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Public Comment Proposal

Guidance on Optimizing VCA Recovery from Deceased Donors

OPTN/UNOS Vascularized Composite Allograft (VCA) Transplantation Committee

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Guidance on Optimizing VCA Recovery from Deceased Donors

Affected Policies: *N/A*
Sponsoring Committee: *Vascularized Composite Allograft (VCA) Transplantation*
Public Comment Period: *January 22, 2018 to March 23, 2018*

Executive Summary

Engaging in vascularized composite allograft (VCA) recovery from deceased donors requires a significant amount of planning and development by organ procurement organizations (OPOs) and VCA transplant programs. OPOs currently recovering VCAs have reported as long as a two-year development period for standard operating procedures (SOPs) or protocols and training on the same. To assess the barriers to VCA authorization and recovery, the OPTN/UNOS VCA Committee (Committee) conducted an on-line survey of OPOs in the U.S. The Committee felt barriers identified in this survey likely contribute to low numbers of deceased VCA donors, and further delays in the development of VCA recovery SOPs/protocols at OPOs.

The Committee believes this guidance will address an unmet need for the OPO community. As a result of this proposal, OPOs without experience in VCA recovery will have access to effective practices identified by those OPOs with experience in the field. This guidance also reinforces the concept that OPOs can support VCA transplant programs outside their donation service area (DSA), and potentially even outside their region.

The Committee feels this proposal is in keeping with Goal 1 of the OPTN Strategic Plan. By increasing VCA awareness to OPOs that have not yet recovered VCAs, there will hopefully be an increase in deceased donors screened for VCA donation and VCA recoveries.

What problem will this resource address?

Engaging in vascularized composite allograft (VCA) recovery from deceased donors takes a significant amount of planning and development by organ procurement organizations (OPOs) and VCA transplant programs. OPOs currently recovering VCAs have reported as long as a two-year development period for standard operating procedures (SOPs) or protocols and training on the same. Of the 58 OPOs in the U.S., only 13 have successfully recovered VCAs for transplant since July 3, 2014.[1]

The OPTN/UNOS VCA Committee (the Committee) coordinated a survey of OPOs in the U.S. in 2016. The results demonstrated that OPOs see the following as barriers to VCA recovery:

- distance to nearest VCA program
- concern over additional operating room time at donor hospital
- potential for interference with life-saving organ recovery
- concern over donor family resistance
- variability in organ acquisition fees passed on to VCA transplant programs[2]

These barriers likely contribute to missed potential VCA donors and further delays in the development of VCA recovery SOPs/protocols.

[1] Based on OPTN data as of November 24, 2017.

[2] Cherikh, W, Harper, A, Luskin, R., Wholley, C, McDiarmid, S., “Results of a survey of organ procurement organizations to identify barriers to VCA authorization and recovery in the US”, *Vascularized Composite Allotransplantation* no 3, (2016), doi.org/10.1080/23723505.2016.1232979

This survey also identified that several OPOs would be developing VCA recovery SOPs/protocols in the next 12 months, and other OPOs were willing to consider developing VCA recovery SOPs/protocols. The Committee feels the survey results, and the absence of published guidance on this topic, make this an important project to pursue.

Why should you support this resource?

The Committee feels this guidance addresses an unmet need for the OPO community. As a result of this proposal, OPOs without experience in VCA recovery will have access to effective practices identified by those OPOs with experience in the VCA recovery. This guidance also reinforces the concept that OPOs can support VCA transplant programs outside their DSA, and potentially even outside their region. The guidance was created with the flow of a donor case in mind. The document begins with pre-donation collaboration with donor hospitals, donor recognition, surrogate decision-maker approach, access to the VCA candidate list, donor evaluation, recover and post-recovery considerations, and post-donation media considerations.

How was this resource developed?

In April 2016, the Committee reviewed the results of a survey to identify barriers to VCA recovery. This survey was conducted in collaboration with the Association of Organ Procurement Organizations (AOPO) and 44 OPOs responded. Based on the feedback obtained in the survey, the Committee determined there was a need for guidance on optimizing VCA recovery from deceased donors.

The OPO Guidance Subcommittee (Subcommittee) was formed in November 2016 and charged with developing the project. Members were composed of a diverse background of VCA transplant surgeons and a member of the OPTN/UNOS OPO Committee.

During early project discussions in 2017, the Subcommittee felt guidance would be most effective by engaging procurement and transplant subject matter experts (SMEs) from around the U.S. The Subcommittee acknowledged the diversity of recovery experiences by OPOs and agreed it was important to share these experiences to the extent possible. The Subcommittee also noted that SMEs in executive leadership, hospital development (HD), donor family support, OPO clinical operations, and media/public relations would add valuable perspective. Further, these SMEs would also communicate with colleagues of similar background most effectively. As a result, the Subcommittee invited SMEs from several OPOs and transplant programs to directly contribute to the guidance.

The Subcommittee met by conference call over the next several months and discussed how to address barriers identified in the survey, including: This included challenges posed by distance from an OPO to nearest VCA program (if outside the DSA), concern over additional operating room time at donor hospital, potential for interference with life-saving organ recovery, the perception of a donor's family over a subsequent authorization request for VCA donation, variability in organ acquisition fees passed on to VCA transplant programs, and challenges initiating VCA recovery SOPs/protocols.

Absence of local VCA Program or Extended Distance between the Host OPO and VCA Transplant Program

Subcommittee members discussed their respective experiences with VCA donor recoveries in order to identify any similarities. Central to this discussion was to assess if VCAs have been recovered outside the immediate geographic area of the transplant program. Some members commented that the majority of their donor recoveries occurred within the local DSA, while others shared that they have traveled outside their DSA and region for VCA recoveries. Table 1 below shows whether deceased VCA donors in the U.S. since July 3, 2014 were shared locally, regionally, or nationally.

Table 1: Share Type for Deceased Donor VCA Transplants in the US after July 3, 2014

VCA Type	Locally Shared	Regionally Shared	Nationally Shared	Total
Abdominal Wall	1 (100.0%)	0 (0.0%)	0 (0.0%)	**1**
Craniofacial	5 (100.0%)	0 (0.0%)	0 (0.0%)	**5**
Penile	1 (100.0%)	0 (0.0%)	0 (0.0%)	**1**
Scalp	1 (100.0%)	0 (0.0%)	0 (0.0%)	**1**
Upper Limb Bilateral	4 (66.7%)	0 (0.0%)	2 (33.3%)	**6**
Upper Limb Unilateral	1 (25.0%)	1 (25.0%)	2 (50.0%)	**4**
Uterine	1 (33.3%)	1 (33.3%)	1 (33.3%)	**3**
Total	**14 (66.7%)**	**2 (9.5%)**	**5 (23.8%)**	**21**

Based on most recent available information provided by members to the OPTN as of December 8, 2017. Data subject to change based on future data submission or correction.

Table 1 above shows that two thirds of VCA recoveries occurred within the DSA serving the VCA transplant program. However, 33% of VCA recoveries occurred outside the DSA of the VCA transplant program, and these are predominantly upper limbs. In light of these data, OPOs should consider the potential to recover VCAs even if there are no VCA transplant programs within the DSA.

The Subcommittee acknowledged the amount of allowable ischemic time will vary by transplant program, type of VCA, and size of the allografts. Longer travel times could be possible for some VCA types and may not be realistic for other VCA types due ischemic time concerns or logistical needs of the team. The Subcommittee agreed that, in general, a VCA with greater amounts of muscle would be more sensitive to ischemia and therefore may not be recovered and transported over a far distance. The Subcommittee agreed the guidance should reinforce that OPOs not dismiss the opportunity to collaborate with VCA transplant programs outside their DSA or region due to the belief the distance between the organizations would prevent VCA recovery.

Additional Operating Room Time at a Donor Hospital

The Subcommittee discussed the concern highlighted in the OPO survey over extended operating room times that may arise from a VCA procurement. Subcommittee members felt that this sentiment was the result of the media highlighting very long VCA procurement and transplant case times. Additional intraoperative time will clearly be required when VCA recoveries are added to solid-organ donor recoveries.[3] However, the concerns over exceedingly lengthy intraoperative times have not been realized by those OPOs who have recovered VCAs. The lack of onerous operating room times is not accidental. OPOs have universally seen benefit from diligent and open communication with all groups involved in organ donor cases involving VCA recovery.[4] The Subcommittee agreed it was critical to emphasize careful communication and logistical planning throughout the guidance document.

