

**OPTN Patient Affairs Committee
Meeting Summary
September 10, 2024
Detroit, Michigan**

**Molly McCarthy, Chair
Lorrinda Gray-Davis, Vice Chair**

Introduction

The Patient Affairs Committee met in Detroit, Michigan on September 10, 2024, to discuss the following agenda items:

1. Welcome and Introductions
2. Public Comment Review: *Revise Conditions for Access to OPTN Computer System*
3. Continuous Distribution Update- Reviewing the Impact of Lung CD
4. Public Comment Review: *Promote Efficiency of Lung Donor Testing*
5. Continuous Distribution Update- Policy Development Efforts for Other Organs
6. CMS Update on IOTA Model
7. OPTN Modernization and Independence Update
8. Patient Awareness of Listing Status (PALS) Subcommittee Update
9. Public Forum

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

1. Welcome and Announcements

The Committee Chair welcomed attendees in the room and online. All meeting participants introduced themselves. Afterwards, the Chair celebrated the diversity of experiences around the table.

The Chair shared her surprise at a memo released earlier that morning noting that the OPTN President would not be speaking at the House Committee on Energy & Commerce hearing scheduled for September 11, 2024 to check in on progress related to OPTN modernization. Committee members requested a copy of this memo for review.

Next Steps:

A link to the hearing memo was circulated to Committee members during a break.

2. Public Comment Review: *Revise Conditions for Access to OPTN Computer System*

The Committee chose to submit a public comment on this proposal.

Committee members continued their discussion of the Network Operations Oversight Committee's (NOOC) public comment proposal, receiving an overview of the survey completed in preparation for this meeting, as it prepared to finalize its comment for submission.

Summary of Presentation:

The Chair of the NOOC presented the proposal to the Committee during its August 20, 2024 meeting. The NOOC proposes strengthening the protections of OPTN data and the OPTN Computer System by revising the conditions for access to the OPTN Computer System in the following ways:

- Require OPTN membership as a condition of access to the OPTN Computer System
- Reduce potential barriers to OPTN business membership
- Limit access to the OPTN Computer System to the following functions: facilitating organ transplantation, fulfilling OPTN obligations, and quality assurance and performance improvement (QAPI)
- Require reporting of privacy incidents involving data obtained from the OPTN Computer System
- Require all members with system interconnections to the OPTN Computer System to develop an Interconnection Security Agreement (ISA) with the OPTN
- Require OPTN business members who access the OPTN Computer System to follow the same information security requirements that apply to other member types who access the OPTN Computer System

While the OPTN Computer System has robust measures in place to protect against security incidents, these additional proposed actions further support adherence to National Institute of Standards and Technology (NIST) requirements.¹ The goal of this proposal is to enhance the security of the OPTN Computer System by revising conditions for access. This proposal will expand accountability for securing the OPTN Computer System to business organizations, many of whom are third party contractors, who access the computer system. Enhancing the security of the OPTN Computer System protects candidate, recipient, and donor data, and increases public trust. Furthermore, the institution of OPTN ISAs is necessary to ensure adherence to NIST requirements.²

A Committee member reviewed results from an informal survey of members assigned to the review of this proposal as a precursor to full Committee discussion.

Summary of Discussion:

The OPTN Patient Affairs Committee did not specifically support or oppose the proposal, but offered the following questions and comments for consideration:

- Has appropriate expertise been engaged in developing this proposal to safeguard this PHI with modern tech practices? The Committee believes this proposal would benefit from seeking data and associated governance expertise from the private sector, including IT and legal resources, with specific subject matter expertise on these technology landscape practices and topics.
- Which specific roles will manage and implement the security compliance assessments regarding granting access to data? Will this involve minimum requirements/tiered requirements/timeboxed requirements dependent on the level of sensitivity of data to be accessed?
- Are there financial benefits to the OPTN related to increasing membership or reducing the barrier/broadening eligibility for membership?

¹ National Institute of Standards and Technology (NIST) Special Publication 800-53 Revision 5: Security and Privacy Controls for Information Systems and Organizations. <https://doi.org/10.6028/NIST.SP.800-53r5>. (December 2020).

² Ibid.

- The time for developing an interconnection security agreement (ISA) should be reduced to six months, as a template is made available to companies in the proposal. The current proposed timeline would allow companies to continue to do business for up to a year without an ISA in place.
- There is concern regarding this proposal potentially leading to reduced access to OPTN data for the purposes of research. If this is not the case, the policy wording should be clarified.

OPTN Contractor staff shared that as the number of organ recoveries and transplants has increased over time, the necessity of these third-party organizations has increased (e.g. assistance in evaluating organ offers). This proposal seeks to strengthen the security and privacy of the system by making these third-party business organizations members, which provides a higher level of security around the OPTN data and the OPTN computer system.

The concern of additional administrative burden to meet these requirements as OPOs and transplant centers are establishing relationships with business members has arisen through public comment, and this is also something that the NOOC will consider in its review of all comments.

A Committee member had raised a concern regarding whether these new members would receive voting privileges in the survey. The Committee member shared that staff had clarified that the Bylaws³ do not allow business members to vote.

The Committee was particularly concerned about this proposal considering the data incident letters that went out recently to thousands of patients and living donors, and the security currently in place to protect this sensitive data. Committee members raised strong concerns regarding sharing this sensitive information more broadly.

Committee members offered their technical expertise and experience as appropriate, requesting the review of any architectural diagrams and governance models of the proposal.

Next Steps:

OPTN Contractor Staff will summarize today’s comments and share survey responses as the Committee’s formal comment after review and approval by Committee leadership.

3. Continuous Distribution (CD) Update- Reviewing the Impact of Lung CD

The Committee received an update and did not make any decisions.

The Committee reviewed data from 1-year pre- and post-continuous lung distribution implementation.

Summary of Presentation:

A member of the Lung Transplantation Committee presented data comparing the year before and the year since implementation of continuous lung distribution. The following was shared:

³ OPTN Bylaws, 1.7 Business Members, C. Business Membership Voting Privileges.
https://optn.transplant.hrsa.gov/media/lgbmahi/optn_bylaws.pdf Accessed on 9/24/2024

- The number of lung waiting list additions increased by 8.5% since implementation (3,180 additions in the year before implementation versus 3,452 additions in the year since implementation)
- The number of transplants per month increased by 11% in the year since CD implementation (2,741 before implementation, 3,047 post-implementation)
- The number of removals from the waiting list for death or too sick to transplant was reduced by 32% since CD implementation (234 removals in the pre-implementation year versus 159 removals in the post implementation year)
- The number of lung donors per month increased by 14% in the post-implementation year (2,956 pre-implementation year versus 3,361 after CD implementation)
- More DCD donor lungs were utilized in the post-implementation period
- There was a 29% decrease in deaths or removals from the waiting for too sick in the post implementation period per 100 patient years
- There was a 16% increase in overall transplant rate per 100 patient years in the post-implementation period.
- Transplant occurred faster with shorter waitlist times in the post-implementation period. This rate was already decreasing but has continued a downward trend with the ABO score modification following lung CD implementation.

