VANDERBILT UNIVERSITY
MEDICAL CENTER

Section of Surgical Sciences

Seth J. Karp, M.D.
Professor of Surgery and Anesthesiology
H. William Scott Jr. Chair in Surgery
Chair, Section of Surgical Sciences
Surgeon-in-Chief, Vanderbilt University Medical Center
Director, Vanderbilt Transplant Center

Written Testimony of Seth J. Karp, M.D.
Director, Vanderbilt Transplant Center
Chair of Surgical Sciences and Surgeon-in-Chief, Vanderbilt University Medical Center
H. William Scott Jr. Professor and Chair in Surgery and Anesthesiology
Vanderbilt University School of Medicine
Nashville, Tennessee

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Subcommittee on Economic and Consumer Policy

"The Urgent Need to Reform the Organ Transplantation System to Secure More Organs for Waiting, Ailing, and Dying Patients"

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Chairman Krishnamoorthi, Ranking Member Cloud and distinguished Members of the Committee, I express my sincerest gratitude for your collective efforts to study and advance ways to increase life-saving organ transplants in the United States. As a practicing transplant surgeon, researcher and Director of one of the largest transplant programs in the United States, I have studied this problem for many years. I have come to the conclusion that much of the organ shortage for hearts, lungs, and livers could be quickly solved, and thousands more kidneys could be made available for those in desperate need.

The present moment presents a unique opportunity to increase the availability of life-saving organs for transplant, and I applaud the recent decision of the Biden Administration to move forward with implementation of the *Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs.* This final rule, which is the culmination of work by the previous two Administrations, holds great promise to improve organ donation practices, as I will explain in my testimony. However, there are additional steps we must also take.

The need for organ donation reform is disproportionately shouldered by communities of color. COVID-19, in increasing the burden of end stage organ failure, especially among underserved populations, will almost certainly increase the need for transplants and further exacerbate both the need for transplants and these existing healthcare disparities.[1]

VANDERBILT UNIVERSITY
1161 21st Avenue South
D-4316 Medical Center North
Nashville, TN 37232-2730
tel 615.322.2363
fax 615.343.5365
seth.karp@vumc.org

For these reasons we must act, and we must act quickly. Every day another 33 people die waiting for a transplant. We owe it to these patients and their families to go beyond self-interest and urgently work together for the benefit of all patients in need. Time matters. Whereas the recently finalized OPO rule is a critical first step, the immediate attention and oversight of Congress is required to ensure that people are not dying unnecessarily due to lack of accountability among government contractors.

Here are the principal issues preventing us from reaching the goal of providing more organs for transplantation in the United States:

Problem #1) Organ procurement organizations (OPO) performance is inconsistent and underperforming due to previous lack of an enforceable metric.

Prior to the implementation of the new rule revising outcome measures for OPOs, their performance metrics relied on self-reported data. The deficiencies of such a system might be self-evident but consider one illustrative example. When threatened with decertification, one OPO successfully argued that because their performance data was self-reported and unaudited, the metrics failed to meet a reasonable standard and the OPO should therefore not be held accountable.

In other words, the metrics supposed to measure performance didn't measure performance. Multiple other lines of evidence support this same conclusion. According to objective metrics, there is a 400% difference in performance between the best and worst performing OPOs, which is not identified in current OPO evaluation data.[2] Furthermore, targeted interventions can significantly and quickly increase the number of donors.[3]

Many OPOs have experienced dramatic increases in their performance, and in some cases more than doubled the number of organs procured after a new CEO was hired. Problematically, these OPOs were not flagged as underperforming at any time. This corroborates the OPO's legal argument that the metrics historically used to evaluate OPOs could not identify even glaring failures. As DJ Patil, Chief Data Scientist of the United States from 2015 to 2017, Greg Segal, and I wrote in a Viewpoint for the *Journal of the American Medical Association – Surgery*, what can't be measured can't be fixed, and the appropriate metrics were not being measured.[4] Now that the new final rule has been put in place, it must be enforced as quickly as possible.

I will also note that attempts by government contractors themselves to undermine the final rule on OPO metrics have been deeply concerning. Misinformation has been fact checked again and again – see for example the letter from a previous Chief Technology Officer of the Department of Health and Human Services (HHS) to HHS Secretary Azar, as well as a fact-check of the Association of OPOs by one of its own Board members.[5,6]

Solution #1) Provide standardized tools for evaluation of OPO performance and ensure accountability.

In finalizing the new federal rule on OPO performance, the administration took an important stride in assuring that the entire community will have access to objective, actionable data. <u>It is now essential that the data reported under the new Federal rule is used in a transparent, public manner and that underperforming OPOs are held to the new standard as quickly as possible. By HHS' own estimation, every year OPOs are unaccountable means 7,000 Americans could die waiting for</u>

minimum OPO performance. Economists estimate this carries an additional $1 billion in Medicare costs.

Problem #2) OPO oversight is ineffective.

