

Report to the Board of Directors on Living Donor Data Collection

***OPTN Living Donor Committee
December 5, 2022***

This report to the OPTN Board of Directors reflects the deliberations of the OPTN Living Donor Committee (hereafter, the Committee) from July 2021 - October 2022. During this time, the Committee sought to identify opportunities to improve living donor data collection and follow-up. The Committee discussed challenges with current data collection, the need for longer-term data collection, and opportunities for collaboration and innovations for improved living donor data collection. These discussions support robust data collection and follow-up efforts that reflect the necessity of understanding the effects of live organ donation long-term in order to support those who give the gift of life.

Introduction

The Committee seeks to increase transparency and understanding of potential risk associated with live organ donation, further improve living donor safety and outcomes, and strengthen public trust by evaluating living donor data collection and recommending areas of improvement. The Committee's report establishes the basis for the need to extend follow-up on living organ donors, as there are existing gaps in understanding the long-term outcomes of living organ donation.

The report provides an overview of the current state of living donor data collection as well as recommendations regarding long-term living donor data collection. Next steps, detailed below, are contingent on the OPTN Board of Director's feedback to ensure alignment and communication of goals and scope.

For the purposes of contextualizing different roles in living donor data collection, the Organ Procurement and Transplantation Network (OPTN) and Scientific Registry for Transplant Recipients (SRTR) are defined here. The work of both the OPTN and SRTR are performed under separate contracts with the Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services (HHS).

Established via 42 U.S.C. §274, the OPTN maintains the national waitlist and matches deceased donor organs with transplant candidates; collects, analyzes, and publishes data; and establishes membership criteria and medical criteria for organ allocation.¹ In 2006, the Department of Health and Human Services (HHS) stated that oversight over living donation of all types falls under the authority of the OPTN.² The SRTR is required to support ongoing evaluation of scientific and clinical status of solid organ transplantation via section 373 of the Public Health Service Act.³ The SRTR is responsible for providing statistical and other analytic support to the OPTN for purposes of policy

¹42 U.S.C. §274 – Organ Procurement and Transplant Network

² 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-procurement-and-transplantation-network-optn-living-donor>.

³ "Driven to Make a Difference: Mission, Vision, and Values", Scientific Registry of Transplant Recipients. Available at <https://www.srtr.org/about-srtr/mission-vision-and-values/>.

development and evaluation, system performance metrics, economic analysis, and preparation of recurring and special reports to Congress.⁴ In addition to SRTR's scope, SRTR has established a living donor registry that aims to study the long-term outcomes of living organ donation.⁵ The registry began as a pilot program per contract requirement with HRSA, with recent contract requirements to formalize the registry as a national program, and expand participation.

Current State of Living Donor Data Collection

OPTN Living Donor Data Collection

While the OPTN has been collecting living donor follow-up data since 1999, it was not until 2005 that the OPTN required living donor programs to submit follow-up data on living donors. Subsequent data from 2006 to 2009 demonstrated that many living donor programs were not reporting meaningful living donor follow-up information at the required intervals (6, 12, and 24 months post-donation⁶).⁷ As a result, the OPTN Board of Directors approved two proposals that established minimum reporting requirements for living kidney and liver donor follow-up.^{8,9}

Both of these proposals highlight that the OPTN relies on the Living Donor Follow-up (LDF) form to collect data on the short-term health status of living donors.^{10,11} The timeframe for living donor follow-up (6, 12, and 24 months) has not changed since these proposals, which established minimum reporting requirements, were approved. While there may be opportunity for expanding OPTN living donor data collection longer-term, this underscores that the OPTN only collects data on living donor outcomes up to two years post-donation.

The rate of data completion submitted to the OPTN on short-term (6, 12 and 24 month) outcomes of living donation has increased since the implementation of Policy 18.5: *Living Donor Data Submission Requirements*. After implementation of Policy 18.5 follow-up rates for living kidney donors increased from approximately 40 percent in 2006 to over 80 percent in 2019.¹² However, the data demonstrate that collecting follow-up information becomes more challenging as more time passes after donation.¹³ Analyses of living donor characteristics also found that even shorter-term follow-up rates may vary by clinical and demographic characteristics.¹⁴ This is necessary to note when considering the possibility of extending living donor data collection past 24 months.

In 2019, the most recent full year not impacted by the COVID-19 pandemic, transplant programs submitted on time, complete OPTN living donor clinical data for 87 percent of living kidney donors at 6

⁴ Ibid.

