OPTN

Report to the Board of Directors on Enhancing Living Donation

OPTN Living Donor Committee
June 17, 2024
Prepared by: Kieran McMahon

This report to the OPTN Board of Directors (hereafter, Board) reflects the deliberations of the OPTN Living Donor Committee (hereafter, the Committee) from December 2023 – June 2024. During this time, the Committee sought to identify opportunities to enhance living donation, per a request made by OPTN leadership. The Committee also reviewed existing roadblocks, challenges with current data collection, ideas to optimize the system to promote living donation, and opportunities for collaboration and innovations to improve living donation. The Committee identified seven key recommendations for enhancing living donation for Board consideration:

1. Reduce systematic barriers to becoming a living donor
2. Expand OPTN data collection on living donation and collaborate with other entities for data collection to increase public trust and promote living donor safety
3. Develop and promote best practices for key components of the living donation process
4. Improve and expand upon paired donation opportunities and investigate other ways to expand the living donor pool
5. Increase awareness about living donation among the general public
6. Leverage technology and embrace innovation within the living donation process
7. Reduce disincentives for creating and maintaining a living donation program at transplant centers

The order of these seven recommendations reflects the Committee's consensus on how to prioritize the ideas according to scope, feasibility, urgency, and impact. These aspects are further elaborated upon in the "key takeaways" box at the end of each recommendation. The recommendations build upon each other, as the Committee sees *Recommendations 1* and *2* as foundations from which to expand upon.

This report first briefly discusses the trend in living donation transplantation over time, then provides the seven recommendations and associated proposed next directions for the Board of Directors' consideration. The Committee also provides two appendices. *Appendix A* (page 23) includes a list of key stakeholders and *Appendix B* (page 25) provides further data of interest and value to action items proposed here. The Committee notes that the request for this report was to think boldly and as such, some of the ideas for enhancing living donation may fall outside the current scope of the OPTN. Where possible, the Committee has noted this, and believed in the importance of these ideas for consideration by the Board.

As discussed as a common theme throughout the recommendations, the Committee recognizes the need for diverse stakeholder engagement in any effort to enhance living donation. The Committee points to the success of the OPTN Expeditious Taskforce in rapidly identifying problem areas and working across sectors to develop solutions, and notes that this is a possible approach to accomplishing many of the items mentioned in this report.[1] The Committee was eager to help

[1] OPTN. (n.d.). *Improving organ usage and placement efficiency.* HRSA. optn.transplant.hrsa.gov/professionals/improvement/improving-organ-usage-and-placement-efficiency/#TheExpeditiousTaskForce.

identify ways to improve living donation and thanks the Board for the opportunity to deliver this report. It is worth noting that according to the Committee's charge, the goal of the Committee's work is to continue to improve the informed choice of prospective living donors, and the safety, protection, and follow-up of all living donors. Therefore, as an overarching recommendation to all the items provided in this report, the Committee stresses the importance of ensuring that any future effort to enhance living donation also ensures the safety, protection, and follow-up of all living donors as the top priority.

Key Findings and Recommendations for Enhancing Living Donation

Before considering the Committee's recommendations, it is important to keep in mind the benefits of living donation to the transplantation system overall and the trend in living donation over time.

The benefits of living donation to both the system and the individual recipient are well-documented and should be understood as important context for the recommendations in this report. Grafts from living kidney and liver donors last longer, are usually of higher quality than deceased donor grafts, and are often better matches between the donor and recipient.[2,3] Also, pre-emptive living donor kidney transplant permits a recipient to avoid dialysis, significantly improving recipient survival and quality of life and affording overall cost savings to the system.[4,5] It also makes transplant an elective planned procedure performed at optimal timing for the recipient. Additionally, by removing someone from the deceased donor waitlist and reducing the recipient need for re-transplantation, living donation results in additional organs available for others waiting and thereby reduces waitlist mortality.

Figures 1 and 2 show the number of living donor transplants plotted against the number of deceased donor transplants over time for kidney and liver. The number of living donations performed each year has remained relatively stable since the mid-2000s, underscoring the need for change to enhance living donation to achieve the full potential of the benefits mentioned above. Additional figures more specifically tied to an individual recommendation are provided throughout the report, and supplemental data can be found in *Appendix B*.

[2] Avrami C. Why is living kidney donation important? In: Avrami C, Liossatou A, Ho TM, editors. Current Strategies for Living Donor Kidney Transplantation [Internet]. Hergiswil (CH): European Dialysis and Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA); 2021. CHAPTER 2. Available from: https://www.ncbi.nlm.nih.gov/books/NBK581476/

[3] Jackson, W. E., Malamon, J. S., Kaplan, B., Saben, J. L., Schold, J. D., Pomposelli, J. J., & Pomfret, E. A. (2022). Survival Benefit of Living-Donor Liver Transplant. JAMA surgery, 157(10), 926–932. https://doi.org/10.1001/jamasurg.2022.3327

[4] Avrami C. Why is living kidney donation important? In: Avrami C, Liossatou A, Ho TM, editors. Current Strategies for Living Donor Kidney Transplantation [Internet]. Hergiswil (CH): European Dialysis and Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA); 2021. CHAPTER 2. Available from: https://www.ncbi.nlm.nih.gov/books/NBK581476/

[5] A 2019 study (Gourlay, William MD, FRCSC1. Preemptive Kidney Transplantation: What's the Hold Up?. Transplantation 102(7):p 1035-1036, July 2018. | DOI: 10.1097/TP.0000000000002160) found that the Medicare annual costs for hemodialysis are over $88,000 whereas the annual cost of renal transplantation is just $34,000. If additional pre-emptive transplants were completed, this cost savings could be translated into improving other areas of the system all while improving recipient outcomes. Additionally, research has demonstrated significant cost savings for living liver transplant when compared to deceased donor liver transplant (see Abu-Gazala, S., & Olthoff, K. M. (2019). current Status of Living Donor Liver Transplantation in the United States. Annual review of medicine, 70, 225–238. https://doi.org/10.1146/annurev-med-051517-125454)

Figure 1: Number of Kidney Transplants by Donor Type and Year: 1988-2023

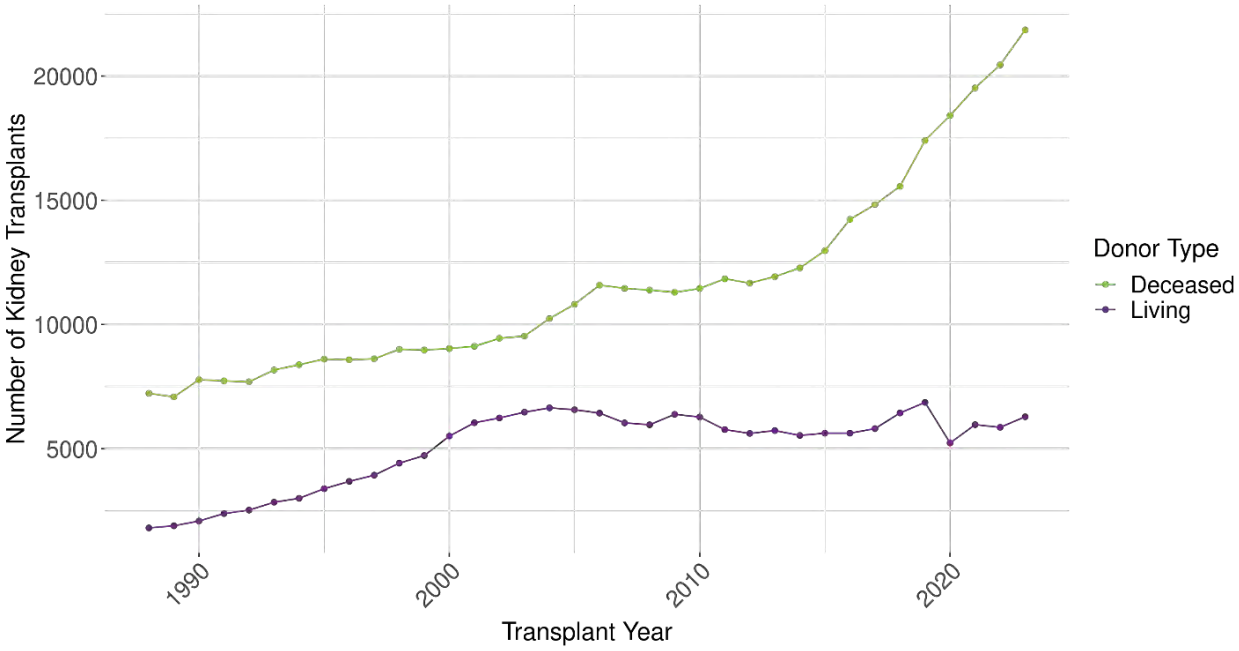
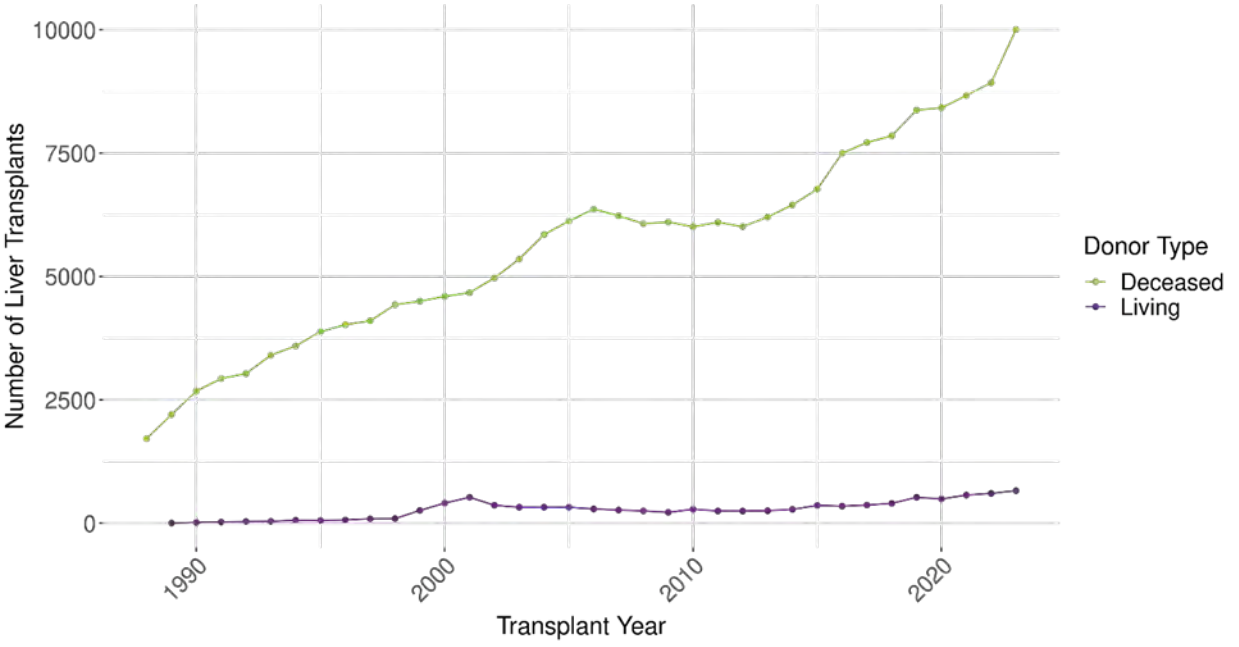