Hearts and lungs are typically recovered before abdominal organs and allocated prior to their recovery. If the lungs do not appear suitable for transplant, they may not be recovered. The addition of perfusion technology has allowed for recovery of some lungs that may not be suitable for transplant. Placement on ex vivo lung perfusion (EVLV) devices can “treat” the lungs and sometimes make them suitable for transplantation.

- Lung utilization, or transplant of a lung from a donor who had at least once organ recovered slightly increased in the post-implementation era for both DCD and non-DCD donors. The difference was slightly higher, but not statistically significant. Utilization of lungs has not decreased with continuous distribution.
- The non-use rate for lungs was reduced in the post-CD implementation era (meaning the percent of lungs recovered for the purpose of transplant but not transplanted out of all lungs recovered for transplant). Non-use rate for DCD lungs dropped from 30.7% to 28.6%. The difference was smaller for non-DCD lungs, dropping from 6.4% to 6.3%.
- Transplant rate by center size showed a decrease in transplants post-CD implementation for small centers (with 2 or less lung transplants per month) and increases in the post-CD implementation era for both medium and large volume lung transplant programs. Large programs (more than 4 lung transplants per month) were shown to have the largest increase in transplant rate
- The distance traveled by donor type was expected to increase with implementation of CD. This has shown to be true:
 - For DCD donors, pre-CD era travel was a median of 177 nautical miles. Post-CD era travel is now 310 nautical miles
 - For non-DCD donors, pre-CD era travel was a median of 192 nautical miles. Post-CD era travel is now 397 nautical miles
 - The median distance overall was 192 nautical miles pre-CD era and 385 nautical miles for post-CD era.

In summary, the presenter noted that more patients received lung transplants in the post-CD policy era. The most medically urgent candidates had the highest transplant rates. There was also an increase in

transplant rate of blood type O candidates following ABO modification. Fewer patients died while waiting for lung transplant since CD was implemented. While travel distance increased (as expected) utilization rates and non-use rates remained similar. The Lung Transplantation Committee will continue to monitor this policy closely.

Summary of Discussion:

The Chair asked how often EVLP was successful in making lungs thought to be inappropriate for transplant transplantable. The presenter noted that the two primary companies in this space have different approaches to lung treatment. One uses warm perfusion and the other uses cold. Without specific data in front of him, he suggested that EVLP is successful approximately 60% of the time in treating lungs. He noted variety in how these companies work, with some centers purchasing the equipment and another company contracting with OPOs. Regardless, he noted a positive impact on the number of transplantable lungs.

A Committee member asked about some of the challenges that have come up since CD was implemented, including the ABO issue. The presenter noted that the CD formula weighted factors that the lung community believed to be important. ABO falls into biological disadvantage along with height for lung. ABO was assigned 5% difference. In looking at the first six months post-implementation, the Committee recognized that blood type O candidates were getting transplanted at a lower rate than they were prior to the implementation of CD. Additional points were added to the CD formula for blood type O candidates, and this has improved the number of transplants for this blood type. The CD system remains under close monitoring, with height being another area of monitoring in the scope of biological disadvantages as the Lung Committee continues to weigh utility versus justice in considering changes to the CD formula.

A Committee member asked about the increased travel distances noted after CD was implemented. OPTN Contractor staff noted that while organs are traveling farther, the most medically urgent candidates are experiencing shorter wait times to transplant. CD appears to allow for transplant of the most medically urgent candidates faster, with this additional travel distance allowing for more organ offers to come to them. The presenter provided an example, noting that if there was an extremely ill candidate in Michigan and there was a great donor in Florida, he would have to wait for multiple regional offers before he may receive one for his patient (even if his patient was the sickest in the country). CD allows the sickest patients to appear higher on the match run, but this may require programs to be more aggressive about traveling further to retrieve them. A decrease in wait list mortality has been one of the biggest impacts of CD to date. When asked if CD performance to date has aligned with what was anticipated in modeling, the presenter confirmed this to be the case. He noted that modeling showed an increase in transplant rates, a decrease in waitlist mortality, and an increase in travel distance. Performance to date aligns with expected outcomes.

4. Public Comment Review: *Promote Efficiency of Lung Donor Testing*

<p>The Committee chose to submit a public comment on this proposal.</p>
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Committee members received an overview of the Lung Transplantation Committee’s public comment proposal, reviewed its internal survey results, and shared comments that will be developed into a formal committee response to the proposal.

Summary of Presentation:

On March 9, 2023, the lung allocation policy transitioned to a continuous distribution framework.⁴ Continuous distribution uses a point-based system to determine the order of candidates on a match run when a medically suitable lung donor becomes available. All lung candidates are prioritized using a composite allocation score (CAS), which is determined based on their medical urgency, post-transplant survival, aspects of candidate biology (blood type, CPRA, height), patient access (pediatric, prior living donor), and efficiency (proximity to donor). One of the main goals of removing the strict geographic boundaries from allocation was to reduce the waiting list mortality rate by better prioritizing medically urgent candidates across the country.⁵ Post-implementation monitoring showed that in the first year of continuous distribution the lung transplant rate increased and the waiting list mortality rate decreased.⁶ Additionally, the most medically urgent candidates had the highest transplant rate and the shortest median time to transplant.⁷ Despite the benefits of continuous distribution, the shift to a national distribution system has also introduced efficiency challenges, including increased distances from the donor hospital to the transplant center and an increase in the median number of programs that received lung offers on a match run. Over the last year, the Lung Committee has been working to propose policy changes and system enhancements that aim to reduce burden and increase allocation efficiency overall, including the introduction of lung offer filters and the recent approval of new data collection and system enhancements.⁸

The Committee has heard that the increase in the total number of lung offers from across the country has placed an additional burden on transplant hospitals and OPOs. Transplant programs have expressed concern about the quality of the organ offers they are receiving. Most often members state that the donor data available at the time they are expected to review and respond to offers is outdated or incomplete. Based on the increased workload for both OPOs and lung transplant programs associated with allocating lungs nationally, the Committee has reconvened the Promote Efficiency in Lung Allocation Workgroup (the Workgroup), comprised of members from the OPTN Lung Transplantation and Organ Procurement Organization (OPO) Committees, to refine solutions that improve the efficiency of lung donor testing.⁹

This paper proposes changes to lung donor testing in OPTN Policy 2.11.D: Required Information for Deceased Lung Donors and Guidance on Requested Deceased Lung Donor Information.¹⁰ The goal of this proposal is to improve the efficiency of lung allocation for OPOs and lung transplant programs by making it easier for lung transplant programs to say “yes” to organ offers.