⁵ "Who We Are", Living Donor Collective: An SRTR Initiative. Available at <https://livingdonorcollective.org/about-ldc/who-we-are/>.

⁶ OPTN Policy 18.1.B: Timely Submission of Certain Data, Table 18-1: Data Submission Requirements

⁷ OPTN Living Donor Committee, *Briefing Paper*, Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up. Public Comment September 16, 2011 to December 23, 2011.

⁸ Ibid.

⁹ OPTN Living Donor Committee, *Briefing Paper*, Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up. Public Comment September 6, 2013 to December 6, 2013.

¹⁰ Ibid.

¹¹ OPTN Living Donor Committee, *Briefing Paper*, Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up. Public Comment September 16, 2011 to December 23, 2011.

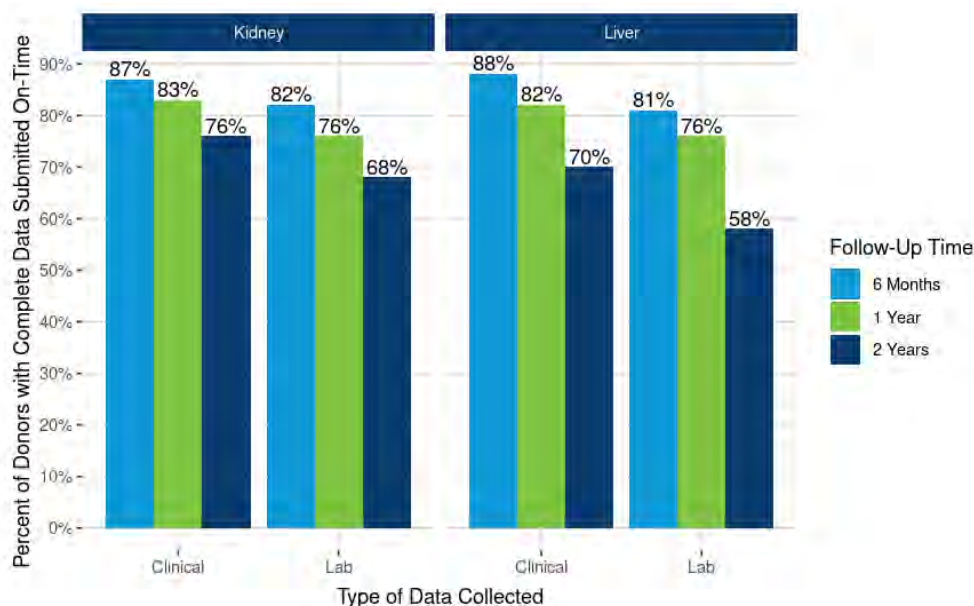
¹² OPTN data as of July 2022.

¹³ Henderson, M., Thomas, A., Shaffer, A., et al. "The National Landscape of Living Kidney Donor Follow-Up in the United States," *American Journal of Transplant*. 2017 Dec;17(12):3131-3140. doi: 10.1111/ajt.14356.

¹⁴ Reed, R., Shelton, B., MacLennan, P., et al. "Living Kidney Donor Phenotype and Likelihood of Postdonation Follow-up," *Transplantation*. 2018 Jan;102(1):135-139. doi: 10.1097/TP.0000000000001881.

months after donation, 83 percent of living kidney donors at 12 months after donation, and 76 percent of living kidney donors at 24 months after donation. These clinical data include any kidney complications or readmissions, whether the living donor has developed hypertension that requires medication, whether the living donor is working, and other information. Laboratory data submission patterns for living kidney donors are similar, but with slightly lower rates (82 percent, 76 percent, and 68 percent at 6, 12, and 24 months after donation, respectively). Laboratory data include serum creatinine and urine protein. OPTN follow-up rates for living liver donors are also similar, but with lower 24 month laboratory data submission rates. This may be due to differences in the timeframes established in policy for reporting thresholds; Mandatory reporting thresholds for living liver donor data collection apply to 6 and 12 months¹⁵, while mandatory reporting thresholds for living kidney donors apply to 6, 12, and 24 months.¹⁶ For long-term outcomes, the OPTN links data submitted through the OPTN living donor data collection forms with external data sources for outcomes such as end-stage renal disease (ESRD) and death.

