

Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

*OPO Committee
June 1-2, 2015*

The Problem

- Current policy prohibits recovering or transplanting an organ from a deceased donor with HIV
- HIV Organ Policy Equity Act (HOPE Act)
 - Enacted 2013
 - Permits research into transplanting organs from HIV positive donors to HIV positive recipients
 - Requires the OPTN to revise its “standards of quality” (i.e. policies) by November 21, 2015.

Strategic Plan Alignment

Goal 1: Increase the number of transplants

- By increasing the number of organs available for transplant

Goal 2: Increase access to transplants

- By increasing the organs available for HIV+ candidates

Proposed Solutions

- Create an open variance for the allocation and transplantation of HIV+ organs into HIV+ recipients
- Establish specific member requirements for participation in the variance
- Require second verification of HIV+ candidates' willingness to participate in the study
- Create an exception to the exclusion criteria for living donors
- Prohibit storage of extra vessels from HIV+ donors

Public Comment Themes

- Inclusion of living donors
 - Mixed responses
 - Concern about informed consent, follow-up, and medical evaluation for living donors
 - Unknown long-term effects for HIV+ living donors
- Other Issues
 - IRB process
 - Impact on PSRs
 - Vessel storage

Post-public comment action

- Added requirement that transplant hospitals also notify the OPTN contractor if they are no longer participating in a research study
- Added notice that the list of participating transplant programs will be publicly available.
- Added requirement for specific member action for directed donations to candidates not appearing on the match run due to ABO

What Members will Need to Do

- Transplant centers:
 - Notify the OPTN contractor if participating in an IRB-approved research protocol that meets the requirements in the Final Rule regarding the recovery and transplantation of HIV positive organs
 - Complete a two-person reporting and verification process in order for HIV positive candidates to appear on the match run
 - Obtain specific informed consent before transplant of HIV positive organs
 - Members must not store extra vessels from HIV positive donors

What Members will Need to Do

- OPOs may allocate organs only after determining the potential deceased donor is HIV positive and the HIV positive candidate is willing to accept an HIV positive organ as part of a research protocol.

NIH Research Criteria Review

Publication in the Federal Register – Date TBD

- Hope Act Work Group will review the criteria and submit recommendations to the Executive Committee
- Executive Committee will finalize the OPTN response

Overall Project Impact

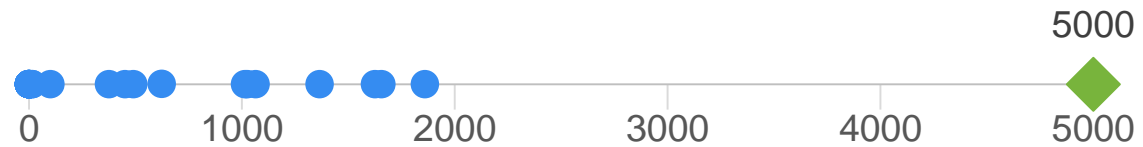
Product

Policy

Target Population Impact:

HIV+ Transplant Candidates and Recipients

Total IT Implementation Hours



Total Overall Implementation Hours



Board Policy Group Recommendation

- Discussion agenda, approve

Resolution 17 (page 77)

- RESOLVED, that additions and modifications to Policies 2.7.A (Exceptions to HIV Screening 1 Requirement), 5.3.C (Liver Acceptance Criteria), 5.4.B (Order of Allocation), 5.4.F (Allocation to 2 Candidates Not on the Match Run), 13.6.B (Requirements for Match Run Eligibility for Potential 3 KPD Donors), 14.4.E (Living Donor Exclusion Criteria), 15.3 (Informed Consent of Transmissible 4 Disease Risk), 15.4.A (Transplant Program Requirements), 15.6 (Open Variance for the Recovery 5 and Transplantation of Organs from HIV Positive Donors), 16.7.B (Vessel Recovery, Transplant, 6 and Storage), 16.7.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), and 7 16.7.E (Blood Type Verification Prior to Transplant of Living Donor Vessels), as set forth in Resolution 17, are hereby approved, effective pending implementation and notice to members.

Backup Slides

Supporting Evidence

- The OPTN does not currently collect the HIV status of candidates on the waiting list so the exact number of potential candidates that could benefit from this policy change is unknown.
- Over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013.
- 2011 publication by Boyarsky et al maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year.
- A recent abstract by A. Cash et al, presented at the American Transplant Congress, estimates there are nearly 2500 potential HIV deceased donors per year in the United States.