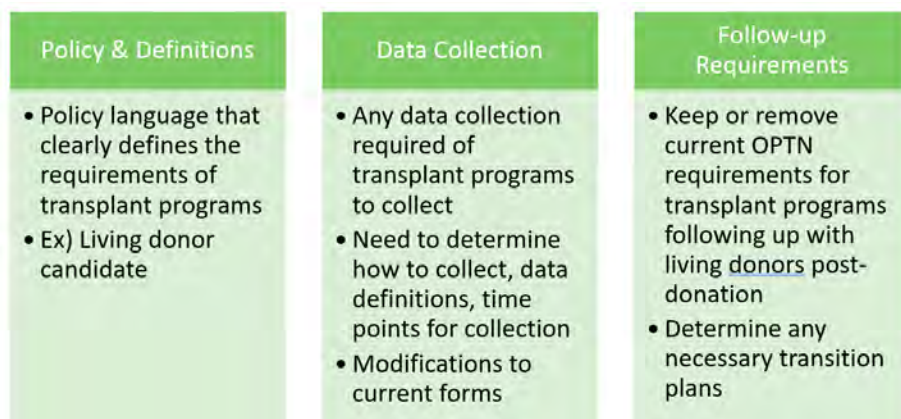
**2. Refine Scope: Concepts for a Collaborative Approach to Living Donor Data Collection**

The Committee worked to refine the scope of the project and decide on next steps.

Presentation Summary:

Staff recapped project development to date and explained where the Committee is in the overall policy development process. The following graphic was shown to explain what components would be important to incorporate into a proposal for public comment. Staff encouraged members to think about the minimum elements that the proposal should contain, noting that the Committee could refine and iterate the project over multiple proposals, if necessary.

**Figure 1: Concepts for a Collaborative Approach to Living Donor Data Collection Proposal Components**



The graphic below shows collaboration that may be required among agencies to finalize the proposal:

**Figure 2: Determinations for a Collaborative Approach to Living Donor Data Collection Proposal**

Transition	Follow-up	Feedback loops	Education
<ul style="list-style-type: none"> <li>• If any OPTN follow-up requirements are removed, it will be important to determine a plan to ensure there are no gaps in follow-up for living donors</li> </ul>	<ul style="list-style-type: none"> <li>• Determine a plan for ongoing collaboration between the OPTN and SRTR for development and continual review of long-term follow-up data collection</li> </ul>	<ul style="list-style-type: none"> <li>• Determine capability/plan for how transplant programs can be alerted on post-donation outcomes for living donors</li> </ul>	<ul style="list-style-type: none"> <li>• Determine a plan for ongoing collaboration between the OPTN and SRTR for the development of education*</li> </ul> <p><small>*Any requirements related to transplant programs having to educate living donor candidates or living donors would require policy</small></p>

Summary of Discussion:

The Vice Chair encouraged members to keep in mind public comment feedback as the Committee moves forward in the project, noting that the first step would be deciding on a concrete framework to bring to the OPTN Policy Oversight Committee for consideration. A member explained that the Committee should focus on transition plans, and staff added that in developing transition plans, it is important to decide if the Committee is proposing to remove any follow-up requirements. Another member stated that it may be helpful to break down the project into who, what, when, where, and why, and then get community feedback on each of these elements.

A member expressed concern about some of the language used in talking about the project, explaining that it may be concerning for a community member to hear that the follow-up is being “removed” when it is actually proposed to be transitioned to another party. A member agreed and explained that public comment indicated confusion on some of the language used, so having very clear definitions and roles will be important for the proposal. The Vice Chair noted the concern heard in public comment from transplant programs about follow-up, and advocated for the Committee to review literature and hear additional data from the SRTR to support the concepts in the proposal as the next steps.

Staff stated that from this discussion, it seems as though the next step for the Committee would be to determine what to do regarding follow-up. The Vice Chair agreed that this is a critical first step.

A member asked how the Committee can be sure that the SRTR is appropriately resourced to conduct the follow-up as proposed. A member asked if SRTR could present data about current state and future capabilities to the Committee, and the Vice Chair noted that a prior presentation on this topic to the Committee was very helpful. The Vice Chair explained that information about SRTR capacity, funding, current state, and planned future framework would all be important to know for the Committee in developing this project. An SRTR representative explained that they are happy to coordinate a presentation for an upcoming meeting. They continued that it is important to understand the scope of the project in order to answer any questions about capacity, noting that this may be a chicken and the egg problem, and that questions regarding funding would be better directed to HRSA.

A member expressed concern about project scope, explaining that the volume of living donor candidates versus living donors is currently unknown. The Vice Chair responded that it would be important to

understand the volume, or at least estimate it, from the Committee's agreed upon definition of living donor candidate. Staff noted that the OPTN does not collect data on living donor candidates because this is before they enter the OPTN system, however, ways to estimate the number would be to ask the SRTR to provide an estimate based on transplant programs participating in the Living Donor Collective, or to reach out to transplant programs of various sizes and ask them to provide an estimate based on a given definition. The Vice Chair explained that the definition of living donor candidate that the Committee determines may be different than the SRTR's definition, and it is important to ask if the SRTR can estimate these numbers using the Committee's definition by running a separate analysis.

A member explained that the Committee should also have a sense of how much time the data collection changes will take transplant programs to complete as a part of developing the proposal.

Next Steps:

Staff will reach out to the SRTR to coordinate a presentation.

**Upcoming Meetings**

- December 13, 2023 (teleconference)

## Attendance

- **Committee Members**
  - Alexandra Shingina
  - Annie Doyle
  - Ashtar Chami
  - Camille Rockett
  - Danielle Reuss
  - Dylan Adamson
  - Henkie Tan
  - Hoylan Fernandez
  - Karen Ormiston
  - Kelley Hitchman
  - Nancy Marlin
  - Stevan Gonzalez
  - Erik Lum
  - Laura Butler
  - Tyler Baldes
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Mesmin Germain
  - Vanessa Arriola
- **SRTR Staff**
  - Avery Cook
  - Caitlyn Nystedt
- **UNOS Staff**
  - Cole Fox
  - Emily Howell
  - Kieran McMahon
  - Laura Schmitt
  - Meghan McDermott
  - Samantha Weiss
  - Sara Rose Wells
  - Tamika Watkins
- **Other attendees**
  - Macey Levan
  - Andromeda Torre