Figure 1: 2019 OPTN On-Time and Complete LDF Submission Rates by Organ, Follow-Up Time, and Data Type¹⁷



SRTR Living Donor Data Collection

Beginning in 2018 the SRTR conducted a pilot project with ten kidney and six liver transplant programs that established a registry – the Living Donor Collective – to examine access and long-term outcomes attributable to living donation. The Living Donor Collective registers living donor candidates for living donation who come to a transplant program, in person or virtually, and undergo an evaluation to determine suitability for donation. In addition, if donation does not occur, the Living Donor Collective collects reasons a living donor candidate ended up not donating. Note: while “candidates” has a specific meaning in OPTN policy in referring to individuals registered on the waiting list for a transplant, SRTR uses the term “living donor candidates” based on the 2017 KDIGO Living Donor Guideline for individuals

¹⁵ OPTN Policy 18.4.B: Reporting Requirements after Living Liver Donation

¹⁶ OPTN Policy 18.4.A: Reporting Requirements after Living Kidney Donation

¹⁷ OPTN data as of July 2022.

evaluated for living donation. The term is used here to accurately reflect the language used in the registry.

The Living Donor Collective is focusing on making participation in the registry as effortless as possible for living donor programs. In 2023 SRTR will also focus on establishing optimal long-term (lifetime) follow-up of registrants by: 1) establishing linkages to other data sources, 2) sending targeted surveys, and 3) working with living donors and other stakeholders to determine what information is important to living donors/living donors candidates and how the information can best be collected. Of note, by registering living donor candidates, the Living Donor Collective is designed to capture a control population of individuals who underwent living donor evaluation but did not end up donating. The Living Donor Collective data collection differs from that of the OPTN by registering living donor candidates at the time of initial evaluations and does not duplicate the short-term follow-up of the OPTN (Table). As the SRTR Living Donor Collective is relatively new and data are still accumulating, this report focuses on OPTN living donor data.

Table. A comparison of current living donor data collection efforts by the OPTN and the SRTR Living Donor Collective.	
OPTN	SRTR Living Donor Collective
Registers living donors	Registers living donor candidates for living donation: ^a <ul style="list-style-type: none"> Examines living donor candidate barriers to donation^b Establishes comparators for living donors^c
Registration is mandatory for programs	Registration is voluntary for programs
Mandatory follow-up 6, 12, 24 months	Planned lifetime follow-up
^a Individuals who are pre-screened and come (in-person or virtually) to a transplant center for living donor evaluation. ^b Comparing living donor candidates who donate with those who do not donate may help identify barriers to donation. ^c Candidates for donation who do not donate for reasons unrelated to their health are the best possible controls to compare outcomes of living donors.	

Background on Project Development

An OPTN Living Donor Data Collection Workgroup (the Workgroup) was established in July 2021 to define a vision for the future of living donor data collection by discussing the kinds of data collection that are needed and the appropriate mechanisms to collect said data.¹⁸ The Workgroup had collaborative discussions with representatives from the OPTN Living Donor and Data Advisory Committees, SRTR representatives, and HRSA representatives.

During the initial meetings, the Workgroup established that collecting data on living donors and potential living donors will aid in:

- Enabling living donors’ informed consent, including outcomes beyond two years
- Better understanding of barriers to living donation and how to overcome these barriers

¹⁸ OPTN Living Donor Committee, Living Donor Data Collection Workgroup, *Meeting Summary*, July 21, 2021. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

- Better understanding of lifetime risks and benefits to living donors attributable to organ donation¹⁹

Since that time, the Committee has taken the initiative to holistically discuss and evaluate living donor data collection. The Committee, in conjunction with the Workgroup, has begun a review of living donor data elements while also determining the necessity of longer-term living donor data collection. The initial review of data elements focuses on those in the OPTN Living Donor Registration (LDR) and LDF forms.

The Committee reviewed the OPTN Data Collection Principles²⁰ and identified the following principles as they relate to living donor data collection:

- 1) Determine member-specific performance;
- 2) Ensure patient safety when no alternative sources of data exist;
- 3) Develop transplant, donation, and allocation policies.²¹

¹⁹ Ibid.

²⁰ OPTN Board of Directors, *Meeting Summary*, June 2006.

²¹ OPTN Living Donor Committee, *Meeting Summary*, May 18, 2021. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

The Committee’s holistic approach to discussing living donor data collection includes a granular review of specific data elements as well as evaluating the overall purpose and timeframe of collection. The Committee is granularly reviewing each data element and providing rationale for keeping, modifying, removing, or adding new data elements. To date, the data elements reviewed are outline in **Table 1**.^{22,23,24,25} Review of these elements intend to support a public comment proposal to ensure efficient and effective OPTN data collection for living donors out to two years.

