OPTN Living Donor Committee
Living Donor Decision Data Collection Workgroup
Meeting Summary
September 19, 2024
Conference Call

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Introduction

The Living Donor Committee's Living Donor Decision Data Collection Workgroup ("Workgroup") met via Teams teleconference on September 19, 2024, to discuss the following agenda items:

1. Welcome and Recap of Goals
2. Living Donor Committee In-Person Debrief
3. Explanation of Proposed Workflow
4. Approach to Data Collection: Level Setting
5. SRTR: Follow-up Information

The following is a summary of the Workgroup's September 19, 2024, discussion.

1. Welcome and Recap of Goals

The Workgroup Chair welcomed participants to the group's second call and outlined goals for the meeting. This Workgroup's overall focus remains: (1) Establishing a comprehensive of long-term risks and benefits that may be attributed to living donation; and (2) Analyzing any barriers to living donation.

This will be accomplished through collaboration with the SRTR's Living Donor Collective, using their kidney- and liver-related reasons for living donor declination. The OPTN will be expanding the current population of living donor data collection to not only those who donate, but also those individuals who pursue living donor evaluation but do not ultimately donate. The who do not donate will be classified as living donor candidates. Currently, data is only collected on living donors and not candidates that begin the evaluation process. This change will allow the OPTN to collect the donation decisions (and why they may not have donated) and continue to perform follow-up on living donors for the purposes of patient safety monitoring for the first two years. The SRTR will then use the initial OPTN information from pre-donation to the two-year mark to continue long-term follow-up through its Living Donor Collective data to follow living donor candidates and living donors, performing analyses on barriers to living donation and long-term outcomes of living donors versus living donor candidates.

This Workgroup is tasked with:

- Determine how to best collection donation decision data and how to best operationalize that collection at the center level
- Reviewing currently collected SRTR data elements for donation decision
- Helping to establish a workflow for the new data collection (reporting requirements, when to begin and end data collection timeframes, etc.)
- Serving as subject matter experts to Committee as needed

The Living Donor Committee will continue to refine the exact, protocolized definition of a living donor candidate. This Workgroup will operate based upon what the Living Donor Committee has reached consensus on for now:

- Population will include those individuals who began a living donor evaluation but fell out at some point during the process
- Will be anchored by OPTN Policy
- Will cover in-person clinic and telehealth appointments
- Will not include those individuals screened out using a living donor program's online, user-based screening tools
- Will not require programs to complete any testing beyond what has already been completed as part of working up the donor candidate (e.g. if the donor only got blood typing and then withdrew, imaging completion will not be required)

2. Living Donor-In Person Debrief

No decisions were made.

Workgroup members debriefed on the Living Donor Committee's September 12, 2024 in-person meeting, held in Detroit, Michigan.

Summary of discussion:

During the full Committee discussion of this effort, members suggested seeking feedback from both the OPTN Transplant Administrators and Transplant Coordinators Committees to help further define and protocolize the definitions of living donor candidate versus living donor based on their operational experience and expertise in living donor evaluation. Seeking insight from a broader spectrum of programs through these committees was anticipated to help refine the definition more effectively.

Data collection considerations will begin after the definitions are drafted. The Workgroup or Committee may then modify any data collection to better meet these two classifications (living donor candidate versus living donor) as needed.

Next Steps:

Staff will discuss options for seeking the feedback from Transplant Administrators and Transplant Coordinators Committees with Living Donor Committee leadership and share any feedback received with this Workgroup.

3. Explanation of Proposed Workflow

No decisions were made.

The Workgroup received a presentation from OPTN Contractor Staff on the proposed workflow.

Summary of presentation:

The revised living donor workflow was shared, including modifications to clarify the process after presentation to the full committee the previous week. Several scenarios were outlined in the workflow, including any data collection forms that would be required. It was noted that these forms would be re-named for clarity as part of this project. Scenarios in the workflow include:

- A potential living donor with an uncomplicated donor evaluation that moves straight to living donation

- A potential living donor that meets pre-screening criteria (regardless of format: Breeze, hard copy, etc.) and does not meet criteria (requiring no further documentation)
- A potential living donor that meets pre-screening criteria (regardless of format), moves on to evaluation and testing, testing is completed and evaluation is found to be straightforward, and advances to donation
- A potential living donor that meets pre-screening criteria (regardless of format), moves on to evaluation and testing, testing is completed and evaluation is found to be straightforward, and advances to donation
- A potential living donor that meets pre-screening criteria (regardless of format), moves on to evaluation and testing, and at some points decides not to donate
    - If something is found during evaluation and testing, there is no need to complete the rest of the testing because the individual has been ruled out
    - If the individual is approved for living donation but chooses not to proceed (e.g. personal medical issue, changes to the recipient, other personal decision)