Figure 2: Number of Liver Transplants by Donor Type and Year: 1988-2023



Recommendation 1: Reduce systematic barriers to becoming a living donor

The Committee underscores that barriers to becoming a living donor are numerous and pose potentially modifiable challenges for those already motivated to become a living donor to help a transplant

candidate. System-level disincentives, such as financial and logistical considerations, mean that some people interested in pursuing living donation do not ultimately do so.[6] Importantly, the Committee considers these barriers distinct from the medical and psychosocial determination of suitability for safe living donation. As mentioned in the introduction, the safety and wellbeing of living donors is always paramount. Living donation should only be pursued in the case that it is safe for the individual.

The Committee discusses lack of understanding and knowledge about living donation as a separate, though related, barrier in *Recommendation 5*.

Proposed Direction 1A: conduct additional research to identify and understand barriers to living donation to inform concrete solutions

The Committee acknowledges while there are many researched barriers to living donation that should be addressed, there are also a number of barriers that are unknown or not fully understood. [7,8] The Committee advocates for additional research into these barriers, with a specific focus on equity in access, as a complementary step to addressing the known barriers described in Proposed Directions 1B, 1C, and as described in *Recommendation 5*.

The Scientific Registry for Transplant Recipients (SRTR)'s Living Donor Collective has begun analyzing barriers to becoming a living donor at the level of living donor candidates, that is, those who have initiated at least one part of evaluation at a living donor program.[9,10] The Living Donor Collective is interested in expanding this analysis to a national level with the help of the OPTN. The Committee has been collaborating with the Living Donor Collective in the development of OPTN requirements for transplant programs to submit data on living donor candidates, which would then be shared to the SRTR to further enrich these analyses on barriers. More information on this current project is detailed in *Recommendation 2*.

These efforts will yield important insight into barriers for completing evaluation but may not provide a holistic understanding: there are barriers that motivated individuals experience ahead initiating living donation evaluation. Therefore, the Committee also recommends partnering with organizations who may be better able to determine which barriers motivated individuals encounter before ever being seen for evaluation.

---

[6] Sandal, S., Schiller, I., Dendukuri, N., Robert, J. T., Katergi, K., Alam, A., Cantarovich, M., Fiore, J. F., Suri, R. S., Landsberg, D., Weber, C., & Fortin, M. C. (2022). Identifying Modifiable System-Level Barriers to Living Donor Kidney Transplantation. Kidney international reports, 7(11), 2410–2420. https://doi.org/10.1016/j.ekir.2022.08.028

[7] Lentine, Krista L.; Mandelbrot, Didier. Addressing Disparities in Living Donor Kidney Transplantation: A Call to Action. Clinical Journal of the American Society of Nephrology 13(12):p 1909-1911, December 2018. | DOI: 10.2215/CJN.06250518

[8] A finding in the Committee's 2022 Report to the Board of Directors on Living Donor Data Collection was a lack of understanding of barriers living donors face, and this report noted the need for increased data collection to identify and inform solutioning for these barriers.

[9] Kasiske BL, Ahn YS, Conboy M, Dew MA, Folken C, Levan M, Israni AK, Lentine KL, Matas AJ, Newell KA, LaPointe Rudow D, Massie AB, Musgrove D, Snyder JJ, Taler SJ, Wang J, Waterman AD. Outcomes of living kidney donor candidate evaluations in the Living Donor Collective pilot registry. Transplant Direct. 2021 Apr 22;7(5):e689. doi: 10.1097/TXD.0000000000001143.

[10] Kasiske BL, Ahn YS, Conboy M, Dew MA, Folken C, Levan ML, Humar A, Israni AK, Rudow DL, Trotter JF, Massie AB, Musgrove D; Living Donor Collective participants. Outcomes of living liver donor candidate evaluations in the Living Donor Collective pilot registry. Clin Transplant. 2021 Aug 3. doi: 10.1111/ctr.14394.

Another avenue that may be helpful is conducting an ethical review of access and disincentives to living donation. The OPTN Ethics Committee had previously proposed a white paper to investigate this, and the Committee is supportive of this effort, as it would provide the foundation for more concrete solutioning.

Proposed Direction 1B: reduce known financial barriers to becoming a living donor

There are multiple known yet modifiable financial barriers to becoming a living donor. Research has demonstrated that existing "resources available to provide financial relief to living kidney donors are ultimately insufficient, scattered, and underutilized."[11] The Committee considers that making living donation as cost-neutral as possible for individuals as an important step in improving living donation.

National Living Donor Assistance Center

The National Living Donor Assistance Center (NLDAC) was established in 2006 by the Department of Health and Human Services (HHS) to offset certain costs for the living donor, including travel expenses, lost wages, and dependent care expenses, with a maximum reimbursement per donor of $6,000.[12] There are numerous eligibility requirements, including that the living donor must be a US citizen or lawful resident, maintain a primary residence in the US, and that the recipient's household income must not exceed 350% of the HHS Poverty Guidelines. A living donor is ineligible if they receive any reimbursement from their associated recipient as permitted by the National Organ Transplant Act (NOTA). NLDAC also performs a means assessment on the recipient's ability to provide permitted financial reimbursements to the living donor but does not take into account the financial status of the living donor. As of 2022, NLDAC provided assistance to less than 10% of living kidney donors per year, a percentage that has not meaningfully increased since the creation of the program.[13] The mean reimbursement through NLDAC is roughly $2,350[14], and research shows that the estimated total cost of disincentives/barriers facing a living donor are $37,745.[15]

The Committee acknowledges the benefits of NLDAC and its undoubted aim at reducing financial barriers to living donation, however, recommends engaging federal stakeholders to address the apparent insufficiency of the program and ways to modify it such that it is meeting the needs of more (and ideally all) living donors. As mentioned in a 2020 public comment from the OPTN on the proposed rule to Remove Financial Disincentives to Living Organ Donation, NLDAC is a "payer of last resort. …Currently, the complexity of that requirement puts the burden on living donors to prove or disprove other sources of funding as a condition of NLDAC support. The OPTN believes this merits review as the complexity of this requirement could be a

[11] Polireddy, K., Crepeau, R. L., & Matar, A. J. (2023). Eliminating financial disincentives to living kidney donation. ncbi.nlm.nih.gov/pmc/articles/ PMC10347391/pdf/fmed-10-1061342.pdf.
[12] National Living Donor Assistance Center > Home. https://www.livingdonorassistance.org/
[13] Polireddy, K., Crepeau, R. L., & Matar, A. J. (2023). Eliminating financial disincentives to living kidney donation. ncbi.nlm.nih.gov/pmc/articles/ PMC10347391/pdf/fmed-10-1061342.pdf.
[5] Ibid.
[15] McCormick F, Held PJ, Chertow GM, Peters TG, Roberts JP. *Removing disincentives to kidney donation: a quantitative analysis*. J Am Soc Nephrol. (2019) 30:1349–57. doi: 10.1681/ASN.2019030242

disincentive to living organ donation."[16] As part of this overall engagement, the Committee recommends a concerted effort to reduce known financial barriers to living donation.

Non-Governmental Organizations

The Committee also recognizes the important role that many non-governmental organizations (NGOs) and nonprofit organizations play in assisting living donors with financial aspects of donation. The Committee recommends updating the existing informational pages about living donation on the OPTN website to include a centralized list of these organizations and which types of assistance they provide.[17] The NLDAC website maintains a similar page, which helps equip living donor candidates with appropriate information to help them navigate the process.[18] Providing this information on the OPTN website as well would increase the chance that the resources will reach living donors who may benefit.[19]

Paid Leave for Living Donors

Lost wages after donation remain a barrier to living donation, even with assistance provided through NLDAC and other organizations.[20,21] The Organ Donor Leave Law allots federal employees with 30 days paid leave for donation of an organ, while individual state legislation varies widely as to living donor leave laws, tax reimbursements, and other methods of protecting living donors.[22] Furthermore, individual companies have their own policies for paid leave following organ donation. This patchwork of approaches means that while some living donors may receive adequate paid leave following their donation, many others do not.

The Committee acknowledges that it is out of scope for the OPTN to propose changes to legislation. However, the Committee underscores the need for paid leave for living donors to reduce barriers and encourages the OPTN to engage in novel thinking about ways to encourage more employers to institute paid leave policies on their own accord. Committee members pointed to the success of the Living Donor Circle of Excellence, a program run by the American Society of Transplantation (AST), which provides recognition to employers who provide salary support of at least 80% for living donors for a minimum of four weeks.[23] This type of approach to recognize employers actively working to reduce barriers to becoming a living donor is a straightforward, relatively low-effort way to encourage both knowledge of living donation and participation in it. The Committee recommends engaging with the AST and participating

---

[16] OPTN Board of Directors. (2020) Ref. HHS Docket No. HRSA-2019-0001. optn.transplant.hrsa.gov/media/4zsnradw/2020-02-18-optn-public-comment-hrsa-removing-financial-disincentives-to-living-donation.pdf.

[17] Organ Procurement and Transplantation Network. *Living Donation*. OPTN. https://optn.transplant.hrsa.gov/patients/about-donation/living-donation/living-donation/

[18] Living Donor Resources and Information. *National Living Donor Assistance Center*. livingdonorassistance.org/Resources/Additional-Resources.

[19] Data shows that there were 3,455 total page visits and 2,867 unique users who visited the OPTN Living Donation Patient Brochure (see footnote 13) in the year 2023. This provides support for the idea to link additional resources, as it demonstrates that users are using the OPTN website as a source of information.

