U.S. Department of Health and Human Services
Health Resources and Services Administration

REPORT TO CONGRESS

Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation

Executive Summary

During the period covered by this report, fiscal year 2023, the Health Resources and Services Administration (HRSA) supported the nation's solid organ transplantation infrastructure through oversight of the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. Other agencies within the U.S. Department of Health and Human Services supporting the national organ procurement and transplantation system include the Centers for Medicare & Medicaid Services, the National Institutes of Health, and the Centers for Disease Control and Prevention.

The Charlie W. Norwood Living Organ Donation Act, enacted in 2007, requires that "[n]ot later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation." 42 U.S.C. § 273b.

This report offers an overview of developments in living organ donation throughout fiscal year 2023, shedding light on emerging trends and HRSA's proactive measures to enhance the safety and efficiency of this vital practice.

In addition to detailing the current landscape of living organ donation, particularly focusing on kidney-paired donations and the pertinent issue of living donor mortality, the report delves into recent academic research relevant to the field. It presents updates on two key HRSA initiatives: the Living Donor Collective, an ongoing registry overseen by the Scientific Registry of Transplant Recipients to monitor the long-term health outcomes of living donors, and the Living Organ Donation Reimbursement Program, facilitated by the National Living Donor Assistance Center.

Furthermore, the report integrates findings from National Institutes of Health-backed studies investigating the enduring health effects of living organ donation and recent peer-reviewed literature, providing stakeholders with a comprehensive understanding of the evolving landscape and informing future decision-making processes.

Table of Contents

List of Tables

List of Figures

Acronym List

A2ALL	Adult-to-Adult Living Donor Liver Transplantation Cohort Study
APOL1	Apolipoprotein L1
APOLLO	APOL1 Long-term Kidney Transplantation Outcomes
CMS	Centers for Medicare & Medicaid Services
FY	fiscal year
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
KPD	kidney paired donation
KPDPP	KPD Pilot Program
LDC	Living Donor Collective
LDF	living donor follow-up
LDLT	living donor liver transplantation
LKD	living kidney donor
LLD	living liver donor
LODRP	Living Organ Donor Expense Reimbursement Program
MPSC	Membership and Professional Standards Committee
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
OPTN	Organ Procurement and Transplantation Network
SRTR	Scientific Registry of Transplant Recipients

I. Legislative Language

The Charlie W. Norwood Living Organ Donation Act, enacted in 2007, requires that "[n]ot later than 1 year after December 21, 2007, and annually thereafter, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a report that details the progress made towards understanding the long-term health effects of living organ donation." 42 U.S.C. § 273b.

II. Introduction

During the period covered by this report, fiscal year (FY) 2023, the Health Resources and Services Administration (HRSA) is the primary federal agency overseeing of the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR). OPTN maintains the national system to electronically match deceased donor organs to transplant candidates; develops organ allocation policies; and implements policies related to the evaluation, safety, and protection of living organ donors. [1,2,3,4] SRTR analyzes and reports on the extensive data collected by OPTN and the National Institutes of Health (NIH) National Institute of Diabetes and Digestive and Kidney Diseases' U.S. Renal Data System. Other agencies within the U.S. Department of Health and Human Services (HHS) also support the national organ procurement and transplantation system. The Centers for Medicare & Medicaid Services' (CMS) Medicare program is a major payer of organ transplants in the United States and oversees organ procurement organizations and all transplant centers that participate in Medicare. Finally, NIH funds a variety of research in immunology and organ transplantation.

HRSA coordinates with HHS agencies on issues related to organ donation, procurement, and transplantation. In addition, HRSA, through OPTN, oversees transplant centers and organ procurement organizations complementary to the regulatory role of CMS. CMS and HRSA have maintained an information-sharing agreement since 2008, and staff meet regularly to discuss issues related to the coordination of oversight responsibilities for the transplantation system.[5] In 2021, HRSA and CMS established the Organ Transplantation Affinity Group collaborative to strengthen accountability, equity, and performance to improve access to organ donation, procurement, and transplantation for patients, donors, families, caregivers, and providers.

HRSA's work with other HHS agencies creates opportunities for information sharing, transfer, and collaboration on strategies to increase the number and use of organs available for transplant.

---

[1] 42 CFR Part 121 is available at: https://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol1/pdf/CFR-2011-title42-vol1-part121.pdf.
[2] FR 71 34946 is available at https://www.govinfo.gov/content/pkg/FR-2006-06-16/pdf/E6-9401.pdf.
[3] Public Law 110-144 enacted in 2007 is available at: https://www.govinfo.gov/content/pkg/PLAW-110publ144/pdf/PLAW-110publ144.pdf.
[4] 42 U.S.C. section 274e is available at: https://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title42-section274&num=0&edition=prelim
[5] U.S. Government Accountability Office. (April 29, 2008). Organ Transplant Programs: Federal Agencies Have Acted to Improve Oversight, but Implementation Issues Remain. Available at: https://www.gao.gov/products/gao-08-412.

For example, via HRSA's OPTN contractor, HRSA works with the Centers for Disease Control and Prevention to identify issues related to disease transmission through transplantation and works with the U.S. Food and Drug Administration on a variety of transplant-related issues, including donor screening tests for infectious agents and organ perfusion devices to increase the number and quality of transplantable organs.

The OPTN and SRTR contractors during this reporting period both supplied data and analysis used in this report, with additional content from HRSA and NIH.

Additional data and background are available in the OPTN/SRTR 2022 Annual Data Report.[6]

III. Overview

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for many of the more than 103,000 individuals on the national transplant waiting list (as of September 30, 2023), particularly those awaiting a kidney or a liver. Living organ donation has several benefits for transplant recipients, including better outcomes compared to those who receive organs from deceased donors, the enhanced likelihood of optimal transplantation timing through pre-scheduled surgery, and the increased availability of donor organs. The health benefits of living organ donation for the living organ donors are difficult to measure and must be weighed against risks to the donor. However, recent research reported evidence of tangible benefits such as closer relationships with the recipient and family, spiritual and/or religious benefits, preservation of the family unit, involvement in donation advocacy, and a sense of courage, confidence, and resilience.[7]

Short-term health risks associated with living organ donation appear to be minimal; however, limited data are available for long-term (greater than 2 years) health risks. Living organ donation does carry potential physiological, psychological, and economic risks in addition to the medical risks inherent with any surgery. NIH continues to support research and evaluation of the long-term health risks of living organ donation through multi-year clinical research programs. In 2020, HRSA added a task to the SRTR contract to develop and maintain an ongoing registry of living donors to track the long-term outcomes of living organ donation. This report provides information on Living Donor Collective (LDC) activities in FY 2023.

[6] OPTN/SRTR. (2022). Annual Data Report. Available at: https://srtr.transplant.hrsa.gov/annual_reports/2022_ADR_Preview.aspx

[7] Rasmussen, S.E.; Robin, M.; Saha, A.; et al. The Tangible Benefits of Living Donation: Results of a Qualitative Study of Living Kidney Donors. *Transplantation Direct.* 2020; 6: e626. doi: 10.1097/TXD.0000000000001068.