Table 1: Data elements reviewed to date

Data Element	Form
Marital status at time of donation	LDR
Donor type	LDR
Did the donor have health insurance	LDR
History of cancer/Cancer free interval	LDR
History of cigarette use	LDR
Other tobacco use	LDR
Date of initial discharge	LDR
Donor status	LDR
Date last seen or death	LDR
Non-autologous blood administration	LDR
Date of last contact or death	LDF
Most recent donor status since	LDF
ER or urgent care visit related to donation since last follow-up	LDF
Has the donor been readmitted since	LDF
Regularly administered dialysis as an ESRD patient	LDF
Loss of insurance due to donation	LDF
Functional status	LDR & LDF
Physical capacity	LDR & LDF
Working for income	LDR & LDF
Diabetes/treatment	LDR & LDF
Cause of death	LDR & LDF

²² OPTN Living Donor Committee, *Meeting Summary*, June 13, 2022. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

²³ OPTN Living Donor Committee, Living Donor Data Collection Workgroup, *Meeting Summary*, August 31, 2022. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

²⁴ OPTN Living Donor Committee, Living Donor Data Collection Workgroup, *Meeting Summary*, October 7, 2022. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

²⁵ OPTN Living Donor Committee, *Meeting Summary*, October 17, 2022. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

In addition to the granular review of living donor data, the Committee has discussed the purpose and need for long-term living donor data collection. The remaining sections of the report summarize these discussions and highlight the conclusions of the Committee for the OPTN Board of Directors. The Committee presents six findings and recommendations for OPTN Board of Directors consideration:

- 1) Living donors should be followed for their lifetimes.
- 2) There are barriers and burden associated with transplant programs performing living donor follow-up.
- 3) A registry may be better situated to perform long-term living donor follow-up.
- 4) Resource constraints remain a logistical concern for long-term living donor follow-up.
- 5) There are opportunities for increased efficiencies and integration across organizations that support the transplant community.
- 6) Broader living donor engagement is necessary.

Findings and Recommendations

Living donors should be followed for their lifetimes.

The Committee unanimously endorses that each living donor should be followed for their lifetime. As outlined above, the OPTN's collection of data on living donors ends after two-years. There have been longitudinal research studies on living donors, however, the existing research is not sufficient to correlate all outcomes to a national cohort.²⁶ There is consensus, in the transplant community, that long-term data collection on living donors is necessary.^{27,28,29,30,31,32} In the past twenty years, members of the community have repeatedly identified to the OPTN that the current follow-up periods for living donors do not provide sufficient data to understand long-term

²⁶ Ibrahim, H., Foley, R., Reule, S., et al. "Renal Function Profile in White Kidney Donors: The First 4 Decades," *Journal of the American Society of Nephrology*. (2016);27(9), 2885–2893. doi: 10.1681/ASN.2015091018.

²⁷ Takagi, K., Umeda, Y., Yoshida, R., et al. "Short-term and long-term outcomes in living donors for liver transplantation: Cohort study," *International Journal of Surgery*. 2020 Dec;84:147-153. doi: 10.1016/j.ijssu.2020.11.013.

²⁸ Hanson, C., Sautenet, B., Craig, J., et al. "Informative for Decision Making? The Spectrum and Consistency of Outcomes After Living Kidney Donation Reported in Trials and Observational Studies," *Transplantation*. (2019);103(2), 284–290. doi: 10.1097/TP.0000000000002489

²⁹ Samaniego-Picota, M., Patel, A., Davis, C. "Live Kidney Donation: Gaps Remain," *Advances in Chronic Kidney Disease* 2012 Jul;19(4)205-206. doi: 10.1053/j.ackd.2012.05.005

³⁰ Dew, M., Butt, Z., Humar, A., DiMartini, A. "Long-Term Medical and Psychosocial Outcomes in Living Liver Donors," *American Journal of Transplant*. 2017 Apr;17(4):880-892. doi: 10.1111/ajt.14111.

³¹ Lentine, K., Schnitzler, M., Xiao, H., et al. "Racial variation in medical outcomes among living kidney donors," *The New England Journal of Medicine*. (2010);363(8), 724–732. Doi" 10.1056/NEJMoa1000950

³² Lentine, K., Lam, N., Segev, D. "Risks of Living Kidney Donation: Current State of Knowledge on Outcomes Important to Donors." *Clinical Journal of the American Society of Nephrology*. (2019);14(4), 597–608. doi: 10.2215/CJN.11220918

outcomes.^{33,34,35,36,37,38,39,40,41} As previously cited, current data on long-term living donor outcomes is insufficient and longer-term data is needed in order to quantify the risks that a living donor takes on when they consent to donate an organ. The need for long-term data collection on living donors has been well documented and the Committee seeks feedback on these recommendations in order to better the system.