[20] Fu, R., et al. (2020). Economic consequences of adult living kidney donation. *Systemic Literature Review*, 24(4), 592-601. doi.org/10.1016/j.jval.2020.10.005.

[21] Rodrigue, J. R., Fleishman, A., Carroll, M., Evenson, A. R., Pavlakis, M., Mandelbrot, D. A., Baliga, P., Howard, D. H., & Schold, J. D. (2018). The Living Donor Lost Wages Trial: Study Rationale and Protocol. *Current transplantation reports*, 5(1), 45–54.

[22] American Transplant Foundation. (2022). *Living donor laws*. American Transplant Foundation. americantransplantfoundation.org/wp-content/uploads/2022/11/Living-Donation-Laws.pdf.

[23] Living Donor Circle of Excellence. (n.d.). *Resources for HR Professionals.* AST. livingdonorcircle.com/hr#what-to-expect.

employers in the Living Donor Circle of Excellence to explore how a similar or tandem initiative could be undertaken within the context of the OPTN.

Other Financial Barriers
The Committee also recommends engaging diverse stakeholders in discussions about how best to address other financial barriers, including varied insurance coverage for living donation, miscellaneous direct and indirect costs, and costs that may impact regions unequally dependent on geographic factors, through a multi-organizational taskforce approach.[24]

Proposed Direction 1C: reduce known logistical barriers to becoming a living donor

The Committee recognizes that in addition to known financial barriers, there are several known logistical barriers that should be addressed.

A primary logistic barrier anecdotally known to members is completion of evaluation.[25] Evaluation can mean multiple trips to the living donor program to complete the required 30+ tests and evaluations, and individuals may spend weeks to months waiting for appointments and test results. Inefficient evaluation processes not only prove frustrating to living donor candidates, but also may result in missed opportunities for transplants as the intended recipient's disease state progresses.[26] As expanded upon in *Recommendation 3*, the Committee proposes engaging diverse stakeholders to develop and promote best practices for evaluating living donors to reduce this known logistical barrier.[27]

The Committee also acknowledges other potentially modifiable logistical challenges, and encourages consideration of the following barriers, several of which are expanded upon in other parts of this report:

- Language barriers among care team and living donor/intended recipient
- Lack of cultural competence in evaluation procedures and policies, which may create unnecessary logistical challenges
- Distance of some motivated living donor candidates from a living donor transplant center and access to transportation to appointments
- Access to programs to aid with weight loss and smoking cessation

[24] Fu, R., et al. (2020). Economic consequences of adult living kidney donation. *Systemic Literature Review*, 24(4), 592-601. doi.org/10.1016/j.jval.2020.10.005.
[25] OPTN Living Donor Committee. *Meeting Minutes.* February 9, 2024.
[26] Habbous, S., et al. (2018). The efficiency of evaluating candidates for living kidney donation. *Transplant Direct*, 4(10), 394. ncbi.nlm.nih.gov/pmc/articles/PMC6233672/.
[27] Weng, F. L., Morgievich, M. M., & Kandula, P. (2018). The Evaluation of Living Kidney Donors: How Long Is Too Long?. *American journal of kidney diseases : the official journal of the National Kidney Foundation*, *72*(4), 472–474. https://doi.org/10.1053/j.ajkd.2018.07.001

Key Takeaways: Recommendation 1

The Committee views the stagnant growth in living donation to be in part due to the many barriers and urges increased prioritization in the OPTN to determine ways to address them.

- First, (see 1A), analysis of barriers to living donation is planned through existing data collection projects and collaboration with the SRTR, further elaborated upon in *Recommendation 2*.
- Proposed Directions 1B and 1C will require increased collaboration and cooperation with a variety of stakeholders (See *Appendix A*), which may be best accomplished through a taskforce approach.

The Committee views reducing *any* barrier to living donation as a worthwhile endeavor. With increased attention to reducing barriers, meaningful enhancement to living donation overall will follow.

Recommendation 2: Expand OPTN data collection on living donation and collaborate with other entities for data collection to increase public trust and promote living donor safety

The Committee emphasizes that establishing a comprehensive understanding of long-term risks and benefits attributable to living donation as well as analysis of access and barriers to living donation could have a substantial impact on the field of transplant. Improved data collection on living donation may provide additional evidence demonstrating that living organ donation is safe, which could in turn encourage prospective living donors to donate. Ensuring that potential living donors have robust understanding to inform their consent could bolster trust in the system and affirm patient safety in a way that may enhance living donation. The Committee has long noted the need for increased understanding through data and is currently working on a project that would expand living donor data collection in collaboration with SRTR's Living Donor Collective program.

The Committee's initiatives for expanding and updating living donor data collection date back to December 2022 when the Committee presented their findings and recommendations on the current state of living donor data collection, the need for longer-term data collection, and opportunities for collaboration and innovations for improved living donor data collection to the Board.[28] The Committee points out that both living kidney and living liver donation are understood and well-researched as safe procedures, and that there is good understanding of short-term risks and outcomes.[29,30] However, as the 2022 report described, there is a lack of understanding of long-term risks and outcomes for living liver and kidney donation. The Committee sees addressing this lack of data as a top priority.

From those initial discussions and positive feedback from the Board, the Committee identified a project that achieves their goals of increasing efficiency, reducing redundancy, and acquiring key data through a

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

[29] Lentine, K. L., Lam, N. N., & Segev, D. L. (2019). Risks of Living Kidney Donation: Current State of Knowledge on Outcomes Important to Donors. Clinical journal of the American Society of Nephrology : CJASN, 14(4), 597–608. https://doi.org/10.2215/CJN.11220918

[30] Abu-Gazala, S., & Olthoff, K. M. (2019). Current Status of Living Donor Liver Transplantation in the United States. Annual review of medicine, 70, 225–238. https://doi.org/10.1146/annurev-med-051517-125454

collaborative approach. This project entails the OPTN requiring collection and reporting of living donor candidate and donation decision data. This would be shared with the Living Donor Collective to establish a foundation that enables the Living Donor Collective to directly follow-up with living donor candidates and living donors long-term on a national level. As noted in *Recommendation 1*, this project also supports further analysis of access and barriers to living donation through expanded data collection on the living donor candidate population. The project also proposes critical updates to the OPTN living donor data collection instruments, which have not been updated in some cases since 2006 and contain numerous inefficiencies and outdated data elements. By updating these and ensuring accuracy, timeliness, and need for the data collected, the Committee hopes to reduce unnecessary burden and ensure that the data collected is useful and complete for informing patient safety and outcomes.[31]

The Committee submitted these concepts to the community for feedback during the Summer 2023 public comment period.[32] The community was largely supportive of the concepts of expanding data collection to understand long-term outcomes as well as barriers to living donation. Following this, the Committee has continued developing this project into a formal policy proposal.[33]

The Committee recommends expanding living donor data collection as a priority. The sentiment that long-term data collection on living donation is necessary also aligns with the consensus of the transplant community. A recent multi-stakeholder consensus conference, which included 30% patients, underscored the need for data on long-term living donor experiences including quality of life and patient-centered outcomes.[34] These recommendations cited that collecting long-term data on living donor outcomes is a moral and ethical obligation.[35]

Proposed Direction 2A: continue development of current project in collaboration with SRTR's Living Donor Collective program

As summarized above, the Committee has already spent a substantial time and effort developing a project that would improve living donor data collection from multiple angles. Improvements to the living donation system need to be evidence-based as the informed choice of prospective living donors, wherein the safety, protection, and follow-up of all living donors is paramount. Without accurate and complete data, these goals cannot be supported in ways that strengthen living donation. Additionally, understanding the gaps and current state of living donation through improved data collection will help address the stark disparities in donation rates by race, ethnicity, and sex, and improve equity.[36] Improved data collection could help identify the reasons behind these disparities and inform evidence-based solutions for mitigation.

---

[31] Challenges with data collection and ways to combat these are also described in Proposed Direction 3A.

[32] OPTN Living Donor Committee, *Concepts for a Collaborative Approach to Living Donor Data Collection*, Concept Paper. Public Comment Period, July 27, 2023 – September 19, 2023. Available at: https://optn.transplant.hrsa.gov/media/ee5jqj23/ldc_living-donor-data-collection_concept-paper_pcsummer2023.pdf.

[33] The project, titled *Update and Improve Efficiency in Living Donor Data Collection*, is in the project approval phase at the time of publication of this report. This proposal builds off of the Committee's prior concept paper on this topic which was out for public comment in Summer 2023.

[34] Snyder, J., Schaffhausen, C., Hart, A., et al. "Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference." Am J Transplant. 2023.

[35] Ibid.

[36] See Figures 2 and 5

The Committee strongly recommends continuation of this project as it feels it is one of the most impactful projects that could be accomplished within the scope of the OPTN. Importantly, the SRTR has been supportive and engaged throughout the development of this project. The goals of this project are only achieved through continued collaboration with the Living Donor Collective.

Key Takeaways: Recommendation 2

Improvements to living donation must be made with evidence-based decisions to protect the safety and well-being of living donors. Therefore, the Committee continues to emphasize the necessity of improved and expanded data collection. The Committee is currently developing a proposal in collaboration with SRTR's Living Donor Collective that aligns with this recommendation as well as *Recommendation 1*.

- The Committee intends to continue forward with this project as it has the potential to be the most impactful option for enhancing living donation within the scope of the Committee's role in the OPTN.

Recommendation 3: Develop and promote best practices for key components of the living donation process

The living donation process encompasses the interested potential living donor candidate reaching out to a transplant center, their screening and evaluation by the center, and their progression to donation or decline to donate for any reason. The Committee notes that substantial variation exists in living donor evaluation, data collection, and other key components of the living donation process from start to follow-up. This is in part due to a lack of best practices within the living donation system. By promoting open discussion and collaboration among programs with different approaches to create and share best practices, the Committee believes that inefficiencies can be reduced, outcomes can be improved, and additional living donation transplants can become successful.

Proposed Direction 3A: develop best practices for living donation evaluation and data collection through collaborative improvement models

The Committee recognizes the lack of evidence-based best practices as a challenge that could be relatively easy to address through collaborative improvement coupled with the increased data collection as described in *Recommendation 2*. Members pointed to the success of the OPTN Offer Acceptance Collaborative in discovering, developing, and implementing best practices by taking advantage of diverse perspectives and protocols.[37] The collaborative improvement model allows for increased support for members, enhancement of system efficiencies, and overall improvement with associated monitoring.[38] Members note that information sharing to develop best practices will also promote increased transparency for living donor candidates to aid their informed decisions. Collaborative efforts could be used in conjunction with a taskforce approach.

