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

REPORT TO CONGRESS

Fiscal Year 2022 Progress Report on Understanding the Long-Term Health Effects of Living Organ Donation

Executive Summary

During the period covered by this report, fiscal year (FY) 2022, 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 provides an update for FY 2022 on trends in living organ donation and HRSA's actions to improve the safety and practice of living organ donation. The information in this report reflects the effect of COVID-19 on the practice of living organ donation during FY 2022.

The FY 2022 report also provides an update on the status of kidney paired donation and living donor deaths and adverse events and summarizes recent relevant academic literature. The report provides updates on two HRSA initiatives: the Living Donor Collective - an ongoing registry of long-term living donor health outcomes managed by the Scientific Registry of Transplant Recipients; and the Living Organ Donation Reimbursement Program administered through the National Living Donor Assistance Center. This report also summarizes findings released from the National Institutes of Health-supported research on the long-term health implications of living organ donation.

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Acronym List

A2ALL	Adult-to-Adult Living Donor Liver Transplantation Cohort Study
ACTBSA	Advisory Committee on Blood and Tissue Safety and Availability
APOL1	Apolipoprotein L1
APOLLO	APOL1 Long-term Kidney Transplantation Outcomes Network
AST	American Society of Transplantation
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
ESRD	end-stage renal disease
FY	fiscal year
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HOPE Act	HIV Organ Policy Equity Act
HRSA	Health Resources and Services Administration
KPD	kidney paired donation
KPDPP	KPD Pilot Program
LDC	Living Donor Collective
LDF	Living Donor Follow-up
LDKT	Living Donor Kidney Transplantation
LDLT	living donor liver transplant
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
OPO	organ procurement organization
OPTN	Organ Procurement and Transplantation Network
RELIVE	Renal and Lung Living Donors Evaluation Study
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, October 1, 2021, to September 30, 2022, the Health Resources and Services Administration (HRSA) served as the primary federal agency responsible for oversight of the nation's solid organ transplantation system, which includes oversight of the contracts operating the Organ Procurement and Transplantation Network (OPTN) and the Scientific Registry of Transplant Recipients (SRTR).[1,2,3,4] 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. 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' (NIDDK) NIH 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 has regulatory oversight of organ procurement organizations (OPO) and transplant centers that participate in the Medicare program. 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 provides oversight of transplant centers and OPOs complementary to the regulatory role of CMS. CMS and HRSA have maintained an information-sharing agreement since 2008 and 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. For example, via HRSA's OPTN contractor, HRSA works with the Centers for Disease Control and Prevention (CDC) 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

[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] Federal Register notice is available at: http://www.gpo.gov/fdsys/pkg/FR-2006-06-16/pdf/E6-9401.pdf.
[3] Public Law 110-144 enacted in 2007.
[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] Organ Transplant Programs: Federal Agencies Have Acted to Improve Oversight, but Implementation IssuesRemain. Published in April 2008 by the U.S Government Accountability Office and is available at: https://www.gao.gov/products/gao-08-412

screening tests for infectious agents and organ perfusion devices to increase the number and quality of transplantable organs.

This report provides an overview of activities and data during fiscal year (FY) 2022, including trends in living organ donation and the demographics of living organ donors, highlights initiatives related to the safety and protection of living organ donors, and presents research findings and data collection efforts describing the long-term health outcomes of living organ donation. There was a decrease in FY 2022 of 1.5 percent (98 transplants) of all living donor transplants compared to FY 2021, which may reflect the impact of the COVID-19 pandemic on organ donation and transplantation in the United States. As a further breakdown, in FY 2022, there were 5,786 transplants performed using living kidney donors (LKD), a 2.5 percent decrease from FY 2021(n=5932). In comparison, there were 596 transplants performed using living liver donors (LLD) in FY 2022, an 8.8 percent increase from FY 2021(n=548). Additional data and background are available in the OPTN/SRTR 2021 Annual Data Report.[6]

III. Overview

Living organ donation is an important option for the nearly 105,982 individuals on the national transplant waiting list (as of September 30, 2022). Living organ donation has several benefits for transplant recipients, including better outcomes compared to those who receive organs from deceased donors, a higher chance of transplantation occurring at the best time for the donor and recipient due to pre-planned surgery, and increased availability of donor organs. However, the benefits for living organ donors, such as saving or improving the life of another individual, are difficult to measure and must be weighed against donor risk. Living organ donation provides no direct physical benefits for the donor, but donation carries potential physiological, psychological, and economic risks in addition to the medical risks inherent with any surgery. 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, 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. NIH continues to support research and evaluation of the long-term health risks of living organ donation throughmulti-year clinical research programs. In 2020, HRSA added a task to 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 2022.

The transplant community is also concerned with the ethical issues that living organ donation raises, including that of informed consent. Assuring that the surgeon, other health care providers, and caregivers are knowledgeable about the individual risks, benefits, and potential outcomes of living organ donation is difficult. Even more imperative is determining 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

[6] OPTN/SRTR 2021 Annual Data Report. Published 2023. http://srtr.transplant.hrsa.gov/annual_reports/Default.aspx
[7] Rasmussen SE, 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.

