

OPTN Living Donor Committee

Meeting Summary

June 13, 2022

Conference Call

Heather Hunt, JD, Chair

Nahel Elias, MD, Vice Chair

Introduction

The OPTN Living Donor Committee (the Committee) met in Richmond, Virginia and via Citrix GoTo Meeting teleconference on 06/13/2022 to discuss the following agenda items:

1. Introductions & Recognition
2. Living Donor Collective Presentation
3. Living Donor Data Collection

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

1. Introductions & Recognition

The Committee members offered welcoming introductions and recognition of the members whose Committee service is ending.

2. Living Donor Collective Presentation

The Scientific Registry of Transplant Recipients (SRTR) staff presented information on the Living Donor Collective.

Summary of discussion:

A member highlighted their transplant program's recent findings on living donor follow-up data collection barriers.¹

A member asked if SRTR has piloted text messaging as a mechanism to follow-up with living donors. SRTR staff stated that is something they seek to explore. Another member suggested that follow-up for living donors after two years may be less extensive than the current 6-month, 1-year, and 2-years. The member stated that a less extensive follow-up may be capable of being completed via text messaging.

The Committee discussed additional mechanisms to increase living donor follow-up:

- Engage the transplant recipient
- Appeal to the living donor's altruism
- Create electronic surveys to target specific populations within the living donor community
- Engage major internet carriers to provide free plans to individuals in need to increase access to health care

¹Orandi, B. J., Reed, R. D., Qu, H., Owens, G., Brooks, S., Killian, A. C., Kumar, V., Sheikh, S. S., Cannon, R. M., Anderson, D. J., Lewis, C. E., & Locke, J. E. (2022). Donor-reported barriers to living kidney donor follow-up. *Clinical transplantation*, 36(5), e14621. <https://doi.org/10.1111/ctr.14621>

3. Living Donor Data Collection

The Committee reviewed data elements on the OPTN Living Donor Registration (LDR) and Living Donor Follow-up (LDF) forms.

Summary of discussion:

Data Element: Marital status at time of donation (LDR)

Summary of feedback received prior to the meeting:

- This data element helps inform demographics for who donates, potential barriers to donation, potential trends in successes or failures of donation, as well as understand the social support structure of living donors
- This data element is objective and reliable, but there may be instances where the donor becomes married/divorced shortly after donation
- Response are standard to U.S. census
- It is collected in the electronic medical record (EMR)
- Consider changing “life partner” to “unmarried partner”
- Consider changing to “legally separated”
- Collect only at time of donation

A member stated that “partner” may need to be added as an option. The current data collection has “life partner” as an option, which the member stated suggests long-term association, while “partner” suggests current association. Another member stated that the data responses in this data element should be limited in order to limit confusion.

The Committee discussed the purpose of collecting this data element. The Committee agreed that this data collection may be used to make assumptions about an individual’s caretaker, which may not be valid assumptions. A member stated that this data element may be aiming to capture a living donor’s current support structure. Another member stated that focusing data collection on relationship status neglects other sources of support such as parents or siblings.

Another member suggested that a better data collection field may be “does the individual have caregiver support for the first two weeks post-transplant operation?” The member emphasized that the support system is what is most important to capture, not marital status of an individual.

A member stated that this data element could be analyzed long-term to see if there are correlations between marital status and outcomes. Members recognized that marital status fluctuates, and that it is an evolving concept in society.

Another member stated that the Committee should fully understand the role this data element plays in broader data collection before recommending removal. The member stated it may be important in understanding an individual’s psychosocial wellbeing and social support structures.

A member stated that it may be important to capture whether a living donor is travelling for transplant surgery to understand potential geographic isolation from the living donor’s typical support network. The Vice Chair responded that the living donor’s zip code and the transplant program’s zip code may inform the understanding of potential geographic isolation from typical support networks.

The Committee discussed whether this data element is beneficial for the OPTN collect. The Committee agreed that the current data collection element is not necessary. The Committee agreed that the data element should be refined to inquire about the living donor’s primary source of support.