[37] OPTN. *National collaborative focusing on organ offer acceptance to enhance system efficiency will kick off in person in January 2023*. (2023, January 16). HRSA. optn.transplant.hrsa.gov/news/national-collaborative-focusing-on-organ-offer-acceptance-to-enhance-system-efficiency-will-kick-off-in-person-in-january-2023/.

[38] OPTN. (n.d.). *Collaborative Improvement.* (n.d.). HRSA. optn.transplant.hrsa.gov/professionals/improvement/collaborative-improvement/.

Living donor evaluation and exclusion

Evaluations vary quite significantly from program to program, and while programs should retain the ability to structure their evaluations according to the complexities of their program and the population it serves, increased information sharing could yield more efficient and transparent practices.[39] Members pointed out that collaborative improvement could help programs develop policies and practices surrounding use of social media to find donors, to avoid unnecessary repeated testing, reduce potential discrimination and exclusion for non-medical, non-evidence-based reasons, and create avenues for transparency around non-medical reasons for exclusion.[40] The Committee views the lack of transparency for living donor candidates in evaluation and exclusion practices as an area for improvement through this collaborative improvement approach.

As described in *Recommendation 1*, the length of living donor evaluation can also pose a logistical barrier to donation. Learning from the practices and experiences of centers with efficient evaluation processes is a logical next step for improving the overall system.[41] For example, some transplant programs have implemented one day evaluations that have helped reduce logistical barriers. Success has been demonstrated with this one-day approach in other countries, as well.[42,43,44] Collaborative improvement could also help improve processes for when multiple living donor candidates come forward for one recipient (including evaluation procedures for these cases and appropriate messaging surrounding consideration of non-directed donation).

Data collection practices

Collaborative improvement could also help identify solutions for challenges in data collection. The Committee recognizes that programs sometimes face difficulties submitting required OPTN data and use a variety of staffing models and contact procedures. OPTN data demonstrates that programs may face challenges following up with living donors, particularly at the two-year mark.[45] By utilizing a collaborative improvement model, information sharing may help centers improve their own procedures and processes for collection of data. This may, in turn, facilitate

[39] Mandelbrot, D. A. and Pavlakis, M. (2012). Living donor practices in the US. *Adv Chronic Kidney Dis*, 19(4), 212-219. 10.1053/j.ackd.2012.04.010.

[40] For example, one Committee member mentioned anecdotally that a common situation at their program is when a living donor comes forward with multiple caretakers following donation because of their cultural family norms, but hospital policy states that the living donor must have one dedicated caretaker. This member mentioned that this may be a non-evidence based, non-culturally competent reason for denial.

[41] Weng, F. L., Morgevich, M. M., & Kandula, P. (2018). The evaluation of living kidney donors. American Journal Kidney Disease, 72(4), 472-474. 10.1053/j.ajkd.2018.07.001.

[42] Graham, J. M., and Courtney, A. E. (2017). The Adoption of a One-Day Donor Assessment Model in a Living Kidney Donor Transplant Program. *Am. Journal of Kidney Diseases*, 71(2), 209 215. doi.org/10.1053/j.ajkd.2017.07.013.

[43] Yohanna, S., et al. (2024). Implementation of a one-day living kidney donor assessment clinic to improve efficiency of the living kidney donor evaluation. *Canadian Journal Kid Health and Disease*. ncbi.nlm.nih.gov/pmc/articles/PMC10896046/.;

[44] Graham, J. M. and Courtney, A. E. (2017). Adoption of a one-day kidney donor assessment model in a living kidney donor transplant program. *Am. Journal of Kidney Diseases,* 71(2), 209-215. ajkd.org/article/S0272-6386(17)30891-0/abstract.

[45] OPTN data demonstrates that for LDF forms due in 2022, the percent of kidney clinical forms completed on-time for donors was 86% (6mo), 84% (1-yr) and 77% (2-yr). The percent of kidney lab forms completed on-time for donors was 79% (6mo), 74% (1-yr), and 65% (2-yr). For liver, the percent of liver clinical forms completed on time for donors was 86% (6-mo), 82% (1-yr), and 71% (2-yr). The percent of liver lab forms completed on-time for donors was 84% (6mo), 80% (1-yr), and 66% (2-yr).

greater completion of living donor follow-up, which as noted above in *Recommendation 2*, is a critical piece to an overall strong system of living donation.

Referral to living donation
The Committee emphasizes that living donation begins with referral of a transplant candidate to a transplant center and early consideration of living donation as a treatment option. Collaborative improvement could help living donation stakeholders connect with stakeholders who work more closely with candidates for transplant to identify and implement ways to improve this process.

Proposed Direction 3B: develop OPTN guidance and educational materials for key components of living donation process

Once best practices are informed by expanded data collection as described in *Recommendation 2* and identified through collaborative improvement or other methodologies, the Committee recommends developing guidance documents for programs, and educational materials for a variety of stakeholders. By creating and updating guidance documents for living donor evaluation, data collection, and referral to living donation, the OPTN would demonstrate its commitment to sharing effective practices and transparency. While the Committee has developed some guidance along these lines, a focus on generating additional guidance and updating existing guidance according to updated best practices would be a step towards improving living donation.[46] Similarly, collaborative improvement may identify areas where additional educational materials would be useful. The Committee recommends a focus on developing educational modules, pamphlets, and other mechanisms to reach diverse stakeholders about key topics in living donation, a topic expanded upon in *Recommendation 5.*

Key Takeaways: Recommendation 3

The Committee sees development of best practices as a logical step towards enhancing living donation.

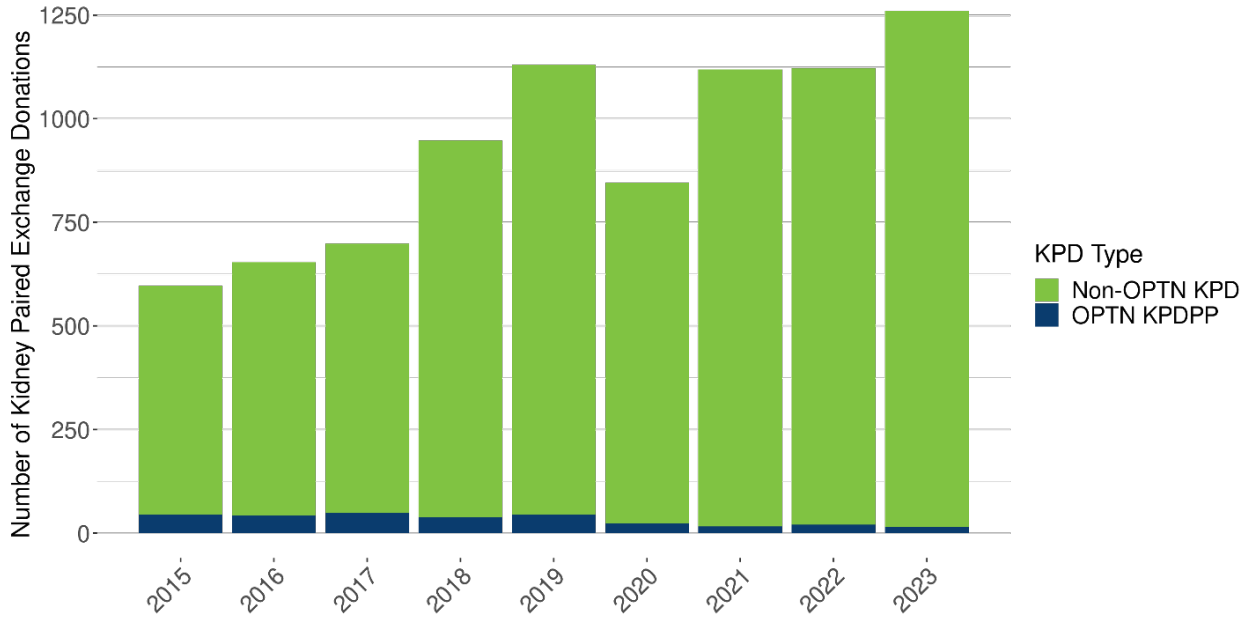
- Collaborative improvement projects already have a positive reputation (and associated results) within the transplant community, so it makes sense to harness this approach for living donation as well.
- Consideration of the topics described in *Proposed Directions 3A* and *3B* (development of living donation process evaluation and data collection best practices guidance and educational materials) through a collaborative improvement-type approach will likely reduce inefficiencies, promote information sharing, and increase transparency for living donor candidates to aid their informed decisions.
- Given the existing OPTN appropriate infrastructure for collaborative improvement projects, the Committee ranked this recommendation highly in terms of feasibility, scope, and potential impact when coupled with the steps described in *Recommendations 1* and *2.*

[46] OPTN. *Guidance*. (n.d.). HRSA. optn.transplant.hrsa.gov/professionals/by-topic/guidance/.

Recommendation 4: Improve and expand upon paired exchange opportunities and investigate other ways to expand the living donor pool

The Committee also underscores the importance of improved and expanded paired exchange opportunities as ways to optimize the living donation system. It has been well-documented that paired exchanges are a necessary component to a modern, efficient living donation system.[47] In the United States, a patchwork of paired donation approaches exist. Private companies that run paired exchange registries have been successful, but participation can be expensive for programs.[48] The OPTN Kidney Paired Donation Pilot Program (KPDPP) is the OPTN's own program to facilitate kidney paired donations. However, the Committee points out that due to funding constraints, the size, and programming capacity, the overall success of the pilot program has been limited. The OPTN KPDPP performed only 15 (1.2%) of paired kidney donations in the US in 2023 (see Figure 3).[49] That said, because the program is offered at no cost to members, it is an important resource to maintain, especially for smaller transplant programs, which are more likely providing transplant services to underserved and minority patient population.

Figure 3: Number of OPTN Kidney Paired Donation Pilot Program Transplants vs. Non-OPTN Kidney Paired Donation Transplants by Year



[47] Kher, V. and Jha, P. K. (2020). Paired kidney exchange transplantation. *Transplant International*, 33(9), 975-984. onlinelibrary.wiley.com/doi/abs/10.1111/tri.13693.

[48] National Kidney Registry. *Member Center Terms and Conditions.* NKR. *https://portal.kidneyregistry.org/docs/NKR_MC_Terms_Conditions.pdf*

[49] The state of the OPTN/UNOS KPD Pilot Program. (2014). *OPTN*. optn.transplant.hrsa.gov/media/1827/kpd_report.pdf.

