

Barry Massa, Ohio  
*President*

Colleen McCarthy, Wisconsin  
*President-Elect*  
*Member Representative OPO Group 1*

Jan Finn, Kansas  
*Immediate Past President*

Marty Sellers, MD, Tennessee  
*Medical Advisor*

Luke Shen, MD, Texas  
*Medical Advisor-Elect*

Kyle Herber, Nebraska  
*At Large Member*

Tasha Flowers, Arkansas  
*Secretary/Treasurer*

Sarah Fewell, Iowa  
*Member Representative OPO Group 2*

Kurt Shutterly, Pennsylvania  
*Member Representative OPO Group 3*

Rick Hasz, Pennsylvania  
*Member Representative OPO Group 4*

Steve Miller, CAE, Virginia  
*Chief Executive Officer*

August 16, 2022

Senate Committee on Finance  
Attn. Editorial and Document Section  
Rm. SD-219  
Dirksen Senate Office Bldg.  
Washington, DC 20510-6200

Submitted via email to [Statementsfortherecord@finance.senate.gov](mailto:Statementsfortherecord@finance.senate.gov)

### **Statement for the Record of the Association of Organ Procurement Organizations**

On August 3, 2022, the Senate Finance Committee held a [hearing](#) and released a [report](#) entitled: "A System in Need of Repair: Addressing Organizational Failures in the U.S. Organ Procurement and Transplantation Network." The Association of Organ Procurement Organizations (AOPO) shares the Committee's goal of creating and maintaining a more equitable and efficient system.

**The year 2021 marked the eleventh record year in a row for deceased organ donors and the ninth consecutive year of increases in the number of organ transplants nationwide<sup>1</sup>.** We are actively working to ensure this upward trend continues. As part of that effort, we are committed to improvement and seek feedback from impacted individuals, communities, and other stakeholders.

AOPO agrees that by investing in new, promising technologies, aligning policies and metrics towards shared, system-wide goals, and establishing mutual accountability for participants in the organ donation and transplantation process, we can improve the efficiency and equality of our system and ultimately save more lives. To move forward, the Committee should endorse the findings from the National Academies of Sciences, Engineering, and Medicine (NASEM)<sup>2</sup> report which assesses where the system currently stands, delineates the role each stakeholder plays, and charts a path to a more equitable donation and transplantation system. We agree that continued improvements are necessary to advance care for patients.

### **Organ Acceptance Rates and Non-Utilization**

The underuse of viable organs, leading to an increase in organ waste, is an urgent issue that all donation and transplant stakeholders must solve as it is a major contributing factor to the nationwide waitlist exceeding 100,000 patients. According to research cited in the NASEM report, a person who dies on the waitlist has, on average, been offered 16 organs. Unfortunately, transplant center acceptance rates are low, and one fundamental way to advance equity is by increasing acceptance rates for organs from older and more medically complex donors.

OPOs are currently engaging in groundbreaking technologies, pushing the boundaries of what is possible. For example, lung perfusion technology can potentially rehabilitate and transplant up to two-thirds of lungs that would otherwise be unusable<sup>3</sup>. However, transplant programs are directly responsible for the patients in their care, and they decide whether to utilize organs that OPOs make available. In addition, transplant programs are evaluated based on survival rates that discourage them from taking on "riskier" patients or transplants.

-----  
<sup>1</sup> OPTN Press: "[All-Time Records Again set in 2021 for Organ Transplants, Organ Donation from Deceased Donors](#)"

<sup>2</sup> NASEM Publication: "[Realizing the Promise of Equity in the Organ Transplantation System](#)"

<sup>3</sup> UNOS Press: "[Companies at the Forefront of Organ Perfusion Technology](#)"

At the hearing, specific cases of kidneys were discussed where the witness described declining an organ based on an assessment of its condition upon arrival. However, it should be noted that not all of these organs were discarded. In fact, one of the kidneys the witness rejected was re-allocated and successfully transplanted into a patient at another transplant program.

