OPTN Living Donor Committee
Meeting Summary
April 23rd, 2025
Conference Call

Stevan Gonzales, Chair
Introduction

The OPTN Living Donor Committee met via Cisco WebEx teleconference on 4/23/2025 to discuss the following agenda items:

- Announcements
- Update and Improve Efficiency in Living Donor Data Collection: Goals for Today
- Review Workflow and Next Steps
- Review Data Advisory Committee (DAC) Feedback
- Discussion: SRTR Data Sharing
- Review Draft Policy Language Changes and Additions
- Discussion: Determine Form Names
- Discussion: HOPE Act – Living Donor Research Protocol
- Review Proposed Metrics and Monitoring Plan
- Meeting Wrap up and Next Steps

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

1. Announcements

Announcements included updates on upcoming listening sessions for committee members to discuss recent changes and future plans, scheduled for the week of May 5. Additionally, the Board of Directors meeting was announced for June 9-10, with several proposals expected to be discussed. The summer public comment period for the data collection project is tentatively set for August 8 to October 7, with a planned vote on the data collection project on May 14.

2. Update and Improve Efficiency in Living Donor Data Collection: Goals for Today

The Chair outlined the primary goals for the day, focusing on improving the efficiency of living donor data collection. He highlighted the importance of the project, which aims to create a new data collection form (Form B) for potential living donors who do not donate. The project also seeks to establish a framework for long-term follow-up of living donors and potential donors, assessing barriers to living donation and understanding long-term outcomes. The Committee planned to review and finalize the data elements for Form B, discuss feedback from the Data Advisory Committee (DAC), and ensure alignment with existing forms.

3. Review Workflow and Next Steps

Staff provided an overview of the workflow for living donor data collection. She explained the process for potential living donors, starting from initial contact with the living donor center to the multidisciplinary committee review and approval for donation. The workflow included scenarios for donors who are screened out immediately, those who are ruled out during evaluation, and cases of

aborted procedures. The committee discussed the importance of defining the starting point for data collection and ensuring clarity in the workflow.

A. Review/Discuss Form B:

Form B is a new data collection form intended to capture demographic, clinical, and donation decision data for potential living donors who do not proceed with donation. The form also includes surgical questions for cases where the donation procedure is aborted. The goal is to understand the barriers to living donation and establish a comparator group for living donor outcomes.

Summary of Discussion and Changes:

Demographic Information-

The committee reviewed the demographic fields, including name, social security number, contact information, ethnicity, race, citizenship, birth sex, organ type, and intended recipient. There was a consensus to keep these fields consistent with existing forms to ensure standardization.

Clinical Information-

The clinical information section includes family history, measurements (height, weight, BMI), substance use (tobacco, nicotine, cannabis), and lab values. The committee discussed the importance of capturing accurate and comprehensive clinical data while minimizing the burden on transplant centers.

Nicotine and Tobacco Use-

The Committee decided to simplify the nicotine and tobacco use field to a yes/no format with options for current or past use, removing the need to specify the type of nicotine or tobacco product. The nicotine and tobacco use field was simplified to a yes/no format with options for current or past use. The cannabis use field was similarly simplified.

Cannabis Use-

Similarly, the cannabis use field was simplified to a yes/no format with options for current or past use.

Donation Decision Information-

This section captures the reasons why a potential living donor did not proceed with donation. The committee emphasized the importance of understanding these barriers to improve living donor programs.

A field for "Donor not interested in paired exchange" was added under donor choice to capture data on immunological incompatibility and the donor's willingness to participate in paired exchange.

Immunological Incompatibility-

The Committee discussed the need to capture data on immunological incompatibility and the donor's willingness to participate in paired exchange. It was decided to include a field for "Donor not interested in paired exchange" under donor choice.

Surgical Addendum-

For cases where the donation procedure is aborted, the form includes surgical questions to capture relevant data. The committee reviewed these questions and ensured they align with existing practices for capturing surgical data.

B. Review/Discuss Data Definitions:

The committee reviewed the data definitions to ensure clarity and consistency. Definitions for terms like "Potential Living Donor" and "Recovery Hospital" were added or modified to match membership policies.

There were no discission items submitted by Committee members.

4. Review Data Advisory Committee (DAC) Feedback

The Committee reviewed feedback from the DAC, which emphasized the need to minimize the burden of data collection and ensure feasibility. The DAC requested an estimate of the increase in volume for completing forms and suggested conducting a survey among committee members to gather data from their transplant programs. The DAC also highlighted the importance of discrete fields for data extraction and the potential for interfacing with software for automatic data extraction. The Committee agreed to refine the data elements and seek endorsement from the DAC again.

Next Steps:

- Staff to send survey to collect data from the Committee and the Workgroup. The request will be for living donors and potential living donors (who did not donate) who came in for an in person meeting between January and December 2024.
- Staff will draft a response to send to the DAC on behalf of the Living Donor Committee.

5. Discussion: SRTR Data Sharing

The Committee discussed the SRTR data sharing plan, which will involve collecting phone and email data from OPTN forms to contact donors and non-donors for voluntary follow-up. The SRTR will reach out to living donors after one year and potential donors annually with data collected by the OPTN. The Committee emphasized the importance of educating potential living donors about the data sharing process and ensuring their information remains protected throughout. Staff from SRTR confirmed the collaborative nature of the data sharing plan and the commitment to maintaining patient safety.