Proposed Direction 4A: Improve and expand opportunities for paired donation within the OPTN

The Committee recommends that the OPTN look closely at ways to improve, expand, and invest in opportunities for paired donations within the OPTN. If the OPTN KPDPP were expanded, it may prompt more living donor programs to utilize it. This may mean that centers would not need to participate in higher-cost KPD programs run by private companies, which may in turn free up resources to improve and expand components of their own living donation programs. Additionally, members mentioned that programs may also appreciate partnership with a larger government-sponsored paired donation to promote greater oversight and regulation in the paired donation space. This is beyond the purview of the OPTN, so the Committee recommends the Board defer this proposed direction to HRSA, which oversees the OPTN KPDPP.

Proposed Direction 4B: Explore opportunities to facilitate liver paired donations within the OPTN

The Committee also recommends that the OPTN explore opportunities to help facilitate liver paired donations. In the United States, living donor liver transplants accounted for just 6.2% of total liver transplants in 2023.[50] Kidney paired donations are common in the US, however, living liver paired exchange is still relatively rare. Research has demonstrated that the most common reason that motivated living liver donors are turned down is due to ABO incompatibility with their intended recipient.[51] Therefore, increasing opportunities for liver paired donation would promote increased transplants by allowing incompatible pairs to participate in paired exchanges.

Proposed Direction 4C: Explore possibilities to expand the paired donation donor pool

The Committee also recommends exploring other ways to expand the living donor pool related to paired donation. Increasing opportunities for non-directed donors to start paired donation chains, as well as exploring the feasibility of using deceased donor organs to start paired donation chains, would be feasible first steps.[52] The Committee suggests exploring ways to involve motivated international living donors as a part of paired donations (and living donation in general), and notes that the OPTN Ad Hoc International Relations Committee is actively exploring best practices in this area.[53]

---

[50] From OPTN data as of December 31, 2023

[51] Gunabushanam V, Ganesh S, Soltys K, Mazariegos G, Ganoza A, Molinari M, Tevar A, Hughes C, Humar A. Increasing Living Donor Liver Transplantation Using Liver Paired Exchange. J Am Coll Surg. 2022 Feb 1;234(2):115-120. doi: 10.1097/XCS.0000000000000036. PMID: 35213430.

[52] Wang, W., et al. (2022). Kidney paired donation chains initiated by deceased donors. Kidney International Reports. ncbi.nlm.nih.gov/pmc/articles/PMC9171627/.

[53] The OPTN Ad Hoc International Relations Committee is undertaking a project to develop guidance which will provide transplant programs with best practices that will aid in more effectively and efficiently managing international living donations within the United States. The guidance document is expected to be out for public comment in July 2024.

Key Takeaways: Recommendation 4

The OPTN is well-positioned to develop the key infrastructure for paired donation in the United States: creating a national registry, improving algorithms for matching, providing logistical support, and monitoring living donor and recipient outcomes.[54]

- The Committee notes that there are limitations to 4A and 4B considering the scope of the OPTN but that opportunities to discuss with stakeholders may exist.
- 4C may require additional scoping and feasibility analysis, but the Committee recommends a taskforce consider this suggestion.

Recommendation 5: increase awareness and knowledge about living donation among the general public

The Committee recognizes limited public awareness and understanding about living donation as a critical factor to address in the broad goal of enhancing living donation. Research demonstrates "inadequate knowledge of the benefits, risks, and opportunities for living donation is an important, potentially modifiable barrier to living donor transplantation."[55] The problem is complex: there is a lack of awareness for living donation among the general population (especially among minority populations), as well as a lack of understanding among transplant candidates that living donation is a treatment option.[56,57] Furthermore, the lack of data on risks, outcomes, and disparities as described in *Recommendation 2* continues to pose challenges regarding building awareness surrounding these topics. The Committee again underscores the need for accomplishing the steps as described in *Recommendation 2* to increase data collection, which in turn will increase trust and understanding of living donation as an option. The Committee has several suggestions regarding these topics to go alongside improved data collection as outlined in *Recommendation 2*.

Proposed Direction 5A: Harness media outlets and social media networks as avenues for increasing awareness of living donation

Committee members discussed the power of both traditional media outlets and social media networks as avenues for increasing awareness of living donation in a responsible and ethical manner (to ensure that the pitfalls of social media as an awareness effort does not lead to unintended consequences).[58] While some transplant candidates use social media or similar campaigns to find a suitable living donor for their specific case, the Committee thought these avenues could also be leveraged to raise awareness about living donation and non-directed donation as an option. Specifically, members suggested Q&A sessions with prior living donors to

[54] Agrawal, D., Gupta, S., & Saigal, S. (2022). European Association for Study of the Liver. journal-of-hepatology.eu/action/showPdf?pii=S0168-8278%2822%2903156-7.

[55] Hunt, H. F. (2018). Strategies for increasing knowledge, communication, and access to living donor transplantation. *Curr Transplant Rep*, 5(1), 27-44. ncbi.nlm.nih.gov/pmc/articles/PMC6413325/.

[56] Kaplow, K., et al. (2023). National attitudes towards living kidney donation in the United States. Canadian Journal of Kidney Health and Disease, 6(3). ncbi.nlm.nih.gov/pmc/articles/PMC6376531/#.

[57] Purnelll, T. S., Hall, Y. N., Boulware, L. E. (2013). Understanding and overcoming barriers to living kidney donation among United States racial and ethnic minorities. Advanced Chronic Kidney Disease, 19(4), 244-251. ncbi.nlm.nih.gov /pmc/articles/PMC3385991/.

[58] Meena, P., Kute, V. B., Bhargava, V., Mondal, R., & Agarwal, S. K. (2023). Social Media and Organ Donation: Pros and Cons. Indian journal of nephrology, 33(1), 4–11. https://doi.org/10.4103/ijn.ijn_158_22

learn about the process, post-donation recognition/storytelling, and focusing on common "myths" about living donation.[59]

Proposed Direction 5B: develop living donation educational materials and efforts with emphasis on cultural competency

The Committee appreciates cultural and societal differences among regions across the country and specific demographic groups such as age, race/ethnicity, sex, and first language as relevant. It is important to understand how these differences impact understanding of living donation and ensure that a demographic difference is not prohibiting access to living donation. The Committee urges that the development of knowledge-building efforts aimed to increase education and awareness of living donation do so with particular attention to the principles of cultural competency.[60] These awareness-building campaigns could be particularly impactful in communities where there are increased misconceptions about the living donor process.

The Committee underscores the importance of public trust in the donation and transplant system for improving living donation. Therefore, understanding myths and misconceptions about living donation and actively working to dispel them is vital.[61] Committee members recommend partnering with trusted organizations within the medical system and in relevant communities to aid with this. Research has shown that specific racial groups, most notably Black/African American and Hispanic/Latino, are overrepresented on the waitlist as compared to the living donor pool and that within these populations trust in the medical system can be limited for a variety of factors. [62,63,64] Figures 4 and 5 show the breakdown of living liver and kidney donors by race/ethnicity and year. The Committee recommends working to increase public trust and awareness of living donation within these populations.

[59] Davis, L., Iraheta, Y. A., Ho, E. W., Murillo, A. L., Feinsinger, A., & Waterman, A. D. (2022). Living Kidney Donation Stories and Advice Shared Through a Digital Storytelling Library: A Qualitative Thematic Analysis. *Kidney medicine*, 4(7), 100486. https://doi.org/10.1016/j.xkme.2022.100486

[60] "Cultural competency in health care describes the ability of systems to provide care to patients with diverse values, beliefs and behaviors, including the tailoring of health care delivery to meet patients' social, cultural and linguistic needs." See: American Hospital Association. *Becoming a Culturally Competent Health Care Organization.* AHA. https://www.aha.org/ahahret-guides/2013-06-18-becoming-culturally-competent-health-care-organization#:~:text=Cultural%20competency%20in%20health%20care,social%2C%20cultural%20and%20linguistic%20needs.

[61] American Transplant Foundation. (n.d.). *15 most common myths and concerns about ...* American Transplant Foundation. http://www.americantransplantfoundation.org/wp-content/uploads/2014/04/The-Top-15-Concerns.pdf

[62] Buford, J. (2023). Race, age, and kidney transplant waitlisting among patients receiving incident dialysis in the United States. *Kidney Medicine*, 5(10). https://doi.org/10.101 6/j.xkme.2023.100706.

[63] Martínez-López, M. V., McLaughlin, L., Molina-Pérez, A., Pabisiak, K., Primc, N., Randhawa, G., Rodríguez-Arias, D., Suárez, J., Wöhlke, S., & Delgado, J. (2023). Mapping trust relationships in organ donation and transplantation: a conceptual model. *BMC medical ethics*, *24*(1), 93. https://doi.org/10.1186/s12910-023-00965-2

[64] Taylor, L. A., Nong, P., & Platt, J. (2023). Fifty Years of Trust Research in Health Care: A Synthetic Review. *The Milbank quarterly*, *101*(1), 126–178. https://doi.org/10.1111/1468-0009.12598

