

**OPTN AD Hoc International Relations Committee
Management of International Living Donors in the U.S
Meeting Summary
August 22, 2023
Conference Call**

**Pramod Bonde, MD, Chair
Peter Stock, MD, Vice Chair**

Introduction

The OPTN Management of International Living Donors in the U.S. (the Subcommittee) met via Citrix GoToMeeting teleconference on 08/22/2023 to discuss the following agenda items:

1. Public Comment Presentation: Concepts for a Collaborative Approach to Living Donor Data Collection
2. Group Project Updates

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

1. Public Comment Presentation: Concepts for a Collaborative Approach to Living Donor Data Collection

The committee heard a public comment presentation on the Concepts for a Collaborative Approach to Living Donor Data Collection from the Living Donor Committee. The purpose of the concept paper is to identify gaps in knowledge related to the long-term outcomes of living donors and barriers to living donation. The Living Donor Committee is seeking feedback on the following:

- Input from living donors
 - What are living donors' preferences on how to engage with long-term follow-up?
 - What data do potential living donors need to inform decision-making and post-donation healthcare?
- Input on definition/terminology
 - Is the living donor candidate the correct term? Is the proposed definition appropriate?
 - How do living donor programs define evaluation?
- Input on data collection
 - What is the minimum amount of data necessary to collect on living donor candidates? What are the specific necessary data elements?
 - What recommendations do transplant coordinators have for updating OPTN living donor data collection forms?
- Input on concepts
 - How do living donor programs recommend operationalizing data collection on living donor candidates and donation decisions to reduce the burden

Summary of discussion:

Decision: There were no decisions made by the Committee.

A member asked how many centers are enrolled in the Scientific Registry of Transplant Recipients (SRTR) living donor collective (LDC) and the incentive or disincentive for being enrolled in it. He inquired about the significance of combining the Organ Procurement Transplantation Network (OPTN) and SRTR living donor data collection efforts if very few centers are enrolled in the LDC. The presenter replied that ten programs are enrolled in the LDC; 6 are kidney and liver programs, and 4 are kidney-only programs. He explained that these centers participating in the LDC submit data to the OPTN and SRTR. The member further inquired why very few centers are participating in the LDC. The presenter replied that few centers are participating because it's a pilot program.

The Chair expressed concerns about the comparator groups amongst living donor candidates and individuals who do not proceed with organ donation. He questioned what is being compared between the potential donor group that does not proceed with organ donation and the potential donor group that proceeds with donation. The presenter replied that understanding psychosocial reasons for why an individual would be medically or non-medically ruled out for donation. She explained that the ideal comparator group is the group that was approved to donate but for some reason did not proceed; this may be because they may have changed their mind, the recipient may have received a deceased donor, etc. The group that was ruled out for various reasons and then followed can still provide helpful information. There is value in the different subgroups of these candidates regardless of whether they proceeded with donation or not.

Another member asked how programs get the candidates to engage in the LDC once they have been denied for living donation and how it is paid for. A member replied that the Living Donor Committee understands that this is a significant challenge, and the response rate from the candidates may not be as high as it is from the donors who are already engaged in this process. It's essential to inform the candidates why their engagement in the LDC is still critical, although they did not proceed with donation. Also, data collection will be self-reported annually; therefore, it will not be an onerous type of engagement.

The chair commented that, hopefully, some of the data collected will include long-term follow-up data on non-U. S Citizens/Residents (NCR). Another member suggested clarifying the goal of the concept paper upfront and then proceeding with background information. Another member commented that it would be helpful to know the questions that will be included in the SRTR living donor collective survey ahead of time; otherwise, it's difficult to provide critical feedback on the value of the data collection process. He suggested that the survey questions be incorporated into the concept paper.

2. Group Project Updates

The Subcommittee comprises of 5 groups: Communications group, logistics group, donor follow-up group, risk of exploitation, inducement, and coercion group, and undocumented living donors and recipient group. Each group gave a project update on the topic of the Subcommittees' project. The groups were asked to discuss the following:

- Does the Subcommittee support a literature review?
 - Will a literature review be helpful for all groups, given the scarce literature?
 - Literature review was performed in August 2022
- Does the Subcommittee want to proceed with a data request?
 - Are there additional questions that should be included in the data request.
- Retrieving protocols
 - Review of protocols from AST
 - Contact high-volume programs with experience with NCR living donors.
 - Seek feedback from TCC and TAC

Summary of discussion:

Decision: The Committee determined that a data request and additional information is for the project.

Undocumented Living Donors & Recipients Group

The Chair noted challenges with how non-U.S. citizens/non-U.S. residents (NCNR) are classified. He explained that the classification status of NCNR donors and recipients is unclear. It's important to consider the citizenship status of donors and recipients because it may impact their access to insurance for donations. Furthermore, access to Medicaid insurance for undocumented donors may vary by state and region within the state. He shared that in California, undocumented residents can qualify for Medicaid under certain circumstances. The group also emphasized challenges for donors who experience post-donation complications. He explained that the recipient's insurance may cover the undocumented donor for organ donation. However, if the undocumented donor experiences difficulties from the surgery, then that may cause a more significant concern. The group also highlighted financial support for living donors and recipients that should be considered.