[3] Brazio, PS, Barth, RN, Bojovic, B, Dorafshar, AH, Garcia, JP, Brown, EN, Bartlett, ST, and Rodriguez, ED, "Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor", *American Journal of Transplantation* no 13: 2743–2749, (2013). doi:10.1111/ajt.12382

[4] Tullius, SG, Pomahac, B, Kim, HB, Carty, MJ, Talbot, SG, Nelson, HM, and Delmonico, FL, "Successful Recovery and Transplantation of 11 Organs Including Face, Bilateral Upper, Extremities, and Thoracic and Abdominal Organs From a Single Deceased Organ Donor", *Transplantation* no 100, 2226-2229 (2016), DOI: 10.1097/TP.0000000000001200

Interference with Solid Organ Donation

The Subcommittee discussed the concern that VCA recovery would negatively impact solid-organ recovery. The survey identified that several OPOs were concerned that the VCA authorization request could cause a donor's family to withdraw authorization for life-saving solid organ donation. Additional, there was concern the additional time associated VCA recovery may negatively impact solid organ recovery. Members verbalized hearing this concern outside of the survey and responded that this was not observed in VCA deceased donor cases at their OPOs. The Subcommittee acknowledged the legitimacy of these concerns. However, OPO members on the Subcommittee felt these concerns were successfully mitigated by early and effusive communication by all stakeholders involved in the donation process (host OPO, solid-organ teams, and VCA teams), and preplanning for contingencies (e.g. donor intraoperative instability, impact of longer recovery times on flight crews, etc.) The Subcommittee felt any potential for interference with solid organ donation could be successfully mitigated by high levels of coordination and planning for VCA recoveries.

Donor Family Resistance

The Subcommittee members were aware of and sensitive to the sentiment from the OPO community that a request for VCA authorization would be perceived as abrupt or traumatizing to a donor family. Further, there is concern that a VCA authorization request could dissuade all organ and tissue donation. The VCA Committee has long held that VCA donation must not interfere with life-saving organ donation, both in the authorization process and clinical practice. The Committee previously created guidance for deceased VCA donor authorization in 2014.[5] This guidance highlights that effective VCA authorization practices show that authorization discussions for VCA donation should occur **after** authorization for organ and tissue donation. Subcommittee members discussed their family approach experiences, noting that compassion and thoughtful messaging were keys to maintaining donor family trust. Further, members shared the respective experiences that donor family members have not been alarmed by, nor has solid-organ authorization been negatively impacted by a VCA donation request. The Subcommittee felt the guidance should highlight that OPO staff requesting VCA authorization should be knowledgeable and skilled advocates for VCA donation. OPOs should also develop a standard practice around authorization for deceased VCA donation.

Variability in VCA Acquisition Fees

Over the course of discussions, Subcommittee members discussed varying VCA recovery charges that were submitted by OPOs to VCA transplant programs. Members reported that some OPOs are participating in VCA recovery at no charge to help develop the field, while others are submitting charges that vary widely. Subcommittee members acknowledged that it was outside the scope of this guidance and outside the authority of the OPTN to define VCA recovery charges. Further, the charges associated with a VCA recovery varied greatly based on the type and number of VCAs recovered from a deceased donor. The Subcommittee felt this was an important factor to consider when developing VCA recovery SOPs/protocols. As a result, the guidance encourages early and diligent discussions between an OPO and VCA transplant program to include cost considerations well before any VCA recoveries.

The Subcommittee also discussed other important elements for the guidance. This included perspective from OPO executives on the decision to participate in VCA recovery, strategies for hospital development, instructions how to access the VCA candidate list in Secure Enterprise[sm], recommendations for VCA donor evaluation, VCA recovery and post-recovery considerations, and media/public relations. SMEs from OPOs and transplant hospitals were engaged to contribute to these sections of the guidance in order to engage the diversity of VCA experiences in the U.S.

[5] https://optn.transplant.hrsa.gov/resources/guidance/opo-guidance-on-vca-deceased-donor-authorization/

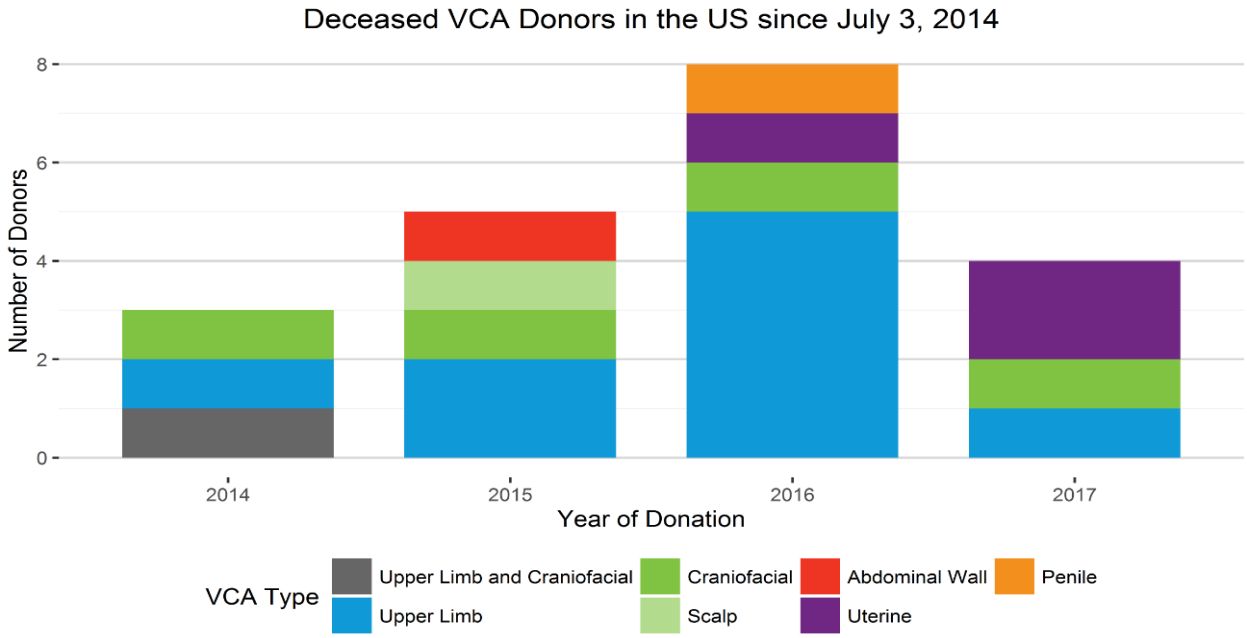
Full Committee Consideration and Vote

The Committee reviewed the guidance document during a conference call in December 2017. Discussions centered on minor amendments to the document for clarity. The Committee unanimously supported moving forward to solicit public comment on this guidance in January 2018 (Yes - 13, No - 0, Abstain - 0).

How well does this resource address the problem statement?

VCA recoveries in the U.S. are trending upward since July 3, 2014. Figure 1 below shows the deceased VCA donor cases by year and VCA type.

Figure 1: Deceased VCA Donors in the U.S. By Year since July 3, 2014



The Committee feels both the upward trend and the diversification of VCAs recovered from deceased donors further supports the need to guidance in the area.

The Committee performed a literature review of peer-reviewed journals to assess if there is a bona-fide need for this guidance. Datta and colleagues reported in 2015 that VCA procurements are very complex procedures demanding extensive training and development. Further, the authors felt that a single procurement protocol that encompasses all VCAs in the setting of multi-organ recovery was not practical. Other available papers support this position and shared institution-specific experiences that included "face first – concurrent completion" (for craniofacial recovery), or sequential recoveries (VCA recovery, followed by solid organ recovery). [6, 7] These diverse experiences highlight the need for guidance not only on the clinical aspects of VCA recoveries, but also the pre- and post-donation periods that are very impactful to the success of VCA recoveries. The holistic look at VCA donation in this guidance

[6] Datta, NA, Yersiz, HB, Kaldas, FB, Azari,KA, "Procurement strategies for combined multiorgan and composite tissues for transplantation", *Current Opinion in Organ Transplantation* no 20:121-126, (2015), DOI: 10.1097/MOT.0000000000000172

[7] Brazio, PS, Barth, RN, Bojovic, B, Dorafshar, AH, Garcia, JP, Brown, EN, Bartlett, ST, and Rodriguez, ED, "Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor", American Journal of Transplantation no 13: 2743–2749, (2013). doi:10.1111/ajt.12382

emphasizes the need for close collaboration with the involved OPOs and VCA transplant programs throughout the donation process.

One written comment submitted in the 2016 survey shared skepticism about the need to engage more OPOs in VCA recovery in light of the low VCA waiting list numbers. The Committee acknowledged this sentiment, however they felt the need exists to identify a larger number of potential deceased VCA donors. Matching criteria for VCA transplantation are more specific and go beyond blood type and histocompatibility matching. Anatomical size, skin tone, hair color, and other clinical factors make VCAs more challenging to match as compared to solid organs. As a result, more potential deceased donors need to be screened for VCA donation.

