



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

September 12, 2022

Via E-Mail

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Dear Mr. Duvall:

Thank you so much for your interest in ASTS' Transplant Cooperative Demonstration Project Proposal. We appreciate CMMI's focus on the need to improve access to kidney transplantation for those with ESRD and late-stage chronic kidney disease (CKD).

Since the ASTS Cooperative Demonstration Project Proposal was initially submitted, major changes have been made in the allocation formula used by the Organ Procurement and Transplantation Network (OPTN), with the aim of facilitating broader organ sharing of deceased donor kidneys and other deceased donor organs. These allocation formula changes have significantly increased the number of organ procurement organizations (OPOs) with which each kidney transplant program interacts and the number of kidney transplant programs with which each OPO interacts. For example, one transplant program reported that while it historically obtained 80% of its deceased donor kidneys from its local OPO and 20% from OPOs outside its Donor Service Area (DSA), that transplant center now receives only 20% of its deceased donor organs from its local OPO and 80% from OPOs located outside its DSA.

ASTS' original Transplant Cooperative Demonstration Project Proposal envisioned the formation of a cooperative of OPOs, transplant programs and other stakeholders located within a delineated geographic area (i.e., the local OPO's DSA), and was premised on the assumption that most organs procured by the participating OPO were transplanted locally. Under these circumstances, a geographically defined cooperative made sense. However, considering the modified kidney allocation formula, which involves substantially broader dissemination of deceased donor kidneys, a local cooperative geographically defined by its OPO's DSA may be unable to achieve our shared goals in many areas of the country. Therefore, recent changes in the deceased kidney allocation formula have provided an opportunity to rethink the fundamental structure of our proposal.

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The need for a Demonstration Project in this area remains urgent. There is a pressing need to increase living donor transplantation and to reduce racial disparities in living donor kidney transplantation. Seventy one percent of living donor kidney transplant recipients are white,¹ while only 7% are African American.² Living donation constitutes 20-35% of all kidney transplants performed in the US.³ The pressing need to address disparities in transplantation was highlighted in a recent report issued by the National Academies of Science and Medicine (NASM), entitled, *Realizing the Promise of Equity in the Organ Transplantation System (2022)*⁴ which recommends establishing the goal of achieving equity in transplantation in the next five years. However, this report specifically excludes transplants from live donors.

I. Increasing Access to Living Donor Transplantation and Reducing Disparities

Living donor kidney transplantation generally yields clinical results that are superior to the results of deceased donor kidney transplantation, making the racial disparity even more problematic.⁵ Furthermore, living donor transplant has been shown to significantly reduce the cost of care for renal failure, resulting in significant financial benefits.

However, the rate of living donor kidney transplants performed by transplant programs varies widely, resulting in significant geographic disparities in access to this life saving treatment. Programs vary in their use of non-traditional living donors (e, g. older, hypertensive, or pre-diabetic patients). While donor safety is paramount, centers should be incentivized to expand their donor acceptance criteria. As discussed above, the most glaring racial disparity in the field of transplantation is the disparity between the number of living donor kidney transplants performed for white patients and those for patients of color. This disparity reflects differences in the prevalence of conditions that historically preclude donation (hypertension, obesity, and diabetes) in these communities. Despite these barriers, novel approaches to the recruitment and support of living donors from communities at risk can increase living donor kidney transplantation rates in both candidates with advanced CKD but not yet on dialysis and for those already on dialysis.⁶ However, increasing numbers of transplants will require investments in staff and programs to provide outreach, education, and counseling for disadvantaged communities.⁷ For these reasons, we urge CMMI to implement a demonstration project to evaluate the impact of increased investment in living donor outreach on the risk adjusted rate of living donor kidney transplants performed and the degree of racial disparity among recipients of living donor kidney transplantation.

We continue to believe that the basic concept of our initial Transplant Cooperative Demonstration Project Proposal – incentivizing transplantation through shared savings and regulatory relief – should serve as the organizing principle for a demonstration project involving living donor kidney transplantation. The basic concept underlying the revised demonstration proposal is to incentivize increases in living donor transplantation by sharing the savings resulting from the performance of living donor transplantation over dialysis (which may be different depending on whether the transplant is performed preemptively or after dialysis has begun) and to provide regulatory relief to transplant centers necessary to facilitate that goal. The participant in such a demonstration could be either a single transplant center or multiple transplant programs (for example, two or more transplant programs interested in establishing and expanding a system for paired donation or donor chains).

II. Care Model Questions

- What actions can transplant centers take to increase the rates of living donation?

Transplant Centers can take numerous actions to increase the rates of living donation, including:

- Increasing early referral for transplant evaluation by establishing relationships with community nephrologists, focusing especially on minority patients and those with increased biological risks, to allow for some of these patients to be optimally treated with pre-emptive living donor transplants.
- Provide culturally sensitive resources for significant minority populations to promote donation. Examples include providing Spanish language education sessions, hiring coordinators and staff who are native Spanish or other language speakers, and hiring diverse workforces.
- Developing programmatic resources to address specific health needs of the minority referral populations, such as specific efforts to minimize the risk of harming live donor long-term health. This is especially true for the African American population with the higher risk of CKD/ESRD
- Utilize shared savings to pay for biological immunosuppressive drugs administered to inpatients during the transplant admission, which may improve access to patients with higher degrees of allosensitization and which is known to promote long term allograft survival.
- Augment relationships with area dialysis centers to educate dialysis patients about the clinical benefits of transplantation and the living donor transplant option.
- Establish IT platforms to share candidate data between transplant programs, large dialysis organizations, and nephrology practices to more efficiently reduce time from evaluation to listing, particularly for pre-emptive candidates. This would have the effect of increasing the rate of pre-emptive transplants.
- Broaden transplant program criteria for inclusion of living donor candidates (e.g., allowing living donor candidates with evidence of Type 2 diabetes mellitus but without diabetic nephropathy to donate; promoting higher body mass index (BMI) cut-offs for living donor candidates).
- Broader and more effective use of living donor exchange programs to reduce barriers to transplant for patients with high degrees of allosensitization.
- Waive recipient (but not donor) outcomes jeopardy for recipients of certain types of living donors (e.g., geriatric living donors donating to geriatric recipients.) The risk-averse decision making fostered by transplant recipient outcomes requirements may be a meaningful factor in limiting the growth of living kidney transplantation.
- Outreach to community organizations, including local houses of worship, to disseminate information about living donor kidney transplantation and otherwise assist in educational efforts.

- Provide financial support to potential living donor transplant recipients, along the lines provided to living donors under the National Living Donor Assistance Center (NLDAC).
- How can incentives from a payment model increase the effective supply of organs, allowing more transplants to occur?

Shared savings could be utilized to cover the additional inpatient costs associated with non-traditional recipients; to pay for biological immunosuppressive drugs administered to inpatients during the transplant admission, which may allow non-traditional Living Donor recipients to be transplanted more safely and improve graft survival rates; to subsidize the start-up costs of new living donor programs; to provide for additional dedicated staffing to promote living donor candidate evaluation and care; for community outreach activities; and to subsidize costs incurred by living donors and recipients within the constraints established by the National Organ Transplant Act (NOTA).

- In the absence of other regulatory changes, would a CMMI payment model be successful in increasing transplant rates?

While it is possible that the proposed Living Donor Kidney Transplant Demonstration Project may be successful without regulatory waivers, the likelihood of success would be dramatically increased if certain regulatory waivers were granted. First, and most importantly, because the one-year outcomes of living donor kidney transplants approach 100%, the acceptance of non-traditional recipients (and potentially non-traditional donors) poses a risk both under the OPTN Transplant Center Performance metrics and under the SRTR star ratings system. Ensuring that there is some mechanism to obtain a variance from OPTN Transplant Project Performance measures and an exception from star ratings for non-traditional recipients and donors is critically important. Similarly, candidates accepted for these transplants may have a higher risk of mortality while waiting for transplant. Elimination of those waitlist mortality metrics would be important to this Demonstration Project.

