

## **OPTN Living Donor Committee**

### **Meeting Summary**

**April 26, 2023**

**Conference Call**

**Nahel Elias, MD, Chair**

**Stevan Gonzalez, MD, Vice Chair**

### **Introduction**

The OPTN Living Donor Committee (the Committee) met via Citrix GoToMeeting teleconference on 04/26/2023 to discuss the following agenda items:

1. Project Overview & Meeting Goal
2. Discussion: Living Donor Candidate Definition

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

#### **1. Project Overview & Meeting Goal**

The Committee reviewed their project *collect living donor candidate and donation decision data*. The Committee sought to have consensus on a definition for the term living donor candidate during the meeting.

##### Summary of discussion:

There were no comments or questions.

#### **2. Discussion: Living Donor Candidate Definition**

The Committee provided pre-meeting input on potential definitions for the term living donor candidate. The definition of living donor candidate is important because it is the point in time in which required data collection would occur in context of the concepts of this project. The Committee reviewed the pre-meeting input, reviewed recommendations provided by the OPTN Living Donor Data Collection Working from the April 21, 2023 meeting, and focused on coming to a consensus for one potential definition.

##### Summary of discussion:

Input provided prior to the meeting on potential definitions for a living donor candidate:

- Potential definition: Someone who has contacted a living donor program with an interest
  - This is too broad – these individuals should not be classified as candidates because this point in time is specific to providing information, not screening
  - This is too early – it may include individuals who are looking for more information, but not truly initiating the living donor process
  - Anyone interested in living donation may be worth studying; But could capture mistakes
  - Many individuals aren't candidates for living donation and do not undergo donation, thus tracking their long-term outcomes would be arduous
  - Potentially labor intensive
  - Consider this a "potential" living donor candidate
  - Most inclusive definition of identifying someone as a potential living donor; However high attrition rate

- Potential definition: Someone who underwent a phone screening with a transplant program
  - Change to “a phone, in-person or online screening”
  - Depends on definition of “phone screening”
  - Would be interesting from a data-gathering perspective, but may increase burden to programs
  - Data is collected at this point, but most will not follow through with evaluation/donation making a control group or meaningful data more difficult
  - May be helpful to learn about reasons for declines but potentially labor intensive
  - Every transplant program uses different criteria for a phone screen
  - Advocate for this definition if the goal is to understand barriers
  - Data burden due to volume with this definition would be high
- Potential definition: Someone who was seen at the transplant program for evaluation
  - May be ideal – truly identifies a candidate and may not increase burden on transplant programs as much since they are already engaging and obtaining data at this stage
  - Most meaningful data
  - This would make a good control group if they do not proceed with donation
  - Learn more about reasons for declines or failure to progress
  - Potentially labor intensive
  - Screens out a large portion and will allow grey area individuals which will allow for better analysis of long-term risks
  - A good way to collect data and manage outcomes but does not define a living donor candidate
  - Data collection would be more manageable but this definition would not afford insights into barriers to living donation
- Potential definition: Someone who underwent the evaluation at a transplant program and is approved to be a living donor
  - This is too late – would miss the opportunity to look at barriers to living donation
  - Would lose a large part of the control group, resulting in less meaningful long-term data
  - Least labor intensive
  - Would represent real potential living donors and allow a good contrast group to assess risk
  - The most fitting choice for definition of a living donor candidate
  - Easiest on transplant programs and least administrative burden
  - This definition would still be a higher gain in data collected compared to current state

The Chair suggested that the Committee consider the volume of population size of each definition and the associated burden with collecting data. The Chair stated that the Committee should consider the purpose of collecting the data.

The Chair noted that the definition of a living donor candidate will also establish a comparator group for living donation. The Chair explained that the comparator group can also be followed longitudinally to understand risks and benefits that are attributable to living donation.

The Committee agreed that it is important to collect data in order to determine the barriers to living donation.

A member suggested the Committee consider whether the goal of the data collection is to safeguard living donors or understand barriers and increase living donation.

Another member suggested to ask the community what their priorities are for the goals of living donor data collection.

*Potential definition: Someone who has contacted a living donor program with an interest*

A member supported a potential definition that encompasses every potential living donor. The member reasoned that every potential living donor should be included in order to collect the most meaningful data. The member stated that this possibility would allow for multiple comparator groups.

Another member supported defining living donor candidate at the earliest possible time point in order to understand barriers to living donation. However, the member recognized that the data would be low quality and it may not be valuable enough considering the burden it would take to collect.

A member expressed concern with this definition due to the volume of individuals in this population. The member explained that some transplant candidates will have a campaign to get living donors, such as a social media campaign, which may lead to a large influx of potential living donors for one transplant candidate. The member explained that would be a large burden that transplant programs may not be able to keep up with due to limited resources.

The Committee agreed to not use this potential definition as a way to define living donor candidate.