Living donor safety is paramount. Living donation is an entirely elective surgery that offers no physiological benefit to the live organ donor. Living donors are providing gifts of life to transplant candidates. In addition to the gift of life, living donors contribute to the transplant system by donating to one waitlisted candidate, and in doing so, enable transplantation of another waitlisted candidate when a deceased organ next becomes available. While the benefit of live organ donation is clear and well demonstrated, the impact of donation on a living donor's psychosocial, economic, and wellbeing has yet to be understood or fully studied. Given the sacrifice of living donors and the benefit they provide to others, there must be improved understanding, monitoring and analysis of living donor long-term outcomes beyond organ failure and death.

Long-term data is necessary for improving informed consent. It has been noted by living donors that data-based disclosures not only help with their own understanding of the risk of live organ donation, but also when communicating with their families. Living donors desire to ensure that their caregivers and families are supportive of the decision to donate, and having data-based information to provide regarding the lifetime risk of live organ donation will help potential living donors communicate with their families about their decision. Potential living donors and living donors may need more data available to them on the lifetime implications of live organ donation.

³³ Excerpt of Region 2's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Finally, there was general agreement that two year follow-up does not provide information that is valuable for determining donor survival rate or long-term status." (Public Comment period September 16, 2011 to December 23, 2011).

³⁴ Excerpt of Region 9's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "A comment was made that the laboratory tests required in this proposal are useless at the two year mark as living donors develop renal disease over a longer period of time." (Public Comment period September 16, 2011 to December 23, 2011).

³⁵ Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "The time frame for this proposal, along with the plan to monitor compliance by peers and colleagues assigned to UNOS/OPTN Committees, will mean that in another 12 years, in 2023, another Living Donor Data Task Force (LDDTF) will likely conclude that OPTN data is 'woefully inadequate'." (Public Comment period September 16, 2011 to December 23, 2011).

³⁶ Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Because living donors choose to voluntarily assume a great deal of potential risk, including possible death, the medical profession should be doing everything that it can in order to help prospective donors to be accurately informed of any potential risks, including the impact on long-term health." (Public Comment period September 16, 2011 to December 23, 2011).

³⁷ Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "A two year study is not adequate enough to discover information that is important for the donation process and for the donor to understand." (Public Comment period September 16, 2011 to December 23, 2011).

³⁸ Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "Hopefully in the future the period of time required for follow-up can be extended." (Public Comment period September 16, 2011 to December 23, 2011).

³⁹ Excerpt of community member's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "While current evidence shows that living donation does not change life expectancy and does not appear to increase the risk of kidney failure, additional data collection on the long-term outcomes for living donors is needed." (Public Comment period September 16, 2011 to December 23, 2011).

⁴⁰ Excerpt of National Kidney Foundation's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "Lifetime follow-up and data collection on the health status of donors, including blood pressure, is helpful information that may be used in the future to inform potential living donors." (Public Comment period September 6, 2013 to December 6, 2013).

⁴¹ Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "I strongly support this proposal, and hope that this minimal first step, which is merely parity with the already approved minimum followup for living kidney donors, leads to mandatory lifetime followup of all living donors and living donor candidates, past, present, and future as a condition of remaining a transplant center." (Public Comment period September 6, 2013 to December 6, 2013).

Longer-term data collection on living donors may broadly and positively influence living donation. Lifetime follow-up of living donors may increase knowledge regarding the benefits of living organ donation to the live donor. Longer-term follow-up may allow for more data in order to analyze emotional and psychosocial benefits for living donors, some of which has been documented in research.^{42,43,44} The Committee notes it will be important to engage with living donors to receive feedback on what living donors seek to understand regarding the long-term benefits attributable to live organ donation.

It may also safeguard living donors' long-term wellness and safety by having data to identify risk factors and long-term outcomes, which will subsequently inform living donor policy. Achieving this may allow for a more evidence-based approach to broadening opportunities for living donation while protecting living donors. Additionally, the Committee recognizes that long-term outcomes could reveal unanticipated results that may negatively affect living donation, such as insurance companies utilizing the data to determine coverage.⁴⁵

The Committee emphasizes that long-term living donor follow-up data collection is the best way to ensure living donor safety. Promoting living donor and transplant recipient safety is a strategic priority of the OPTN.⁴⁶ The necessary data will allow the transplant system to safeguard living donors in an evidence-based approach.

There are barriers and burden associated with transplant programs performing living donor follow-up.

