OPTN Living Donor Committee
Meeting Summary
September 12, 2024
In-Person Meeting

Steve Gonzalez, MD, Chair
Aneesha Shetty, MD, Vice Chair

Introduction

The OPTN Living Donor Committee ("Committee") met via Cisco WebEx teleconference on 09/12/2024 to discuss the following agenda items:

1. **Project Progress Recap**
2. **Scientific Registry of Transplant Recipients (SRTR) Presentation: Living Donor Collective**
3. **Decision Point: Registration Data Elements**
4. **Workgroup Updates**
5. **Prior Living Donor Priority in Continuous Distribution and Domino Donors**
6. **Building a Workflow: New Data Collection**
7. **Enhancing LD Follow-Up**

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

1. Project Progress Recap

No decisions were made.

Summary of Presentation:

The Chair presented the current state of the Enhancing Living Donor Data Collection project and progress so far. He reviewed Phase I modifications, which include adding data collection for living donor candidates and donation decision data collection in pre-donation, minimal necessary modifications to reduce duplicate data entry in the perioperative period and removing 24-month follow-up post-donation. The Chair reviewed the working living donor candidate definition. The Chair described the summary of public comments from the 2023 Concept Paper.

Summary of discussion:

A member asked about implementation of technology requirements, and the Chair responded that implementation will be included in the transition plan with costs to members finalized later. An SRTR representative asked which phases had been approved, and staff responded that phase I has been approved.

2. SRTR Presentation: Living Donor Collective

No decisions were made.

Summary of Presentation:

An SRTR representative presented on the Living Donor Collective pilot along with research on living donation reasons for not donating. SRTR also reviewed current state follow up, along with current data collection. They presented the phased approach into the new era of the Living Donor Collective. SRTR discussed priorities for the Collective moving forward, such as survey data and improving data collection. They reviewed their steering committee progress, which has included brainstorming long-term follow-up priorities.

Summary of discussion:

The Vice Chair asked how patient follow-up was handled if someone completed evaluation but is waiting on decision, and SRTR responded that if they went through the workup and presented at donor selection plus did approval, then they would enter the form as approved. The committee discussed patient follow-up, with a member stating that a patient shouldn't be "closed out" too early in case someone decides to reverse their decision to not proceed with donation. A member asked if a candidate's OPTN ID number follows them to different centers, and staff stated that some candidates do receive more than one ID number if they register at multiple centers or begin a separate evaluation much later. The member responded that social security numbers could be tracked to eliminate redundancy.

SRTR stated that the technologies are already in place for new processes. The Chair asked how far along the Living Donor Collective is on new follow-up, and SRTR responded that the data collection started in 2018 with annual follow-up starting this year. SRTR also stated that engagement, especially around external communications, needs to be improved. A member suggested that SRTR could collaborate with insurance agencies with linkages to help eliminate redundancies. SRTR stated they do not collect reasons for a candidate denying follow-up, just notes. The Vice Chair asked if a donor comes back years later with health complications, how can this information be collected? The Chair emphasized that linkages would help in this area. A committee discussed secondary contacts to allow someone to communicate on behalf of a donor.

The Chair stated that after hearing an overview of SRTR's work, the OPTN needs to decide priorities and data collection options. A member asked if life satisfaction will be captured, and staff responded that the workgroup could consider this data element. The Chair asked if the SRTR had adequate resources to continue this work, and SRTR responded that their contract is up for rebid and this is something included in that process.

3. Living Donor Decision Data Workgroup Updates

No decisions were made.

Summary of Presentation:

Vice Chair discussed updates and framework of Decision Data Collection Workgroup. This includes work they are currently doing on decision data collection.

Summary of discussion:

A member asked about the status of VCA in decision data collection. The Chair said that not all elements are specific to only liver and kidney. The Chair also discussed the timeline of how long one might be considered a living donor candidate as to not cause redundancy within candidate tracking if someone returns for re-evaluation. The Vice Chair emphasized communication between the workgroup and committee to keep everyone involved in the data collection process.

4. Consensus: Registration Data Elements for Living Donor Candidates

No decisions were made.

