

OPTN Living Donor Committee

Meeting Summary

October 3, 2023

Detroit, MI

Nahel Elias, MD, Chair

Stevan Gonzalez, MD, Vice-Chair

Introduction

The Living Donor Committee (the Committee) met in Detroit, MI on 10/03/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Prior Living Donor Priority
3. Patient Safety Contact at Living Donor Programs
4. Concepts for a Collaborative Approach to Living Donor Data Collection Public Comment Feedback
5. Break-out Groups
6. Report out from Break-out Groups
7. Discussion: Concepts for a Collaborative Approach to Living Donor Data Collection

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

1. Welcome and Announcements

The Chair welcomed Committee members to the call and the Committee participated in an ice breaker. Additional announcements included including an update on the development of an OPTN Taskforce on Efficiency and the Vice Chair appointment process. A member who serves on the Workgroup for the OPTN Ad Hoc International Relations Committee's project on *Best Practices for the Management of International Living Donors* gave a quick update to members on project development.

Summary of discussion:

A few members asked questions regarding the development of the OPTN Taskforce, and staff responded that they are still in the very early stages and are working to define a plan and their scope. The Vice Chair asked members to think about any system inefficiencies from a living donor standpoint and to bring them back so that the Taskforce may consider these as a part of their work. The Chair added that accurate and complete data on living donation is a big part of efficiency in the system but often gets overlooked as a systems priority. Another member stated that the various kidney paired donation (KPD) programs create an inefficiency in the system because there is not standardization and accountability between them. A member added discussion about KPD programs should involve the OPTN Membership and Professional Standards Committee (MPSC).

A member added that one component of efficiency regarding living donation is the independent living donor advocate (ILDA), explaining that communication is an area for improvement and that requirements and the definitions contained in the requirements should be an area of further scrutiny. The Chair shared their experience with this process, and a member added that the governmental regulations can also pose significant roadblocks. Another member described that staffing at the transplant program can be a barrier. A member shared that the initial goal of the Taskforce was to

reduce non-use and allocations out of sequence, and living donation may have been seen as something outside of those aims. However, promoting efficient living donation is the best way to get people off the waiting list. A member responded that incorporating technological advancements should be prioritized within the scope of the Taskforce.

Next steps:

The Committee's feedback will be relayed to the Taskforce.

2. Prior Living Donor Priority

The Committee heard presentations on the development of prior living donor priority, both historically and as planned for inclusion in continuous distribution. The Committee reviewed the impact of prior living donor priority within the recently implemented lung continuous distribution system, and an update on prior living donor priority in the development of kidney pancreas continuous distribution.

Summary of discussion:

A member asked for more data on how long the prior living donors who were eventually waitlisted waited for an organ. A member stated that the average seems to be a kidney waitlist time of about four months. A member asked for more granular data to be provided to the Committee, including if the waitlisted prior living donors were listed for multiple organs. Another member added that it would be helpful to see the denominator, as the percentage of prior living donors who are waitlisted is extremely small. A member responded, saying that prior living donor priority affects a small number of people, but the impact is very big and extremely important.

The Chair added that in his experience, time on the waitlist, especially for prior living donors, has to do with a lot of different factors and that it may not be the best metric by which to evaluate the effect of the priority.

A member added that the National Kidney Registry's paired donation program has a feature where you can receive a living donor transplant if you need one after donating your own kidney. A few members discussed complications related to this and the intricacies of a program like this.

On the topic of continuous distribution and prior living donor priority, a member stated that for the rare cases of a waitlisted prior living donor, they should go to the top of the list and not have this incorporated into the complicated composite allocation score (CAS). The Chair responded that the goal of continuous distribution is to eliminate classification-based allocation so that no one attribute will dictate the order of the match run, but that prior living donors will get appropriate priority in this new system. The original member expressed concern that prior living donors may not receive adequate priority. Another member explained that there are many ethical considerations involved in the scores and they all need to be considered. Staff responded that the lung attribute subscores have been typically very clustered, however, they account well for candidates with exceptional circumstances who need a more immediate transplant on a continuous scale.