Proposed policy changes include:

- Addition of more specific requirements for obtaining arterial blood gases

⁴ “Establish Continuous Distribution of Lungs,” OPTN, Policy Notice, available at https://optn.transplant.hrsa.gov/media/b13dlep2/policynotice_lung_continuous-distribution.pdf.

⁵ Lung Continuous Distribution One Year Monitoring Report,” OPTN, May 9th, 2024, available at https://optn.transplant.hrsa.gov/media/srino34s/data_report_lung_cd_1year_20240509.pdf

⁶ Ibid.

⁷ Ibid.

⁸ “Promote Efficiency of Lung Allocation,” OPTN, Briefing Paper, available at https://optn.transplant.hrsa.gov/media/jnpd0icf/lung_efficiency_board_briefing_paper_draft.pdf.

⁹ See OPTN Promote Efficiency in Lung Allocation workgroup meeting summary, January 30, 2024, available at https://optn.transplant.hrsa.gov/media/beumdbd4/20240130_lungefficiencywg_msfinal.pdf.

¹⁰ “Guidance on Requested Deceased Donor Information,” OPTN, June 2018, available at <https://optn.transplant.hrsa.gov/policiesbylaws/public-comment/guidance-on-requested-deceased-donor-information/>.

- Require reporting of
 - chest computed tomography (CT) scan, if performed
 - an echocardiogram or a right heart catheterization
 - chest x-ray images or interpretation of chest x-ray
- Require chest x-rays to be updated every 24 hours
- Remove requirement for description of sputum for a sputum gram stain

Proposed guidance changes include:

- Change “mycology sputum smear” to “fungal culture results”
- Add “bacterial culture results”
- Recommend providing a chest CT within 72 hours prior to initial offer
- Suggest providing chest CT images that show the lungs
- Specify that chest x-ray images are preferred over interpretations
- If an echocardiogram has been done and there are still questions or concerns, recommend obtaining a right heart catheterization.

Following the Lung Committee presentation, a Committee member reviewed results from an informal survey of members assigned to review this proposal as a precursor to full Committee discussion.

Summary of Discussion:

A Committee member asked if smaller lung programs were able to travel greater distances to recover organs for transplant. The presenter noted that centers make best judgment, weighing each donor thoughtfully based on the information available. In some cases, an OPO’s procurement surgeon might be utilized, but lung programs are making decisions based on donor details and candidate condition.

A Committee member suggested that the matching system itself may benefit from technology to remove some of the manual back and forth and decision making in the system. The presenter noted that standardizing the information made available is one way of bringing more efficiency to the system. Additionally offer filters also help in this area. The presenter did emphasize that medicine is an art as well as science, and while added efficiencies are critical, they don’t want to compromise the decision-making process.

The Committee appreciated the Lung Committee’s efforts to strike a balance between obtaining accurate information on the donor for the transplant programs to make informed decisions, and the burden on donor hospital staff and OPOs in collecting this information in the required time period. In particular, the Committee acknowledged the burden on smaller community hospitals in meeting these requests. While generally supportive of the proposal, the Committee offers the following questions and feedback for consideration:

- What are the clinical impacts of pushing back the CT scan requirement time from 24-48 hours to 72 hours prior to organ offer? Does the alleviation of OPO burden truly outweigh the insights gained from a shorter time period? What is the reasoning behind not making chest imaging a requirement, rather than just a preference? What are some of the major indicators that would prompt a transplant center to request a follow up heart catheterization?
- Do organ filters have criteria for transplant centers to automatically reject offers that don't contain center specific requirements (they need images, CT, heart catheterization)?

- What is the procedure for the workflows to be adjusted and subsequently monitored? What new metrics will be tracked?
- If standardization of practice across the system isn't already in place, doesn't that introduce the potential for personal judgement and bias to be injected into the decision?
- Are the changes mainly to increase the number of lung transplants that are successfully completed? Will this improve one's chances of getting a suitable lung transplant? What are the potential downsides to patients from these changes? What does the patient have to do differently to ensure they have the best chance of receiving a lung transplant?
- The change from mycology sputum smear to fungal and bacterial culture results was troubling to one member. While this language is used more commonly in practice, cultures provide more false negative and false positive results that may delay the process or lead to missed infections. The Lung Committee was urged to look at other technologies besides cultures, as there are other FDA-cleared tools that can detect bacterial and fungal infections in a few hours.

Next Steps:

OPTN Contractor Staff will summarize comments and share survey responses as part of formal Committee comment after review and approval by Committee leadership.

5. Continuous Distribution Update- Policy Development Efforts for Other Organs

The Committee received an update on the development of CD proposals across other organs.

The Committee received an update and did not make any decisions.

Summary of Presentation:

OPTN Contractor staff provided a brief overview of CD, a points-based system for organ allocation. CD aims to remove the hard boundaries created by classifications, rather considering all the characteristics of a patient at one time when matching a donor with a potential recipient. The system is more equitable, more agile in adapting to changes in science, behavior and community preferences.

The presentation began with showing how the former lung distribution system functioned versus how CD functions, ranking candidates by an overall score that considers all factors that define a candidate's unique need for lungs all at once rather than putting them into classifications or groups. CD is based on a reusable conceptual framework that is ultimately envisioned to be used for allocation across all organ types. It addresses:

- **medical urgency (prioritizing medically urgent candidates)**
- **post-transplant outcomes**
 - *With these first two elements combining to determine "net benefit"*
- biological disadvantages (e.g. ABO, CPRA, height)
- patient access (e.g. pediatric, prior living donor)
- placement efficiency (proximity efficiency, travel efficiency)

The framework will allow for customization based upon organ type. For example, the biological disadvantages framework, which can also be applied to kidney and other organs, though not necessarily with the same factors, is flexible enough such that if the community did have a strong rationale for caring more about one type of biological disparity compared to another, it can accommodate this through different sub weights. This was demonstrated in changing the weight for blood type O donors in lung, as discussed earlier in the meeting.

An important and repeatable concept built into continuous distribution is the flexible weighting of the medical urgency sub score and the post-transplant outcomes sub score, i.e., equity vs. utility, and the precise way these two are weighed in the score relative to each other determines whether, and in what form, the “net benefit” concept is incorporated into a CD system. Since LAS went into effect in 2005, allocation of lungs has been primarily based on the net benefit concept. With LAS, it wasn’t a pure net benefit measure – rather it weighted waiting list mortality risk twice as much as post-transplant survival – but in the new CD policy, the importance of predicted post-transplant survival has increased, making the system closer to a pure net benefit construct. Some organs, like liver and heart, don’t incorporate any degree of net benefit but solely rely on a medical urgency measure, like MELD, or illness severity statuses or tiers.