The Committee feels the guidance diligently addresses concerns outlined in the 2016 OPO survey. Given the necessary time for OPOs to develop VCA recovery SOPs and protocols, an increase in VCA donors may not be observed for several months following approval of this guidance. The Committee acknowledges that emerging VCA types, especially genitourinary VCAs, would require the guidance be updated to reflect clinical practices.

Which populations are impacted by this resource?

This guidance document will be a resource for OPOs. Guidance documents from the OPTN are not required to be used, and do not carry the weight of policies or bylaws. The Committee hopes this guidance will help OPOs to consider VCA donation when donor referrals are received from hospitals, an increase in VCA donation from deceased donors, and VCA recovery from OPOs that have not historically participated in this practice.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* Through this guidance, the VCA Committee is optimistic the number of VCA donors and transplants will increase. By spreading awareness to OPOs that may not routinely consider VCA authorization and recovery, this will increase awareness and hopefully deceased donor volume as well.
2. *Improve equity in access to transplants:* There is no expected impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no expected impact to this goal
4. *Promote living donor and transplant recipient safety:* There is no expected impact to this goal
5. *Promote the efficient management of the OPTN:* There is no expected impact to this goal

How will the OPTN implement this resource?

Due to community interest in and the complexity surrounding this topic, an instructional program will be developed once the guidance is approved by the Board. The OPTN anticipates that there will be questions from the community related to information within the guidance, and thus will provide an opportunity for subject matters experts to speak on the topic and answer those questions. UNOS will communicate this new information through TransplantPro and the OPTN website.

This proposal will not require programming in UNet^{sm}.

How will members implement this resource?

OPOs

This guidance is intended to help OPOs overcome barriers to VCA authorization and recovery. OPOs that use this document to develop internal SOPs/protocols may incur additional expense associated with:

- staff time for hospital development with VCA transplant programs
- staff time for hospital development with donor hospitals
- staff time for internal protocol development
- equipment purchases
- procurement rehearsals
- additional donor testing for VCA donor evaluation
- increased intensive care unit (ICU) and operating room charges at donor hospitals

Transplant Hospitals

Though this guidance is not directed at transplant hospitals, impact may be experienced at the operations level:

- consider the impact of VCA procurement on solid-organ acceptance or decline decisions
- need for solid-organ transplant teams to collaborate with VCA procurement teams on multi-organ donor cases
- consider logistics of organ procurement and transport to include VCA procurement

Will this resource require members to submit additional data?

No additional data submission will be required at this time.

How will members be evaluated for compliance with this resource?

Guidance from the OPTN does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.

How will the sponsoring Committee evaluate whether this resource was successful post implementation?

It will be challenging to establish causation of a change in VCA donation practices based on this guidance document and corresponding education/outreach. In order to assess if the guidance and related education/outreach has positively impacted VCA donation and transplantation, the Committee will monitor the number of VCAs recovered and transplanted from deceased organ donors in the U.S. UNOS staff will report this information to the Committee at regular intervals following approval by the Board. The Committee will also review this guidance every two years, or more frequently if changes in clinical practices are encountered, to ensure relevance of this guidance.

Guidance Document

Guidance on Optimizing VCA Recovery from Deceased Donors

Summary and Goals

Vascularized Composite Allograft (VCA) clinical transplantation has been practiced in the U.S. since 1998. The first transplant case was a larynx transplant. Coordination of deceased VCA donation was performed by the individual organ procurement organization (OPO) and VCA transplant program. Linkage to OPOs outside a local Donation Service Area (DSA) was solely dependent on the efforts of the VCA transplant program and was quite variable. VCA donation and transplantation was integrated into the Organ Procurement and Transplantation Network (OPTN) in 2014 establishing a national network for VCA donation.

The following guidance contains broad effective practices that apply to general VCA donation as well as specific guidance pertaining to head and neck, and upper limb donation. The Committee strongly encourages OPOs to collaborate with transplant hospitals that intend to perform additional VCA transplants, (e.g., larynx, penis, or uterus).

The goal of this guidance document is to better inform OPO leaders and their staff of the benefits of VCA transplantation and provide effective practices in VCA procurement.

Contents

Background

Vascularized Composite Allograft (VCA) clinical transplantation has been practiced in the U.S. since 1998. The first transplant case was a larynx transplant. Coordination of deceased VCA donation was performed by the individual organ procurement organization (OPO) and VCA transplant program. Linkage to OPOs outside a local Donation Service Area (DSA) was solely dependent on the efforts of the VCA transplant program and was quite variable. VCA donation and transplantation was integrated into the

Organ Procurement and Transplantation Network (OPTN) in 2014 establishing a national network for VCA donation.

OPOs were concerned that VCA donation could detrimentally impact solid organ donation. The VCA Transplantation Committee (Committee) performed a survey in 2016 to identify obstacles to VCA authorization and donation. Forty-four of the 58 OPOs in the U.S. participated and the results identified:

- Of the 19 OPOs with a written VCA recovery SOP/protocol
  - 39% never access the VCA candidate list before family approach, 22% access the VCA candidate list less than half the time before family approach
  - 67% do not have SOPs/protocols with VCA transplant programs outside their DSA
- Of the 26 OPOs without a written VCA recovery SOP/protocol
  - 62% are considering a VCA recovery protocol in the next 12 months
  - Several barriers were identified (no local VCA program, distance to nearest VCA program, additional OR time at donor hospital, potential for interference with life-saving organ recovery) [8]

The survey results document the need for clear guidance to the OPO community to optimize VCA authorization and procurement.

The following guidance contains broad effective practices that apply to general VCA donation as well as specific guidance pertaining to head and neck, and upper limb donation. The Committee strongly encourages OPOs to collaborate with transplant hospitals that intend to perform novel VCA transplants, (e.g., larynx, penis, or uterus). As case volume for these novel types of VCA increase, the Committee will amend this guidance to reflect effective practices.

Benefits of VCA Transplantation

As the field of VCA transplantation nears the 20th year of clinical application, the benefits and challenges are becoming apparent to larger and wider group of patients, clinicians, and families. Public attitudes toward VCA donation is reported as favorable and much of this is based on media reports of transplant outcomes.[9] There is some understanding outside the VCA transplant community that the therapeutic goal of VCA transplantation is functional restoration, not cosmetic restoration.[10] At the June 2017 American Transplant Congress (ATC) meeting in Chicago, multiple meeting attendees visited the American Society of Reconstructive Transplantation (ASRT) booth and remarked that they did not know hand and face transplants were even being done. Since this reaction occurred at a transplant meeting, one might expect even less awareness in the general public, and more specifically, that there is a need for guidelines and education regarding VCA for Organ Procurement Organizations.

Nearly 150 hand transplants and almost 50 face transplants have been done worldwide. The field of VCA is expanding. In addition to transplantation of the upper extremity and face, abdominal walls, larynx, lower limbs, uterus, and penile transplantation are now a clinical reality.

The benefit of VCA is simple. In every type of VCA the surgeon is able to replace like with like. The hand and face are extraordinarily complex units that encompass function, body image, and our ability to communicate on subtle levels with our families, friends, and coworkers. There simply is no artificial

[8] Cherikh, W, Harper, A, Luskin, R., Wholley, C, McDiarmid, S., "Results of a survey of organ procurement organizations to identify barriers to VCA authorization and recovery in the US", Vascularized Composite Allotransplantation no 3, (2016), doi.org/10.1080/23723505.2016.1232979

[9] Rodrigue, JR, Tomich, D, Fleishman, A., and Glaxier, A. "Vascularized Composite Allograft Donation and Transplantation: A Survey of Public Attitudes in the United States", *American Journal of Transplantation* no 10 (2017), 2687-2695, doi: 10.1111/ajt.14302.

[10] Caplan, A., "An Ethics Infrastructure for VCA", presentation at the Evolving Issues of Vascularized Composite Allo-transplantation, Baltimore, MD September 19, 2017.

substitute that comes even close. Hand and face VCA comes with the price of systemic immunosuppression, and this significantly changes the risk/benefit ratio for many who might benefit. However, should the panacea of tolerance be achieved, the lives of many patients living with catastrophic tissue loss will be irrevocably changed. Parents would be able to hold and kiss their children with warm hands and faces. Children would be able to just be kids. Only those who have lived without hands or faces or have had family members that struggle with these disabilities can really understand the extent of the benefit.

