

OPTN Ad Hoc Disease Transmission Advisory Committee

Meeting Summary

December 9, 2022

Conference Call

Lara Danziger-Isakov, MD, MPH, Chair

Stephanie Pouch, MD, MS, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee HIV positive vs. HIV infected Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 12/09/2022 to discuss the following agenda items:

1. Workgroup Purpose Overview and Meeting Recap
2. Two Year Evaluation of the Modification of OPTN HOPE Act Variance to Include Other Organs
3. Current HOPE Act and HIV Data
4. Discussion

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

1. Workgroup Purpose Overview and Meeting Recap

The Vice Chair gave an overview of the primary goals of the Workgroup. She emphasized the intention of this Workgroup is to ensure patient safety by clarifying OPTN policy, so no Human Immunodeficiency Virus (HIV) infected organs are transplanted into HIV uninfected recipients. She explained that current policy uses the term "positive" not "infected" for HIV.

Multiple situations have arisen in which OPOs have had at least one positive HIV result, however based on clinical judgment and additional negative tests, it is believed that the positive test result is inaccurate, and that donor is not infected with HIV. These situations are sometimes referred to as false positives. Policy states that HIV positive organs must be allocated within the HOPE act framework and the OPTN Computer system is set up that any HIV positive result for a deceased donor entered in the system will then automatically shift the donor to only show up for HOPE Act eligible candidates. Policy does not have any allowances or variances for donors that may have had a positive result but are not believed to be HIV infected.¹

The goals for the Workgroup are to either:

1. Clarify policy that any deceased donor HIV positive result requires allocation only to HIV infected candidates

This would mean that the use of an algorithm, further testing, or clinical judgment to classify a donor with an HIV positive test that may not reflect HIV infection would be prohibited specifically in OPTN policy.

2. Determine circumstances in which a deceased donor with an HIV positive result can be allocated as HIV uninfected to an HIV negative candidate (circumstances in which a testing algorithm with

¹ OPTN Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors (Accessed December 15, 2022) https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

potential clinical judgment can be used to determine that a positive result is likely not indicative of HIV infection)

This would mean that an algorithm could be utilized (with potential clinical judgment) in situations where the Workgroup could define a test result not to be a true positive HIV result indicating HIV infection.

The Vice Chair noted that the previous meeting had led to a lack of clarity on the size of the problem. Workgroup members questioned how many donors and recipients this would impact, and how the potential removal of the research variance for kidney and liver HIV Organ Policy Equity (HOPE) Act transplants could impact these numbers.

Summary of discussion:

There was no further discussion by the Workgroup.

2. Two Year Evaluation of the Modification of OPTN HOPE Act Variance to Include Other Organs

Staff presented on the two-year evaluation (as of August 2022) of the modification of OPTN Hope Act Variance to include other organs. Staff concluded that:

- The first HIV positive to HIV positive heart transplant was performed in the last quarter
- There are now two heart transplant programs approved under the HOPE Act Expansion
- Most HOPE Act transplants are kidney and liver transplants

Data Summary:

After the implementation of the [HOPE Act OPTN policy variance](#) for kidneys and livers on November 21, 2015, the number of HIV positive donors recovered per month has fluctuated between 0 to 8 donors recovered per month. On May 21, 2020, the HOPE Act variance was expanded to include all organs. Most HOPE Act transplants have been kidney transplants. In April 2022, there was one heart transplant that occurred under the variance, which is the only non-kidney and non-liver transplant performed under the HOPE Act.

The number of programs approved under the HOPE Act has declined slightly in the last couple of quarters. This is likely driven by the decrease in deceased donor kidney programs overall. There are two programs approved for heart transplants under the HOPE Act. The number of current OPTN Waiting List registrants willing to accept an HIV positive organ has declined over time. This is primarily due to kidney candidates indicating in the OPTN Computer System they are less willing accept HIV positive organs over time.

As of 12/9/22, there have been 392 transplants performed under the HOPE Act.

Summary of discussion:

Staff noted we do not collect HIV status of candidates on the OPTN Waiting List. A member asked the geography of those transplanted under the HOPE Act and the geography of HIV positive candidates waiting on the OPTN Waiting List. She noted allocation changes may affect these trends. Staff responded most transplants under the HOPE Act have been performed by two programs on the east coast.

A member asked about the number of HIV positive donors that have been utilized and whether these trends are the same as they are for recipients. Staff responded the number of HIV positive donors has been relatively steady across time. Staff stated there were 235 donors recovered through early this year, and 186 resulted in at least one transplant.

HRSA staff asked the reason for the decrease in the number of centers that perform transplants under the HOPE Act. Staff shared that several programs have decided not to perform these transplants and several programs have an OPTN approved variance under an IRB protocol but have not performed a HOPE Act transplant.

A member asked if HIV positive candidates have access to HIV negative organs. Staff responded yes.

3. Current HOPE Act and HIV Data

Data Summary:

As of 11/21/22, there were almost 90,000 candidates awaiting transplantation of kidneys and almost 11,000 candidates awaiting transplantation of livers. There is an evolving gap in the increased number of candidates and the number of organs procured. There are an estimated 50-100 donor organs each year that have had a positive HIV test that was believed not to reflect a true HIV infection or termed “false positive”. The study that produced this estimate also posited that if those organs were all utilized, .3% of the heart transplant list and 1% of the lung transplant list could be transplanted per year².