Each organ-specific committee has worked through values prioritization exercises. These efforts have evolved with each iteration and have included more community participation than almost any other public comment proposals. It is important to note that the weights provide valuable information to the committee in terms of community priorities but should not be interpreted as final weights.

Progress to date was highlighted, with kidney and pancreas awaiting SRTR modeling, liver and intestine in the process of collecting public priorities, and heart identifying attributes. CD was approved by the Board as a new system for allocating organs in 2018. Lung CD was the first to be implemented in March 2023. The original plan was to stagger the transition by organ. In September 2023, the Executive Committee directed the Kidney and Pancreas committees to ensure that any future CD proposals will consider how the framework will impact the following, and report back to the Executive Committee on incorporating these goals prior to future public comment cycles related to CD:

- decreased non-use/non-utilization of kidneys and pancreata
- decreased out of sequence allocation of kidneys
- consideration of expedited placement pathways for kidneys at high risk of non-use

This Executive Committee request slowed the committee’s work and did remove some of the stagger that was originally intended.

The Executive Committee request led to a three-pronged approach to the topic. The Kidney Committee is working with the SRTR, MIT, and outside researchers on this effort. This will expand to other organs over time. The Kidney Committee’s SRTR request was submitted in early March but differs from traditional requests and will not necessarily include a report on utilization for a proposed CD policy. Rather, it will assess whether SRTR was able to generate utilization models that validate well against historic data.

The Kidney Committee has reviewed data and literature in its efforts to build a foundation for understanding the drivers of non-use. This includes collaboration and recommendations to the Expeditious Task Force. The Kidney Committee began developing a data driven consensus definition of “hard to place” kidneys using a multi-pronged approach that included clinical indicators, cold ischemic time, and allocation indicators. There has been communication and collaboration with the Expeditious Task Force, sharing the Kidney Committee’s extensive literature review, submitting several recommendations for projects and other key efficiency improvements, and establishing the Kidney

Expedited Placement Work Group to support expedited placement variance protocols and their ultimate transition to policy.

The Pancreas Committee is focused on increasing utilization of pancreata (and decreasing non-use) and minimizing the distance traveled for pancreas alone (and related cold ischemic time). The Pancreas Committee has identified a potential project to create a guidance document that will provide awareness and share best practices for consideration related to pancreas procurement and organ offer acceptance. If approved, the committee will seek feedback from the community on issues facing the pancreas community as it relates to procurement and efficiency during a future public comment period.

Facilitated pancreas allocation is also under consideration. The Pancreas Committee is re-evaluating proposed policy changes including the timeframe in which OPOs are permitted to apply facilitated pancreas allocation and the qualifying criteria for facilitated pancreas program. The committee is currently awaiting results from SRTR on a modeling request to inform this facilitated pancreas work.

The history of using distance in organ allocation was highlighted. In CD, a continuous scale for distance is used. This removes cliffs or hard boundaries based upon distance. These scales will likely change over time based upon advances in science and technology. Organ perfusion was offered as an example that allows some organs to travel much further than they could in the past.

In addition to the allocation algorithm, CD is an entire allocation system. This includes other enhancements. Offer filters were first rolled out for kidney, and the OPTN has committed to have offer filters in place for every organ before they transition to CD (recognizing that lung did not have offer filters in place when it transitioned to CD). Donor testing policies will need to be more uniform as organ offers are going out to greater distances. Historically, transplant hospitals have had existing agreements with their local OPOs regarding testing preferences and expectations beyond basic policy requirements. Earlier in this meeting, changes to lung testing policies were discussed that more closely align with practices in the field. The OPTN will do the same thing with other organs before they transition to CD. The OPTN is also working on other operational enhancements such as how to handle offers from geographically isolated areas.

Summary of Discussion:

A Committee member asked how much weight the organ specific committees are putting on the feedback received from the values prioritization exercises. OPTN Contractor Staff shared that committees have been carefully reviewing the results. The reports are posted on the OPTN website. Differences across each organ are attributed to their different attributes. For example, pancreas does not have a medical urgency score yet, so there was not a direct way to incorporate that into the values prioritization exercise. This is one of the things the Pancreas Committee is working on now to determine how this might be incorporated. Heart, liver, kidney, and pancreas all have CD updates out in the current public comment.

Clarity regarding out of sequence distribution was requested by the committee. OPTN Contractor Staff shared that some organs have expedited placement pathways in place to avoid non-use of an organ. Liver and pancreas were recognized as having these pathways to help place an organ more quickly. It was noted that kidney does not have a specific policy in place for expedited placement at this time, but that some OPOs have been utilizing expedited placement methods to avoid non-use. The OPTN's Membership and Professional Standards Committee (MPSC) reviews these out of sequence placements. Subsequently, the OPTN Board of Directors has requested that the Kidney Committee explore such a pathway as part of continuous distribution. This would help to create a national expedited placement pathway and reduce out of sequence allocation. A Committee member asked if there was a sign off from programs that would be bypassed that is collected by the OPO in these instances. OPTN Contractor staff

noted this question aligns with some concerns received from the transplant community and confirmed that there is not a requirement for such a program acknowledgement at this time.

A member questioned whether continuous distribution would benefit this very time sensitive process of multiple offers and reviews. The Lung Committee's previous presentation was referenced by OPTN Contractor Staff, noting that more transplant centers are receiving and reviewing offers. With this has come a slight increase in allocation time for lungs. Lung offers and allocation is generally happening before the lungs are recovered from the donors. For kidneys, allocation really begins in earnest after recovery is complete. For each organ there are different dependencies related to time.

A Committee member commented that states that border on the ocean still seem to be upset by the impact of nautical miles, in that they do not receive the benefit of a full circle. OPTN Contractor Staff noted that continuous distribution has helped in this area, as a relatively low weight has been set for distance overall. Even out to a thousand miles, candidates are still receiving most of the placement efficiency points. As these centers (with Seattle being offered as an example here) are receiving more offers and offers from a greater distance, offer filters help programs manage and screen offers to help them receive desirable offers and remove offers that they would not be willing to accept. The member then asked if patients would receive education regarding organ offer filters. OPTN Contractor Staff noted that, while there is not policy requiring programs to disclose their organ offer filters to patients, there will need to be shared decision-making regarding expedited placement for those kidneys that might be at a higher risk of non-use. There may be different considerations for patients in terms of whether they want to accept these kidneys or not as some may not be expected to last as long or could carry an increased risk of graft failure. This is an area of continued opportunity and development as the expedited placement policy is developed. Another Committee member noted that this could be hospital specific, as he was given all of this information up front regarding the types of organs he would accept. Some Committee members shared their experiences, noting that information also may differ by organ type and by anticipated time on the wait list. It was also acknowledged that individual's risk tolerance may vary dependent on their time waiting, age, state of health, etc.

