OPTN Patient Affairs Committee
Meeting Summary
March 12, 2025
Conference Call

Molly McCarthy, Chair
Lorrinda Gray Davis, Vice Chair

Introduction

The OPTN Patient Affairs Committee (the Committee) met via WebEx teleconference on 3/12/2025 to discuss the following agenda items:

1. Welcome and Introductions
2. HRSA Update
3. Public Comment: Clarify Requirements for Reporting a Potential Disease Transmission
4. Public Comment: Monitor Ongoing eGFR Modification Policy Requirements
5. Regional Meeting Debrief, Transitional Nominating Committee Updates, and Open Forum Discussion
6. Closing

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

1. Welcome and Introductions

Committee members introduced themselves and shared their personal connection to donation and transplantation.

2. HRSA Update

The Committee received an update from HRSA on OPTN modernization, including the Transitional Nominating Committee, the special election timeline, ongoing discovery projects, and patient safety support.

Summary of discussion:

A member asked how the former OPTN Board of Directors will coordinate with the newly elected OPTN Board of Directors to ensure continuity. The HRSA representative said it is a robust project, and it will not just be a quick hand-off. The HRSA representative emphasized the importance of continuing the work of the committees and educating Board members on what has happened in the past and their expectations for the future, noting that there will also be continuity at HRSA. The speaker emphasized the importance of considering what has been done in the past from an education perspective – awareness of the past without preconceived conclusions. The member reiterated the importance of a smooth transition to protect patient safety in this complex system.

A member commented there has been a lot of activity with the federal government and asked if that will have an impact on the transplant community. The HRSA representative said there are some changes occurring but transplantation modernization tends to have bipartisan support.

The Chair commented the size of the Board seems to be too large compared to the boards of publicly traded companies and asked if that has been part of the discussion. The HRSA representative said it has

been a topic of academic discussion longer than it has been part of the policy discussion. The HRSA representative responded the tension between a large Board and a small Board is aiming to represent the diversity of perspectives in terms of adult and pediatric, living donor and deceased donor, etc. so that is why HRSA has been conducting the listening sessions at the regional meetings. Moving forward, it is important to have the necessary expertise and the trust of the community and assurance that the Board is representing everyone's interest. One approach could be to rotate in individuals for specific topics for additional expertise. While all perspectives need to be heard, different talents and experiences may be necessary to address the challenges. The Chair supported the idea of rotating in expertise.

A member noted there have been emails sent by Board members expressing concern about the timeline for the transition and suggesting that there may be some legal complaints against how the work is proceeding. The member asked if there are concerns about the transparency of the process that have not been addressed. The HRSA representative said there have been situations in which HRSA has not been able to provide requested information. He said this is a tense situation for members currently sitting on the Board and some sitting Board members feel slighted. He pointed to the congressional guidance and comments of the Senate Finance Committee calling for improved governance of the system. The HRSA representative said that the changes to the Board are not targeting anyone personally but are aligned with the guidance from Congress.

A member commented patients are concerned about the changes that are coming, particularly patients who rely on Medicaid. The member asked how many transplant patients are covered by Medicaid. The HRSA representative said he does not have any inside knowledge regarding changes to Medicaid or Medicare. However, HRSA has been working on the pre-waitlist data collection effort which will help with understanding the gap of patients who are not able to make it to the waiting list. The HRSA Representative shared that Medicaid patients make up about 13.9 percent of the waiting list per OPTN data.

A member shared that their family is Native American and their child received a liver transplant. The member expressed concern about the increasing nonuse rate of organs. The member described challenges with access to health care in Indian territory and commented that while it could be important to increase organ donation rates within Indian country, they may be deterred from organ donation due to the nonuse rates. The HRSA representative noted that nonuse will never be zero as organ procurement organizations are working to recover as many organs as they can, and transplant programs have to consider whether to accept those organs for their individual candidates. As donation has been increasing, it is taking transplant programs time to catch up and they are using new technologies to accept more of these organs. HRSA has also been working on the ventilated patient referral form to better understand further opportunities for organ donation.

A member expressed concerns about the large Board size and the ability of a Board to be agile and respond to changing times. The member suggested that the committees can provide additional expertise to the Board. The member asked if there are any proposed changes to the structure of how committees interface with the Board, and if the agility of the Board is under consideration. The HRSA representative noted that the Executive Committee is a subset of the full Board that provides more agile decision-making, and it is important to ensure the patient voice is in that room. The HRSA representative said there are no proposed changes to the committee structure at that time but HRSA is considering how to ensure committee concerns are elevated to the Board and that lessons learned from one committee are shared with another committee.

