

Report to the OPTN Board of Directors on

Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with Positive HIV Test Results

OPTN Ad Hoc Disease Transmission Advisory Committee

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Clarification of OPO and Living Donor Recovery Hospital Requirements for Organ Donors with Positive HIV Test Results

Sponsoring Committee: Ad Hoc Disease Transmission Advisory
Public Comment Period: July 27, 2023 – January 19, 2023
Board of Directors Date: December 4, 2023

Executive Summary

The Ad Hoc Disease Transmission Advisory Committee (the Committee) aimed to gather relevant data to consider the creation of an algorithm that would account for situations where a donor may have a positive Human Immunodeficiency Virus (HIV) test but does not have HIV infection. The Committee hoped to identify:

1. What (if any) test results could be used to classify a deceased donor as not infected with HIV although the donor has at least one positive HIV test result?
2. What (if any) test results could be used to classify a living donor as not infected with HIV although the donor has at least one positive HIV test result?
3. What (if any) clinical judgment or individual protocols would be appropriate and consistent with requirements to assess situations where the donor is not thought to be infected although there is a positive HIV result?

The exact number of times a donor has a positive HIV test but is later found to be HIV uninfected and is therefore allocated to a recipient without HIV is unknown. Therefore, the Committee had little data to support the creation of the algorithm. The purpose of this concept paper was to request feedback from the community to inform a future policy proposal. The Committee received and reviewed feedback from public comment. The Committee is not moving forward with developing a public comment proposal at this time but may reassess the need in the future.

Overview of the Request for Feedback

Purpose

The Committee aimed to gather data on the number of donors with a positive HIV test who are not infected in order to inform the development of an algorithm. The OPTN Membership and Professional Standards Committee (MPSC) requested the Committee develop an algorithm to address these situations due to instances where an OPO has allocated an organ as HIV uninfected despite a positive HIV test. An algorithm would help standardize practices among OPOs and living donor recovery hospitals, and reduce the risk of HIV transmission through organ transplantation.

The Committee submits this proposal under the authority of the NOTA, which states, "In adopting and using standards of quality under paragraph (2)(E), the Organ Procurement and Transplantation Network may adopt and use such standards with respect to organs infected with human immunodeficiency virus (in this paragraph referred to as "HIV"), provided that any such standards ensure that organs infected with HIV may be transplanted only into individuals who- (A) are infected with HIV before receiving such organ..."¹ and under the authority of the OPTN Final Rule, which states, "Organs from individuals infected with human immunodeficiency virus (HIV) may be transplanted only into individuals who— Are infected with HIV before receiving such organs..."²

Questions asked of the Community

- How often do OPOs or laboratories encounter donors who have at least one test that is positive for HIV but are not thought to be infected? Please be as specific as possible.
- Do OPOs need a testing algorithm to address donors who have at least one test that is positive for HIV but are not thought to be infected?
- Due to risk of transmission, does it make sense to create this algorithm only for pediatric donors?
- What percent of organs from donors with a positive HIV test are not utilized? Please be as specific as possible.
- How often are living donor recovery hospitals encountering living donors who have at least one test that is positive for HIV but are found not to be infected through confirmatory testing? Please be as specific as possible.
- How often are OPOs and living donor recovery hospitals receiving positive fourth generation HIV test results for a SARS-CoV-2 positive donor? Please be as specific as possible.

Summary of Public Comment Feedback

Commenters covered many different topics, including the following themes. Each theme is described based on the feedback provided. Themes included:

- Support for an algorithm
- Request for clear guidelines for testing
- Concern about turnaround time and availability of confirmatory testing
- Concern about utilization of HIV-positive organs

¹ 42 USC §274(b)(3)(a).

² 42 CFR §121.6(b)(1)(i).

Support for an algorithm

There was general support for the development of an algorithm that would allow OPOs and living donor recovery hospitals to classify a donor as HIV uninfected despite having a positive HIV test. Members expressed sentiment that an algorithm would help maximize organ utilization while minimizing the risk of transmission of HIV through organ transplantation. Members also agreed that the discrepant terminology between 'HIV positive' in OPTN policy and 'HIV infected' in the OPTN Final Rule needs clarification.

Request for clear guidelines for testing

In addition to support for an algorithm, members requested clear guidelines and consistent protocols when allocating HIV-positive organs to increase organ utilization while maintaining patient safety.

Concern about turnaround time and availability of confirmatory testing

Some members expressed concern over the length of time required to receive HIV confirmatory testing results. They also noted some OPOs and smaller laboratories will not have access to certain types of HIV tests.

Concern about utilization of HIV-positive organs

Members voiced concern about discrepant test results increasing nonuse rates of HIV-positive organs. Some members emphasized the increasing nonuse rates of HIV-positive organs, but other members cautioned that different HIV test results could further exacerbate this issue.

Next Steps

The Committee discussed the feedback gathered through public comment and reconvened the HIV positive vs. HIV infected Workgroup to discuss next steps. The Workgroup agreed an algorithm that would classify a donor with a positive HIV test as uninfected with HIV would be challenging due to testing turnaround time. The Workgroup also agreed that the concept paper showed a limited scope of this issue and that this should not be prioritized over other Committee work. Some Committee members commented that nonuse of HIV-positive organs disproportionately affects thoracic organs. The Committee agreed this should continuously be monitored, but an algorithm is not currently feasible and could threaten patient safety. Workgroup members noted that donor history is often unreliable and unavailable, so relying on this information to help develop an algorithm in specific situations could increase the risk of transmission.

The Workgroup also discussed aligning the language in OPTN policy with the OPTN Final Rule to state 'HIV infected.' The Committee cautioned against this change as it would allow for clinical decision-making at OPOs and living donor recovery hospitals where the required expertise does not exist. Centers for Disease Control and Prevention (CDC) staff suggested that the MPSC use infectious disease member expertise and clinical judgment to review and determine the appropriateness if a donor organ has been allocated as HIV uninfected despite a positive HIV test.