Data Element: Donor Type (LDR)

Summary of feedback received prior to the meeting:

- This data element helps inform demographic data on who is donating, target areas for potential improvement, areas where recipients are successful in obtaining a living donor as well as determining social support and whether relationship helps with long-term risk
- This may lend information on who is able to become a living donor from a medical or human leukocyte antigen (HLA) perspective
- It is a reliable and unchanging measure
- Consider modifying “non-biological, other unrelated directed donation: specify” as it broadly encompasses several different categories of donor type
- Non-directed donor is not interchangeable with anonymous donor
- It is collected in the EMR, and there is no additional testing or burden
- Collect only at time of donation

It was noted that this field is necessary in terms of donor safety to understand the relation to the recipient and potential family history of renal disease. The Committee considered whether family history of renal disease should be added as a separate data element. A member suggested that family history of dialysis or transplantation in addition to renal disease. Another member suggested the proposed data element should be broader to capture family history of any organ-specific disease.

The Committee discussed “non-directed donor” as an option. “Non-directed donor” is the response option chosen for living donors that are a part of a kidney paired donation exchange. However, this response option does not inform the living donor’s relation to the intended recipient. Therefore, it misses critical information regarding family history of renal disease.

A member stated that an argument could be made that the living donor’s intended recipient should be the data captured in a kidney paired donation exchange, not the ultimate recipient. The member stated that the donor type data element should be clarified to capture data on either intended recipient or ultimate recipient.

Another member stated that “adopted” should be added as a donor type because there are epigenetic factors that relate to environmental risks that are important to consider. The member suggested the option could be “non-biological sibling, child, or parent”.

A member stated that “partner” as an option may need to be added in lieu of “life partner”.

Another member asked whether the donor type data element is necessary for determining living donor safety. SRTR staff responded that there has been research that suggests higher incidence of end stage kidney disease among living donors. SRTR staff stated that this is speculated to be because of hereditary risk of kidney disease.

Data Element: Did the donor have health insurance (LDR)

Summary of feedback received prior to the meeting:

- This data element is relevant to understand whether an individual has a lack of health insurance which can put them at risk post-donation as well as determine long-term follow-up risk
- The data collection is binary and objective. However, there is potential for the individual to gain or lose insurance prior to donation
- Consider separating into “had insurance ever” and “has insurance currently”
- It is a requirement under OPTN policy to review “health insurance status” of living donor candidates
- Collection should not be an additional burden as it should be in the psychosocial note

- Consider bill sharing or medical cost-sharing programs, and whether these would be considered insurance for OPTN purposes
- Collect only at time of donation

The Committee agreed this data element is necessary data collection for living donors.

A member noted if an individual does not have insurance it may be beneficial to ask whether the individual has previously had insurance. The member explained that gain and loss of insurance is common.

Another member asked if data captures whether the recipient's insurance covers living donation. The member stated this is important information because there may be additional need to advise living donors on financial impact of transplantation based on the recipient's insurance coverage.

Data Element: Loss of insurance due to donation (LDF)

Summary of feedback received prior to the meeting:

- Historical loss of insurance is an identified risk for living donation
- It is necessary to monitor and gauge risk to be able to inform living donors of the risk level
- Reliability may be somewhat compromised, since it is self-reported
- Consider separating "loss of insurance" from "loss of insurance due to donation"
- Self-reported and documented in the EMR
- Several states have made it illegal to deny coverage due to living donation. Additionally, there is currently a bill in the U.S. Congress (Living Donor Protection Act). It is prudent to monitor loss of insurance even if the bill is enacted as law.
- This data should be collected long-term (15, 20, 30 years)

The Committee agreed this data element is necessary data collection for living donors.

A member noted that several states have laws enacted which protect living donors' ability to have insurance coverage. The member stated that even if this protection becomes enacted at a federal level, it is still important to collect data on to ensure living donors are not illegally denied coverage.

