

OPTN Patient Affairs Committee

Meeting Summary

April 15, 2025

Conference Call

Molly McCarthy, Chair

Lorrinda Gray Davis, Vice Chair

Introduction

The OPTN Patient Affairs Committee met via WebEx teleconference on 04/15/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Public Comment: Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates
3. Expedited Placement of Kidneys Project Discussion
4. Public Forum

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

1. Welcome and Announcements

The Chair welcomed the members. The Visiting Board Member (VBM) asked if members had any questions related to the OPTN Board of Directors (the Board).

Summary of discussion:

A member asked why some patient representatives chose to remain on the Board rather than resign. The VBM said they and other patient and donor representatives chose to stay on the Board to see the Board transition through, while other patient and donor representatives chose to resign. A member asked if new patient and donor representatives will be invited to join the Board. The VBM said the Board is actively working to back fill the gapped seats for the remainder of their terms, which end June 30. Establishing the new Board as of July 1 is a separate process and that process is continuing. A member thanked the VBM for staying on as they believed that is in the best interest of the organization and transplant patients. The VBM said they would be happy to join a future call with the committee or leadership to talk about recommendations the VBM provided to HRSA about how PAC could evolve. The Vice Chair asked how patient representatives will be informed about the current vacancies. The VBM said the Board is working on a plan to address this. The Vice Chair asked that the VBM send a message to HRSA to ensure that any patient representatives who are seated on the current Board to fill vacancies are not negatively impacted.

2. Public Comment: Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates

The Chair of the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) presented an overview of the special public comment proposal *Revisions to Human Immunodeficiency Virus (HIV) Policies to Align with Federal Regulatory Updates*.

Summary of discussion:

Committee members provided the following feedback in advance of the meeting:

- Support for intended changes and moving proposal forward to the Board of Directors as written
 - Support for the additional safety requirements being proposed
 - Respondents commented the proposal is thorough and straightforward
- Educational Considerations:
 - Candidates/recipients should read a summary version of the proposal
 - Clear pathway of communication to impacted candidates at programs not previously covered under the OPTN variance
- Additional Feedback: Suggestion to add clear policy on when and how candidates, at programs not previously covered on OPTN variance, will be notified of the new changes

The Chair asked if willingness to accept an organ with HIV is part of the efforts to promote broader acceptance of organs and shorten waiting list times. The DTAC Chair responded that currently, only candidates living with HIV can be offered organs from donors with HIV.

A member asked if there is any additional risk for a candidate living with HIV to accept an organ from a donor with HIV. The DTAC Chair responded that the outcomes in published literature have been very positive and the outcomes for these transplants are similar to outcomes for recipients with HIV who accept HIV negative organs.

A member noted that there are different types of diagnostic tests for HIV with different timelines for reporting results. The member asked if there have been cases of inadvertent HIV transmission from donor to recipient. The DTAC Chair said there have not been any inadvertent transmissions considering current screening approaches.

The Chair asked if the DTAC Chair had any further questions for the PAC. The DTAC Chair asked for any additional feedback on how to educate impacted candidates at programs not previously covered under the OPTN variance, as well as ensuring that the language in the policy is respectful and appropriate, and inclusive of all groups that are impacted.

A member asked how many candidates would need to re-confirm their acceptance of these organs and how many transplant programs had previously participated in the variance that left the variance. The DTAC Chair said they believe that to be a very small number of programs so few candidates would be impacted. The DTAC Chair said it is important to the Committee that re-documentation of willingness to accept HIV+ organs occur in a timely manner so as not to delay those candidates from appearing on match runs for HIV+ organs.

Next steps:

The Committee's feedback will be summarized for review by Committee leadership to be posted on the proposal public comment page on the OPTN website.

3. Expedited Placement of Kidneys Project Discussion

A member of the OPTN Kidney Transplantation Committee presented an update on the *Kidney Expedited Placement* project and requested feedback from the Committee.

