

**OPTN Patient Affairs Committee  
Meeting Summary  
December 13, 2022  
Conference Call**

**Garrett Erdle, MBA, Chair  
Molly McCarthy, Vice Chair**

## **Introduction**

The OPTN Patient Affairs Committee (the Committee) met via Citrix GoTo Meeting teleconference on 12/13/2022 to discuss the following agenda items:

1. Introduction to Organ Procurement Organization (OPO) Performance Monitoring
2. Organ Procurement Organization (OPO) Performance Improvement
3. Panel Discussion/Questions

The following is a summary of the Committee's discussions.

### **1. Introduction to Organ Procurement Organization (OPO) Performance Monitoring**

The Chair of the OPTN Membership & Professional Standards Committee (MPSC) reviewed the role of the MPSC in OPO performance monitoring. Additionally, the Chair of the OPTN OPO Committee reviewed the Centers for Medicare and Medicaid Services (CMS) new OPO performance metrics.

#### Summary of presentation:

The MPSC's role within the OPTN is to perform peer review-based OPTN policy compliance monitoring and aide in collaborative performance improvement. MPSC developed metrics to measure key aspects of the patient journey through transplant. The OPTN Board of Directors approved MPSC's *Enhance Transplant Program Performance Monitoring System* proposal on December 6, 2021.<sup>1</sup> The MPSC will begin to develop new OPO performance metrics in 2023.

CMS is the federal regulatory authority body overseeing OPOs and transplant programs. CMS has the authority to certify and decertify entities. CMS has a separate and distinct set of metrics from the OPTN. A final rule was released in November 2020 due to President Donald Trump's Executive Order in July 2019, "Advancing American Kidney Health." The new rule seeks to solve for "donor potential" by utilizing Centers for Disease Control and Prevention (CDC) death certificate data, establishing new definitions of "donor" and "organ", and establishing a new approach to reviewing OPOs for recertification.

Due to this new rule, OPOs are now placed in three tiers of performance. Tier 1 encompasses the highest performing OPOs that are ranked in the top 25 percent and these OPOs are automatically recertified for another four years. Tier 2 encompasses OPOs where performance on both measures exceed the median but do not reach Tier 1. Tier 2 OPOs will not automatically be recertified and will

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<sup>1</sup> OPTN Membership & Professional Standards Committee, *Briefing Paper*, Enhance Transplant Program Performance Monitoring System. Public comment period: August 3, 2021 – September 30, 2021. Available at <https://optn.transplant.hrsa.gov/media/yctffgt2/20211206-bp-mpsc-enhnc-tx-prgrm-prfrmnc-mntrng-syst.pdf>

have to compete to retain their donation service areas (DSAs). Tier 3 encompasses OPOs that have one or both measures below the median. Tier 3 OPOs will be decertified and will not be able to compete for any other open DSA.

## **2. Organ Procurement Organization (OPO) Performance Improvement**

The President & CEO of Life Connection of Ohio<sup>2</sup> presented on areas of improvement for OPOs.

### Summary of presentation:

Life Connection of Ohio was ranked as the 38<sup>th</sup> performing OPO in the country, and now fluctuates between the 1<sup>st</sup> and 2<sup>nd</sup> performing OPO in the country. Previously, Life Connection of Ohio had about 32 employees and facilitated about 76 organ donors a year. Currently, Life Connection of Ohio has about 120 employees and has increased their number of organ donors over 100 percent and increased their organs transplanted over 40 percent. The presenter said that Life Connection of Ohio's improvements were based on re-investing their team's core values of a "let's go" mentality, uncompromising advocacy, and authenticity. Life Connection focuses on growth, altruistic innovation, and extreme reliability.

The new CMS metric for donation rate is the number of organ donors in the DSA as a percentage of inpatient deaths among patients 75 years old or younger with a primary cause of death consistent with organ donation.<sup>3</sup> A donor is defined as a deceased individual from whom at least one vascularized organ (heart, liver, lung, kidney, pancreas, or intestine) is transplanted, not just procured for transplant, or an individual from whom a pancreas is procured and is used for research or islet cell transplantation.<sup>4</sup> Since the establishment of this metric, there has been a 351 percent increase in the number of pancreata placed for research. Life Connection of Ohio recommends this metric be removed because organizations can manipulate this metric which may result in less individuals receiving transplant.<sup>5</sup>

Two donor hospitals in North Carolina have filed a waiver to work with the higher performing OPO in the area. This highlights the importance for OPOs to provide good customer service to their donor hospitals and transplant programs, particularly if they are located near another high-performing OPO.