The following forms are utilized as part of the work flow:

- Form A1 (currently the living donor feedback form) to be completed by the recovery center after a donor is approved for living donation but prior to the actual donation
    - Would collect basic demographic information and assign an ID. Differences in how centers manage this process were acknowledged and this process does not mean to limit this flexibility.
- Form A2 (currently the living donor registration) to be completed by the recovery center after the living donor organ is recovered and the recipient is removed from the waitlist.
- Form A3 (the living donor follow-up form) to be completed by the recovery center, submitting living donor follow-up data.
- Form B (NEW FORM) to be completed by the evaluating center/recovery center if the living donor candidate is ruled out as part of evaluation or withdraws after approval for living donation
    - There is not currently a tool in the system that allows a center to see all living donors approved for donation but have not yet donated. This will be developed as part of this effort.

This workflow was meant to capture a new population, living donor candidates

Summary of discussion:

A Workgroup member posed a question regarding the completion of Form A2. If a living donor is evaluated by one living donor program and travels to the recipient's center for organ recovery, which center will be responsible for form A1 and Form A2 completion? Will the registration documentation travel with them to the recipient center? Current OPTN Policy requires that the living donor recovery center completes Forms A1, A2, and A3. A Workgroup member noted that the timing of Form A1 completion varies between centers, with many completing close to the recovery procedure. There is currently no desire to be prescriptive in this area, and the intent would be for current policy regarding form completion to remain in place, with the recovery center taking responsibility for forms A1, A2, and A3. It was noted that it is fairly uncommon for the donor to travel to the recipient center, but this workflow should still address that scenario.

The Living Donor Committee was noted as wanting to preserve as much as possible of what currently is being done. The new element here is tracking why a living donor candidate did not proceed to living donation, as captured in Form B. A Workgroup member questioned the timing of completion for

proposed Form B. OPTN Contractor staff noted that any individual that has cleared any pre-screening entered the evaluation process will be categorized as a living donor candidate (based on discussions to date). If this living donor candidate is subsequently ruled out in evaluation or withdraws from becoming a living donor, they will require Form B completion. The formal definition of living donor candidate is still in discussion, but this is a working draft meant to capture this population. Auto-population or cascading of data from one form to the next is anticipated as a way to reduce data burden or fatigue for the living donor recovery centers in adding this new form. Additionally, the new tool that was noted to help centers identify all living donor candidates approved for donation but have not yet donated will also curb the creation of multiple donor IDs for one individual. The example of a living donor candidate listed at two separate programs with two Form Bs being generated should be addressed with this new tool.

The Workgroup discussed whether the Independent Living Donor Advocate (ILDA) interview would fall into the screening or evaluation phase for the purposes of this workflow. Based on OPTN policy requirements related to evaluation, there was agreement that the ILDA interview is an element of the evaluation process. A member suggested that there may be value in clarifying this point with living donor centers before implementation, as some centers may consider the ILDA interview to be part of their screening process. The Chair recognized value in creating case examples or scenarios to help educate living donor programs on addressing any questions or gray areas on how to apply the living donor candidate versus living donors.

4. Approach to Data Collection: Level Setting

The Workgroup favored option 2, collecting some information on all living donor candidates and living donors, and collecting specialized information per individual living donor candidate related to donation decision reason code.

The Workgroup focused on development of Form B, meant to capture information regarding why some living donor candidates do not proceed to organ recovery whether due to rule out during the evaluation process or withdrawal after approval for living donation.

Summary of presentation:

Understanding why some living donor candidates do not proceed to organ recovery and donation is important to better understanding barriers to living donation. Public comment feedback from the Living Donor Committee's 2023 concept paper on expanded living donor data collection reflected comments in several areas, including:

- Privacy concerns (protection of the data collected)
- Focus needed on removing barriers to living donation and gaining insight as to why people were falling out of process
- Data collection to determine long-term outcomes should be separate from data needed to decrease barriers to donation
- Concern that transplant programs may not be the appropriate collectors of these data
- Concerns regarding added data burden on programs collecting the data, and the need to recognize variation in how operationalize processes to meet policy requirements.

