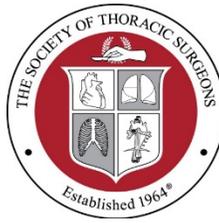


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October 10, 2018

**SENT VIA E-MAIL**

Kimberly Uccellini, MS, MPH  
UNOS Policy Department  
OPTN/UNOS Thoracic Organ Transplantation Committee

**Re: OPTN/UNOS Thoracic Organ Transplantation Committee Proposals**

Dear Ms. Uccellini:

On behalf of The Society of Thoracic Surgeons (STS), I am writing to provide comments in response to the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) proposals on “*Framework for Organ Distribution*” and “*Guidance on Pediatric Transplant Recipient Transition and Transfer*.” STS appreciates 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 7,500 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.

**Framework for Organ Distribution**

*Background*

The OPTN/UNOS Ad Hoc Geography Committee has requested feedback from the community regarding three proposed distribution frameworks, with the goal of identifying a single framework to be used for distribution of all transplant organs. The stakeholder community has been encouraged to provide rationales for preferring one specific framework of the three proposed, and to comment on both the immediate and long-term budgetary impact of resources that may be required by the distribution frameworks.

*General Comments*

STS applauds efforts by the OPTN/UNOS Board of Directors to develop policies of organ allocation that adhere to principles and requirements of the Organ Procurement and Transplantation Network Final Rule (referred to as the OPTN Final Rule). More specifically, STS supports the statement by the OPTN/UNOS Board of Directors in its Principles of Geographic Distribution that “[d]eceased donor organs are a national resource to be distributed

as broadly as feasible. Any geographic constraints pertaining to the principles of organ distribution must be rationally determined and consistently applied.”

The OPTN/UNOS Ad Hoc Geography Committee has proposed three potential geographic frameworks. The three frameworks outlined by the Committee include:

1. Fixed Distance from the Donor Hospital
2. Mathematically Optimized Boundaries
3. Continuous Distribution

While each framework has important advantages and disadvantages, STS would require considerably more detailed information regarding each proposed framework in order to rationally assess the associated budgetary impacts.

The first geographic scheme, using a fixed distance from the donor hospital, is the easiest of the three models to implement and can be readily modified to accommodate the differing tolerances of cold ischemic time for each organ. This model has recently been adopted for donor lung allocation and will soon be implemented for donor heart allocation. Additional time is needed to assess the effects of a fixed distance model on thoracic organ allocation. The Society recognizes that, while easy to implement, a fixed distance model may unnecessarily limit the ability of high urgency waitlisted patients, who reside just beyond the defined fixed distance from the donor hospital, to gain access to donor organs.

The mathematically optimized boundaries model has the advantage of incorporating selected objectives (e.g. minimize the effect of geography) and constraints (e.g. amount of travel) into the model to define optimized districts, optimized neighborhoods, and population density bubbles. However, many versions of the model maintain fixed borders that result in waitlisted patients having different levels of access to organs, similar to the fixed distance model.

The continuous distribution model is attractive because it eliminates specific geographical boundaries and accounts for the feasibility of donor organ procurement as a function of the distance between a waitlisted patient’s residence and the donor hospital, but details of the modeling for each specific organ would need to be developed.

STS supports a geographic allocation policy that results in the fair and equitable distribution of scarce donor organs to our patients. In the course of developing that policy, the OPTN/UNOS Board of Directors should take the following guiding principles into consideration:

- Consider how ill a potential recipient is, as well as that individual’s potential for a successful outcome, with the goal of maximizing cumulative years of life for both the patient who receives the transplant and those patients who remain on the waiting list. We reference the existing Model for End-Stage Liver Disease and the Lung Allocation System as examples of ensuring equitable and fair methodologies that consider the medical variables that may indicate a predicted prognosis for transplantation.

