

OPTN Vascularized Composite Allograft Transplantation Committee**Meeting Summary****April 6, 2022****Chicago, Illinois/Conference Call****Bohdan Pomahac, MD, Chair****Sandra Amaral, MD, Vice Chair****Introduction**

The Vascularized Composite Allograft (VCA) Transplantation Committee met in-person and via Citrix GoTo teleconference on 4/6/2022 to discuss the following agenda items:

1. Review and discuss public comment feedback on Modify Graft Failure Definition for VCA, Finalize Proposal, and Committee Vote
2. Breakout sessions: *Guidance on Optimizing VCA Recovery from Deceased Donors*
3. VCA in UNetSM Update
4. Uterus Transplantation Overview
5. VCA Data Update
6. Recognition of outgoing members

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

1. Review and discuss public comment feedback on *Modify Graft Failure Definition for VCA, Finalize Proposal, and Committee Vote*

The Committee briefly covered the overall proposal and reviewed the public comment feedback received for discussion. The feedback was generally supportive with only one oppose comment from a stakeholder organization. Below is a summary of the discussion around the themes of the public comments submitted.

Summary of discussion:*Feedback: Re-Registration*

Stakeholder organization comments recommended including definitions for when limited or decreased function of a graft is no longer acceptable and for the Committee to consider graft-specific functional expectations similar to what is defined for pancreas. The Chair noted that while this is something the Committee would like to revisit in the future, currently there is not enough data to definitively know what is a good or poor outcome for VCAs and that there is a strong patient perspective aspect that would also need to be incorporated as well. The Committee also previously discussed this topic as part of a previous project that will capture some functional outcome data and would not be part of the scope of this project.¹

Feedback also asked that the process for reporting graft failure in the case of re-registration be clarified and the transplant program would need to report the graft failure in the Data System for the OPTN and

¹ Update to VCA Transplant Outcomes Data Collection, Data Collection Changes Notice, accessed April 27, 2022, <https://optn.transplant.hrsa.gov/media/3889/update-to-vca-transplant-outcomes-data-collection.pdf>.

separately re-register the candidate for the same VCA in the OPTN Computer System. These functions are not linked, so re-registering a candidate will not trigger a graft failure report.

Feedback: Limiting “Planned Removal” to Uterus

Public comment feedback supported limiting planned removal to uterus only since it is the only VCA transplant currently performed with the intent of being temporary.

Prompted by these comments, the Committee reached out to abdominal wall programs to gauge how likely it will be that abdominal wall grafts are transplanted in order to provide temporary coverage due to the swelling that occurs with abdominal organ transplant. The Chair explained that the feedback from abdominal wall programs was mixed noting that while it may be considered in the future, transplanting an abdominal wall with a planned removal has not occurred yet. The Chair also noted that the Committee has generally not created policy based in hypotheticals. A member agreed that the Committee should not make conjecture about the future possibility for abdominal walls to be used as temporary coverage. Another member supported leaving the definition open so that in the event an abdominal wall is transplanted for temporary coverage it would not be reported as a graft failure in the future, but noted that there is a risk of programs claiming a planned removal when the graft is failed.

UNOS staff clarified the process for revising the definition in the future, which would include a new project proposal, public comment, and OPTN Board of Directors approval. The Vice Chair asked if the definition is limited to uterus and an abdominal wall program removes a graft after temporary coverage, is there a way for the program to appeal that removal being a graft failure and it was clarified that there is no appeal process and the removal would be documented as a graft failure. However, having that information would help inform the Committee for a future project that no longer limits planned removal to uterus.

A member noted that the intent of the transplant being a planned removal should be documented prior to the transplant, which was defined as part of the policy in this proposal. Another member added that there is still the opportunity for that to be misused. A member asked what the impact of having a planned graft removal reported as a graft failure if abdominal wall was not included and the Chair clarified that there would be no impact to those transplant programs because there are no program specific reports (PSRs) for VCA since the current volumes are so low. It was also clarified that while VCA programs do not have PSRs, projects like these are setting up the future for those reports having accurate reporting and there should be some consistency with other organ types (i.e. using the term failure).