Data collection goals of this effort include:

- Provide information about barriers to becoming a living donor (through gathering of information on those who did make it through selection committee approval as well as those that did not).

- Define and provide information about the comparator group for long-term outcomes of donation (with the ideal group including those who were approved by selection committee but did not proceed to donation for non-medical reasons).

The Living Donor Committee is mindful that data collection to achieve these goals at the "donation decision" step is a big change in how living donor data collection is currently managed in programs. There is a desire to collect enough information to be informative without being overly burdensome.

Workgroup members were asked to consider what general information would be important for living donor candidates (outside of basic demographics) that might provide a helpful baseline for understanding this population. This could include additional demographic details, clinical information, or qualitative data.

OPTN Contractor staff shared that internal staff had explored three options for this OPTN goal of understanding barriers to living donation:

1. The "as complete as possible" picture
2. Collect some information on all candidates, and collect specialized information related to donation decision reason code
3. Collect specialized information related to donation decision reason code

The is a desired focus to get the right information from living donor candidates at the point where it makes the most sense to collect it to better understand reasons why an individual does not proceed to donate and related information regarding an barriers to donation or comparisons in long-term outcomes.

Summary of discussion:

The Workgroup discussed potential recipient-related issues that might impact a living donor candidate's decision. If the potential recipient's health insurance does not have sufficient coverage for living donation, this could present a barrier. Financial issues/concerns were noted as a potentially useful data element to understanding barriers. Additional granularity could be pursued if the group would find this to be valuable.

The intention to donate to a pediatric candidate versus an adult candidate was also recognized as a potential barrier, as criteria and reasons for turn down are different between adult and pediatric living donor evaluation.

Concerns related to the degree of completion required for Form B were discussed. Depending on where a living donor candidate exits the process, there should not be requirements for completion of all fields as the full evaluation process and all of its required testing may not be pursued. The Workgroup will consider the inclusion of not done fields as part of form development.

Workgroup members also discussed whether the new form should track which transplant candidate the living donor candidate was being evaluated for in the system. If their intended candidate receives a transplant from another living donor or a deceased donor, the living donor candidate may choose to withdraw. Currently, there is a kidney paired donation (KPD) data field that collects the intended recipient on the living donor feedback form. An option to denote altruistic donation is also available. To date, there has been no further discussion on adding this to other forms. The group may wish to consider whether it wants this element included on Form B. The timing of form completion was briefly discussed as relevant here as well. Additionally, the complexity of KPD and multiple living donor candidates being evaluated for a single organ transplant candidate. In the case of a living donor candidate who is denied in selection committee will not have a Form A1 (where the intended recipient

information is currently collected) but would progress directly to Form B. While HIPAA may not allow for specific intended candidate identification, the relationship could be qualified (related donor, unrelated donor, etc.) and reason for not pursuing living donation could be transplanted from another donor. This will be important in cases where multiple living donor candidates come forward for a transplant candidate. Dropping out of the living donor process may not indicate a failure, but rather that the best living donor candidate was chosen.

The SRTR was noted as gathering their collective information through two forms:

- Living Donor Candidate Registration Form
    - This form, largely modeled off of the OPTN Living Donor Registration Form is submitted by the living donor program with all applicable information regarding the living donor candidate's evaluation.
- Donation Decision Form
    - This form has a multi-select list of reasons why the candidate did not proceed with donation but does not require any additional data entry beyond the registration form.

SRTR acknowledged that this is a two-step process done in a prospective flow. SRTR acknowledged that developing the form for living donor candidates will augment this effort. Within Form B, the Workgroup is focused on gathering this information on one form.

OPTN Contractor staff offered that those who proceed with donation will have complete demographic and clinical elements on the living donor registration. The Workgroup could consider requiring programs to fill in this same information on all living donor candidates to get this "complete as possible" snapshot of a living donor. Not all candidates would have all elements completed at the time of donation decision and this option would not require programs to complete any further testing at this decision point. A "not done" option would be available for incomplete testing. This approach would standardize data collection for living donor programs to capture information on all those living donor candidates whether or not they proceed to organ recovery. This approach would, however, substantially increase data burden and likely result in a high number of "not done" values due to individuals falling out of the evaluation or approval process. This would collect data that may not be relevant to the donor decision (e.g. do we need kidney function labs on someone who did not donate due to financial reasons?).

