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March 13, 2019

Sent via e-mail

Kimberly Uccellini, MS, MPH
Transplant Community Administrator
Regions 1 & 11
OPTN Data Advisory, Patient Affairs, & Thoracic Committees

RE: OPTN/UNOS Ad Hoc Disease Transmission Advisory and Thoracic Organ Transplantation
Committee Proposals

Dear Ms. Uccellini,

On behalf of The Society of Thoracic Surgeons (STS), I am writing to provide comments on proposals by the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) Ad Hoc Disease Transmission Advisory and Thoracic Organ Transplantation Committee to “*Modify HOPE Act Variance to Include Other Organs*” and “*Eliminate the Use of DSAs in Thoracic Distribution.*” We appreciate the opportunity to provide comments on these important proposals.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,400 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

Modify HOPE Act Variance to Include Other Organs

UNOS/OPTN currently allows kidneys and livers donated by HIV-positive donors to be given to HIV-positive patients in need of a transplant. This program requires an Institutional Review Board-approved research protocol to evaluate the safety and effectiveness of these donor organs. Short term analyses suggest organ transplant outcomes in HIV patients are comparable to outcomes in non-HIV infected recipients. Therefore, UNOS/OPTN is proposing to expand this program to allow other organs to be transplanted, including the heart and lungs.

STS supports this proposal. It would increase the donor pool, addressing the critical shortage of donors for heart and lung waitlist patients who are HIV positive. Experience from centers within our membership suggests that heart and lung transplant outcomes in HIV infected recipients have been favorable. As OPTN/UNOS expands the program, STS reiterates the need to use the Universal Precautions to avoid harm to caregivers both during the donor and recipient operations and that OPTN/UNOS continually review policies and practices to ensure safe utilization of HIV-positive organ donors.

Eliminate the Use of Donation Service Areas (DSAs) in Thoracic Distribution

OPTN/UNOS is also proposing to modify the geographic algorithm applied in heart allocation. The current heart geographic algorithm utilizes defined distances (500 nautical miles) as well as DSAs defined

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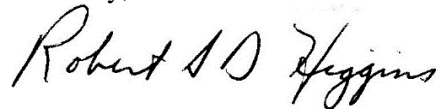
as the geographic area served by one Organ Procurement Organization (OPO). Concerns were raised by the Department of Health and Human Services that OPTN policies may not provide equitable access to donor organs. As a result, changes were made in the lung and liver allocation system to eliminate the use of DSAs. This proposal seeks to replace the DSAs with a 250 nautical mile distance from the donor hospital for heart allocation.

There are several potential advantages to this proposal. First, it appears to reduce some of the geographic variability seen in waitlist mortality and variability in time on the waitlist. Second, the proposal would better align OPTN policy with language in the OPTN “Final Rule” which requires equitable access to donor organs no matter the recipient’s geographical location. Third, it would create a heart allocation model that harmonizes with other cadaveric organs. Potential drawbacks are the potential to increase the distance from the donor hospital to the recipient hospital, therefore increasing travel time, heart ischemic time, costs, and the frequency with which caregivers are exposed to the hazards of non-commercial air travel.

In principle, STS supports the elimination of DSAs in the heart allocation system. However, the heart allocation model, whose framework remained essentially unchanged for approximately 20 years, was drastically reconfigured in October 2018. The impact of this new heart allocation paradigm remains uncertain. The modeling used in the assessment of the current proposal reflects heart transplantation practices prior to the recent heart allocation change. The impact of the current proposal on the newly implemented allocation system is unknown. Therefore, STS supports a future plan to eliminate DSAs but recommends that implementation is delayed until there is a better understanding of the impact of the recent October 2018 heart allocation model, particularly with regards to waitlist mortality, post-transplant survival, and cost.

We appreciate the opportunity to comment on these proposals and would welcome the opportunity to serve as a resource to OPTN/UNOS as it continues its work on these important issues. Please contact Courtney Yohe Savage, STS Director of Government Relations, at cyohe@sts.org or 202-787-1230 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink that reads "Robert S.D. Higgins". The signature is written in a cursive, flowing style.

Robert S.D. Higgins, MD
President