6. Review Draft Policy Language Changes and Additions

Staff presented the proposed changes to the policy language, including the addition of "Potential Living Donor" and modifications to the definition of "Recovery Hospital." New data submission requirements were added for potential donors who do not donate, including deadlines for Form B and the Living Donor Feedback Form. The Committee also reviewed the removal of outdated reporting requirements and the clarification of therapeutic donor definitions. The changes aimed to ensure clarity and alignment with the new data collection framework.

There were no discussion items submitted by committee members in advance of the meeting.

7. Discussion: Determine Form Names

The Committee revisited the naming conventions for various forms used in the living donor process. The discussion emphasized the importance of aligning form names with existing policy language and standardization practices. The Committee recommended retaining the names "Living Donor Feedback Form," "Living Donor Registration Form," and "Living Donor Follow-Up Form" for consistency. For the

new form, the Committee overwhelmingly agreed in naming it "Living Donor Non-Donation Form" to clearly indicate its purpose and align with the terminology used in policy language.

8. Discussion: HOPE Act – Living Donor Research Protocol

The Committee reviewed the Hope Act proposal, which aligns with the federal rule to allow transplants from donors with HIV to candidates living with HIV without requiring participation in the variance. The proposal includes additional patient safety measures, such as verification and informed consent requirements, to ensure the safety of both donors and recipients. The discussion highlighted discussion about the long-term risks for living donors with HIV, particularly regarding kidney disease and the impact of HIV medications. The Committee considered drafting a memo to the DTAC summarizing these concerns and questions.

During the discussion, the Committee expressed several concerns about the long-term risks for living donors with HIV, particularly regarding the potential for kidney disease and the impact of HIV medications. While the Hope Act has been successful, the number of living donor transplants performed under the act is relatively small, raising questions about the adequacy of data on long-term outcomes for these donors. The committee highlighted the need for more comprehensive data to understand the potential risks and ensure that donors are fully informed about the implications of their decision to donate.

One of the key points raised was the importance of collaboration with the SRTR to monitor and collect data on living donors with HIV. This collaboration would help ensure that the long-term outcomes of these donors are tracked and analyzed, providing valuable insights into the safety and efficacy of the policy. The committee discussed the possibility of formally requesting data from the SRTR on the long-term outcomes of living donors with HIV, emphasizing that this data is crucial for evaluating the effectiveness of the policy and ensuring that donors are adequately protected.

The Committee also reviewed feedback from other organizations, including the AST, which expressed concerns about the proposal. The AST's comments emphasized the need for careful consideration of the risks and the importance of maintaining stringent patient safety measures. This feedback resonated with the committee, reinforcing the need to address the potential risks for living donors with HIV and ensure that the policy includes robust safety measures.

The Committee considered the broader implications of the proposal. They discussed the potential impact on access to transplants for individuals living with HIV and the importance of balancing increased access with patient safety. The Committee acknowledged that while the proposal aims to expand access, it is essential to ensure that the safety of donors and recipients is not compromised.

The discussion included the need for specific informed consent elements for living donors with HIV. The committee emphasized that donors must be fully informed about the risks associated with donating an organ while living with HIV, including the potential impact on their health and the long-term outcomes. This informed consent process is critical to ensuring that donors make an informed decision and understand the implications of their donation.

The Committee decided to draft a memo to the Disease Transmission Advisory Committee (DTAC) summarizing their concerns and questions. This memo will highlight the need for additional data on long-term outcomes and emphasize the importance of patient safety measures.

<u>Next Steps:</u>

- Staff will draft a memo to send to the DTAC summarizing this discussion.

9. Review Proposed Metrics and Monitoring Plan

Research staff presented the proposed metrics and monitoring plan to evaluate the effectiveness of the new policy and identify any unintended consequences. The plan includes monitoring reports at six months, one year, and two years post-policy implementation, based on available data. The primary goals are to identify barriers to living donation and establish a comparator group for living donor outcomes. The monitoring will include frequency tables for reasons not to donate, distributions and counts comparing donor and potential donor characteristics, and the percent of Form B completed on time. The Committee discussed the importance of collaboration with the SRTR to monitor long-term outcomes and ensure adherence to data collection requirements.

10. Meeting Wrap up and Next Steps

- Staff will email the draft public comment feedback questions to the Committee since there was not enough time to discuss this at the meeting. This topic will be on the May agenda meeting.
- Staff will send out a survey to collect living donor data from committee members' transplant programs for the DAC
- Staff will draft a memo on behalf of the Living Donor Committee to send to the DTAC summarizing the discussion about the HOPE Act proposal.

Upcoming Meetings:

- 5/15/2025

Attendance

- **Committee Members**
  - Stevan Gonzalez
  - Trysha Galloway
  - Tiffany Caza
  - Annesha Shetty
  - Michael Chua
  - Laura Butler
  - Nathan Osbun
  - Nancy Marlin
  - Frankie McGinnis
  - Trysha Galloway
  - Lisa Thomas
  - Anita Patel
  - Annie Doyle
  - Danielle Reuss
  - Nahel Elias
  - Lisa Thomas
- **SRTR Representatives**
  - Krista Lentine
  - Katie Siegert
- **HRSA Representatives**
  - N/A
- **UNOS Staff**
  - Sara Langham
  - Samanthia Weiss
  - Emily Ward
  - Lauren Mooney
  - Sara Rose Wells
  - Laura Schmitt
  - Melissa Gilbert
  - Cole Fox
  - Asma Ali
  - Carly Layman
  - Jesse Howell