Since participating transplant programs may wish to enter various types of financial relationships with other area providers that may serve as referral sources, including dialysis facilities, community nephrologists, and primary care physicians, waiver of the physician self-referral and anti-kickback laws may be advisable. In addition, waiver of patient inducement restrictions currently imposed by CMS may be advisable to better allow transplant centers to assist potential donors or recipients with transportation, childcare, or other expenses necessary for them to participate in required pre-transplant testing and other appointments, lost wages, and other donation-related expenses.

In addition, recently revised transplant program certification requirements currently require transplant programs to contact anyone who potentially may be interested in becoming a living donor to advise the potential donor of the risks before it is even known whether the individual is a suitable living donor or whether the individual has a blood type that is compatible with the blood type of the potential recipient. Since the demonstration program objective may involve broad solicitation of potential living donors, it may be necessary to waive this requirement and allow this counseling to occur after initial basic laboratory results and health screening is complete.

- How can communication be improved between OPOs and transplant centers to increase acceptance of kidneys?

OPOs would not be participants in a demonstration project focusing on increasing living donor transplantation.

- Given the size of the current waitlist, are any additional incentives needed for nephrologists and dialysis to improve transplant waitlist referrals or to better set up beneficiaries for success in the transplant process?

Additional incentives should be carefully targeted to specific potential recipient populations. Efforts to encourage referral for transplant evaluation should focus on referral of CKD 4 and CKD 5 patients who may be potential candidates for living donor kidney transplantation. Since time on dialysis significantly impacts post-transplant outcomes, dialysis facility incentives should focus on encouraging referrals pre-dialysis CKD candidates and those dialysis patients who have been on dialysis for one year or less.

- Should any other organs besides kidneys be included?

No. Including other organs would create additional complexities and very likely prevent the consensus building among stakeholders needed to bring this project to fruition.

- Nature of the collaborative

- What would you want to see if a model were just focused on the transplant centers and OPOs instead of the larger set of participants?

The participants in the proposed living donor kidney transplant demonstration program would be transplant programs; however, participants may partner with area nephrologists, dialysis facilities and others to increase education about the advantages and risks of living donor kidney transplantation.

- Which participants should be required for a collaborative?

As indicated above, individual transplant center(s) would be the participant(s) in the proposed Living Donor Kidney Transplant Demonstration Project, and it is anticipated that each participant (or group) would make arrangements with area nephrologists, dialysis facilities, community organizations, donor registries and others, depending upon local circumstances.

- Could a single transplant center or multiple transplant centers working together coordinate with the necessary other providers?

Yes. A transplant center or multiple transplant centers working together would be appropriate participants for the Living Donor Kidney Transplant Demonstration Project.

- Performance Metrics

- How should we set a benchmark for transplant centers for number of transplants?

With the number of Living Donor Kidney Transplants performed for people of color being so low in the US, any increase over historical performance should be beneficial. A system goal should be to close the gap between the ethnicity of the program kidney waitlist and the ethnicity of living donor kidney transplants.

- How can transplant centers help to keep more folks active on the transplant waitlist? Is this a goal that should be incentivized?

Waiting list measures may be relevant to deceased donor transplantation but would not be particularly appropriate for the living donor transplant demonstration project described here. However, it should be noted that current incentives with respect to waitlist size are conflicting. At this time, transplant programs are incentivized to maintain short waiting lists, while many referring nephrologists and dialysis facilities want longer waitlists, since they are incentivized to get their patients waitlisted. These conflicting incentives should be harmonized by modifying or eliminating transplant program incentives to limit waitlist access.

- How can you improve the disparities in who gets a transplant? What tools would be specifically most helpful to address disparities? How do you identify disparities in transplant?

Disparities in living donor kidney transplantation already has been identified as a significant issue. The data suggests that the primary barriers to access relate to the proportion of patients of color who are referred for transplant evaluation; the number of such patients who self-refer; and potentially bias in waitlist practices.

It is not possible in a transplant demonstration project to fix issues in access to coverage, access to health care, access to referral, and other social determinants of health that are deeply embedded with race and lower socioeconomic status in our health care system, and all of these contribute to the existing disparity in access to living donor kidney transplantation. Nonetheless, early referrals of CKD late stage 4 and early 5 patients as well as optimization of care of these patients prior to starting dialysis has the potential to decrease racial and socioeconomic disparities in living donor transplantation and waitlisting in the US. More widespread dissemination of information regarding living donor transplantation and waitlist eligibility in communities of color also has the potential to reduce disparities in transplantation. It is anticipated that the proposed Living Donor Kidney Demonstration Project participants will focus on these and other tactics to reduce disparities.

- Are there any specific quality metrics that have been developed that would be useful to be a part of this model?

While the primary purposes of the proposed Demonstration are to increase the number of living donor kidney transplants performed and to reduce disparities compared with baseline, care should be taken to ensure the safety of living donor recipients and donors

and to ensure that living donor transplants performed are clinically appropriate. One model would simply be to create a flat floor for transplant outcomes within the model. That flat floor would be well above outcomes for ESRD without transplant, but below current median transplant outcomes achieved outside of the collaborative demonstration

- Payment rates

- What magnitude of payments is needed to encourage investment in a potential model?

We would anticipate that the portion of savings shared with participants would need to be significant. Shared savings should be sufficient to cover the start-up costs of new living donor kidney transplant programs and the costs of expanding existing programs. Every program is funded to its existing volume and the expansion and further development of new programs will require investment.

- Is there space for downside risk and should there be different tracks?

No. There is a lot of real and perceived downside risk for transplant programs associated with any endeavor that results in more aggressive utilization of donor organs, that encourages listing and transplanting of non-traditional candidates, or that expands the inclusion criteria for living donor candidates.

- If we are incentivizing transplants, how should we account for organs that fail? What should our expected rate of transplant failure be?

Outcomes expectations could be built into the demonstration project by modifying the portion of savings shared with the participant on a sliding scale. However, so long as outcomes exceed those that would have occurred if the patient had begun or remained on dialysis, the participant(s) should continue to be eligible for at least some shared savings and should not be terminated from the demonstration.

- Are up-front incentives required to support investment in the program? If needed, are they needed for all centers or just for smaller centers?

Yes. They would be helpful and should be available to all participants. Locking out large or small transplant programs would be problematic.

- Other

- What limitations do you see from the existing fraud and abuse laws?

See discussion above.

- What CMS rules/regulations do you think could be waived?

See discussion above.

- Would any CMS or SRTR data be helpful to assist with transplant coordination?

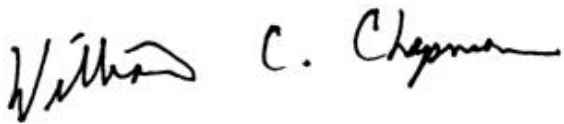
CMS data relating to late CKD 4 and CKD 5 patients and their primary care physicians and nephrologists would be helpful. SRTR data relating to living donor kidney transplant rates also would be helpful.

- Is there anything CMS could do to assist in setting up living donor chains?

The proposed Living Donor Kidney Transplant Demonstration Project is intended to incentivize living donation. CMS should avoid regulatory overreach in this regard. Incentives of decreased regulatory burden and financial incentives for growth in the number of living donor kidney transplants would be highly effective. Enhanced assistance for the costs that living donors incur would be very helpful and should be pursued as well. Having more centralization and regulation of paired donor exchange would be counterproductive and should be avoided.

We look forward to continuing our discussions with you regarding demonstration project opportunities related to transplantation.

Sincerely yours,



William Chapman, MD
President
American Society of Transplant Surgeons

¹ OPTN/SRTR 2020 report, (March 2022).

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5827936/>;

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4929989/>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4447489/>

⁴ <http://nap.edu/26364>.