The Chair commented a lot of efforts in OPTN modernization right now seems to be focused on getting candidates to the operating room table. The Chair asked how the post-transplant experience is being

considered, and how the Committee can support high quality of life following transplant. The HRSA representative said he learned in residency that one of the best ways to maximize our organ supply is to take care of our recipients, since it has a meaningful impact on the supply of donor organs. The Chair agreed this is an opportunity for the system to learn and grow.

The Vice Chair asked about the new performance metrics being implemented for organ procurement organizations (OPOs) in 2026 and whether that is in the purview of OPTN modernization. The HRSA representative said that falls under the purview of the Centers for Medicare & Medicaid Services (CMS). The HRSA representative commented historically, HRSA and CMS have not coordinated well but the agencies have been collaborating much more closely recently. CMS will need to consider how to manage patient access with enforcement of the OPO regulations. The Vice Chair mentioned the Increasing Organ Transplant Access (IOTA) model and said that it feels like the patient is being pulled in different directions. The HRSA representative said if that model is not providing the intended outcomes for patients, then HRSA should provide that feedback to CMS early. The HRSA representative said this is a new payment model. CMS manages the payment for kidney transplants so this is an effort to ensure the best use of those resources.

A member noted that the Committee had previously been discussing patient awareness of waiting list status and presented to the Executive Committee in the fall. The member noted that the Executive Committee indicated this has been a known problem but it has not been addressed. The member asked that the new Board provide transparency and respond quickly when there is a known issue. The HRSA representative said that OPTN modernization comes with additional resources that the OPTN has not previously had. The HRSA representative said HRSA is not hesitating to use the Secretary's authority. The HRSA representative agreed that candidates should have information regarding their waiting list status and whether they have been skipped in organ allocation. A member commented the OPTN needs to eliminate the current policy development process and address problems as they arise. The HRSA representative agreed that inertia or wanting a policy to be perfect should not prevent work from moving forward, and emphasized the importance of responding to the patient voice. A member agreed that perfection should not be the enemy of good and the Committee has discussed that even having a simple yes or no regarding whether a patient is on the waiting list would be helpful.

A member mentioned the complexity of the multi-organ allocation public comment item and expressed concern about multi-organ recipients being left behind. The member asked for any thoughts on that group. The HRSA representative described the multi-organ public comment approach as a success of the OPTN to provide more direction to OPOs and more understanding of what multi-organ candidates can expect while waiting for transplant.

The Chair asked if the HRSA representative had any questions for the Committee. The representative asked the Committee to consider how the patient voice could be better incorporated into the OPTN. The Chair suggested that the Committee could work on developing a Patient Bill of Rights outlining expectations for patient care. A member suggested that members of the Committee could attend other committee meetings to stay apprised of what is going on within the OPTN. The HRSA representative said one approach to managing the size of the Board is considering the role of regional representatives, but there could also be patient representatives focused on critiquing policies rather than developing them.

Members discussed the importance of inclusion of the patient voice and not just presence. A member noted that some boards have a voting board and board observers to ensure there is a smaller group of decision-makers to manage board size but invite in additional expertise as needed. A member said that might not work since ideally people with different voices have power. Proper representation of the group is important, and board observers do not have much power since voting is key. The member

noted there is a question as to whether the OPTN Board will be a policy board, or an advisory board where HRSA holds most of the decision making power.

Next steps:

Committee members are encouraged to reach out to the HRSA representative with any additional feedback.

3. Public Comment: Clarify Requirements for Reporting a Potential Disease Transmission

The Committee received a presentation on this public comment item and discussed their feedback.

Summary of discussion:

A member shared a summary of feedback provided by committee members ahead of the meeting, including questions about the proposal, suggested changes to the proposal, and educational considerations for understanding the potential changes.

- Most members supported the proposed definition of an unexpected transmission event to provide clear expectations for reporting, though one member was unsure if there might be gaps in reporting based on the definition.
- Members supported the timeframe in which a disease would be reported.
- Members supported the definition of a sick lung recipient but had some questions about the details of when reporting would be required.

A member advised against using positive blood cultures for determining whether a recipient has an infection as they can result in false positives and false negatives due to poor sensitivity of the tests.

The presenter responded to the questions asked by the Committee.

