

Briefing to the OPTN Board of Directors on

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

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Concepts for a Collaborative Approach to Living Donor Data Collection

Sponsoring Committee: Living Donor
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Executive Summary

Long-term outcomes and barriers to living donation are not well understood due to limited data. To that end, the OPTN Living Donor Committee (the Committee) has sought to identify solutions to fill these current gaps in knowledge. Establishing a comprehensive understanding of long-term risks and benefits attributable to living donation as well as analysis of access and barriers to living donation could have a substantial impact to the field of transplant. With this objective in mind, the Committee presented a conceptualized future state of data collection by detailing the shared responsibility of the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry for Transplant Recipients (SRTR) Living Donor Collective in collecting data on living donor candidates and living donors. In doing so, both the OPTN and SRTR are carrying out contract tasks established by the Health Resources and Services Administration (HRSA) and recognizing their shared commitment to the transplant and living donor communities.

The conceptualized future state of living donor data collection includes the OPTN requiring collection and reporting of living donor candidate and donation decision data, which would be shared with the Living Donor Collective to establish a foundation that enables the Living Donor Collective to directly follow-up with living donor candidates and living donors long-term on a national level. The Committee's intention with this conceptualized collaborative approach is to increase efficiency, reduce redundancy, and acquire key data that the transplant and living donor communities deem important. The Committee requested feedback on the potential future state of living donor data collection described in the concept paper and the role that the OPTN could assume if this collaborative approach were adopted and implemented.

Overview of the Concept Paper

Purpose

The Committee identified the goals of living donor data collection to aid in the ability to analyze risks and benefits attributable to living donation, as well as to analyze access and barriers to living donation. The Committee developed a conceptualized future state of living donor data collection to achieve these objectives with the intention of increasing efficiency, reducing redundancy, and acquiring key data the transplant and living donor communities seek. The Committee submitted the concept paper to public comment to engage the community on the potential for a new approach to living donor data collection and sought feedback on how best to achieve acquiring the data that have been repeatedly deemed to be necessary.

An overview of how the Committee envisions a future state of living donor data collection is described below as well as the OPTN's role within the conceptualized future state. For more information on the current state of living donor data collection, please reference the Committee's concept paper.¹

Conceptualized Future State

Due to the significant barriers associated with collecting extended living donor follow-up by transplant programs juxtaposed with the consensus that longer-term data are needed, the Committee determined that some other entity, such as a registry, may be better situated to connect directly with living donors.² To that end, the Committee collaborated with the SRTR to conceive a future state of living donor data collection as the SRTR has piloted a living donor registry, known as the Living Donor Collective.³ Since the Living Donor Collective is a voluntary living donor registry, it has been difficult to engage transplant programs to participate while simultaneously meeting OPTN data collection requirements.⁴ Thus, the Committee proposed the concept of shifting current OPTN living donor data collection requirements to earlier in the living donor evaluation process (upstream) in an effort to support the Living Donor Collective as the national living donor registry performing long-term follow-up. With the additional goal of improving efficiency, areas of redundancy or overlap involving current OPTN and SRTR can be identified and eliminated.

Figure 1 provides a visualization of the main concept detailed in the paper submitted for public comment. This visual shows that the OPTN would require collection and reporting of living donor candidate and donation decision data. These data would be shared with the Living Donor Collective to establish a foundation in which the Living Donor Collective could directly follow-up with living donor candidates and living donors long-term at a national level.

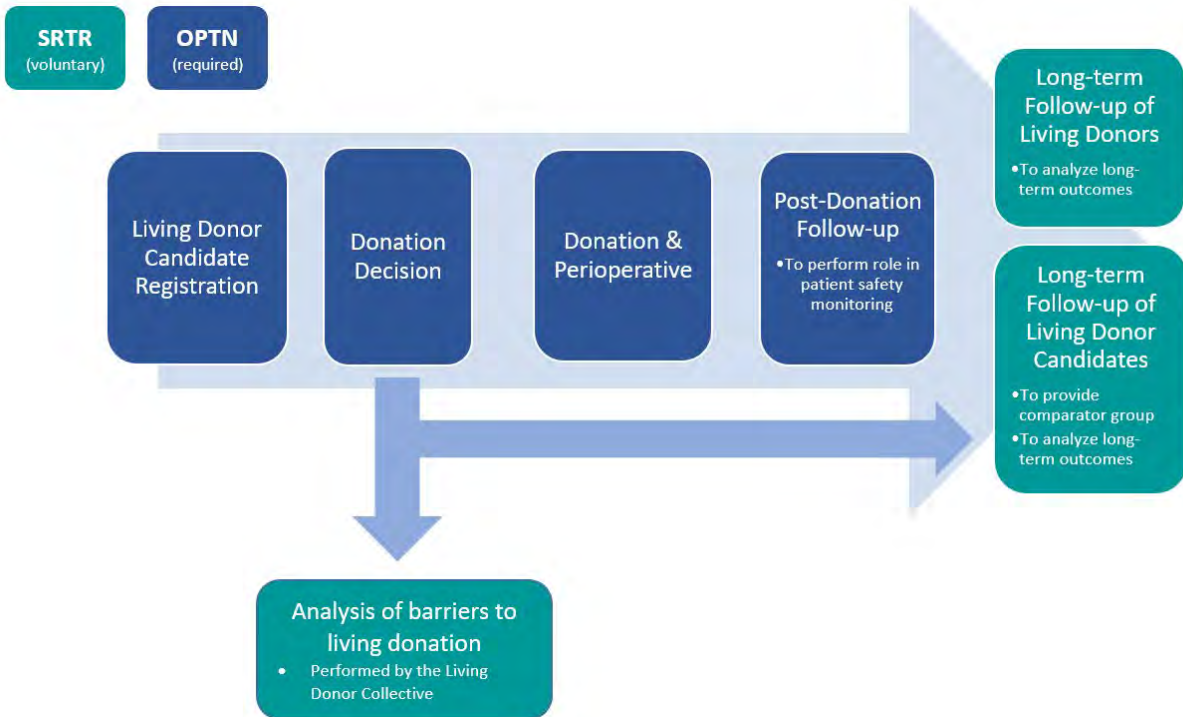
¹ OPTN Living Donor Committee, *Concept Paper*, Concepts for a Collaborative Approach to Living Donor Data Collection. Public Comment Period: July 27, 2023 to September 19, 2023. Available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/>.

² OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.

³ Living Donor Collective: An SRTR Initiative. Available at <https://www.livingdonorcollective.org/>.

⁴ OPTN Policy 18.1: Data Submission Requirements. Available at https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

Figure 1: Concept of Future State of Living Donor Data Collection via the OPTN and SRTR



Expanding required OPTN data reporting upstream may allow for the Living Donor Collective to focus solely on the follow-up of living donor candidates and living donors. The Committee supports the OPTN’s role in monitoring patient safety events in the perioperative period and is not contemplating changing data reporting for this timeframe (6-months).⁵ The Committee sought feedback on whether the current required 12- and 24-month data collection for living donor follow-up are necessary and valuable to the community. This topic received mixed feedback and is detailed in the *OPTN Follow-up Requirements* section below.

If it is determined that it may not be necessary for the OPTN to require 12- and 24-month follow-up data collection for living donors, there are many different transition periods that could be enacted to ensure the Living Donor Collective is adequately supported to take over living donor follow-up. For example, a potential transition plan could have the OPTN retain the current required follow-up until it is established that the Living Donor Collective has proven acceptable follow-up rates to ensure that there would not be a lapse in living donor follow-up.

In this conceptualized future state of living donor data collection, the Living Donor Collective would perform the long-term follow-up of living donor candidates and living donors. The Living Donor Collective would engage in a patient-centered approach with living donor candidates and living donors by way of surveys administered through email, telephone, or mail.

The follow-up experience in the Living Donor Collective is preliminary, as the pilot phase has focused on living donor candidate registration and composition. The Living Donor Collective seeks to collaborate with stakeholder OPTN committees and the transplant community to enhance the necessary follow-up

⁵ OPTN Board of Directors, OPTN Living Donor Committee Report to the Board of Directors on Living Donor Data Collection, December 5, 2022.

data forms. This conceptualized future state supports the Living Donor Collective to become a national living donor registry and would allow the Living Donor Collective to allocate additional resources for follow-up activities.

Additionally, in terms of data linkages, the SRTR and OPTN could coordinate data linkages related to long-term living donor candidate and living donor outcomes to enhance data analyses and reduce any redundancy of both contractors potentially performing the same data linkages.

The Committee noted that logistical and transparency issues, such as the process of modifying data collection captured within the Living Donor Collective, will need to be addressed. For example, the OPTN is required to submit any changes to data collection for public comment to solicit community feedback; the SRTR is not beholden to the same processes. However, the Committee noted that addressing these issues is feasible and the need for long-term data surmounts any accompanying issues.

Collect Living Donor Candidate & Donation Decision Data

Within the conceptualized future state of living donor data collection, the OPTN would take on the role of collecting living donor candidate and donation decision data. A main reason to begin collecting data on living donor candidates rather than limiting only to living donors is that it is important to assess whether the reasons some living donor candidates do not donate are potentially modifiable, and to track these patterns over time. Only by following living donor candidates who were turned down or decided not to donate due to concerns that living organ donation would adversely affect their health can it be determined whether those concerns were justified and provide the information for transplant programs to overcome modifiable barriers to living donation.

Secondly, registering living donor candidates will allow collection of follow-up information on living donor candidates who end up not donating. Fully evaluated living donor candidates who do not donate for reasons unrelated to the risk of donation (e.g., when there were other donors for the transplant candidate including a deceased donor, or the transplant candidate did not undergo transplantation) can offer a suitable control group for long-term outcomes. Stakeholders in collection of these data include not only current living donors, but also future living donor candidates and living donors, patients in need of transplantation, families, healthcare providers, payers, and the general public. A multi-stakeholder consensus conference on metrics relevant to the transplant community that included 30 percent patients, advocated for moving living donor data collection upstream and downstream from the current mandated OPTN data collection.⁶

Living Donor Candidate Definition

The Committee proposed defining an individual who was seen at a transplant program for evaluation as a “living donor candidate.”⁷ The definition of a living donor candidate is important because it will indicate the point in time when required collection and reporting of data would occur. The Committee sought to further clarify this definition with the help of the transplant community, and an overview of this feedback is detailed in the *Terminology & Definitions* section below.

⁶ Snyder, J., Schaffhausen, C., Hart, A., et al. “Stakeholders’ perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients’ consensus conference.” *Am J Transplant*. 2023.

⁷ OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at <https://optn.transplant.hrsa.gov/>.