One Committee member shared that she heard at a regional meeting that there had been about a 45% increase in out of sequence kidney allocation and that several OPOs accounted for the majority of these out of sequence allocations. The member questioned whether there was any data yet on how continuous distribution might positively impact this. OPTN Contractor Staff noted that this data was shared as part of the Expeditious Task Force presentation during a past regional meeting cycle, and this is what led the Board to task the Kidney Committee with creating a pathway for expedited placement.

One-year survival was also questioned, with a member asking if the one-year mark had been rethought as part of patient success or outcomes. OPTN Contractor Staff noted that the long allocation score utilized prior to continuous distribution was based on one-year post-transplant survival. For lung continuous distribution, there was a shift to a five-year post-transplant survival model. The Lung Committee agreed that one year is not the goal and that a five-year survival would be a better measure of success. It was noted that this was the longest timeframe supported by data at this time. OPTN Research hasn't been able to include post-transplant outcomes measures in the monitoring reports yet due to sample size. As the sample size grows, the data will be included. Committees were encouraged by this but still believe a longer span is more appropriate.

OPTN Contractor staff recognized that there has been a lot of discussion in the transplant community regarding expedited placement and increasing the use of kidneys that have been going unused. A Committee member noted that their center has been taking a lead in terms of accepting those "high risk" kidneys. As a patient, they hear that they are having just as much success with those lesser quality kidneys, which they now know they probably received as well. They suggested that consistency around

continuing to study and understand what it means to utilize these kidneys will better position the OPTN to build a dynamic system that more effectively matches donors and candidates not just for expediency but to ensure that they receive a long-lasting organ. They recognized limitations on the capacity of smaller rural programs, but questioned why larger centers would not accept these kidneys.

A member asked if there were any restrictions or limitations on the number of times a center can decline or in the number of reasons why they might decline an organ. They questioned whether the zip code where a patient is listed may impact whether or not you receive a transplant, Committee members suggested that there must be a way to hold centers who decide not to accept a kidney accountable. OPTN Contractor Staff noted that the MPSC now reviews recently implemented offer acceptance metrics to review programs that have a low offer acceptance rate. This allows them to check in and work with them to improve these numbers. Center acceptance rates are also available in the program specific reports on the SRTR website. Additionally, the new OPTN strategic plan has a focus on offer acceptance and continuing education across transplant programs to try to expand acceptance while maintaining patient outcomes.

6. CMS Update on IOTA Model

The Committee received an update and did not make any decisions.

The Committee received an update from the Division Director of the CMS Innovation Center (CMMI), on its new proposed payment model, Increasing Organ Transplant Access (IOTA).

Summary of Presentation:

The CMMI speaker noted that there have been other payment models related to kidney care, focused on coordinated care and home dialysis. There was a desire to test a more specific model focused on transplant alone. He outlined the divide between the number of patients on the kidney wait list versus the number of transplants performed, calling out the number of procured kidneys that go unused. He shared that 13 Americans die each day while awaiting a lifesaving kidney transplant.

Different components of Health and Human Services (HHS) hold different pieces of the puzzle that make up transplant oversight, including:

- CMMI – manages system innovation
- HRSA – oversight of the OPTN and OPTN Contractor
- CCSQ – Regulation of OPOs and Transplant Centers
- CMS – payment for transplants

The Organ Transplant Affinity Group (OTAG) began in 2021 and was created to coordinate a series of aligned initiatives across CMS and HRSA to increase transplantation through a series of payment, quality, and regulatory efforts. The OTAG's goals are to:

1. Ensure access to organ transplantation by reducing variation of pre-transplant/referral practices
2. Improve accountability for U.S. organ transplantation system performance.
3. Increase availability and use of donated organs.
4. Implement policies that promote equitable access to organ transplants
5. Increase patient and family/caregiver education of process

The IOTA Model was introduced in May 2024 as a mandatory model testing whether payment incentives for selected transplant hospitals can increase the total number of kidney transplants. Transplant hospitals would focus on working with other clinicians and providers to overcome barriers to transplant;

better utilize the current supply of deceased donor organs; assisting more potential living donors through the process; and improving the equity of the transplant process. Participation in IOTA will be mandatory for 50% of donation service areas (DSAs) within the U.S. All eligible transplant hospitals (those non-pediatric facilities performing at least 11 kidney transplants annually) with active kidney transplant programs within a DSA will be required to participate. The program's target populations include candidates on the kidney wait list and those recipients who received a transplant from a participating hospital. The program is not limited to Medicare beneficiaries. The speaker noted that while this model is focused solely on kidneys, it is part of a series of Health and Human Services efforts.

The IOTA model will score participating hospitals on three different domains: achievement, efficiency, and quality. Hospitals will receive a score out of 100 points which will determine the amount paid for each Medicare fee-for-service kidney transplant conducted during the performance year, reserving the highest bonus payments for those performing the highest number of transplants. This formula will also have centers focus on being efficient with their organ offers and their organ offer acceptance ratio while remaining focused on quality of care and post-transplant graft survival. Based on their performance, centers will be eligible for an upside payment or a potential downside. There is no downside risk in year one, as CMMI's recognition of wanting programs to transition into this model and its value-based care system.

The achievement domain was described as the largest, and focused on the most important question-how much can you increase your number of transplants relative to a target. This target is based on the center's own historical number of kidney transplants performed. A program's highest number of deceased or living donor transplants performed during the baseline years was trended forward by the national growth rate (recognizing that donor numbers and overall transplant numbers have been growing each year). This goal includes a health equity adjustment for underserved individuals that counts these transplants as 1.2 rather than 1 (recognizing underserved individuals as low income or uninsured). Deceased and living donor transplants are scored equally, allowing programs to determine the best way to increase their numbers and help more patients receive transplants.

The efficiency domain looks at a program's organ offer acceptance rate. It is the same metric used by the OPTN and SRTR to look at the ration of observed organ offer acceptance versus expected as compared to all centers in the U.S. This takes into account the center's absolute score and opportunity for improvement. IOTA's goal is to focus on overall efficiency of the system so that centers can improve their performance in this area by accepting more organs or by revisiting their offer filters and accepting only organs that they are most likely to use.

The quality domain looks at two pieces. Composite graft survival rate measures the total number of functioning grafts over the total number of kidney transplants completed. CMMI wants to monitor survival benefits for the longer term, not just the one and three-year metrics here. Three additional quality measures focusing on different aspects of the transplant process were also proposed. The first is a shared decision-making score, testing patient centered care and how much patients are informed of health issues and included in the decision-making process. The second is a three-item care transition measure that is designed to focus on discharge after transplant to see if patient preferences are accounted for and if recipients understand what they need to do post-discharge. The third piece is colorectal screening recognition that is in alignment with the larger CMS quality strategy and the higher risk of cancer in organ recipients versus the general population.

