OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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February 24, 2023

BY ELECTRONIC MAIL

Mr. Christopher McLaughlin
Division of Transplantation
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Mr. McLaughlin,

The intent of this letter is to relay our concerns regarding the implementation of the recommendations of the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) to the U.S. Secretary of Health and Human Services (the Secretary).[1] The OPTN is supportive of deleting the HIV Organ Policy Equity (HOPE) Act variance in OPTN policy for kidney and liver transplants, and supports revising OPTN designated transplant program experience criteria to allow for increased participation in performing these transplants. The OPTN is concerned that the removal of specific variances may lead to inequitable barriers for non-kidney and non-liver HOPE Act transplants and that the 15-month timeline implementation for an OPTN organ-specific variance is too limited for OPTN data collection processes. The OPTN Disease Transmission and Advisory Committee (DTAC) leadership and the OPTN Executive Committee reviewed the ACBTSA's recommendation to the Secretary and identified potential considerations around developing additional data collection and organ-specific outcomes for candidates and recipients. The ACBTSA recommended that "the Secretary direct the OPTN to develop and implement…new special policies…" and the OPTN's responses to each are detailed below.

1. OPTN organ-specific variance for each organ other than kidneys and livers

It is unclear what an OPTN "organ-specific" variance entails. It is assumed the OPTN could continue with something like the current HOPE variance that covers all organs. While it is possible that any change to remove required research criteria may require revision to the OPTN Final Rule, it is uncertain if or what other changes may be required if some organs remain under a required research criteria component other than what exists today. In accordance with the Final Rule requirements, the HHS Secretary has published specific criteria through the Federal Register process. Putting the OPTN in charge of developing these criteria, as opposed to the current process under the National Institutes of Health, may impact how and what needs to be changed. While the OPTN would offer assistance as needed or requested, it may require further legal analysis and changes that have not been fully anticipated.

[1] https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/recommendations/2022-11/index.html.

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Section 121.6 (b)(1)(2)(b) of the OPTN Final Rule requires the Secretary to publish, "through appropriate procedures" if it is determined that participation under the current research requirements is no longer warranted. Please see Appendix A at the end of this document for some highlighted relevant sections of federal law and regulation.

2. Additional organ-specific candidate criteria and transplant program requirements analogous (but not "identical") to the NIH Research Criteria developed specifically for the unique patient safety and outcomes monitoring characteristics of transplants other than kidneys and livers in HIV patients

The OPTN could essentially continue to incorporate the current NIH criteria into OPTN bylaws or policies but change the experience criteria that transplant programs must meet. Defining "…unique patient safety and outcomes monitoring characteristics…" would require work by subject matter experts and the formation of an OPTN Workgroup. This expertise does not exist on the organ specific committees currently, nor on the DTAC. For some organs, such as vascularized composite allografts (VCA), there is no data at all. No other donor or recipient requires the level of regulation that HIV positive donors and recipients do. Additionally, the OPTN does not currently collect status of HIV candidates on the OPTN Waiting List. The implications of this recommendation depend on how broadly the Secretary ultimately applies the ACBTSA's recommendation.

3. Additional organ-specific OPTN outcomes monitoring for candidates of organs other than kidneys and livers on the Waiting List and recipients following transplantation

This requirement could be a challenge if it requires the OPTN to define and collect these data. The OPTN does not collect HIV status of candidates. The OPTN monitors transplant outcomes specific to the organ received. The Office of Management and Budget (OMB) approved follow-up forms are not designed specifically to monitor impacts from infectious disease. These disease transmission impacts are monitored through required safety reporting. Additional data collection would require determination of authority and going through the OPTN's data collection processes (including distributing a proposal to collect these new data for public comment, obtaining OPTN Board of Directors approval, and submitting the new information collection to the OMB to go through its approval processes). Despite the positive impact of removing the research criteria for kidney and liver HOPE Act transplants, it will take significant time to develop a dataset that reflects the safety of non-kidney and non-liver HOPE Act transplants due to the lack of active centers and the barriers the research criteria pose.

Furthermore, currently, there are very few candidates listed for organs other than kidney and liver. There have only been a few heart candidates ever listed. Developing evidence-based organ-specific outcomes for non-liver or kidney transplants could therefore be quite challenging.

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4. Each center/institution must have an IRB-approved protocol that will include measures of outcomes and safety

This recommendation is consistent with current processes.