- Changes would be communicated to OPTN members upon Board approval of the proposal and ahead of the implementation of the changes. Education may also be provided to members.
- Pathogens of Special Interest (POSI) would need to be reported to the OPTN whether or not the recipient is sick as a result of the presence of the pathogen. However, transplant programs would not need to report the presence of other pathogens that are not causing clinical illness in a lung recipient.
- The POSI list is reviewed annually by the OPTN Disease Transmission Advisory Committee (DTAC) in conjunction with the Centers for Disease Control and Prevention (CDC). The most recent update was posted to the OPTN website in October 2024. The POSI list includes pathogens of interest for public health. A member noted that the CDC called out a new pathogen of special interest in December 2024 that is not incorporated into the list in October, and whether an interim review would occur. DTAC plans to review the list again prior to the implementation of this proposal.
- Hepatitis E virus (HEV) was not included on the POSI list because it is not very common in the United States with a zero percent prevalence over the last decade. The presenter found one case report from China where this virus was transmitted from an organ donor to an organ recipient. DTAC is selective in terms of what is covered on the POSI list. A member said they know of a liver transplant recipient who was recorded as coming down with HEV last year.
- The workgroup discussed whether pathogens from organ transport media should be addressed under this policy and decided not to include it, but the presenter offered to bring the question back to the workgroup.

- The OPTN does not collect information on how lung transplant programs handle additional testing or the rate of pathogen testing at transplant programs versus donor hospitals. The presenter said it is common for lung donors to be cultured at the donor hospital.
- Unexpected transmissions are reported to the Patient Safety Portal. If the OPTN becomes aware of a case that was not reported as required, the OPTN will follow up with the member to collect the appropriate documentation. The Committee will monitor the policy.

The Vice Chair asked if insurance coverage to support utilization of increased risk organs is considered in policy development. The Vice Chair shared anecdotal challenges of recipients struggling to get insurance coverage for necessary medications following acceptance of these organs. The presenter agreed on the importance of ensuring recipients have access to those medications. This issue is not within the scope of the proposal but the presenter appreciated the concern. Contractor staff noted that insurance coverage is not within the scope of the OPTN. The Vice Chair said the OPTN should consider this issue in developing policies for transplant programs to follow.

A member suggested there is a gap between what is reported by the OPO and what the transplant program sees in their testing. A member noted that the goal of the proposal is to reduce the reporting burden but it is difficult to assess the impact without knowing how different the results are currently between what the OPO finds and what the transplant program finds. The presenter said the goal is to strike the right balance between underreporting and overreporting. For example, transplant programs currently struggle with whether to report *E. coli* found on a lavage two days after transplant that does not appear to have any impact on the recipient's condition.

Next steps:

A summary of the committee's feedback will be posted on the public comment page on the OPTN website and shared with DTAC.

4. Public Comment: Monitor Ongoing eGFR Modification Policy Requirements

The Committee received a presentation on this public comment item and discussed their feedback.

Summary of discussion:

The Chair reviewed feedback and questions provided by members ahead of the meeting. Members had questions about whether automatic adjustments could be made instead of requiring modification requests, and why the need for the modification process persists. Members supported communication to patients about this issue, including on how they can support their programs in completing the process. Members supported the application of updated, more explicit notification requirements for all candidates registered on or after January 4, 2024. Members offered the following points of feedback:

- Increase outreach to African American patients.
- Inform patients about required documentation to avoid delays and assess eligibility.
- Include this information in consent discussions during evaluations.
- Diverse forms of notifications are crucial and clear, but clarify changes due to use of race-inclusive eGFR scores.
- Ensure consistent information delivery to patients and centers.
- Support new notifications to address historical racism in eGFR calculations.
- Mixed views on retroactive application, with fairness concerns for candidates from January 4, 2024, onward.
- Ensure wide publicity, including on the public website.
- Maintain transparency for patients on the waitlist.

The Chair asked if another tool could be used to measure kidney function other than estimate glomerular filtration rate (eGFR). Contractor staff pointed to the ongoing work in this area by the OPTN. The goal is because the use of race-inclusive eGFR is prohibited, the instances that modifications are being submitted will decrease and eventually stop.

The Committee discussed that transplant programs are asked to have a process for reviewing documentation for their candidates to determine if modifications need to be submitted. The Vice Chair expressed concerns about leaving it up to the transplant program to determine their process since that will lead to variability and potential inequity.

The Chair asked what it means for a transplant program to be out of compliance with policy. Contractor staff explained that transplant programs are monitored for compliance via site surveys. Transplant programs that are out of compliance may be referred to the OPTN Membership and Professional Standards Committee for further review.

A member noted that some candidates may not want to self-identify as African American which may impede their ability to receive a waiting time modification under the proposal. The member noted that living donors may also be impacted by these calculations. The member noted that they were not eligible to be a living donor for their family member because their eGFR was borderline, but they received a call back from the program that they had miscalculated and the member was eligible to be a living donor. Contractor staff confirmed that race-inclusive eGFR calculations are prohibited for OPTN purposes.