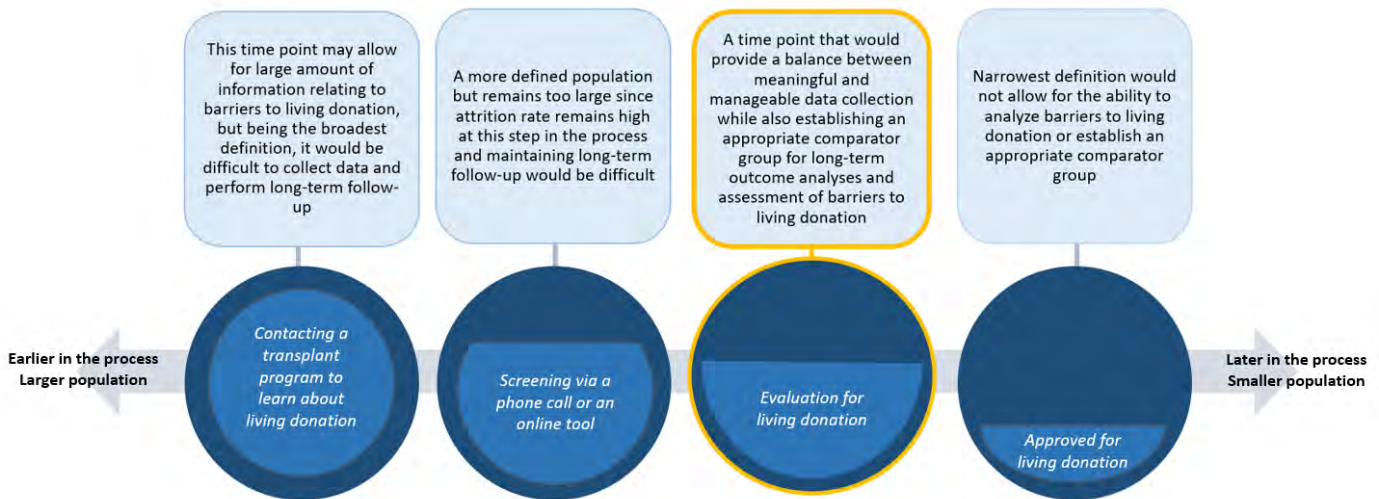
The proposed definition also aligns with how the Living Donor Collective defines living donor candidate.⁸ Capturing data at this stage in the process will allow for analysis on access and barriers to living donation as it encompasses individuals who do not proceed to living donation. While it would not encompass all information on barriers to living donation due to the specific time point indicated, the Committee agreed that collecting data on the volume of this population would be more manageable than earlier phases in the living donation process.⁹ Additionally, the Committee reasoned that this definition would provide a balance between meaningful data collection and data collection burden.

At this point in time, living donor programs are interacting with the individuals and are initiating early data collection that could be streamlined into OPTN reporting. Additionally, the Committee noted that individuals who undergo evaluation are more invested at this part of the process and may be more likely to engage in long-term follow-up regardless of whether they proceeded with donation or not.¹⁰

The Committee reasoned that collecting data on this population of individuals may allow for an appropriate comparator group.¹¹ Identifying an appropriate comparator group is important because comparing prior living donors to the general population presents limitations due to the prior living donor population tending to have a higher overall wellbeing. Collecting data on living donor candidates who are seen at transplant programs for evaluation creates an appropriate comparator group because these individuals undergo extensive clinical testing. Candidates for living donation who do not donate for reasons unrelated to their health are the best possible controls to compare outcomes of living donors. Additionally, this population may allow for analysis of barriers to living donation beyond medical reasons, which are often screened out earlier in the living donation process.

The Committee considered alternative definitions which are summarized in **Figure 2** and more information on these discussions are detailed in the concept paper.¹²

Figure 2: Summary of Committee Considerations for “Living Donor Candidate” Definition



⁸ This definition was developed by a steering committee made up of transplant programs who participated in the pilot phase of the Living Donor Collective.

⁹ OPTN Living Donor Committee, *Meeting Summary*, April 26, 2023. Available at <https://optn.transplant.hrsa.gov/>.

¹⁰ *Ibid.*

¹¹ *Ibid.*

Living Donor Candidate Data Collection

Within the conceptualized future state, the Committee sought to balance living donor candidate data collection with transplant programs' resources by determining the minimum amount of necessary data collection for living donor candidates. To help with this determination, the Committee reviewed pre-donation living donor data collection within the OPTN and SRTR systems.¹³

The Committee wants to ensure that the added burden on transplant programs is minimized while also collecting key factors that help identify barriers to living donation and understand baseline risk factors that allow for a longitudinal comparison of living donor candidates and living donors. To that end, the Committee requested feedback on how best to approach this data collection to increase efficiency and reduce redundancy while also collecting the key data. Most feedback submitted on this topic highlighted the importance of leveraging technology solutions such as data interfaces.

The following paragraphs provide an estimation on the amount and type of data that the Committee proposed to be collected and reported on living donor candidates. Much of the Committee's estimations are based on the current data collected via the *Living Donor Feedback (Add Donor)* and *Living Donor Registration (LDR)* forms, which also is the basis for the Living Donor Collective's initial living donor candidate registration form. The Committee's goal is to maintain a single integrated approach in which there would be no redundancy in data reporting into multiple systems (i.e., OPTN and SRTR).

The Committee proposed adding approximately 20 general data elements, with over half of these capturing basic contact information data elements in order to establish methods for future follow-up.¹⁴ Since these data support Living Donor Collective's ability to perform long-term follow-up with living donor candidates and living donors, it is important to collect detailed contact information at the front end.¹⁵ Collecting information on a living donor candidate's preferred method of contact as well as back-up contact information will aid in the Living Donor Collective's efforts to follow-up with living donor candidates and living donors long-term. Other data elements incorporated in this estimation include information such as name, social security number, and organ type.