Figure 4: Number of Living Kidney Donors by Donor Race/Ethnicity and Year

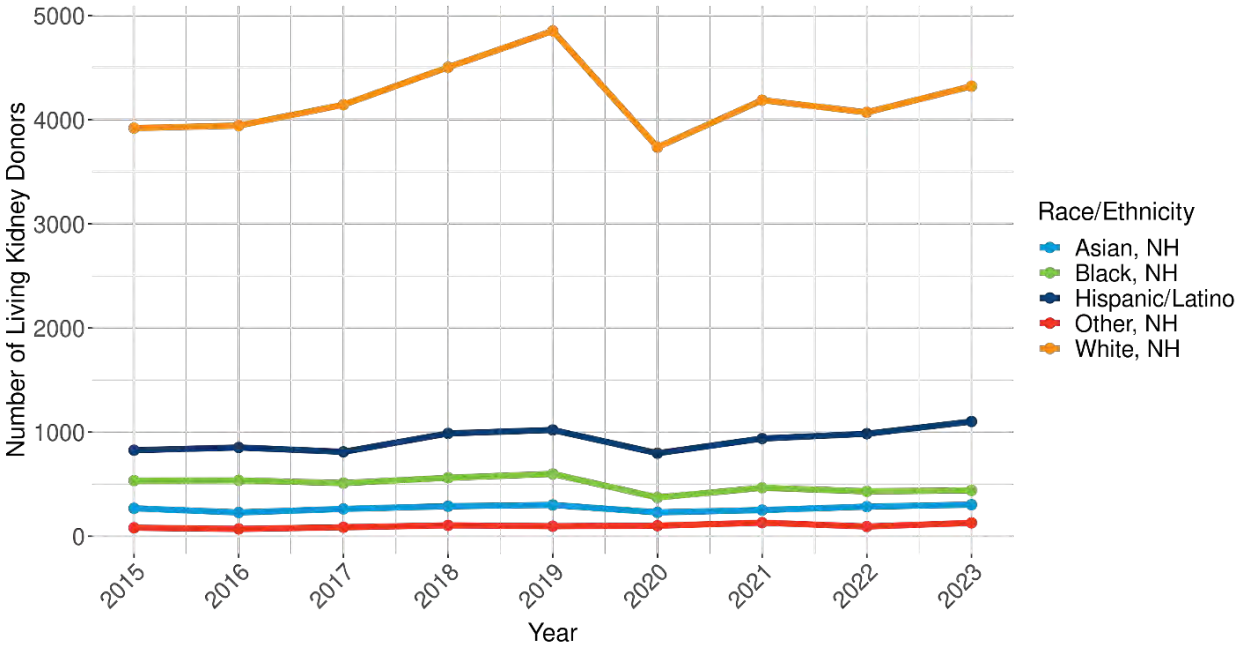
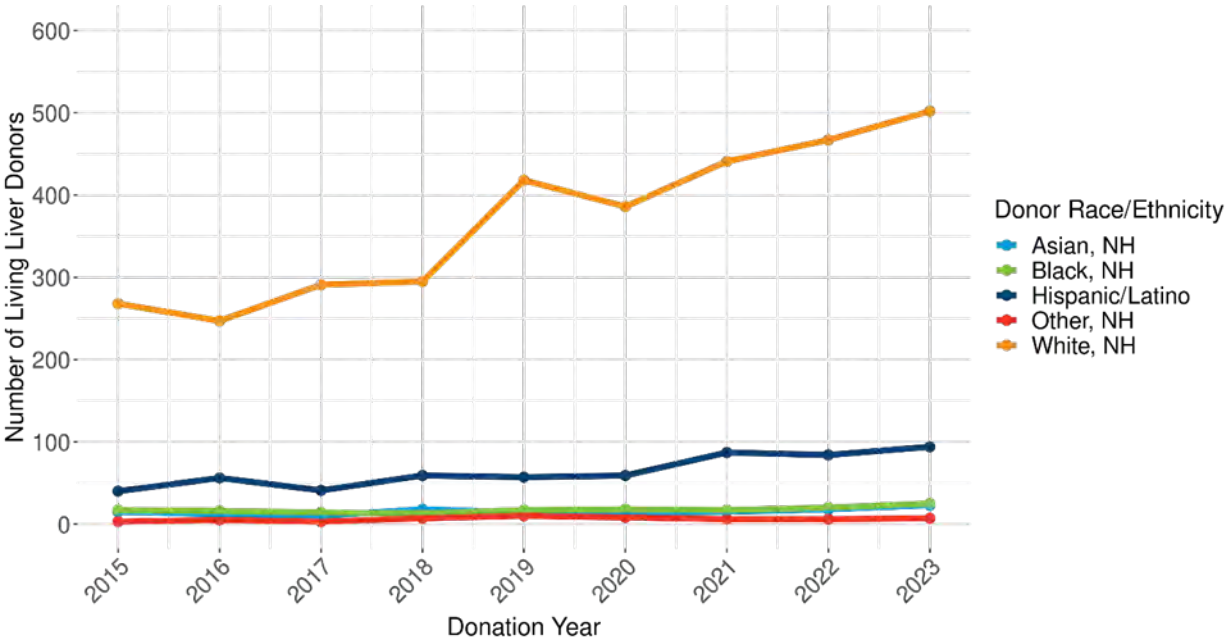


Figure 5: Number of Living Liver Donors by Race/Ethnicity and Year



Proposed Direction 5C: emphasize education about living donation as a treatment option for transplant candidates

Importantly, efforts should also be made to increase knowledge about living donation as a treatment option within the transplant candidate population. Many recipients who receive a living organ graft had a living donor from their community, so educating transplant candidates about the possibility of living donation (and participation in paired exchange programs) as a

treatment in addition to the deceased donor waitlist is paramount. The Committee notes that many of the same strategies described in the paragraphs above can be used to achieve this goal.

Key Takeaways: Recommendation 5

Awareness and education about living donation are key to a robust and growing living donation system and recommendations in this section are likely to provide immediate impact.

- Specifically, the Committee recommends devoting resources to 5B. Data shows that those most likely to be living donors are white, educated, and of a higher socioeconomic status, and this shows, in part, that the right information may not be reaching those from other socioeconomic statuses or racial backgrounds.[65] While it may be difficult to measure the impact of these items, the Committee recommends that they not be overlooked.
- 5A may pose scope concerns, but the Committee recommends possibly partnering with outside organizations. The Committee also notes that raising awareness about living donation may also be aided through many of the other proposed directions.

Recommendation 6: leverage technology and embrace innovation within the living donation process

The Committee recognizes technology across all industries is rapidly evolving, yet some processes used in living donation remain outdated and inefficient. The Committee encourages developing technological tools and embracing innovative ideas within living donation to enhance the system. Prior living donors and clinicians on the Committee noted that inefficiencies in the workup and evaluation process are a major challenge. Centers have varied acceptance criteria, which often are not made readily apparent to living donor candidates.[66] Members anecdotally explained that if a living donor candidate makes it partway through evaluation at one center, is declined by that center, and then proceeds with evaluation at another center, evaluation tests are often repeated unnecessarily, or the entire process is delayed by inefficient data transfer. This may lead to frustration and confusion, and ultimately may mean that a motivated living donor backs out simply because of process inefficiencies.

Proposed Direction 6A: develop a national application for standardized intake of living donors

Members brainstormed that one way to combat the above challenges would be to create an application or national screening database where living donor candidates complete a standardized intake process, and then be able to view transplant programs where they meet the criteria to proceed with donation. From there, the living donor candidate would be able to choose a transplant program that meets their needs and have a transparent view into acceptance criteria and evaluation procedures. Members also stated that this idea could be expanded upon to include a hub to coordinate testing and follow-up, as well as provide a centralized location for resources available to living donors. Members described frustrations and challenges with existing screening tools such as Breeze and the National Kidney Registry (NKR)

[65] Ross, L. F., & Thistlethwaite, J. R. (2021). Gender and race/ethnicity differences in living kidney donor demographics: Preference or disparity?. *Transplantation reviews (Orlando, Fla.)*, *35*(3), 100614. https://doi.org/10.1016/j.trre.2021.100614
[66] Cantarelli, C. and Cravedi, P. (2019). Criteria for living donation from marginal donors. *Nephron*, 142(3), 227-232. karger.com/nef/article/142/3/227/227060/Criteria-for-Living-Donation-from-Marginal-Donors

evaluation platforms. These tools can often be expensive for programs and inefficient and hard to use for staff and living donor candidates.[67] Therefore, exploring a national screening tool as an alternative would be worthwhile.[68] A national screening tool may offer benefits such as affording living donor candidates the opportunity to see which transplant program they may be accepted at as a living donor based on their initial input of information. This idea would require a large amount of resources and may pose logistical and feasibility challenges given the structure of the healthcare system in the US; however, that it would be an interesting idea to explore, possibly through a multi-organizational taskforce approach.

Proposed Direction 6B: Collaborate with technology experts to develop tools, websites, and processes to address specific challenges in living donation

Members also brainstormed several other ideas to leverage technology which may mitigate process inefficiencies or other points of frustration in the system:

- Optimize internet search engine searches to drive appropriate information to potential living donors and those who may benefit from living donation at the right times
- Explore applications for artificial intelligence throughout the living donor evaluation process to promote efficiency

Proposed Direction 6C: Encourage and embrace innovation within living donation through guidance regarding new technologies

The Committee also recommends embracing innovation within living donation through development of guidance. One area that has shown significant promise is robotic living donor surgeries.[69,70] Additionally, there have been at least two instances of simultaneous live liver kidney paired donation. While the Committee recognizes this is a rare confluence of circumstances and may not be worthwhile to explore at scale at this time, it is a great example of how embracing new ideas in living donation can enhance the overall system.[71]

It is important to equip programs with adequate knowledge regarding these emerging technologies, so the Committee recommends development of OPTN guidance or discussion in a collaborative improvement format on these topics, and other innovations, as appropriate.

[67] Meeting Summary. *OPTN Living Donor Committee*. May 8, 2024

[68] The OPTN deceased donor data collection platform may be easily modified to become a data collection tool for living donors and sharing that data across multiple centers.

[69] Broering, D., Sturdevant, M. L., & Zidan, A. (2022). Robotic donor hepatectomy. Am. Journal Transplant, 22(1), 4-23. pubmed.ncbi.nlm.nih.gov/34783439/.

[70] Khajeh, E., et al. (2023). Robot-assisted versus laparoscopic living donor nephrectomy. Journal of Robotic Surgery, 17, 2513-2526. link.springer.com/article/10.1007/s11701-023-01681-0.

[71] Torres, A., et al. (2019). Bi-organ paired exchange. Am. Journal Transplantation, 19(9), 2646-2649. pubmed.ncbi.nlm.nih.gov/30977579/.

Key Takeaways: Recommendation 6

The Committee underscores that a robust technological foundation is key for a strong living donation system.

- The Committee understands 6A as an idea that would require a significant amount of resources to develop and maintain, and may pose additional scoping and feasibility concerns; however, the potential impact in improving the system is high.
- Aspects of 6B may be relatively easy to address, and the Committee notes that many private companies have also attempted to address some of these items.
- The Committee sees the development of guidance and discussions to embrace innovation as recommended in 6C as a critical component to a strong living donation system and recommends this as an item to address through a muti-organizational taskforce.

In all, the technological aspects of living donation should not be neglected. However, members noted that many technological challenges currently faced may be addressed through the other recommendations presented above, such as improving data collection and developing best practices.