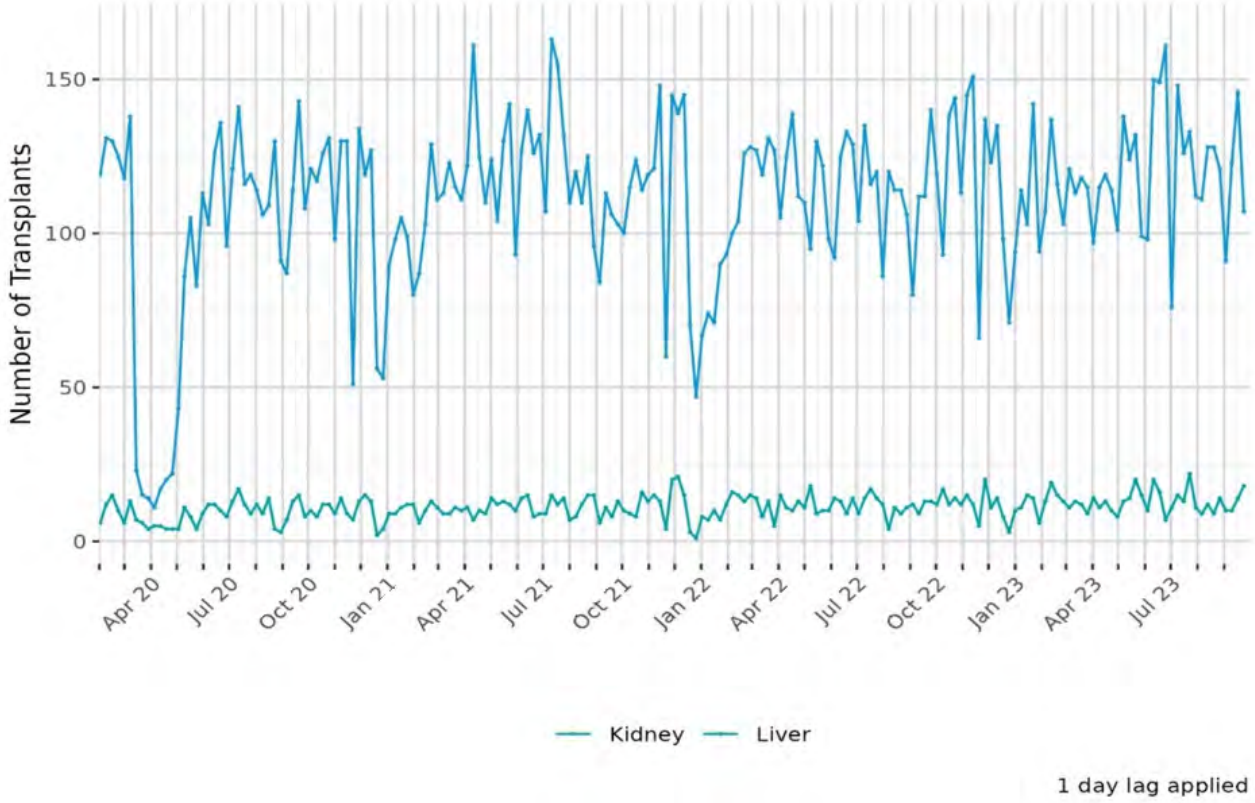
The transplant community is also concerned with the ethical issues that living organ donation raises, including that of informed consent. Assuring that the surgeon and other members of the multi-disciplinary transplant team are knowledgeable about the individual risks, benefits, and potential outcomes of living organ donation is difficult. It is also imperative to determine whether the decision to donate is made freely, with adequate and accurate information, and without coercion. These challenges are inherent for all living organ donors, but the risks and benefits vary by individual and type of organ. To facilitate informed decision-making, HHS supports education for individuals considering living organ donation to ensure they are aware of the risks. In addition, OPTN policy requires the living donor recovery hospital to obtain and document living donor informed consent and provide education to living donors about the risks, benefits, and potential outcomes.[8]

IV. Impact of COVID-19 on Living Organ Donation

The COVID-19 pandemic significantly affected living organ donation in the United States from FY 2019 through FY 2021 and had residual affects to a lesser degree thereafter. As demonstrated in **Figure 1**, transplant programs determined that the risks to living kidney donor (LKD) and kidney candidates (being in the hospital where they may contract the virus) outweighed the benefits of transplantation, leading to a decrease in LKD transplant volume during the early months of the pandemic. In addition to concern for the transmission of SARS-CoV-2 (the virus responsible for causing COVID-19), transplant centers were experiencing staffing challenges and needed to reprioritize transplant team members to care for both transplant and nontransplant patients who were acutely ill. OPTN recognized the risks associated with unnecessary hospital visits for routine living donor follow-ups (LDF) and suspended the LDF form submission requirements (that forms be submitted within 14 days) from March 13, 2020, through March 31, 2021, and provided a single deadline of July 1, 2021, for all forms. While the volume of LKD transplants initially decreased in early 2020, it began to stabilize and the number of transplants in FY 2021 (n=5,932) surpassed the FY 2020 (n=5,538) performance. The number of LKD transplants performed in FY 2023 (n=6,158) surpassed the number of those performed in FY 2022 (n=5,786), FY 2021 (n=5,932), and FY 2020 (n=5,538), but is less than those completed in the pre-COVID year of FY 2019 (n=6,860).

[8] OPTN Policy 14 (Living Donation). (n.d.). Available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

Figure 1: Living Kidney and Liver Donor Transplants from February 2020 – September 2023*



Notes:
*Data Source: Based on OPTN data as of September 30, 2023. Data is subject to change based on future data submissions or corrections.

Despite the adverse effects of the COVID-19 pandemic, during FY 2023, 46,072 transplants were performed using organs from both deceased and living organ donors, representing a 10.5 percent increase from the 41,705 transplants performed during FY 2022. Approximately 85.2 percent (n=39,257) of the FY 2023 transplants involved organs from deceased donors, who usually provide multiple organs for transplantation. Transplants using organs from living organ donors accounted for the remaining 14.8 percent (6,815). The percentage difference between the distribution of deceased organ and living organ donors in FY 2023 was comparable to that in FYs 2019, 2020, 2021, and 2022.

V. Living Organ Donor Trends and Demographics

The number of LKD transplants performed in FY 2023 increased for donors in the 35 to 49, 50 to 64, and 65 or older age groups, but decreased for donors aged 18 to 34. Meanwhile, the number of living liver donor (LLD) transplants in FY 2023 increased for all donor age groups, except for donors younger than 18 years. In FY 2023, female donors represented a larger percentage of LKDs and LLDs (63 percent and 60 percent, respectively), continuing a 20-year trend of more female living donors than males.

A. Living Kidney Donors

Since OPTN began collecting living organ donor data in 1988, the trend in annual numbers of LKDs has fluctuated. The effects of the initial stages of the COVID-19 pandemic likely caused a large decrease in the number of LKD between FY 2019 and FY 2020. The FY 2023 volume (n=6,158) did not reach the total previously achieved in FY 2019. The number of donors increased annually from 1988 to 2004, culminating in 6,665 LKDs involved in transplants. The annual number of LKDs fluctuated from 2005 to 2019, reaching a record high of 6,860 donors in FY 2019.

Demographic trends in living kidney donation during FY 2023 include:

- Biologically related family members received 36.5 percent of living kidney donations.
- A majority of LKDs were younger than 50 (62.3 percent) and female (63.1 percent).
- The second largest group of donors were aged 50 to 64 years old (31.7 percent), with the remaining 6.4 percent aged 65 or older.
- 68.9 percent of LKDs were White, 17.7 percent Hispanic or Latino, 7.0 percent Black or African American, 4.7 percent Asian, 0.3 percent American Indian or Alaska Native, 0.2 percent Pacific Islander, and 1.2 percent multiracial.[9]

B. Living Liver Donors

In FY 2023, the number of LLDs totaled 655, marking an approximate 9.7 percent increase compared to 597 LLDs in FY 2022. Significant annual increases in LLDs occurred from FY 2017 through 2019, with a 34.9 percent overall increase. Although LLDs continued to rise, their growth slowed during the peak of the COVID-19 pandemic, with a 6.8 percent increase from FY 2019 to FY 2020 and a 6.2 percent increase from FY 2020 to FY 2021.

Demographic trends in living liver donation in FY 2023 include:

- Biologically related family members received 47.8 percent of living liver donations.
- The majority of LLDs were younger than 50 years of age (84.1 percent) and female (60.3 percent).
- Approximately 75.9 percent of LLDs were White, non-Hispanic, 15.1 percent Hispanic or Latino, 3.5 percent Black or African American, 3.9 percent Asian, 0.3 percent Pacific Islanders, 0.5 percent American Indian/Alaska Native, and 0.8 percent multiracial.