A member stated that they do not see a negative to planned removal being inclusive to abdominal wall, but felt it would be more straightforward to limit planned removal to uterus. They continued to say that the downside would be that the policy development process to open the planned removal definition to other VCAs would take at least a year to implement. A member added that their interpretation of the goal of this project was accurate reporting and data collection, therefore the Committee should not worry too much about gaming the system and allow all VCA programs to utilize planned removal to accurately report intent.

The Vice Chair asked if a timeframe could be imposed to aid in monitoring the use of planned removal and members explained that set timeframes would be difficult to define and would vary by VCA type with the possibility to change over time due to new clinical practices. The Vice Chair asked if there was a way to flag any occurrence of planned removal as an option for closer monitoring and it was clarified that specific language for that is not typically included in policy since everything is subject to review by the OPTN.

A member supported limiting the planned removal option to uterus and noted that while they understand the negative connotation of graft failure, this is all reported under graft status in the Data System for the OPTN and the specific status and removal can be described in the free text field. The Chair asked if altering the proposed graft status selection options to functioning or removed and then if removed is selected choosing either functioning or failed would be an improvement and a member agreed that it would remove the barrier for possible innovation in VCA programs. The Chair added that it may create more of a gray area and a member agreed adding that there are no clear definitions of function in abdominal wall transplants. A member added that decisions should be made assuming that programs have the best intentions of providing accurate and useful data since there is no overall solution to people's honesty and supported keeping the proposal simple and evaluate for any potential issues.

Committee members voiced support for limiting the planned removal definition to uterus so that policy is not being written in hypotheticals and supported revisiting the definition should other VCA types start transplanting with the intent to remove them after they are successful. A member opposed this limitation since it hinders data collection and another member supported the limitation, but felt this should be revisited as soon as it is relevant to avoid hindering progress in the field because of the negative connotation of graft failure.

Process Documentation, Recommended Policy Changes, and Future Projects

The Committee also discussed the scenario in which a patient has one successful uterus transplant, the graft is removed, but then later in life wants to pursue a second uterus transplant and how to best outline that process. The Committee reviewed the possible change to the proposed policy and the opportunity to outline the data reporting process in the project briefing paper and felt it would be best to outline the process instead of altering the policy language.

The Committee reviewed the recommended changes to *Policy 18.1* to stop the generation of a Transplant Recipient Follow-up (TRF) form if the recipient's graft has a planned removal. Staff clarified that the OPTN has authority to collect data on recipients and once the graft is removed the authority is not necessarily the same and that transplant programs may not continue to follow those patients. It was also added that the outcomes data collection pending implementation does include a number of questions on uterus to capture any complications.² The Committee supported the policy change to stop the generation of a recipient's TRF after a planned removal.

A stakeholder organization suggested that a future Committee project include allowing VCA programs to set individualized goals for their transplant candidates prior to transplant to allow for future assessment of whether the VCA graft met the patient's goals. The Committee agreed that this is a priority for the VCA community but there are not enough solid metrics to implement as a policy yet. A member stated that work on this is being done currently through the American Society for Reconstructive Transplantation and members questioned whether this is an OPTN role or the role of professional societies in which the OPTN would be included.

Committee Vote

The Committee voted 14 support, 1 oppose, and 0 abstentions.

² *Update to VCA Transplant Outcomes Data Collection*, Data Collection Changes Notice, accessed April 27, 2022, <https://optn.transplant.hrsa.gov/media/3889/update-to-vca-transplant-outcomes-data-collection.pdf>.

2. Breakout sessions: *Guidance on Optimizing VCA Recovery from Deceased Donors*

Committee members split into breakout session groups to discuss the different sections of the guidance document to identify places that may need updating once VCA in the OPTN Computer System is implemented and presented their recommendations to the full Committee.

Summary of discussion:

Group 1: Strategic Decision to Participate in VCA Donation & Family Support and Authorization Approach

Members in this group identified that language should be updated to refer to match runs rather than candidate list, should elaborate more on timing considerations, and that the Committee should consider adding guidance on procurement “dry runs” where there is recovery without the intent to transplant which would not be under the OPTN purview, but could be helpful for members.