The final portion of this model is a request for information to seek feedback on two areas. The first is whether a transplant specific patient reported outcome measure should be developed. There is interest in working with the OPTN here to determine how much quality of life improves post-transplant and better understand the patient experience during transplant. The speaker noted that CMMI is also considering the kidney transplant waitlist, recognizing that there is wide variability in how programs manage their waitlists, including listing patients and managing existing candidates on the list. Organ transplantation and donation in the U.S. remains highly inequitable amongst racial and ethnic minorities as compared to White Americans, with many factors influencing disparities. While disparities in those who are on the waitlist versus those who receive a transplant are known – disparities in who are referred for a transplant and who subsequently gain access to a waitlist are largely unknown. CMMI would like to explore what quality metrics could be developed to measure overall management in this area.

The scoring for these three elements will then determine the size of a kidney program's Medicare fee-for-service kidney transplant performance-based payment. Performance-based payments exist on a continuous scale, with a maximum upside payment of \$8,000 for high performers, and a maximum downside payment of \$2,000 for low performers.

Additional policies included as part of the model are:

- Increased transparency- Participants will be required to publicly disclose their transplant evaluation criteria and review rejected organ offers with their patients
- Health equity plans and health equity data reporting- Participants will be required to submit health equity plans beginning in the second year of the program and notice of proposed rulemaking included an RFI on health equity data reporting. (Comments on this proposed rule were due on July 16, 2024).
- Safe harbors and flexibilities- Participants will have access to Anti-Kickback Statute safe harbors to enable them to address barriers related to social determinants of health (such as transportation and attributed patients' out of pocket drug costs)

CMMI is in the process of reviewing comments received from the Federal Register posting and considering next steps. The proposed model's start date was January 1, 2025. The speaker cautioned that his office is carefully reviewing and considering all of the feedback received and how to respond and build a final model. Any updates would be posted in the Federal Register and on the CMS website to share final plans publicly before implementation.

Summary of Discussion:

A Committee member questioned the size of the incentive payment, noting that larger amounts on the table may encourage transplant programs in a more meaningful way. The CMI speaker noted that this incentive payment is above and beyond what programs are already receiving related to organ acquisition costs and hospital surgery, noting the balance between incentivizing and also saving money for the government in the long run by transplanting more patients.

The definition of a functional kidney graft was raised by a Committee member. Are there more specific elements tied to this (e.g. GFR of x or creatinine of y)? The CMMI speaker noted that this is something that continues to be considered in the model, including the definition of a functional transplant as well. Graft and patient survival were proposed as the bare minimum, but the desire is to have a transplanted individual off of dialysis and not back into late stages of CKD. One alternative explored was GFR below a certain number at one year, and a number of comments were received in this area. He encouraged the transplant community to think about the right metrics to show not only graft survival but a functional

transplant. He recognized the complexity of the questions and noted that there is desire to optimize patient experience and measure that in some way to create metrics.

A Committee member asked which transplant centers will be participating and also sought data regarding discrepancies in transplant numbers for white versus non-Hispanic black patients. The speaker noted that centers have not been selected yet, but a randomized methodology to include approximately half the geographies of the country in the model had been proposed. Comments were received on this topic and different alternatives were included. All of the non-pediatric programs that do more than eleven kidney transplants per year would be considered and the list of programs selected would be posted when/if a Final Rule is released. The speaker could not recall where the transplant by race/ethnicity data was found, but he believed it was quoted from a reported analysis. He will look up the results and send them to the Committee.

The idea of commercial insurance providers dictating where their insured patients can go to receive a transplant was raised as a concern by a Committee member. They noted that if a program participating in IOTA is not a provider approved option for patients, this could impact equity and access. The CMMI speaker recognized the concern, noting that insurers have their own markets set up for private insurance and Medicare Advantage. In general, this model measures performance across all payers, so a center's ability to increase their number of transplants regardless of payor (Medicare, Medicaid, Medicare Advantage or commercial insurance). Private insurance centers of excellence networks do not include all centers. CMMI is looking for centers to figure out how to best set patients up for success. He does not believe there will be a situation created where centers will have organs that are ready to go in patients but not have any willing candidates. Each program's target is based on its own past experiences, recognizing that more is expected from them. He believes that each center will determine how to best navigate within their own confines to increase their numbers.

A Committee member asked how offer notifications will be managed. For example, if they were number 50 on the list, wouldn't it take too much time to notify them that there could be an offer? Instead, will the centers have to notify the top 10 or 15? The speaker noted that notification of offers will not happen in real time, but rather be a post-hoc notification on a monthly basis to increase transparency. CMMI does not plan to be prescriptive in how the information is shared, but rather making candidates aware of meaningful offers that were declined.

Transplant evaluation criteria was also discussed. Kidney programs will be required to publicly disclose their evaluation criteria for being listed. The OPTN does not dictate listing criteria for centers and there is no disclosure of these listing criteria required by policy. Clinical data collected by the centers is used to feed into the waitlist and subsequent allocation algorithms. The speaker noted that CMMI is not looking to be prescriptive to say that centers must accept a certain type of candidate or organ, recognizing that centers do things in different ways. However, if a potential kidney transplant patient lives in a city with multiple transplant centers, having this level of transparency will be beneficial to patients as they are beginning the process. An example of obesity was offered here. Which of these centers might list a patient on the waitlist (versus which center may first encourage them to lose weight before listing).

A Committee member asked if the overall transplant system would ever reach the technical ability of something akin to ride service like Lyft, where a patient could enter their insurance/billing information, their sensitization level, and any relevant medical information to then be advised on which center they should go to for evaluation and listing. It was noted that patients don't understand the difference between showing up at a community hospital versus a transplant hospital. A solution that takes the burden off of patients having to navigate for themselves is desired. This is not even mentioning literacy barriers and access to technology. The CMMI speaker noted that the transplant space is unique in the

depth of data it contains. OPTN and SRTR collect this data and there is opportunity to conduct analyses in a patient centric way to better understand practices.

A Committee member asked if there are safeguards in place to prevent transplant programs from “padding” incentive numbers to hide underperformance. The speaker shared that the CMMI data calculations come from the OPTN and SRTR data. CMMI will tell centers what their performance is, as the model does not include self-evaluation. The system is also set as a “denominatorless” transplant measure. There is no particular way around not doing more transplants that would score highly. He believes the system was designed robustly enough to avoid potential gaming opportunities. Additionally, the IOTA model does not exist on its own, but as part of the larger transplant ecosystems. Centers remain subject to OPTN and CMS evaluation that holds them accountable for policies, regulations and metrics. IOTA is meant to be supplementary to this, but any bad behaviors would be offset by these other enforcement mechanisms already in place.