Summary of Presentation:

Staff presented a project overview of registration data element collection, including the goal of deciding which elements from SRTR should be included in phase 1 of the project. The committee had been asked to complete a survey asking if each SRTR element was critical to phase 1 of the project, would aid project goals but not critical, and if it was not necessary to achieve project goals. Survey feedback included that there was a current lack of understanding of long-term holistic health impacts of donation, that only the most critical information is needed and to allow SRTR to collect historical information, that lab tests may or may not be feasible for all candidates, and that long-term data is important to counseling future candidates considering living donation.

Summary of discussion:

A member suggested aligning with *OPTN Policy 14* due to differences among center practices. A member discussed center burden and stated that policies implemented should not greatly change center practices. A member said that starting lab test results could indicate the start of evaluation and patients may be ruled out with labs. Another said that if the definition only includes candidates seen in-person it could increase administrative burdens. A member said that a living donor candidate definition that does not include steps before evaluation, such as questionnaires, will be weak in scope. The committee discussed their screening practices and at what point they get lab results, with members having different practices at their centers. SRTR discussed that they have used a definition that included if someone was seen at a center and if someone received an MRN number. The committee suggested reaching out to the greater nephrologist community about this issue, to determine any commonalities in when centers consider an evaluation to begin.

The Committee discussed the definition of a living donor candidate and challenges with defining this cohort accurately and ran out of time to go through each element. The Committee was in favor of getting more clarity on a specific definition of living donor candidate before deciding on what data collection would be appropriate.

SRTR discussed baseline function collection and proposed alignment with *OPTN Policy 14* for data collection guidelines. Staff stated that a “not done” option could be included but all elements will need to be completed to be considered “done.” The Chair stated that someone could go through the entire candidate process without donation, which would involve data collection throughout. A member said that shifting lab data earlier could be burdensome. A member said lab tests start the evaluation, and a person needs to be monitored to check elements. A member responded that labs could reject people before registration. A member said that data could be missed for people that were screened by a questionnaire, and lack of information on certain elements could be a barrier to data collection. Members discussed their organization’s practices, with a member stating that their center is a single-day evaluation that begins with screening via a health history phone call.

5. PLD Priority in CD and Domino Donors

The Committee requested an OPTN data request to update the data regarding how many prior living donors were waitlisted, for all organ types.

Summary of Presentation:

The Chair presented on prior living donor priority status in continuous distribution. Key points include prior living donors receiving priority when listed for transplant no matter the organ, no time restriction, no organ type limitations, and no option to opt-out of priority. Research staff presented on the existing metrics of prior living donors who have gone on to receive an organ transplant to emphasize the importance of these small impacts. The Committee requested an OPTN data request to update the data regarding how many prior living donors were waitlisted, for all organ types. Staff presented on the definition and policy language for domino donors, which does categorize domino donors as prior living donors.

6. Building a Workflow: New Data Collection

The Committee reached consensus on the proposed Workflow.

Summary of Presentation:

Staff presented a proposed workflow for data collection based on the Committee's prior feedback and user research. To simplify, forms were given letters A1, A2, A3, and B. The Committee will determine appropriate names for these once consensus is reached.

1. A potential living donor (LD) contacts the living donor recovery center and expresses interest in donation.
2. The living donor recovery center screens the person to determine if they meet screening criteria. They may use an automated tool or screen manually.
    a. If yes, proceed to #3.
    b. If no, proceed to #13.
3. The person, now a living donor candidate, presents at clinic (or remotely) for multidisciplinary evaluation as outlined in *OPTN Policy 14.1 to 14.4*.
4. During the evaluation process, a living donor candidate may complete some or all evaluation testing as outlined by policy. Has all their evaluation testing been completed?
    a. If yes, proceed to #5.
    b. If no, proceed to #14.
5. Once all evaluation testing has been completed, the multidisciplinary team will review the results of the LD candidate evaluation.
6. Did the multidisciplinary team determine that the LD candidate was suitable for donation?
    a. If yes, proceed to #7.
    b. If no, proceed to #17.
7. The recovery center must complete **Form A1** prior to donation. This form generates a Donor ID.

Note: *Committee to establish timeframe and determine form name.*

8. Does the LD candidate withdraw or are they deemed ineligible prior to donation?[1]
    a. If yes, proceed to #15.
    b. If no, proceed to #9.
9. The living donor undergoes surgery and the organ is recovered.
10. The recipient of the living donor's organ is removed from the waitlist using living donor transplant (code 15).
11. The recipient's removal from the waitlist generates **Form A2**, and the recovery center submits necessary data within required timeframe.