There are significant barriers and burdens with transplant programs collecting longer-term living donor data collection. As referenced previously, while transplant programs are mandated to meet specific thresholds for LDF data submission, current compliance declines with each required follow-up reporting period.⁴⁷ These challenges and costs become more significant as required living donor follow-up periods increase. The Committee notes that while transplant programs are mandated to report living donor follow-up, transplant programs are unable to require living donors to visit for follow-up. Living donors may not be local to the transplant program because they either traveled for donation or moved post-donation. Financial coverage of the follow-up appointments may be an additional barrier. These challenges reflect that transplant programs may not be the best vehicles for collecting these data long-term because living donors may seek healthcare via their established primary care provider.

The Committee sought feedback from transplant administrators during these foundational discussions. OPTN Transplant Administrators Committee (TAC) leadership stated that any increase in mandated OPTN living donor follow-up data collection would entail a financial impact. TAC leadership noted that even if funding concerns could be addressed, there are transplant programs in

⁴² Van Pilsam Rasmussen S., Robin, M., Saha, A., Eno, A., et al. "The Tangible Benefits of Living Donation: Results of a Qualitative Study of Living Kidney Donors." *Transplant Direct*. 2020 Nov 10;6(12):e626. doi: 10.1097/TXD.0000000000001068.

⁴³ Rodrigue, J., Paek, M., Whiting, J., et al. "Trajectories of perceived benefits in living kidney donors: association with donor characteristics and recipient outcomes." *Transplantation*. 2014; 977762–768

⁴⁴ Clemens, K., Thiessen-Philbrook, H., Parikh, C., et al.; "Donor Nephrectomy Outcomes Research (DONOR) Network. Psychosocial health of living kidney donors: a systematic review." *American Journal of Transplantation*. 2006; 6122965–2977

⁴⁵ OPTN Living Donor Committee, *Meeting Summary*, September 14, 2022. Available at <https://optn.transplant.hrsa.gov/>.

⁴⁶ OPTN Executive Committee, *Briefing Paper*, Strategic Plan 2021 – 2024. Public Comment January 21, 2021 – March 24, 2021. Available at <https://optn.transplant.hrsa.gov/>.

⁴⁷ Refer to **Figure 1**: 2019 OPTN On-Time and Complete LDF Submission Rates by Organ, Follow-Up Time, and Data Type.

which there is no physical space to house the additional personnel that would be needed to perform the necessary work needed for living donor follow-up.⁴⁸

Previous efforts to address living donor follow-up via transplant programs have been contentious given the responsibility that would be placed on transplant programs.^{49,50} A similar sentiment was arrived upon during a 2010 consensus conference which noted that transplant programs would not be effective in maintaining an unfunded mandate for long-term living donor follow-up.⁵¹ Another mechanism for long-term data collection of living donors needs to be identified and supported as transplant programs may not be the effective vehicle for maintaining long-term follow-up of living donors.

A registry may be better situated to perform long-term living donor follow-up.

Due to the significant barriers associated with collecting extended living donor follow-up by transplant programs and the consensus that longer-term data is needed, some other entity, such as a registry, may be better situated to connect directly with living donors.

Collaborating with and supporting living donor data collection through a national registry is not a new idea to the public. Suggestions that a national registry may be a better entity for long-term collection of living donor data have been well documented. In 2000, the Living Donor Consensus Conference endorsed a Live Organ Donor Registry to collect demographic, clinical, and outcome information on all living donors.⁵² Part of the rationale for endorsing a national registry was the limitations of current knowledge regarding long-term consequences of donation. This theme remains apparent over twenty years later.

In 2003, the OPTN Board of Directors adopted the following positions regarding the long-term follow-up of living donors:

- Long-term follow-up of living donors is essential to define the risks and benefits of living donation in order to protect donors and facilitate accurate informed consent
- Research projects using sampled data may provide important information regarding center-specific practices but they will not ensure that quality and compliance data for all centers are captured and addressed. Only a registry collection mechanism can achieve these goals.⁵³

⁴⁸ OPTN Transplant Administrators Committee, *Leadership Meeting*, August 16, 2022.

⁴⁹ Excerpt of OPTN Transplant Administrators Committee's public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, "The Committee did not support this proposal as written and has the following comments for the LDC to consider, Unfunded mandate." (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁰ Excerpt of a community member's public comment on *Proposal to Establish Minimum Requirements for Living Liver Donor Follow-up*, "So, it seems rather punitive to me to ask the transplant programs to cover this financially and then be "blamed" if they cannot get the donors to respond." (Public Comment period September 6, 2013 to December 6, 2013).