Data Element: Functional Status (LDR & LDF)

Summary of feedback received prior to the meeting:

- This data element determines if functional status changed due to organ donation
- It is not always reliable, and may be self-reported
- The Karnofsky Scale is highly subjective, and there is no objective, unbiased tool
- Functional status could change due to reasons other than living donation
- It is not easily discoverable in the EMR as it depends on provider specific documentation
- Accuracy and reliability of measure is subjective, it tends to change overtime, and thus may not adequately capture performance status
- This data should be collected prior to donation, 6 months, 1 year, and 2 years post-donation

A member noted that the purpose of the data element is to determine whether living donation affected functional status of an individual. However, the member explained that there is no objective way to measure functional status without seeing the individual in person.

The Chair stated as a living donor, they found the functional status questions to be irrelevant. The Chair explained that the question that living donors should be asked is whether they have any concerns they

seek to report that may be a result of living donation. Another member agreed that functional status does not capture the physical or medical implications of donation, such as long-term incisional scar pain.

A member stated that collecting functional status pre-donation provides a baseline in order to understand an impact post-donation. Another member suggested modifying the data element to collect “functional limitation”.

A member stated that functional status is focused on physical ability, whereas quality of life measures are more important considerations as they include both mental and physical abilities. Another member agreed that quality of life measures are important, but expressed concern for the workload associated with collecting this data.

Another member stated that this data element is not a beneficial nor sensitive measure because transplant programs would not accept a living donor that is determined to have a low functional status.

A member noted that for older individuals, who were prior living donors, functional status may start to decline but it is not due to transplantation.

Data Element: Physical Capacity (LDR & LDF)

Summary of feedback received prior to the meeting:

- This data element determines if physical capacity changed due to organ donation
- There may be overlap as it is similar to functional status
- It is not always reliable, and may be self-reported
- The Karnofsky Scale is highly subjective, and there is no objective, unbiased tool
- “More limited” and “limited mobility” appear to have similar meaning
- Frailty testing may be better measure of physical capacity
- Recommend to remove because it is duplicative and overlaps with functional capacity

The Committee agreed that this data element is not necessary to collect for living donors.

Data Element: Working for Income (LDR & LDF)

Summary of feedback received prior to the meeting:

- The purpose of this data element is to discover if organ donation impacted ability to work. Additionally, it documents societal contribution.
- It is a subjective response on the part of the living donor
- It would not require additional testing
- Potential link with social security database if confirmation is needed
- This data should be collected prior to donation, 6 months, 1 year, and 2 years post-donation

A member suggested the data element should be modified to determine whether working for income was impacted by living donation. Another member stated that since the data element is collected pre-donation and post-donation, then the LDF data collection element should have a follow-up field. The member explained that if it is determined that the individual is not working for income on the LDF, the follow-up field would determine whether that is due to living donation. Staff clarified that there is a follow-up field. A member stated the option of “homemaker” on the follow-up field may not be a relevant response option.

The Chair stated that when they answered this question, they found it to be overly complicated. The Chair explained that the purpose is to determine whether or not living donation impacted the ability to work. The Chair suggested to modify this data element to be more succinct and clear.

Another member questioned why this data element is needed. A member responded that the data can be used to help analyze financial impact of living donation. Another member emphasized that the most important question to ask is “loss of income due to donation.”

Data Element: Diabetes/Treatment (LDR & LDF)

Summary of feedback received prior to the meeting:

- The purpose of this data element is to determine if donors develop diabetes after organ donation or if diabetic status worsens after donation
- It is relevant since individuals with type 2 diabetes may be considered for living kidney donation
- It assesses the burden of comorbidities in a living donor that may influence outcomes
- Fairly reliable – accessible in EMR or by measuring hemoglobin A1C (HgbA1C) on follow-up lab work
- There is a gray area in the definition between type 1 and type 2 diabetes
- Consider expanding definition to include particular agents to treat diabetes, as well as allow multiple agent regimens to be inputted (this may reflect the severity of the disease)
- This information is widely available, and could potentially be linked with medication prescription data from pharmacy or insurance company
- Burden may include HgA1C testing
- Patients may have elevated HgbA1C without being on insulin, or taking oral diabetic medications, therefore, answering questions regarding medications may not be enough
- This data should be collected prior to donation, 6 months, 1 year, and 2 years post-donation

The Committee noted that this data element is collected for all living donors on the LDR, and only living kidney donors on the LDF. The Committee agreed that this data element should be expanded to be collected on all living donors on the LDF.