For demographic data, the Committee estimated shifting approximately 5 – 10 data elements from the current *LDR* form to collect upstream on living donor candidates, including information such as sex, social support, health insurance, and education level.¹⁶ Demographic data are critical to understand barriers and access to living donation. The Committee supported collecting demographic data on living donor candidates because it may help the ability to assess change in the living donor population which could support the development of programs to increase living donation for populations that donate less frequently.¹⁷ Demographic data would also provide more information on social determinants of health and provide context for clinical information.

In terms of clinical information, the Committee estimated collecting approximately 10 – 15 data elements necessary for all living donor candidates.¹⁸ This would include clinical information such as blood type, history of cancer, tobacco use, diabetes, and hypertension. Clinical data are necessary

¹³ For more information on the Committee's review of OPTN and SRTR pre-donation data, please refer to the *Concepts for a Collaborative Approach to Living Donor Data Collection* paper. Available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/>.

¹⁴ OPTN Living Donor Committee, *Meeting Summary*, Month 17, 2023. Available at <https://optn.transplant.hrsa.gov/>.

¹⁵ *Ibid.*

¹⁶ OPTN Living Donor Committee, *Meeting Summary*, Month 17, 2023. Available at <https://optn.transplant.hrsa.gov/>.

¹⁷ OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at <https://optn.transplant.hrsa.gov/>.

¹⁸ OPTN Living Donor Committee, *Meeting Summary*, May 17, 2023. Available at <https://optn.transplant.hrsa.gov/>.

because they may allow the ability to analyze potential risk factors for living donors who experience worse outcomes. Additionally, the Committee supported collecting clinical data on living donor candidates because that would allow for the opportunity to compare clinical change pre- and post-living organ donation.¹⁹ The Committee recognized information such as hypertension is important but wants to ensure that the burden associated with collecting it remains low while the data remain meaningful.

The Committee proposed collecting some organ-specific clinical data on living donor candidates and sought the community's feedback on what clinical data is necessary to collect on living donor candidates specific to their intended organ donation. While public comment feedback provided a lot of topic areas of data collection, feedback on specific organ-related data was minimal. The Committee seeks to continue to engage subject matter experts as the project is developed.

Additionally, the Committee discussed the potential to collect psychosocial data on living donor candidates.²⁰ The Committee recognized the importance of this data but as noted several times, seeks to collect the minimum data necessary. During the evaluation phase of living donation, psychosocial information is gathered such as mental health history, substance use history, potential financial impact on donation, and social support. The Committee suggested that mental health information may be the most important to collect and sought the community's feedback on whether to include any psychosocial data, and if so, what. Public comment feedback noted the importance of psychosocial data, but again lacked specificity on which data points may be most imperative to collect during the evaluation phase.

The Committee also considered that data collected on living donor candidates who do not proceed with donation could be different than the data collected on living donor candidates who go on to donate.²¹ For example, a more limited data set could be acceptable for living donor candidates who do not proceed with donation, while a more detailed set of data would be necessary for the living donor candidates that continue to living organ donation. This variation in data collection could occur once the transplant program has indicated the donation decision.

Donation Decision Data

As noted earlier, one of the Committee's goals is to understand access and barriers to living donation. While some barriers to living donation are well documented in literature, there remain gaps in understanding of other barriers, such as insurance coverage.²²

Collecting a living donor candidate's donation decision will allow for a more holistic analysis on reasons that some living donor candidates do not proceed to living donation. Having the ability to track trends in donation decisions may help inform whether there are opportunities to improve access to living donation. The Living Donor Collective is currently collecting donation decisions from participating transplant programs.^{23, 24} The proposed concept (**Figure 1**) would require transplant programs to report

¹⁹ OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at <https://optn.transplant.hrsa.gov/>.

²⁰ OPTN Living Donor Committee, *Meeting Summary*, May 17, 2023 Available at <https://optn.transplant.hrsa.gov/>.

²¹ OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at <https://optn.transplant.hrsa.gov/>.

²² Orandi, B., Reed, R., Qu, H., et al. "Donor-reported barriers to living kidney donor follow-up," *Clinical Transplantation*. 2022 May;36(5):e14621. doi: 10.1111/ctr.14621.

²³ Kasiske, B., Ahn, Y., Conboy, M., et al. (2021). "Outcomes of living liver donor candidate evaluations in the Living Donor Collective pilot registry." *Clinical transplantation*, 35(9), e14394. <https://doi.org/10.1111/ctr.14394>

²⁴ Kasiske, B., Ahn, Y., Conboy, M., et al. (2021). "Outcomes of Living Kidney Donor Candidate Evaluations in the Living Donor Collective Pilot Registry." *Transplantation direct*, 7(5), e689. <https://doi.org/10.1097/TXD.0000000000001143>

donation decision and reason why for all living donor candidates to the OPTN to create a national understanding of access and barriers to living organ donation.

The Committee noted that these data may not be necessary to collect indefinitely.²⁵ After a certain period of time, barriers to living donation may become evident in which case donation decision may no longer need to be required data collection.