C. Other Living Organ Donors

Living Pancreas Donors: According to OPTN, transplant centers in the United States have not performed a living donor pancreas-alone transplant since 2008, and the last living donor simultaneous pancreas-kidney transplant in the United States took place in 2013. One factor contributing to the absence of living pancreas donor transplants is the consideration of transplantation of the pancreas as a complex and risky procedure for both the donor and the recipient.

[9] Hispanic or Latino background is not included in the other racial and ethnic categories.

Living Lung Donors: According to OPTN, transplant centers in the United States have not performed a living lung transplant since 2013. The primary factor is because of the morbidity and mortality risk involved for both donor and recipient.

Living Intestine Donors: For some life-threatening conditions, particularly for pediatric patients, living donor intestinal transplants are the most expedient medical solution. OPTN reports only 44 living donor intestinal transplants in the United States since 1990; the last living intestine donation and transplant occurred in 2017.

Living Donors of Vascularized Composite Allografts: Vascularized composite allografts involve transplanting complex anatomical structures composed of multiple tissue types and are most known for hands and face transplants. Continued advancements in research and transplantation have led to the use of uterus transplants from living donors. Transplant professionals reported the first such case to OPTN in 2016. As of September 30, 2023, there have been 24 uterus transplants from living donors: five in 2016, one in 2017, six each in 2018 and 2019, one in 2020, two in 2021, one in 2022, and two in 2023. Notably, two-thirds of uterus transplants from living donors had a slightly improved surgical success rate over uterus transplants from deceased donors. This suggests that the surgeries performed using uteri from living donors were slightly more successful in achieving the desired outcome. However, survival of the graft at 1 year was found to be equivalent between living and deceased donors, showing that although the initial success rate might be slightly higher for living donors, the long-term survival of the transplanted organ was similar regardless of whether the donor was living or deceased.[10]

VI. Kidney Paired Donation Programs

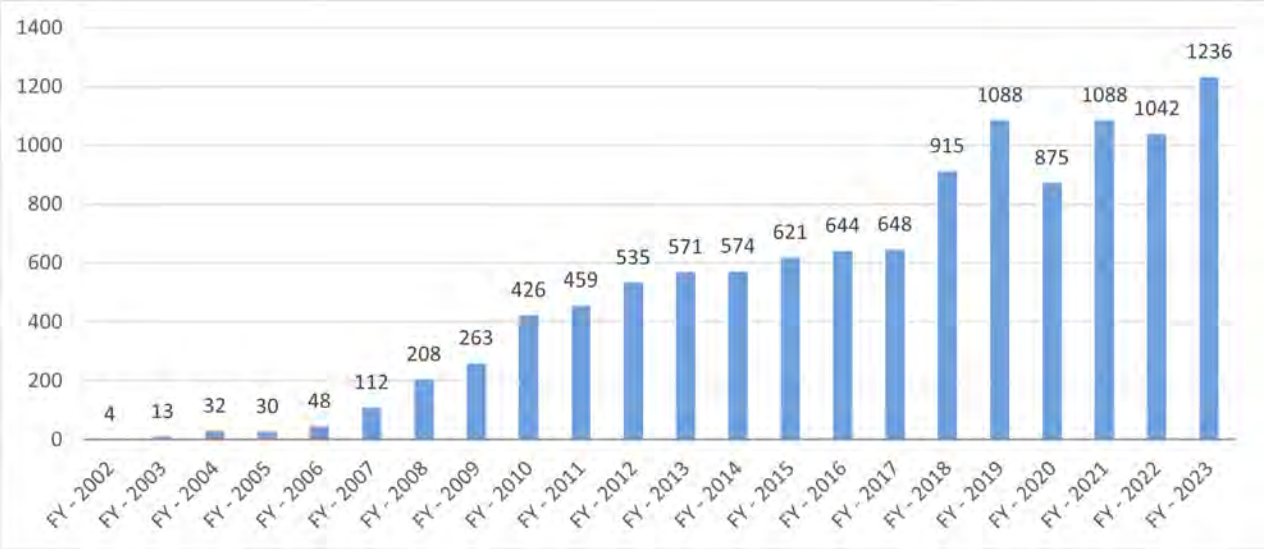
Every year, thousands of transplant candidates with potential LKDs join the national transplant waiting list because they are blood type or human leukocyte antigen incompatible with their potential living donors. This incompatibility represents a lost opportunity for transplant candidates seeking a living donor transplant as well as for the individuals seeking to donate to a specified candidate. Kidney Paired Donation (KPD) programs enable organ exchanges between two or more incompatible transplant candidate/donor pairs to maximize the opportunity for transplantation. The simplest KPD exchange occurs between two candidate/donor pairs. However, multiple pairs can be involved in a cascade (or chain) of exchanges involving three or more pairs. Paired donations are most likely to occur when several incompatible candidate/donor pairs are available. KPD programs focus on identifying matching pairs. In addition to those KPD programs that are sponsored by single transplant hospitals, some programs identify matching pairs among regional or national groups of transplant hospitals. In addition to identifying matched pairs, KPD programs coordinate logistical aspects of the KPD transplant process with transplant centers.

As seen in **Figure 2** below, the number of KPD-facilitated transplants increased annually through FY 2019 until a downturn in FY 2020, followed by an increase in FY 2021, another drop in FY 2022, and an increase in FY 2023. The number of KPD transplants performed in FY 2023 is the highest recorded, with 1,236 KPD transplants representing 20.1 percent of all living donor kidney transplants. The number of KPD transplants performed in FY 2023 represents an 18.6 percent increase over the 1,042 KPD transplants performed in FY 2022.

[10] Slomski, A. Uterus Transplant a Clinical Reality. *JAMA.* 2022 Sep 6; 328(9): 817. doi: 10.1001/jama.2022.14273.

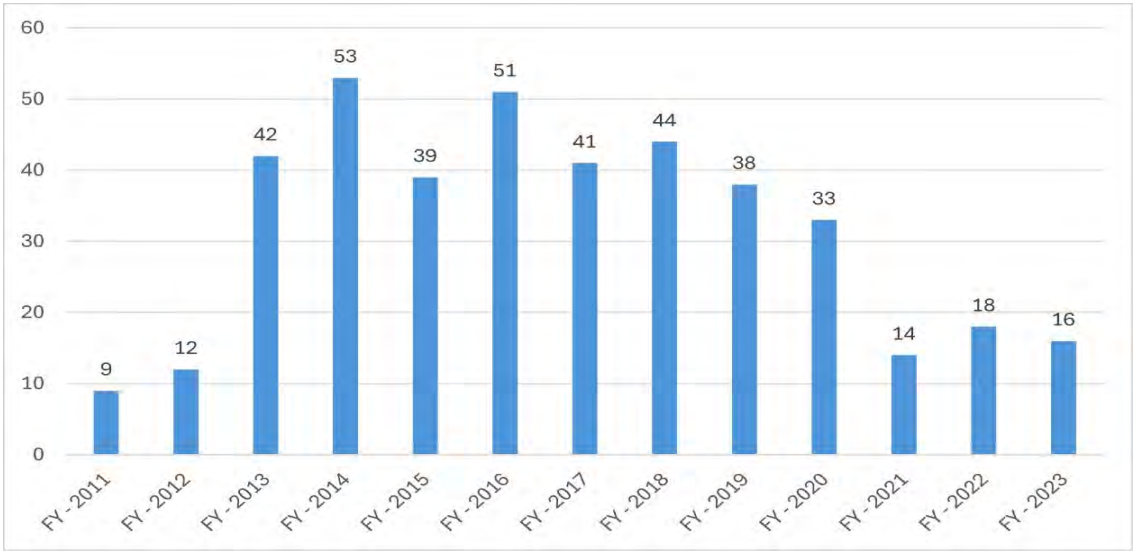
In October 2010, OPTN initiated a KPD Pilot Program (KPDPP) to explore the feasibility of a national KPD program operated by the OPTN to address the challenge of finding suitable pairs. As shown in **Figure 3**, OPTN KPDPP identified and facilitated 410 KPD transplants between October 2011 and September 2023, which represented four percent of all KPD transplants performed during that period. OPTN KPDPP strives to increase opportunities for all transplant candidates to receive a living donor kidney. The program has helped identify matched pairs for extremely hard-to-match candidates who are not matched through other KPD programs.

