OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
January 14, 2025
Conference Call

Stephanie Pouch, MD, MS, Chair
Rachel Miller, MD, Vice Chair

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via WebEx teleconference on 01/14/2025 to discuss the following agenda items:

1. Review Policy Language & Vote: Remove Kidney and Liver from HOPE Act Variance

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

1. Review Policy Language & Vote: Remove Kidney and Liver from HOPE Act Variance

In November 2024, the Health and Human Services (HHS) Final Rule was issued to remove the research requirement for kidney, liver, and liver-kidney organs from donors with HIV to recipients with HIV. This means that under the Final Rule, kidney, liver, and kidney-liver transplant programs are no longer required to participate in the OPTN HOPE Act variance. The variance permits programs to participate in the HOPE Act (organs with HIV transplanted into candidates living with HIV) in compliance with the HHS and Institutional Review Board (IRB) research requirements.

Since these programs are not required to participate in the variance and submit clinical research in order to transplant an organ with HIV into a recipient living with HIV, OPTN policies must be updated to align with the changes in the HHS Final Rule. The Final Rule also removes the requirement from research criteria of 5 HIV donor-negative to recipient-positive transplants over 4 years for non-kidney and non-liver organs. These changes aim to broaden access by 1) removing the research criteria requirement for kidney and liver to reflect the safety of these transplants that have been demonstrated and 2) opening the criteria for the other organs.

These changes include:

- Update OPTN Policy to reflect liver, kidney, and liver-kidney no longer need to meet clinical research protocols. Non-kidney and non-liver organs would still need to participate in the variance and meet IRB protocols.
- Update OPTN Policy to require verification of HIV status and who verifies the status. Upon listing, identification of donor testing positive for HIV and prior to transplant. This proposed requirement is to provide additional patient safety measures.
- Update OPTN Policy to reflect non-stigmatizing language. This includes HIV-positive candidates to "Candidates living with HIV," etc.

The Committee met to review proposed changes to OPTN Policy regarding the HOPE Act and ensure that while access is broadened, patient safety is maintained.

<u>Data summary:</u>

- The HIV Organ Policy Equity (HOPE) Act was enacted in November 2013 and required research criteria for the transplantation of organs from donors with human immunodeficiency virus (HIV) into recipients with HIV.
- In 2015, the OPTN published an open variance that provided standards for transplant programs conducting HOPE Act transplants.
- In 2019, the variance was expanded to include all solid organs from just liver and kidney organs from donors with HIV.

Summary of discussion:

Decision #1: The Committee will continue to discuss the proposed policy language of OPTN Policy 15.7.D.

Decision #2: The Committee supported the policy language to send to the OPTN Board of Directors.

Regarding the proposed changes to policy language about requiring a physician to verify that the candidate is living with HIV and is willing to accept an organ for a donor with HIV, a member from HRSA provided context and stated that this was based on a case where there was a misreading of the HIV NAT results by a transplant coordinator. Due to this, it was critical to have two individuals review the results, with one of the individuals being a physician who could confirm the candidate's HIV status. A member expressed concerns about the physician being responsible for verifying the candidate's HIV status in the OPTN Donor Data and Matching System because not every transplant physician knows how to navigate the OPTN Computer System. She agreed that the physician should be responsible for interpreting and confirming the candidate's HIV status but should not be required to complete the verification in the OPTN System. She suggested that the transplant coordinator could document that the labs were reviewed by the transplant physician and include the name of the physician.

Another member asked if programs are asked to attest to verify the candidates and donor HIV status, will programs be required to attest to the verification status in the OPTN computer system or external to the system. Staff replied that the attestation is recorded in the medical record, not in the OPTN computer system.

Regarding the verification of the candidates' HIV status and willingness to accept an organ from a donor with HIV, the presenter asked the committee if it was appropriate to require a third verification to ensure patient safety measures when the patient is in the operating room (OR). The Chair replied that a third verification while the patient is in the OR is acceptable to ensure an extra layer of patient safety safeguard. Members did not disagree with the proposed policy language regarding the verification process.

The Committee reviewed the proposed policy language outlining the requirements for transplant programs participating in the variance. Specifically, programs must adhere to NIH protocols and participate in an institutional review board (IRB)-approved research protocol that meets the criteria of the HHS NIH Final Rule for recovering and transplanting non-kidney and non-liver organs from donors with HIV. Non-liver and non-kidney programs will also be required to have a data safety monitoring board (DSMB) and submit DSMB reports to the OPTN upon request. Members expressed concerns about what the OPTN will do with these reports and where the reports would be sent. Staff asked the committee if the proposed policy requirements were sufficient to ensure participation in the variance can be maintained safely. A member asked how the OPTN received the DSMB reports. Staff replied that these reports are received through a mechanism separate from the OPTN Patient Safety Reporting Portal. Another member stated that it needs to be better understood what the obligations of the OPTN

are when monitoring the variance and understanding how to collect information in an organized way to ensure that the variance is being appropriately utilized.

Does the Ad Hoc Disease Transmission Advisory Committee support the policy language to send to the OPTN Board of Directors?

Support: 13 Abstain: 0 Oppose: 0

Next steps:

The Committee will continue to discuss the HOPE Act project.

Upcoming Meeting

- January 24, 2025

Attendance

- **Committee Members**
    - Stephanie Pouch
    - Lara Danziger-Isakov
    - Rachel Miller
    - Dong Lee
    - Fernanda Silveira
    - Cindy Fisher
    - Helen Te
    - Riki Graves
    - Gerald Berry
    - Jas Kaur
    - Gabriel Maine
    - Shirish Huprikar
    - Riki Graves
- **HRSA Representatives**
    - Marilyn Levi
- CDC Representatives
    - Pallavi Annambhotla
    - Kelsey McDavid
    - Irma Sison
    - David McCormick
    - Sridhar
    - Ian Kracalik
- **SRTR Staff**
- **UNOS Staff**
    - Tamika Watkins
    - Cole Fox
    - Susan Tlusty
    - Rebecca Murdock
    - Houlder Hudgins
    - Dzhuliyana Handarova
    - Sandy Bartal
    - Logan Saxer
    - Andrew Klein
- **Other Attendees**
    - First Name Last Name