A Workgroup member shared concern that this model may not adequately capture barriers to living donation and would also include many "not done" fields with no explanation of why tests were not done while still carrying the data burden of their entry. Other Workgroup members agreed with the data burden but suggested that a dropdown could be added to capture the reason why donation was not executed (e.g. medical decline, surgical decline, lack of caregivers, financial, etc.). Workgroup members acknowledged the importance of balancing relevance and efficiency when considering data elements for Form B. The addition of any new form will increase data burden but there was recognition of the need for granularity in this dropdown to be valuable in understanding barriers.

Recognizing that the "complete as possible" option would not be the most feasible, conversation then moved to collect some information on all candidates, and collect specialized information related to donation decision reason code. OPTN Contractor staff shared that the Workgroup would consider what specialized information is relevant to understanding both barriers to living donation and long-term outcomes. Donation decisions could be multiple option selection. OPTN Contractor staff offered an example of significant renal disease as a reason for not advancing in the donation process. This response would prompt for entry data regarding related lab or biopsy results relevant to the selection. The Workgroup would help to define critical data points for achieving the goals with the mindset of streamlining data collection to reduce burden. This would also allow for targeting of more specific

information based on commonly used reasons. The SRTR collective data could serve as a resource here. Workgroup members were generally supportive of this option, seeing it as less burdensome but still providing important information with more granularity. This would also allow for iterative updates as collected data is reviewed and the form can be finetuned to capture relevant fields and remove potentially lower value ones. There was some concern regarding the commitment to reducing data burden on centers at the 24-month interval and a question regarding the understanding the volume of new data collection when including all living donor candidates. There was also a desire to explore routinely pulling information from the living donor candidates electronic health record (EHR) rather than having a data coordinator search for it.

OPTN Contractor Staff then outlined the third option, which is to only collect specialized information relevant to the donation decision reason code. In this option, the living donor program would only fill in information relevant to what the program selected for the donation decision reason(s). This would streamline data collection and reduce entry burden. This would allow for targeting of more specific information for most commonly used decision reason codes. This could be considered a starting point that could be expanded later. This would not give the "complete" medical picture of a living donor candidate and might limit the conclusion able to be drawn regarding barriers to living donation and/or long-term outcomes. Workgroup members noted that this option is similar to option 3 but would be less burdensome to living donor programs.

A Workgroup member offered a fourth option, suggesting filling out detailed information on a random sample of living donor candidates. This was noted as logistically more difficult but may provide a better comparator group. This would need to be explored for feasibility within the OPTN.

A Workgroup member noted that option 3 is only focused on barriers while option 2 provides key information on all candidates- which will be helpful in long-term follow-up. The long-term data is what will inform on risks and outcomes that will inform policy in the long run. The value of counseling living donor candidates on risks and long-term outcomes using data was discussed, and the type of data in option 2 would help to inform this data pool. This, however, must be balanced with the data burden. Members considered whether this could also be achieved with a random sample. Members also questioned whether this could be approached as a ramp up, starting with option 3 and working towards option 2 in the future.

The Workgroup also acknowledged that different barriers show up and different phases of the evaluation process. Earlier barriers may include family coercion that could come to light in a social worker visit ahead of clinical testing. A member offered that when a living donor candidate makes it through the selection committee process, the most likely reason will be related to recipient barriers.

In summary, OPTN Contractor staff acknowledged that the majority of the Workgroup was supportive of exploring option 2 as a vehicle to gather information about both barriers to living donation and defining a comparator group. There is a desire for this information to be routine and easily gathered, potentially linking to EHRs if possible, to ease data burden. The Workgroups saw value in collecting basic information for all living donor candidates to get a baseline for analysis of living donor candidates versus living donors. The more specific data to be collected may need to change based on the donor decision data that is collected for an individual.

Workgroup members briefly discussed the time that will be needed for centers to create a way to submit the data, phasing in minimal information and give programs time for buy in regarding this new data collection. OPTN Contractor Staff noted that any proposal that involves significant data collection or system changes includes significant notice and education. The phased approach may be an alternative here, slowly adding more elements to Form B over time. Members also discussed whether

this effort would go live and collect data from that point forward in new living donor candidates going forward or require bringing all current living donor candidates up to date on Form B. Retrospective data collection was not supported by the Workgroup.