OPOs are certified by the Centers for Medicare and Medicaid Services (CMS), however the final rules adopted under the National Organ Transplant Act charge the Organ Procurement and Transplantation Network (the "OPTN") with the on-going responsibility to evaluate OPO performance. *See* CFR **§121.10.b1(iii) (**stating that the "…OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of… Conducting ongoing and periodic reviews and evaluations of each member OPO… for compliance with these rules and OPTN policies."). This dichotomous structure between CMS and the OPTN under the Health Research and Services Administration (HRSA) purview creates confusion, essentially ensuring lack of consistent oversight and accountability for OPO performance. In many cases, OPO oversight at UNOS is managed by OPO leaders who serve on the UNOS board, creating serious and obvious conflicts of interest. As evidence of the challenges inherent in this structure, it is worth noting that over decades, the OPTN has only ever placed two OPOs as "members not in good standing".

Solution #2) Clarify and simplify oversight of government contractors in organ donation (OPOs and the OPTN).

Given the confusion in the current system, there needs to be clear delineation of who is responsible for OPO performance and oversight. The OPTN contract itself is managed by one agency – the Health Resources Services Administration (HRSA), whereas the costs of poor OPO performance are borne by another agency – the Centers for Medicare and Medicaid Services (CMS). The ability to ensure that government contractors in the organ space are serving the public is critical. That is why I support the elevation of an Office of Organ Policy within the Office of the Assistant Secretary of Health (OASH), as announced to Congress in January 2021, to be established to oversee the OPTN contractor and the OPOs. It is my sincere hope that the Biden-Harris Administration carries forward this bipartisan, common sense idea with urgency given the equity implications of current system failures, which will further be exacerbated by COVID-19.

Problem #3) The overall structure of federal oversight of OPOs and the OPTN is flawed.

The OPTN is operated under contract with the U.S. Dept. of Health and Human Services by the United Network for Organ Sharing (UNOS). Although the OPTN is legally a separate entity from UNOS, the UNOS and OPTN Board are the same. This leads to a situation in which the OPTN Board is obligated to simultaneously advocate for the contractor and contractee and creates powerful and protectionist conflicts of interest. For example, if parts of UNOS are underperforming, there is a disincentive for every member of the OPTN Board to raise these issues due to their fiduciary responsibilities as a simultaneous member of the Board of the contractor (UNOS). Reliance on a single contractor to manage all of the OPTN functions poses other risks as well. For example, the computer systems which are needed to run the organ donation and allocation system are proprietary to UNOS, which gives them enormous leverage in influencing the awarding of the contract. In addition, the requirements to bid for the UNOS contract specifies that the applicant have significant experience in running the OPTN which functionally eliminates competition.

The OPTN has a voting structure in which critical constituent groups are simply not represented in policy decisions. This recently led to contentious policies that split the transplant community

regarding where organs can be matched and pitting states against each other. This has occurred in a situation of organ scarcity dramatically worsened by the OPTN contractor's focus away from its primary duty to increase the number of organs available for transplant and efficiently match organs to appropriate donors.

Solution #3) Restructure the OPTN.

As discussed, the current structure has the following problems: 1) overlap of the UNOS and OPTN Boards creates conflicts of interest between the OPTN and the contractor, 2) the functional inability of an entity other than UNOS to compete for the OPTN contract, 3) the inability to contract separately for the constituent functions of the OPTN, and 4) the limited ability HHS has to influence decisions made by the OPTN. To solve this problem, I would recommend for consideration:

- Creation of a new 'Office of Organ Policy' to manage the OPTN contract;
- Separation of the Boards of the OPTN and UNOS;
- Competitive bidding for the component parts of the OPTN contract; and
- Clarification of the reporting structure such that the OPTN is fully accountable to HHS, especially on policy decisions.

I further recommend Congress consider amending NOTA section 274(b)(ii) to include that the national system to match organs should be developed and maintained by the most qualified vendor(s) using modern technology. Importantly, there has never been a competitive bid for the OPTN contract in nearly 40 years, a time that has seen enormous advances in technology.

I note that the House Appropriations Committee supported the need for competition for the OPTN contract in 2020, underscoring the bipartisan nature of this basic reform.[7] Alumni of the United States Digital Service detailed a straightforward strategy for procurement reform which could save thousands of lives and billions of dollars.[8] By subdividing the component pieces of the OPTN contract, the best possible stewards for each component can serve the public interest.

Problem #4) There is no defined mechanism within the current system to rapidly introduce new technologies in organ transplantation.

Technologies including machine perfusion already exist and could dramatically decrease the organ shortage.[9] Unfortunately, there is no effective mechanism to rapidly implement these advances. As an example, in 2019 there were 8 heart donors from donation after circulatory determination of death donors (DCDD). In 2021 there were more than 126. This is entirely due to improvements in technology and use of new methodologies for organ retrieval. To give an example of the impact rapid adoption of this technology could bring: In 2020, there were about 3224 DCDD in the United States. In contract, each year approximately 500 people on the waiting list for heart transplant die or are deemed too sick for transplant. Therefore, if we could convert only 500 of these 3224 existing DCDD donors (16%) into heart donors, we could get to the point where a death waiting for a heart would be rare. This could be done very quickly with appropriate leadership.

Solution #4) Establish, within an 'Office of Organ Policy', a group dedicated to assessment and dissemination of new technologies.

This office would help 1) coordinate timely review by FDA of new devices or technologies, 2) adjust outcome metrics to encourage use of new technologies, 3) actively educate the community on best practices, and 4) incentivize payors to cover the cost of these new technologies.

Thank you for the opportunity to present these observations and recommendations to the Committee. I look forward to continuing to place my energy in improving transplantation in the United States.

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