

OPTN/UNOS Patient Affairs Committee
Meeting Minutes
February 20, 2018
Conference Call

Kristie Lemmon, MBA, Chair
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Introduction

The Patient Affairs Committee met via Citrix GoToTraining teleconference on 02/20/2018 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 two proposals out for public comment.

Review Board Guidance for Hypertrophic and Restrictive Cardiomyopathy Exception Requests

The OPTN/UNOS Patient Affairs Committee (PAC) appreciates the Thoracic Committee's efforts to increase equity in access to transplant for hypertrophic and restrictive cardiomyopathy candidates by proposing objective exception criteria to standardize the evaluation and award of exception requests for these patients. Removing variability in awarding exceptions for HCM/RCM patients will only positively impact this population if Regional Review Boards (RRBs) adopt and follow the guidance which, by the nature of OPTN guidance, is voluntary and not enforceable. While this guidance may help HCM/RCM candidates get transplanted more expeditiously, it might do so at the expense of other heart transplant candidates who may consequently experience longer wait times. Are there other disease groups that represent a small portion of the waiting list who may not be as vocal, and thus disenfranchised? Most patients do not know about exceptions. How can HCM/RCM patients be assured that this exception is being sought on their behalf by their transplant programs (if appropriate) and that RRBs are utilizing this guidance? Is there data or information on how many regional review boards have an HCM/RCM expert? Because this is a small patient population, is there a more efficient way for the OPTN to review and grant exceptions (e.g. standardizing exceptions?) for this group? This guidance proposal does not address how the transplant community will educate patients about the change. An external member of the community asked whether this guidance would be applicable to the pediatrics population. The Thoracic Committee answered all questions to the Committee's satisfaction. The Committee moved to support this proposal.

Clarify Informed Consent Policy for Transmittable Conditions

PAC commends the Ad Hoc Disease Transmission Advisory Committee's (DTAC) efforts to clarify informed consent requirements prior to transplant and is appreciative of the opportunity to collaborate during the development of the policy. Potential unintended consequences include misunderstandings on possible transmissible diseases (including those for which there are cures), misconceptions from potential donors on whether they can donate organs, candidates needing or desiring more time to seek education and make informed decisions, and information overload resulting in an increased volume of patients declining organs. Therefore, education should be patient-centric and understandable and done at the time of listing, rather than just prior to transplant. One member asked if quality of life was considered and might be discussed with patients prior to listing during the informed consent process.

Should informed consent policy include an actual patient signature or is discussion and medical record documentation sufficient?

One member noted she would not support the proposal if a patient signature was required because she did not feel a signature from the patient carried any more validation of a patient's comprehension of the information provided, and that documentation of patient education in the medical record was sufficient. She also felt it would be a burden to require a patient signature for every transmissible disease. However, a majority of the PAC felt strongly about requiring an actual patient signature in addition to documentation of patient in the medical record. Several PAC members asked what would be included on the consent form, or if DTAC would be proposing specific elements for the consent form. One member asked if two consent forms would be feasible, one at time of listing and another just prior to transplant.

Do you have any concerns or comments about the list of conditions in the current candidate screening (Policy 5.3.B Infectious Disease Screening Criteria) and re-execute the match (5.5.B Host OPO and Transplant Hospital Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results) policies?

A member of PAC asked whether EBV should be added for the pediatric population only, and should CMV be added to all populations as the medications to treat the condition after transplant are expensive and need to be considered.

The PAC supported the proposed policy clarifications and a majority supported the requirement of a patient signature.

Upcoming Meetings

- March, 2018