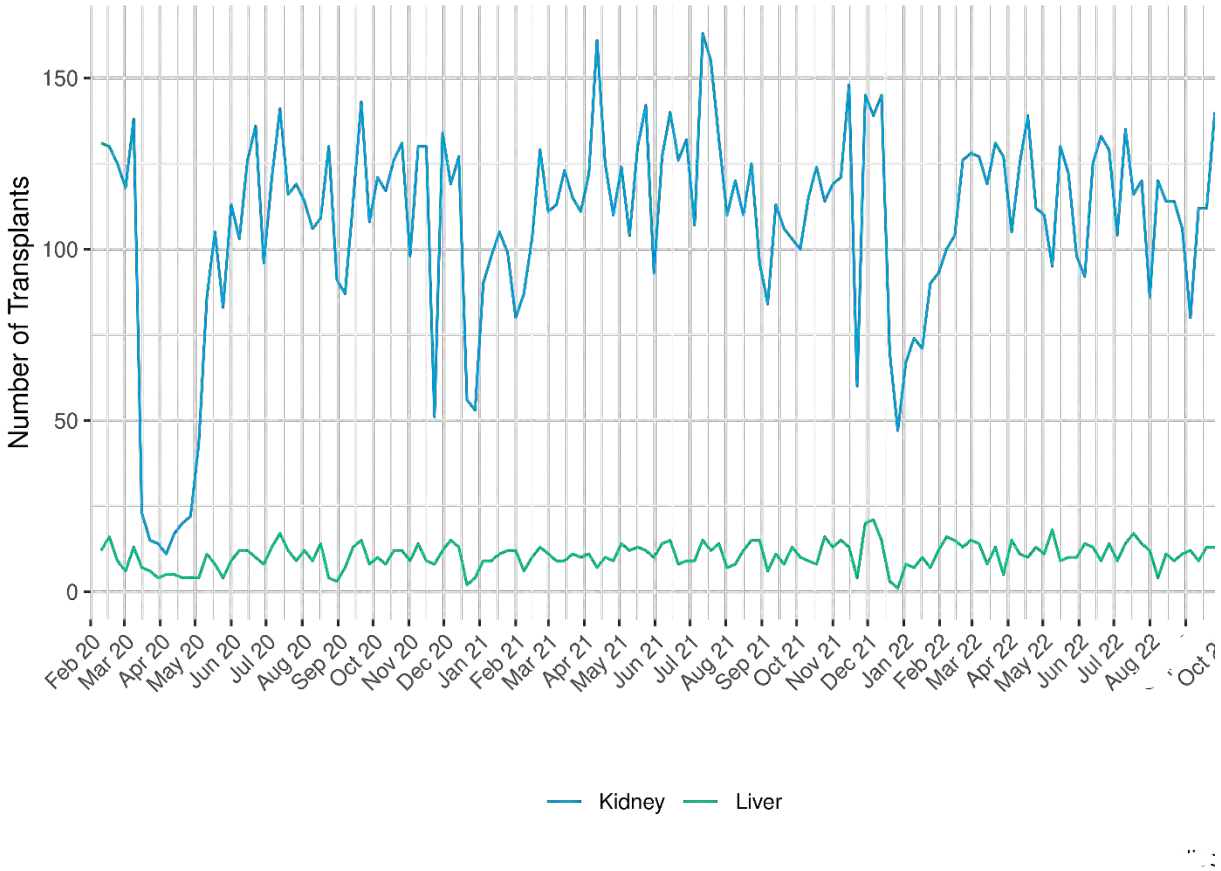
organ donation to ensure they are aware of the risks. In addition, OPTN policy requires the living donor recovery hospital to obtain and document living donor informed consent, and provide education to living donors about the risks, benefits, and potential outcomes.[8]

IV. Impact of COVID-19 on Living Organ Donation

As demonstrated in **Figure 1**, living donor kidney transplant volume decreased during the early months of the COVID-19 pandemic. At the beginning of the pandemic, transplant programs determined that the risk to LKDs and kidney candidates, due to being in the hospital, outweighed the benefits of transplantation for most living donor kidney transplant procedures. In addition to concern for the transmission of SARS-CoV-2, transplant centers were experiencing staffing challenges and the need to reprioritize transplant team members to care for both transplant and nontransplant patients who were acutely ill. For living donor routine follow-ups, OPTN recognized the risk associated with unnecessary hospital visits and temporarily suspended the Living Donor Follow-up (LDF) form submission requirements (normally submitted within 14 days) during the period from March 13, 2020, through March 31, 2021, allowing an extension of the submission deadline of these forms to July 1, 2021. While the volume of LKD transplants initially decreased in early 2020, it began to stabilize and the total number of transplants in FY 2021 (n=5,931) surpassed the FY 2020 (n=5,538) performance. Though slightly decreased from FY 2021, the number of LKD transplants performed in FY 2022 (n=5,786) remains greater than those completed in FY 2020 (n=5,538), but less than FY 2019 (n=6,867).

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

Figure 1: Living Kidney and Liver Donor Transplants from February 2020 – September 2022*



Notes:
*Data Source: Based on OPTN data as of September 30, 2022.
+Data is subject to change based on future data submissions or corrections.

A preliminary review of transplant candidate mortality rates from March 2020 to May 2020 showed an increase in mortality for all candidates listed for kidney transplants. These increases in mortality rates varied based on geography. In comparison, there was no change in mortality for those on the waiting list for other organs.

The number of LLD transplants performed has continued to increase, with 596 performed in FY 2022 compared with FY 2020 (n=473).

During FY 2022, 41,705 transplants were performed using organs from both deceased and living organ donors, representing a 0.8 percent increase from the 41,345 transplants performed during FY 2021. Approximately 84.5 percent (35,321) of the FY 2022 transplants involved organsfrom deceased donors, who usually provide multiple organs for transplantation. Transplants using organs from living organ donors accounted for the remaining 15.5 percent (6,384). The percentage difference between the distribution of deceased organ and living organ donors in FY 2022 was comparable to that in FYs 2019, 2020, and 2021.

V. Living Organ Donor Trends and Demographics

The number of LKD transplants in FY 2022 decreased for donors across all age groups except for those 65 or older, which increased by 19 percent compared to the previous FY. Meanwhile, the number of LLD transplants in FY 2022 increased for all age groups, except for those 65 and older. In FY 2022, women represented a larger percentage of LKDs and LLDs (64 percent and 54 percent, respectively), which is a continuation of a 20-year trend of more female living donors than males.

A. Living Kidney Donors

Since the 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 were the primary cause of the large decrease in the number of LKDs between FY 2019 and FY 2020. The FY 2022 volume (5,786 LKDs) did not reach the total previously achieved in FY 2019.

The number of donors increased annually from 1988 to 2004, at which point 6,648 LKDs were involved in transplants. The annual number of LKDs fluctuated from 2005 to 2019, with a record 6,860 donors in FY 2019.