Figure 2: National KPD Transplants per Year from FY 2001 – FY 2023*



Notes:
*Data Source: OPTN data as of September 30, 2023. Data is subject to change and may differ from previous or future charts based on subsequent data submissions and/or corrections. This data may not include all KPD transplants due to data reporting variation.

Figure 3: Transplants Facilitated by OPTN KPDPP from FY 2011 – FY 2023*



Notes:
*Data Source: OPTN data as of September 30, 2023. Data is subject to change based on future data submissions and/or corrections. This data may not include all KPD transplants due to data reporting variations among transplant centers. A list of transplant centers is available at: https://optn.transplant.hrsa.gov/media/xbtml5mj/optnkpdppcentersbystate.pdf.

VII. Living Organ Donor Deaths and Adverse Events

Aligning with patient safety oversight in transplantation, the transplant professionals closely monitor for deaths and other adverse events related to living organ donation. OPTN's Membership and Professional Standards Committee (MPSC) reviews deaths of living organ donors and other adverse events affecting living organ donors through a confidential medical peer review process. MPSC's review determines if a death or adverse event relates to an OPTN member's failure to comply with federal law, OPTN policies, including whether the event posed a threat to patient safety. If MPSC determines that the member has been non-compliant or if a threat to patient safety exists, it can recommend that the OPTN Board of Directors or, in certain circumstances, the HHS Secretary, act against the OPTN member. Such action often leads to MPSC increasing monitoring and oversight.

A. Living Organ Donor Deaths

Transplant programs are required to report all living organ donor deaths to OPTN within 72 hours of the program becoming aware of the death for 2 years post-donation. Additionally, OPTN must report living organ donor deaths to HRSA within 24 hours of receipt of the information from the transplant programs. Determining if there is a relationship between the living organ donor death and the donation can be difficult, especially as the time between the donation and the donor's death grows. The collected data categorizes living organ donor deaths into groups that reflect the nature of the death (i.e., cancer, suicide, accident, homicide, overdose, medical in nature but not necessarily related to donation, and other/unknown). **Table 1** depicts deaths for LKDs, and **Table 2** shows the number of deaths for LLDs within 2 years of donation. These data show no apparent trends in post-operative mortality for LKDs or LLDs.
Although submission of official LDF data to OPTN was suspended due to the COVID-19 pandemic, the program did not modify the 72-hour requirement for reporting living donor deaths to OPTN. OPTN continued to review all reported living donor deaths as potential patient safety events.

Table 1: LKD Deaths within 2 Years of Donation from FY 2013 – FY 2023*

Year	Medical (not Cancer)	Accident/ Homicide	Suicide	Overdose	Cancer	Other/Unknown	Total
FY 2019	0	4	2	0	0	1	7
FY 2020	0	1	0	3	1	0	5
FY 2021	0	3	1	2	0	1	7
FY 2022	2	1	3	0	0	0	6
FY 2023	0	0	0	1	1	0	2
Total	**2**	**9**	**6**	**6**	**2**	**2**	**27**

Notes:
*Data Source: OPTN data submitted to the OPTN Improving Patient Safety system as of September 30, 2023. Data is subject to change based on future data submissions and/or corrections.

Table 2: LLD Deaths within 2 Years of Donation from FY 2013 – FY 2023*

Year	Medical (not Cancer)	Accident/ Homicide	Suicide	Overdose	Cancer	Other/ Unknown	Total
FY 2019	0	0	0	0	0	0	0
FY 2020	0	0	0	0	0	1	1
FY 2021	1	0	0	0	0	0	1
FY 2022	0	0	1	0	0	0	1
FY 2023	0	0	0	0	0	0	0
Total	**1**	**0**	**1**	**0**	**0**	**1**	**3**

Notes:
*Data Source: OPTN data submitted to the OPTN Improving Patient Safety system as of September 30, 2023. Data is subject to change based on future data submissions and/or corrections. Excludes domino liver donors (individuals who undergo necessary organ transplantation, but whose native organ is suitable for transplant to another person).

B. Living Organ Donor Complications

When transplant hospitals perform living organ donor transplants, they are required to report any complications (unfavorable evolution or consequence of a disease, a health condition, or a therapy) encountered by the living organ donor to OPTN. To enable more accurate data collection and better capture of incidents related to surgery, but delayed in presentation, hospitals complete this report either at discharge or up to 6 weeks post-donation, whichever occurs first. **Table 3** depicts the incidence of reported complications in living organ donation for LKDs and LLDs.

Table 3: Living Kidney and Liver Donor Complications Reported to OPTN from FY 2021 – FY 2023*

	FY 2021	**FY 2022**	**FY 2023**
Living Kidney Donor Complications	LKDs (n=5,934)	LKDs (n=5,785)	LKDs (n=6,158)
Vascular complications requiring intervention	16 (0.3%)	9 (0.2%)	14 (0.2%)
Other complications requiring intervention	124 (2.1%)	113 (2%)	101 (1.6%)
Living Liver Donor Complications	LLDs (n=546)	LLDs (n=591)	LLDs (n=649)
Biliary Complications	17 (3.1%)	15 (2.5%)	16 (2.5%)
Vascular complications requiring intervention	4 (0.7%)	6 (1%)	4 (0.6%)
Other complications requiring interventions	13 (2.4%)	39 (6.6%)	31 (4.8%)

Notes:
*Data Source: OPTN data are current as of September 30, 2023. These figures exclude domino liver donors. As a result, the numbers here are smaller than the numbers reported earlier in this report. For a definition of domino liver donors, see Table 2 notes.

C. Living Organ Donor Adverse Events

OPTN policy requires hospitals performing living organ donor transplants to report certain living organ donor adverse or unanticipated events related to the donation surgery to OPTN for review. As shown in **Table 4**, the most common adverse events reported to OPTN between FY 2020 and FY 2023, were halted living organ donation procedures. This is a situation in which a living donor recovery procedure is halted after the donor begins receiving general anesthesia, but prior to organ recovery.[11] Other reported adverse events include living donor death and redirection of the living donor organ to an unanticipated recipient.

Table 4: Living Organ Donor Adverse Events Reported by OPTN Members from FY 2021 – FY 2023*

Living Organ Donor Events	FY 2021	FY 2022	FY 2023
Halted Procedure	21	25	25
Death	8	7	2
Native Organ Failure	0	0	0
Redirection	2	1	7
Other	4	8	4
Total	**35**	**41**	**38**

Notes:
*Data Source: OPTN data are current as of September 30, 2023, and combined across living organ donors. OPTN policy requires recovery hospitals to report living donor deaths within 2 years of donation, LLDs listed on the liver waiting list within 2 years of donation, and LKDs listed on the kidney waiting list or beginning regularly administered dialysis for end-stage renal disease within 2 years of donation. Recovery hospitals are also required to report halted procedures, redirection of living donor organs to someone other than the intended recipient and living donor organs recovered but not transplanted.

VIII. Data Collection and Research on the Long-Term Effects of Living Organ Donor Donation

HRSA supports both data collection and research on the long-term effects of living organ donation with the goal of understanding and minimizing the health risks faced by living organ donors. NIH supports research on the long-term health implications of living organ donation.

A. HRSA-Supported Activities

[11] Diwan, D.; Singh, P. Anesthesia for Transplant Surgery. Updated 2023 Jan 29. In: StatPearls [Internet]. Treasure Island (FL). Available at: https://www.ncbi.nlm.nih.gov/books/NBK572086/.