Data Advisory Committee representatives on the Workgroup framed several questions related to how and where the data should be collected and the timeline for data collection as important elements to keep in mind as part of this discussion. It was also noted as important to consider that third party non-clinician vendors are used by many programs to complete these forms. This must be kept in mind as well as whether clinical judgment is needed and whether information is easily found in the chart. All of these elements are important to programs. Workgroup members also raised questions regarding discrete quantitative data versus qualitative data. The need to balance the goals of this project with relevance and efficiency of the process to create something achievable for all living donor programs was echoed. The value of pulling as much relevant data from the EHR versus applying an interpretation here was reiterated. Workgroup members were curious regarding the capacity to offer this from an IT perspective. Members acknowledged multiple new data burdens facing transplant programs.

Next Steps:

The Workgroup will continue to consider data elements for inclusion on Form B based upon this discussion.

5. SRTR: Follow-up Information

The Workgroup received follow-up on the full Living Donor Committee presentation. The SRTR was completing free text analysis to review with Clinical Leader and recategorize these responses into a correct category. This effort reduced free text kidney responses from 142 to 23 and liver free text responses from 50 to 7.

Summary of presentation:

SRTR Contractor Staff outlined the updated top reasons for not donating a kidney to include:

- Hypertension, blood pressure control, or borderline high blood pressure
- Low or borderline kidney function, -GFR or creatinine clearance
- Decided against donation for undisclosed reason(s)
- Intended candidate underwent deceased donor transplant
- Candidate reluctant or ambivalent as indicated by missed appointments, failure to return calls, etc.
- Risk of kidney stones
- Anatomical abnormalities (e.g. scarring, small kidneys, hydronephrosis)

For liver living donation, the top reasons for not donating a kidney included:

- Intended recipient underwent deceased donor transplant
- Intended recipient became too ill for transplant or died
- Inadequate living volumes on imaging
- Decided against donation for undisclosed reason(s)
- Donor liver steatosis on imaging or biopsy
- Liver disease
- Vascular or biliary abnormalities on imaging

During the last presentation, a report on the minimally selected data elements was requested. This has been shared with the OPTN Contractor Staff for dissemination. For kidney, 12 reasons were selected in

single digit numbers. Those kidney options selected by 2 living donor candidates included “another living donor candidate was better HLA match” and “lack of insurance coverage, and another living donor candidate was a better choice for psychosocial reasons. For liver, 30 reasons were selected in single digit numbers and three options were not selected at all. Those not selected included lack of health insurance coverage, another living donor candidate was a better HLA match, and lung disease (including sarcoidosis, nodules, and pulmonary hypertension).

Lessons learned from this analysis included:

- It is valuable to include risk factors in the definition of a disease that is included. For example, “liver disease and associated risk factors.” The SRTR specific donor decision form’s data elements are very specific. Because of these, more interpretation than expected was necessary. For this reason, this Workgroup may wish to consider less specificity for reasons concerning the recipient
- Recommendation to add a data element that encompasses other lab abnormalities.

SRTR Contractor Staff noted that if a free text option is available, it will be frequently used. This will create more challenges in using the data downstream. As a result, the Workgroup may wish to consider a workflow to analyze any free text/other options if this becomes part of Form B.

Summary of discussion:

There was no discussion specific to the presentation.

Next Steps:

OPTN Contractor staff will circulate the full list of SRTR minimally selected data elements for Workgroup review.

Workgroup members were asked to review the SRTR analysis on commonly used reason codes and map them to similar OPTN concepts that already exist to help with consistency. This will provide for discussion on the next call to continue to dial in on specific data collection questions for Form B based on what Workgroup members commonly see in their programs and what information would be associated with each reason code.

Upcoming Meetings

- October 3, 2024 conference call
- October 10, 2024 conference call

Attendance

- **Committee Members**
  - Aneesha Shetty
  - Aaron Ahearn
  - Amy Olsen
  - Jennifer Peattie
  - Katie Dokus
  - Katie Siegert
  - Michael Chua
  - Julie Prigoff
  - Stevan Gonzelez
  - Tiffany Caza
  - Trysha Galloway
- **HRSA Representatives**
  - Allison Hutchings
  - Arjun Naik
  - Mesmin Germain
  - Nawraz Shawir
  - Shannon Dunne
- **SRTR Representatives**
  - Avery Cook
  - Caitlyin Nystedt
  - Krista Lentine
- **UNOS Staff**
  - Jamie Panko
  - Sarah Langham
  - Cole Fox
  - Kieran McMahon
  - Laura Schmitt
  - Samantha Weiss
  - Sara Langham