The Vice Chair added that the graphs presented are reassuring for lung, however, the data needs to be seen for the other organs as well. Staff responded that different types of modeling and statistics can help evaluate possible impact ahead of implementation for different proposed policies. The Vice Chair asked for regular updates on each organ's status with prior living donor priority in moving to continuous distribution.

The Chair asked if the OPTN Lung Transplantation Committee is happy with this outcome, and staff responded that they are evaluating the impacts, but that discussion of changing the prior living donor rating scale or weight has not come up. A member stated that there are an increasing number of people

who are donating both a kidney and liver via living donation, and wondered if a non-binary scale for prior living donor priority may be appropriate in this instance. This member recommended data collection to determine the number of living donors who have donated both a kidney and a liver and their risk. Members discussed possible implications of this. The Vice Chair added that the Committee previously determined that *all* living donors should receive priority regardless of which organ was donated.

A member thanked staff for this presentation and noted that a focus on how to communicate these explanations to the broader transplant community should be a priority for the OPTN Kidney Transplantation Committee and the OPTN at large.

Next Steps:

The Committee will continue to collaborate with organ-specific committees and review prior living donor priority impact in the continuous distribution systems.

3. Patient Safety Contact at Living Donor Programs

The Committee discussed Policy 15.1 Patient Safety Contact and proposed modifications in order to provide feedback to the OPTN Ad Hoc Disease Transmission Advisory Committee's (DTAC) new project.

Summary of discussion:

Committee members asked clarifying questions on infectious disease reporting requirements. The Chair noted that these are extremely rare events.

A member suggested that the living donor coordinator for each kidney and liver programs should be the patient safety contact. The member added that a back-up contact would also be necessary in the event that the primary patient safety contact is not available.

Another member suggested that DTAC should revisit the required ten year storage for living donor specimens.

Next steps:

The Committee's feedback will be relayed to DTAC.

4. Concepts for a Collaborative Approach to Living Donor Data Collection: Public Comment Review

The Committee staff reviewed the OPTN living donor data collection and public comment on the concept paper that was submitted for public comment from July – September 2023.

Presentation Summary:

The Committee Staff reviewed the project background for the review of OPTN living donor data collection and discussed various ways to improve upon the system, which was then submitted for public comment from July through September 2023. In preparation for the next steps, the Committee reviewed and discussed feedback, determined potential pathways for the project and sought approval from a variety of stakeholders.

Staff then discussed several themes from public comment review. Several important points related to long-term data were addressed including, discussing terminology and definitions, barriers to living donor donation, and the evaluation process. There were several suggestions for enhancing clarification for living donors. In addition, concerns regarding the efficacy and reliability of following long-term donors were examined. Living donor preferences for engaging in long-term follow up pointed toward the use of online tools for self-reporting.

Regarding the OPTN follow-up requirements there was support for removing OPTN 12- and 24-month requirements and opposition for removing OPTN 12- and 24-month requirements. Concerns surrounding consent and privacy toward donation decisions included confidentiality and using strictly necessary personal identifiers.

Burden was also discussed, where the need to help reduce burden and suggestions for easing it were discussed. Additionally, recommendations for additions and removals of specific OPTN living donor data elements were reviewed. Living donor education and the importance on engaging in long-term follow up were discussed with attention to future communication and education strategies.

Lastly, unintended consequences were identified such as the malicious use of an individual's personal data, access issues with commercial health insurance, among other topics. In response, the Committee proposed mitigation measures to these unintended consequences.

The Committee then broke out into groups to discuss themes, recommendations, and further project requirements for data collection.

Summary of discussion:

There were no questions or comments.

5. Break-out Groups

The Committee broke into small groups to discuss public comment feedback.

6. Report out from Break-out Groups

The break-out groups reported summaries of their discussions.