Community feedback noted support for understanding barriers to living donation. However, there was some opposition and concern due to the potential to reduce barriers to living donation prior to having enough data to understand long-term implications as well as acknowledging there are a myriad of barriers that occur prior to any living donor candidate undergoing evaluation that are yet to be understood. This feedback is summarized in the *Donation Decision & Analyzing Barriers to Living Donation* section below. Additionally, public comment highlighted concern for the OPTN collecting donation decision data due to the highly personal and confidential nature of such a decision. A summary of this feedback can be found in the *Consent & Privacy* section below. However, the Committee recognized that the OPTN and SRTR are both public health authorities with established data use agreements and seek to assure the community that if the OPTN is to collect donation decision data that it will be adequately protected.

Follow-up

Fully understanding the risks of living donation supports informed consent, living donor candidate selection, shared decision making, and post-donation care. Towards that goal, the transplant community can best fulfill ethical obligations to seek the most complete information possible on the effects of donation on living donors by instituting a comprehensive national registry.

Potentially important effects of living organ donation on outcomes such as death, kidney failure, or liver failure are expected to be infrequent among living donors screened to be healthy, and therefore large numbers of living donors need to be followed for long periods of time to measure donation-attributable risks and benefits for outcomes important to living donors.

Finally, practices evolve and so will the evaluation and selection of living donor candidates in the future. Therefore, it is not sufficient to study the outcomes of potential living donors and living donors over a limited period of time. There will be an ongoing need to understand the effects of changes in the community's evaluation and selection process, and it will be important to continue to monitor outcomes of future potential living donors and living donors. As long as living donation is practiced, there will be a need for comprehensive follow-up.

While the content of this project would require living donor candidate and donation decision data collection, the central part of this concept is long-term follow-up. It is worth reiterating that the rationale for OPTN requiring living donor candidate data collection is to support the Living Donor Collective to take on long-term follow-up of living donor candidates and living donors at a national level. To support this shift in data collection, the Committee is considering necessary trade-offs in terms of resources needed and data collected.

²⁵ OPTN Living Donor Committee, *Meeting Summary*, May 10, 2023. Available at <https://optn.transplant.hrsa.gov/>.

In terms of the resources needed to support the concepts, the Committee encouraged the community to weigh in on the potential to scale back the OPTN's required follow-up to focus on patient safety monitoring (i.e., maintain only the 6-month living donor follow-up reporting requirements). This may allow transplant programs to shift resources to collecting living donor candidate and donation decision data. With the OPTN registering living donor candidates, it would allow the Living Donor Collective to pivot resources to support the shift in 12- and 24-month follow-up data collection and beyond. When considering the data collected, the Committee encouraged the community to consider the type of follow-up data collected by the Living Donor Collective compared to the OPTN. For example, the *Living Donor Follow-up* (LDF) form includes clinical and laboratory data elements required for transplant programs to report, while the Living Donor Collective relies on self-reported data from living donor candidates and living donors. If the Living Donor Collective decided, in collaboration with OPTN committees and the transplant community, to collect laboratory data for long-term follow-up, then it would rely on living donor candidates and living donors to self-report this data. However, the Living Donor Collective is committed to performing long-term follow-up through patient-centered approaches, therefore, the longer-term follow-up in combination with multiple avenues of data linkages provided by the Living Donor Collective may be a worthy trade-off.

Concisely, it may be necessary to realign resources to enable upstream data collection to support the Living Donor Collective in long-term follow-up, which may result in a trade-off of current 12- and 24-month follow-up data reported to the OPTN. As noted previously, feedback on this topic was mixed and more detailed information can be found in the *OPTN Follow-up Requirements* section below.

It is important to observe that an emerging theme from public comment cited concerns regarding following living donor candidates long-term for varied reasons. This feedback is summarized in the *Concerns for Long-term Follow-up of Living Donor Candidates* below.

Other Concepts Considered

The Committee considered other concepts, such as expanding living donor follow-up requirements for transplant programs. Ultimately, the Committee determined that another mechanism for long-term data collection of living donors needed to be identified and supported as transplant programs may not be the effective vehicle for maintaining long-term follow-up of living donors.²⁶

Granular Review of OPTN Living Donor Data Collection

The Committee's second effort detailed in the concept paper is a granular review of OPTN living donor data collection forms.²⁷ The Committee, in conjunction with the Living Donor Data Collection Workgroup (the Workgroup) is reviewing data elements on the *Living Donor Feedback (Add Donor)*, *LDR*, and *LDF* forms. These data collection forms have been irregularly updated since initial development, and a comprehensive review of all OPTN living donor data collection forms has never been performed. In order to ensure that the data elements on these forms are accurate, reliable, approachable, and relevant, a systematic granular review of the data is necessary.

²⁶ For more information on alternate concepts that the Committee considered, please refer to the *Concepts for a Collaborative Approach to Living Donor Data Collection* paper. Available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/>.

²⁷ For more information on the Committee's granular review of OPTN Living Donor Data Collection, please refer to the *Concepts for a Collaborative Approach to Living Donor Data Collection* paper. Available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/>.

In a future proposal, the Committee will provide recommendations to modify, add, or remove data elements from these three data forms. Additional recommendations include updates to data definitions and the structure of the forms for ease of data entry. The Committee has not yet concluded their review, and sought public comment feedback, specifically from living donor program staff who interact with these forms, on modifications, additions, or removals of data elements and data definitions currently in the system. Most of the public comment on this topic provided insight into the type of information that living donors seek pre- and post-donation to inform health care decisions, this is detailed in the *Data Collection* section below. Additional public comment provided some feedback on specific updates to OPTN living donor data elements as well as suggestions for how the Committee should approach the granular review of data elements.