What are the benefits of VCA organ donation? Is there a benefit? The answer is unequivocally yes. Donation of VCA grafts does not reduce the availability or number of solid organs donated. VCA donation makes the precious gift a family has made, more so. Several years ago an individual with a severely disfigured face was recorded attending a Christmas lighting ceremony outside a busy department store window. People stared at him. Children turned away in fear. A year later the individual attended the same Christmas event, but this time after his face transplant. This time the crowd just watched the busy window; as did the recipient. The generosity of a donor family changed his life and the lives of several other patients by giving him the gift of acceptance and normalcy.

The goal of this document is to provide information to OPOs that are considering collaboration with VCA transplant programs. VCA transplants are successfully performed involving procurements outside DSA or regional boundaries. The Jewish Hospital (Louisville, KY) successfully transplanted an upper limb that was procured in Texas. We hope these guidelines provide a path to increase the utilization of the precious resources for the patients and families that can benefit.

Recommendations

1) Strategic Decision to Participate in VCA Donation

Organ procurement organizations identify, screen and coordinate the procurement of VCAs. While not all OPOs have developed VCA protocols, most OPOs that have implemented routine VCA screening did so through partnerships that supported VCA transplant programs within their DSA. In fact, one requirement in the VCA transplant center application to UNOS is assurance from the transplant center's local OPO that they will procure the specific allograph.[11] With the implementation of OPO protocols to support local VCA transplant programs and the OPTN creation of the national VCA candidate list in 2014, came the opportunity for OPOs to routinely screen donors for suitable matches with all VCA candidate types waiting. Many of the OPOs that support their local VCA transplant program have taken the logical next step, supporting VCA transplantation throughout the country.

With the expected expansion of VCA transplantation, it is vital that additional OPOs expand their practice protocols to include routine screening and coordination of VCA allograft donation *regardless of whether an OPO has a local VCA transplant center in their service area*. The resulting expansion of the potential donor pool will contribute to reduced waiting times for VCA candidates and allow better alignment with recipient matching specifications.

Effective July 3, 2014, the U.S. Department of Health and Human Services Division of Transplantation designated the addition of VCAs to the definition of organs covered by the OPTN Final Rule. OPTN Policy 1.2 lists the criteria for body parts to qualify as VCAs.[12] If these criteria are met, this subjects VCAs to requirements of the OPTN Final Rule including compliance with applicable OPTN policies and bylaws. It is important for OPO leadership to be aware of implications for this as it has regulatory and potential financial impact on the OPO cost report. Additional testing for VCA suitability may be realized as a part of

[11] https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf#nameddest=Appendix_J

[12] https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

the VCA donor case. This may include, but is not limited to, additional imaging, operating room time, or specialty consults costs.

When OPOs implement VCA donor protocols, high level coordination is required between the OPO and potential VCA transplant center. Protocols to establish a controlled setting in which communication and technical aspects are well planned are key to successful VCA donation. Factors such as preparing donor families for the potential media and public interest in these cases while trying to maintain their anonymity may be challenging and best handled through joint planning between the OPO and transplant center. Other recommendations around coordination are highlighted throughout this document.

2) Planning and Hospital Partnerships

Partnerships with donor hospitals are an important component to implementing a VCA donation program. The approach to hospital development (HD) will vary significantly for each OPO depending on number of donor hospitals, the spread of organ donation potential in hospitals in the OPO's service area, and geographic size of the OPO's service area. These variables should be considered in a HD VCA donation plan as well as the OPO's knowledge of the hospitals in their DSA.

A few approaches to hospital education about VCA donation and transplantation that can be considered are:

- Widespread, high-level overview of VCA donation options and transplantation applications within an OPO's standard organ and tissue donation education programs for providers and medical professionals
    - This approach may cause some confusion to hospitals that have little to no organ donation potential and are unlikely to see a potential VCA donation event. Customization of the education to the institution's needs is advisable
    - The approach process, should it vary from its normal/traditional course, should be clarified in provider education
- Targeted VCA donation and transplantation education to donor hospitals with high organ donation potential and/or hospitals within a geographic range of VCA transplant centers
- Real-time VCA donation and transplantation education to donor hospitals when a potential VCA donation event occurs
    - The OPO may decide to minimize the visibility of VCA donation to maintain donor confidentiality and to prevent potential media leaks- in light of VCA's current rarity. The transplant center may desire to manage the message carefully. In addition, the transplant center may wish to carefully reveal the incidence of VCA transplant, timed in such a way as to ensure its success, before wide dissemination takes place. The OPO should work closely with their VCA center to perform a risk assessment and set priorities around PR and education and discuss whether to inform or limit information to donor hospitals.
    - In circumstances where the decision is to limit donor hospital discussion about the VCA until there is some reassurance of the recipient's health communication should be limited to key donor hospital representatives to ensure their support of potential patient transfer and to prevent unplanned media attention. Those key conversations can happen with the Chief Medical Officer, Chief Nursing Officer, Chief Executive Officer, Nurse Manager or Administrative Director.
- VCA donation FAQs and other resources for hospital staff
- Consultations with donor hospital leaders to provide information and resources about the opportunity and benefits of VCA donation and transplantation, both in advance of VCA donation events and in real-time
- VCA should be included in post donor outcomes disseminated to the participating hospital staff and donor councils
- VCA donation and transplantation education at local and regional donor hospital education events
- Education for organ transplant programs within the DSA

- Include reassurance of minimal impact of VCA donation on traditional solid organ recovery and transplantation[13]
- Utilize the interest in VCA to support annual collaborative sessions

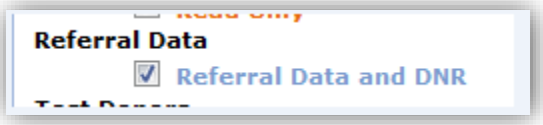
HD personnel, per their position as process consultants with area hospitals, should be involved in process planning particularly when there is a need to transfer the donor to the transplant center. The Medical Examiner/Coroner and Funeral Home liaisons should be part of the HD team to ensure laws regarding the transfer of deceased patients across county lines are observed or waivers obtained in advance.

Real-time HD is highly advisable in the circumstance of VCA donation due to the emerging nature of this type of organ donation. Utilizing the natural curiosities of the donor hospital staff is highly advantageous to future engagement.

3) Accessing the VCA Candidate List in Secure Enterprise

VCAs are not allocated off electronic match run lists that appear in DonorNet®. The VCA candidate list used for allocation is available to OPOs on the Secure Enterprise. For staff members who need access to the VCA Candidate List prior to any potential VCA donor case, have your UNet℠ System Administrator change the security permissions. This list is only viewable to those OPO staff members who can view the DSA Monthly Report.

- Go to the UNet Permissions link under Security Administration,
- Open each group, or create a new group for those needing access to these reports and check the Referral Data check box in the DonorNet section,



- Click on the **Update** button to complete the process.

Registering a Deceased VCA Donor:

To register a deceased donor who will be a VCA donor, whether an organ donor and a VCA donor or a VCA-only donor, enter the demographic and clinical information as you usually would in DonorNet. In the "Donor Highlights" section, please use the following language to note that this donor is a VCA donor, **"VCA donor: [organ type]**", for example: "**VCA donor: upper limb [laterality or bilateral]**". You may add any VCA details/highlights after this language.

To Access the VCA Candidate List:

- Log-in to Secure Enterprise. Under "My Data Reports", then "DSA Monthly Reports", open your OPO's copy of the VCA candidate list. Only the most current version of the VCA candidate list will appear in this section. This list is in Excel 1997-2003 format.

  If a VCA candidate appears on the list with a notation of needing a lifesaving organ, defer allocation of the lifesaving organ to the appropriate Match Run List, not from the VCA Candidate List.