⁵ <https://doi.org/10.1111/ajt.16982>

⁶ <https://pubmed.ncbi.nlm.nih.gov/31898417/>

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3374007/>

https://www.hopkinsmedicine.org/transplant/patient_information/live-donor-program.html

American Society of Transplant Surgeons

CMMI Presentation on Increasing Access and Reducing Disparities in Living Donor Kidney Transplantation

SEPTEMBER 15, 2022

Our Initial Proposal

- Participants: Kidney Transplant Collaborative(s) – OPO and transplant centers, dialysis facilities, nephrologists and others in the OPO's DSA.
- Increase Transplantation through:
 - **Financial Incentives:** Shared savings paid to the Collaborative(s) for transplants exceeding historical baseline. Savings based on projected Medicare savings resulting from transplantation over dialysis.
 - **Regulatory Waivers:** e.g., waivers of OPTN transplant center performance metrics, SRTR star ratings, and various Medicare requirements.

What's Changed?



- OPTN Organ Allocation Methodology modified to significantly increase organ sharing
- COVID-19 increased public awareness of health care disparities.
- Biden Administration identifies the reduction of health care disparities as a major health care policy objective.
- NASEM Report emphasizes the most significant disparity in transplantation: the disparity in access to living donor kidney transplantation

Our Revised Proposal: Focus on Living Donor Transplantation and Reduction in Disparities

- Built on same concept as original proposal:
 - Establishment of historical baseline and payment of shared savings for transplant exceeding baseline.
 - Regulatory waivers as necessary to facilitate increase in access to living donor transplantation and reduction in disparities.
- More focused and easier to implement

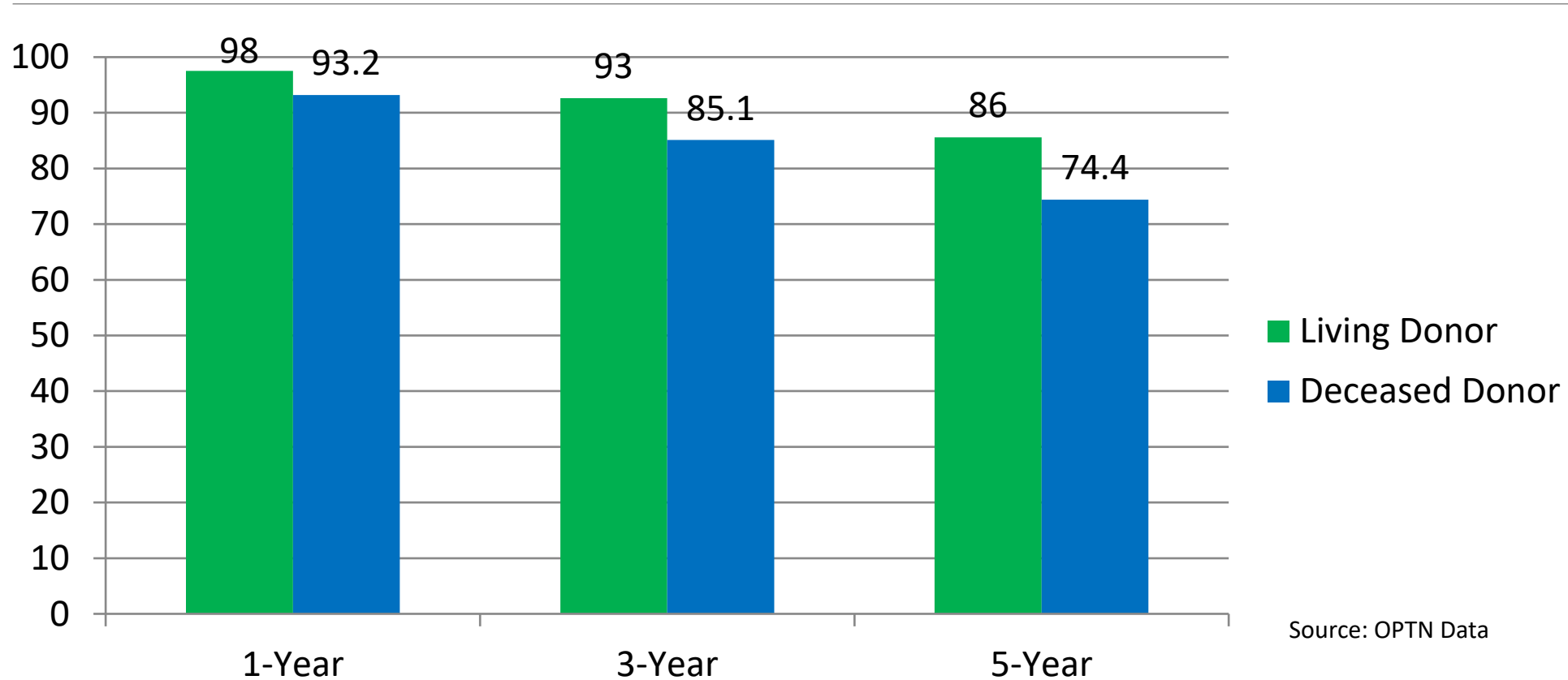
Focus on Living Donor Transplantation and Reduction in Disparities

Advantages of Focusing on Living Donation

- Simpler:
 - Does not require formation of new collaborative(s)
 - Participants: Individual Transplant Programs
 - **Individual transplant centers would create networks with referring nephrologists and dialysis centers to encourage/facilitate early referral, with culturally sensitive education on living donation for both pre-dialysis patients and those already on dialysis.**
- Focuses on an area of transplantation where disparities are evident.
- Not affected by new OPTN Organ Allocation Methodology
- If successful, could be expanded to include deceased donor transplantation

Living Donor Kidney Transplantation: Clinical Advantages

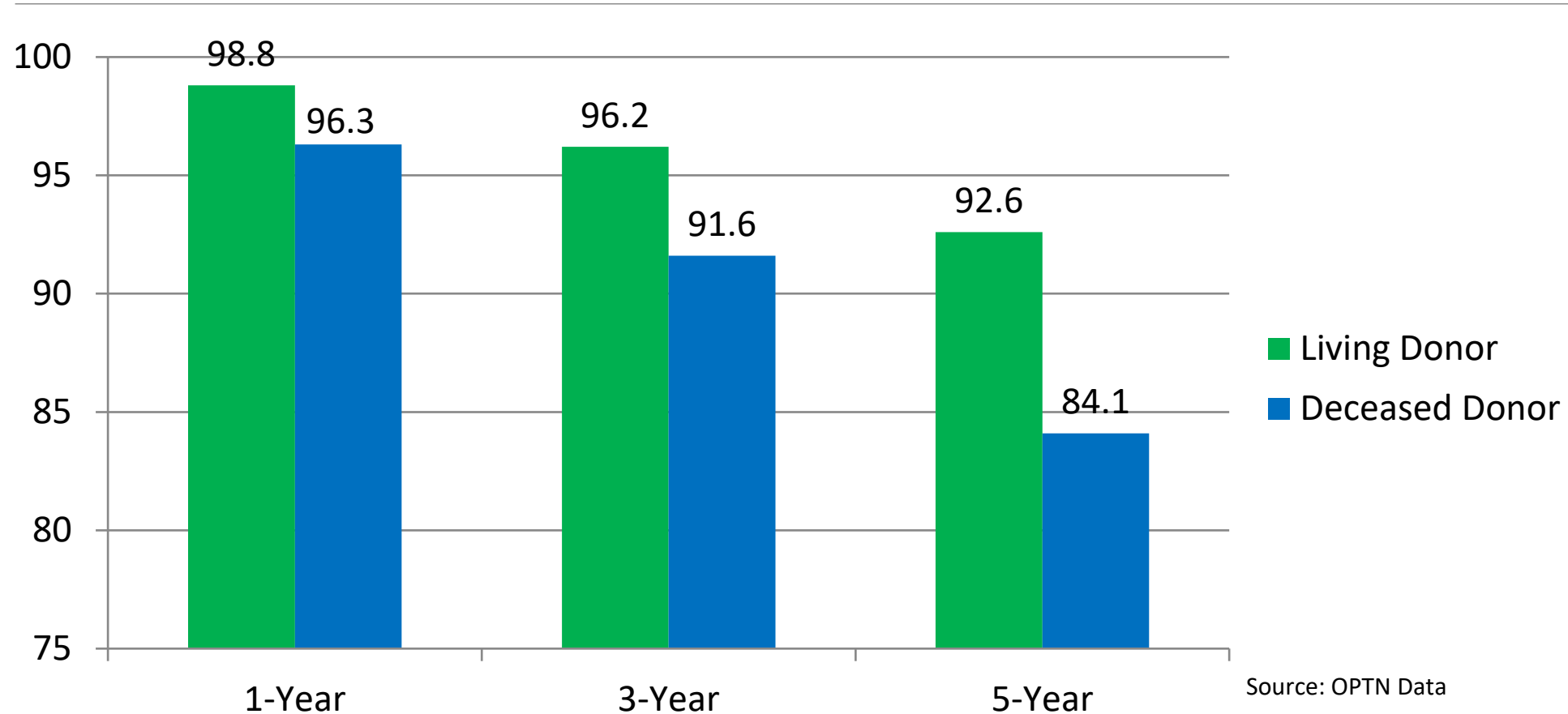
Graft Survival Over Time by Kidney Donor Type (2008-2011)