Summary of discussion:

CDC staff noted not all organs would be utilized, so the idea that .3% of the heart transplant list and 1% of the lung transplant list could be transplanted per year is not completely accurate. It was shared that the national average of organs utilized per donor is 3.2. CDC staff stated that not every heart or lung would be recovered, so this would only apply if every organ from every donor was utilized. It was noted by others that it could be accurate to use the 3.2 average organs per donor (as this accounts for the fact that not every donor has all organs recovered) and multiply by the estimated range of 50-100. A member stated this is the maximum number of transplants that could be performed if this number of positive HIV tests was determined to be from HIV uninfected donors. A member commented this may be a low percentage, but it is meaningful when saving lives.

A member noted it is a cumbersome process to transplant under the HOPE Act. A member stated organ allocation should be maximized by ensuring positive test results are from HIV infected donors. A member responded he is unsure how many programs would sort through which donors are HIV positive but HIV uninfected.

CDC staff explained the dynamics of HIV infection has changed as more at-risk people are on pre-exposure prophylaxis (prEP) which interferes with the diagnostics. CDC stated it is too risky in adult donors to discern a non-infectious status aside from a positive result, and risk criteria are not always known. A member agreed that this is different in the presence of prEP. CDC staff stated it is easier to know when a pediatric donor is on prEP. Staff responded that if an organ from a donor with at least one HIV positive result has been utilized in a HIV-negative recipient, the case is referred to the OPTN Membership Professional Standards Committee.

A member stated the community needs guidance and organ procurement organizations (OPOs) need policy to guide them in these scenarios. He also explained that at least 30% of donors have risk factors and organs are still utilized, and the risk in not providing an algorithm and losing around 300 potential transplants. The Vice Chair emphasized that policy would have to either allow an algorithm to determine

² Durand, Christine M., Samantha E. Halpern, Mary G. Bowring, Gilad A. Bismut, Oyinkansola T. Kusemiju, Brianna Doby, Reinaldo E. Fernandez, et al. “Organs from Deceased Donors with False-Positive HIV Screening Tests: An Unexpected Benefit of the Hope Act.” *American Journal of Transplantation* 18, no. 10 (2018): 2579–86. <https://doi.org/10.1111/ajt.14993>.

an HIV positive test from an HIV uninfected donor or prohibit HIV-negative recipients receiving an organ from a donor with any HIV positive test.

A Workgroup member asked if organ non-utilization attributed to a HIV positive donor could be examined. Staff explained that certain codes allow staff to see when an organ is not utilized based on a positive infectious disease test, but not specifically for HIV. The member emphasized that this data needs to be collected. Staff explained that organ utilization for donors that go through the HOPE Act match runs could be examined. The member responded this data would be contaminated by the lack of HIV positive candidates on the OPTN Waiting List.

A member stated if HIV positive donors who are HIV uninfected can be allocated to a greater population, every candidate would benefit. The member noted this is most beneficial to pediatric candidates. A member responded this algorithm could be conservative and keep in mind risk of transmission and organ utilization.

CDC staff stated there are false negative Nucleic Acid Testing (NAT) tests as well. CDC staff explained that there are plenty of organs lost to other infectious diseases as well, and HIV tests have some of the highest specificity on the market.

4. Discussion

The need for a decision that the Workgroup is charged with making was repeated for clarity of scope:

1. Clarify policy that any deceased donor HIV positive result requires allocation ONLY to HIV infected individuals

This would mean that the use of an algorithm, further testing, or clinical judgment to classify a donor with an HIV positive test that may not reflect HIV infection would be prohibited specifically in OPTN policy.

OR

2. Determine circumstances in which a deceased donor with an HIV positive result can be allocated as HIV uninfected to an HIV negative candidate (circumstances in which a testing algorithm with potential clinical judgment can be used to determine that a positive result is likely not indicative of HIV infection)

This would mean that an algorithm could be utilized (with potential clinical judgment) in situations where the Workgroup could define a test result not to be a true positive HIV result indicating HIV infection.

Summary of discussion:

Members agreed that a risk benefit assessment should be allowed. Members agreed to attempt to provide an algorithm to determine a situation where a donor has an HIV positive test and can be allocated as HIV uninfected. A member noted the treatment of HIV has completely changed. A member suggested part of this effort should attempt to gather data on HIV positive tests that come from HIV uninfected donors. The member stated the OPO community would be in favor of this.

CDC staff noted that the OPTN could focus on improving allocation of HIV positive organs to HIV positive recipients. A member responded that management of HIV has changed, and the geography of HIV candidates is unknown.

Upcoming Meeting

- TBD

Attendance

- **Committee Members**
 - Emily Blumberg
 - Dong Lee
 - Jonah Odim
 - Kelly Dunn
 - Marty Sellers
 - Stephanie Pouch
 - Ricardo La Hoz
 - Lorenzo Zaffiri
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **CDC Staff**
 - Michele Owen
 - Sridhar Basavaraju
- **UNOS Staff**
 - Amber Fritz
 - David Klassen
 - Krissy Laurie
 - Samantha Weiss
 - Susan Tlusty
 - Taylor Livelli