The group also suggested adding language about considering prospective crossmatching before talking to a donor family. A member expressed concern over prospective crossmatching holding up the overall process, but recommended using language such as preliminary immunologic evaluation or virtual crossmatching. The Chair asked if programs are utilizing virtual crossmatching, and the member stated that many donors could be ruled out with only the virtual crossmatch.

The group also added that VCA authorization could be documented on a separate form or a standard authorization form, with examples that could be included in the guidance document appendices.

Group 2: Planning and Hospital Partnerships & Media and Public Relations Strategy

Overall, the group supported the guidance regarding the collaboration between organ procurement organizations (OPO) and hospitals, but suggested adding guidance for limiting personnel both in the OPO and the donor hospital for privacy and for recovery team focus and education. The group also recommended adding information on the possible movement of donors to a procurement facility for donor family awareness and the potential of these transfers having an impact on privacy concerns.

Regarding media and public relations strategy, the group strongly recommended moving the paragraph referencing the donor family’s comfort level regarding media attention and interviews to the top of the section because of the importance of this issue. The group also noted that it is important to disclose the possibility of media leaks with donor families, especially with the prevalence of social media. The group also discussed the preparation of media leak statements and suggested timeframes for media engagement. They stressed that media engagement has include the involvement of all of those impacted for transparency and also suggested that set timeframes may not be appropriate for all situations (in the event that a recipient wants to speak to their experience sooner).

Group 3: Registering a Deceased VCA Donor and Accessing the VCA Candidate List & Criteria for the Evaluation of Donors for VCA Transplantation

The group stated that the language instructing members on registration would need to be updated once VCA is in the OPTN Computer System since the process will change. The group noted that the language referring to multi-organ transplantation and VCA will likely need to be revisited with the projects that the OPTN Ad-Hoc Multi-Organ Transplantation Committee is working on and that the use of the term “life-saving” should be reconsidered due to the subjectivity of the phrase. The group also identified that at the time the guidance document was created, living VCA donation was not considered and should be updated to include that information. Members mentioned that the reference to donors with “increased risk” needs to be updated since that term is no longer used and that uterus is no longer an emerging field so more specific information for uterus should be included.

Group 4: VCA Recovery Considerations & Post-Recovery Considerations

This group also suggested that there be language and guidance for cases where the VCA donor is moved from the donor hospital to a centralized recovery center or VCA transplant center, including across OPO boundaries. They also recommended that there be language to guide OPO recovery teams that do not have experience with VCA recovery. A member also noted that there is reference to a conference call in advance of the recovery and typically it is not known who the recovery team is going to be so it is usually helpful to have a huddle in the operating room once the full team has arrived. They added that the order or sequence of recovery should just be structured according to the arrangements of the recovery team. Additionally, if medical examiners or coroners are involved in the case, the deceased is probably not a suitable donor. A member asked if anything specific should be added for uterus and another member did not think there was anything specific needed.

For post-recovery considerations, the group recommended amending the language to state that the appropriate prosthetics be made available based on the donor family's preferences and that the application of the prosthetics may also provide comfort to the perioperative teams. The group stressed that donor dignity is the priority and made recommendations on how to secure prosthetics.

This group also added their suggestions for the media and public relations strategy section, noting that general public relations advice does not need to be included and that the timeframes should only be limited to the coordinated timing that makes sense for all parties involved. They also felt that the language on maximizing the return on investment may not be appropriate since this guidance should be more based on donor family wishes.

Next Steps:

Seek OPTN Policy Oversight Committee for project approval and work on finalizing the updated guidance sections and language.

3. *Programming VCA Allocation in UNetSM Update*

The Committee overviewed an update on the progress of the implementation of *Programming VCA Allocation in UNetSM* and the pending implementation projects that will also be implemented along with *Programming VCA Allocation in UNetSM*.³

The Committee was also asked for their feedback on some VCA organ abbreviations, the uterus living donor acceptance criteria default, skin tone/pigmentation, and available the OPTN Computer System training and educational resources for members.