Source: OPTN Data

Living Donor Kidney Transplantation: Clinical Advantages

Patient Survival Over Time by Kidney Donor Type (2008-2011)



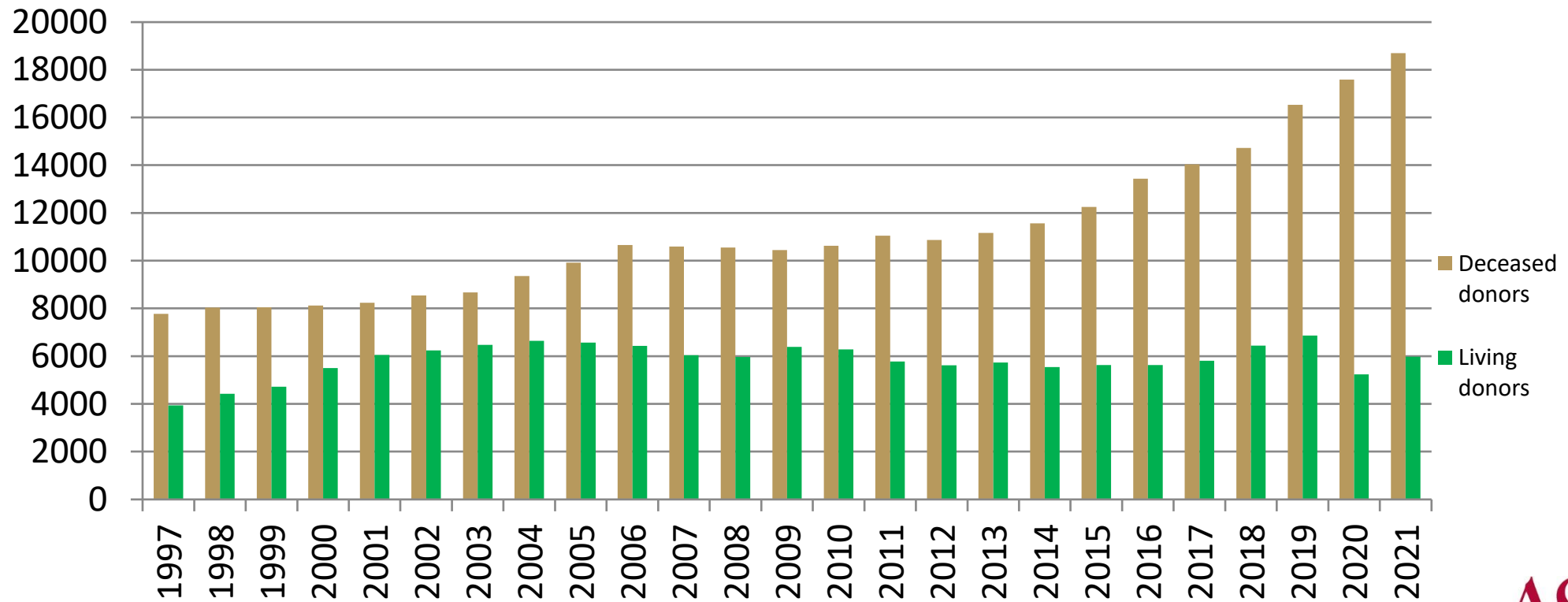
Source: OPTN Data

Living Donor Kidney Transplantation: Financial Advantages

- It is well-established that kidney transplantation is the most cost-effective therapy for ESRD.
- Relative to deceased donor kidney transplantation, living donor kidney transplantation is associated with significant cost savings.¹
- Potential sources of these cost savings:
 - Markedly lower delayed graft function (DGF) rates and avoidance of associated dialysis charges²
 - Decreased costs for hospitalizations after transplant
- Improved productive capacity for recipients of living donor transplants
- Longer graft and patient survival³
- **Critical to note that every living donor kidney transplant frees up a deceased donor organ that can then be used in another recipient in need.**

1. Smith CR, Woodward RS, Cohen DS, et al: Cadaveric versus living donor kidney transplantation. A Medicare Payment Analysis. *Transplantation* 2000, 69; 311
2. Abecassis MA, Bartlett ST, Collins AJ, et al. Kidney transplantation as primary therapy for end-stage renal disease: a National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQI™) conference. *Clin J Am Soc Nephrol.* 2008;3:471-480.
3. United States Renal Data System. *2014 Annual Data Report: An Overview of the Epidemiology of Kidney Disease in the United States.* Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2021

Living Donor Kidney Transplant Trends



Living Donor Kidney Transplantation: Donor Disparities

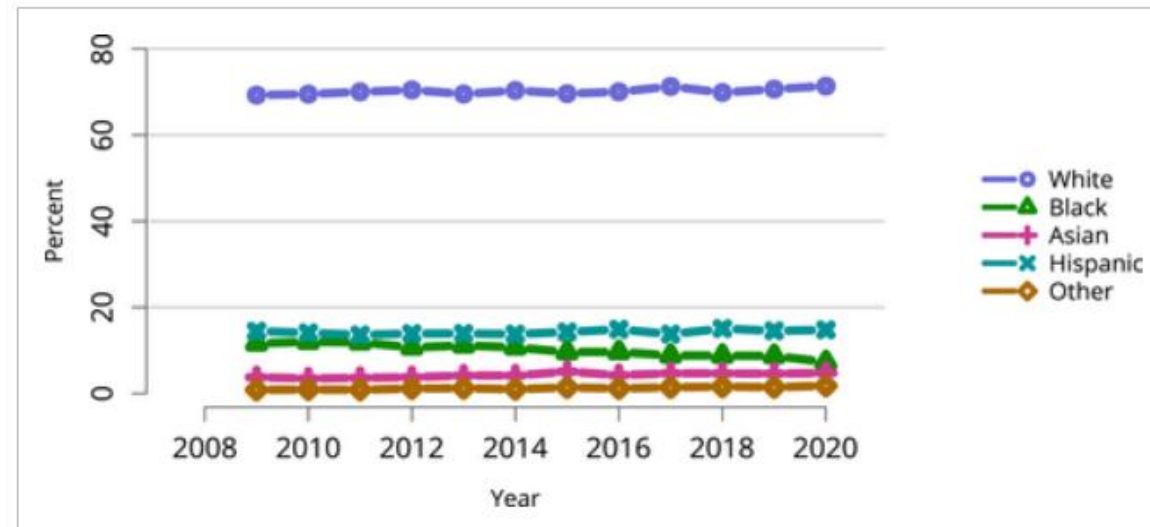


Figure KI 67

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Living kidney donors by race. As reported on the OPTN Living Donor Registration Form.