Recommendation 7: Reduce disincentives for creating and maintaining living donor programs at transplant centers

The Committee notes that an important area that is often neglected in conversations about how to improve living donation are transplant center-based challenges. Out of 230 OPTN members with approved kidney transplant programs, 207 have living kidney transplant programs. Out of 143 OPTN members with approved liver transplant programs, only 74 have living liver transplant programs. Anecdotally, Committee members noted that difficulties creating and maintaining living donor programs at transplant centers are important factors in understanding the lack of overall growth in living donation over time.

Proposed Direction 7A: Identify barriers for creating and maintaining living donor programs at transplant centers

The Committee recommends utilizing a multi-disciplinary approach to identify the barriers that prevent creation of living donor programs, and the struggles that existing programs face in trying to maintain and grow. While members spoke anecdotally of some challenges faced, more comprehensive research and analysis about these disincentives and challenges will inform which solutions will be most impactful. Ways to identify these barriers may include surveys to program staff, interviews/public forums with key stakeholders, and analysis of existing center data.

Proposed Direction 7B: Once identified, explore ways to reduce disincentives for creating and maintaining living donor programs at transplant centers

Once these barriers have been identified and clearly defined, the Committee recommends the OPTN explore ways to mitigate them, likely by using a similar multi-disciplinary approach as mentioned above. While these solutions will be best informed by the identification and scoping of the barriers themselves, members discussed a few potential ideas, including:

- The potential to incentivize centers not only to have excellent outcomes, but also to increase rates of successful transplants for the communities experiencing the greatest need for transplant
- The potential to engage C-Suites in discussions, similar to how the OPTN Expeditious Taskforce has done this relating to growing deceased donor transplant

Key Takeaways: Recommendation 7

The Committee recognizes that there are barriers to creating and maintaining living donor programs, though additional work is needed to determine the nature of these barriers and associated solutions.

- While this recommendation may not have as much immediate impact on the goal of enhancing living donation as some of the others in this report, the Committee requests that this aspect not be overlooked as it is important in understanding the landscape of living donation at the program level.
- Focusing on helping programs develop stronger infrastructure and business plans will undoubtedly strengthen the system overall.
- Holding discussions about the topics mentioned in 6A and 6B utilizing a multi-organizational approach as mentioned in several other places in this report will yield insight into challenges that centers face and likely provide innovative solutions to address them.

Next Steps

Due to the broad scope of recommendations within this report, the Committee is eager to receive feedback and engage with the Board in determining next steps.

Notably, the Committee will continue forward developing their project, in collaboration with the Living Donor Collective, to address *Recommendations 1* and *2*. Evidence-based interventions are paramount in protecting the safety and well-being of living donors. Therefore, the committee continues to prioritize their current efforts to improve data collection as the most impactful project to set the foundation for further efforts to enhance living donation.

If the Board determines enhancing living donation to be a priority, the Committee requests that the Board leverage their partnerships within the community to help initiate and carry out the ideas that require multi-organizational engagement for success through the creation of a taskforce specifically aimed at living donation to address *Recommendations 2-7*. The Committee is available for further discussion, brainstorming, and feedback while it continues its focus on improving and expanding OPTN data collection.

Conclusion

The Committee thanks the Board for the opportunity to help identify ways to enhance the living donation system. In this report, the Committee provides seven key recommendations, which are complimentary and build upon each other according to impact, feasibility, and scope:

1. Reduce systematic barriers to becoming a living donor
2. Expand OPTN data collection on living donation and collaborate with other entities for data collection to increase public trust and promote living donor safety

3. Develop and promote best practices for key components of the living donation process
4. Improve and expand upon paired donation opportunities and investigate other ways to expand the living donor pool
5. Increase awareness about living donation among the general public
6. Leverage technology and embrace innovation within the living donation process
7. Reduce disincentives for creating and maintaining a living donation program at transplant centers

As described, the Committee views *Recommendations 1* and *2* as most impactful to the overall goal of enhancing living donation and sees the efforts to expand and update living donor data collection as critical to all other items described in this report. The Committee emphasizes that the lower-ranked recommendations are not less important, but rather that the Board may wish to think more carefully about feasibility and resources, as well as the aspects of each that may be accomplished through implementing *Recommendations 1* and *2*. As described in the *Next Steps* section, the Committee intends to continue development of the data collection project described in *Recommendation 2.* If the Board determines enhancing living donation to be a priority, the Committee requests the creation of a living donation taskforce and is eager to engage with the Board on developing appropriate next steps.

Appendix A: Key Stakeholders

The Committee recommends the following key stakeholders be included in any future discussions and initiatives to enhance living donation.

Living Donors

First and foremost, the Committee recommends that living donors themselves be engaged in projects and decision-making surrounding living donation. Living donors are experts of their own experience, and their input is invaluable in creating a system that is efficient, effective, and safe. While the OPTN Living Donor Committee is a great resource to solicit input from living donors, the Committee recommends further engagement with living donors and living donor candidates to ensure robust discussion and informed decision making.

Transplant candidates and recipients

As it is critical to engage living donors in any discussions about enhancing living donation, the Committee recommends involving transplant candidates and recipients. They will be able to share insight into how the living donation system impacts them as a transplant candidate and an ultimate recipient. The ideal living donation system benefits the living donor, the candidate, and the ultimate recipient.

Transplant healthcare teams and primary care providers

As always, it is vital to engage transplant healthcare teams. The Committee recommends that this would, at minimum, include nephrologists, hepatologists, surgeons, transplant coordinators, transplant administrators, independent living donor advocates (ILDAs), social workers, and data entry specialists. An initiative to improve the system will only work if the components fit in with the workflow and processes in use by transplant healthcare providers. Additionally, the Committee advocates for including primary care providers as stakeholders. Increased touchpoints with those who care for living donors following donation will improve safety, awareness, and follow-up.

Governmental entities and regulatory agencies

The Committee recognizes the important role that governmental entities and regulatory agencies play in the living donation system. Therefore, the Health Resources and Services Administration (HRSA), Centers for Medicare and Medicaid Services (CMS), congress, and state governments, are all considered key stakeholders. While the Committee recognizes that recommending any changes to the regulatory structures, laws, and programs involved in living donation is outside the scope of the OPTN, it underscores the importance of collaboration and cooperation with these important institutions.

Payers, including nonprofit organizations that provide assistance to living donors

As described above, the Committee recognizes that financial aspects can often be a barrier to living donation. The Committee recommends that payers, including public and private insurance programs, be engaged in discussions about living donation. Importantly, the Committee also recommends including nonprofit organizations that provide assistance to living donors (financial and otherwise) as a stakeholder.

Professional societies and other transplant communities

The Committee recommends engaging professional societies and corporations with a focus on transplant, including the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the National Kidney Foundation (NKF), and the American Liver Foundation (ALF). Also, societies focused on primary care (such as the Society of General Internal Medicine) should be included, as mentioned above. The OPTN should leverage these and other communities and for their expertise.

OPTN Committees and public comment

Importantly, the Committee recognizes that all of the stakeholders listed above are either represented through OPTN Committees or engaged in OPTN work through the public comment process. These existing channels should be leveraged in the pursuit of improving living donation. The Committee sees the following OPTN Committees as particularly relevant, but notes that the expertise represented on other Committees will also be valuable:

- OPTN Living Donor Committee
- OPTN Kidney Transplantation Committee
- OPTN Liver Transplantation Committee
- OPTN Minority Affairs Committee
- OPTN Ethics Committee
- OPTN Operations and Safety Committee
- OPTN Transplant Coordinators Committee
- OPTN Transplant Administrators Committee
- OPTN Organ Procurement Organization Committee
- OPTN Patient Affairs Committee

Appendix B: Additional Figures

Additional Kidney Figures

Figure 6: Number of Living Kidney Donors by Year: 1988-2023

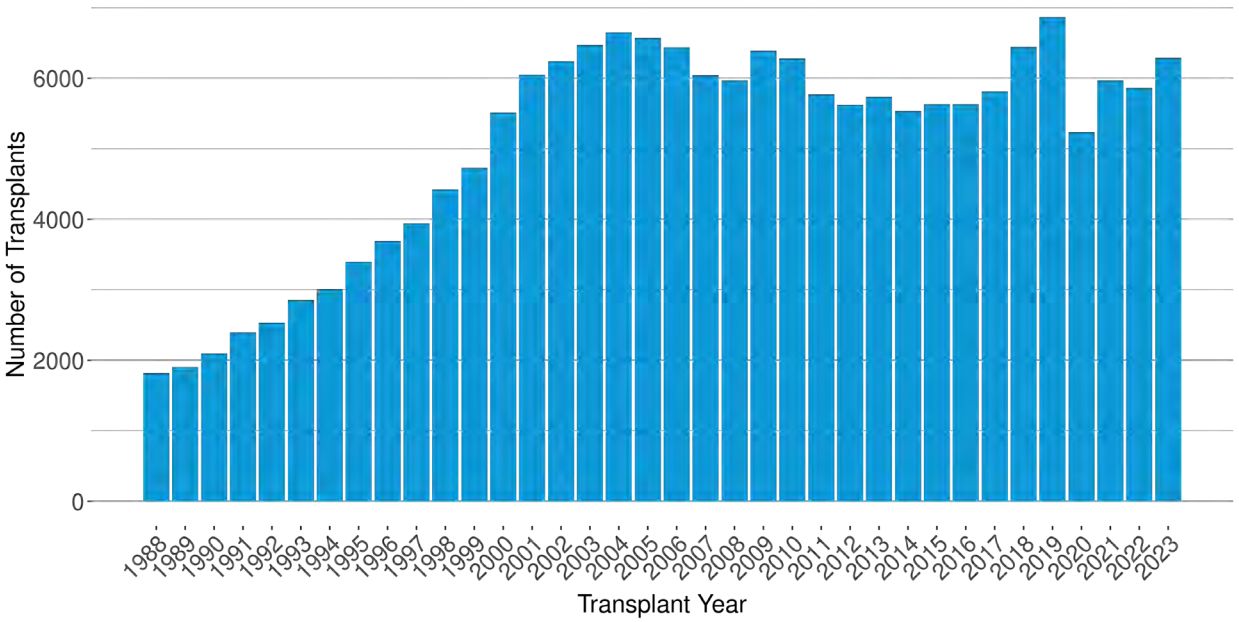
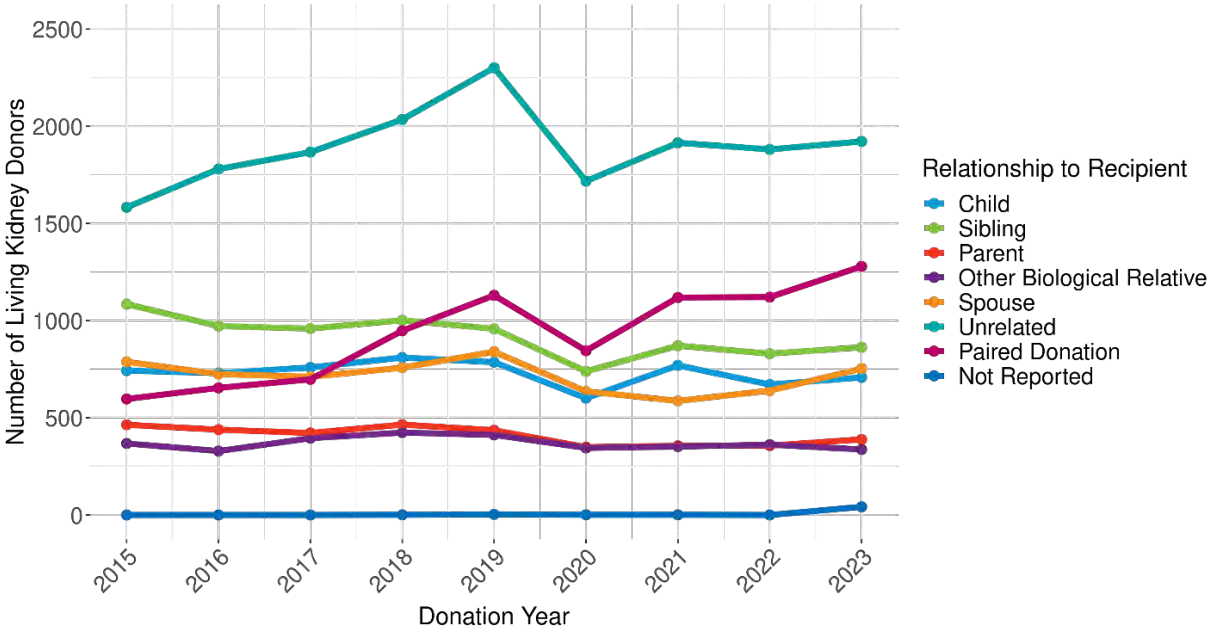