This example highlights the significant role that the variability in clinical practice by transplant center plays in organ acceptance practices. In fact, UNOS will now evaluate transplant centers by their acceptance rates and make that information available to the public. The acceptance rates are also affected not just by the donor's clinical factors but also by when the donor organ was recovered. The NASEM report cites research supporting the "weekend effect" as a reason for non-utilization, stating:

"There has been compelling research on the "weekend effect" for kidneys and livers. In SRTR data from 2000 to 2013, and compared with weekday kidneys, organs procured on weekends are significantly more likely not to be used...even after adjusting for organ quality. Program structure and staffing, particularly during weekends and in smaller programs, affects kidney use and ultimately affects a patient's chances of receiving a transplant. This is unacceptable for a lifesaving surgical procedure such as transplantation." <sup>4</sup>

High and increasing non-utilization of available organs is a significant problem involving all components of the donation and transplantation system. Between 2018 and 2020, the number of donor kidneys not transplanted increased by 34%<sup>5</sup>, partly due to low acceptance rates and high variability in acceptance practices across transplant programs. AOPO supports implementing a robust system to document the cause of every organ which is not utilized and the implementation of strategies to increase organ acceptance and minimize organ waste. For example, advancements in and the usage of screening tools could reduce the number of patients offered an organ with a known deferral, expediting the matching process and lowering the number of discards.

## System Efficiency and Performance

The United States has the most effective system in the world for maximizing donation and transplantation. **In the last five years, OPOs have increased the number of deceased organ donors by 35% and increased the number of recovered organs by 27%**<sup>6</sup>. Although we are proud of the increase in the number of available organs for transplantation, there is more work to be done. AOPO concurs that improvements are necessary to advance care and equity for patients.

AOPO does note that the Senate Finance Committee report references the non-peer-reviewed Bridgespan report, which claims that more than 28,000 additional organs could be transplanted each year. AOPO submits that this is not validated and is conditioned upon certain circumstances which will not occur, including a 100% donation rate and 100% utilization of donated organs. Some organs are simply not safe for transplant.

The Senate Finance Committee report also attributes increased donation and transplantation rates in recent years to increased suicides and opioid-related deaths. The study cited to support this claim is based on a dataset that includes all donors who had at any time in their life used an illegal drug or were reported as a one-time drug user by a family member. While the opioid epidemic impacted donation, it is far from the only factor. Much more significant are advancements such as donation after circulatory determination of death (DCDD), which has increased an unprecedented 123% over the last five years, and organ preservation technologies extending the time between organ recovery and transplantation.

AOPO supports meaningful performance measurement that holds all system stakeholders accountable for reaching our shared mission of saving as many lives as possible. We are working with our member OPOs to meet the new performance metrics established by the Center for Medicare & Medicaid Services (CMS). In fact, several OPOs identified as having issues within the Senate Finance report have become top performing OPOs with a "Tier 1" status according to CMS's latest release of data<sup>7</sup>.

-----  
<sup>4</sup> NASEM Report: "[Realizing the Promise of Equity in the Organ Transplantation System](#)" (pages 6-24)

<sup>5</sup> AOPO Report: "[50,000 Annual Organ Transplants in 2026 Goal](#)", based on OPTN data as of February 17, 2021.

<sup>6</sup> AOPO Infographic: "[U.S. Organ Donation and Transplantation Highlights](#)", based on OPTN data as of January 30, 2022.

<sup>7</sup> CMS Quality, Certification, and Oversight Reports (QCOR): "[OPO Public Performance Report](#)"

The report states that 22 out of 57 OPOs would fail the new outcome measures and be decertified. It is critical to understand that the new methodology used in evaluating OPO performance is a comparative measure defining the bar to “pass” as the top 25<sup>th</sup> percentile. Therefore, by design, the metrics can result in OPOs assigned to “Tier 2” and “Tier 3” categories being subject to possible decertification or competition, regardless of continued improved performance over the certification cycle.

## Organ Evaluation

The Senate Finance Committee report shares that 249 recipients experienced disease transmission following an organ transplant or an error in blood typing, and 70 recipients died due to failures in the donation and transplantation system. Any death resulting from an error is tragic, and the system must ensure that when errors occur, they are reviewed and understood, and steps are taken to prevent them in the future.

Despite systems in place to prevent mistakes and best practices in place to identify the risk of transmission, the risk of disease transmission following an organ transplant is extremely low but will never be zero. The numbers reported by the Committee represent .03% of the 231,180 organs transplanted over the indicated seven-year period<sup>8</sup>. The numbers show that nearly 99.9% of transplants resulted in successful outcomes and did not result in illness or death due to infected organs. The minimal risk must be understood in the context of the extremely high risk of death from organ failure for patients not being transplanted.