Select demographic trends in living kidney donation during FY 2022 include:

- Biologically related family members received 39 percent of living kidney donations.
- A majority of LKDs were younger than 50 (65 percent) and female (64.3 percent).
- The second largest group of donors were aged 50 to 64 years old (28.7 percent), with the remaining 6.3 percent aged 65 or older.
- 69.4 percent of LKDs were White, 16.4 percent Hispanic or Latino, 7.6 percent Black or African American, 4.8 percent Asian, 0.4 percent American Indian or Alaska Native, 0.2 percent Pacific Islander, and 1.1 percent multiracial. [9]

B. Living Liver Donors

In FY 2022, there were 596 LLDs, an approximate 9 percent increase compared with 548 LLDs in FY 2021. Significant annual increases in LLDs occurred from FY 2017 through 2019 (23 percent increase from FY 2018 to FY 2019). LLDs continued to increase, but more slowly since the beginning of the COVID-19 pandemic, with a 6 percent increase from FY 2020 to FY 2021.

Select demographic trends in living liver donation in FY 2022 include:

- Biologically related family members received 56.5 percent of living liver donations.
- The majority of LLDs were younger than 50 years of age (87.3 percent) and female (54.4 percent).
- Approximately 79.7 percent of LLDs were White, 13.3 percent Hispanic or Latino, 3.5 percent Black or African American, 2.5 percent Asian, 0.3 percent Pacific Islanders, 0 percent American Indian or Alaska Native, and 0.7 percent multiracial.

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

C. Other Living Organ Donors

Living Pancreas Donors: According to OPTN, there has not been a living donor pancreas-alone transplant performed since 2008, and the last living donor simultaneous pancreas-kidney transplant in the United States was performed in 2013. One factor in the lack of living pancreas donor transplants being performed is that transplanting a pancreas is considered a complex and risky procedure for both the donor and the recipient.

Living Lung Donors: Given the morbidity and mortality risk, very few lung transplants use lungs from living donors. According to OPTN, there has not been a living lung transplant performed in the United States since 2013.

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 the transplantation of complex anatomical structures composed of multiple tissue types and are most commonly known for hand and face transplants. Recent research and advancements in transplantation have led to the use of uterus transplants from living donors. The first such case was reported to OPTN in 2016. As of September 30, 2022, there have been 22 uterus transplants from living donors. \Notably, two-thirds of uterus transplants from living donors had a slightly improved surgical success rate over uterus transplants from deceased donors. However, survival of the graft at 1-year was found to be equivalent between living and deceased donors.[10]

D. Human Immunodeficiency Virus Organ Policy Equity Act

Prior to the Human Immunodeficiency Virus (HIV) Organ Policy Equity Act (HOPE Act), P.L. 113-51, 127 Stat. 579 (Nov. 21, 2013), federal law and OPTN policy prohibited recovering and transplanting organs from deceased donors with HIV. The HOPE Act removed the prohibition on the transplantation of organs from donors with HIV into transplant candidates with HIV under approved research protocols designed to evaluate the effectiveness and safety of such transplants. The requirement for all or some of these transplants to occur under research protocols may be lifted if the HHS Secretary, after reviewing research results and recommendations, determines that such a requirement is no longer warranted. Three living donor HOPE Act kidney transplants have also been performed since the enactment of this law.

Following the enactment of the HOPE Act in 2015, NIH published the required research criteria for transplant programs to participate under approved research protocols and OPTN subsequently established a process for identifying and matching donor kidneys and livers infected with HIV to applicable candidates at participating programs. In May 2020, OPTN added other solid organs that could be screened for infectious disease and potential use under the HOPE Act criteria.

In 2021, an ongoing OPTN Safety Review Workgroup reviewed data safety monitoring board reports and an OPTN data analysis of over 300 patients with HIV receiving organs under OPTN-approved research protocols, and unanimously concluded that OPTN policy should be revised to make transplantation of organs from individuals infected with HIV permissible for patients who are HIV-

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

positive outside of research requirements. In conjunction with this finding, OPTN submitted a letter to recommend that the Secretary remove the research requirement for organ transplants from organ donors with HIV to transplant recipients with HIV.

In response to OPTN recommendation to the Secretary in 2021, the HHS Advisory Committee on Blood and Tissue Safety and Availability (ACTBSA) convened a workgroup of subject matter experts from NIH, CDC, the Food and Drug Administration, HRSA and others in transplant community to review OPTN data and clinical experience in HIV-positive to HIV-positive transplantation for all organs. Based on presentations on data for kidney, liver and heart transplants under the HOPE Act the workgroup endorsed the recommendations of OPTN that transplantation of HIV-infected liver or kidneys for HIV-positive recipients could be done safely and to remove research and Institutional Review Board requirements. However, due to insufficient data for patient safety and outcomes for non-liver and non-kidney HOPE Act transplants, specifically with only one heart transplant and no lung transplants performed to date, the workgroup recommended that continued modified research criteria with institutional review board monitoring should continue to be required for non-kidney or non-liver transplants. In November 2022, ACTBSA convened to review the workgroup recommendations to update the HOPE Act and recommended that the Secretary direct OPTN to adopt (for HOPE Act transplants of organs other than kidneys and livers) organ-specific policies imposing requirements similar to NIH Research Criteria and mandated that such transplants are conducted under an Institutional Review Board-approved research protocol. ACTBSA recommendations included OPTN outcomes monitoring of transplant candidates and recipients to be reviewed and reevaluated after 2 years following implementation. These recommendations were later approved by the HHS Blood, Organ and Tissue Senior Executive Council, an advisory forum for senior leadership from HHS entities, involved in blood, organ and tissue safety and availability.

Between 2015 and December 31, 2022, 383 HOPE Act organ transplantations have occurred, with the largest number of transplants performed in 2020 (75). Transplant hospitals performed the first two living donor HOPE Act kidney transplants in 2019, and an additional living donor HOPE Act kidney transplant in 2020; no additional living donor HOPE transplants of any organ have occurred. Notably, the first and only heart transplant performed under OPTN research protocols for HOPE Act transplants occurred in April 2022.

During FY 2022, 17 transplant hospitals with approved HOPE Act programs performed 55 deceased donor kidney, liver, and heart transplants.