[13] Aycart, MA, Alhfezi, M, Sharma, D, Krezdorn, N, Bueno, EM, Talbot, SG, Carty, MJ, Tullius, SG, Pomahac, B, "Outcomes of solid organ transplants after simultaneous solid organ and vascularized composite allograft procurement: A nationwide analysis", *Transplantation* no. 6 (2017), 1381-1386, doi: 10.1097/TP.0000000000001262

Using the VCA Candidate List:

- In the VCA candidate list, select your OPO from the yellow drop down box to initiate the first level of sorting of candidates based on the VCA allocation algorithm.
- Enter the Donor ID obtained from DonorNet for each of the VCA organs from the donor. Record the offer acceptance status for every candidate on the waiting list through the acceptor.
    - For any VCA candidates who are bypassed, record the bypass reason.
    - For any VCA candidates who refuse, record the refusal reason.
- If multiple VCA grafts are recovered from a single donor, complete a separate VCA candidate list for each graft. This includes a candidate who requires multiple grafts, i.e.: right and left upper limbs, or unilateral upper limb and face.
- After allocation of the VCA graft is complete, send the VCA candidate list with bypass and refusal reasons given through the VCA recipient to the OPTN via secure email (VCA@unos.org).
    - Please use your institution's secure email client or reply using the Cisco client appearing in a secure email already received from VCA@unos.org.
- After the recovery:
    - For a VCA donor who also donated non-VCA organ(s), complete the DDR as you normally would.
    - For a VCA only donor, select "No" for the "Referral Only" question on the disposition page in DonorNet. Then select the appropriate disposition for each organ type that follows. Then complete the DDR that is generated. Note that some fields will not populate on the DDR since only VCA organs were recovered.
- For any VCA donor, email the OPTN at VCA@unos.org and ask them to insert the following comment on the DDR record: "VCA donor: [organ type]"

If the OPO reviews the VCA candidate list to assess for potential matches with a deceased donor but VCAs are not allocated, OPOs are strongly encouraged to complete the list with applicable refusal or bypass codes and submit by secure email to the OPTN (VCA@unos.org).

4) Family Support and Authorization Approach

With the advancement of VCA transplants, some donor families can now make an additional gift apart from organ and tissue donation. Requestors need to become knowledgeable, skilled advocates for VCA donation. Thus, OPOs should develop a standard practice around authorization for VCA donation.

Preparing Staff for VCA Discussion:

Preparation for VCA authorization is key to a successful outcome. VCA transplant surgeons should be engaged with OPO requestors to articulate the need for VCA transplantation and the procurement process. Learning about outcomes of past VCA transplants, and the hopes of restored functionality and improved quality of life for currently listed VCA candidates help requestors facilitate the approach and become advocates for VCA transplant candidates.

Similar to general family approach practices, OPOs that have successfully procured VCAs report benefit of rehearsal conversations with OPO staff. These OPOs can provide suggested scripts and VCA authorization documents.

How to Identify a Potential Recipient:

When alerted to a donor referral, OPO staff should check the VCA candidate list to assess if there is a potential recipient that could be a match with the donor. OPO staff are encouraged to contact the VCA transplant program to assess whether there is early interest. If the VCA transplant program representative expresses early interest, the OPO should consider this referral a potential VCA donor. Further information on the donor should be gathered to assess for contraindications for VCA donation.

Authorization for VCA recovery must be documented carefully and cannot be assumed from general organ donation authorization or registry information. OPTN Policy 2.15.E requires OPOs to document the specific authorization for VCA donation from deceased donors.[14] Effective VCA authorization practices show that VCA authorization should occur **after** authorization for organ and tissue donation.[15] Further, any discussion on VCA authorization should only occur after a potential recipient has been identified on the VCA candidate list. This subsequent approach ensures that the approach for VCA authorization does not dissuade decision-makers from life-saving organ donation. Families should be offered opportunity for VCA donation once a potential recipient has been identified, regardless of whether they have authorized eye or tissue donation.

Help Families Understand the Need for VCA Transplants and Empower Them to Make a Decision:

Donor families need accurate information about VCA donation. First and foremost is this unique and rare opportunity to make a life-changing donation to a VCA candidate. This may include high-level details of functional restoration for the types of VCA being discussed.[16] Throughout the discussion, the family needs to be assured of the mutual commitment from the OPO and VCA transplant program to treat the donor with the utmost respect and integrity. Also, the OPO must disclose the potential for media coverage, potential identification of the recipient by the transplant hospital, and how you will protect the donor's identity and confidential information. OPO staff should discuss the options of prosthetics if cremation is not pursued.

There also needs to be transparent communication about the impact of VCA donation on the entire donation process. Additional testing will be needed to understand the quality of the VCA being considered. As a result, additional time may be required to thoroughly evaluate and coordinate the donation.

5) Criteria for the evaluation of donors for VCA transplantation

As with solid-organ transplantation, there are transplant program-specific criteria utilized for the evaluation of organs from deceased donors. The criteria and tools used to evaluate potential VCA donors will differ by VCA type. Additional considerations include whether to use allografts from U.S. PHS Increased Risk deceased donors, deceased donors with brain cancer (e.g., glioblastoma multiforme), or donors with diabetes. Good outcomes have been achieved in solid-organ transplantation using these types of donors. However, the decision to include or exclude VCA from deceased donors based on these criteria should be left to the individual VCA transplant programs.

Minimal criteria for acceptance of all VCAs are based on guidelines for solid organ transplantation, with additional criteria to ensure best possible outcomes of the VCA transplant. Common VCA donor evaluation criteria include:

- Donor allografts must be medically acceptable for transplantation according to the transplant center's criteria for solid organ transplantation with respect to stability of the donor, infectious disease status, and acceptable and unacceptable donor social, medical, and surgical history. VCA transplant programs may exclude deceased donors with disseminated intervascular coagulation (DIC), rheumatoid arthritis, or other allograft specific syndromes on a case by case basis.

[14] OPTN Policy 2.15.E, https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_02

[15] https://optn.transplant.hrsa.gov/resources/guidance/opo-guidance-on-vca-deceased-donor-authorization/

[16] Tullius, SG, Pomahac, B, Kim, HB, Carty, MJ, Talbot, SG, Nelson, HM, and Delmonico, FL, "Successful Recovery and Transplantation of 11 Organs Including Face, Bilateral Upper, Extremities, and Thoracic and Abdominal Organs From a Single Deceased Organ Donor", *Transplantation* no 100, 2226-2229 (2016), DOI: 10.1097/TP.0000000000001200

- Donor allografts can be recovered and transported within program acceptable limits of cold ischemia time. The amount of allowable ischemic time will vary by transplant program, type of VCA, and size of the allografts. In general, the more muscle a graft contains the more sensitive it will be to ischemia. As with any transplant, the shortest ischemic time possible is ideal.
- Recipient specific matching (age/gender/skin tone/hair color/BMI/size) is always a consideration. The presence of tattoos or scars are not absolute rule-outs. Allografts with distinguishing marks may be used at the discretion of the recipient and VCA transplant program.
- Depending on the type of VCA, additional tests not usually requested for solid organ transplantation may be required to assess the donor allograft(s). This may include photographs, X-Rays, vascular ultrasound, or computerized tomography (CT) scans.
- As with the practice in solid organ donation, on-site visual inspection of the donor prior to recovery and intraoperative assessment are the final components of VCA donor suitability evaluation prior to removal of the grafts.

Emerging types of VCA transplants may require additional types of consults or testing that have not been requested by OPOs in the past, for example, obstetrics and gynecology, or urology. OPOs are strongly encouraged to develop SOPs or protocols with VCA programs that intend to transplant emerging types of VCAs.

After VCA authorization is obtained, an OPO team member should speak with the VCA procurement surgeon to thoroughly understand VCA recovery. This knowledge is essential to inform the donor's family, funeral home, medical examiner/corner, and/or law enforcement representatives of the VCA donation.

6) VCA Recovery Considerations

Coordinating the recovery of VCAs and solid organs for transplant requires collaboration and communication between the OPO and all transplant hospitals accepting organs from the deceased donor and involved in the recovery. Considerations include the timing of VCA recovery and organ recovery, OPO staffing during the recovery, and plans for unexpected donor instability. A conference call between all recovery teams and the OPO in advance of the recovery procedure allows everyone to plan what will happen and in what sequence.

OPOs should work with the VCA transplant programs both within and outside their DSA to gain approval for VCA recoveries. Additionally, it is prudent for VCA recovery team members to be added to the AOPO Credentials Information Network (ACIN).[17]

Timing

The addition of VCA recovery to thoracic and/or abdominal organ recovery will add a significant amount of time that the donor is in the operating room. OPOs should plan for such extended lengths. This will include assigning primary OPO staff and relief staff to the recovery, and frequent communication with the donor hospital's operating room when booking the organ recovery.

Most head and neck VCA recoveries have preceded the thoracic and/or abdominal organ recovery. This allows for the operating room to be arranged with anesthesia at the foot of the donor instead of the head providing enough space for the VCA recovery team to perform the delicate facial recovery. If a sentinel patch is being recovered from the donor's forearm, the arms can be outstretched for this procedure. Extra care should be taken to secure the ET tube and protect the airway, though in some cases an elective tracheostomy may have to be performed on the donor in advance of the recovery. Following the recovery of the graft, the operating room can be re-arranged to enable the thoracic/abdominal organ recovery to proceed with anesthesia at the head of the donor.