The racial and ethnic composition of living donors in 2020 was relatively stable compared with 2019, with 71.4% White, 14.8% Hispanic, and 7.3% Black donors (Figure KI 67). Notably, this reflects an ongoing decline in the proportion of Black living donors, from 8.7% in 2019 and from 12.0% in 2010 (Figure KI 67)

Living Donor Kidney Transplantation: Recipient Disparities

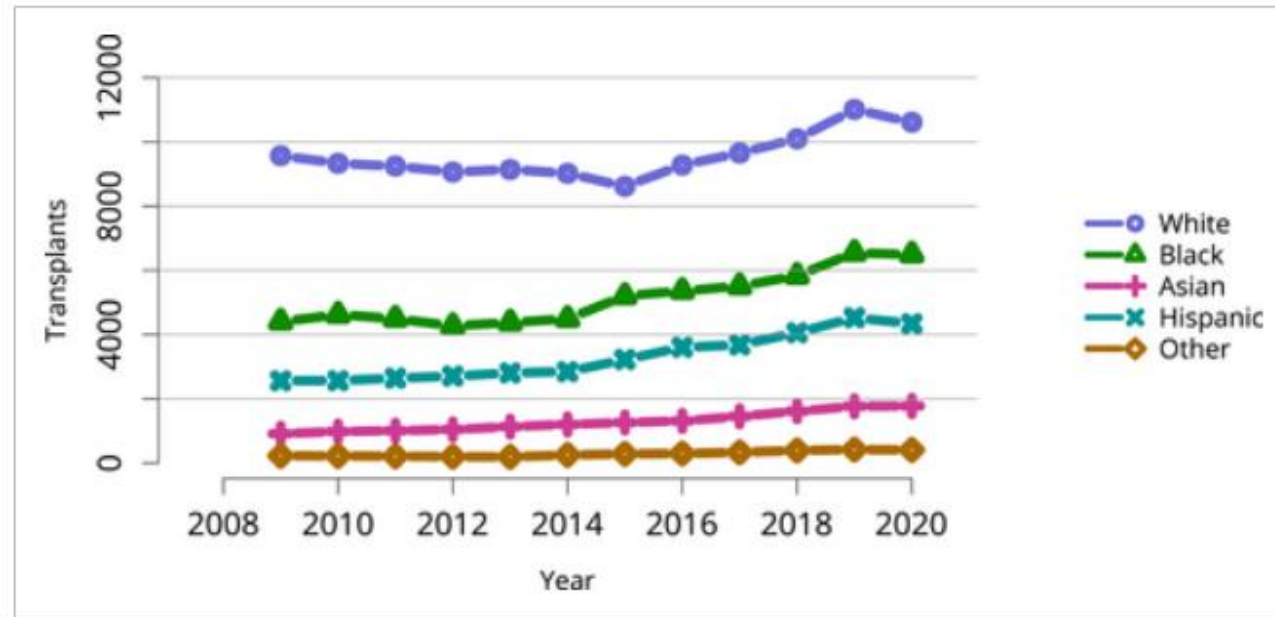


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Total kidney transplants by race. All kidney transplant recipients, including adult and pediatric, retransplant, and multi-organ recipients.

Living Donor Kidney Transplantation: Recipient Disparities

While 32.2% of waitlisted candidates in 2020 were Black, Black patients composed only 11.7% of LDKT recipients, versus 32.3% of DDKT recipients, in 2020.

-- OPTN/SRTR 2020 Annual Data Report: Kidney

Living Donor Kidney Transplantation: Variation in Access

“Racial parity was not seen at any of the 275 transplant centers in the United States. At centers with the least racial disparity, African Americans had 35% lower odds of receiving LDKT; at centers with the most disparity, African Americans had 76% lower odds...Higher rates of LDKT (interaction term, 1.25; $P < 0.001$) were associated with less racial disparity.”

-Hall EC, James NT, Garonzik Wang JM, Berger JC, Montgomery RA, Dagher NN, Desai NM, Segev DL. Center-level factors and racial disparities in living donor kidney transplantation. *Am J Kidney Dis.* 2012 Jun;59(6):849-57. doi: 10.1053/j.ajkd.2011.12.021. Epub 2012 Feb 25. PMID: 22370021.

Increasing Living Donor Kidney Transplantation: Actions Transplant Programs Can Take

- Increase pre-emptive transplantation and early referral for transplant through enhanced networking with community nephrologists and dialysis facilities
 - This may require a waiver of Stark Law/anti-kickback statutes
- Utilize shared savings to pay for biological immunosuppressive drugs during the transplant admission, to increase access to patients with higher degrees of allosensitization, which is of particular importance to African American and Hispanic patients.¹
- Establish IT platforms to share candidate data between dialysis centers and referring physicians to more efficiently reduce time from evaluation to listing.
- Waive recipient (but not donor) outcomes jeopardy for recipients of certain types of living donors

¹Association of Racial Disparities With Access to Kidney Transplant After the Implementation of the New Kidney Allocation System. Kulkarni S, Ladin K, Halkin D, Greene E, Li L, Deng Y. JAMA Surg. 2019 Jul 1;154(7):618-625.

Increasing Living Donor Kidney Transplantation: Actions Transplant Programs Can Take

- Utilize data driven approaches to broaden transplant program criteria for inclusion of living donor candidates
- Broader and more effective use of living donor exchange programs
- Provide financial support to potential living donor transplant recipients, along the lines provided to living donors under the NLDAC.

Increasing Living Donor Kidney Transplantation: Actions Transplant Programs Can Take

- Augment relationships with nephrologists and area dialysis centers to educate CKD and dialysis patients about the clinical benefits of the living donor transplant option and encourage transplantation.
- Provide culturally sensitive resources for significant minority populations to promote donation.
- Develop programmatic resources to address specific health needs of the minority referral populations.
- Outreach to community organizations, including local houses of worship, to disseminate information about living donor kidney transplantation.

Conclusions and Discussion

1. ASTS writes that the demonstration project that it initially proposed is no longer feasible because allocation formula changes have significantly increased the number of organ procurement organizations (OPOs) with which each kidney transplant program interacts and the number of kidney transplant programs with which each OPO interacts.

- Is it a worthwhile policy goal to continue to encourage local utilization of organs, albeit in the larger 250 NM circle around the donor hospital?

Yes. Cold ischemic time (CIT) matters and is predictive of outcomes and of organ turn-down rates. We spent years developing a more equitable system by eliminating DSA and region as allocation units and are now moving towards allocation via continuous distribution models for all organs. However, proximity still matters for acceptance rates, outcomes, and costs. Allocation within a fixed boundary (250 NM) or continuous distribution that awards priority on a continuous gradient from the donor hospital both take into account the importance of allocation distance.

- Is collaboration between a transplant center and OPO only possible within the bounds of the DSA? If so, what are the barriers to collaboration & partnership over greater distances?

No. As previously noted, the new allocation system has created a marked increase in the complexity of OPO/transplant center interactions.¹ However, for the purposes of the transplant enterprise (organ procurement, allocation, transportation, and transplantation) cooperation is possible-- and necessary-- between all OPOs and transplant centers. Our comments on the challenges of these relationships relate to the new relationships and arrangements (administrative, procedural, and financial) that would be needed for a demonstration project along the lines initially proposed.

- The challenges of broader allocation being noted, would it be an appropriate tradeoff to incentivize collaboration between OPOs and Transplant Centers to improve utilization of deceased donor organs if the result is more equitable access to transplantation?

To the extent that the objective of a demonstration project in this area is to increase equitable access to transplantation, we feel that living donor kidney transplantation (LDKT) represents a more focused target with a likely higher return on invested resources—simply put, living donation provides a more immediate method to increase access to high quality, long-lasting organs. ASTS strongly that any program focused on living donation **must** address the issues of equity and access. Living donation access and practices are not tied to OPOs as they are based in the transplant center and the collaboration between the transplant center, referring physicians, and dialysis providers.

Allocation inefficiency, logistical hurdles (transporting kidneys over long distances with acceptable CIT), and transplant center practice patterns are more significant limiting factors that keep discard rates stubbornly higher than we would like and prevent more rapid growth in transplant volumes, access, and equity. Eliminating performance monitoring (MPSC/OPTN) and outcomes reporting (SRTR and

¹ Adler, Joel T., et al. "Greater complexity and monitoring of the new Kidney Allocation System: Implications and unintended consequences of concentric circle kidney allocation on network complexity." *American Journal of Transplantation* 21.6 (2021): 2007-2013.