VI. Kidney Paired Donation Programs

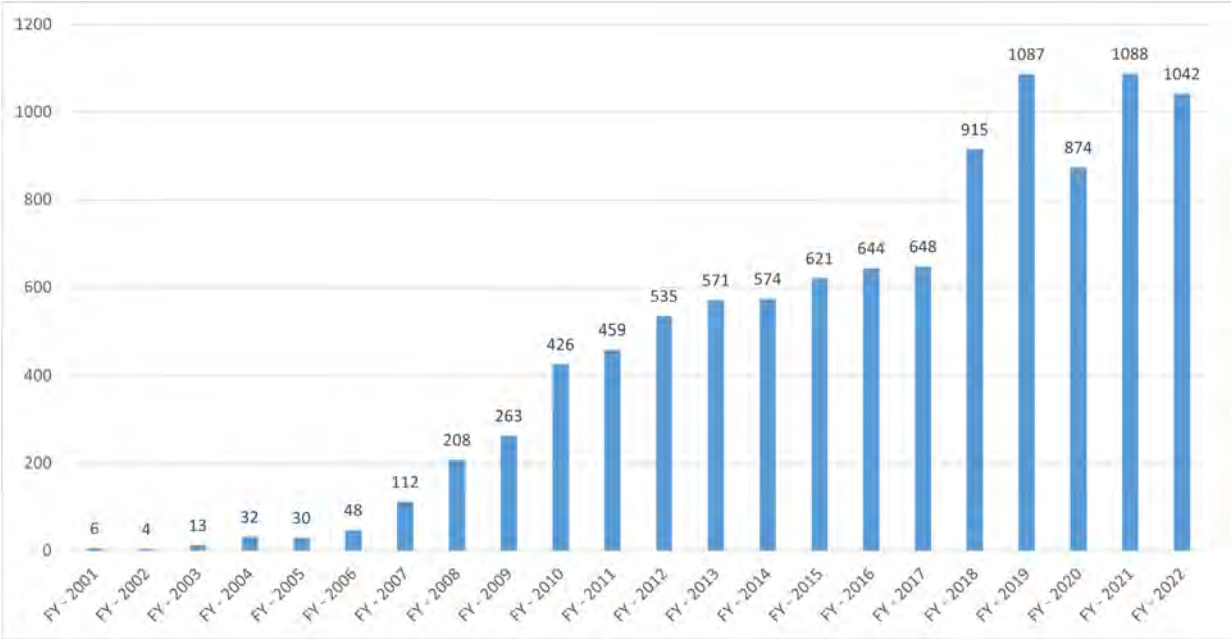
Every year, thousands of transplant candidates with potential LKDs join the national transplant waiting list because they are blood type or human leukocyte antigen incompatible with their potential living donors. This incompatibility represents a lost opportunity for transplant candidates seeking a living donor transplant as well as for the individuals seeking to donate to a specified candidate. Kidney Paired Donation (KPD) programs allow 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 2013 and continued to grow until a downturn in FY 2020, followed by an increase in FY 2021 and another drop in FY 2022. The number of KPD transplants performed in FY 2021 remains the highest recorded, with 1,088 transplants, representing 18.4 percent of all living donor kidney transplants. In FY 2022, there were 1,042 KPD transplants, a 4.2 percent decrease compared to the number of transplants performed in FY 2021.

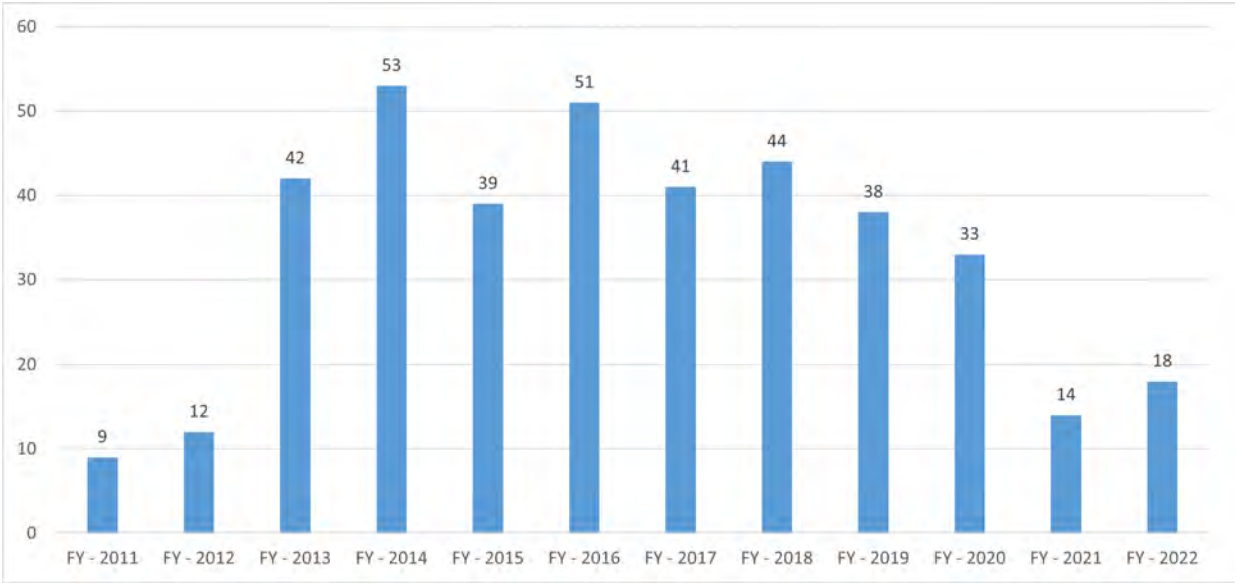
In October 2010, OPTN initiated a KPD Pilot Program (KPDPP) to explore the feasibility of a national KPD program operated by OPTN to address the challenge of finding suitable pairs. As shown in **Figure 3**, OPTN KPDPP identified and facilitated 394 KPD transplants between October 2011 and September 2022, which represented 2.2 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. It 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 2021 – FY 2022*



Notes:
*Data Source: OPTN data as of September 30, 2022.
+ 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 the OPTN KPDPP from FY 2011 – FY 2022*



Notes:
*Data Source: OPTN data as of September 30, 2022. 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

Deaths and other adverse events related to living organ donation are of great concern to the field of transplantation. 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 review determines if a death or an adverse event relates to an OPTN member's failure to comply with federal law, OPTN policies, and/or bylaws, 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 OPTN Board of Directors or, in certain circumstances, the HHS Secretary, take action against OPTN member. Such action often leads to the MPSC increasing monitoring and oversight.