The group expressed interest in submitting a data request but has concerns about the accuracy of the data due to the misclassification of NCNR versus NCR.

Communications Group

The group highlighted language and methods of communication as a barrier when evaluating potential international living donors. He noted some concerns include contacting individuals using a method that is Health Insurance Portability and Accountability Act (HIPAA) compliant. He said that it's essential to communicate with potential international living donors where there is no cost expense to them. The group discussed using Whats App, Zoom, and Microsoft Teams links as a possible form of communication; along with a translator who can be on the call if needed. The group also considered providing potential international living donors with educational resources and how to get these materials in their language to ensure they understand the evaluation process. Additionally, the group pointed out that obtaining and translating medical records can be challenging. Also, it's critical to communicate financial impacts with the potential donor and ensure they understand how organ donation will affect them financially. A member also expressed concerns about possible payments after donation, from the recipient to the donor, and ensuring that this is monitored to ensure there is no coercion. In addition to communication barriers, the group also discussed cultural considerations. A member noted that considering the potential donor and recipient relationship is essential. He explained that what may be considered coercion, may not be identified as coercion in other cultures.

The group expressed interest in reviewing data from high-volume programs that have established protocols for evaluating international living donors and identifying how many individuals have come from abroad to donate. Another member noted that it's vital that potential donors understand that once they go through the evaluation process, it's not guaranteed that they will be approved as a donor.

Risk of Exploitation, Inducement, and Coercion Group

A member stated that their group had discussed ways and timing of better-assessing donors' motivation for organ donation; this would be to determine if someone is at risk of being exploited, induced, or coerced into donation. Assessment of motivation for donation would also include determining if the donor and recipient are engaging in preliminary discussion before the donor comes to the U.S. for evaluation. She explained that it's vital to assess the motivation for donation because if it is determined that there are significant concerns about their relationship, then it would avoid time and resources put

towards the evaluation process and monetary expenses. In this incidence, the donor would no longer need to come to the U.S. to be informed that they can no longer proceed with the donation process.

The group also discussed how to achieve an understanding of the motivation for donation and minimize the risks of ethically concerning donation. This could be achieved by ensuring the donor understands the donation process, identifying community partners to help with translation, and understanding the cultural context of the donor and recipient. Lastly, the group sought to understand the impact of donations on employment and livelihood opportunities in areas with professions where the implications may not be fully understood because that job may not be common in the U.S. A member commented that state department toolkits may be helpful for screening for donation.

Another concern is ensuring appropriate follow-up care of the donor post-donation. She also noted it's critical to understand transplant centers' obligation to the donor if they experience complications post-donation in the U.S. or when they return to their country of origin. Additionally, the group considered the obligations of the transplant program for treating a donor if they developed end-stage renal disease (ESRD) post-donation. A member asked if the international living donor will receive the same priority as a domestic living donor if they develop ESRD. The presenter replied that it is unclear if the international living donor would receive the same priority.

Logistics Group

The group expressed that most donor screening and evaluation should be completed before coming to the U.S. to minimize travel expenses. The group is interested in seeking logistical information related to the shipment of vacutainers to the potential donor, collecting blood samples, and obtaining the samples from the potential living donor. Understanding the logistics of shipping blood internationally and the viability of the blood samples for analysis would be helpful. The member explained that collecting blood samples from the potential living donor would be a good way of obtaining some blood work before the international living donor travels to the U.S. The logistic group also expressed concerns about post-donation while the donor is recovering and ensuring that they have appropriate access to care.

The group emphasized that they need additional information regarding:

- Are there existing regulations concerning shipping blood samples internationally?
- Could the center ship vacutainers to the potential living donor with triple packing and prepaid envelopes for return?
- How long is blood viable for analysis?

Next steps:

The Committee will consider submitting a data request at their upcoming meeting.

Upcoming Meeting

- September 26, 2023

Attendance

- **Subcommittee Members**
 - Abby Ruiz
 - Angele Lacks
 - Ashtar Chami
 - Carrie Thiessen
 - Chang Liu
 - Cynthia Forland
 - Ehab Saad
 - Eliana Agudelo
 - George Bayliss
 - Nancy Marlin
 - Peter Stock
 - Pramod Bonde
 - Scott Sanoff
 - Taryn Shappell
- **HRSA Representatives**
 - Kala Rochelle
 - Marilyn Levi
 - Shelley Grant
- **SRTR Staff**
 - Avery Cook
- **UNOS Staff**
 - Elena Liberatore
 - Laura Schmitt
 - Meghan McDermott
 - Tamika Watkins
 - Taylor Livelli
- **Other Attendees**
 - Tyler Baldes