OPTN/UNOS Thoracic Organ Transplantation Committee Meeting Minutes March 16, 2018 Conference Call

Kevin Chan, MD, Chair Ryan Davies, MD, Vice Chair

Introduction

The Thoracic Committee (Committee) met via Citrix GoToTraining teleconference on 02/23/2018 to discuss the following agenda items:

1. Spring 2018 Public Comment Proposals

The following is a summary of the Committee's discussions.

1. Spring 2018 Public Comment Proposals

The Committee reviewed three proposals out for public comment.

<u>Manipulation of the Waitlist Priority of the Organ Allocation System through the Escalation of</u> <u>Medical Therapies</u>

The Committee commends the Ethics Committee's efforts to consider the ethics of manipulating waitlist priority of the organ allocation system through the use of medically unnecessary interventions that are used to increase a transplant candidate's priority on the waitlist. Several Committee members applauded the Ethics Committee recognizing this occurs in the transplant community, but noted the paper provides very little in regards to solutions or recommendations should a pattern of manipulation be identified. Would a member be referred to the MPSC? One member emphasized the Committee's attempts to mitigate this abuse by including specific, objective criteria in the new heart allocation policy. Another member felt the white paper went too far and was redundant, overly prescriptive and descriptive. This member felt it was important that every member of the transplant community take an oath endorsing UNOS policies and the ethics of organ donation and transplantation, and vow not to unduly influence transplant delivery by "gaming" the system.

The presenter asked the Committee whether there were objections to the title of the white paper. The Committee did not voice concern.

Expedited Organ Placement Concept Paper

The Committee commends the OPO Committee's efforts to develop a framework for expedited organ placement. Such a policy should be useful to OPO's and hopefully will facilitate placement of organs at risk of being discarded. The concept paper mentioned potential significant delay in organ procurement to allow for allocation of organs turned down by procurement teams in the operating room. Any delay may adversely impact the thoracic organs because: 1) donor organ function may deteriorate under these conditions, and 2) the recipient operation will very frequently have already started resulting in unacceptably prolonged delays after induction of anesthesia and after incision and proceeding with the recipient surgical procedure; this include prolonging cardiopulmonary bypass time. This needs to be taken into account if extra time is spent on allocation of the turned down organs. The Committee pointed out it may be challenging to define an "aggressive" center and achieve consensus around the actual triggers that would be used to move to expedited placement. A majority of members disagreed with using DonorNet data to identify centers that would be eligible to receive

expedited offers, and there was some concern around what evidence would be utilized to determine what a center would or would not accept (i.e. modeling would not be applicable). However, a few members supported a system-driven mechanism to determine eligibility, versus leaving it to the OPO's discretion.

There was consensus that an allocation system **should** include an expedited placement trigger based on an event like an organ declined in the OR that would allow an OPO to expedite organ placement, **could** allow an OPO to move to an expedited list after a well-defined point in the process and that transplant centers **should** be allowed to choose whether or not they want to have their candidates on an expedited list. There was less agreement amongst committee members in their responses to the other questions posed by the OPO Committee.

Clarify Informed Consent Policy for Transmittable Conditions

The Committee commends the Disease Transmission Advisory Committee's (DTAC) efforts to clarify informed consent policy for certain transmittable conditions.

There was consensus that requiring additional patient signatures in the informed consent policy should be avoided and left up to transplant centers. Forcing transplant centers to obtain additional consents from candidates' leads to decreased donor options for the candidates who refuse IRD's and increased mortality on the waitlist. Likewise, increasing specific consenting requirements for extremely low-risk situations such as Hep B core +/HBV NAT negative and the HCV Ab +, but HCV NAT negative donors will likely lead to even more candidates refusing these life-saving allografts due to difficulty in understanding the relative risks of utilizing or not utilizing these donors.

There was some concern with the current requirement to offer prophylaxis to candidates receiving organs from all donors deemed "high-risk," including hemodiluted specimens. Forcing centers to offer prophylaxis will needlessly increase anxiety among recipient families, and one member doubted data would support this requirement, at least in pediatrics. Instead of "when available," it might make more sense to substitute the phrase "where medically appropriate" or something similar.

Upcoming Meetings

• April, 2018