A. Living Organ Donor Deaths

Transplant programs are required to report all instances of living organ donor death to OPTN within 72 hours of the program becoming aware of the death. Additionally, OPTN must report living organ donor deaths to HRSA within 24 hours of the receipt of the information. 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 increases. 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 deaths for LLDs within 2 years of donation. These data show no apparent trends in post-operative mortality for LKDs or LLDs.

Table 1: Living Kidney Donor Deaths within 2 Years of Donation from FY 2018 – FY 2022*

	Medical (not Cancer)	Accident/ Homicide	Suicide	Overdose	Cancer	Other/ Unknown	Total
FY 2018	1	0	3	0	0	0	4
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
Total	**3**	**9**	**9**	**5**	**1**	**2**	**29**

Notes:
*Data Source: OPTN data submitted to the OPTN Improving Patient Safety system as of September 30, 2022. Data is subject to change based on future data submissions and/or corrections.

Table 2: Living Liver Donor Deaths within 2 Years of Donation from FY 2018 – FY 2022*

Year	Medical (not Cancer)	Accident/ Homicide	Suicide	Overdose	Cancer	Other/ Unknown	Total
FY 2018	1	0	0	0	0	0	1
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
Total	**2**	**0**	**1**	**0**	**0**	**1**	**4**

Notes:
*Data Source: OPTN data submitted to the OPTN Improving Patient Safety system as of January 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 complete data collection forms that report to OPTN any complications (unfavorable evolution or consequence of a disease, a health condition, or any complications related to the living donor procedure as described in OPTN Policy 18.4)) affecting the living organ donor.[11] Transplant hospitals complete this report either at discharge or up to 6 weeks post-donation, whichever occurs first, to enable more accurate data collection and better documentation of incidents related to surgery but delayed in presentation. **Table 3** depicts the incidence of reported complications in living organ donation for LKDs and LLDs.

[11] OPTN policy includes an extensive list of data reporting requirements following living donor procedures including multiple entries under the general heading of "complications." This information is available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

Table 3: Living Kidney and Liver Donor Complications Reported to the OPTN from FY 2020 – FY 2022*

	FY 2020	FY 2021	FY 2022
Living Kidney Donor Complications	LKDs (n=5,538)	LKDs (n=c	LKDs (n=5,786)
Vascular complications requiring intervention	13 (0.2%)	16 (0.3%)	10 (0.2%)
Other complications requiring intervention	112 (2.0%)	124 (2.1%)	111 (1.9%)
Living Liver Donor Complications	LLDs (n=510)	LLDs (n=546)	LLDs (n=590)
Biliary Complications	13 (2.5%)	17 (3.1%)	15 (2.5%)
Vascular complications requiring intervention	4 (0.8%)	4 (0.7%)	6 (1%)
Other complications requiring interventions	28 (5.5%)	13 (2.4%)	39 (6.6%)

Notes:
*Data Source: OPTN data are current as of September 30, 2022.
+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 transplant hospitals for certain living organ donors to report adverse or unanticipated events related to the donation surgery. As shown in **Table 4**, the most common adverse events reported between FY 2020 and FY 2022 across living organ donors 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.[12] Other reported adverse events include living donor death and redirection of the living donor organ to an unanticipated recipient.

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

Table 4: Living Organ Donor Adverse Events Reported by OPTN Members from FY 2020 – FY 2022*

Living Organ Donor Events	FY 2020	FY 2021	FY 2022
Halted Procedure	11	21	25
Death	6	8	7
Native Organ Failure	0	0	0
Redirection	5	2	1
Other	2	4	8
Total	**24**	**35**	**41**

Notes:
*Data Source: OPTN data are current as of September 30, 2022, 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 ESRD 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

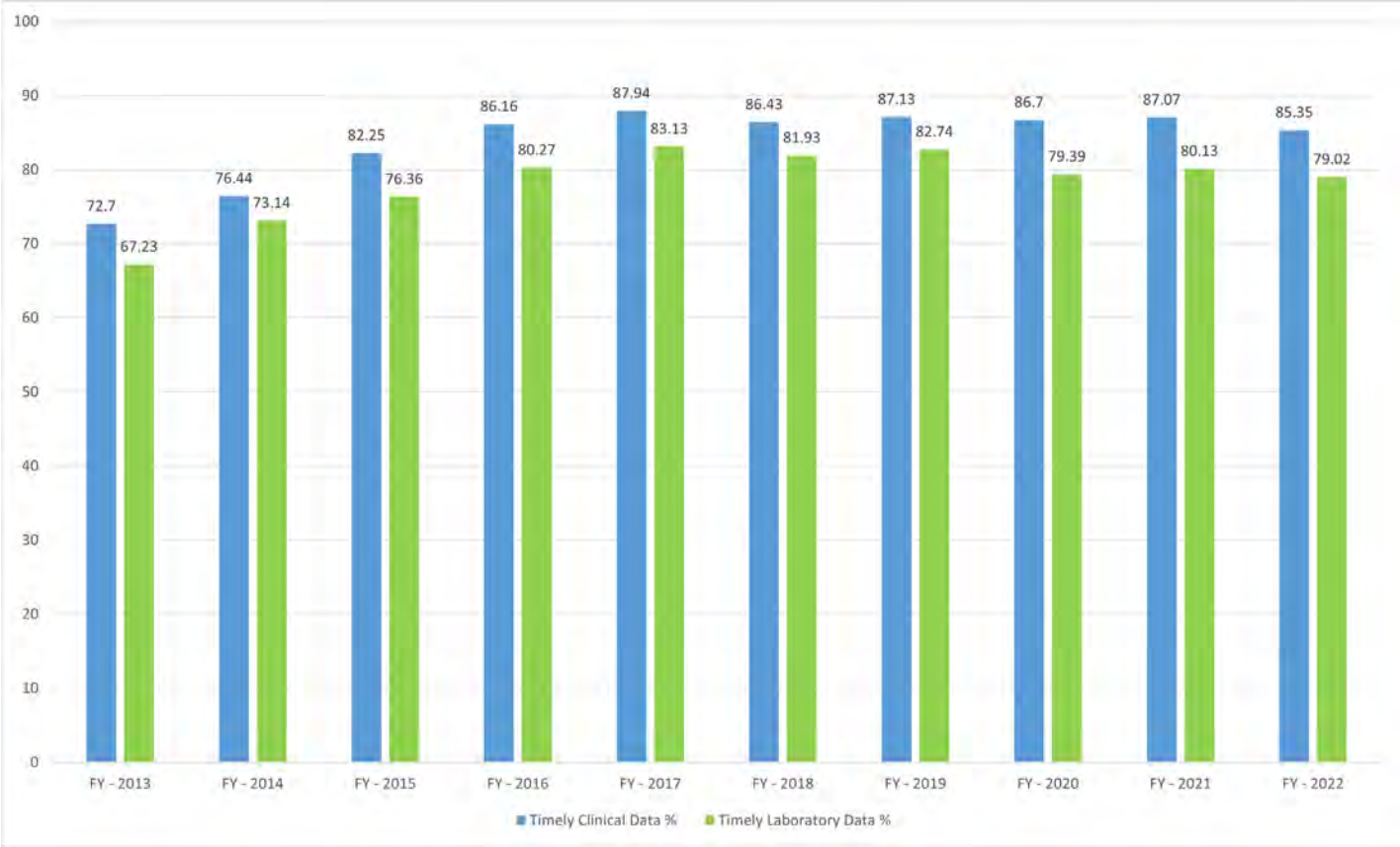
OPTN LKD Follow-up Data: Per OPTN policy and federal data submission requirements, living organ donor transplant programs submit follow-up data on their living organ donors for 2 years following donation. Living donor transplant programs often report LKDs as "lost to follow-up" if the center is unable to contact the donor for current information, leading to forms having missing or incomplete data. In calendar years 2013 and 2014, OPTN-approved policies and subsequent data collection forms were revised to improve and expand the reporting of follow-up data, as detailed in prior annual reports.[13,14] **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

