OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee
Meeting Minutes
March 14, 2018
Conference Call

L. Scott Levin, M.D., FACS, Chair
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Introduction

The VCA Transplantation Committee met via teleconference on March 14, 2018 to discuss the following agenda items:

1. Public Comment - Concept Document on Improving OPTN Committee Structure
2. Public Comment - Clarify Informed Consent Policies for Transmissible Disease Risk

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

1. Public Comment - Concept Document on Improving OPTN Committee Structure

UNOS staff shared a presentation of a proposal from the OPTN/UNOS Executive Committee.

Summary of discussion:

UNOS staff were invited to the conference call to present a concept document to improve OPTN committee structure. The current OPTN committee structure is a "one-sized fits all" approach that limits opportunity for participation, and makes it difficult to incorporate diverse perspectives in the policy development process. This approach, along with how we currently collect public comment from stakeholders (regions, committees, societies, and the public) also doesn't allow the Board to fully consider the sentiment of those groups when making decisions.

UNOS staff pointed out that the current committee structure is not mandated by the National Organ Transplant Act (NOTA) or the OPTN Final Rule. It has been used over time to provide subject matter expertise, advance diverse perspectives from stakeholders, and generate buy-in on health policy from the transplant community.

The goal is to build a committee structure that achieves several aims:

- Increase opportunities for participation, for example, by adding more spots to be official volunteers for the OPTN (greater than the limited number of committee and Board positions currently available).
- Increase minority representation on the committees, by taking an even more concerted approach to ensuring that the volunteer workforce reflects the system we serve.
- Ensure diversity in perspectives on committees – by amplifying the voices of certain types of members across groups rather than containing them within a group, and by strengthening that individual's sole contribution to a group discussion by helping them know they have the backing of lots of people from their same perspective.
- Strengthen connections between the Board and committees – by building in Board positions on the committees and expert councils to be the connection between the groups, and to create a better structure for promoting someone through the volunteer lifecycle.

The Executive Committee is proposing a new committee framework in a concept paper to gather early input from the transplant community and other interested individuals. This framework would include:

- Subject Committees present policy proposals to the Board, and leaders are often identified for Board service
- Expert Councils communicate with Subject Committees through their representatives, and Councils are educated on proposal development
- Representatives from the Board sit on Expert Councils providing:
    - Knowledge sharing
    - A direct link to the Board
    - A more established pipeline for succession planning
    - Leaders often identified for Board service

UNOS staff then profiled the tasks and functions that could be assigned to the subject committees and the expert councils.

The Executive Committee carefully considered the form and function of committees and felt there were distinguishing features:

- Subject Committees
    - Single subject
    - Frequently propose specific policies
    - Debate specific policy language – needs smaller working group
    - Send proposals to Board – needs balanced regional representation
- Expert Councils
    - Multiple subjects
    - Weighs in on the work of many others
    - Identifies gaps and opportunities – needs as many participants as possible
    - Comments to Board on current and future issues

With this in mind, the following list was drafted for potential subject committees and expert councils:

- **Subject Committees**
    - Heart
    - Histocompatibility
    - Kidney
    - Liver/Intestine
    - Lung
    - Pancreas
    - Operations
    - Disease Transmission
    - Organ Procurement (or Donation)
    - Quality Improvement (MPSC)
    - VCA
- **Expert Councils**
    - Bioethicists
    - Candidate and Recipient Affairs
    - Deceased Donor Family
    - Living Donors
    - Minority Affairs and Vulnerable Populations
    - OPO Executives
    - Procurement Coordinators
    - Transplant Administrators
    - Transplant Coordinators
    - Transplant Pediatric Specialists

UNOS staff noted that the first ten days of public comment, this concept document struck a chord with many groups who may no longer be considered a subject committee (Pediatrics and Living Donor). With the transition to expert councils, the intent is for more pediatric representatives on committees, organ-specific pediatric work groups for projects, and overall more involvement from the pediatric community.

The Chair thanked UNOS staff for the presentation and opened the floor for questions. Members shared several points after reading the proposal in detail. Members verbalized support for the goals of the concept document (gather more input, increase diversity, and broader input). The Committee did not see any detrimental impact on the subject committees described in the concept (including VCA). However, there was skepticism whether the concept of expert councils would help achieve the described goals. There appears to be risk of disenfranchising some groups by 1) a transition from an existing committee with some "executive power" to an expert council with "advisory power", and 2) restricting the possibility of councils to sponsor policy proposals. This impact could be most significant in the groups the OPTN wants to amplify by the concept, e.g.: Patient Affairs, or Pediatrics. Members shared understanding for the perspective already shared by the pediatric community on this proposal; that it is already extremely challenging to advocate effectively for pediatric transplant patients in the adult-dominated environment of the OPTN committees. This appeared to conflict with the National Organ Transplant Act (NOTA) that mandates the medical needs of pediatric patients be given special consideration. Members also verbalized concern that expert councils run the risk of being very large and difficult to manage. While input from large audience is important, members noted existing opportunities for input is served by existing public comment periods. Members did support utilizing expert councils for complicated issues as they arise.

