OPTN Vascularized Composite Allograft Committee
Meeting Summary
October 7, 2021
Conference Call

Bohdan Pomahac, MD, Chair
Sandra Amaral, MD, MHS, Vice Chair

Introduction

The Vascularized Composite Allograft Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/07/2021 to discuss the following agenda items:

1. Establish Membership Requirements for Uterus Transplant Programs
2. Graft Failure Project
3. Living Donor Committee Recommendations on Prior Living Donor Priority

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

1. Establish Membership Requirements for Uterus Transplant Programs

The Committee reviewed the proposal that went out for public comment and considered the feedback submitted during the public comment period. The Committee considered what was submitted and discussed possible revisions to the proposal. Feedback was submitted through the OPTN Public Comment website and OPTN Regional Meetings which included all member types, individuals, and stakeholder organizations. Of the eleven regions, all were generally supportive of the proposal, with approximately 75% of votes being either support or strongly support, and 20% of the votes being neutral/abstain. Within the breakdown of regional meeting sentiment by member type, UNOS staff clarified that the data presented within the category "Non-Member" only reflected the response of one member.

Following a brief overview of the proposal by the Chair, UNOS staff briefly noted to the Committee that a minor technical change was made to remove the terminology "covered VCA transplants" in places it was found to be exclusionary, instead replacing it with "VCA transplants". This had no impact on the policy proposal, and aligns the wording more closely with the intent because these are "exclusionary" versus "inclusionary" policies.

Summary of discussion

The first area of discussion presented to the Committee was the proposed experience requirements for the living donor uterus surgeon. It was noted that the Committee had discussed similar considerations in a prior meeting, and had come to the conclusion that high standards should be set, as these are living donor recoveries and safety is paramount. The Chair clarified that the responses were raising issue with the difficulty in obtaining the two necessary living donor recoveries as the primary surgeon or co-surgeon. However, the Chair agreed with the comment, stating that traveling to obtain living donor uterus recoveries outside of a surgeon's program would be exceedingly difficult, while also acknowledging that the consideration of changing to "observation" could not substitute direct experience. The Vice Chair contributed that, following a prior presentation to the OPTN Living Donor Committee, the Living Donor Committee recommended the bar be set high and subsequently relaxed as

time goes on. A Committee member also added that these restrictions could inhibit programs attempting to start a uterus transplant program by setting infeasible requirements.

Opening up the discussion, the Chair offered that, instead of requiring two living donor uterus recoveries, the requirements could include deceased donor procurements performed as primary or co-surgeon. The Vice Chair, however, added that, "If we really want to move the field forward…being quite rigid with safety is an important approach", with the Chair also noting that, "it's very different to recover from deceased versus living [donors]". The Committee then amended the proposed change with a third possible bullet, requiring that, if the surgeon has performed only two deceased donor procurements, they must directly observe two living donor recoveries. The committee felt that two was a "fair" number, as it encompassed both safety and feasibility. Ultimately, the Committee agreed that the final restrictions should require ten total living donor uterus recoveries or radical hysterectomies, while also requiring two living donor recoveries or deceased donor uterus procurements. Of those two, the living donor recoveries may count to the ten total, whereas the deceased donor procurements cannot. If the surgeon has completed no living donor uterus recoveries, they must directly observe at least two living donor uterus recoveries. When presented to the Living Donor Committee Chair and representatives present, they agreed with the Committee's recommendations, while also adding that the requirements should be continuously evaluated as uterus transplant becomes more frequent.

The Committee proceeded to review the comments on combining the proposed genitourinary (GU) VCA types into "Internal and External Female Genitalia" and "Internal and External Male Genitalia". The Chair stated that the main reason behind the distinctions for consideration was to include any part of the GU tract that could possibly be transplanted, and to provide a groundwork for proper regulation. Specifically, they noted testicles and ovaries would fall under the category "Other VCA" in the current proposal. Ultimately, however, they continued to support their decision from a previous Committee discussion that the rules should follow which transplants are currently being done, rather than all possible in the future. A Committee member noted that having the extra organ-level specificity built into policy, rather than the comment's proposed changes, would be helpful when explaining to and acquiring authorization from the donor family.

The addition of the obstetrician and gynecologist (OB/GYN) role was evaluated as the next theme in public comment feedback. The feedback received questioned the need for a third required position, as well as requested consideration into requiring more extensive immunosuppression experience for the OB/GYN. The Chair introduced the discussion by reminding the Committee that earlier, the Committee agreed that a third position was needed due to different expertise in the management of the patient, transplant issues, and the obstetric and gynecological issues. The Vice Chair noted that there would be difficulty in OB/GYN practitioners acquiring transplant experience, as they do not encounter uterus transplant patients frequently. Finally, the Committee discussed that two practitioners could theoretically fill the three proposed roles. Sentiment within the Committee, ultimately, remained that the third role was still necessary, and continued to support their previous decision.

The final issue discussed within the Public Comment feedback was the requirements for medical expert support. The current practice of medical expert support was discussed, and The Committee felt that no increased restrictions were necessary to be placed on uterus VCA programs.

Voting was deferred to the Committee's October 13th meeting in order to encompass the proposed changes to living donor experience for the primary surgeon discussed above.

2. Graft Failure Project

The Committee reviewed the current definitions of graft failure, which state in current policy, that graft failure for all organs except pancreas is defined by either removal, recipient death, or the recipient re-

registering on the VCA waiting list. The project seeks to update the graft failure definition to allow for the possibility of intended removal, most notably in cases such as uterus, where the graft is intended to be removed following live birth. It also seeks to update pertinent Transplant Recipient Registration (TRR) and Transplant Recipient Follow-Up (TRF) fields.