Note: *Committee to establish timeframe and determine form name.*

12. At 6 months, and 12 months, the recovery center submits the living donor's follow up data on **Form A3.** This concludes the recovery center's data submission responsibilities. At 1 year, the SRTR begins follow up of living donor candidates and living donors.

Note: *Committee to determine form name.*

13. No further documentation is required for individuals who are screened out prior to donation.
14. Is the living donor candidate's evaluation still active?

    Note: *Committee to determine if definition is necessary for consistency.*

    a. If yes, proceed to #3 until all required evaluation elements are completed.
    b. If no, proceed to #17.
15. The recovery center must use the new donor management tool to close a previously approved living donor (incl. corresponding Donor ID). This generates **Form B.**

Note: *Committee to determine form name.*

16. **Form B** prepopulates with all available demographic and clinical data that was entered into Form A1.
17. The recovery center completes **Form B** within the required timeframe.

Note: *Committee to determine timeframe.*

Staff walked through some example scenarios to illustrate these proposed steps.

Summary of discussion:

Members asked clarifying questions about what each step entails and who each proposed form would be filled out for. The Vice Chair noted that the workflow makes sense and achieves the committee's stated goals while being as faithful as possible to current process to address center concerns about changing the process drastically. A member asked for more information about the new management tool, stating that this tool will make it a lot easier for programs. This member explained that the tool is an incentive for programs to fill out A1 so that their candidates would appear in the management tool. The Chair explained that this workflow will help to address concerns about burden, both by pre-populating data and by having consistent steps. Members expressed that the proposed workflow makes sense and addresses concerns adequately. A prior living donor expressed support for the workflow, explaining that this is capturing the right information at the right time and would benefit other living donors long term. Staff asked if there were any components of the workflow that were not feasible, and members did not have any concerns that were not able to be resolved with clarifying questions. One thing that the committee focused on was the benefit in being able to separate out those who were

[1] A LD candidate who is no longer interested in donation may withdraw themselves from the process, or a recovery center may decide the candidate is ineligible for donation due to a change in health status or new medical finding.

approved for donation via selection committee versus those who were ruled out, or withdrew, prior to consideration by selection. A social worker on the Committee explained that this will also help with public trust, because those who are not appropriate donors will be ruled out, and there will be a record of this.

A coordinator explained that the burden will depend on what the actual form content will be, but that the workflow seems appropriate from a burden perspective given the committee's goals. The committee discussed when living donor candidates are considered by selection committee, and this varied center to center. One administrator explained that their center considers a person in selection committee at the point at which a decision can be made (example- abnormal test results for a rule-out).

The Committee discussed the challenges with defining the "start" of data collection. A member suggested instead of trying to find an appropriate timepoint, to instead have a list of things that must be completed to consider someone a living donor candidate. The Vice Chair explained prior challenges with this approach. The Chair explained that one way to approach this would be to define a living donor candidate as someone who has completed at least one part of evaluation *plus* that they were discussed in multidisciplinary selection committee. Members liked this approach, and a coordinator explained that this makes sense from a burden point of view. The Vice Chair noted that this was less nebulous from a policy perspective. A member explained that this approach would likely mean a loss of data from those who were only discussed "offline" and not in a formal multidisciplinary committee.

The Vice Chair stated that it will be important to define a concrete timepoint for the proposal. An administrator explained that having multidisciplinary review as a component of the definition is desirable because centers have a clear record and documentation of this event. An SRTR representative stated that this makes sense, but there is currently nothing in policy about the multidisciplinary review so it would be challenging to anchor policy to this.

The committee also discussed generally what information should be required on each form. After discussion, the committee reached initial consensus to keep the information required on A1 minimal to capture the population and contact details, but then clearly define required information on B and A2. This way, the information can be tailored to specifically capture the data points required from the differences in those populations (non-donors vs donors). The Committee noted that an important data element to capture on A1 will be the date of the multidisciplinary selection committee.

The group will need to consider how to handle those who decline donation and then wish to restart an evaluation who start an evaluation at another center. Staff will look into how the system might handle these cases.