Next steps:

Committee members were asked to complete an on-line survey for their feedback on the proposal.

UNOS staff will prepare a draft response and share with the Chair and Vice Chair. Once approved, the response will be posted on the OPTN website.

2. Public Comment - Clarify Informed Consent Policies for Transmissible Disease Risk

The Chair of the OPTN/UNOS Ad-hoc Disease Transmission Advisory Committee (DTAC) presented a proposal to clarify OPTN policies pertaining to transplant informed consent.

Summary of discussion:

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) sent a memo to the DTAC asking for clarification on OPTN Policy 15.3 (Informed Consent of Transmissible Disease Risk). The MPSC expressed concerns that a broad interpretation of current policy implies the need to get individual consent for any and every positive result including Epstein Barr Virus (EBV) and Cytomegalovirus (CMV) results or positive donor cultures. Implementing that in practice might not be reasonable and cause an undue burden for programs. In addition, it is currently very difficult, if not impossible, to monitor and enforce. DTAC never intended for common organisms such as EBV and CMV to be broadly included as part of this policy and felt that some changes to the policy could help to remove the ambiguity.

The speaker shared the policy changes were the product of a work group with members from the American Society for Transplantation (AST) and the American Society for Transplant Surgeons (ASTS). The policy language was rearranged to emphasize the general discussion and education requirement of potential transplant candidates that occurs at the time of listing a candidate. The proposal also adds a clause to this general discussion at the time of wait listing

to have transplant hospitals highlight that donor results can affect post-transplant care and management. The work group had deliberation to what recognized transmissible conditions should be included in policy. They concluded to tie the specific consent process to conditions that candidates are screened for in UNet^{SM} according to OPTN Policy 5.3.B (Infectious Disease Screening Criteria). DTAC feels the modifications proposed provides for a clear and enforceable policy as requested by MPSC.

The speaker noted this proposal is a minimum standard and transplant hospitals can do more based on their local practices. It should be noted that other informed consent requirements at transplant such as when using donor organs that from U.S. Public Health Service (PHS) increased risk donors do exist. The proposed policy would apply to recipients receiving organs from **all** donor types (living and deceased). The proposed policy is not intended to prescribe or modify how transplant programs obtain or document informed consent.

The speaker closed by thanking the Committee and asking two specific feedback questions.

1.) Should OPTN policy specify patient signature, or is documentation of discussion between the provider and the recipient (or next of kin) sufficient?
2.) Are conditions named in policy for candidate screening and re-executing the match run still applicable and complete?

The Chair thanked the speaker for the presentation and opened the floor for questions. Members shared several points after reading the proposal. The OPTN strategic plan emphasizes the need to increase the number of transplants. As a result, establishing minimum requirements for informed consent for transmissible disease risk is prudent, and should be aligned with other areas of OPTN policy. Members agreed that some transplant programs may elect to go beyond the requirements contained within this proposal.

The call attendees then discussed what, if any, role human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV) positive donors should play in VCA transplantation. The group acknowledged that transplantation of HIV positive organs are limited to kidney and liver transplant only (HOPE Act requirement). However, there should be some discussion in the VCA community about HBV and HCV positive donors. Medications that can cure HCV have changed this calculus for solid organ transplantation. The practice of transplanting HCV positive organs into HCV negative recipients has expanded beyond kidney transplants into heart, liver, and lung transplants. These medications have been used successfully to increase the donor pool.

The speaker commented that the key to this proposal is, if a transplant program uses a donor that is found to be positive for one of referenced conditions, does this warrant informed consent from the potential recipient? Members on the call verbalized the opinion that if the donor is known to be positive for a transmissible condition outlined in the proposal, it warrants inclusion in the consent conversation prior to transplant.

Members noted VCA transplantation is substantively different from solid organ transplantation. VCA transplants are not “life-saving”, but are a quality of life transplant. Some noted there was not a shortage of potential VCA donors. Rather, lengthy VCA candidate waiting times are often due to specific donor-recipient matching requirements. With this in mind, it was reasonable that a thinking of a VCA candidate (and their medical team) could evolve with the passage of time, and subsequently be willing to consider offers from a different, or broader, profile of donors. Members felt this scenario would require, and benefit from, two informed consent discussions. One informed consent discussion with the candidate at the time of registration, and a second immediately prior to transplant. The safety of the potential VCA recipient is the first priority and diligent consent is appropriate for this population.

At the conclusion of the discussion, there was consensus that there is benefit for the VCA community to follow the minimum requirements that the proposal suggests. The Committee supported the DTAC proposal as written.

Next steps:

UNOS staff will prepare a draft response and share with the Chair and Vice Chair. Once approved, the response will be posted on the OPTN website.

With no other business to discuss, the call was adjourned.

Upcoming Meetings

- April 6, 2018 9 AM-3 PM (Central) Chicago, IL
- May 9, 2018 4-5 PM (Eastern)
- June 13, 2018 4-5 PM (Eastern)