Summary of discussion:

VCA Organ Abbreviations

The Committee reviewed the proposed VCA organ abbreviations, which would be used on the match run to indicate if a candidate is registered for multiple organs and would also be shown on the candidate page in the OPTN Waiting List. The intent is to use abbreviations that both the transplant programs and OPOs would understand. It was also mentioned that Committee leadership had suggested replacing UL and LM for upper and lower limb to UE and LE for upper extremity and lower extremity. Members agreed that UE and LE are what would be more commonly used in the community and supported the change.

³ Programming VCA Allocation in UNet, Policy Notice, accessed May 2, 2022, https://optn.transplant.hrsa.gov/media/4246/policy-notice_vca-in-unet_december-2020.pdf.

Default Donor Acceptance Criteria

The default donor acceptance criteria were reviewed and Staff clarified that these would just be the default and programs would be able to go in and change their preferences as needed. The Committee supported the use of the suggested donor acceptance criteria being:

- No for donors after cardiac death (DCD)
- Yes for brain dead donors
- Yes for living donors for uterus candidates
- No for living donors for all other VCA candidates

Skin Tone and Pigmentation

The Committee was asked for feedback on an accepted standardized way to collect skin tone for matching. It was added that the Fitzpatrick scale was previously discussed as an option, however, skin tone color swatches are not something that could be added in the OPTN Computer System directly as selection options.⁴ It was mentioned that if there was a standard swatch that the Committee wanted to link to in educational documentation, that would be a possibility. A member asked if the purpose of the selection options was to have broader categories that can then be narrowed down as compatible donors are matched and the Chair clarified that the intent is to indicate what skin tones the candidate would be willing to accept which is also helpful with communication between the transplant program and the OPO at the time of procurement. A member stated that the broad ranges can add complexity and that their program uses silicon prosthetics swatches for more accurate skin tone matching. They continued that the Fitzpatrick scale is a good screening tool while being broad and the individual programs can add granularity at the time of a match and another member agreed. A member added that initially there was an attempt to make sure that their recovery coordinators had color swatches to aid in matching which proved to be too much of a burden, so sharing a picture of the skin with a brief description is the starting point for matching. A member mentioned that there is a technology company that is working on a way to match photographs, which may be something to be considered in the future. Members also noted that there are challenges with photographs and lighting. A member added that while there are many things that are helpful as screening within the OPTN Computer System, there are additional steps that may not need to be captured within the OPTN Computer System.

The Committee was asked for their recommendation on the word descriptions for the skin type scores that would be descriptive enough while also being culturally sensitive. A member stated that while something may be culturally appropriate now, there is the chance that these will have to be revised in the future. The Vice Chair recommended omitting language like “typical Mediterranean skin tone” because it does sound subjective. The Vice Chair also asked for clarification on whether this was a field on the candidate side or donor side and Staff clarified that this is only what the candidate’s skin type is, but that there is a text box to indicate what the candidate is willing to accept. The Chair suggested that only the “Type I-VI” be included in the choice option and leave out the “score 0-35+” for simplicity.

A member asked how important it is for the transplant to be exact in color matching since there are VCAs where matching may be more important, such as face versus abdominal wall. They also added that this idea was initially brought up since the increased risk of sunburn or skin cancers may be higher when coupled with immunosuppressive risk. A member stated that if the patient or program does not have a preference, that can be indicated. The Vice Chair mentioned that a large part of this is patient centered so there should be flexibility on what can be selected.

⁴ Fitzpatrick skin phototype, DermNet NZ, accessed May 2, 2022, <https://dermnetnz.org/topics/skin-phototype>.

The Chair felt that this field should be for indicating what the candidate is willing to accept with the ability to multi-select skin types and members agreed. It was clarified that what the candidate is willing to accept for a donor would be indicated under acceptance criteria. The Vice Chair felt that it would be important to capture the information on the candidate and the donor acceptance. It was clarified that the text box was added to the donor acceptance criteria to capture that information since the match screening would not be able to incorporate that information. A member stated that the link to a color swatch reference next to the text box would be helpful. The Vice Chair added that it should be incorporated to aid in efficiency when running matches, but it was clarified that for the initial implementation of VCA in the OPTN Computer System, skin tone screening was not something that could be incorporated due to the resources it would need to implement.