[13] 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.
[14] 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.

attempts, researchers are examining efforts, including using financial incentives and implementing mobile health technologies.[15, 16]

The FY 2022 results are nearly identical to those in FY 2021 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 2021 cohort, approximately 85 percent of LKDs had timely 6-month clinical data reported, and 79 percent had timely laboratory data reported.

Figure 4: Percent of Living Kidney Donors with Timely Clinical and Laboratory Data on 6-Month Living Donor Follow-up Form from FY 2013 – FY 2022*



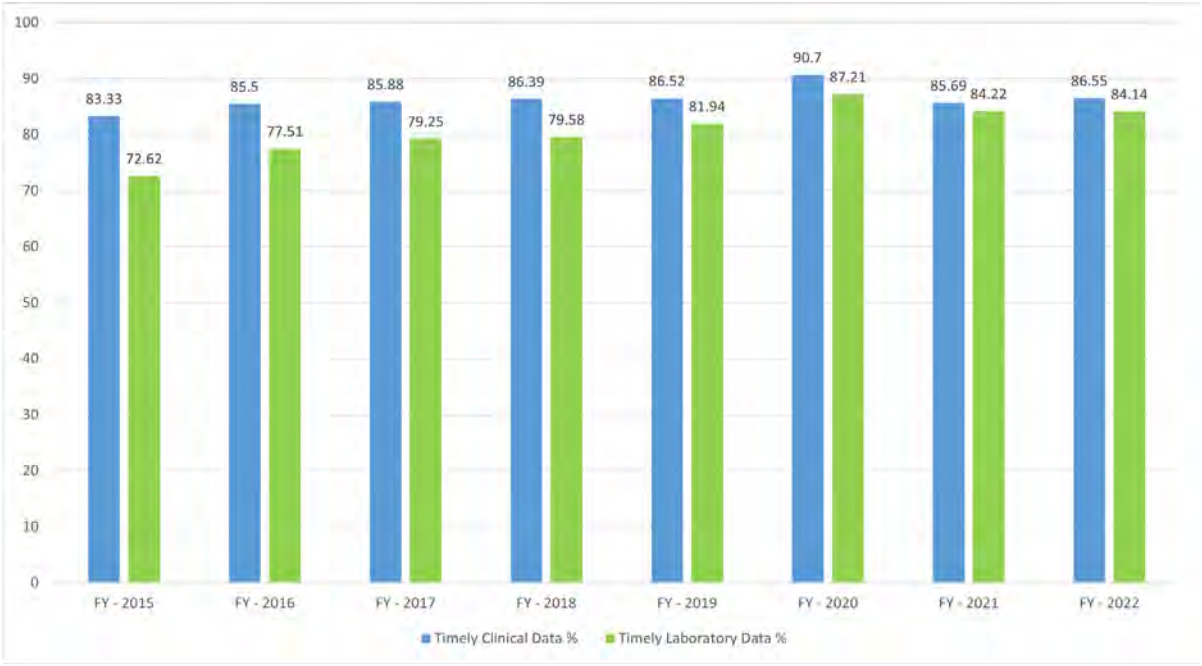
Notes:
*Data Source: OPTN data as of September 30, 2022. Data is subject to change based on future data submissions and/or corrections.
+Timely data submission defined in OPTN policy 18.5.B is available at:
https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

[15] 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.
[16] 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.

OPTN Living Liver Donor 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 CYs 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 85.7 percent in FY 2021 and a slight increase to 86.6 percent for the FY 2022 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 84.1 percent for the FY 2022 cohort.

Figure 5: Percent of Living Liver Donors with Timely Clinical and Laboratory Data on 6-Month Living Donor Follow-up Form from FY 2015 – FY 2022*



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+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.

B. SRTR's Living Donor Collective

SRTR completed the pilot phase of LDC in 2020 per its previous contract with HRSA, and had three publications of its research detailing the results of this effort: one article (2021) describing LKD candidates and donors, one article (2021) describing LLD candidates and donors, and the first LDC chapter in the OPTN/SRTR Annual Data Report (2022).[17,18,19] Subsequently, under the current HRSA contract, SRTR has worked on the recruitment of additional transplant programs to participate in the LDC. Recruitment efforts have included presentations at OPTN regional meetings, newsletters, social media posts, and presentations by SRTR directors at conferences and webinars.[20] In addition, SRTR had introductory meetings with staff at several living donor transplant programs.