OPTN LKD Follow-up Data: Per OPTN policy and federal data submission requirements, living organ donor transplant programs submit follow-up data on their living organ donors for 2 years following donation. Living donor transplant programs often report LKDs as "lost to follow-up" if the center is unable to contact the donor for current information, leading to forms having missing or incomplete data. In calendar years 2013 and 2014, OPTN revised its approved policies and subsequent data collection forms to improve and expand the reporting of follow-up data, as detailed in prior annual reports.[12,13] **Figure 4** illustrates the effectiveness of the 2013 and 2014 LKD policies on the collection of 6-month follow-up data from FY 2013 through FY 2022. To incentivize follow-up attempts, researchers are examining efforts, including using financial incentives and implementing mobile health technologies.[14,15]

The FY 2023 results are similar to those in FY 2022 for both clinical and laboratory data and continue to represent a marked improvement in collection over pre-2013 data, which preceded the new policies. In the FY 2023 cohort, approximately 81.3 percent of LKDs had timely 6-month clinical data reported, and 76 percent had timely laboratory data reported.

Figure 4: Percent of LKDs with Timely Clinical and Laboratory Data on 6-Month LDF Forms Completed from FY 2013 – FY 2023*

Notes:

[12] HRSA uses both calendar year and FY throughout this report to accurately reflect information shared by OPTN, which uses both orientations in tracking and sharing certain data for ease of consumption across the transplantation community.

[13] OPTN. (n.d). Procedures to collect post-donation follow-up data from living donors. Available at: https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/procedures-to-collect-post-donation-follow-up-data-from-living-donors/#exec.

[14] Henderson, M; et al. (2019). 307.3: Do financial incentives improve patient compliance with living donor follow-up? An analysis of a pilot randomized controlled trial. *Transplantation*. 103(11S), S62-S63. doi: 10.1097/01.tp.0000611896.31898.89.

[15] Eno, AK et al. (2019). Perspectives on implementing mobile health technology for living kidney donor follow- up: In-depth interviews with transplant providers. *Clinical Transplantation*. 33(8), e13637. doi: 10.1111/ctr.13637.

*Data Source: OPTN data as of September 30, 2023. Data is subject to change based on future data submissions and/or corrections. Timely data submission defined in OPTN policy 18.5.B is available at: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

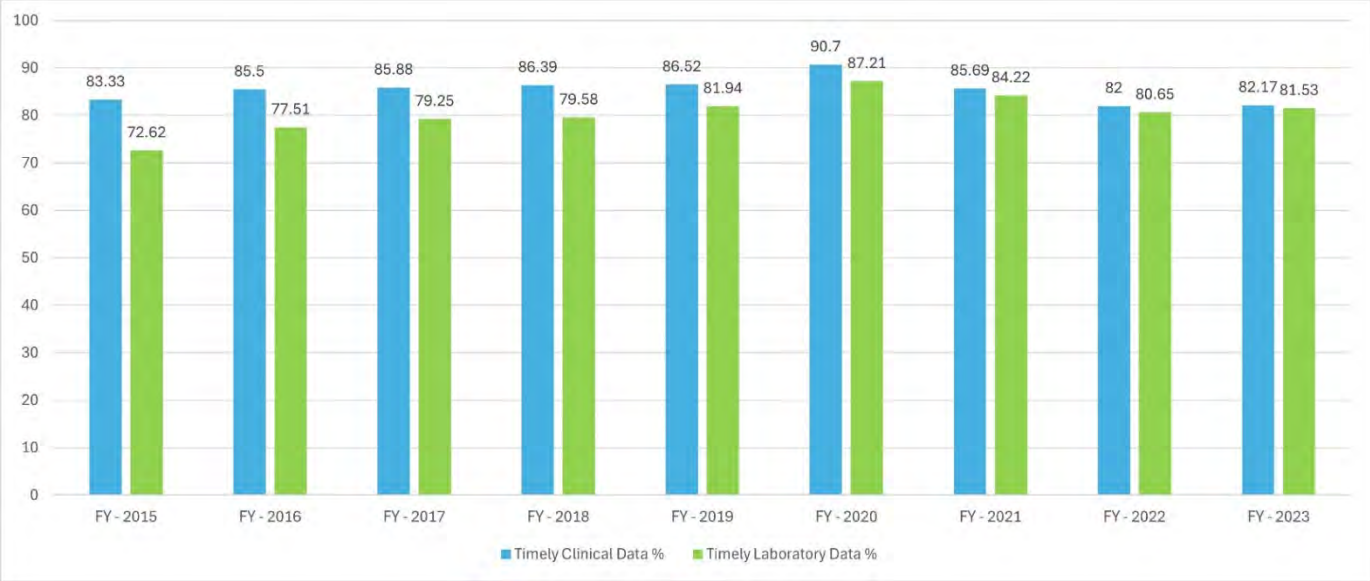
Data are also available for the 2-year follow-up requirements. OPTN reported the following post-donation outcomes for LKDs from FY 2019 through FY 2021, at the 2-year follow-up which would have occurred from FY 2021 through FY 2023:

- 68.8 percent of LKDs were employed at the time of their 2-year follow-up.
- 9.3 percent of LKDs reported a positive urine test, indicating the presence of protein consistent with abnormal kidney function within 2 years of donation.
- 3.1 percent of LKDs developed hypertension requiring medication by the time of their 2-year follow-up.
- 0.5 percent of LKDs lost insurance due to donation at the time of their 2-year follow-up.
- 0.2 percent of LKDs developed diabetes by the time of their 2-year follow-up.
- No LKDs were reported to be added to the transplant candidate waiting list within 2 years of donation.

OPTN LLD Follow-up Data: Follow-up data for LLDs have similar limitations as those collected for LKDs, with LLDs reported as "lost to follow-up" if the transplant program was unable to contact the donor for current information. OPTN implemented new policies in FYs 2014 and 2015 to improve reporting of LLD clinical and laboratory follow-up data used to determine patient status, liver complications, or liver failure. These policies promote living organ donor safety by improving OPTN collection of data about the outcome of living liver donation and were detailed in prior annual reports.

Figure 5 illustrates the increase in national rates of timely clinical data from the FY 2015 LLD cohort (83.3 percent) to the FY 2020 cohort (90.7 percent), with a decrease to 82.0 percent in FY 2022 and a slight increase to 82.2 percent for the FY 2023 cohort. There was also an increase in timely laboratory data from FY 2015 (72.6 percent) to the FY 2020 cohort (87.2 percent), with a decrease to 81.5 percent for the FY 2023 cohort.

Figure 5: Percent of LLDs with Timely Clinical and Laboratory Data on 6-Month LDF Form from FY 2015 – FY 2023*



Notes:
*Data Source: OPTN data as of September 30, 2023. Timely data submission defined in OPTN policy 18.5. Available at: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Data is subject to change based on future data submissions and/or corrections.

Most LLDs report no complications during follow-up visits. A review of the 2-year follow-up data for LLDs recovered between FY 2019 through FY 2021, which would have occurred from FY 2021 through FY 2023, reveals:

- 93.1 percent reported zero complications, 6.1 percent reported one complication and 0.8 percent reported two complications during follow-up visits within 2 years of donation;
- 80.2 percent of LLDs were employed by their 6-month follow-up visit;
- 7.6 percent reported a hospital readmission within 2 years of donation with the majority reporting these admissions at the 6-month follow-up visit;
- 5.4 percent reported an emergency room or urgent care visit within 2 years of donation, with the majority reporting these visits at the 6-month follow-up visit;
- 0.7 percent (n=11) of LLDs reported losing their insurance within 2 years due to donations, and;
- No LLDs were reported to be added to the transplant candidate waiting list within 2 years of donation.

