

April 27, 2022

Dr. Kenneth W. Kizer, MD, MPH
Ms. Rebecca English
Ms. Meredith Hackmann
The National Academies of Sciences, Engineering and Medicine
500 5th St. N.W.
Washington, DC 20001

VIA ELECTRONIC MAIL

Dear Dr. Kizer, Ms. English and Ms. Hackmann:

The Organ Procurement and Transplantation Network (OPTN) offers its appreciation for the holistic recommendations outlined in the National Academy of Science, Engineering, and Medicine's (NASEM) February, 2022 report, "Realizing the Promise of Equity in the Organ Transplantation System," developed by the Ad Hoc Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution ("the Committee"). We commend all members of the Committee for their nearly two years of dedication to this seminal report.

In 2021, the U.S. organ donation and transplant system surpassed 41,000 transplants for the first time in a single year. 2021 also marked record numbers of kidney, heart, and liver transplants and the eleventh consecutive year of growth for deceased donor transplants.¹ The Committee's fourteen recommendations identify additional opportunities for the system to continue to grow and improve. Many of the Committee's recommendations align with and support our current ongoing work.

Below are important updates and additional information about existing efforts related to **patient inclusion and education**, followed by updates and corrections to the three areas outlined in the report: **achieving equity, improving system performance, and maximizing organ use**.

Patient Inclusion, Education and Shared Decision-Making

We agree with the Committee that elevating patient voices is a vital step in improving the national system, improving outcomes, and increasing transparency and accountability. We are proud that patients, donors and their families have a voice in the OPTN policymaking process from inception to enactment, with at least one voting representative on all committees and a Board that is one-quarter patient and donor affairs representatives. These individuals are able to cast votes in the policymaking process and are empowered to engage in discussion and debate. In fact, our system is unique in that patients have a voice at the table from the beginning. Some ongoing efforts include:

¹ "All time records again set in 2021 for organ transplants, organ donation from deceased donors." Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/news/all-time-records-again-set-in-2021-for-organ-transplants-organ-donation-from-deceased-donors/>. 11 January 2022.

- *Improving patient engagement in OPTN policy development:* We thank the Committee for their support of “continuous distribution” in Recommendation 4. Continuous distribution is a new organ allocation framework aimed at making the national system even more equitable and accessible. This innovative approach to policymaking provides more meaningful, accessible engagement with patients, professionals and the general public about the values that should guide organ allocation in the U.S. The patient voice is essential in the policy development process, and obtaining this input even earlier in the process ensures these voices are heard.
- *Public Comment:* Part of our ongoing work includes OPTN efforts to increase patient engagement in public comment, where we gather diverse input on different policy proposals. As participants in the OPTN governance system, patients have a unique perspective and an important voice that we need to see reflected more in the public comment process.

Additionally, our belief in the importance of educating patients informs our work as we develop resources that address their evolving needs, including:

- *Patient education and shared decision-making:* The OPTN is in the process of exploring ways to further enhance our current education offerings to better serve the needs of patients, including the development of new tools that support increased transparency in the organ offer process. Making more data available about transplant hospital performance, patients’ waitlist status, detailed information and potential financial support for living donors, and offers declined on the patients’ behalf will enable patients to become empowered partners in their care.

Achieving Equity

We appreciate the Committee’s patient-focused approach to the challenges facing the organ donation and transplantation community. All members of the system are committed to the best possible outcomes for patients. We agree that expanded data collection, improved federal payment policies, shared decision-making, patient education, and enhancing inclusivity in policymaking are important steps.

The OPTN is committed to maintaining equity in access to transplant for waitlisted patients. The Committee’s recommendations on equity touch on several current OPTN initiatives, including:

- *Development of the “Continuous Distribution” framework:* We appreciate the Committee’s support of this important new policy framework. The OPTN will also consider ways to balance these recommendations and their impact on timelines while continuing to ensure that all voices, including those from communities facing disparities, are included. Importantly, one of the defining features of this framework is its ability to incorporate feedback from a wide range of stakeholders. This framework will also make small, frequent adjustments to the programming more feasible, and allow policy to more quickly respond to data about results.²

² “Continuous distribution: A closer look.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/continuous-distribution/>. Accessed 15 April 2022.

- *Removal of race in estimating kidney function (“eGFR”)*: In June of this year, the OPTN Board of Directors will take action on a proposal to prohibit the use of race-based estimation of kidney health in OPTN policy.³
- *Monitoring waitlist management practices*: In December of 2021, the OPTN adopted new, patient-centric transplant program performance metrics that will begin to go into effect in 2022. The new metrics include pre-transplant measures of waitlist mortality and organ offer acceptance rates, providing a more complete picture of a patient’s journey from waitlisting to successful transplantation. This data will inform future efforts to further expand transplant equity.⁴
- *Supporting improvements to federal payment policies*: During recent rulemaking, the OPTN has recommended CMS consider adjustments to payment policies that would incentivize increased utilization of hard to place organs and increase the number of transplants.