[17] http://www.aopo.org/wikidonor/optn/regulations/

In other types of VCA recoveries there has been variability in the timing. In some cases, the VCA recovery has occurred before the thoracic and/or abdominal organ recovery. In other circumstances, the VCA and thoracic and/or abdominal organ recoveries began at the same time with each recovery team being given the amount of time necessary while the other teams wait.[18] In the cases of teams working together, the VCAs are often removed shortly before cross clamp, then the thoracic and/or abdominal organ teams are able to cannulate in preparation for cross clamp in the standard way.

The VCA team accepting the graft may be coming from outside of the DSA and may need support with ground transportation to and from the donor hospital. If the VCA team is flying into the DSA, the timing of the recovery may also impact the duty time of the aircraft crew involved in the trip.

Specialized Needs of the VCA Recovery Team

VCA procurement will likely require specialized surgical equipment not available at all hospitals. If a VCA recovery team will be traveling to a donor hospital, the recovery team is responsible for bring any specialized equipment that may be required to complete the recovery. If the VCA recovery is complex, the VCA transplant program and OPO should consider the risks and benefits of transporting the VCA donor to the transplant hospital where the VCA program is located.

Changes in Donor Stability

If the VCA recovery is planned to proceed before the thoracic and/or abdominal organ recovery, measures should be taken to ensure there is no loss of organs if the donor becomes unexpectedly unstable during VCA recovery. The thoracic and/or abdominal organ recovery teams should be available at the donor hospital in case instability occurs and the immediate recovery of other organs becomes necessary.[19] Preservation solutions for the thoracic and/or abdominal organ recovery should be on hand during the VCA recovery. Blood products for the donor should also be available in the donor operating room in the event of blood loss from the VCA recovery and the need for transfusion.

Preservation and Packaging

OPOs and VCA transplant programs should discuss the plans for use of organ preservation solutions and needs for sterile packaging materials. Sterile packaging needs will be determined by the type and size of grafts being recovered. Separate packaging will be necessary for multiple VCA grafts recovered from the same donor. TransNet must be used for VCA as it is with all other organs.

7) Post-recovery considerations

The application of prosthetics to replace the VCA graft removed is an important component. This is most applicable for head and neck or upper limb procurements.

With head and neck donation, the facial prosthetic should be applied following the organ and/or tissue recovery. When the donor is moved, the prosthesis may become dislodged. Sterile dressing should be placed over the recovery area and then the prosthetic secured on the donor after the organ or tissue recovery. If corneas are to be recovered, care should be taken to protect the donor's corneas as not to compromise cornea suitability and transplantation.

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[18] Brazio, PS, Barth, RN, Bojovic, B, Dorafshar, AH, Garcia, JP, Brown, EN, Bartlett, ST, and Rodriguez, ED, "Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor", American Journal of Transplantation no 13: 2743–2749, (2013). doi:10.1111/ajt.12382

[19] Datta, NA, Yersiz, HB, Kaldas, FB, Azari,KA, "Procurement strategies for combined multiorgan and composite tissues for transplantation", Current Opinion in Organ Transplantation no 20:121-126, (2015), DOI: 10.1097/MOT.0000000000000172

Following upper limb recoveries, the prosthetics may be secured prior to or after organ recovery, or after tissue recovery. Care should be taken with the prosthesis to avoid the prosthetics becoming dislodged.

OPOs should prepare a way to document the recovery of VCA in ways similar to thoracic and/or abdominal organ recoveries. Details such as times, preservation solutions, graft description and documentation of VCA organ quality should be maintained in the donor record. A process for review and receipt of donor information, ABO, serologies, and verification of organ donor identification and labelling should be adopted.

Funeral Home and Medical Examiner Involvement

Communication with the donor family's funeral home of choice is an important step in the VCA donation process, as it is with the standard organ and tissue donation process. This communication ensures the funeral home understands that extra care of the donor may be necessary due to the nature of the organ recovery, and the expected disfigurement of the donor. As VCA donation can impact and extend the organ donation process, this will impact the funeral arrangements and the funeral director's work to prepare for any memorial services.

Similar concerns apply to medical examiners or coroners who may be investigating the donor's circumstances of death. Seek approval from the medical examiner or coroner following VCA authorization to ensure there are no restrictions that impact the VCA donation.

8) Media and Public Relations Strategy

The section was written by a transplant center PR office, detailing how media strategies for VCA procedures were determined, how opportunities were handled, what can be expected, lessons learned, and how OPOs and transplant centers can work together at the time of a VCA transplant to collaborate and maximize media coverage.

Planning

A majority of the planning for VCA-related media will fall to the public relations team at the transplant center, with support from the OPO. To maximize potential, the OPO public relations team should connect with the transplant center public relations office to establish a direct line of communication before the transplant takes place—as early as possible, perhaps at the time when a recipient is being evaluated for transplant and prior to being listed. The two teams should then establish a core group to handle VCA media.

Together, the two should build a public relations strategy, specifically with a timeline for any media moments based on transplantation and subsequent patient milestones. Having this plan in place will mitigate any rushed announcements and/or media events. As part of this working group, public relations contacts at the additional institutions or centers associated with the VCA transplants should be involved and/or aware of the strategy and timeline. Together the collaborative group should determine whether there will be a press conference and, if so, who will host and lead the on-site coordination (recommendation is this would be the transplant center).

Ideally the group should coordinate any announcements to take place four to six weeks following the transplant, in order to ensure the procedure was a success, the patient is recovering well (early on) and to provide an added layer of privacy for both the recipient and donor/donor family. Transplant program staff should counsel the VCA candidate and caregivers about disclosing information to friends/family and on social media. Some transplant programs have intentionally not released the VCA transplant date as an additional layer of protection for the donor.

One of the most important first steps, before any media plans are executed, is for the clinicians and public relations team at the transplant center to find out whether the recipient and his/her family are comfortable

with media attention and interviews, and to what extent—this could include photography and videography, on-camera/phone/in-person interviews, press conferences, etc.

If the transplant recipient and donor family are open to this, they must sign HIPAA consents for media via the transplant center. The transplant recipient and donor family should also be introduced – ideally face-to-face – to the public relations point person who will be their direct point of contact so they can begin to establish a relationship. The public relations team, and the clinical team, should be prepared for the following possibilities:

- Transplant recipient/donor family requests for compensation for media appearances – patients/families should not participate in media appearances tied to compensation (as is sometimes the case with tabloid media)
- Transplant recipient/donor family to look to PR contact to act as an "agent" for prominent requests/marketing & advertising partnerships inquiries – recommendation is to manage the transplant recipient/donor family expectations and define that the public relations person's primary responsibility will be to respond to and facilitate media requests that come through the transplant center and/or requests that arise for clinical team interviews.
- Transplant recipient/donor family to want to remain anonymous, but still support media efforts – this is up to the discretion of the transplant center and OPO, and these opportunities must be conducted to ensure their privacy (consultation with hospital privacy officers/legal counsel is recommended)

Confidentiality/Anonymity

If the transplant recipient wishes to remain anonymous the public relations team can consider telling his/her story with limited personal details, leaning more on the clinical/surgical story not the human-interest. Another alternative would be to pivot strategy from focusing on generating media coverage to collecting information and planning for research/educational purposes (i.e. for journal publication, clinical briefing, or information for referring physicians).

The team can also collect photo assets that do not show the patient's face – for hand transplants, for instance, this could include photos taken over the patient's shoulder as they rehab. The transplant recipient may be open to sharing these images with reporters who want to cover the procedure but who agree to do so without any identifying details (name, age, hometown, etc.).

When it comes to the donor and donor family, privacy is paramount. All parties involved should never release or confirm the date of transplantation, details about where the donor organs came from, whether travel was involved, and/or any details about the donor/ family.

Media covering the transplant will undoubtedly ask for a date of transplant and/or donor information, so the public relations team should train each spokesperson and the recipient patient/family ahead of time to not specifically answer this question. If needed, a statement along the lines of "*In order to protect the identity of the donor and donor family, we cannot disclose the date of the procedure*" can be prepared and distributed. The public relations team should also prepare a "leak statement" to have on hand in the event word gets out to the media that a VCA transplant has occurred, before the 4-6-week timeframe has passed following the transplant.

Communications and Written Materials

Once a communications team is identified, a public relations plan is put in place, and the recipient has been HIPAA consented, the public relations team from both the transplant center and then OPO should identify a spokesperson(s) who will participate in media interviews following formal press announcement/as media inquiries arise. This is generally the lead surgeon(s), OPO CEO or Clinical Director, and the patient/family.

If needed for a press announcement, the public relations team should write a press release detailing the patient's story as well as the process for transplant (at a high level, and in lay language) which made the procedure possible. When working with several institutions/centers, coordinate with the press offices at each location to create one central press release – including quotes from a spokesperson at each center. Generally the transplant center would take the lead on a draft, with support from OPO/others involved to provide approval and their spokesperson quote. See appendix with two sample press releases.