Summary of discussion:

Group 1: Donation Decision & Analyzing Barriers to Living Donation

The group wondered whether it was necessary to follow-up long-term with living donor candidates who did not complete an evaluation due to reasons such as family concern or time commitment issues. The Chair noted that even those that sub population may not be the most valuable control group, there may important data that will arise. A member added that it is important to understand why individuals do not complete evaluations.

The group also recommended that the population of individuals who completed evaluation, were approved for donation, and ultimately decided to not donate will need robust education on the importance of engaging with long-term follow-up as this is the most valuable data. A member noted that education will be important for this population as well as individuals who were declined in order to understand how they can still contribute to the living donation community.

The group noted concern with the privacy of individuals who were ruled out for living donation during the evaluation and how that data will be protected. An SRTR representative stated that having long-term follow-up of individuals who were ruled out for living donation will help ensure that inclusion and exclusion criteria are evidence-based.

The group acknowledged public comment feedback that stated the largest barriers to living donation occur outside of the transplant programs. The group stated that this is an important issue, yet it would not be addressed by the project in its current state.

The group noted that public comment feedback expressed concern on whether this conceptualized future state of living donor data collection will work. A member asked whether SRTR could provide more information on the Living Donor Collective's experience with long-term follow-up. The member stated

that if the Committee is able to show the community data, then it would help change perception of the project. An SRTR representative stated that the Living Donor Collective's effort has been on registering living donor candidates but there has been follow-up in an early stage. The Vice Chair agreed that it will be important to have reassurance in order to have buy-in from the community.

Group 2: Burden

The group stated that more HRSA support will be necessary to strengthen follow-up efforts.

The group noted that technology solutions need to be leveraged in order to ease burden. The group added that data integration and APIs will be beneficial to reduce time needed for data entry. A member noted support for a national screening tool that is standardized for transplant programs.

The group discussed creating a definition for evaluation could reduce burden. The group suggesting defining evaluation as when informed consent is signed because that is a standard process for transplant programs regardless of the timing of when it occurs in an evaluation.

The group discussed burden relative to transplant programs versus burden relative to living donor candidates and living donors. A member noted the importance of education while considering the amount of education the living donor candidates and living donors receive.

A member stated it will be important to determine the security of a system in which living donor candidates and living donors are submitting data long-term.

Group 3: Definition and Terminology

The group noted that the definition of living donor candidate needs to be balanced in order to not be overly prescriptive while also providing enough detail to identify which individuals may be considered a living donor candidate.

The group reviewed public comment feedback which recommended that it is feasible to consider an individual a living donor candidate who had undergone evaluation per OPTN Policy 14: Living Donation. The group agreed that using policy as an anchor to define a living donor candidate may be an appropriate approach. The group acknowledged that transplant programs may carry out the policy in different orders but as long as any part of the policy is initiated then that could indicate a living donor candidate. The group suggested defining living donor candidate as "an individual that initiated any part of living donor evaluation per Policy 14.1, 14.2, 14.3, or 14.4".

The group also discussed defining a living donor candidate as anyone who has completed evaluation, instead of initiated. The group noted that identifying living donor candidates as those who have completed evaluation may be too late because it would miss out on information for barriers that occur during the evaluation processes. An SRTR representative suggested that if the Committee seeks to use completed evaluation then perhaps it should be "completed to the point of decision making".

The group considered defining living donor candidate as individuals who had completed OPTN Policy 14.4: Medical Evaluation for Living Donors. However, the group acknowledged that these processes are highly variable among transplant programs as well as it would not capture enough information on barriers to living donation.

The Committee discussed anchoring the definition on when an individual is in contact with an independent living donor advocate (ILDA) since CMS requires an ILDA interview at the initiation of living donor evaluations. A member noted that would be very burdensome because it be a much larger population than the Committee was previously considering. The member added that in their transplant program a lot of individuals do not follow-up after the initial ILDA interview.