## **3. Panel Discussion/Questions**

The Committee discussed OPO performance.

### Summary of discussion:

A member asked if there is a correlation between OPO performance metrics and finance of organ acquisition and placement. The President & CEO of Life Connection of Ohio responded that there may be a correlation depending on where OPOs are investing their funds. The President & CEO of Life Connection of Ohio stated that their organization analyzes efficiency numbers based on finances,

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<sup>2</sup> <https://www.lifeconnection.org/our-work>

<sup>3</sup> "Organ Procurement Organization (OPO) Conditions for Coverage Final Rule: Revisions to Outcome Measures for OPOs CMS-3380-F," CMS, November 20, 2020, accessed January 10, 2023, <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>.

<sup>4</sup> Ibid.

<sup>5</sup> The final rule for the Organ Procurement Organizations (OPOs) Conditions for Coverage notes, "We agree with the commenters that pancreata for research are specific to the local research demands and may not reflect universal OPO practice. Nonetheless, their inclusion in the outcome measures is consistent with the requirements of the statute, and we are finalizing them as such." See <https://www.federalregister.gov/documents/2020/12/02/2020-26329/medicare-and-medicaid-programs-organ-procurement-organizations-conditions-for-coverage-revisions-to>, accessed January 10, 2023.

numbers of organs being transplant, and number of full-time employees to ensure the organization is not being wasteful. The member noted that OPO performance may also correlate with the quality of health care in a given area.

The member stated it is concerning that higher rates of non-utilization may be due to OPOs not having enough pumps to transport kidneys due to finances. The Chair of the OPTN OPO Committee stated that the majority of OPOs pump kidneys due to broader allocation. The Chair of the OPTN OPO Committee stated that a challenge is having the pump returned to the OPO. The Chair of the OPTN MPSC noted that currently kidney pumps are not able to be transported on commercial flights. The Chair of the OPTN MPSC added that kidney pumps require oversight from a person to add ice, change out water, etc., which is another logistical issue when considering commercial flights. The President & CEO of Life Connection of Ohio stated that their organization has made the commitment to send all kidneys on pumps. The President & CEO of Life Connection of Ohio added that the organization they partner with to provide organ tracking also has the ability to track pumps. The President & CEO of Life Connection of Ohio emphasized that customer service is an important aspect. The Vice Chair requested the Committee revisit the topic of pumps. The Vice Chair stated that not having a process of return and logistical complexities should not stand in the way of protecting previous organs.

Another member asked how the United Network for Organ Sharing (UNOS) can help donation and transplantation. The Chair of the OPTN OPO Committee stated that it is important for OPOs and transplant programs to be aligned. The Chair of the OPTN OPO Committee added that it is important for metrics to work for both OPOs and transplant programs. The Chair of the OPTN MPSC, speaking from their perspective as a member of the community rather than the as MPSC Chair, noted that a lot of goals have competing interests. They gave an example regarding the goal of equity in access to transplant competes with the goal of organ utilization due to organs travelling great distances, thereby increasing cold time and possible changes in potential transplant recipients that may result in organ non-utilization. They emphasized that the community needs to align and determine a main goal.

A member asked how the national transplant community has received the news of Life Connection of Ohio doubling their numbers. The President & CEO of Life Connection of Ohio stated they have not showcased their improvements much at the national level.