⁵¹ Living Kidney Donor Follow-Up Conference Writing Group, Leichtman, A., Abecassis, M., Barr, M., et al. "Living kidney donor follow-up: state-of-the-art and future directions, conference summary and recommendations," *American Journal of Transplant*. 2011 Dec;11(12):2561-8. doi: 10.1111/j.1600-6143.2011.03816.x.

⁵² Abecassis, M., Adams, M., Adams, P., et al. "Live Organ Donor Consensus Group: Consensus statement on the live organ donor," *JAMA*, (2000);284(22), 2919–2926. <https://doi.org/10.1001/jama.284.22.2919>

⁵³ OPTN Board of Directors, *Ad Hoc Living Donor Committee Report to the Board of Directors*, June 26-27, 2003.

In 2012, public comments advocated for longer-term follow-up, with suggestions of utilizing a national living donor registry.^{54,55,56,57,58}

There are now established registries that aim “to collect and analyze information provide through the registration of potential living donors, in an effort to expand the knowledge base of what happens to living donors after living organ donation”.⁵⁹ In order to collect necessary data, the OPTN may need to acknowledge that long-term follow-up of living donors via transplant programs has not been feasible nor will it likely become a feasible avenue to collect long-term data on live organ donors. The Committee recommends the OPTN seek collaborative opportunities for the betterment of the system.

Additionally, a national registry may have the ability to collect data on potential living donors, thus effectively working towards the ability to have a cohort comparison. Follow-up data provided by individuals who were evaluated for organ donation but decided not to donate for non-medical reasons may be able to provide a national comparison group. A national registry may also be able to effectively analyze barriers to living donation, such as insurance coverage⁶⁰, another gap in the current knowledge base.

The Committee notes that logistical issues, such as the process of modifying data collection captured within a national registry, will need to be addressed. However, the Committee further notes that addressing these issues are feasible and the need for long-term data surmounts any accompanying issues in a recommended solution.

The Committee recognizes and supports the OPTN role in monitoring patient safety events in the perioperative period. As such, the Committee is not recommending for the currently required living donor follow-up periods to be changed. The Committee supports the current 6, 12, and 24 month follow-ups as required OPTN data collection through transplant programs.⁶¹ The Committee seeks to continue reviewing compliance rates and ensuring whether the current mandated time frames for follow-up are necessary and valuable.

⁵⁴ Excerpt of a community member’s public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, “We need a prospective registry of living donors now, conceptualized and managed independently from those with professional and commercial interest in transplantation.” (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁵ Excerpt of a community member’s public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, “Transplants recipients have a comprehensive and long-term registry. So do bone marrow donors. Meanwhile, despite international, medical and ethical calls for a living donor registry, living donors have been given the equivalent of a box of band-aids.” (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁶ Excerpt of a community member’s public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, “Also this conversation will stimulate early data on problems that may help to show the definite need for other means of longer term follow up, such as an OPTN national registry with more vigorous funding and data collection.” (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁷ Excerpt of a community member’s public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, “this should be changed to form a living kidney donor registry, set up and run by a group independent of doctors, hospitals and health companies that benefit from this operation.” (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁸ Excerpt of a community member’s public comment on *Proposal to Establish Minimum Requirements for Living Kidney Donor Follow-up*, “I agree and we should collectively work towards a nationally funded program that would provide the resources for life-long followup of the donor after the first few years.” (Public Comment period September 16, 2011 to December 23, 2011).

⁵⁹ “Who We Are”, Living Donor Collective: An SRTR Initiative. Available at <https://livingdonorcollective.org/about-ldc/who-we-are/>.

⁶⁰ 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.

⁶¹ OPTN Living Donor Committee, *Meeting Summary*, September 14, 2022. Available at <https://optn.transplant.hrsa.gov/about/committees/living-donor-committee/>.

Resource constraints remain a logistical concern for long-term living donor follow-up.

The Committee stresses the importance of ensuring that adequate resources for living donor long-term follow-up be provided on a continual and consistent basis. Some of the challenges that transplant programs face in collecting post-donation data would still be true of any entity collecting the data long term. Adequate financial, logistical, administrative resources are necessary regardless whether long-term follow-up of living donors is performed via the OPTN or another entity. A registry may relieve some burden from transplant programs if data is collected directly from living donors, but it may then displace more burden on living donors themselves, a burden that should be minimized.