The Committee agreed to revisit this data element in the context of the impending modifications to living donor exclusion criteria in OPTN policy.

Data Element: History of Cancer (LDR)

Summary of feedback received prior to the meeting:

- The list of options may be too comprehensive
- If the list of options is simplified, consider adding grade of malignancy or treatment with curative intent
- Objective and reliable – while it is self-reported, cancer is significant to someone’s health and would not be easy to overlook or forget
- Consider how other databases and guidelines define various malignancies
- Consider aligning response options with SRTR’s Living Donor Collective data element

A member suggested aligning this data element with the data element the SRTR collects within the Living Donor Collective.

Another member questioned whether this data element is used for screening individuals as living donors. The member questioned whether it is beneficial for the OPTN to collect for living donor safety.

The Committee agreed to revisit this data element in the context of the impending modifications to living donor exclusion criteria in OPTN policy.

Data Element: Cancer free interval (LDR)

Summary of feedback received prior to the meeting:

- This data element is important for establishing long-term risk related to malignancy in the donor as well as risk of transmission to the recipient
- May be limited by a patient's recollection of when "cancer-free" status was achieved
- This data is usable but may not be standardized conformity depending on different tests and timelines within various health systems to determine cancer free status

The Committee agreed this data element is important to collect in context of the "history of cancer" data element.

Data Element: History of Cigarette Use (LDR)

Summary of feedback received prior to the meeting:

- This data element establishes potential risk factor for long-term living donor outcomes and is important in assessing candidacy as a living donor and optimizing outcomes
- Inherently carries aspect of reliability concern since self-reported as prospective donor might subconsciously underestimate their usage or inflate duration of abstinence in order to not delay ability to donate
- Pack years is a mostly straightforward concept to explain and calculate and necessary to capture various types of smoker history into a comparable number
- Minimal burden unless require tobacco test (which may be warranted)
- Consider duration of time from quitting until donation

A member questioned if pack years is an appropriate measure. The member added that the gradations of pack use could also be simplified. Another member responded that pack use per year is a standard metric.

Another member agreed that duration of abstinence is important to continue to collect in relation to cigarette use.

A member suggested that marijuana use may be a data element that should be collected for living donors. The Committee will discuss this topic further in the future.

The Committee recognized the reporting on this data element may be subjective, but agreed it remains necessary to collect on living donors.

Data Element: Other Tobacco Use (LDR)

Summary of feedback received prior to the meeting:

- This data element is important in establishing risk for tobacco exposure that is not included in smoking
- Inherently carries aspect of reliability concern since self-reported as prospective donor might subconsciously underestimate their usage or inflate duration of abstinence in order to not delay ability to donate
- Consider clarifying to include chew, patch, and vaping (and any others)
- Minimal burden unless require tobacco test (which may be warranted)
- If this data element is left vague, then it is not as helpful

The Committee agreed that this data element should be modified to collect "other smoking use" to address instances such as marijuana and vape products.

Upcoming Meetings

- July 13, 2022 (teleconference)
- August 10, 2022 (teleconference)

Attendance

- **Committee Members**
 - Aneesha Shetty
 - Angie Nishio Lucar
 - Camille Rockett
 - Doug Penrod
 - Heather Hunt
 - Mark Payson
 - Mary Beth Stephens
 - Nahel Elias
 - Omar Garriot
 - Stevan Gonzalez
 - Tyler Baldes
 - Vineeta Kumar
 - Yee Lee Cheah
- **HRSA Staff**
 - Adriana Martinez
 - Arjun Naik
 - Jim Bowman
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Bert Kasiske
 - Katie Siegert
 - Krista Lentine
- **UNOS Staff**
 - Brooke Chenault
 - Carol Covington
 - Cole Fox
 - Courtney Jett
 - Delaney Nilles
 - Jennifer Wainright
 - Kim Uccellini
 - Lauren Motley
 - Lindsay Larkin
 - Maureen McBride
 - Meghan McDermott
 - Sam Weiss
 - Tina Rhoades
- **Other Attendees**
 - Brad Kornfeld
 - Nancy Marlin