When looking at the donor acceptance criteria field mockup, members asked if cytomegalovirus (CMV) screening information would be available, particularly in the case of uterus transplant. Staff clarified that it was not initially included since this is the initial implementation, which mostly includes what is already available for other organ types. A member stated that currently that is important in uterus transplant, but can be managed downstream by the transplant programs. The Committee was asked if the field for acceptable donor birth sex could be omitted for uterus and external male genitalia and the Committee supported excluding it.

A member asked if more screening criteria should be included such as measurements of the upper limb and a member mentioned that they typically start with these broader screening criteria and have a more granular conversation with the OPO when there is a possible match. A member stated that in terms of the workflow, when a match run happens, the transplant program gets an electronic notification where they can look at any imaging, lab results, etc., and then the transplant program responds to that electronic notification versus a call. They added that if the donor passes the initial screening, the transplant program can then call the OPO and have a more detailed conversation on whether it is an acceptable match.

Members asked about whether or not pictures will be able to be uploaded of the potential VCA from the donor or if there were too many privacy concerns. It was clarified that imaging is allowed to be uploaded in the OPTN Computer System. The Vice Chair asked if there were certain VCAs that would be too sensitive to upload pictures such as face and external male genitalia and a member added that process will vary by OPO. However, in general, if a photograph is needed for donor assessment that will be included in the imaging. They mentioned that while they may feel comfortable sending imaging to the surgeon, they may hesitate to upload those images to the OPTN Computer System. Another member stated that these images are important for donor matching and uploading them to the OPTN Computer System should be encouraged rather than leaving it to members to find alternative methods that would be even less secure. The Vice Chair mentioned that this may an opportunity to provide guidance to members on best practices. A member noted that after consent photographs are reasonable, but during screening it ends up being more of a gray area. Members agreed that photographs can be critical for matching of certain VCA and supported continuing the conversation to have a standardized and secure way of sharing photographs when needed. UNOS staff identified this as a good question for the OPTN Ethics Committee to review regarding the ethical evaluation of identifiable imaging being uploaded to the OPTN Computer System prior to when consent is obtained during the donor screening process. Staff also added that this can be discussed with the UNOS imaging team.

Training and Educational Resources

The Committee reviewed the currently available resources for members to learn about the OPTN Computer System and its processes and were asked for feedback on any additional resources that may be needed. A member stated that the most useful resource for them when they started in VCA was to

be able to talk to colleagues who were already familiar with the OPTN Computer System and the processes. The member suggested having a list of people willing to help members who are new to using the OPTN Computer System as a resource since it is more helpful to talk someone through the process versus clicking through a video. It was asked if a webinar that walks through the process would be helpful and a member noted that most personnel are required to attend so many webinars that it would be likely underutilized.

4. Uterus Transplantation Overview

A Committee member (presenter) presented a primer to uterus transplantation including its history, current practices, and future considerations. Uterus transplantation serves to correct the problem of uterine factor infertility. Currently, most of the uterus recipients are born without a uterus, however, the future of uterus transplantation will have more candidates who have had a prior hysterectomy or a non-functioning uterus. The presentation also covered that while there are other ways to grow a family outside of uterus transplantation, there are financial and legal barriers to those options that need to be considered.

The presentation outlined the recipient milestones, which include their medical evaluation, embryo creation, receiving the uterus transplant, embryo transfer and pregnancy, cesarean delivery, and finally the removal of the uterus graft. The recipient can try for multiple pregnancies with the same uterus graft and the large consensus in the community is that two pregnancies with the uterus graft is the longest the graft should be in place.

The risks of uterus transplantation were also covered including the rate of graft loss due to thrombosis, the occurrence of post-transplant lymphoproliferative disorder (PTLD), the use of immunosuppression in pregnancy, and renal compromise.

Summary of discussion:

A member asked how difficult a post-transplant hysterectomy is to perform since a post-transplant nephrectomy is considered very difficult and the presenter stated that they had similar concerns, but the procedure is much easier than one would expect.