It is also important to note that living donors at the highest risk of ESRD^{62,63} are also those who are at highest risk for not having complete follow-up.^{64,65} Living donor lost-to-follow-up may remain a challenge even with adequate resources, but the gaps in data could be significantly reduced, and improving long term data collection for living donors could have an important impact on vulnerable populations. Some challenges may be exacerbated in the context of voluntary submission of data compared to mandatory. For a long-term data collection effort to be successful in reducing gaps in data collection, continual adequate resources should be identified.

There are opportunities for increased efficiencies and integration across organizations that support the transplant community.

The Committee supports looking for technological efficiencies and opportunities to collaborate in the context of supporting better health and follow-up care for all living donors. Exploring opportunities for integration across organizations may allow for a more holistic approach to longer-term follow-up. Beyond the effort to granularly review current OPTN living donor data collection, which will be released as a future data collection proposal, potential opportunities identified by the Committee to consider for improved efficiency include:

- Avoidance of multiple entry of living donor data across all data collection systems and forms
- Creation of a process map to visualize all inputs and outputs of living donor data collection and better identify any redundancies

The Committee has discussed opportunities for providing resources to living donors and potential living donors that empower these individuals in navigating post-donation care; this potential resource could support further integration across organizations.

The Committee is also soliciting input from living donors to understand what long-term data they identify as most important. The Committee welcomes OPTN Board of Directors feedback on further suggestions for supporting efficient management of data for living donors long-term.

⁶² Massie, A., Muzaale, A., Luo, X., Chow, E., et al. "Quantifying Postdonation Risk of ESRD in Living Kidney Donors." *Journal of the American Society of Nephrology*: (2017);28(9), 2749–2755. doi: 10.1681/ASN.2016101084.

⁶³ Wainright, J., Robinson, A., Wilk, A., et al "Risk of ESRD in prior living kidney donors," *American Journal of Transplantation*. 2018 May;18(5):1129-1139. doi: 10.1111/ajt.14678.

⁶⁴ Henderson, M., Thomas, A., Shaffer, A., et al. "The National Landscape of Living Kidney Donor Follow-Up in the United States," *American Journal of Transplantation*. 2017 Dec;17(12):3131-3140. doi: 10.1111/ajt.14356.

⁶⁵ Reed, R., Shelton, B., MacLennan, P., et al. "Living Kidney Donor Phenotype and Likelihood of Postdonation Follow-up," *Transplantation*. 2018 Jan;102(1):135-139. doi: 10.1097/TP.0000000000001881.

Broader living donor engagement is necessary.

Central to the Committee's discussions is the necessary need to engage the broader living donor population. The Committee recognizes that what transplant professionals seek in long-term data collection may be different than what living donors find to be important. Engagement and input directly from living donors is imperative in creating a holistic long-term data collection effort. With living donor input, future data collection may help with potential living donor decision-making, as well as post-donation health care.

Additionally, it will be necessary to further engage living donors in order to understand the barriers encountered during follow-up post-donation. As noted earlier, a registry may help with this effort, and some literature has provided initial analyses to understand living donor reported barriers.⁶⁶ Early and continued engagement with a broader population of living donors will lend to a collaborative and meaningful effort to effectively create long-term data collection. The Committee welcomes OPTN Board of Directors feedback on how best to engage a broader population of living donors.

Next Steps

The Committee requests OPTN Board of Directors feedback regarding the core tenets of this report. Following OPTN Board of Directors feedback, the Committee will seek community input on the recommendations contained in this report.

In Spring 2023, the Committee plans on disseminating the recommendations and engaging the transplant community with specific targeted outreach to living donors in order to ensure broader input. The Committee seeks to engage living donors directly in the conversation about long-term follow-up to understand what living donors seek to have collected and further understand burden of longer-term follow-up for living donors themselves. Additionally, the Committee seeks to engage with other relevant stakeholders for input to ensure the efforts to build long-term data collection reflect thoughtful and responsible planning on the part of the organizations that collect the data. Community feedback will help inform future work of the Committee such as policy changes, data collection updates, or guidance documents.

The Committee will continue to collaborate with other OPTN committees and SRTR in reviewing current data collection of OPTN living donor forms to ensure currency, efficiency, and relevancy. This data collection project aims go out for public comment in the fall of 2023.

Conclusion

As charged, the Committee seeks to improve the informed choice of prospective living donors, and the safety, protection, and follow-up of all living donors. Longer-term data collection on living organ donors is needed for improved understanding, informed decision-making, and the protection of all living donors. This report outlines challenges and potential improvements, as well as areas of further community engagement and collaboration. The Committee requests OPTN Board of Directors input for alignment ahead of further steps.

⁶⁶ 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.