5. When multiple organs are transplanted simultaneously, the default approach will be to use the guidelines of the organ with more conservative policies

This recommendation would likely require OPTN policy revisions and subsequent operational implementation changes. While this can be achieved, it would add complexity both in implementation and community education for a rare event and may have an unintended consequence of delaying patient access. For example, only two programs in the US are currently approved to perform HOPE Act heart transplants.

6. The OPTN should develop and implement the above-listed new special policies within 15 months of receiving this request from the Secretary of Health and Human Services

Depending on what the new organ-specific OPTN outcomes monitoring includes, this timeline could be difficult to achieve due to the regulatory requirement that the OPTN develop its policies with the opportunity for public comment and the contractual requirement to obtain Office of Management and Budget (OMB) approval for any new data elements; as well as sufficient time for system implementation and community education. If the Secretary ultimately requests the OPTN implement ACBTSA's recommendations, a broader directive without a specific timeframe, or a timeframe that matches up with the OPTN's typical public comment and Board meeting cycles, would be preferable.

Conclusion

We are supportive of removing barriers to performing additional transplants for HIV positive candidates with organs from HIV positive donors. We appreciate your attention to our concerns. We would welcome the opportunity to discuss any of these issues further as the HHS Secretary considers recommendations on the next steps for this important work.

Sincerely,

Jerry McCauley, MD, MPH
President, OPTN Board of Directors

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Appendix A
Select National Organ Transplant Act (NOTA) and OPTN Final Rule Sections Related to the HOPE Act

NOTA: 42 USC 274: Organ procurement and transplantation network

§274f–5. Criteria, standards, and regulations with respect to organs infected with HIV

(a) In general

Not later than 2 years after November 21, 2013, the Secretary shall develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with human immunodeficiency virus (in this section referred to as "HIV") into individuals who are infected with HIV before receiving such organ.

(b) Corresponding changes to standards and regulations applicable to research

Not later than 2 years after November 21, 2013, to the extent determined by the Secretary to be necessary to allow the conduct of research in accordance with the criteria developed under subsection (a)-

(1) the Organ Procurement and Transplantation Network shall revise the standards of quality adopted under section 274(b)(2)(E) of this title; and

(2) the Secretary shall revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(c) Revision of standards and regulations generally

Not later than 4 years after November 21, 2013, and annually thereafter, the Secretary,[1] shall-

(1) review the results of scientific research in conjunction with the Organ Procurement and Transplantation Network to determine whether the results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

(2) if the Secretary determines under paragraph (1) that such results warrant revision of the standards of quality adopted under section 274(b)(2)(E) of this title with respect to donated organs infected with HIV and with respect to transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV, direct the Organ Procurement and Transplantation Network to revise such standards, consistent with section 274 of this title and in a way that ensures the changes will not reduce the safety of organ transplantation; and

(3) in conjunction with any revision of such standards under paragraph (2), revise section 121.6 of title 42, Code of Federal Regulations (or any successor regulations).

(July 1, 1944, ch. 373, title III, §377E, as added Pub. L. 113–51, §2(b), Nov. 21, 2013, 127 Stat. 580 .)

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a

OPTN Final Rule: 42 CFR 121 Organ Procurement and Transplantation Network

§ 121.6 Organ procurement.

(b) HIV.

(1) Organs from individuals infected with human immunodeficiency virus (HIV) may be transplanted only into individuals who -

(i) Are infected with HIV before receiving such organ(s); and

(ii)

(A) Are participating in clinical research approved by an institutional review board, as defined in 45 CFR part 46, under the research criteria published by the Secretary under subsection (a) of section 377E of the Public Health Service Act, as amended; or

(B) The Secretary has published, through appropriate procedures, a determination under section 377E(c) of the Public Health Service Act, as amended, that participation in such clinical research, as a requirement for transplants of organs from individuals infected with HIV, is no longer warranted.

(2) Except as provided in paragraph (b)(3) of this section, the OPTN shall adopt and use standards of quality with respect to organs from individuals infected with HIV to the extent the Secretary determines necessary to allow the conduct of research in accordance with the criteria described in paragraph (b)(1)(ii)(A) of this section.

(3) If the Secretary has determined under paragraph (b)(1)(ii)(B) of this section that participation in clinical research is no longer warranted as a requirement for transplants of organs from individuals infected with HIV, the OPTN shall adopt and use standards of quality with respect to organs from individuals infected with HIV as directed by the Secretary, consistent with 42 U.S.C. 274, and in a way that ensures the changes will not reduce the safety of organ transplantation.