B. SRTR's Living Donor Collective

SRTR completed the pilot phase of the LDC and had three publications detailing the results of this effort.[16,17,18] Subsequently, SRTR has worked on the recruitment of additional programs to participate in the LDC. Recruitment efforts have included presentations at OPTN regional meetings, newsletters, social media posts, and presentations by directors at conferences and webinars.[19] In addition, SRTR has conducted introductory meetings with staff at several programs.

The pilot experience, conversations with program staff, and a recent survey identify challenges for transplant program participation in the LDC. Program data submission (focused on candidate registration and the donation decision form) is currently voluntary. Many programs have expressed that collecting additional data for the LDC to be difficult to carry out, especially during the COVID-19 pandemic. A published survey recently quantified transplant program staff perceptions regarding barriers and facilitators to LDC participation.[20] Some programs may consider joining the LDC in the future when pathways for participation become more efficient and streamlined.

Recognizing these challenges, the LDC formalized a new Program Management Plan. This plan includes a new organizational structure with the addition of an operations director to work with the scientific director; a well-defined leadership committee, including new deputy directors to augment resources for program onboarding and donor/donor candidate engagement and retention in follow-up; formalized strategic planning; and creation of project charters. In addition to formalizing robust processes, the focus for the new FY will include re-engaging with pilot sites to introduce the current team; reviewing every current site's pattern and currency of data submission; and assisting in education and support of transition teams at sites, if needed and identified.

SRTR has taken several steps to ease the burden of data collection for programs participating in the LDC. SRTR is making efforts to facilitate electronic batch uploads of registration data by programs. SRTR is working with the software company MedSleuth, Inc. MedSleuth, Inc. has developed a digital platform called BREEZE™ that allows living donor candidates to enter data for transplant program evaluations themselves.[21] SRTR, in turn, has developed a template that allows programs to upload these data to the LDC. Some data collected as part of the registration process can be exported from BREEZE™, thereby easing the burden of data collection for programs. Complexities include the need to filter BREEZE™ records for cases that meet the definition of LDC donor candidates and supplement them with additional information in the new FY. The LDC is testing and validating this system with Saint Louis University, including an assessment of the degree of data capture. If successful, the tool may be offered to other BREEZE™ programs.

---

[16] Kasiske, B.L.; Ahn, Y.S.; Conboy, M.; et al. Outcomes of living kidney donor candidate evaluations in the Living Donor Collective pilot registry. *Transplantation Direct.* 2021;7(5):e689. doi: 10.1097/TXD.0000000000001143.
[17] Ibid.
[18] Kasiske, B.L.; Lentine, K.L.; Ahn, Y.; et al. OPTN/SRTR 2020 Annual Data Report: Living Donor Collective. *American Journal of Transplantation*. 2022;22(Suppl 2):553-586. Available at: https://doi.org/10.1111/ajt.16983.
[19] Lentine, K.L., Snyder, J.J. Optimizing Living Donor Follow-Up in Contemporary Practice: Overcoming Barriers with Innovative Solutions. Living Bank Webinar. Available at: https://livingbankwebinars.inreachce.com/Details/Information/f7a59b10-f952-41c8-afb4-e4f500e47ac7.
[20] Lentine, K.Ll; Dew, M.A.; Xiao, H.; et al. Factors Enabling Transplant Program Participation in The Scientific Registry of Transplant Recipients (SRTR) Living Donor Collective: A National Survey. *Clinical Transplantation.* 2023:e14908. doi: https://doi.org/10.1111/ctr.14908.
[21] Med Sleuth, Inc. website is available at: https://www.medsleuth.com.

Similarly, SRTR is exploring the creation of a similar tool with the National Kidney Registry.[22] In addition to a highly successful paired-exchange program, the National Kidney Registry has a data collection platform called the Donor Automated Screening & History. The Donor Automated Screening & History is an online platform for living donor candidate registration and tracking. Progress to date has focused on data use agreements but will advance to some development in the coming FY.

Finally, SRTR has been working with OPTN to harmonize the data collected by the LDC and OPTN for living donor candidates who go on to become donors. The OPTN Living Donor Committee formed a work group made up of donors, program representatives, and members of the OPTN Data Advisory Committee, with support from SRTR and the United Network for Organ Sharing. The findings of this work group are discussed in more detail within Section IX of this report.

The OPTN Living Donor Committee is now considering a project to work on ways to synergize with the LDC to collect the data the community needs in an efficient, collaborative manner.[23] Patient feedback from the July 2022 Task 5 consensus conference speaks to the vital importance of continuing these efforts.[24]

C. NIH-Supported Research on the Long-Term Health Effects of Living Organ Donation

NIH provides financial support for research aimed at improving our understanding of the long-term health implications of living organ donation. While these studies hold great potential, they also face several challenges. These challenges include the need to track donors over extended periods, identify and recruit suitable participants, establish and manage an appropriate control group, and ensure effective long-term follow-up. Addressing these challenges is essential to advancing our understanding of this important issue.

NIH Apolipoprotein L1 Long-Term Kidney Transplantation Outcomes Initiative: Black or African Americans have an increased risk of developing end-stage kidney disease compared to non-African American populations. NIH research identified *APOL1* (Apolipoprotein L1) gene variants that may partially explain why kidney disease progresses faster among people who are Black or African American than in those who are White, Non-Hispanic. To improve safety in living kidney donation and outcomes for all kidney transplant recipients and increase knowledge of *APOL1* effects in transplantation, the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute on Minority Health and Health Disparities, and the National Institute of Allergy and Infectious Diseases funded the *APOL1* Long-Term Kidney Transplantation Outcomes (APOLLO) study, which uses data collected by OPTN and study sites. The primary objective of APOLLO is to determine whether the presence of *APOL1* renal high-risk genotypes in deceased

[22] National Kidney Registry website is available at: https://www.kidneyregistry.org.
[23] OPTN Living Donor Committee. (n.d.). Concepts for a Collaborative Approach to Living Donor Data Collection. Concept paper. Available at: https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/concepts-for-a-collaborative-approach-to-living-donor-data-collection/.
[24] Hunt, H.F. 2022 SRTR Task 5 Consensus Conference Day 3 Part 2. Transplant Metrics. Patients and Living Donors Breakout Report by Heather Hunt, JD. Time stamp 31:50 - 35:10: Available at: https://www.youtube.com/watch?v=GsX-nRmU5oA&list=PLLcpJ_RhfYAAc3ck_ssB_LP0llshGon8Y&index=9.

donors is associated with decreased recipient renal allograft survival. Study enrollment began in 2019, and by the end of 2023, the study enrolled over 3,700 deceased donors (via consent from donor's next of kin), which resulted in more than 6,700 kidney transplant recipients for follow-up. The APOLLO study results could increase the use of *APOL1* low-risk genotype deceased donor kidneys, leading to more kidney transplants, improved quality of life for recipients, and reduced health care costs.

Long-term Effects on Living Liver Donors: The Adult-to-Adult Living Donor Liver Transplantation Cohort Study (A2ALL), supported by NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), researched LLD transplantation to facilitate an understanding of the short- and long-term effects of transplantation on the donor and recipient and to gain insight into liver regeneration and other biological processes unique to the LLD procedure. The study identified factors that influence outcomes for both living donors and recipients by comparing the outcomes of these patients to a cohort that received livers from deceased donors. The study determined the short- and long-term health and quality of life impacts of donation, standardized and assessed the role of informed consent, and assessed motivations of LLDs. This assessment determined that certain personality traits predispose individuals to donate. The study correlated donor satisfaction with measurable outcomes. A2ALL represents the largest and longest study of LLDs in the United States. Comprehensive reports from the A2ALL study have helped inform the transplant community and served as a benchmark for future interventions and strategies that measure and reduce risks to donors and recipients alike. Specimens and datasets from the A2ALL study continue to be made available for research through the NIDDK Central Repository.[25]

Additionally, the NIDDK released a funding opportunity in FY 2023 to support research on organ and tissue donation among populations that experience health disparities.[26] For example, one study in people with end-stage liver disease and of potential living liver donors is assessing multi-level barriers contributing to racial disparities in access to donation and transplantation.[27]

IX. OPTN Policy Development and Guidance

OPTN develops policies regarding the safety and protection of living organ donors which guide the monitoring of member compliance by OPTN. Members of the transplant community participate in the OPTN policy development process. This participation occurs through OPTN committee and board meetings and includes an OPTN public comment process. The OPTN policy-making process enables OPTN to receive input from a range of stakeholders, including members, transplant professional organizations, organ donation and transplantation professionals, transplant recipients, donors and their families including living organ donors, before finalizing policies. HRSA's role is one of oversight to ensure compliance with statutes, regulations, and OPTN contract requirements.