NOTA and Final Rule Analysis

In 2006, the Department of Health and Human Services (HHS) determined in a Federal Register notice that OPTN living donor guidelines should be given the same status of other OPTN policies.²⁸ In that notice, under 42 CFR 121.4(a)(6), the Secretary directed the OPTN to develop policies regarding living organ donors and living organ donor recipients, including policies for the equitable allocation of living donor organs, in accordance with [42 CFR 121.8].²⁹ The Committee submits their project concepts under the authority of this Secretarial directive; and the National Organ Transplant Act (NOTA), which requires the OPTN to “collect, analyze, and publish data concerning organ donation and transplants.”³⁰ Further, 42 U.S.C. 273a authorizes HHS to establish and maintain mechanisms to evaluate the long-term effects associated with living donations. Federal regulations at 42 CFR 121.11 also authorize the OPTN and SRTR to collect information concerning living organ donors and prospective living organ donors as the Secretary deems appropriate.

The concepts outlined in this paper address living organ donors by suggesting options for collecting data on individuals evaluated for living donation and updating living donor policy in an effort to determine barriers to living donation and risks and benefits attributable to living donation. Additionally, the project would include review of OPTN living donor data collection forms to propose modifications in order to ensure accurate data collection on living donors and improve analyses to inform evidence-based policy making.

Questions asked of the Community

The Committee requested feedback on all aspects of this concept paper, including the following questions:

- What are living donors’ preferences on how to engage with long-term follow-up?
- Is living donor candidate the correct term? Is the proposed definition appropriate?
- How do living donor programs define evaluation?
- What is the minimum amount of data necessary to collect on living donor candidates?
 - What are the specific necessary data elements?
 - What organ-specific clinical data are necessary for living donor candidates?

²⁸ Department of Health and Human Services, Health Resources and Services Administration, “Response to Solicitation on Organ Procurement and Transplantation Network Living Donor Guidelines,” 71 Fed. Reg. 34946 No. 116 (June 16, 2006). <https://www.federalregister.gov/documents/2006/06/16/E6-9401/response-to-solicitation-on-organ-procurementandtransplantationnetwork-optn-living-donor>.

²⁹ *Ibid.*

³⁰ 104 42 USC § 274(b)(2)(I).

- What are the transplant communities' recommendations related to shifting 12- and 24- month follow-up from the OPTN to the Living Donor Collective?
- How do living donor programs recommend operationalizing data collection on living donor candidates and donation decision to reduce burden?
- What data do potential living donors need to inform decision-making and post-donation health care?
- What recommendations do transplant coordinators have on updates to OPTN living donor data collection forms?
 - What data elements and data definitions require modifications or deletions?
 - What data elements are missing from current OPTN living donor data collection forms?

Summary of Public Comment Feedback

Due to the Committee seeking feedback on all aspects of the conceptualized future state of living donor data collection, several public themes arose and are summarized below.³¹

Support for Long-term Living Donor Data Collection

The concept paper outlined a potential future state of living donor data collection to understand long-term outcomes attributable to living donation. Overall, the community was supportive of efforts that achieved these goals. Reasons for supporting this initiative included the following:

- Longer-term data on outcomes for living donors supports informed decision making, determining criteria for living donation as well as informing the public understanding of why some living donor candidates are declined as living donors.
- Lack of data on long-term outcomes of living donation has been noted for a long time and needs to be addressed.
- Analyzing long-term outcomes is important for future growth and success of living donation.

Terminology & Definitions

The concept paper asked for feedback on terminology and definitions related to living donor candidates. There was acknowledgement that living donor candidate was the appropriate term to utilize, with no suggestions for different terminology. There was feedback related to the definition of a living donor candidate, including the following:

- Suggestion to define living donor candidates as those presenting at clinic (or remotely) for multidisciplinary evaluation.
- Sentiment that the definition is inaccurate due to different transplant programs having different operations with screening and the variation will lead to data collection disparities.
- Suggestion to begin at an earlier time point because identifying barriers by taking lab values before coming into the clinic is helpful.

³¹ All public comments submitted on the Committee's *Concepts for a Collaborative Approach to Living Donor Data Collection* are available at <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/>.

- Sentiment that it is reasonable to consider any living donor candidate who was educated, consented, and underwent any of the consultations or testing defined in OPTN Policy 14 to have begun the evaluation process whether they physically presented to the program or not.
- Agreement that the proposed definition would provide a balance between meaningful data collection and data collection burden and would capture a group of individuals who are sufficiently invested in the process and may be more likely to engage in long-term follow-up.
- Suggestion to include foreign nationals for the purpose of obtaining a reliable sample. The value of data collection on foreign nationals, who may have an initial evaluation in their home countries and then travel to the U.S. to become a living donor, should not be minimized.

The Committee and community acknowledged that more specificity is needed regarding the terminology of “evaluation.” Specifically, the community offered the following suggestions:

- We define evaluation when “the potential donor passes the telephone screening and begins testing.”
- Evaluation process should be excluded from the project’s requirements.
- We define evaluation as “an individual who showed up at one’s transplant center.”