MPSC/OPTN) practices that are incentivizing risk-averse clinical decision making/practice patterns would be a powerful way to address one of those root causes. Additionally, CMS should also consider addressing different Standard Acquisition Charges (SAC) for higher risk organs which reflect the differences in the cost of transplant. ASTS notes and appreciates the recent DRG creation to address delayed graft function.

2. What policies would be needed in a living donation focused model to ensure that donors receive post-transplant care, particularly structurally disadvantaged donors who may face more challenges in reliably accessing health care? Is the 6 months, 1 year, and 2-year follow up recommended by the OPTN adequate?

The policies currently in place to ensure living donor follow-up and safety are comprehensive enough to motivate centers but not so burdensome that they provide a disincentive to perform living donor transplants. The current follow-up intervals with the transplant center appears to be adequate.

To the extent that financial barriers impede follow up care for living donors, the provision of health insurance as a benefit of being a living donor would be great way to promote access to care and health maintenance in living donors. An extension of the NLDAC provisions to cover payment for transportation and other costs associated with post donation care would also ensure that economically disadvantaged donors can receive appropriate care. Transplant centers may also choose to utilize shared savings to help subsidize access to follow up care for living donors. In addition, current CMS payment policy does inhibit appropriate follow-up as there is no method for transplant centers to appropriately allocate post donation costs after 6 months.

3. What specific incentives would be needed for transplant centers to expand their donor acceptance criteria?

To clarify, we interpret this question as asking about living donor acceptance criteria. Expansion of living donor acceptance criteria would be promoted by transplant hospital education (on best practices) and regulatory relief (for the recipients of living donor kidneys, not for the living donors). We emphasize that in **all** issues regarding donation, safety of the donor is paramount. In addition, transplant centers must engage in a process of shared decision-making with both the living donor and intended recipient.

If the intent of the question is increased deceased donor acceptance criteria, then removal of punitive regulatory oversight for outcome measures would be necessary to increase deceased donor utilization.

4. ASTS urges "CMMI to implement a demonstration project to evaluate the impact of increased investment in living donor outreach on the risk adjusted rate of living donor kidney transplants." Is it also important to address the ~50% attrition of potential donors through the living donor evaluation?

This is an important question, and the answer is complex. Some attrition occurs because the evaluation reveals that potential candidates face outsized biologic risk that rules them out. Many donor candidates enter evaluation without clarity on what is involved in donating, and many are ambivalent about donation and only exploring options. It is vital that donor candidates be able to back out of the process at any time, and this remains an ethical tenet of the process. Providing the gift of life through living organ donation is an incredible ask of donor candidates, and inevitably many will elect not to move forward as they receive the ethically and programmatically required informed consent and education.

Pragmatically, it is unavoidable that transplant centers evaluate many more donor candidates than the number of realized living donors.

We are cognizant that successful living donor programs require an enormous amount of work, and that includes the staffing and financial burdens of working up many donor candidates who do not become actualized donors. Some programs are likely unable or unwilling to commit the resources needed to efficiently identify and evaluate large volumes of living donor candidates. Incentives (regulatory/structural reforms and financial incentives) could ameliorate those real and perceived limitations of transplant centers.

At the same time, we understand that there is some data that suggests that potential minority donors and donors with lower socioeconomic status drop out of the evaluation process more often. We acknowledge and strongly endorse the need to increase living donation across all communities and for all individuals. Transplant centers should be encouraged to promote culturally sensitive donor programs which work with community organizations to promote living donation in all communities. This includes work to make donation more accessible and accepted.

Through NLDAC, ASTS supports donors and families by decreasing financial barriers and CMMI should continue to support initiatives that *decrease non-medical barriers* to transplant in the donor and recipient. This includes support for travel, lodging, and follow-up care for donors. In addition, CMS should cover donor related care after transplant through 2 years at minimum. Creating a means for supporting disadvantaged recipients through similar payment for travel, parking, lost wages, and other out of pocket expenses would promote faster and more equitable completion of recipient work up.

5. Could ASTS provide examples of transplant centers that have successfully implemented living donor outreach programs that could be expanded in the model?

A high-quality living donor kidney program requires significant expertise from all elements of the multidisciplinary team. The challenge is to consistently provide a high-volume and high-quality living donor kidney program. Perhaps the question can be refocused as: “assuming that quality is being delivered at a high-level by the vast majority of living donor programs, why are some of these programs underperforming on a volume basis, while others are outperforming?” High-volume programs do not have one common phenotype. In fact, high-volume programs achieve success in different ways based on their perception of their referral base, resources, and institutional and team strengths. That is a critical point and is a fundamental rationale for our trepidation about efforts to “nationalize” or further regulate living donor programs. High-performing programs leverage their environments and strengths in different ways, including reliance on single-center paired donation (Methodist Specialty and Transplant Hospital San Antonio) or paired kidney exchange via the National Kidney Registry (MedStar Georgetown University Hospital, Mayo Clinic Arizona). Similarly, Johns Hopkins Donor Champion Program and Beth Israel’s programs to educate patients’ communities with home-based outreach have proved successful. However, high-performing programs have some commonalities:

A). They aggressively promote living donation with every recipient candidate that enters the evaluation process.

B). The promotion of living donation is repetitive and iterative and wait-listed patients have the importance of finding a living donor reiterated to them at every opportunity.

C). They spend both money and time to build teams capable (by expertise and staffing levels) of identifying and evaluating large volumes of living donor candidates and efficiently getting them through the evaluation process.

D). They treat living donor candidates with the respect and flexibility befitting those who are donating the gift of life.

E). They have vast technical proficiency, and exclude donors based on evidence-based, objective suitability to donate, but not on the anticipated difficulty of the donor operation. Additionally, anatomic variation is safely addressed through outstanding surgical care.

F). They include innovative donor assessment, such as genetic testing that allows donation for previously excluded donors.

G.) They provide exceptional care to living donors after donation.

6. ASTS notes that transplant centers can “[e]stablish IT platforms to share candidate data” Should a model include incentives for transplant centers to adopt and implement APIs to facilitate interoperability and data sharing?

Improving the efficiency of transplant evaluation and listing is crucial. As donor testing needs to be current, generally within one year of listing, evaluations which are inefficient lead to higher costs for CMS, decreased access to transplant, and limits multiple listings, which has been demonstrated to improve access to transplant.

However, it is unclear to us whether IT-related incentives should be incorporated into a demonstration whose primary focus is to increase the number of living donor transplants. While we believe that increased data sharing may have the potential to increase access to transplantation (both living and deceased), we caution against structuring the demonstration program in a manner that encourages transplant center participants to adopt one approach to increasing living donor transplantation over another. For example, while increasing interoperability and data sharing among transplant centers may have significant potential to ensure that a potential transplant recipient with specific clinical needs is listed, it is unclear how this IT infrastructure would increase living donor transplantation for demonstration participants. We ask CMMI to refrain from broadening the focus of the demonstration program to address the myriad of systems improvements that may improve transplantation.

The aim of this demonstration is to improve access and equity in LDKT and investing in IT infrastructure may not be as effective in increasing living donor transplantation as dedicating those same funds to other purposes (such as decreasing financial barriers for both living donors and potential recipients.) Considering the substantial variation in the barriers to living donor transplantation in various areas of the country, we urge CMMI to allow participating transplant centers broad flexibility to determine how to attain the goal, without incentivizing (or disincentivizing) various potential approaches.

7. Small pools of incompatible donors and recipients seem to be not in patients’ best interest as a recipient is more likely to quickly find a match in a larger pool. We appreciate ASTS’ comments about the nuance involved in facilitating KPD and chains once a match is secured. Regarding finding a match, does ASTS agree that patients should have access to the largest pool of incompatible donors and

recipients possible? If so, how should CMMI incentivize this? If not, why and what should CMMI incentivize instead?

All things being equal, larger pools are better. However, if a large pool is inefficiently managed, then few transplants may result despite the size of the pool. We agree that patients should have access to every relevant opportunity that could get them transplanted. CMMI should incentivize LDKT via education and dissemination of best practices; regulatory relief; financial relief; and expansion of programs that decrease the financial disincentives to donate faced by living donor candidates.