[25] More information about A2ALL is available at: https://repository.niddk.nih.gov/studies/a2all1/.
[26] https://grants.nih.gov/grants/guide/rfa-files/RFA-DK-22-003.html
[27] Gordon, Elisa J. Assessing Multi-Level Barriers to Racial Equity in Living Liver Donation study is available at: https://reporter.nih.gov/search/GCPqnXALD0Ghh-1csc7uOg/project-details/10730834

As mentioned in Section VIII, B of this report, the OPTN Living Donor Committee supports the development of OPTN policy and guidance related to the donation and transplantation of organs from living donors. As noted in previous reports, the Living Donor Committee supports increased efforts to determine long-term living donor outcomes and continues to explore opportunities to improve long-term data collection. In late 2021, the Living Donor Committee continued discussing the topic of long-term living organ donor follow-up and developed a report to the OPTN Board of Directors that summarized their deliberations.[28]

The Living Donor Committee presented and discussed this report during the OPTN Board of Directors' meeting in December 2022. The OPTN Board of Directors supported the Living Donor Committee's findings and recommendations. Thus, the Living Donor Committee continued forward with determining a project that would address long-term LDF. At the beginning of 2023, the Living Donor Committee concluded that a project to require transplant programs to report data to OPTN on living donor candidates would be most impactful. This project requires collaboration with the SRTR. SRTR is tasked with managing and expanding LDC, a national living donor registry. OPTN requires the collection and reporting of living donor candidate and donation decision data, which it shares with LDC to establish a foundation that enables the Living Donor Committee to directly follow up with living donor candidates and living donors long-term on a national level. The Living Donor Committee determined it important to collect data on living donor candidates because it will allow for an appropriate comparator group as well as provide analysis on barriers and access to living donation. This framework of collecting data on living donor candidates builds off LDC's structure. Therefore, the Living Donor Committee's intention with this collaborative approach is to increase efficiency, reduce redundancy, and acquire key data that the transplant and living donor communities deem important.

During the first half of 2023, the Living Donor Committee developed the concepts for this project and published a concept paper for public comment. The concept paper detailed a future state of living donor data collection. The Living Donor Committee requested feedback on the potential future state of living donor data collection and the role of OPTN under this collaborative approach. The public comment period started on July 27, 2023, and ended on September 19, 2023. The Living Donor Committee received support from the community regarding the concepts as well as constructive feedback on how to operationalize them.

X. Living Organ Donor Financial Assistance

HRSA's Living Organ Donation Reimbursement Program (LODRP), authorized per 42 USC § 274f (reimbursement of qualified travel and subsistence expenses incurred toward living organ donation), provides financial assistance to individuals wishing to be living organ donors.[29] Qualified expenses include reimbursement of travel, lost wages, and dependent care (childcare and eldercare) expenses related to the donor's evaluation, surgery, and follow-up visits. The travel expense reimbursement covers transportation, lodging, and meals for the donor and a support person on evaluation, donation surgery, and follow-up trips to the transplant center for up to 2 years after the donation surgery. HRSA administers the program through a cooperative agreement with the University of Kansas,

[28] OPTN. (n.d.). OPTN Living Donor Committee. Meeting Summary, December 14, 2022. Available at: https://optn.transplant.hrsa.gov/media/rfcbsr5w/20221214_ldc_summary_final.pdf.
[29] A description of the LODRP application process and downloadable application worksheets are available at https://www.livingdonorassistance.org/How-to-Apply/Application-Process.

School of Medicine, which partnered with a multidisciplinary team of transplant professionals to operate this national program through the National Living Donor Assistance Center.

Funds are available to donors through LODRP only if funding is not available from any state compensation program, any insurance policy, any federal or state health benefits program, any entity that provides health services on a prepaid basis, or the recipient of the organ. LODRP bases eligibility on both the recipient's and donor's household incomes. The income eligibility threshold is 350 percent of the Federal Poverty Guidelines.[30] If the recipient's income qualifies, but the donor's income is above the income eligibility threshold, then the donor may have to show financial hardship. The donor hardship requirement is responsive to the statutory requirement that the Secretary give preference to individuals who are unable to pay for qualified expenses. Similarly, if the recipient's income is above the income eligibility threshold, the donor may still be eligible for assistance if the recipient can show financial hardship.

In FY 2023, 378 transplant programs in the United States participated in LODRP. During that time, as demonstrated in **Table 5**, LODRP received 2,346 applications for assistance, of which 2,128 (90.7 percent) met LODRP eligibility guidelines. LODRP facilitated more than 1,400 living organ transplants and provided over $6.1 million in financial assistance. The median household income of the transplant recipients was $44,668, and the donors' median household income was $80,200.

[30] ASPE. (n.d.). 2023 Poverty Guidelines: 48 Contiguous States (all states except Alaska and Hawaii). Available at: https://aspe.hhs.gov/sites/default/files/documents/1c92a9207f3ed5915ca020d58fe77696/detailed-guidelines-2023.pdf .

Table 5: LODRP Data Summary from FY 2017 – FY 2023*

Fiscal Year	Total Applications	Applications Approved	Percentage (%)	Surgeries completed	Total Funds Spent	Donor Income Median	Recipient Income Median
2019	1,039	894	86.0%	583	$2,103,257	$45,000	$28,015
2020	870	764	87.8%	464	$1,680,694	$50,489	$29,140
2021	1,459	1,302	89.2%	860	$3,657,324	$52,669	$34,658
2022	1,987	1,803	90.7%	1,111	$4,599,655	$57,010	$36,275
2023	2,346	2,128	90.7%	1,418	$6,107,448	$80,200	$44,668

Notes:
*Data Source: National Living Donor Assistance Center on February 29, 2024.

XI. Key Literature on Living Organ Donation

This section reports on scientific and medical literature that influenced living organ donation policy development and discussions and includes information on trending topics being monitored such as risk variants in the *APOL1* gene, implications of drugs for the Hepatitis C Virus, and other areas of significance that may potentially impact the long-term effects of living donor donation.

A. Factors Enabling Transplant Program Participation in the SRTR LDC: A National Survey

To better understand facilitators and barriers to transplant center participation in SRTR LDC, researchers electronically surveyed United States transplant program staff (October 26, 2021, to December 17, 2021).[31] The study analyzed 132 responses, with at least one response from 87 living donor programs (46 kidney programs, 33 kidney and liver programs, and eight liver programs alone), and was published in 2023. Among the findings, 86 percent of program representatives agreed or strongly agreed that adequate funding to cover the cost of data collection would facilitate LDC participation; 92 percent agreed or strongly agreed with the importance of electronic data submission options; and 74 percent reported that elimination of requirements to submit duplicative preoperative information to OPTN would be helpful. Other potentially enabling factors include reduction in duration of OPTN post-donation follow-up requirements, ease-of-use, protection from data use for regulation, adequate data security, and equity in data access. This survey study identified actions and goals to strengthen participation in the effort to create a national living donor registry in the United States, including that collaboration and investment to overcome barriers to LDC participation among transplant programs are vital to generate long-term data on living donation for donor candidates, donors, and patients in need of transplant.