Concern for Long-term Follow-up of Living Donor Candidates

A theme that emerged through public comment feedback was concern for following living donor candidates long-term. There were many reasons the community cited concern as there may be potential for low engagement thus making the data skewed as well as the potential to retraumatize individuals who were denied or chose not to proceed for personal reasons. It is important to note that in the conceptualized future state, living donors and living donor candidates will always have the option to opt-out of follow-up with the Living Donor Collective, and that decision is respected. Feedback on this topic included the following:

- Living donor candidates may change their minds because of negative pressure from family members or others, or because they hear stories which give them pause. This will make it very difficult to enlist in any long-term study because they have feelings of guilt or shame that they dropped out, and they do not want to be reminded of that fact on a regular basis.
- Sentiment that the few who may be willing to participate will be small in number, not fully invested, and will not provide reliable data.
- There are challenges with obtaining data from living donors, so it seems that it would be even more difficult to collect similar longitudinal data from living donor candidates.
- Suggestion to consider how to conduct follow-ups with living donor candidates who become a non-candidate due to psychological issues to not retraumatize the individual.
- Concern that this creates an excessive amount of data entry burden to transplant programs without a clearly logical reason.
- The ethics of creating a control group of those individuals who have declined donation are questionable and could cause enduring patient harm. A control group of individuals who have never considered donation is needed.

Donation Decision & Analyzing Barriers to Living Donation

Part of the concept paper highlighted the importance of collecting donation decision data to understand barriers and access to living donation. There was mixed feedback for collecting this data, and supportive feedback noted the following:

- Addressing these barriers could potentially increase support for living donation and inform policy efforts in this area.
- If we learn from those that consider donation, but do not donate, we may be more effective in recruiting living donors in the future.
- It will help transplant programs and the public understand the reasoning behind why some living donor candidates are declined as living donors.

Concern and opposition to collecting donation decision data largely cited the privacy of the data, some of which is detailed in the *Privacy & Consent* theme. Further opposition and suggestions regarding the collection of donation decision data included:

- The larger barrier for donation occurs outside the transplant program (public perceptions, myths, lack of knowledge, lack of access to care).
- Understanding and solutioning around barriers to living donation is a potentially separate issue from collecting data on living donor candidates; more study and thought is needed in this area.
- Data collection to determine long-term outcomes should be separate from data needed to decrease barriers to donation. The time needed to collect data pertaining to barriers to living organ donation is shorter than time needed to collect long-term medical and psychosocial data. This means that barriers to living donation will be addressed long before long-term medical and quality of life data may be available.
- Concern that transplant programs may not be the appropriate collector of these data as the living donor candidate's decision, to donate or not to donate, is confidential, especially related to psychosocial turndowns.

Living Donor's Preference for Engaging with Long-term Follow-up

The concept paper asked for feedback on how living donors prefer to engage with follow-up. While the majority of feedback on this topic was from prior living donors, some feedback highlighted below was submitted by transplant programs on their perception of how living donors prefer to engage with long-term follow-up. The overarching preference is for follow-up data to be submitted to a secure patient portal either by living donor candidates and living donors themselves, or by their primary care physician. This feedback supports that transplant programs may not be the best entities for long-term follow-up but rather an entity that can directly interface with living donor candidates and living donors.

- A simple follow up of self-reporting in a secure patient portal.
- Quick access to respond to surveys or entering a survey online.
- When living donors have annual physical exams, the PCP can submit the living donor's clinical results to the registry. The living donor would also complete an online (mobile friendly) financial and psychosocial survey. The registry would monitor each living donor's expected data reporting anniversary, prompt the living donor regularly to stay involved and to schedule an exam, develop a relationship with the living donor's PCP, and issue a report to the living donor each year with individualized longitudinal results relative to benchmarks.

- A voluntary system with automatic reminders for living donors to input data.
- Following-up via electronic means, such as telehealth, and/or by phone as opposed to being seen in person, absent any donation related concerns a prior living donor may have.

OPTN Follow-up Requirements

The concept paper asked for feedback on the potential to remove the current 12- and 24-month follow-up requirements for transplant programs within OPTN policy. This topic received mixed feedback. Supportive feedback included the following:

- It is reasonable to shift donor follow up from the OPTN to the Living Donor Collective.
- Support for this as it would ease the administrative burden on transplant programs and improve data collection.
- Sentiment that the 12- and 24-month laboratory data are not very helpful in all organ donors, particularly kidney donors who may develop ESRD years after donation.
- Support for removing the requirement due to the acknowledgement that transplant programs may not be the best vehicle for collecting these data long-term.

Feedback citing opposition to removing the requirement included the following:

- Concern that removing the 12- and 24-month follow-up requirements may shift the burden to the living donors.
- Concern that removing the requirements would increase perception of transplant programs “not caring about donors.”
- Suggestion to minimize the requirements of data collection, such as requiring a phone call to a living donor to check in and leave the onus of data collection to the Living Donor Collective.
- Opposition to removing the follow-up requirements because it is the responsibility of the transplant program to verify the living donor does not have any medical complications as a result of the donation. Additionally, it would remove the early identification of complications that could be addressed prior to the SRTR identifying something like a dialysis start date.
- A living donor noted appreciation for the transplant program’s medical follow-up at 12 and 24 months and would oppose removing this responsibility. They felt that knowing that the transplant program was going to follow-up gave them some ease of mind in making the decision to donate.
- Consideration that removal of the requirements resulting in follow-up data not being directly collected by the OPTN means there will be less monitoring and enforcement that can occur at the transplant program level.
- Opposition to removing the requirement because it is important to the living donor to maintain a connection to the transplant program and those involved in their donation.