The team should then draft talking points/key messaging for the spokespeople, varying the content slightly based on each person's area or expertise – as well as an FAQ document for spokesperson(s) to prep for interviews. This FAQ can also be made available to media, if appropriate, to answer some of the more basic questions. Spokesperson bios and headshots should also be on hand for media distribution, so that the public relations person(s) can respond to media inquiries swiftly. To note, media materials should acknowledge the selflessness of the donor/donor family for making the transplant possible – see appendix with two sample press releases – which is generally a good sentiment for the quote from the OPO spokesperson.

In additional to written press materials, the team should collectively determine whether the transplant center will host a press conference four to six weeks following procedure. If so, the public relations contacts should plan the following:

- Location, time, length
- Speaker program and remarks (written by transplant center and OPO public relations teams)
- Invitation to cover (written by transplant center public relations team)
- History of the specific procedure, VCA and the transplant program at the center
- Briefing document about the OPO (written by OPO public relations team)

Multimedia

As mentioned previously, the public relations teams at the transplant center can prepare to collect photo and video assets of the transplant process – pre-transplant photo and video, on the day of surgery, inside the OR (if needed), post-op and during rehab sessions. The team should evaluate budget and means to collect such assets. Once gathered, and before the media announcement is made, the public relations team should work with their video vendor and/or in house team to create a b-roll package to be shared with media prior to making any formal press announcements about a VCA transplant – provided the patient has given his/her approval.

Media Interviews

In the lead up to the press announcement/press conference, the public relations team should determine the need to pitch and establish an exclusive media partner. This can be a news outlet that will be given advance access to the surgical team and patient/family so that their story can air/publish on the day or the formal announcement.

At the time of the formal announcement, and in the days following, the public relations team at the transplant center can coordinate interviews for patient/clinicians/OPO spokesperson as they arise – prioritizing news outlets in order to maximize the return on investment on the time of patient/clinicians. The public relations teams at the OPO, transplant centers and any other institutions involved should coordinate regular calls/touch bases to keep each other in the loop as interview opportunities arise, to coordinate on outreach (and avoid duplication of efforts), and to be inclusive of all who made the transplant possible.

Milestones

The public relations point of contact at the transplant center should maintain communication with the patient and family following initial press moment, and evaluate media potential at noteworthy milestones – start with "exclusive" media partner again, and then parse out opportunities to select outlets as time

allows. The public relations team at transplant center and OPO can pitch stories and coordinate interviews as time allows and as interest unfolds.

Results and Social Media

The public relations team at the transplant center and OPO should track their media placements and share with the clinical team as well as with the patient and family on a regular basis. Keeping a running list of coverage, maintained by a single project manager to mitigate any potential for error, will be a beneficial archive to have on hand. The public relations teams from all institutions involved can share media stories and patient milestones (as approved by patient and clinicians) on social media, coordinating on the messaging and timing, and tagging each other to expend the reach – see appendix with for a sample.

Conclusion

The goal of this guidance document is to better inform OPO leaders and their staff of the benefits of VCA transplantation and provide effective practices in VCA procurement. The VCA Committee will review this guidance periodically to ensure clinical relevance and currency. Additional resources are available on the Association of Organ Procurement Organizations (AOPO) website.[20]

The VCA Committee acknowledges the following organizations for their contributions to this guidance document:

- Baylor University Medical Center
- Brigham and Women's Hospital
- Gift of Life Donor Program
- Jewish Hospital and the Christine M. Kleinert Institute for Hand and Microsurgery
- Lifebanc
- LifeSource Upper Midwest Organ Procurement Organization
- LiveON NY
- New England Donor Services
- Penn Medicine (University of Pennsylvania Health System and the Perelman School of Medicine at the University of Pennsylvania)

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[20] http://www.aopo.org/resources/aopo/vca-resource/

Appendix

APPENDIX

Press Release 1:

First Child to Undergo a Bilateral Hand Transplant Marks One Year since Surgery at The Children's Hospital of Philadelphia
CHOP, Penn Medicine and Shriners Hospitals for Children Celebrate Their Collaboration on Groundbreaking Surgery

Philadelphia, August 23, 2016 – Today, nine-year-old Zion Harvey can throw a baseball over home plate. He can write in his journal, prepare himself lunch and manage zippers on his clothes. However, for most of his life, these and many other ordinary actions were impossible for this little boy.

Then, in the summer of 2015, surgeons at The Children's Hospital of Philadelphia (CHOP) and Penn Medicine joined with colleagues from Shriners Hospitals for Children – Philadelphia, to complete the world's first bilateral hand transplant on a child. The surgical team successfully transplanted donor hands and forearms onto then eight-year-old Zion Harvey who, several years earlier, had undergone amputation of his hands and feet and a kidney transplant following a serious infection. Read more about this historic transplant surgery here: http://bit.ly/2aMoU5T

In the days and weeks after surgery, Zion had to start small: wriggling a thumb and flexing his fingers required intense concentration. He spent more than a month at CHOP, recovering from surgery and participating in rigorous occupational and physical therapy, before returning to his home near Baltimore.

Today, Zion is able to swing a bat and throw a football. He can take medicine and get dressed by himself. He can pick up important objects: a pencil, a fork, a piece of pizza.

"He's gaining independence and that is the whole reason why we do this," said L. Scott Levin, MD, FACS., Chairman of the Department of Orthopaedic Surgery and a Professor of Plastic Surgery in the Perelman School of Medicine at the University of Pennsylvania, and Director of the Hand Transplantation Program at The Children's Hospital of Philadelphia. "Zion's remarkable progress would not have been possible without a large team of multidisciplinary specialists, and the foundational work our hand transplant team at Penn Medicine has built, starting with our first adult hand transplant in 2011."

"After the transplant healed, it was very important for Zion to be in therapy full-time," said surgeon Benjamin Chang, MD, co-director of the Hand Transplantation Program at CHOP and associate chief of the Division of Plastic Surgery at Penn Medicine. "This is when we can make the most progress in terms of getting his function to come back, helping the tendons to glide, the muscles to grow stronger, actually re-teaching his brain how to fire those muscles again, and then teaching him how to do things like writing. He and his family have managed this so well, beyond our expectations."

Over the past year, Zion has spent up to eight hours a day in rehabilitation at Kennedy Krieger Institute, near his home in Baltimore. Occupational therapy is essential as Zion's brain relearns how to communicate with limbs that were missing for six years, and his muscles and tendons gain strength and flexibility.

"We needed to balance the functional side of therapy with the more biomechanical and neurological side to maintain supple joint motion positioning, and encourage development and strengthening of active motion, all while making it fun and exciting for him," said Lindsey Harris and Gayle Gross, Zion's occupational therapists at Kennedy Krieger Institute. "We quickly learned Zion's interest in sports and tapped into that. As a result we started with basketball and progressed to baseball, culminating in his recent accomplishment of throwing out the first pitch at an Orioles baseball game."

Additionally, a team of CHOP neuroscientists assembled to conduct brain imaging and analysis to track and aid Zion's mental and physical rehabilitation. For the first time, the team is calibrating functional MRI scans of Zion's brain and directly correlating his therapy to the brain mapping. This approach is being implemented with the goal that the primary motor cortex, the part of the brain that controls his hands, will catch up to the other fully developed areas.

As Zion grows, so will his hands. Zion continues to receive daily immunosuppressant medications to prevent his body from rejecting the new limbs, as well as his transplanted kidney. Dr. Levin and his team will continue to follow Zion throughout his lifetime.

"Double hand transplantation is a complex procedure involving many surgical and non-surgical components. Zion's success is a testament to the skill, dedication, innovation and passion of Dr. Levin, Dr. Chang and the rest of their team," said N. Scott Adzick, MD, CHOP's Surgeon-in-Chief. "As for the future, our CHOP and Penn teams are carefully reviewing and evaluating all aspects of Zion's progress and when the time is right hope to offer this same surgery to other children."

"Zion is a pioneer. With each week since his surgery, our team has learned more that will inform their efforts to perform future bilateral hand transplants and afford more children and adults a better quality of life," said Abraham Shaked, MD, PhD, the Eldridge L. Eliason professor of Surgery in Penn's Perelman School of Medicine and director of the Penn Transplant Institute.