A member shared their preference for making sharing requirements more prescriptive for public disclosure of transplant program selection criteria. What is publicly released may be delivered differently to candidates at or considering evaluation. The member saw benefit in closing this gap to ensure transparency here. In addition to patients being made aware of rejected organ offers, the idea of patients having autonomy and some input on choosing their organ was also offered here. The Committee member noted that a patient’s risk tolerance changes based upon how long they have been listed. The member suggested a website or phone application where the center’s program acceptance criteria could be viewed. The member recalled that SRTR was working on an accessible tool for patients to see this, but funding was removed. The speaker shared that the IOTA model proposal does note that the information is posted on each transplant center’s website. From there, he believes that CMMI would collect and put this information into one place. He recognized that every patient may not go to transplant center websites to look for this type of information. Current CMS standards require transplant programs to provide a copy of their criteria to a transplant patient or a dialysis facility as requested. This change outlined in IOTA would take this a step further. The Committee member noted that he spent a lot of time on websites, as do other candidates, because there is no central repository for this type of information. Additionally, the “upon request” was noted as an extra step for patients to have to take to determine if a program will accept them.

Questions were posed by a Committee member regarding how the health equity and diversity data is any different than what is currently collected and how this information will be addressed or published. The speaker noted that feedback was received on the proposal regarding the data that is currently collected. CMMI wants to see the scope of what was being collected currently and what centers are doing to then think about how to potentially build on this where it makes sense. This is an area where careful review of the feedback and considering potential alternatives is underway. Health related social needs such as transportation deficits were also in consideration as part of this critical evaluation. A Committee member noted that it is important to make sure that patients know where they can go to see this published information. This was seen as being tremendously helpful with patient education.

A Committee member asked if there were approved ratios of patients to pre- and post-transplant coordinators (like for school classrooms and teachers), noting that communication is an important part of patient care. If one center has 200 patients assigned to a coordinator and another has 60, there must be differences in communication, support, and partnership. The speaker noted that it is an interesting idea. In developing the IOTA model, CMMI did try to steer away from this kind of measure, recognizing that different centers do have different staffing models. Transplant programs have very different approaches to managing their waitlists. CMMI was hesitant to define specific approaches when centers still get the same number of patients through the transplant process. This was another area of feedback

that is under review, but CMMI tried to be outcomes focused rather than process focused here in recognizing that centers approach the process in different ways. The speaker did recognize the quality of communication and the overall experience for patients, noting that they hope to build in a quality measure to evaluate this aspect of center performance.

Patient reported outcomes were acknowledged by a Committee member, who shared that the further out from surgery they were, the less interaction they received from their transplant coordinator. The member questioned whether there is a correlation around long-term success with your transplant and your connection to the transplant center, noting that a nephrologist is definitely different than a transplant nephrologist. The COVID pandemic was offered as an example of differing recommendations coming from the community nephrologist versus the transplant nephrologist and transplant coordinator. A request to carefully consider this coordinator to patient ratio, as it seems critically important for schools and colleges as far as teaching and communicating.

The Chair thanked CMMI for the IOTA model update.

Next Steps:

The CMI speaker will review data and forward the results he quoted regarding transplant by race/ethnicity. *This information is available on the OPTN website and was shared directly with the Committee member.*

Feedback from SRTR will be sought regarding the progress and funding of the patient friendly tool to access centers' program acceptance criteria.

7. OPTN Modernization and Independence Update

The Committee received an update, and did not make any decisions.
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The Committee received an update from the OPTN President and a HRSA representative regarding the OPTN modernization efforts.

Summary of Presentation:

The Committee chair set the stage for an open conversation, noting that the slides had been circulated for review in advance of the meeting. Opening comments regarding modernization and the changes to the transplant system were requested of HRSA.

The HRSA representative highlighted successes along the way, including the changes to the National Organ Transplantation Act (NOTA), a bipartisan effort that allowed HRSA to make changes to allow more than one contractor to handle all of the activities of the OPTN. This allowed HRSA to look for best in practice for operations, board support, governance, and IT. Additionally, increased funding will allow flexibility and the ability to provide better oversight and award multiple contracts. While acknowledging the U.S. transplant system as one of the best on the world stage, he recognized that there is always room for improvement. One of these areas is focusing on patient engagement and communication. This is based on feedback from the community, seeking better partnership from HRSA and CMS. Working in the OTAG to increase engagement will help move in a direction that will help patients.

The HRSA speaker recognized participation in regional meetings as a way to hear community and patient feedback and share more directly in addition to its OPTN Modernization website.¹¹ He acknowledged the recent issuing of the new board support contract as one component of the modernization. This

¹¹ <https://www.hrsa.gov/optn-modernization>. Accessed on 10/2/2024.

contract will solely support the efforts and activities of the Board. The operations contract will consist of multiple vendor contractors getting awards as the new foundational structure is set. Current efforts are underway with board leadership to hire an interim executive director for the OPTN. In the future, the new board support contractor will hire a full-time long-term executive in this role.

Summary of Discussion:

A Committee member asked the HRSA representative if there was a timeline for the development of the new board set up and operations. The speaker noted that the current OPTN bylaws and policies will flow into the new structure for the time being. The new board contractor will be completing a deep dive into these documents. Any recommended changes will go out for public comment and be voted upon by the OPTN Board of Directors. In terms of the new board structure, the new contractor started only two weeks ago. They will come in with fresh eyes to review current structure and function and present their recommendations to HRSA regarding setting up a new nominations slate and elections.

The President offered that he suspects the current board structure will stay intact through the course of this discussion and noted that preserving the overall community's voice is critical in this process. He noted that beyond the board contractor, the board leadership itself is committed to moving the process forward. When asked about timeline, he noted that he doesn't see a conversation in a year's time not have concrete specifics if it is not already completed.

A Committee member noted that much of the recent board discussions have had a business management focus rather than the medicine of transplant. He questioned whether the composition of the OPTN Board of Directors should include more subject matter experts if initiatives are skewed more to business management practices. The President noted that, in the current Board structure, there are generally ten seats open each year after seating regional representatives and society representatives as outlined in the bylaws. A needs assessment is completed to ensure that appropriate numbers of patient, donor and donor family representatives are included, and composition needs are met. The size of the current Board was noted as potentially too large, but the Final Rule gives percentages of who should be members. If shrinking the board, the Final Rule must still bind the process. A thoughtful approach to reconstructing the Board will be needed to achieve its goal, which is to govern the OPTN. Committee members questioned the Board's agility based upon its size, comparing large corporations with boards of 12 or fewer members. A Committee member asked if the Final Rule is standing in the way of driving fast improvement for the system and questioned whether adopting the same bylaws and policies for the new independent Board of Directors model will allow for the dynamic leadership needed to drive change and save patient lives. Committee members expressed frustration regarding the speed of change in the system and the missing patient voice in the process.