*Potential definition: Someone who underwent a phone screening with a transplant program*

Another member noted that this potential definition should include phone and online screening. The member noted that feedback from the OPTN Data Advisory Committee cautioned the Committee to limit burden. The member explained that this definition would be a huge burden for transplant programs to collect data.

A member noted that screening tools screen out individuals on factors that are generally understood to be factors not suitable for living donation. The member noted that this population has a high attrition rate and that individuals do not follow-up after the screening. The member explained that if an individual does not follow-up, then there is no way to understand the barrier for why they did not proceed. The member also noted that if the individual is not following up at this stage in the process, it will likely be difficult to engage them in long-term follow-up.

Another member asked whether this population could be contacted more frequently if they are not following up. A member responded that at their transplant program they only follow-up once because anything beyond that may be considered coercion.

The Chair noted that reasons an individual was screened out may be collected by the screening tool. The Chair suggested to review whether there has been published literature on this. The Chair stated this potential definition will be a large volume with low fidelity that may not be useful in the long-term.

A member noted that this time point may help understand medical reasons why an individual was screened out, but it does not give a comprehensive understanding to barriers to living donation.

The Committee agreed to not use this potential definition as a way to define living donor candidate.

*Potential definition: Someone who was seen at the transplant program for evaluation*

The Chair stated that having data on individuals who were ruled out during the evaluation process would be useful data, specifically to determine barriers to donation. The Chair stated this data could also be used as a benchmark to allow transplant programs to compare their current practices with each other.

A member agreed with this definition because it would provide more meaningful data and establish a more appropriate comparator group than the other potential definitions. The Chair noted this potential definition would have more complete data than compared to the two potential definitions that are earlier in the living donation process.

An SRTR representative noted that this potential definition is how the Living Donor Collective defines living donor candidate. The SRTR representative noted that this definition was decided upon through a steering committee that incorporated representatives of transplant programs participating in the pilot program. The SRTR representative noted that at this time point, an individual is most likely to be fully entered into the electronic health record and have more complete information across the evaluation.

The Chair noted that at their program they only evaluate two potential living donors at a time per transplant candidate.

Another member stated that starting data collection at this point in time would only allow for learning about successes. The member stated that it is important to understand the failures of why individuals did not make it to this point in time.

Another member noted that data collected at this point in time would be more meaningful because the reasons for not proceeding to donation will be clearer.

An SRTR representative noted that within the Living Donor Collective about half of living donor candidates are approved, under this definition.

A member stated that this potential definition would not include information on pre-evaluation testing such as 24-hour urine tests that may be important for understanding reasons for decline. The Chair noted that the lab testing would inform medical reasons for decline which may not help establish an appropriate comparator group for long-term follow-up.

A member noted that this potential definition provides a balance between meaningful data collection and burden.

The Committee agree to use this potential definition as a way to define living donor candidate. The Committee recognized the need to further define evaluation.

A member suggested that evaluation begins when the transplant programs orders testing, whether that testing is occurring at the transplant program or elsewhere. Another member wondered the level of benefit of collecting data on individuals who had initial testing but never made it to the transplant program for further evaluation and testing.

Another member suggested considering how transplant programs define evaluation based on the Centers for Medicare and Medicaid Services (CMS) regulations. The member explained that CMS regulations required independent living donor advocates (ILDAs) to make contact with individuals prior to the initiation of evaluation. The member stated that CMS did not define evaluation so a lot of transplant programs had to create their own internal definitions for evaluation.

*Potential definition: Someone who underwent the evaluation at a transplant program and is approved to be a living donor*

The Chair stated that this definition would eliminate the ability to identify barriers to living donation. The Chair stated that individuals approved for living donation will have been cleared medically, therefore the Committee should consider if it is important to gather data to understand why individuals might not be cleared medically during evaluation.

A member noted that within their transplant program, almost 100 percent of individuals who are approved for living donation proceed with the donation. The member explained that this potential definition would not provide an appropriate comparator group. The Chair agreed.

The Committee agreed to not use this potential definition as a way to define living donor candidate.

Next steps:

The Committee will continue to discuss project concepts to aid in the development of a concept paper.

**Upcoming Meeting**

- May 10, 2023 (teleconference)
- May 17, 2023 (teleconference)
- May 24, 2023 (teleconference)

## Attendance

- **Committee Members**
  - Aneesha Shetty
  - Ashtar Chami
  - Camille Rockett
  - Dylan Adamson
  - Henkie Tan
  - Hoylan Fernandez
  - Katey Hellickson
  - Laura Butler
  - Nahel Elias
  - Nancy Marlin
  - Steve Gonzalez
  - Tyler Baldes
  - Vineeta Kumar
- **HRSA Representatives**
  - Vanessa Arriola
- **SRTR Staff**
  - Katie Siegert
  - Krista Lentine
- **UNOS Staff**
  - Jennifer Wainright
  - Krissy Laurie
  - Meghan McDermott
  - Sam Weiss
  - Sara Langham
  - Strkyer-Ann Vosteen