The pilot experience, as well as conversations with staff at the participating transplant centers, identified challenges for transplant program participation in LDC. Program data submission (focused

[17] Kasiske BL, Ahn YS, Conboy M et al. Outcomes of living kidney donor candidate evaluations in the Living Donor Collective pilot registry. *Transplant Direct.* 2021; 7(5): e689. doi: 10.1097/TXD.0000000000001143. Epub 2021 May.
[18] Kasiske BL, An YS, Conboy M et al. Outcomes of living liver donor candidate evaluations in the Living Donor Collective pilot registry. *Clin Transplant.* 2021; 35(9): e14394. doi: 10.1111/ctr.14394. Epub 2021 Aug 3.
[19] Kasiske BL, Lentine KL, Ahn Y et al. OPTN/SRTR 2020 Annual Data Report: Living Donor Collective. *Am J Transplant.* 2022; 22(Suppl 2): 553-586. doi: 10.1111/ajt.16982.
[20] Lentine KL, Snyder JJ. 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. Accessed February 26, 2023.

on candidate registration and the donation decision form) is currently voluntary, and many programs have found the burden of collecting additional data for LDC to be prohibitive, especially during the COVID-19 pandemic. Recognizing these challenges, in FY 2022, LDC began a formalized Program Management Plan. This more structured plan included establishing more robust processes, increased engagement with donors, and re-engaging with pilot sites.

SRTR has taken several steps to ease the burden of data collection for programs participating in LDC. Transplant programs made efforts to facilitate electronic batch uploads of registration data. SRTR worked with a software company that developed a digital platform that allows living donor candidates to enter data for transplant program evaluations for themselves.[21] SRTR, in turn, developed a template that allows programs to upload these data to LDC. The digital platform can export some data collected as part of the registration process, easing the burden of data collection for programs.

Finally, SRTR has been working with OPTN to harmonize the data collected by the LDC and OPTN for living donor candidates who become donors.

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

NIH supports research on the long-term health implications of living organ donation to improve the understanding of the long-term effects of organ donation for living donors. The studies highlight the challenges associated with the research of long-term effects, including long-term tracking of living organ donors, identifying and enrolling donors, the participation of an appropriate control group, and the logistics of long-term follow-up.

Long-Term Effects on LKDs: In 2006, NIH's National Institute of Allergy and Infectious Diseases and HRSA sponsored the Renal and Lung Living Donors Evaluation Study (RELIVE), a cooperative research group to explore kidney donor outcomes at three transplant centers and lung donor outcomes at two transplant centers (no living lung donations have been reported since 2013). The study identified living organ donors retrospectively and evaluated their long-term outcomes using multiple administrative databases and through direct contact.

Supplemental funding supported further development of data and identification of a control group for the nearly 9,000 RELIVE subjects donating kidneys between 1963 and 2007. In 2017, researchers linked the RELIVE data with data from CDC's National Health and Nutrition Examination Survey which enabled them to construct an appropriate control cohort. The medical and scientific transplant community continues to use the data obtained from this study.

The RELIVE group published several articles addressing the demographic, metabolic, and blood pressure characteristics of LKDs over 5 decades. Other topics included morbidity associated with living lung donation, lung and kidney living donor informed consent, health-related quality of life among LKDs, and long-term outcomes such as psychosocial and financial issues, rates of ESRD, and mortality in the LKD population.

[21] Medsleuth, Inc website is available at: https://www.medsleuth.com.

In 2021, investigators published a long-term study in the RELIVE cohort refuting potential serious effects of existing kidney stones in LKDs.[22] Twenty-five percent of U.S. transplant centers exclude donor candidates with kidney stones fearing future obstructive kidney disease and the association between stones and chronic kidney disease. Using data from the RELIVE study, investigators compared the development of hypertension, proteinuria, and reduced estimated glomerular filtration rate in 227 kidney donors with kidney stones to 908 propensity score-matched donor controls without kidney stones who were followed up to 44 years after donation. The investigators could not demonstrate an association between stones and adverse renal outcomes in kidney donors, and the occurrence of post-donation stones was distinctly rare. These data may provide a rationale for possibly a wider acceptance of donor candidates with low kidney stones burden.

Specific genetic renal-risk variants known as G1 and G2 in the apolipoprotein L1 (*APOL1*) gene that may lead to end-stage kidney disease are more common among individuals with African ancestry, potentially also involving LKDs, so the question of safety in donation is undergoing study. NIH's NIDDK developed the *APOL1* Long-term Kidney Transplantation Outcomes Network (APOLLO) study in 2016 with support from NIH's National Institute on Minority Health and Health Disparities and National Institute of Allergy and Infectious Diseases. The goal of the APOLLO study is to determine the effect of the *APOL1* genotype more accurately on transplant outcomes in kidney transplant donors and recipients. Up to 136 kidney transplant programs, 58 OPOs, and 64 histocompatibility laboratories have participated in the study, and OPTN is coordinating provision of their data for the research. APOLLO, as well as data from another NIDDK-funded study, called Living Donor Extended Time Outcomes, will provide preliminary additional results that may help determine whether kidney donors with *APOL1* gene variants may develop kidney disease in their remaining kidney after donation.[3] Ultimately, this research may provide a prospective foundation to help determine whether donors with *APOL1* gene variants are at relative increased risk of kidney related complications.[23] This will be of particular importance for individuals considering donating to a family member when both share the same *APOL1* genetic variant. APOLLO completed patient enrollment in 2023.

Despite similar referral rates to White patients, both Hispanic or Latino patients and American Indian patients are less likely to be wait-listed or to undergo kidney transplant. The Access to Kidney Transplantation in Minority Populations Trial compares two patient-centered methods to facilitate kidney transplant evaluation.[24] Using comparative effectiveness research methods, this study conducts a pragmatic randomized trial to compare the efficacy and cost- effectiveness of two approaches to help Hispanic or Latino and American Indian patients overcome barriers to completing transplant evaluation and receiving a kidney transplant. The results of this trial will provide key information to facilitate the evaluation process, improve patient care, and decrease disparities in kidney transplant.