Committee members voiced their frustration regarding the OPTN President not attending the U.S. House Committee on Energy and Commerce hearing scheduled for September 11, 2024. There was concern regarding the appearance of this decision. It was noted that HRSA also declined the invitation.

A Committee member voiced his concern regarding the Board's challenges in attaining directors and officers insurance earlier this year.

A Committee member shared his frustrations regarding the increase in organ non-use over time. The OPTN President noted the misaligned incentives for OPOs and transplant centers. Centers are trying to maximize organ usage, but not all organs are right for every patient.

The Final Rule was noted as a hindrance by some Committee members, tying hands that could make changes to benefit patients. The OPTN President noted that this frustration is not new, and is also held by many OPTN members, but the Final Rule provides the guardrails for the U.S. transplant system.

A Committee member suggested that AI and checkpoints may be better to help manage and distribute the data that is collected and used for donor and candidate matching. A member noted surprise that the OPTN does not have center criteria for organ acceptance. There was concern that failure to move forward with next steps to understand what is happening with increased non-use and normalizing criteria for who is going to accept the organs will only maintain this disadvantaging of patients that never receive the offers. The OPTN President noted the strong interest in organ utilization and suggested that this is a great space for the Committee to focus on in its work. He suggested that there is benefit to a separate discussion to provide background to provide more clarity on how organ offers are considered, and decisions are made. He made an offer to walk the committee through the logistics of how this typically works to provide a foundation for the Committee's recommendations.

Next Steps:

The President offered to hold a separate call with the Committee to provide background information on how organ offers and acceptance decisions are made to provide a foundation for any future recommendations from the Committee on the topic of organ utilization.

8. Patient Awareness of Listing Status (PALS) Subcommittee Update

The Chair of the PALS Subcommittee provided a brief overview of the status of the committee's proposed project to ensure patient awareness of their status on the wait list.

The Committee received an update, and did not make any decisions.

Summary of Presentation:

The Subcommittee Chair noted that, at this time, only about half of the individuals on the waitlist are in an active status. There is concern that candidates may not know that they are in an inactive status.

To date, this Subcommittee has met twice. The Subcommittee Chair sought agreement from the full committee on whether the Subcommittee has its support on this project. He shared that he has informally discussed potential solutions with the OPTN Ethics, Living Donor, and Transplant Coordinator Committees. Additionally, OPTN Contractor Staff from IT, Data Management and Member Quality have engaged in discussions. There is patient data in the system, but a recommendation from the Contractor that the patient notification of inactive status may be more beneficial coming from the transplant center itself and not the OPTN (as the OPTN could not address any candidate questions about their status or how to change it and also due to security concerns for sharing protected health information). The Subcommittee Chair shared that the committees he had spoken to noted that transplant programs have finite resources that may lead to pushback from this initiative if they are left to create a solution. Subcommittee members do not wish to burden transplant coordinators and see the best path forward as the OPTN Contractor who holds this data providing the technical solution to notify candidates regarding their status on the waitlist. This would remove the human component at centers from making calls or sending letters- creating time for coordinators to do more important things.

Comparisons to drug store phone applications were made as examples where health information is shared in this manner. The data incident breach was acknowledged, noting that a minimal amount of patient information would be needed. The Subcommittee Chair suggested that a customer ID could be used to access OPTN data through the phone app to determine a candidate's active or inactive status on the waitlist rather than leaving the responsibility to 256 transplant centers to come up with resources both in manpower and tech to create a separate system.

The Subcommittee seeks to put something forward that will be impactful and easily implementable. The Subcommittee Chair noted that the OPTN Contractor staff did raise some concern about funding. A member questioned why funding has come up for this project specifically, as they do not recall this being an issue for other proposals.

Summary of Discussion:

A Committee member noted strong support of this idea. While smaller centers have much smaller waitlists to manage, this is not the reality for every coordinator at a large program that may have hundreds or even a thousand on their waitlist. There was also support for a centralized approach to standardize how information is shared.

A member of the Committee suggested that basic tools are available to create this type of phone application that would give patients access to their information. Committee members shared anecdotes of individuals having no idea that they were not receiving organ offers. Additionally, language barriers and educational levels were acknowledged as challenges here. Having a simple way to review this information, such as a red if you are inactive and green if you are active on the waitlist will provide peace of mind to those waiting.

A HRSA representative asked about project approval for this effort. The Subcommittee Chair noted that the group is still scoping and framing the effort and getting feedback with expeditious approval in mind. A comment was shared regarding the feasibility of tying this into the IOTA Model as well since it is an improvement on patient communication.

Committee members were asked to voice their support or concerns around the table for this effort. All were supportive.

As part of this discussion, a Committee member reiterated their desire to better understand center criteria for accepting or declining organs. A Committee member noted that this area appears to need some revision as the number of candidates is increasing. Greater standardization in this area was supported by several committee members related to this process. There was strong interest in the Committee engaging on this topic.

Next Steps:

The Committee will work towards formal project approval for notification of patients regarding waitlist status.

The Committee is interested in better understanding center criteria for organ acceptance/decline and moving towards greater standardization here to allow offers for candidates, noting patients need to know and be actively involved in this process.

9. Public Forum

No public forum items were submitted for discussion.

10. Closing Remarks

The Chair thanked Committee members for their focus on driving change and the OPTN Contractor staff for their help in meeting presentation and content.

Upcoming Meetings

- October 15, 2024
- November 19, 2024

- December 17, 2024
- January 21, 2025
- February 18, 2025
- March 18, 2025
- April 15, 2025
- May 20, 2025
- June 17, 2025

Attendance

- **Committee Members**
 - Molly McCarthy
 - Lorrinda Gray-Davis
 - Patrice Ball
 - Michael Brown
 - Elizabeth DeVivo
 - Garrett Erdle
 - Tonya Gomez
 - Calvin Henry
 - Robert F. Johnson
 - Wendy Leavitt
 - Karlett Parra
 - Andreas Price
 - Cathy Ramage
 - Cody Reynolds
 - John Sperzel
 - Jenny Templeton
 - Steven Weitzen
- **HRSA Representatives**
 - Mesmin Germain
 - Arjun Naik
 - Frank Holloman
- **SRTR Staff**
 - Katherine Audette
- **UNOS Staff**
 - Shandie Covington
 - Desiree Tenenbaum
 - Kaitlin Swanner
 - Kimberly Uccellini
 - Houlder Hudgins
 - Laura Schmitt
 - Samantha Weiss
 - Kelley Poff
 - Lindsay Larkin
 - Liz Robbins Callahan
 - Morgan Jupe
 - Rob McTier
 - Terry Doolittle
- **Invited Speakers**
 - Dennis Lyu
 - Tom Duvall
 - Rich Formica