Summary of Discussion

A Committee member inquired whether the Food and Drug Administration (FDA) had replied to a prior question about sentinel flap coverage by OPTN, to which UNOS staff replied they had not. The Committee also agreed that, in order to ensure compliance with possible coverage by OPTN, the language "except sentinel flap" would be added to help documentation to circumvent the reporting of sentinel flap death.

The Chair posed the question as to how planned removal should be defined. To this, a Committee member voiced concern that, "transplant centers may attempt to 'game' the system by saying [each removal of a failed graft is planned]", but agreed with the Committee overall that this was an unlikely circumstance. The Committee came to the consensus that documentation should exist from the time of transplant surrounding the planned removal date, so as to prevent centers from adding a planned removal date immediately prior to graft failure. In the context of uterus, the Committee agreed that, as a uterus graft is always planned to be removed, planned removal should be defined as intended removal on the planned date noted at the time of transplant, in order to distinguish between uterine graft failure and graft removal. Following a discussion of the graft failure report, the Committee agreed that no additional forms were necessary. The Chair inquired whether there was a way to link, in UNet^{SM}, the relisting of a VCA candidate to trigger a graft failure report, to which UNOS staff will follow up with UNOS Information and Technology. Of the proposed interim forms presented to the Committee for VCA, the Committee preferred the option to select graft status as "Uterus – planned removal following live birth" or "VCA – planned removal following use for temporary coverage" directly from the selections. Of the proposed changes to TRR or TRF, the Committee found no issue with the proposed additions and removals of duplicative causes of death, but requested that "maternal and obstetric mortality, other" be added to the list of causes of death. However, the Committee did have significant discussion surrounding whether planned graft removal should be reported on an interim report of graft failure, death, or lost record. The Vice Chair questioned whether an intended removal constituted "an interim event", and the Chair also wondered "Why would [planned graft removal] need to be reported, it could be included on the next TRR?" In addition, the Vice Chair conceptualized the problem by noting that safety events such as graft failure should constitute an immediate report; planned removal would not be an immediate safety event, and therefore would not fall in line with the intent of the interim report. UNOS staff noted that the reason the interim report was considered was because, in Policy 1.2, graft failure is defined as "anytime a recipient's transplanted organ is removed". The Committee agreed that it was not accurate to report a planned graft removal on a report intended for graft failure, especially when a TRF form must be submitted following graft removal.

Afterwards, a set of six examples demonstrating the updated reporting of graft removal or failure in difference scenarios was presented to the Committee. A Committee member indicated that "failure to conceive" should be added to the list of graft failure causes, following the line of reasoning that "sometimes we don't have those traditional graft failure reasons…there [are] reproductive causes for taking [the graft] out". Additionally, a second Committee member questioned why the voluntary data collected by OPTN following live birth was not mandatory. In response, UNOS staff did note that approximately three years ago, HRSA did determine it would be within OPTN scope to follow live birth data following uterus transplant patients. However, they did also add that any time data collection becomes required by the OPTN, it would have to go through the traditional policy development process.

A discussion followed, with members noting that there would be increasing difficulty in following children of uterus transplant patient as time from delivery increases, and that there could be possible disinterest from the children in having that data collected. The Committee did ultimately agree that there would not be significant difficulty in collecting neonatal data one hour after delivery, but that it would not be a part of this project.

3. Living Donor Committee Recommendations on Prior Living Donor Priority

The OPTN Living Donor Committee presented its recommendations on prior living donor priority in VCA. The recommendations are for organ specific committees considering the challenges of Continuous Distribution, and how prior living donation should factor into candidate score. The Chair of the Living Donor Committee presented their reasoning and recommendations for organ specific committees as to why priority points should be given to prior living donors. The recommendations are as follows:

- Prior living donors should receive priority if they are listed for transplant
- All prior living donors should receive priority for any organ needed
- Prior living donor priority should not have a time restriction
- Prior living donors should not be valued differently based on organ donated

Summary of Discussion

Amongst the Committee there was widespread support for the recommendation, and they felt it fell within the spirit of living donation. The Chair stated that this should be broadly applicable to VCA, but was mildly concerned with the possibility of a "small" VCA donation granting permanent priority for other listings. At present, however, they also were not concerned with this being a significant issue. The Vice Chair similarly noted that many hypotheticals could exist, but that should not weigh down the entire effort. They inquired whether there was any consideration into families of living donors being able to receive the priority instead of the donor, as VCA donors tend to be younger. The Chair of the Living Donor Committee felt that this would not be in the spirit of living donation.

Upcoming Meeting(s)

- October 13, 2021
- November 10, 2021
- December 8, 2021
- January 12, 2022

Attendance

- **Committee Members**
  - Bohdan Pomahac, Chair
  - Sandra Amaral, Vice Chair
  - Brian Berthiaume
  - Liza Johannesson
  - Mark Wakefield
  - Patrick Smith
  - Amanda Gruendell
  - Simon Talbot
  - Vijay Gorantla
  - Alexander Maskin
  - Debbi McRann
  - Debra Priebe
  - Elizabeth Shipman
  - Donnie Rickelman
- **HRSA Representatives**
  - Jim Bowman
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Kristine Althaus
  - Krissy Laurie
  - Isaac Hager
  - Susan Tlusty
  - Meghan McDermott
  - Lindsay Larkin
  - Leah Silfe
  - Sarah Booker
  - Rebecca Murdock
  - Nicole Benjamin
- **Other Attendees**
  - Stevan Gonzalez
  - Heather Hunt