The OPTN publishes the Equity in Access Dashboard, which allows the public to explore trends and factors that impact access to transplant for waitlisted patients.⁵ While the OPTN allocates donor organs equitably among patients on the waitlist, the Committee correctly notes that less is known about inequities prior to waitlisting, in access to referrals, evaluation, and waiting list registration.

The OPTN will continue to support efforts to better understand these inequities in access to the waitlist and stands ready to support the Administration and Congress in addressing these concerns as the OPTN contract allows. Our current partnership with HRSA’s data team to enhance the data and analytics warehouse will increase our collective capability to understand and address these inequities.

Improving System Performance

The Committee’s report makes several key recommendations for the OPTN and the donation and transplant community at large. We agree with or are already engaged in working on many of the opportunities identified within this section of the report:

- *National performance metrics*: The OPTN will support the Secretary in the development and adoption of national performance metrics. The OPTN has reviewed many of the options discussed in this recommendation, and the new OPTN Metrics Dashboard offers the public a view into the current progress.⁶ Further, Goal 1 of the current OPTN Strategic Plan includes continuing efforts to improve national performance metrics, moving from one or two indicators

³ “Understanding the proposal to require race-neutral eGFR calculations.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/patients/by-organ/kidney/understanding-the-proposal-to-require-race-neutral-egfr-calculations/>. Accessed 15 April 2022.

⁴ “Enhancing Transplant Program Performance Monitoring.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/policies-bylaws/enhance-transplant-program-performance-monitoring/>. Accessed 15 April 2022.

⁵ “OPTN Equity in Access Dashboard.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/data/visual-dashboards/equity-in-access/>

⁶ “OPTN Metrics Dashboard.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/data/visual-dashboards/optn-metrics/>.

to a more comprehensive dashboard approach.⁷

- *Improving the OPTN policymaking process:* The OPTN will closely review this recommendation as we continue to refine our policy development process. The difficult balance we must strike is between a quicker process and including as many voices as possible. Consistent progress has yielded a faster, more responsive Board and Committee system; one that includes patients, donors, donor families and advocates from the very beginning. This is most notable when comparing the new kidney allocation system in 2014, which took eight years to develop, to the lung Continuous Distribution policy in 2021, which took two-and-a-half years to develop.⁸ We will pursue membership and resources from the National Quality Forum, as recommended by the Committee, for additional resources that will support expediting policy development while still building consensus among all stakeholders.

Maximizing Organ Use

The OPTN thanks the Committee for these recommendations and agrees that it is vitally important to better understand the organ offer review and acceptance process in order to begin reducing the differences in practices from hospital to hospital. To support these efforts, the OPTN has developed the following initiatives:

- *Kidney Offer Filters:* The OPTN launched the Kidney Offer Filters tool in January 2022, allowing kidney transplant programs to preemptively screen out offers they are unlikely to accept, thereby reducing administrative burden, accelerating organ placement and making it easier for OPOs to find best-fit candidates quicker while optimizing organ function.⁹
- *Increasing transparency and accountability in organ offers:* The OPTN recently implemented a new list of codes transplant programs can use when they refuse an organ offer.¹⁰ This information will provide greater insight into the offer decision-making process. In addition, the recently-adopted transplant program metrics include the offer acceptance rates. Taken together, this focus on pre-transplant performance is intended to help identify programs that are refusing offers more frequently than others and may not be adequately serving their waitlisted patients and provide programs the opportunity to closely review their refusal data in an effort to identify potential changes in program acceptance patterns.
- *Kidney biopsy proposals:* The decision to perform a kidney biopsy and the influence the results have on organ offer acceptance varies widely between programs. In response, the OPTN released two proposals for public comment this winter to standardize these practices in order to improve decision-making:

⁷ "2021-2024 OPTN Strategic Plan." Organ Procurement and Transplantation Network.

<https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/2021-2024-optn-strategic-plan/>.

⁸ "Organ Transplants: Changes in Allocation Policies for Donated Livers and Lungs." Government Accountability Office. 04 Nov. 2020. <https://www.gao.gov/products/gao-21-70>. Accessed 3 April 2022.

⁹ Toll A., McGehee H., Stewart D., McTier R. Centers Avoided 67% of Kidney Offers by Participating in the OPTN's Multifactorial Offer Filter Pilot Project [abstract]. *Am J Transplant*. 2021; 21 (suppl 3). <https://atcmeetingabstracts.com/abstract/centers-avoided-67-of-kidney-offers-by-participating-in-the-optns-multifactorial-offer-filter-pilot-project/>. Accessed 3 April 2022.

¹⁰ "Project to update refusal codes: A closer look." Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/policies-bylaws/a-closer-look/project-to-update-refusal-codes/>. Accessed 3 April 2022.

- *Establish Minimum Kidney Donor Criteria to Require Biopsy*
- *Standardize Kidney Biopsy Reporting and Data Collection*

These proposals are anticipated to be presented to the OPTN Board for their action in June of 2022. The OPTN Kidney Committee will review the results post implementation with the hope that a more discriminate use of biopsies, which currently is the most common cause of allograft declines despite poor concordance with outcomes as reported in the scientific literature, will result in greater utilization of more marginal organs.^{11, 12}

As the Committee is likely aware, increasing offers does not automatically result in higher acceptance rates or more transplants; by itself, increasing offers may only serve to increase declines. To truly address these issues, we first need more targeted data to inform decision making, which the above initiatives are intended to support.