Summary of discussion:

A member asked if there is information about the total cost of an unused kidney once it has been explanted. The presenter said they did not have that information but it is likely available. The member asked if there is an economic argument to be made that preservation devices should be more standard of care, since the viability of the organ drops precipitously after six hours. The presenter said that pump

technology has been used for kidneys for a long time but they are not highlighted as often because the pumps for other organs are newer technology and other organs are less able to withstand storage on ice than kidneys. The member asked what proportion of kidneys are pumped. The presenter said that it varies by organ procurement organization. The member said OPOs are often willing to pump and OPOs are doing everything they can to get organs allocated with the pressure they are facing. The presenter said that a lot of the cost for pumping are covered by the Medicare cost report if the organ is transplanted. A member suggested if the financial incentives are aligned, that should strengthen the donor pool and lead to fewer declines of organs.

A member asked if the rise in organs being placed out of sequence is largely due to less than perfect donor organs. The presenter said that some of it is due to the increased pressures on OPOs in facing decertification but it also appears in part to have started rising with implementation of the updated kidney allocation system in 2021 that provided for broader sharing. The presenter suggested that change in the allocation system may reflect concerns from OPOs about having more difficulty placing organs with cold ischemic time.

A member asked if candidates are adequately informed that some donor organs are less than perfect. The presenter said they personally share as much information as they can about each donor with their patients but practices may differ between transplant programs. The presenter supported a more uniform approach to delineating what patients need to know and understand, including the opportunity cost of declining an organ. The presenter said it would be helpful to have a standardized, easy to understand document or website to outline the essential facts to ensure patients get the information they need and it is not as dependent on individual physicians.

A member stated they were speaking as a recipient and a caregiver for a recipient. The member asked if these discussions are also being had with the caregiver, as patients are overwhelmed and also may lack the mental sharpness to comprehend the discussion and make an informed decision. The member emphasized the importance of the caregiver in this scenario. The member noted the requirement to share the program's acceptance criteria and asked if transplant programs would be required to communicate changes to their acceptance criteria to the patients and their caregivers. The presenter said that no such requirements exist but the CMS Increasing Organ Transplant Access (IOTA) model includes some requirements for patient transparency, including publicizing listing criteria for the transplant program, and acceptance criteria are to be discussed on a recurring basis (every six months). The draft OPTN policy aligns with the thinking of the CMS model. The presenter agreed that a support person for the patient is critical.

The Vice Chair said there are missed opportunities along the path of chronic kidney disease patients prior to dialysis as health literacy and a lack of urgency are problems before a patient gets to transplant.

A member stated that they were speaking as a caregiver and a donor of a kidney. The member asked whether hepatitis C kidneys would be considered hard to place and whether it is being adequately communicated that there is low risk to accepting these organs. The member said they have talked to multiple transplant programs and the guidance around acceptance of hepatitis C kidneys has been different. The presenter said there are two kinds of hepatitis C donors for kidneys. Some donors have history of hepatitis C and some donors have actively circulated hepatitis C virus. There is low risk of transmission for donors with history of hepatitis C. For donors with active hepatitis C virus, informed consent is required and candidates always have the right to say no. Treatment has improved such that these organs can be transplanted successfully. The presenter said some transplant programs may still be avoiding hepatitis C donors but most transplant programs have a pathway for accepting these donors. The member said the inconsistency is whether the programs are educating and informing the candidates up front about these types of offers. Some programs have candidates sign the consent immediately. The

member has spoken to potential recipients who are afraid of accepting these organs due to a lack of education. The presenter said they prefer to have these conversations earlier in the process and prior to an actual organ offer.

The Chair noted that they have had three transplants and do not recall ever having this conversation with a transplant program. The Chair supported the effort to standardize practices across transplant programs.

4. Public Forum

There were no public forum requests for this meeting.

Upcoming Meetings

- May 20, 2025
- June 17, 2025

Attendance

- **Committee Members**
 - Molly McCarthy, Chair
 - Lorrinda Gray Davis, Vice Chair
 - Patrice Ball
 - Michael Brown
 - Liz DeVivo
 - Tonya Gomez
 - Calvin Henry
 - Robert Johnson
 - Karlett Parra
 - Andreas Price
 - Cathy Ramage
 - Cody Reynolds
 - Michael Slipowitz
 - John Sperzel
 - George Surratt, Visiting Board Member
 - Steve Weitzen
 - Justin Wilkerson
- **SRTR Staff**
 - Avery Cook
 - Earnest Davis
- **UNOS Staff**
 - Cole Fox
 - Lindsay Larkin
 - Kaitlin Swanner
- **Other Attendees**
 - Stephanie Pouch
 - Jason Rolls