[31] Lentine, K.L.; Dew, M.A.; Xiao, H.; et al. Factors Enabling Transplant Program Participation in The Scientific Registry of Transplant Recipients (SRTR) Living Donor Collective: A National Survey. *Clinical Transplantation.* 2023:e14908. Available at: https://doi.org/10.1111/ctr.14908.

B. Temporal Trends in KPD in the United States: 2006-2021 OPTN Database Analysis

KPD is rapidly becoming a leading form of living donor kidney transplant. A study published in 2023 analyzed data from OPTN (2006 to 2021) to track evolving trends in KPD.[32] The practice of KPD is on the rise, with one out of every five living donor kidney transplants in 2021 facilitated through this method. The use of KPD in living donor kidney transplants is similar among both non-White and White populations. Moreover, there is a notable increase in the proportion of KPD transplants allocated to non-White recipients. However, the OPTN database does not identify end-chain recipients (i.e., donations from KPD living donor chains to the deceased donor waiting list), making it unclear whether these trends solely reflect changes in kidney allocation or an actual surge in living donation among minorities. In 2021, 40 percent of the programs reported no KPD transplants, underscoring the importance of understanding the obstacles hindering the adoption and expansion of KPD at the center level. Additionally, this study illustrates the pressing need for more comprehensive and precise data collection related to KPD at the national level.

C. The Effect of a Merit Point Incentive System on the Willingness to Donate Organs

Researchers conducted an electronic survey study among undergraduate students who volunteered at a university in the midwestern United States (distribution March 2022 and September 2022).[33] The survey aimed to gauge the viewpoints of young adults regarding their inclination to donate organs, especially when merit points potentially prioritize their family members for transplants, if necessary. Out of the 572 participants who completed the survey, the inclination to donate organs while alive to a family member was notably higher compared to donating to a stranger, with percentages standing at 95.8 percent and 71.2 percent, respectively ($P < .0001$). With the introduction of merit points, the reluctance to provide a living donation to a stranger decreased significantly from 28.8 percent to 16.4 percent ($P < .0001$). These findings suggest that the implementation of a merit point system may reduce the reluctance to act as living donors to strangers. Further exploration with larger sample sizes could shed light on whether adopting a merit points system in the United States could potentially increase organ donation rates, including those for living donation.

[32] Garg, N.; Thiessen, C,; Reese, P.P.; Cooper, M.; Leishman, R.; et al. Temporal Trends in Kidney Paired Donation in the United States: 2006-2021 UNOS/OPTN Database Analysis. *American Journal of Transplantation.* 2024;24(1):46-56. Available at: https://doi.org/10.1016/j.ajt.2023.09.006.

[33] Nazzal, M.; Engelhardt, A.; Hallcox, T.; Van Gorp, L.; Parrish, P.; et al. The Effect of a Merit Point Incentive System on the Willingness to Donate Organs. *Transplantation Proceedings.* 2023;55(10):2326-2332. doi: 10.1016/j.transproceed.2023.09.023.

D. Long-Term Outcomes for LKDs With Early Guideline-Concordant Follow-up Care: A Retrospective Cohort Study

Current guidelines recommend that LKDs receive lifelong annual follow-up care to monitor kidney health. In the United States, the reporting of complete clinical and laboratory data for kidney donors has been mandated for the first 2 years post-donation; however, the long-term impact of early guideline-concordant care remains unclear. This retrospective cohort study, using linked healthcare databases, examined the long-term follow-up care and clinical outcomes of LKDs in Alberta, Canada.[34] The study compared donors who received early guideline-compliant follow-up care (consisting of yearly physician visits and measurements of serum creatinine and albuminuria during the first 2 years post-donation) with those who did not. Among 460 donors studied, 187 (40.7 percent) received guideline-compliant follow-up care consistently during the first 2 years post-donation. Donors without early guideline-compliant care had significantly lower odds of receiving annual follow-up at 5 years (adjusted odds ratio [aOR] 0.18-0.32) and 10 years (aOR, 0.23-0.46) compared to those with early care. The likelihood of continued follow-up remained consistent for both groups over time. However, early guideline-compliant care did not seem to significantly affect estimated glomerular filtration rate or rates of hospitalization over the long term. These data suggest that additional strategies beyond 2-year monitoring may be necessary to mitigate long-term donor risks.

XII. Conclusion

In conclusion, despite the positive increase in deceased organ donation and transplants, the persistent demand for organs exceeds the available supply, highlighting the critical importance of living organ donation in saving lives. The impact of the COVID-19 pandemic on elective living kidney donations led to a notable decline, but efforts to encourage support for donors, enhance monitoring of transplant hospitals and procedures, and conduct research, are ongoing to optimize living organ donation.

In the area of kidney-paired donation, FY 2023 saw ongoing policy developments by OPTN to streamline operations and broaden parameters for informed consent among participants. LODRP saw a significant increase in applications, disbursing over $6.1 million in financial assistance and facilitating more than 1,418 living organ transplants.

Although FY 2023 saw a slight decrease (1.5 percent) in transplants using living donor organs compared to the previous year, HRSA remains steadfast in its commitment to educating the public about this vital option for the, more than 100,000, individuals on the national transplant waiting list while also striving to bolster safety measures for all living organ donors. These collaborative efforts highlight the ongoing dedication to enhancing access to transplantation and safeguarding the well-being of donors and recipients alike. Reflecting on the accomplishments and challenges of FY 2023, it is evident that collaborative efforts, reinforced by a shared commitment to advancing organ donation, procurement, and transplantation, will continue to serve as the cornerstone of future progress in this vital healthcare field.

---

[34] Dhalla, A.; Lloyd, A.; Lentine, K.L.; Garg, A.X.; Quinn, R.R.; Ravani, P.; et al. Long-Term Outcomes for Living Kidney Donors with Early Guideline-concordant Follow-up Care: A Retrospective Cohort Study. *Canadian Journal of Kidney Health and Disease.* 2023;10:20543581231158067. Available at: https://doi.org/10.1177%2F20543581231158067.

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Brett Guthrie
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Guthrie:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients (SRTR). HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Bernie Sanders
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

Dear Senator Sanders:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Bill Cassidy, M.D.
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

Dear Senator Cassidy:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes oversight of the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Representative Pallone:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Kamala D. Harris
Vice President of the United States
President of the Senate
Washington, DC 20510

Dear Madam Vice President:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients . HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

January 14, 2025

The Honorable Mike Johnson
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

I am pleased to provide you with the Fiscal Year 2023 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation. The report was prepared by the U.S. Department of Health and Human Services (HHS) through the Health Resources and Services Administration (HRSA). It is being submitted in accordance with the reporting requirement in section 3 of the Charlie W. Norwood Living Organ Donation Act (the Norwood Act), P.L. 110-144, as codified at 42 U.S.C. §273b.

HRSA is the primary federal agency overseeing the nation's solid organ transplantation system, which includes the contracts operating the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients . HRSA coordinates with other HHS operating divisions, including the Centers for Medicare & Medicaid Services, Centers for Disease Control and Prevention, Food and Drug Administration, and National Institutes of Health, on issues related to organ donation and transplantation.

While deceased organ donation is the most common type of organ donation, living organ donation is an important option for most of the nearly 103,000 Americans on the national transplant waiting list. Benefits associated with living organ donation versus deceased donor organs include better outcomes for transplant recipients, a better chance of transplantation at the optimal time for donor and recipient due to the planning of transplant surgery, and greater availability of donor organs because deceased donor organs are in short supply. While the number of living donations continues to increase, there remains limited national data on long-term health outcomes after living donation. The available data are not definitive and only reflect follow-up studies of donors at a few specific transplant centers. The ongoing project to develop a national living donor registry aims to expand the knowledge base.

This report provides an update on overall trends in living donation, the effects of the COVID pandemic on living donation, and actions taken by HRSA, and actions taken by HHS to improve living donation practice and living donor safety.

I hope you find this information helpful.

Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure