OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee Meeting Minutes June 9, 2017 Conference Call

L. Scott Levin, M.D., FACS, Chair Linda C. Cendales, M.D., Vice Chair

Introduction

The VCA Committee met via teleconference on June 9, 2017 to discuss the following agenda items:

- 1. Update from OPTN/UNOS Board of Directors meeting
- 2. Update from OPO Guidance Subcommittee
- 3. Update from ASRT Chair
- 4. Old business

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

1. Update from OPTN/UNOS Board of Directors meeting

The Vice Chair provided an update from the OPTN/UNOS Board of Directors meeting that was held in Richmond, Virginia from June 5-6, 2017.

Summary of discussion:

The Vice Chair attended the OPTN/UNOS Board of Directors (Board) meeting earlier in the week. Notable at this meeting was:

- 1. <u>Strategic Planning Discussion</u> The current OPTN Strategic Plan was intended to be in effect for three years beginning in 2015. Board members and Committee leaders at the board meeting were invited to a lengthy session on June 5th to discuss the next OPTN Strategic Plan. Participants brainstormed initiatives that would fall under a new plan, then presented content in "Shark Tank" fashion. This session was the first of what will be several discussions. Resource allotments and an approach for dealing with transition from the old plan to the new plan will be discussed in the future.
- 2. <u>Projects</u>– The Board approved two significant projects; a new National Liver Review Board and related guidance, and guidance on U.S. PHS Increased Risk donor organs. The Board did hear a proposal to change en-bloc kidney allocation. However, this proposal was not approved. Revisions are expected to go out for public comment in the fall of 2017.
- 3. <u>Updates</u> The OPTN/UNOS Liver and Intestine Committee Chair provided an update on the Liver Redistribution project. SRTR has done substantial of modeling on different concepts (concentric circles, neighborhoods, districts). Additionally, there have been a handful of large public meetings to engage the community and stakeholders. The eight district model that has been historically discussed will not be pursued. The prevalent models that will be out for public comment will include:
 - priority for MELD lab score candidates with broader sharing, and
 - an increase of 5 points for MELD candidates in the same DSA as the donor.

The months ahead for this project will include public comment from July to October 2017, and tentative Board consideration in December 2017.

Next steps:

 Committee leadership will continue to attend future Board meetings and update the Committee accordingly.

2. Update from OPO Guidance Subcommittee

The Chair of the OPO Guidance Subcommittee shared an update from the last conference call.

Summary of discussion:

The Subcommittee met by conference call on May 12, 2017 to continue discussions on the project. The goal of this call was to move to an actionable stage for the guidance document. UNOS staff were able to provide a synopsis of transplant hospitals and organ procurement organizations (OPOs) that have been involved in VCA transplant cases since 1999. This list was discussed to identify potential collaborators to serve as reviewers and co-authors for the guidance. This included OPO clinical directors, executives, family support representatives, and media/public relations specialists. During the call, "homework" was assigned to develop outlines/draft content for select sections.

- OPO representatives develop outline for <u>Developing Effective Partnerships with VCA</u> Programs
- Enlist help for outline on <u>Surrogate Decision-maker Authorization</u>
- VCA representatives develop outline for <u>VCA Donor Evaluation</u>
- Enlist help for outline on Recovery Considerations & Post-recovery Considerations
- Enlist help for outline on *Public Education and Media Considerations*

This conversation also help understand the gaps in expertise and where the Subcommittee should seek collaboration. In the coming weeks, the Subcommittee will reach out to OPO community members with needed backgrounds to assess their willingness to participate.

The Subcommittee Chair then reviewed the project timeline with the Committee. He felt the project was still on track for public comment in January 2018 and Board consideration in June 2018.

The Chair thanked the Subcommittee Chair for the update.

Next steps:

- Subcommittee members will engage external SMEs to assist.
- The Subcommittee will meet by conference call on July 14, 2017. The next update to the Committee will be on August 9, 2017.

3. Update from ASRT Chair

Sue V. McDiarmid, M.D., Chair of the American Society for Reconstructive Transplantation (ASRT), was invited to the address the Committee.

Summary of discussion:

ASRT has been involved in discussions with the American Society of Transplatation (AST) and the American Society of Transplant Surgeons (ASTS) to better coordinate efforts on issues relevant to VCA transplantation. The Chair invited Dr. McDiarmid to share an update with the Committee on these recent discussions.

Dr. McDiarmid shared that she has been discussing the concept of an "intersociety working group" of VCA specialistswith leaders of AST and ASTS. The intent of such a group would be to collaboratively work on global issues that impact VCA transplantation. Correspondance was sent to both transplant groups and AST was receptive to the concept. ASTS was initially luke-

warm to the idea, fearing their members were very wrapped up in policy discusions impacting liver transplantation in recent months. Following some discussions, ASTS leaders were receptive to the idea of the working group.

Dr. McDiarmid noted that others on the Committee have suggested the idea of a consensus conference to development momentum on large issues. However, she recommended that an interim step of information sharing may be prudent. This concept has been supported by Wendy Dean, M.D. and colleagues at HRSA Division of Transplantation. Dr. McDiarmid concluded her remarks by saying such a meeting may occur in the fall of 2017.

The Chair thanked Dr. McDiarmid for her report, commenting that this mutual effort would be a marathon, rather than a sprint. Members briefly discussed the report. Some supported the need to be inclusive in this meeting and consider representatives of the organ procurement community (e.g.: the Association of Organ Procurement Organizations – AOPO).

4. Old Business

The immediate past chair asked for a status update on two past Committee initiatives.

Summary of Discussion

Dr. McDiarmid inquired as to the status of two past Committee initiatives; implementation of the new VCA transpant program membership requirements, and the status of VCA graft failure/function discussions. UNOS staff responded that membership applications had been sent to the U.S. Office of Management and Budget (OMB) and their review was ongoing. HRSA representatives indicated they would contact colleagues at OMB to check on the status of the review. UNOS staff then addressed Dr. McDiarmid's second question regarding VCA graft failre/function discussions. This project has been on-hold pending the collection of more transplant recipient outcome data. If the Committee wants to pursue this project, they would need to approach the OPTN/UNOS Policy Oversight Committee (POC) to take the project "off hold". One member noted this topic will be discussed at the ISVCA conference in Saltzburg in the fall of 2017. The timing of these discussions may be informative for the Committee.

Next Steps

- HRSA staff will respond to the Committee's request for a project update re: VCA membership requirements.
- The Committee will revisit the graft failure/function in the coming months.

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

Upcoming Meetings

- August 9, 2017 (conference call)
- September 13, 2017 (conference call)
- October 18, 2017 (Chicago, IL)
- November 8, 2017 (conference call)
- December 13, 2017 (conference call)
- January 10, 2018 (conference call)
- February 14, 2018 (conference call)
- March 14, 2018 (conference call)
- April 6, 2018 (Chicago, IL)
- May 9, 2018 (conference call)
- June 13, 2018 (conference call)