Overall, organ transplantation is safe and the best treatment for organ failure. Patient safety is always of utmost importance to the OPO professionals working every day to save lives. All medical procedures have associated risks and complications, and OPOs work to prevent such adverse outcomes. OPOs conduct multiple tests for every organ donor to identify the potential for disease transmission and other safety issues. Many of these tests are guided by transplant centers when considering an organ for their patient to assess organ viability and donor match suitability.

The Organ Procurement and Transplantation Network (OPTN)/United Network of Organ Sharing (UNOS) requires a medical record review and donor risk assessment interview with the potential donor’s next of kin to obtain a five-year history of illness and other social determinants of health. OPTN/UNOS also requires physicians to perform a visual examination and, if warranted, a biopsy of potential donor organs to identify risks. As an extra step to rule out undiagnosed cancers and other diseases, OPOs are actively working to routinely administer CT scans on patients that pose a known possible risk.

As part of organ evaluation, OPOs and hospital partners are also required to identify the potential donors’ blood type to prevent organ rejection in the recipient. Some potential donors have experienced severe trauma requiring blood transfusions which can, in rare instances, impact the blood typing results. Therefore, OPOs and hospitals tasked with donor management and assessment must take extra precautions if the blood type test is unclear or has shown varying results. Following blood typing errors in recent years, new policies were implemented to prevent such incidences.

## Organ Transportation

With mere hours to transplant life-saving organs after recovery, proper transportation is essential to the organ donation and transplantation process. OPOs are tasked with determining the safest and quickest way to transport donor organs. While even one organ lost or damaged in transport is too many, the transit incidents covered in this report are extremely rare<sup>9</sup>, and something OPOs have actively implemented mechanisms to avoid.

-----  
<sup>8</sup> Based on [OPTN data](#) as of August 8, 2022.

<sup>9</sup> During the hearing, it was stated that OPOs are 15 times more likely to lose, damage, or delay an organ in transport than a commercial airline does with passenger luggage. This appears to be based on a misunderstanding of a February 2020 Kaiser Health News article that examined shipments handled by UNOS. As the article correctly points out, UNOS only manages transportation for a small fraction of annual transplants. Regardless of the validity of the analysis concerning UNOS, our OPO members have not experienced adverse transportation incidents of the magnitude claimed.

Post-9/11-rules prohibit OPO staff from taking organs through airport security and directly to an awaiting aircraft, which created a barrier to efficient commercial transport. In response, many individual OPOs use private aircraft, when possible, to avoid delays from restrictive commercial air travel schedules. OPOs also partner with charter, courier, and delivery companies to expedite the ground transportation of organs. Undoubtedly, additional tools from the OPTN to support transportation and track organs in transit will facilitate overall system efficiency and effectiveness. Federal Aviation Agency (FAA) regulations standardizing how airlines handle organ shipments would also improve efficiency and reduce travel-related delays.

It is noteworthy that in the interim, and as referenced during the hearing, **OPOs are collaborating with companies offering organ tracking technology, which has helped improve transportation logistics and efficiencies between the donor hospital and transplant center.** OPOs are also using TransNet, a barcode system, to automate the organ packaging and labeling process, ensuring that organs are transported to the correct recipient. When OPOs experience transportation issues, details are promptly documented and reported to OPTN/UNOS.

## In Conclusion

As the Committee is aware, the recent NASEM report includes several detailed recommendations focused on establishing a more effective and equitable system<sup>10</sup>. The recommendations align with AOPO's goal to achieve [50,000 annual organ transplants in 2026](#) by expanding collaboration with stakeholders, reducing health inequities, increasing organ utilization, and driving innovation and research. We welcome the opportunity to meet with Committee members and staff to discuss the report's recommendations and collaborate to identify changes to policies, practices, and programs that will help ensure the nation's organ procurement and transplantation system meets the needs of all patients.

We stand ready to work with our fellow stakeholders, Congress, and the Biden Administration to pursue the day when every donation opportunity results in lives saved.

---

<sup>10</sup> NASEM Report: ["Realizing the Promise of Equity in the Organ Transplantation System"](#)