Long-Term Effects on LLDs: Liver transplant is the standard of care and the only cure for end-stage liver disease. LLD transplantation may help some individuals receive transplants sooner than those waiting for a deceased donor organ transplant, leading to decreased mortality and better long-term

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[22] Murad DN, Nguyen H, Hebert SA et al. Outcomes of kidney donors with pre- and post-donation kidney stones. *Clin Transplant*. 2021 Feb; 35(2): Dec 25. Available at: https://pubmed.ncbi.nlm.nih.gov/33320374/.

[3] Hsu CY, Lentine KL, Park M, Abbott KC. (n.d.). Living Donor Extended Time Outcomes (LETO) Study is available at: https://reporter.nih.gov/search/9O2Pp9uxckKtHcYXfguPuw/project-details/9906216.

[23] Grams ME, Sang Y, Levey AS, et al. Kidney-failure risk projection for the living kidney-donor candidate. *N Engl J Med* 2016; 374:411-421. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4758367/

[24] OK t

outcomes. LLDs also allow for a longer period of evaluation of the donor and recipient.[25] Children can successfully receive LLD transplants, and liver transplant programs use living donors for adult as well as pediatric patients, although little data exists to guide physicians, donors, or recipients in evaluating the risks and benefits.

The Adult-to-Adult Living Donor Liver Transplantation Cohort Study (A2ALL), supported by NIH's 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.[26]Additionally, NIDDK released a funding opportunity in FY 2023 to support research on organ and tissue donation among populations that experience health disparities.[27] 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.[28]

NIH is also funding research that will identify and intervene on inequities in organ transplant that occur due to health system processes. The Improving Racial Equity in Clinical Decision Making about Access to Organ Transplant project will generate new knowledge of the magnitude and mediators of inequities at each phase of the transplant selection process and how institutional racism embedded in center-level processes and individual clinician biases may influence inequities.[29] The results will elucidate the influence of institutional racism in transplant systems and processes on racial equity in access to transplants. This toolkit will represent the first intervention developed to overcome bias and mitigate inequities at each step in the transplant selection process.

IX. Living Organ Donor Financial Assistance

HRSA's Living Organ Donation Reimbursement Program (LODRP), authorized per 42 U.S.C. § 274f, provides financial assistance to individuals who wish to be living organ donors but might otherwise not be able to donate.[30] Qualified expenses include reimbursement of travel, lost wages, and dependent

[25] Nadalin S, Bockhorn M, Malagó M, Valentin-Gamazo C, Frilling A, Broelsch CE. Living donor liver transplantation. *HPB (Oxford).* 2006; 8(1): 10-21. doi: 10.1080/13651820500465626.
[26] More information about A2ALL is available at: https://repository.niddk.nih.gov/studies/a2all1/.
[27] https://grants.nih.gov/grants/guide/rfa-files/RFA-DK-22-003.html
[28] 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
[29] https://reporter.nih.gov/project-details/10507407
[30] A description of the LODRP application process and downloadable application worksheets are available at: https://www.livingdonorassistance.org/How-to-Apply/Application-Process.

care (care of children and older adults) 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, School of Medicine, which partnered with a multidisciplinary team of transplant professionals to operate this national program through the Living Organ Donor Expense Reimbursement Program (LODRP).

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 and donor's household incomes. The income eligibility threshold is 350 percent of the Federal Poverty Guidelines. 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 HHS Secretary give preference to donors 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 2022, 374 transplant programs in the United States participated in LODRP. During that time, as demonstrated in **Table 5**, LODRP received 1,987 applications for assistance, of which 1,803 (90.7 percent) met the LODRP eligibility guidelines. LODRP provided nearly $4.6 million in financial assistance and facilitated 1,111 living organ transplants. The median household income of the transplant recipients was $36,275, and the donors' median household income was $57,010.

Table 5: LODRP Data Summary from FY 2018 – FY 2022*

Fiscal Year	Total Applications	Applications Approved	Percentage (%)	Surgeries completed	Total Funds Spent	Donor Income Median	Recipient Income Median
2018	1,055	935	88.6%	604	$2,204,627	$45,270	$28,019
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

Notes:
*Data Source: LODRP on January 18, 2023.

X. Conclusion

Even with the continued increase of deceased organ donation and a record number of deceased organ transplants, the need for organs continues to outpace the supply. The imbalance in supply and demand causes a continued interest in living organ donation as a source of transplantable organs to save lives.

The COVID-19 pandemic resulted in a decline in elective living kidney donations that is now improving. To continue to expand and improve living organ donation, ongoing efforts are underway to

increase support to donors, monitor OPTN data for screening of potential LKDs and post-donation monitoring for long-term outcomes, and continue studies to evaluate specific donor populations and provide research funding through NIH.

In terms of KPD, in FY 2022, OPTN continued to develop policies to improve operational efficiency and expand parameters for KPD participants' informed consent. The LODRP program saw a large increase in the number of applications for assistance in FY 2022, and the program provided nearly $4.6 million in financial assistance and facilitated more than 1,100 living organ transplants.

While in FY 2022, transplants performed with living donor organs represented a slight decrease (1.5 percent) relative to FY 2021, HHS continues to support efforts to educate the public regarding this important option for the more than 100,000 individuals on the national transplant waiting list and works to enhance safety for all living organ donors.

DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 10, 2024

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 2021 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), and 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 supports the nation's solid organ transplantation infrastructure through its oversight of the Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients. HRSA coordinates internally 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.

Living organ donation is an important option for more than 106,000 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 for October 1, 2020, through September 30, 2021, on overall trends in living donation 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

December 10, 2024

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

Dear Chairman Sanders:

I am pleased to provide you with the 2021 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), and 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.

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Assistant Secretary for Legislation

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DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 10, 2024

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

Dear Senator Cassidy:

I am pleased to provide you with the 2021 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), and 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 10, 2024

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chair Rodgers:

I am pleased to provide you with the 2021 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), and 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 10, 2024

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 2021 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), and 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.

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DEPARTMENT OF HEALTH & HUMAN SERVICES OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

December 10, 2024

The Honorable Kevin McCarthy
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

I am pleased to provide you with the 2021 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), and 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.

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Sincerely,

/Melanie Anne Egorin/

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Enclosure