"Zion's progress has been spectacular, highlighting what can be accomplished by the committed and coordinated collaborative effort amongst multi-disciplinary teams at CHOP, Penn Medicine and Shriners Hospitals for Children. The dedication to Zion's hand functionality and rehabilitation has expanded to the Kennedy Krieger Institute, as well the amazing community that has rallied behind Zion and his family. Their support has been instrumental to Zion's success. Zion's remarkable improvement, and his newly found ability to perform tasks previously unobtainable, is inspiring. Shriners Hospitals for Children is committed to continuing to advance this field and hopefully providing future children with the opportunity of this life-changing surgery," said Scott Kozin, MD, chief of staff, Shriners Hospitals for Children—Philadelphia.

When asked how his life has changed now that he has hands, Zion said, "I'm still the same kid everybody knew without hands. But I can do everything now. I can do the same things even better." "I believe he could have done anything without hands," said Zion's mother, Pattie Ray. "But now his light will shine even brighter. Whatever he is destined to do, it's going to make it that much better. I know those hands are going to be used in great ways."

"In the past year, Zion's accomplishments have inspired pride and joy in his family, his medical team and people around the world," said Madeline Bell, president and chief executive officer of The Children's Hospital of Philadelphia. "I could not be more proud of Zion and our team's commitment to continued innovation and breakthroughs to help children everywhere."

"Zion's story has been made possible through a unique collaboration between Penn and CHOP that illuminates what's possible when we bridge pediatric and adult medicine in new ways," said Ralph Muller, CEO of the University of Pennsylvania Health System. "No matter the age of our patients, we're focused on mapping the future of medicine."

Before the surgery could be conducted, it was first necessary to locate a suitable donor, a function coordinated by Gift of Life Donor Program, the nonprofit organ and tissue donor program which serves the eastern half of Pennsylvania, southern New Jersey and Delaware. Thanks to the generosity of a family in the midst of terrible loss, donor hands became available for Zion.

"For 42 years, Gift of Life Donor Program has partnered with transplant centers throughout this region to bring innovative transplant procedures to patients in need," stated Richard Hasz, vice president of

clinical services for Gift of Life. "As with all types of transplant, surgeries such as this one could not take place without the generosity of a donor and a donor family. We thank them for their selflessness and for their gift that made this surgery possible."

"People say I'm strong, but you really have to be strong to give the gift they gave," said Pattie Ray. "I think about them and I thank them every day."

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Press Release 2:

From Paris to Philadelphia: International Patient Receives Bilateral Hand Transplant at Penn Medicine

Team from Penn Medicine, Hôpital Européen Georges Pompidou Performed Double Hand Transplant on 28-year-old French Woman

EMBARGOED: PHILADELPHIA — It's 3,705 miles from Paris to Philadelphia, and another 730 from Paris to Corsica, France – that's where Laura Nataf was on vacation when she got the call. In the next 36 hours, Laura would travel more than 4,400 miles to Hospital of the University of Pennsylvania to receive new hands. The 28-year-old Parisian took one police escort and two plane rides to the United States for a bilateral hand transplant.

As the result of a collaborative effort between Penn Medicine, Paris Descartes University, and Gift of Life Donor Program, Laura is the first international patient to receive a double hand transplant in the United States, and is only the second adult to be transplanted at Penn Medicine.
"Laura represents not only the progress being in made in the field of bilateral hand transplantation and the advancements of Penn's Hand Transplant Program, but she is living proof of our ability to collaborate with medical centers around the world to improve the quality of life of international patients, as well as those is the United States," said L. Scott Levin, MD, FACS, chair of Orthopaedic Surgery, a professor of Surgery in the division of Plastic Surgery in the Perelman School of Medicine at the University of Pennsylvania, and director of Penn's Hand Transplant Program. "Our colleagues from Paris Descartes University brought Laura to us a few years ago for initial introduction, and we have been working to prepare for her procedure ever since."

At 19-years-old, Laura's hands and feet were amputated as a result of sepsis, a blood infection which can lead to tissue damage, organ failure, and even death. Living without hands, Laura had been using prosthetics to perform daily tasks. Two years after losing her limbs she began asking her care team about hand transplantation, and sought out those who would be able to perform the procedure in her native country.

"I have been caring for Laura for nearly seven years, after she came to me seeking a double hand transplant in 2009," said Laurent Lantieri, MD, chief of the department of Plastic and Reconstructive Surgery at Hôpital Européen Georges Pompidou at Paris Descartes University, who has previously performed seven face transplants including one combined face and double hand transplant. "We spent the next few years evaluating Laura as a candidate for transplantation, and put a plan in place to prepare and list her for a transplant. In January 2016, with donor hands available, there were complications with our healthcare system and we were unable to complete Laura's transplant in France."

This is when Lantieri brought Laura to Penn Medicine to be listed.

"I first met Laura in 2010 at the American Society of Reconstructive Transplantation meeting in Chicago," said Levin. "She had come to meet with patients from across the world who had received hand and face transplants, and with the doctors who performed them. We had not yet performed our

first transplant at Penn, but I was impressed with Laura's determination; she had her mind set on becoming a bilateral hand transplant recipient. She and I kept in touch through Laurent, and with our first adult bilateral hand transplant a year later, our program was building momentum and would continue to do so."

Over the past 12 months, the collaborative team worked closely with partners at Gift of Life to list Laura and locate suitable organs for transplantation. She was actively listed for transplantation May 2016 and was transplanted three months later. In August 2016, a team of more than 30 members from three surgical specialties spent eight and a half hours in the operating room for the procedure. "Over the last five years, and even leading up to our first transplant in 2011, we have been routinely practicing new techniques and honing our skills in Penn's Human Tissue Lab in an effort the improve, and perfect the procedure," said Benjamin Chang, MD, associate chief of the division of Plastic Surgery and associate professor of Clinical Surgery in the Perelman School of Medicine at the University of Pennsylvania. "We created a method for developing and improving complex surgical procedures with detailed planning, practicing in the Human Tissue Lab, and incorporating feedback for enhancement from the entire team. We repeated the cycle until we felt confident that we were prepared to do Laura's operation. We were able to complete her surgery in eight and a half hours, which is three hours shorter than our first transplant and two hours shorter than our second."

Vascularized composite allotransplantation (VCA), specifically bilateral hand transplantation, is a complex procedure that involves surgical and non-surgical components. Following extensive medical screenings and evaluations, the potential recipient can be listed to receive a transplant. Once donor organs become available, they are evaluated by the surgical team and are deemed fit for transplant for the specific recipient.

Surgeons from various specialties including orthopaedic, plastic, and transplant surgery perform different segments of the procedure: connecting the radius and ulna; connecting arteries and veins with delicate microvascular surgical techniques; establishing blood flow through what's called vascular anastomosis; attaching muscles and tendons; repairing multiple nerves the provide sensibility and motor function; and closing the skin.

"When dealing with hand transplantation, and similar VCA procedures such as face transplants, the requirements of identifying a donor change," said Richard Hasz, vice president of clinical services for Gift of Life. "For these patients we have to take into account additional criteria such as gender, ethnicity, race, skin color and tone, and size. But what's constant is the respect for donors and their families, careful selection of the recipient, and commitment to obtaining family authorization. For 42 years, Gift of Life Donor Program has partnered with transplant centers throughout this region to bring innovative transplant procedures to patients in need. Each one of these procedures would not be possible without the generosity of a donor and a donor family. We extend our condolences on their loss and thank them for their selflessness and for their gift that made this surgery possible." Following this transplant, the recipient is prescribed daily immunosuppressant medications to prevent their body from rejecting the new limbs, which is then followed-up by rigorous physical therapy to regain hand function and use. Once she is able, Laura will return to France to continue treatment with Lantieri and his team. She is expected to participate in daily therapy sessions, with the hope that she will see significant improvement in her function within the first twelve months.

"This international collaboration, both in planning and preparation and in the operating room, was possible not only because of the members of the Penn, Paris Descartes University, and Gift of Life teams, but because of the countless others caring for Laura on the ground in France and those who played a critical role in getting her to the United States," said Levin. "We're now becoming the epicenter of international limb transplantation and salvage."

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Leak Statement, Sample

Penn Medicine Performs First Bi-Lateral Hand Transplant in the Region at HUP

The Penn Transplant Program performed its first bilateral hand transplant which took place in September. While it is too soon to comment on the outcome of the surgery, as the first surgery of its kind in the region, it represents a significant step in the development of Vascularized Composite Allotransplantation, and advances this quality-of-life-enhancing option for individuals with multiple limb loss. The surgery was performed by The Penn Hand Transplant Program which includes experts in solid organ transplantation, orthopaedic surgery, plastic surgery and reconstructive microsurgery. In observance of patient privacy laws and established protocol to protect all involved, no further information will be made available at this time. However, details of the surgery will be forthcoming in the coming weeks, as appropriate.

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