

October 29, 2021

Xavier Becerra, Secretary, HHS
Health Resources and Services Administration
Department of Health and Human Services Rockville, MD 20857

Dear Secretary Becerra,

The Organ Procurement and Transplantation Network (OPTN) is writing this letter to recommend that the Secretary remove the research requirement for organ transplants from HIV positive organ donors to HIV positive transplant recipients. The Human Immunodeficiency Virus Organ Policy Equity Act (HOPE Act, P.L 113 – 51) specifies this research requirement and its review by the Secretary and the OPTN.

Removal of this research requirement will allow wider adoption of the highly successful HOPE Act initiative for transplantation of organs from HIV+ donors. This action will significantly increase organ transplants for HIV+ transplant candidates who continue to have limited access to live-saving organ transplants.

The OPTN was set up under the authority provided by the National Organ Transplant Act (NOTA; P.L. 98 – 507) passed by Congress in 1984. The primary purpose of the OPTN is to operate and monitor an equitable system for allocating organs donated for transplantation, maintain a waiting list of potential recipients, and facilitate the efficient, effective, and safe transplantation for all patients in need. The original NOTA legislation expressly forbade transplantation of organs from donors known to be HIV positive. Patients who are HIV positive have limited access to organ transplantation despite having good transplant outcomes. These good outcomes are the result of progressive improvements in the medical care of HIV+ individuals. In recognizing the limited transplant access and the dramatic improvement in the medical care of HIV+ individuals, Congress passed the HOPE Act in November 2013. The goal of the HOPE Act, which amends NOTA, is to improve access to organ transplantation for HIV positive patients by permitting the transplantation of organs from donors known to be HIV positive into recipients also known to be HIV positive.

The HOPE Act legislation requires these HIV positive donor to HIV positive recipient transplants be done under Institutional Review Board (IRB) approved research protocols and to follow research criteria developed by the National Institutes of Health (NIH). The OPTN revised policies for acquisition and allocation of donated organs from donors positive for HIV in accordance with the HOPE Act in November 2015, and modified policy and programming to allow HIV positive to HIV positive kidney and liver transplantation under an OPTN HOPE Act research policy variance. The HOPE Act requires the Secretary and the OPTN to review annually the results of the scientific research conducted under the NIH research criteria to determine whether the results warrant further revisions to the OPTN standards of quality. Under the HOPE Act, the Secretary may determine that participation in research under the NIH criteria is no longer required for HIV positive donor to HIV positive recipient transplants.

An OPTN Safety Review group has met annually since the implementation of the OPTN HOPE Act variance in 2015 to review data safety monitoring review board (DSMB) reports. These reports are submitted to the OPTN by participating programs as part of the IRB research safety requirements and as a requirement for participation in the OPTN HOPE Act allocation variance. The group is comprised of the OPTN Chief Medical Officer, a biostatistician, and six members of the transplant community including kidney and liver transplant surgeons and infectious disease physicians. The group reviews both OPTN aggregate volume and descriptive data as well as data addressing the NIH research criteria. Seven annual/semi-annual DSMB reports are regularly reviewed: the NIH sponsored kidney UO1 multi-center trial, the NIH sponsored liver UO1 multi-center trial, the HOPE in Action multi-center pilot trial for kidney and liver, the UCSF HOPE trial for kidney and liver, and the UAB HOPE trial. For the first four years of the HOPE Act, the Safety Review group recommended continuation of the HOPE Act research variance and continuing to perform HIV positive to HIV positive transplants under the NIH research criteria.

After five years of HOPE Act transplants, the clinical experience includes over 300 HIV positive patients who have received organ transplants under the OPTN HOPE Act research variance. There have been no patient safety concerns identified by any DSMB. No protocol has been halted, paused, or substantially amended to address recipient safety concerns. Within the well-established OPTN, safety reporting structures there have been no reports of safety issues related to HOPE Act transplantation among Organ Procurement Organization, hospital, or transplant center personnel or in patients in donor hospitals or transplant hospitals.

The OPTN is entering the sixth year of HOPE Act transplantation. With the continued absence of any safety concerns reported to the OPTN directly or through rigorous DSMB oversight, the Safety Review group met in June of 2021 and unanimously agreed to recommend the Secretary remove the research requirement for HOPE Act transplantation. They recommend that the OPTN revise policy to make HIV positive donor to HIV positive recipient organ transplantation permissible for HIV positive patients willing to accept HIV positive organs. It is important to note that this recommendation pertains only to HIV positive donor to HIV positive recipient transplantation and does not allow transplantation of HIV positive organs into HIV negative recipients which is not permitted under NOTA and remains unchanged. It was the opinion of the Safety Review group that the research requirement represents a barrier to fully realizing the potential of the HIV positive donor pool and limits access to transplantation by HIV positive patients.

Current OPTN policy reflects the requirement that HIV organ transplants take place within IRB approved research protocols and according to NIH criteria. If the Secretary determines that these criteria are no longer required, the OPTN will initiate a process to revise its policies regarding HIV positive organs. The OPTN would pair any revised HIV-specific requirements with the existing, well-established OPTN disease transmission prevention and reporting mechanisms that already provide for closely monitoring transplant numbers and outcomes in all transplant recipients. OPTN policy mandates reporting and investigation of any potential donor-derived HIV disease transmission through the existing patient safety portal. The OPTN's evaluation of patient and system safety will provide review and, if necessary, continuing updates to OPTN policy and operations in order to protect patient safety.

The annual HOPE Act report produced by the OPTN and submitted to the Health Resources and Services Administration (HRSA) summarizes data reported directly to the OPTN as well as other data submitted through DSMB reports. This report is attached for review as data supporting the Safety Review workgroup's conclusions. We look forward to your review and recommendation.

Sincerely,

A handwritten signature in black ink that reads "Matthew Cooper". The signature is written in a cursive style and is contained within a thin black rectangular border.

Matthew Cooper, M.D.
OPTN President