The Vice Chair asked if transplant programs have the ability to choose which OPOs they seek to work with. The President & CEO of Life Connection of Ohio responded that there is a process for hospitals to submit a waiver to determine which OPOs they seek to work with. The President & CEO of Life Connection of Ohio noted this does not happen often. Staff asked whether the waiver was for donor hospitals to choose their OPO, since presumably transplant hospitals will accept the organs they can get, regardless of OPO. The Vice Chair stated it is important for candidates to know that their transplant program is in business with the highest performing OPOs. An attendee clarified that donor hospitals are allowed to file for a waiver but transplant centers are not. The attendee explained that the regulations state that services to the hospital are not being provided by the OPO for whom the hospital seeks to enter into an agreement under the waiver.<sup>6</sup>

Another member noted that changing relationships between donor hospitals and OPOs would create a lot of chaos in the system. The member explained that both parties need appropriate partnerships and staffing to support organ allocation and placement, and without established relationships it would be

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<sup>6</sup> 42 USC 1320b-8(a)(2)(A)(ii)

difficult to plan and support. The member stated that transplant programs, donor hospitals, and OPOs all need to work together to align goals and improve the system.

The member added that DSA no longer applies to organ allocation. The President & CEO of Life Connection of Ohio disagreed that DSA is no longer relevant and stated that if a hospital system works with neighboring OPOs, they could double the number of organs transplanted out of that hospital system.

A member asked how OPOs need to evolve to maintain the relevance in the new competitive environment. The President & CEO of Life Connection of Ohio responded that it is important for OPOs to show what kind of value they bring to a donor hospital or transplant program.

The Chair stated that the Committee is interested in increasing donation and transplant rates. The Chair asked what the Committee may work on to help increase the performance of Tier 3 OPOs. The Chair of the OPTN OPO Committee noted that there are multiple reasons for an OPO to be placed in Tier 3, such as donor designation within the area. The Chair of the OPTN OPO Committee stated that it is important for transplant programs, donor hospitals, and OPOs to be aligned and have metrics that work for all. The Chair of the OPTN OPO Committee noted there has been significant improvement over the years and seeks to continue increase the improvement going forward.

An attendee asked for information on the preference of OPOs to work with transplant programs who are more aggressive in performing transplants. The President & CEO of Life Connection of Ohio stated that it is important to develop systems that help quickly allocate organs that are declined late. The attendee emphasized that there are a wide variety of OPO situations across the country. The President & CEO of Life Connection of Ohio agreed.

The Chair asked if waiver requests are anticipated to increase due to the new metrics that will be adopted in 2026. The Vice Chair stated the community should not wait until 2026 to adopt new metrics, they should move faster.<sup>7</sup>

An attendee stated that within a competitive environment, it is important to maintain focus on the care provided to and for donors and donor families while maximizing donation and transplantation. The attendee stated there needs to be a dual focus and balance.

#### Next steps:

The Chair invited attendees to join future Committee meetings for continued dialog focused on the betterment of the patient experience and saving lives.

#### **Upcoming Meetings**

- January 17, 2023 (teleconference)
- February 21, 2023 (Chicago, IL)
- March 21, 2023 (teleconference)
- April 18, 2023 (teleconference)

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<sup>7</sup> CMS implemented the new measures on August 1, 2022. The new measures will be enforced in 2026. See <https://www.cms.gov/newsroom/fact-sheets/organ-procurement-organization-opo-conditions-coverage-final-rule-revisions-outcome-measures-opos>, accessed January 10, 2023.

## Attendance

- **Committee Members**
  - Anita Patel
  - Calvin Henry
  - Dana Hong
  - Diana Dixon
  - Garrett Erdle
  - Julie Spear
  - Kenny Laferriere
  - Lorrinda Gray-Davis
  - Molly McCarthy
  - Sejal Patel
  - Steven Weitzen
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor
  - Arjun Naik
  - Frank Holloman
  - Jim Bowman
  - Lauren Darensbourg
  - Megan Hayden
  - Mesmin Germain
- **SRTR Staff**
  - Katie Audette
- **UNOS Staff**
  - Ann Marie Leary
  - Kaitlin Swanner
  - Kristina Hogan
  - Meghan McDermott
  - Robert Hunter
  - Sally Aungier
  - Sara Rose Wells
  - Sharon Shepherd
- **Other Attendees**
  - Alex Glazier
  - Barry Massa
  - Brandon McKown
  - Dorrie Dils
  - Jan Finn
  - Jennifer Prinz
  - Jim Sharrock
  - Kurt Shutterly
  - Maggie Astrino
  - Matthew Wadsworth
  - Meg Rogers
  - PJ Geraghty
  - Sean Fitzpatrick
  - Susan Larson

- Zoe Stewart Lewis