Transplant centers should be encouraged to consider entering biologically compatible pairs to expand the pool and potentially improve HLA matching or age compatibility. Similarly, CMMI can promote payment mechanisms to offset the increase cost of LDKT (including transportation of the organ). Finally, establishment of a common and consistent "living donor SAC" rather than hospital by hospital variation and single contracts would assist in this endeavor.

8. ASTS noted that "referral for transplant evaluation should focus on referral of CKD 4 and CKD 5 patients who may be potential candidates for living donor kidney transplantation." How does ASTS envision this would be possible in a living donor model that nephrologists are not participants in?

We believe that increasing the percentage of kidney failure patients referred while still pre-dialysis (CKD 4/5) would be beneficial for the transplant ecosystem, and we agree that the participation of community nephrologists is critical in achieving this goal. Transplant center participants should be given the flexibility to determine whether and to what extent, the involvement of community nephrologists, in addition to other resources, is likely to increase the effectiveness of reaching potential candidates. For example, outreach to primary care physicians or community clinics may be more effective in identifying potential candidates for pre-emptive transplantation in some areas, and in others it may prove most efficient to work through local community organizations with close ties to minority populations.

However, this demonstration should coordinate with the ongoing mandatory and voluntary models to ensure that nephrologists involved in the LDKT demonstration receive credit for early referrals. In addition, we believe that the current CMMI initiatives to promote increased listings will only be successful if the transplant centers are provided with sufficient resources to promote living donation to meet demand for organs. Thus, we believe this proposal is compatible and complementary with ongoing CMMI initiatives.

9. In the proposed living donor focused demonstration, the transplant center takes on responsibility for helping patients find a living donor. However, by and large, a patient would not receive this support from the center until s/he is listed for a transplant. What are the current disincentives to adding patients to the waitlist? Is it accurate that transplant centers can feel reticent to list patients because they are accruing wait time while on dialysis? If so, what can be done to overcome this practice so that more patients can be listed and receive education and support in finding a living donor?

The process of helping a recipient find a living donor does not need to be linked to the patient being listed; this process can occur in parallel. For older recipients, many transplant centers only list patients **after** identifying a living donor. This reflects the current scrutiny of waitlist outcomes, transplant rates, and lengthening waiting times. All of this makes listing of medically complex candidates more difficult without a viable living donor.

Increased attention to the evaluation process is important to guide patients efficiently through to listing and transplant. Additional barriers to listing include:

- Cost, which, although covered in part by the cost report, impacts centers' ability to be economically viable with private payers
- High risk of mortality prior to transplant in older patients with long expected wait times
- Burden of maintaining clinical readiness for large waiting lists. Coordinating and ensuring timely testing for large waiting lists poses a significant administrative challenge
- Patient engagement with the transplant process, which diminishes as waiting times are extended

Also, reducing barriers to multiple listings would allow patients to identify centers that are willing to transplant them. We note, however, that in areas with waiting times that routinely exceed 5-6 years and the unfortunate high risk of mortality on dialysis, that early listing may not actually lead to increased transplantation, in the absence of living donation.

Transplant centers with high-functioning living donor programs actively engage with CKD/ESRD candidates about the presence or absence of living donors very early in the referral process. Any candidates with identified potential living donors are aggressively worked up and listed. This is particularly important for elderly or frail candidates who may be unable to survive on dialysis until anticipated first deceased donor kidney offer but may do very well with a living donor kidney transplant. Patients already on dialysis at initial referral to the transplant center for evaluation for listing are, in effect, already accruing time. When listed, adult patients on dialysis receive waiting time from the initiation date of renal replacement therapy. Our hope is that this demonstration project will increase the number of living donor transplants performed, and a combination of regulatory relief and shared cost savings allocation will incentivize that growth

10. ASTS writes [i]t is not possible in a transplant demonstration project to fix issues in access to coverage, access to health care, access to referral, and other social determinants of health that are deeply embedded with race and lower socioeconomic status in our health care system. Which SDOH could be addressed with greater resources provided in a model?

On reflection, our statement with respect to the potential impact of a transplant demonstration program on SDOH is overly broad. There are several SDOH that potentially could be mitigated through the proposed living donor demonstration program. Removing financial disincentives to living donation could be achieved by extending NLDAC-type benefits through the demonstration project to the recipients or by incentivizing a transplant center participant to utilize shared savings to assist potential recipients as well as potential living donors with transplant-related transportation, childcare, or other expenses that are not covered by other sources; to assist with post-transplant support for recipients and donors who may need it; and to otherwise address financial barriers to access to transplantation. We can leverage the best practices of high-performing centers that have been more successful in achieving living donation in historically underserved communities.

As noted above, a potent means of both promoting living donation and improving SDOH in underserved or disadvantaged communities would be the provision of life-time health care insurance coverage to every living donor. That would also eliminate a common conundrum for transplant hospitals, which are often faced with decisions regarding the suitability of living donor candidates who lack health insurance.

11. What donor and recipient outcomes should be measured and reported in a transplant model?

Living donor candidate referrals, evaluations and living donor transplant volumes. Outcome measures are already publicly reported and comprehensive.

12. Studies (e.g., Zhang & Guird, 2021; Basu et al., 2018) have shown that educational materials pertaining to living donation vary significantly across centers (e.g., culturally competent, benefits and risks, social support). In your opinion, do you think that there are realistic options that could be implemented to potentially address these disparities/differences in educational materials, and why? If not, why do you think nationalization of perhaps aspects of this, which could potentially address some of these systemic issues, be productive?

We agree that the character and quality of educational materials provided to living donor candidates and transplant recipients likely have significant inter-program variability. A couple of reasons likely constitute those differences:

1). Centers develop material that highlights the capabilities, services, and resources of that particular center. So, a center that does not perform PKE will likely not educate candidates/patients thoroughly on this avenue for living donation/transplantation.

2). Centers have limited resources and expertise to apply to the development of these resources. The resources available likely vary widely among centers, even those of similar overall size.

Incentivizing living donation would likely lead to increased investment by centers in these educational efforts. In a virtuous cycle, increased investment by centers could lead to increased living donor transplant volumes. We are opposed to “nationalization” of additional aspects of living donor transplantation, and fear that those efforts would have the unintended consequence of impairing access to living donation for many patients in need. However, voluntary national programs to develop and disseminate living donor program best practices and to make available more sophisticated and culturally appropriate educational materials would be helpful.

For example, it is a real challenge, particularly for a small program that serves a majority White and Black patient population, to commit the resources and identify the expertise to develop educational material in Spanish. Furthermore, the Latinx population is incredibly diverse, and material that is developed for third generation Mexican immigrants may be poorly equipped to serve a first-generation Guatemalan immigrant population. No one transplant center houses all the needed expertise or can develop all the required material for the diverse tapestry of cultures and languages that compose our patients in need, and this represents an opportunity for the national development of best practices and educational material designed with the needs of many different populations in mind.



Saving and improving lives with transplantation.

American Society of Transplant Surgeons®

March 24, 2023

Dear Mr. Duvall:

We are pleased that CMMI continues to be interested in a demonstration project targeted at increasing living donor kidney transplantation and reducing disparities. Below please find our responses to your most recent questions:

1. Given the low number of living donor transplants per center, how would you all envision CMS setting an appropriate target number? Should that number increase year over year?

The data does not support the conclusion that the number of living donor (LD) transplants per center is universally “low.” Rather, we believe that it is more correct to conclude that the number of living donor transplants per center varies widely from center to center both in absolute terms and as a percentage of all kidney transplants performed at that center. The heterogeneity of LD volume as a function of realistic potential volume among LD programs is one of the problems we hope to address via the demonstration project. We would point out that some LD programs are clearly outperforming, and one of the challenges of the demonstration project will be to construct targets that allow already high performing centers to participate, grow, and meet target thresholds while also providing realistic targets for underperforming and average centers.