A member felt that highlighting the Turkish uterus transplant is important and felt that it should inform guidelines and regulation in the community while also acknowledging the difficulty that team must have dealt with to achieve a live birth.⁵ The Vice Chair noted that women who feel desperation when dealing with infertility will continue reproductive procedures for as long as they can afford it and with that in mind, wondered if it is an ethical question that balances the clinical limitations and a woman's autonomy. The presenter explained that when looking towards the future the community should not be looking to restrict, but to provide guidelines and encourage those conversations with candidates so that there is transparency with expectations. The presenter also noted that with life enhancing transplants there is a difference in the mission, but that they hope there is room to evolve so the need of the patients can be met. A member agreed and noted the value of the OPTN Committees compared to places in the world where this kind of structure is not established.

A member spoke to their experience and stated that the expectation around uterus transplant was made clear from the beginning, which helped them understand that if the transplant was not successful in the given timeframe acceptable and ethical expectations were set. The presenter asked the member what their perspective is on guidance for uterus transplantation moving forward, especially around

⁵ Omer Ozkan, Ozlenen Ozkan, Nasuh Utku Dogan, Mustafa Bahceci, et al, *Birth of a Healthy Baby 9 years after a Surgically Successful Deceased Donor Uterus Transplant*, Ann Surg, December 16, 2021, accessed May 2, 2022, <https://pubmed.ncbi.nlm.nih.gov/35129480/>.

safety and transparency. The member responded that they are looking forward to this being a viable option for more women struggling with infertility and felt that there should be more opportunity for patients to have a voice when documenting guidelines and policies.

A member noted that uterus transplantation is moving from research protocols and covered by the hospitals to being self-paid which will raise equity concerns in the time that insurance does not cover these procedures. A member stated that there is a program in Europe where the uterus transplants are now being covered by insurance, which can set a precedent for other programs.

5. VCA Data Update

The Committee reviewed the current breakdown of VCA programs, waiting list metrics, and transplant metrics.

Summary of discussion:

The Chair noted that there has been an increase in abdominal wall registrations and asked if those candidates are also registered for another organ. A member added that they recently experienced a match for a multi-organ candidate who flagged as needing an abdominal wall as part of an intestine transplant. Research staff clarified that four of the six candidates listed are multi-organ candidates. A member asked if there was a benefit to a candidate's listing to also be listed for abdominal wall and it was clarified that abdominal wall does not boost a patient's place on the match run.

A member asked for clarification on the breakdown of the number of genitourinary programs and it was clarified that most of those programs indicated they are uterus transplant programs which will be made clearer once the approved, but not yet implemented uterus membership requirements go into effect.⁶

The Vice Chair asked if there was additional information on what may be causing the long wait times for some of the candidates and a member offered that it may be a mismatch in donors (donors being heavier than the recipients). A member asked if there is information on the rate of declines for those listings and the Chair clarified that information would be more available once VCA is in the OPTN Computer System, which will point to medical reasons for declines or program concerns. Another member stated that some programs may have very strict procurement distances.

Sentinel Flap Update

A HRSA representative gave a brief update on the status of sentinel flaps being under the purview of the OPTN or the U.S. Food and Drug Administration (FDA). After discussion, it was decided that HRSA will take the lead to address the concerns raised by the Committee and VCA community.

6. Recognition of outgoing members

Outgoing members were recognized and thanked for all of their hard work on the Committee including the outgoing Chair, Bohdan Pomahac, who has served on the Committee since 2013.

Upcoming Meetings

- May 11, 2022
- June 8, 2022

⁶ Establish Membership Requirements for Uterus Transplant Programs, Policy and Bylaw Notice, accessed April 18, 2022, https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf.

Attendance

- **Committee Members**
 - Bohdan Pomahac, Chair
 - Sandra Amaral, Vice Chair
 - Mark Wakefield
 - Brian Berthiaume
 - Donnie Rickelman
 - Simon Talbot
 - Debra Priebe
 - Paige Porrett
 - Bruce Gelb
 - Debbi McRann
 - Lori Ewoldt
 - Amanda Gruendell
 - Vijay Gorantla
 - Elizabeth Shipman
 - Gary Morgan
 - Stefan Tullius
- **HRSA Representatives**
 - Jim Bowman
 - Raelene Skerda
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kaitlin Swanner
 - Krissy Laurie
 - Sarah Booker
 - Catherine Parton
 - Kristina Hogan
 - Susan Tlusty
 - Delaney Nilles
 - Tamika Qualls