The Chair asked why laboratory results may still be using older equations. Contractor staff said the purview of the OPTN only covers use of these calculations for OPTN operations.

A member noted that patients with low eGFR may struggle to comprehend and retain information. The suggested the sponsoring committee consider including the caregiver in the communications, particularly since some transplant programs require caregivers to be present at appointments.

A member asked why candidates still need to be notified when the policy was changed to prohibit race-inclusive equations in 2024. Contractor staff noted that candidates being added to the waiting list today and later may still be able to qualify for waiting time modifications based on laboratory tests that were performed prior to the 2024 policy implementation.

A member expressed concern about changes at the federal level to remove references to diversity, equity, and inclusion, and asked if the sponsoring committee had concerns about this policy being blocked from moving forward. Contractor staff said they are not aware of potential impacts on this specific policy.

Next steps:

A summary of the committee's feedback will be posted on the public comment page on the OPTN website and shared with the sponsoring committee.

5. Regional Meeting Debrief, Transitional Nominating Committee Updates, and Open Forum Discussion

The Committee received and discussed updates on several topics.

Summary of discussion:

Regional meetings

Members shared their experiences attending the virtual regional meetings. Members missed the opportunity to interact with OPTN members in person but engaged as much as they could in the virtual format. Members appreciated the OPTN modernization feedback sessions and the opportunity to

engage with HRSA representatives. A member shared they felt like the discussion was more robust in the virtual format. The Vice Chair noted that the virtual format provides an opportunity for patient representatives to share feedback with multiple OPTN regions. A member reported an issue with the calendar invitation for the meeting. Contractor staff shared the registration information for the remaining regional meetings.

Transitional Nominating Committee

As a member of the Transitional Nominating Committee (TNC), the Vice Chair did not have further updates beyond what the HRSA representative presented earlier in the meeting. The Vice Chair recently asked for feedback from transplant doctors at a conference about their thoughts on establishing a smaller OPTN Board. As a patient representative on the committee, the Vice Chair is open to all feedback. Members discussed that there is some concern in the transplant community and among current Board members that the process lacks fairness and transparency. The Vice Chair said that the members of the Transitional Nominating Committee are very open to different perspectives. The Vice Chair noted that for this first election, the Board members must not have served on the OPTN Board of Directors in the last ten years and some members have concerns about that, as well as what constitutes a "conflict of interest". A member asked if that means there would only be a small pool of people from which to elect members, since this new Board will be very important. A member asked if there will be a loss of organizational memory that cannot be filled. The Vice Chair said the TNC has been discussing that. There will be a transition period between the Boards. The Vice Chair encouraged members to apply for the Board and to encourage their peers to apply. A member said they sought partners in this journey rather than medical providers and appreciated the Vice Chair speaking to that in these conversations.

Committee Member Terms

The Committee reviewed the list of members whose terms are scheduled to end on June 30, 2025, and Contractor staff reiterated that all members are offered the opportunity to extend their term by one year (not just including those members whose terms were slated to end on June 30, 2025). Committee members who wish to extend their terms or have additional questions should contact the OPTN Board Support contractor.

Allocation Out of Sequence Directive

Members are invited to participate in a workgroup developing policies in response to the HRSA directive on allocation out of sequence. The workgroup is requesting three representatives from the Committee. Members discussed attending the initial meetings and confirming participation after the meeting cadence is confirmed.

6. Closing

The Chair thanked the members for their participation and engagement in the meeting.

Upcoming Meetings

- April 15, 2025
- May 20, 2025

Attendance

- **Committee Members**
  - Molly McCarthy, Chair
  - Lorrinda Gray Davis, Vice Chair
  - Patrice Ball
  - Michael Brown
  - Liz DeVivo
  - Tonya Gomez
  - Calvin Henry
  - Karlett Parra
  - Andreas Price
  - Cathy Ramage
  - Cody Reynolds
  - Michael Slipowitz
  - John Sperzel
  - Steve Weitzen
  - Justin Wilkerson
- **HRSA Representatives**
  - Stephanie Grosser
  - Raymond Lynch
  - Kersten Smith
- **SRTR Staff**
  - Avery Cook
  - Earnest Davis
- **UNOS Staff**
  - Cole Fox
  - Kristina Hogan
  - Lindsay Larkin
  - Rebecca Murdock
  - Kelley Poff
  - Kaitlin Swanner
  - Tamika Watkins
- **Other Attendees**
  - Rachel Miller