Consent & Privacy

Consent and privacy were other emergent themes from the public comment feedback. As noted above, there was concern from the community regarding the privacy of donation decision data. Additionally, the community noted that changes in consent processes would increase burden for transplant programs. However, it is important to note that both the OPTN and the SRTR are public health authorities with established data use agreements which allow for disclosure of the minimum amount of

protected health information necessary to ensure public health and safety. Because of this, OPTN and SRTR can share data without the need for additional informed consent. This also highlights the current privacy standards surrounding OPTN and SRTR data collection. Feedback on this topic included the following:

- It may be more effective if a non-affiliated entity allowed living donor candidates to provide donation decision information securely, independently, and confidentially.
- Recommendation for a comprehensive ethics review of consent, disclosure, and privacy protections related to the registry and the associated data collection. Implications of collecting long-term data without adequate understanding and consent for what data is collected, how it will be collected, and how it will be shared and used is ethically concerning.
- Concern that requiring consent from the living donor candidates would add burden and require additional resources for the transplant programs.
- Protecting living donor candidate's anonymity and their ability to withdraw without giving a reason was deemed crucial due to potential discomfort, privacy concerns, and data breaches.
- The decision to donate (or not) should be remain confidential, and additional safeguards should be added to share this information only as needed.

Burden

The community emphasized concern about the concepts detailed in the paper regarding burden on transplant programs. This feedback included the following:

- Despite data burden being “shifted downstream” this will not be an even exchange of data reporting requirements.
- Opposition to the project, describing it as unnecessary, costly, and burdensome for individuals who do not proceed to donation.
- Significant concerns that implementing some version of this concept will pose an increased burden on transplant program staff, as well as living donors who may not want to be contacted for an indefinite period. Either of these factors could negatively affect completeness of data collection, particularly at longer time points, and dampen the goals of the initiative.
- Concerns about the impact of increased administrative requirements on living donation rates and concern that additional data burdens might discourage transplant programs from engaging in living donor evaluations.
- Concern that inviting living donors to self-report frequently or for long periods of time could also be burdensome because they already give so much of their time to the process.

While there was concern regarding added burden on transplant programs, there was some support noting that the Living Donor Collective's role within the concept will help reduce burden. Additionally, the community offered suggestions for how to ease burden, particularly highlighting the importance of data interfaces.

- Support for the idea of the SRTR Living Donor Collective as it may be a great solution to data collection to decrease burden to the transplant programs.
- Recommendation to limit the data required and working with electronic health record (EHR) vendors to create application programming interfaces (APIs) to avoid manual abstraction.

- Recommendation to both entities to leverage innovation and technology for data collection and reporting to mitigate additional administrative burdens for transplant programs.
- Improvement of the existing interfaces with the OPTN computer systems and hospital electronic medical records (EMR)s would allow better data entry and flow.

Data Collection

The concept paper asked for several areas of feedback on data that is necessary for living donor candidates and living donors to make informed decisions pre- and post-donation. The community also provided feedback related to the Committee's granular review of OPTN living donor data collection in which there were suggestions for additions and removals of specific data elements. Feedback highlighted the importance of the methodology of granular review and provided suggestions for how to approach reviewing data. The community also submitted a significant amount of feedback on topics of interest. A few of these topics of interest included the following:

- Long-term health outcomes
- Barriers to living donation
- Equity and disparity analyses
- Physical activity post-recovery and changes in physical characteristics
- Psychological concerns and outcomes
- Risk of death and surgical complications
- Ability to have children and risks of pregnancy
- Concerns regarding end-stage renal disease (ESRD) or needing a transplant in the future
- Restriction on the use of medications for pain management, treatment of disease, and the need for and/or use of supplements
- Ability to eat certain foods, use tobacco products, use marijuana, drink alcohol, drink coffee, etc.
- Concerns related to finances, denial of insurance, loss of coverage, paying higher premiums
- Impact on the living donor's quality of life, their hobbies, and their families.

Additional Feedback

There are additional areas of feedback provided from the community. Firstly, there was an emphasis on the importance of education for living donor candidates and living donors. Feedback from community members on the topic of education included the following:

- Informing living donor candidates about what the Living Donor Collective is can be very important, as living donors often receive lots of information and surveys that can be confusing and overwhelming.
- Emphasized the importance of education as to why it is valuable to engage in long-term follow-up.
- Consider how data collection may impact diverse living donors and how the approach could possibly differ. In particular, uneducated from underserved communities, which often require that the approach be different to assure they are comfortable even participating and understanding.

Additional feedback highlighted potential unintended consequences with the concepts detailed in the paper.

- There may be some unintended consequences in the relationship between the transplant program and living donors if data reporting is transitioned to SRTR and having a transition period would be extremely important.
- Pediatric transplant programs often rely heavily on living donors, and the conceptualized future state of living donor data collection may disproportionately affect the pediatric transplant programs. Suggestion to engage the OPTN Pediatric Transplantation Committee during future development of the concepts.
- Consider non-U.S. citizens/residents when collecting data.
- Examining pharmacy claims is neither reliable nor valid data collection, in part because some or possibly many living donors do not have access to commercial health insurance in the years following donation.
- Need to be cognizant of potential for this data to be "used against" centers. There could be unforeseen consequences and need to avoid any possibility of leading to either living donor candidates or transplant programs not considering living donation for as many candidates as possible.

Next Steps

The Committee reviewed public comment at a recent in-person meeting during which there was consensus among the members to continue forward with a project.³² The Committee will work over the next several months to refine the project scope while continuing to collaborate with SRTR and other stakeholders. The Committee will then bring a project proposal forward to the OPTN Policy Oversight and Executive Committees for consideration and approval. If project approval is granted, the Committee will develop a proposal for the OPTN to collect living donor candidate and donation decision data as well as recommend overall updates to living donor data collection within the OPTN system.

³² OPTN Living Donor Committee, *Meeting Summary*, October 3, 2023. Available at <https://optn.transplant.hrsa.gov/>.