<u>Breakout groups:</u>

The committee participated in a breakout activity to help decide on some of the outstanding decisions on the workflow. The questions these breakout groups responded to, and their thinking, is below.

Workflow Step(s)	**Question**	**Considerations/Suggestions**	**Breakout group report out**
7.	What should the title of Form A1 be?	One suggestion was *Living Donor Registration and Evaluation*. However, if there is evaluation data	Suggestion to name this "Living Donor Approval" form to convey the purpose of the data collection and try to be consistent with current naming.

		on Form A2 including the term "evaluation" may be misleading.	
7.	Within what timeframe should Form A1 be due?	Policy currently requires the living donor feedback form to be completed prior to surgery. Some centers complete this form at the time surgery is scheduled; others complete the form the afternoon before surgery. There is an option to maintain the status quo or select a new timeframe.	The breakout group recommended keeping this timeframe similar to in current data collection, and allow this form to be filled from anytime after selection committee approval to prior to surgery, or within 90 days of being made aware that the person is no longer proceeding with donation. This group noted that the information required will be captured regardless of if there is a more specific timepoint, and this way gives programs more flexibility. This group did note that this decision may need to change depending on what information is required on each form.
11.	What should the title of Form A2 be?	One suggestion was *Living Donor Candidate Donation.*	The group recommended keeping this the same as it currently is- "Living Donor Registration" form. They explained that this makes sense because at this point, the person is a living donor because they are post-surgical so you are registering them as a donor.
14.	Is there a need to define an "active" candidate? Another way to look at this question is if there should be a window of time in which an approved donor is "auto-closed" and a Form B is required because of the length of time elapsed.	User feedback indicated that the timeframe to complete evaluation varied. Some centers complete evaluations and schedule surgery within a few weeks while others may follow living donors for longer periods of time. In one scenario, a KPD donor started evaluation in 2022 and did not donate until 2024.	The group discussed that there is a timeframe in which evaluation components will need to be repeated, but that this varies by program. The group recommended that there is no timeframe required for this question because the donor is still willing to donate, even though parts of the evaluation may need to be repeated. Because living donor candidates may take a long time from completion of A1 to completion of A2, they should not be "auto-closed" and registered as non-donors, because they still intend to donate. If at any point they decide not to donate, they would just fill out a form B.

15.	Within what timeframe should a recovery center have to report that a living donor, who was previously approved to donate, is no longer proceeding with donation?	Feedback on form due dates varied between centers. Some centers completed evaluations within a few weeks, and others had an evaluation process that lasted several months.	The group recommended that 90 days from the center being made aware (either from the center deciding that the person was ineligible, or from the candidate themselves withdrawing) was an appropriate timeframe. This group noted this mirrors the timeframe currently required in the Living Donor Registration form.
17.	What should the title of Form B be?		The group recommended using "Candidate Non-Donation" form (NDF) as the name, to capture that it could be for any reason that the person is not donating. This group considered other titles, but decided that the naming would be too confusing along with the existing form names.

Next steps:

Staff will come back with information about possibilities for how to concretely define a living donor candidate based on this updated feedback.

7. Enhancing LD Follow-Up

This agenda item was moved to be discussed in another meeting.

Upcoming Meetings:

October 9th, 2024

Attendance

- **Committee Members**
  - Aneesha Shetty
  - Anita Patel
  - Ashtar Chami
  - Dylan Adamson
  - Ginger Ireland-Hoffman
  - Milton Mitchell
  - Laura Butler
  - Michael Chua
  - Frankie McGinnis
  - Nancy Martin
  - Nahel Elias
  - Nathan Osburn
  - Steve Gonzalez
  - Tiffany Caza
  - Trysha Galloway
- **SRTR Representatives**
  - Avery Cook
  - Caitlyn Nystedt
  - Katie Siegert
  - Krista Lentine
- **HRSA Representatives**
  - Mesmin Germain
  - Marilyn Levi
  - Nawraz Shawir
  - Arjun Naik
- **UNOS Staff**
  - Jamie Panko
  - Kieran McMahon
  - Meghan McDermott
  - Sevgin Hunt
  - Cole Fox
  - Laura Schmitt
  - Sam Weiss
  - Kim Uccellini
  - Sara Rose Wells