Due to the wide differences in LD performance among centers, we believe that the target number should be based on percentage increase from a multiyear baseline (for example, the mean of the number of LD transplants performed by a participating center in the three calendar years prior to demonstration project enrollment). Also, we need to keep in mind that it may be harder for high-performing centers to create as big a numeric delta as underperforming programs, which are starting from a much lower baseline, both functionally and operationally. So, a program with a 100-living donor annual mean volume prior to the demonstration project may be doing well to achieve a 10% improvement (10 additional LD transplants), while a low performing center performing a mean of 10 LD transplants annually could meet this target by performing one additional LD transplant. A sliding scale of percentage increase in volume should be considered, with small volume programs expected to achieve higher percentage increases than large volume programs, potentially using brackets to group programs with similar pre-demonstration performance. For example, different [percentage] performance targets could be established for programs with mean volume less than 20/year, 21-49/year, 50-74/year, and over 75/year. Those brackets would have different percentage change goals, with larger programs needing to hit smaller percentage change benchmarks. Alternatively, targets based on the absolute number of living donor transplants performed rather than percentage increases may be appropriate for larger programs.

We envision that the percentage or number of preemptive LD transplants (involving LD transplantation prior to dialysis initiation) as one of the targets for this demonstration project. The percentage of a center’s transplants that are pre-emptive, and the absolute number of LD and preemptive LD transplants performed would be credible and verifiable metrics.

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Likewise, decreasing disparities in access to living donor transplantation is critical, and we envision monitoring the number and percentage of LD transplants performed in historically disadvantaged patient populations as another performance/evaluation metric. This metric should consider the fact that the proportion of historically disadvantaged patients in each participant's service area is likely to vary. One possibility would be to establish metrics with the goal of having the proportion of living donor transplants of historically disadvantaged recipients mirror the proportion of historically disadvantaged potential recipients on the transplant program's waiting list, with appropriate adjustments made for those clinical conditions that are contraindications for living donor (but not deceased) donor transplantation.

2. How much would it cost centers to implement an effort like this under the proposed model? How many additional staff would it take to support the living donor process?

It is difficult to answer these questions in light of the substantial differences among transplant centers' living donor programs. UNOS' transplant center staffing survey may provide useful insight into the answer to this question.

High performing LD programs have all made significant investments in LD staff. The keys to having a high-performing LD program are all operational, such as the ability to rapidly evaluate and schedule LD candidates and paired recipients, and the operational ability to engage in significant volumes of Paired Donor Exchange (PDE) transplants, which is incredibly labor intensive.

For example, one urban (approximately 100 LD/year) center utilizes three FTE LD nurse coordinators, one FTE LD recipient nurse coordinator (who ensures the recipient for a paired exchange is ready for the Paired Donor transplant), and three FTE administrative assistants. Those individuals are just the tip of the spear however, as the support structure for the LD program includes, by definition, all the elements of the multidisciplinary transplant endeavor. A high-functioning LD program requires very significant utilization of transplant social work; scheduling; pretransplant coordinators; administrative support; billing and financial coordinators; pharmacy support; and the surgery and nephrology teams. At this urban center, transplant center staff are fully utilized, and a meaningful increase in the number (or percentage) of living donor transplants would require a proportional increase in staffing resources. Additional resources needed to increase living donor transplant volume significantly at this urban center would likely require at least one more FTE nurse coordinator, one FTE administrative assistant, and a half FTE social worker. The costs are directly related to the costs of hiring, training, and retaining staff critical to the LD program. These costs vary by market, but multiple benchmarks/metrics are available for transplant staffing costs.

By contrast, many smaller programs may have no dedicated FTE LD staff, which of course directly constrains their performance. For small programs, even one FTE dedicated to the LD endeavor would unlock productivity.

It is also important to note that the costs of entering PDEs via the National Kidney Registry (NKR) or other similar donor exchange programs are significant, including not only fees and "per transplant" costs but also additional center costs for repeated HLA typing. Those additional costs should be a consideration as well, as we have clearly identified utilization of PDE as a key approach to increasing living donor kidney volumes.

3. Should this only apply to kidneys, or should it apply to other organs as well?

This demonstration program should be limited to kidneys. If successful, consideration should be given to expanding the demonstration program to other organs.

4. What other outcomes measures besides quality of life should be included in the model?

It is well established that living donor kidney transplantation has significant clinical and economic advantages over other alternatives in the treatment of ESRD and late-stage CKD. In light of the significant advantages of living donor transplantation over other clinical alternatives, we believe that the volume of LD transplants at a given transplant center should be the primary outcome measure. The percentage (or, in the case of large programs, number) of center transplants done preemptively (prior to dialysis) would be another key measure, along with the percentage (or, in the case of large transplant programs, number) of living donor transplants performed for historically underserved populations. Metrics in this latter area should be carefully tailored to take into consideration local or regional demographics.

We urge CMS to refrain from adding performance metrics unrelated to the number or percentage of (overall, pre-emptive, and historically disadvantaged) living donor transplants performed by demonstration participants. In our view, the objectives of the demonstration project are most likely to be achieved if participants remain focused on increasing access to living donor kidney transplantation.

5. Do you see any conflicts between the incentives embedded in this model and the outcomes measures from the OPTN MPSC?

The OPTN/MPSC considers 90 day and one year graft survival among the metrics used in evaluating transplant center performance, and one year patient and graft survival are among the metrics publicly reported under the SRTR star ratings. These metrics have the potential to significantly disincentivize living donor transplant programs from transplanting older or sicker potential recipients because, due to the extraordinarily good outcomes associated with living donor kidney transplantation, even a small perturbation in living donor transplant outcomes can trigger OPTN/MPSC performance review or a reduction in the program's star ratings.

For this reason, we are advocating for regulatory relief as part of this demonstration project. Our aim is to remove or mitigate disincentives to (the perception) of additional center risk that has the unintended consequence of decreasing acceptance of higher-risk recipients for living donor transplantation. That relief may consist of some type of exemption from OPTN/SRTR flagging for high-risk recipients of LD kidneys. We are NOT advocating for change in the outcome measures or expectations for living donors.

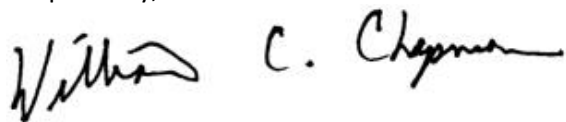
6. Even if the allocation formula makes accountability for transplants difficult, what other metrics are most important to measure transplant center performance with deceased donor organs?

As you are aware, transplant center performance with respect to deceased donor organs is currently measured under OPTN transplant center performance metrics and the SRTR star ratings system, both of which include metrics related to pre-and post-transplant care. In fact, the transplant center performance data currently available to the public and to governmental agencies is already far more extensive than performance data reported for other type of providers. Under these circumstances, any performance metrics applied to transplant centers under a CMMI demonstration should be precisely tailored to achieve the demonstration project's objective.

We strongly support CMMI's continued interest in a demonstration program addressing deceased donor transplantation. In our view, the single greatest impediment to deceased donor transplantation is the severe scarcity (relative to the demand) of high-quality organs, which results in high rates of waitlist mortality. The recent NASEM report recommends that, to increase the availability of deceased donor organs, donor care centers (DCCs) ("organ recovery centers" in the parlance of the NASEM report) should be established in all OPO DSAs. ASTS strongly supports the establishment of donor care centers and believes that a CMMI demonstration program in this area has the potential to lay the groundwork for the establishment of new and more efficient organ procurement processes. For this reason, we would appreciate the opportunity to discuss with you the possibility of a CMMI demonstration program focused on incentivizing the donor care center model of organ recovery. The metrics for participants in such a CMMI demonstration program likely should focus on increases in number of transplantable organs procured over a historic baseline. As the utilization of DCCs has been demonstrated to decrease procurement costs and improve quality, both cost and quality could feasibly be evaluated for inclusion as metrics in a deceased donor demonstration project.

We appreciate the opportunity to discuss these ideas with you and look forward to our next meeting.

Respectfully,



William C. Chapman, MD
President
American Society of Transplant Surgeons