Figure 7: Number of Living Kidney Donors by Relationship to Recipient and Year



Additional Kidney Paired Donation Figures

Figure 8: Number of KPD and Non-KPD Living Donors by Race/Ethnicity in 2023

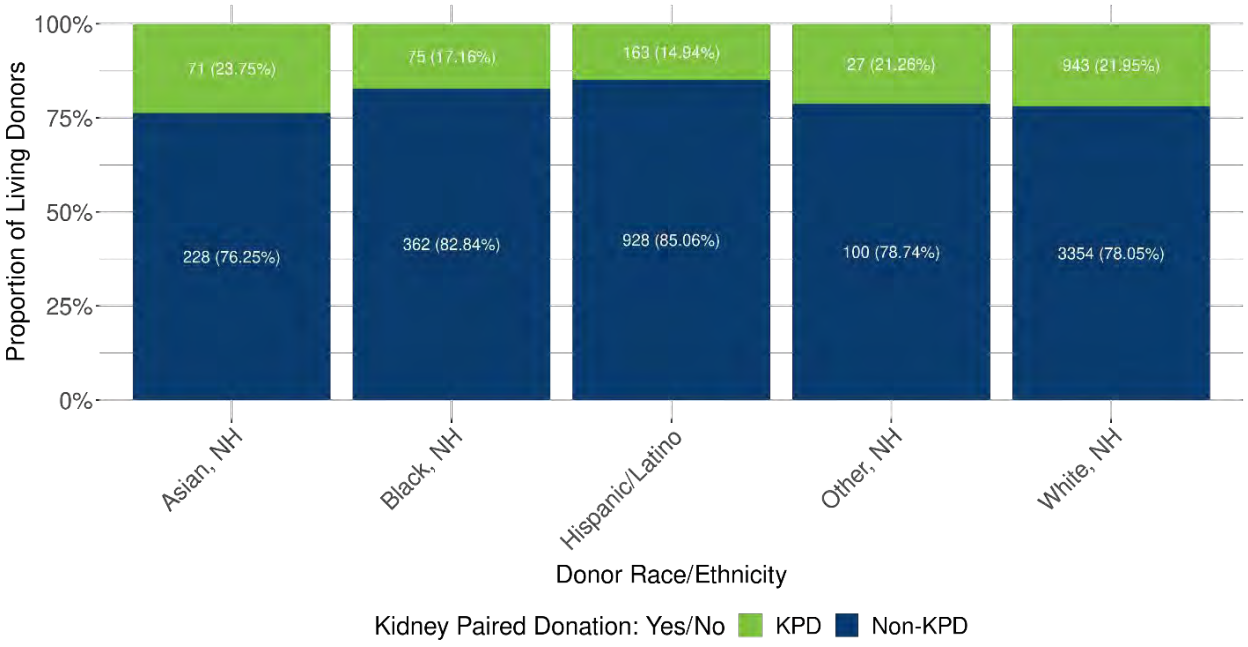
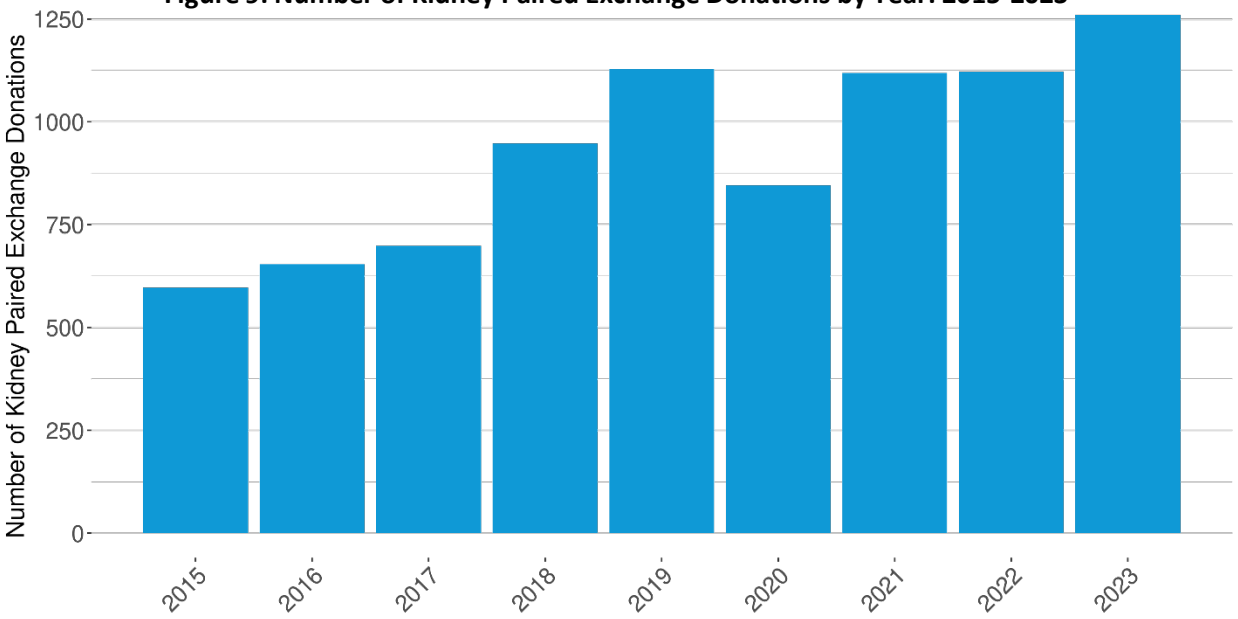


Figure 9: Number of Kidney Paired Exchange Donations by Year: 2015-2023



Additional Liver Figures

Figure 10: Number of Living Donor Liver Transplants by Year: 1988-2023

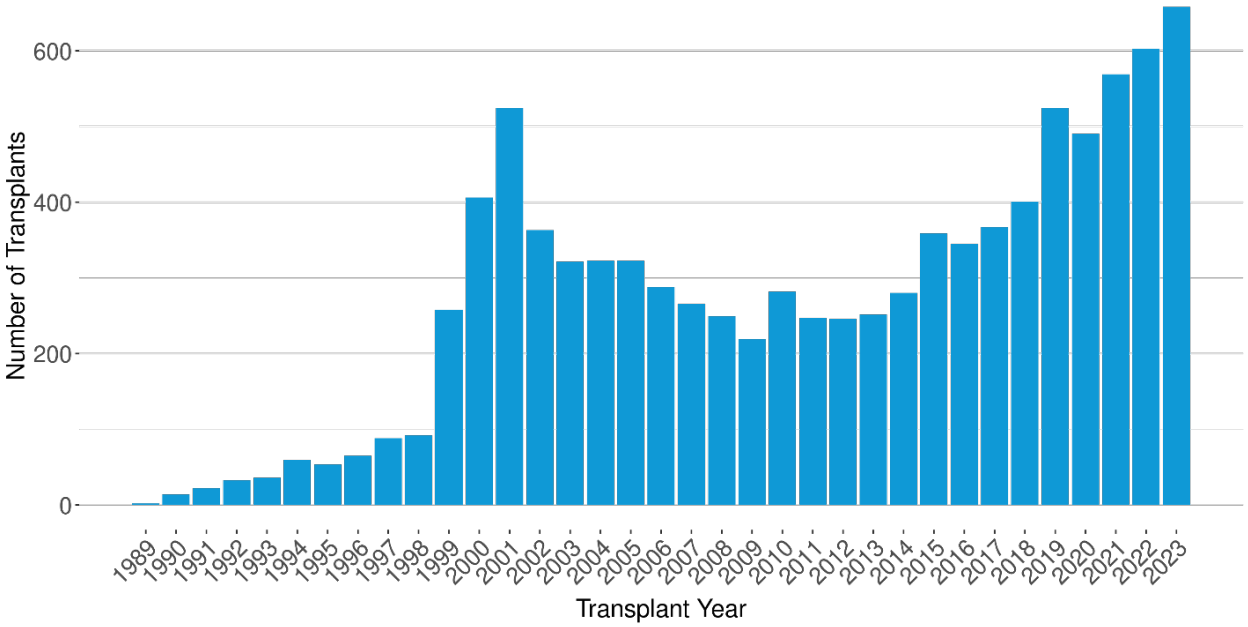


Figure 11: Number of Living Liver Donors by Relationship to Recipient and Year