- Ensure the policy is not overly burdensome or onerous to transplant centers and professionals. A policy that unduly increases the cost and burden of transplantation activities to transplant centers could have adverse consequences on patients' access to transplant services. This is of particular concern for socioeconomically disadvantaged areas in the U.S.
- Ensure the policy does not unduly increase thoracic organ ischemic times and recognize that each transplant center has a preference as to the ischemic time it will tolerate. Thoracic organ ischemic time is an important determinant of recipient survival and long-term viability of the thoracic organ.<sup>1,2</sup>
- Ensure the policy does not unduly increase the need for air transport activities. Air transport activities significantly increase the expense of organ transplantation and need for additional personnel, and pose additional risk to medical personnel who participate in air transport activities.
- Permit variance to address issues unique to each organ. This is of particular importance in the case of thoracic organs, where the relatively shorter durations of safe ischemic times must be considered in maintaining safe geographical limits. Newly available alternative technologies or strategies to provide organ preservation could possibly extend the period of safe ischemic time, permitting extension of geographical limits in a new geographical framework. However, these technologies, to date, remain either investigative or lack significant robust data demonstrating transplant outcomes. Additionally, these technologies significantly increase both donor acquisition cost and the need for additional transplant personnel, and have not been routinely adopted into clinical practice.

Any geographic allocation policy developed by the OPTN/UNOS Board of Directors should include steps to assess the impact of a specific geographic allocation scheme in light of the above factors.

Finally, it should be noted that beginning in mid-October of 2018, a new heart allocation policy will be put into effect. STS believes it is important to fully understand the impact of this change in heart allocation policy, as well as the recent change in donor lung allocation, prior to implementing further changes in thoracic organ allocation based upon geographic factors. It is important that data on the impact of these new policies for donor heart allocation and donor lung allocation be reviewed and appropriate data-driven changes be considered in the development of any new geographic allocation policy.

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<sup>1</sup>Russo MJ et al. The effect of ischemic time on survival after heart transplantation varies by donor age: an analysis of the United Network for Organ Sharing database. *J Thorac Cardiovasc Surg.* 2007;133:554-9.

<sup>2</sup>Hong KN et al. Who is the high-risk recipient? Predicting mortality after heart transplant using pretransplant donor and recipient risk factors. *Ann Thorac Surg* 2011;92:520-7.

STS deems it imperative that OPT/UNOS continually engage transplant professionals and professional societies, along with all other stakeholders, in the development of a geographic allocation policy. To that end, STS looks forward to working with OPTN/UNOS in the ongoing development of a geographic allocation policy that addresses the needs and views of all stakeholders.

### **Guidance on Pediatric Transplant Recipient Transition and Transfer**

#### *Background*

Suboptimal transition and transfer processes for pediatric transplant recipients have been associated with increased risk of non-adherence with their plan of care and graft loss. Breakdowns in transition and the transfer to adult medical care may contribute to “lost to follow-up” designations for pediatric transplant recipients on OPTN data collection forms. As a result of transplant hospitals sharing effective practices for recipient transition and transfer from pediatric to adult medical care, transplant outcomes data will be more complete and more representative of clinical practices. Accurate and complete long-term post-transplant survival data are vital to understanding outcomes for all pediatric transplant recipients and to the development of health care policy that facilitates improvement of these outcomes.

#### *General Comments*

STS supports, in principle, the proposal to provide guidelines for transferring a patient from a pediatric transplant center to another provider as that person transitions to adult age, with the goal of reducing patients lost to follow-up and potentially improving compliance and survival. STS believes these recommended guidelines represent a reasonable standard to help ensure optimal transition of pediatric patients to adult care providers. STS also believes that further data should be obtained on the impact of proposed changes on transplant providers’ existing workload.

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, STS Director of Government Relations, at [cyohe@sts.org](mailto:cyohe@sts.org) or 202-787-1230 should you need additional information or clarification.

Sincerely,



Keith S. Naunheim, MD

President