Lastly, we respectfully offer the following additions and corrections to Recommendations 4 and 5 in the report:

- On page 5-8, the report erroneously concludes that “20% of kidney offers are to deceased individuals on the waitlist.” In fact, the study cited found 68,781 offers went to deceased candidates out of 14.6 million, or *less than one half of one percent* of all offers. Given the potential harm this type of misinformation can cause, we respectfully request the Committee issue a correction.
- On page 4-6 (“Time from waiting list to transplant”), the report cites a 2012 study to draw a conclusion on an allocation policy not implemented until 2014. The author has since participated in a subsequent study in 2017, reflecting the new data.¹³ The kidney allocation system adopted in 2014 was explicitly designed to reduce or eliminate racial inequities in waiting time for waitlisted patients, and contemporary data demonstrate that the new policy has been successful.^{14, 15}
- On page 5-2, two studies are cited as evidence of inequities between rural and urban waitlisted candidates. Though these references do reveal geographic variability in access, the report in

¹¹ “Establish Minimum Kidney Donor Criteria to Require Biopsy.” Organ Procurement and Transplantation Network Kidney Transplantation Committee. <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/establish-minimum-kidney-donor-criteria-to-require-biopsy/>. Accessed 15 April 2022.

¹² “Standardize Kidney Biopsy Reporting and Data Collection.” Organ Procurement and Transplantation Network Kidney Transplantation Committee. <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/standardize-kidney-biopsy-reporting-and-data-collection/>. Accessed 15 April 2022.

¹³ Melanson, T.A., Hockenberry, J.M., Plantinga, L., Basu, M., Pastan, S., Mohan, S., Howard, D.H. and Patzer, R.E., 2017. New kidney allocation system associated with increased rates of transplants among black and Hispanic patients. *Health Affairs*, 36(6), pp.1078-1085.

¹⁴ Stewart, D.E., Kucheryavaya, A.Y., Klassen, D.K., Turgeon, N.A., Formica, R.N. and Aeder, M.I., 2016. Changes in deceased donor kidney transplantation one year after KAS implementation. *American Journal of Transplantation*, 16(6), pp.1834-1847.

¹⁵ Stewart, D.E., Wilk, A.R., Toll, A.E., Harper, A.M., Lehman, R.R., Robinson, A.M., Noreen, S.A., Edwards, E.B. and Klassen, D.K., 2018. Measuring and monitoring equity in access to deceased donor kidney transplantation. *American Journal of Transplantation*, 18(8), pp.1924-1935.

question did not evaluate disparities by geographic location. In fact, when accounting for other factors, the OPTN Equity Dashboard shows no difference in access for rural or urban candidates.¹⁶

- On pages 5-16, the report restates a common misconception, that for a kidney patient to be waitlisted, they must first be on dialysis or have a specified eGFR. However, no OPTN policy requires dialysis or any GFR to list a kidney patient. Patients can be, and are, added to the list prior to meeting this criteria. While they are unable to accrue waiting time points until a specified GFR, they can and do receive other types of points (CPRA, HLA matching, etc.) and can receive organ offers.¹⁷
- On page 5-35, the report acknowledges the “limited available evidence on the performance of the OPTN IT infrastructure,” but nevertheless proceeds to make several recommendations. The OPTN agrees with NASEM that a modern IT infrastructure is essential to securing and maintaining the nation’s organ donation and transplantation system – the very infrastructure we have spent years developing and improving. In fact, the OPTN system is regularly audited by both HHS and the OIG and we routinely meet or exceed all OPTN contractual standards. We also continue to partner with national industry leaders to ensure the system is effective, safe, reliable and secure. We are surprised that the NASEM made these recommendations without conducting any review of the OPTN’s IT system.

The OPTN would like to once again thank NASEM and the Committee for these recommendations, developed by a diverse and interdisciplinary team of clinicians, professionals and patients. We believe that your work will help to make a strong organ donation and transplant system even better.

We look forward to continuing our work together, welcome efforts in collaboration, and we stand ready to respond to any additional questions you may have.

Sincerely,

A handwritten signature in black ink that reads "Matthew Cooper". The signature is written in a cursive style and is contained within a thin black rectangular border.

Matthew Cooper, MD
President, OPTN Board of Directors

CC: The Honorable Xavier Becerra, Secretary, U.S. Department of Health and Human Services
Ms. Carole Johnson, Administrator, Health Services and Resources Administration

¹⁶ “OPTN Equity in Access Dashboard.” Organ Procurement and Transplantation Network.

<https://optn.transplant.hrsa.gov/data/visual-dashboards/equity-in-access/>. Accessed 15 April 2022.

¹⁷ “OPTN Policies.” Organ Procurement and Transplantation Network. <https://optn.transplant.hrsa.gov/policies-bylaws/policies/>. Accessed 26 April 2022.