OPTN/UNOS Vascularized Composite Allograft Transplantation Committee Meeting Minutes June 13, 2018 Teleconference

L. Scott Levin, MD, FACS, Chairman Linda C. Cendales, MD, Vice Chairman

Introduction

The VCA Transplantation Committee met via teleconference on 06/13/2018 to discuss the following agenda items:

- 1. Update from OPTN/UNOS Board of Directors Meeting
- 2. Update from Ad Hoc Geography Committee
- 3. Clarifying VCA Nomenclature
- 4. New Friend & Old Friends
- 5. Chair's Remarks

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

1. Update from OPTN/UNOS Board of Directors Meeting

The Board of Directors meeting was held in Richmond, Virginia on June 11-12, 2018. Fifteen proposals were considered by the Board; five of the proposals were discussed in detail and approved. Two of the remaining ten proposals dealing with optimizing VCA authorization and recovery, and changes to the VCA membership requirements were approved by the Board by a vote of 37 yes, 0 no, 0 abstentions.

In other discussions, there was an inquiry letter from Secretary of Health and Human Services requesting OPTN review compliance with the Final Rule relating to the liver allocation policy. This is ongoing and comes at the heels of earlier legal action taken by a law firm regarding lung allocation policies in 2017. This is directed at one specific organ allocation algorithm and less so at the entire organ allocation system.

The 2018-2021 strategic plan was adopted. This was presented by the VCA Committee earlier this year. The Board did approve the resource allocation changes so that increasing number of transplants was receiving 40% of resources for projects to increase organ transplants, and that 30% of resources would be dedicated to improving access and equity in transplantation. Each of the remaining goals received 10% allocation. The need to reevaluate the OPTN Strategic Plan comes up every three years, and ensures OPTN work is in alignment with these strategic goals.

Also discussed was proof of concept for constituent committees. The VCA Committee heard a prior proposal on improving the function of OPTN committees during the spring of 2018. This proof of concept will be conducted with the Patient Affairs and Transplant Coordinators Committees to establish ways to get broader engagement from these two populations. They will report back to the Board after six months to discuss if this is a model OPTN can use to get wide engagement for a high functioning transplant system and good input on governing policies.

There were also breakout sessions regarding member quality optimization and overview of organ allocation analytics.

2. Update from Ad Hoc Geography Committee

This committee was formed in December 2017 to include Board members, AST, ASTS, AOPO representatives, and committee leadership. Their charge was to establish guiding principles for

organ distribution, review and recommend frameworks for incorporating these principles. These concepts must be in conformity with the Final Rule regarding geography as a component of the allocation policy.

In the Principles of Organ Distribution, the overarching principle is organs are a national resource to be distributed as broadly as possible and emphasize that any geographic constraints must be rationally determined and consistently applied and should be done to reduce inherent differences in ratio of donor supply and demand, reduce travel time, increase organ utilization, increase efficiencies. The Geography Committee identified three frameworks for geographic distribution that are consistent with the principles and recommend further discussion by the Board and community regarding the distribution frameworks of fixed distance, mathematical optimization, or without no consideration of formalized geographic boundaries. These principles are going out for public comment in the next cycle, beginning August 3, 2018.

The impact on the VCA community will have to be navigated and the outcome of the heart allocation may help inform the future for VCA allocation. As the VCA community gains more case experience and data, informed decisions can then be made as to what the next VCA allocation system may become.

3. Clarifying VCA Nomenclature

The Member Quality unit of UNOS has requested we reach out to clinical experts for clarity in the varying nomenclature found in the applications. Terms such as uterine versus uterus, penile versus penis, and whether the term "genitourinary" should be used were discussed and there was agreement by the Committee that the noun forms should be used. UNOS staff will follow up with programs to make sure everything is consistent in nomenclature.

4. New Friend & Old Friends

New members from Regions Four and Eight will be joining the Committee on July 1st as new members serving at-large terms. The first opportunity to meet them will be during the October 2018 in-person meeting in Chicago.

UNOS staff shared that the Chair will transition to Immediate Past Chair Position. Two at-large members will be rolling off the Committee on June 30, 2018. Each of these individual has made impactful contributions to helping OPTN and UNOS integrate VCA into the fabric of transplantation.

5. Chair's Remarks

The Chair thanked everyone and stated it's been a privilege and recognized all members of committee for their dissent, controversy, hard work, and input. He noted his feelings on falling short in the area of funding efforts for transplants. The issue of aggregate data and standardized protocols may be holding the field back. There have been recent grants from DOD looking at outcomes and patient-reported measures and maybe there will be a chance to aggregate that data to show how well patients have done and that the field remains solid. Peer review work has been recognized at ATC and everyone has done great work and the paper produced has been resubmitted for publication. Being Chairman has been an education and he remains committed to sustaining the field. Members thanked the Chair for his leadership during the last two years. Members disagreed with Chair's feelings of falling short, but did agree that the focus of the field and the Committee need to be sustaining the momentum that has been built.

Open Session

An outgoing committee member thanked everyone on the committee and stated he enjoyed working with everyone.

The committee will reconvene on the second Wednesday in July and a calendar invite will be sent.

With no further business to discus, the call was adjourned.

Upcoming Meetings

- June 28, 2018
- July 26, 2018
- August 23, 2018