The Committee also discussed specifying that a living donor candidate is an individual that was physically in-person for a living donor evaluation. However, several members noted that this would miss out on transplant programs who perform telehealth or virtual visits as well as those who perform initial blood testing outsourced through local laboratories. The Vice Chair added that if policy dictates in-person requirements, then it is not flexible for potential future public health emergencies. Another member added that living donors in Hawaii often complete evaluations virtually because there is no living donor transplant program within their state.

Group 4: OPTN Living Donor Follow-up Requirements & Unintended Consequences

The group recognized public comment feedback which stated concern with removing OPTN living donor follow-up requirements due to the perception that living donors may think transplant programs are abandoning them. Living donors on the Committee noted that they would not feel abandoned because their transplant program never followed up with them after donation or if they did, it was only to collect lab work and not establish care.

The group noted that some public comment expressed concern that the data would be used for punitive measures. The Chair suggested that the Living Donor Collective could provide programs specific reports.

The Vice Chair suggested that in a future state, the Living Donor Collective could send any information back to transplant programs that suggest additional care is needed for any prior living donors in order to have assurance for follow-up care in connection with the transplant program. A member noted that education will be needed in order for the community to understand how follow-up monitoring of living donors may change to ensure living donors that they are not being abandoned in their post-donation care. Another member added the opportunity to include the previously discussed development of a one-pager for living donors to share with their primary care physicians for post-donation care.

A member noted that while living donors are interested in the data collection they also seek post-donation care to know that they are doing well. Another member suggested that education could clarify that the Living Donor Collective is overseeing data collection and the transplant programs continue to oversee care.

Another member noted that an unintended consequence of removing the OPTN living donor follow-up requirements may be that living donors do not understand that they are able to seek post-donation care should any issues arise regardless of the timeframe.

The Vice Chair noted that an unintended consequence of removing the OPTN living donor follow-up requirements may be loss of oversight.

7. Discussion: Concepts for a Collaborative Approach to Living Donor Data Collection

Summary of discussion:

The Committee concluded their small group report outs and continue to discuss the project.

The Committee agreed to continue forward with developing a project to collect living donor candidate and donation decision data. There was no opposition.

The Committee discussed the potential to separate the project into two projects, one which addresses living donor candidate registration and the other to address long-term follow-up. The Committee ultimately decided to it would be best to have one proposal as a phased approach may not be an efficiency way to implement such a project.

A member suggested reviewing outcomes data as a way to provide rationale for potentially removing any of the current OPTN living donor follow-up requirements.

The Committee highlighted that it will be important to determine whether a feedback loop can be developed between Living Donor Collective and transplant programs. Members again highlighted the importance of education for living donors regarding post-donation care. The Chair noted it may be beyond SRTR's role to take on this education.

A member asked whether it is within the purview of the Committee to advocate for payment for long-term follow-up. The Chair stated it is outside the scope of the Committee's work.

Upcoming Meetings

- November 8, 2023 (teleconference)
- December 13, 2023 (teleconference)

Attendance

- **Committee Members**
 - Nahel Elias
 - Stevan Gonzalez
 - Henkie Tan
 - Tyler Baldes
 - Laura Butler
 - Dylan Adamson
 - Nancy Marlin
 - Catherina Huynh
 - Karen Ormiston
 - Ashtar Chami
 - Annie Doyle
 - Anita Patel
 - Danielle Reuss
 - Camille Rockett
 - Ginger Ireland-Hoffmann
 - Kelley Hitchman
- **HRSA Representatives**
 - Mesmin Germain
 - Marilyn Levi
- **SRTR Staff**
 - Krista Lentine
 - Katie Siegert
 - Caitlyn Nystedt
 - Avery Cook
- **UNOS Staff**
 - Emily Howell
 - Jen Wainright
 - Kim Uccellini
 - Krissy Laurie
 - Laura Schmitt
 - Lindsey Larkin
 - Linwood Butler
 - Kieran McMahan
 - Meghan McDermott
 - Samantha Weiss
 - Sara Rose Wells
 - Sara Langham
 - Taylor Livelli