

Briefing to the OPTN Board of Directors on

Update Guidance on Optimizing VCA Recovery

OPTN Vascularized Composite Allograft Transplantation Committee

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Update Guidance on Optimizing VCA Recovery

Sponsoring Committee: Vascularized Composite Allograft Transplantation
Public Comment Period: July 27, 2023- September 19, 2023
Board of Directors Meeting: December 4, 2023

Executive Summary

This proposed guidance document intends to replace the existing *Guidance on Optimizing VCA Recovery from Deceased Donors*, which was approved by the OPTN Board of Directors in 2018.¹ This proposed guidance, titled *Update Guidance on Optimizing VCA Recovery*, provides guidance pertinent to the current state of the Vascularized Composite Allograft (VCA) transplantation field. The OPTN Vascularized Composite Allograft Transplantation Committee (the Committee) presents this updated guidance to inform Organ Procurement Organizations (OPOs) and transplant programs on collaborative, effective VCA graft recovery practices. The updated guidance includes a brief history of VCA transplantation and recommendations on identifying and evaluating a potential VCA donor, family considerations, recovery and post-recovery practices, and media and public relations strategies.

The guidance document was issued for public comment from July 27, 2023 to September 19, 2023. The Committee reviewed the public comments and made minor changes to the document to incorporate feedback, discussed below.

¹ OPTN, *Guidance on Optimizing VCA Recovery from Deceased Donors*, https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf (accessed May 19, 2023)

Purpose

The purpose of this updated guidance document is to increase the recovery and transplantation of VCA organs. The updated guidance aims to inform the community of VCA graft recovery recommendations and expand VCA visibility in the transplant community. It also intends to provide guidance to OPOs that are currently collaborating, or considering collaboration with VCA transplant programs, and to support VCA programs as they pursue VCA transplantation.

Background

In 2018, the OPTN Board of Directors approved *Guidance on Optimizing VCA Recovery from Deceased Donors*.² This historic guidance contained broad effective practices that applied to general VCA donation as well as specific guidance pertaining to head and neck, and upper limb donation. The guidance provided recommendations on eight topics.

The 2023 version, *Update Guidance on Optimizing VCA Recovery* omits "deceased donor" in the title as seen in the 2018 version, as the document provides recommendations relevant to the current state of the VCA field and acknowledges living uterus donation. To provide the community with a useful resource, the Committee restructured discussion topics in this updated guidance document. Additionally, the Committee has expanded the updated guidance document's audience from solely OPOs to OPOs, transplant programs already involved with VCA recovery and transplant, and transplant programs considering becoming involved with VCA recovery and transplant. The expansion of the target audience aims to capture the attention of a greater portion of the transplant community and highlight the importance of collaboration between OPOs and transplant programs when engaging in the VCA recovery process.

Recommendations

The 2023 recommendations in the proposed guidance document are organized into six topics, some of which were updated from the 2018 *Guidance on Optimizing VCA Recovery from Deceased Donors* guidance and some of which are new topics to this 2023 version. The first section, *VCA Background*, introduces the field of VCA with a brief narrative timeline of clinical milestones since the first VCA transplantations in 1998.³ This section also informs on OPTN purview over VCA organs and the quality of life enhancing benefits of VCA transplantation. The following topic, *Considerations for the Identification and Initial Evaluation of the Potential VCA Donor*, provides recommendations to broaden VCA donor evaluation practices and suggests VCA type specific donor evaluation criteria. The third section, *Family Considerations* gives guidance on strategies and proper preparation when seeking VCA authorization from potential donor families. *Recovery Considerations* covers recommendations for timing and sequence of VCA graft recovery and *Post-Recovery Considerations* informs on practices to be completed after the VCA recovery, such as: communicating with funeral homes and medical examiners, or the use of prosthetics. The last section, *Media and Public Relations Strategies* discusses the need for a communications plan that is aligned with the needs of the donor, recipient, and their families.

² OPTN, *Guidance on Optimizing VCA Recovery from Deceased Donors*, https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf (accessed May 19, 2023).

³ Strome M, Stein J, Esclamado R, Hicks D, Lorenz RR, Braun W, Yetman R, Eliachar I, Mayes J. Laryngeal transplantation and 40 month follow-up. N Engl J Med. 2001 May 31;344(22):1676-9. doi: 10.1056/NEJM200105313442204. PMID: 11386266.

Overall Sentiment from Public Comment

This guidance document was issued for public comment July 27, 2023- September 19, 2023. Public comment sentiment was supportive of this guidance as indicated by an overall sentiment score of 3.7.⁴ There was no opposition to this guidance document, but comments indicated more neutral and abstaining sentiment than usual. A possible reason for increased numbers of neutral or abstaining sentiment is that VCA transplants are less frequent than solid organ transplants. Some members of the community may not have enough familiarity or expertise to express support or opposition to the recommendations in this guidance document.

Figure 1 shows the sentiment broken down by member type. Histocompatibility labs showed the most support and all member types indicated strong support, support, or neutral/abstaining sentiment.

Figure 1: Sentient by Member Type for *Update Guidance on Optimizing VCA Recovery*⁵

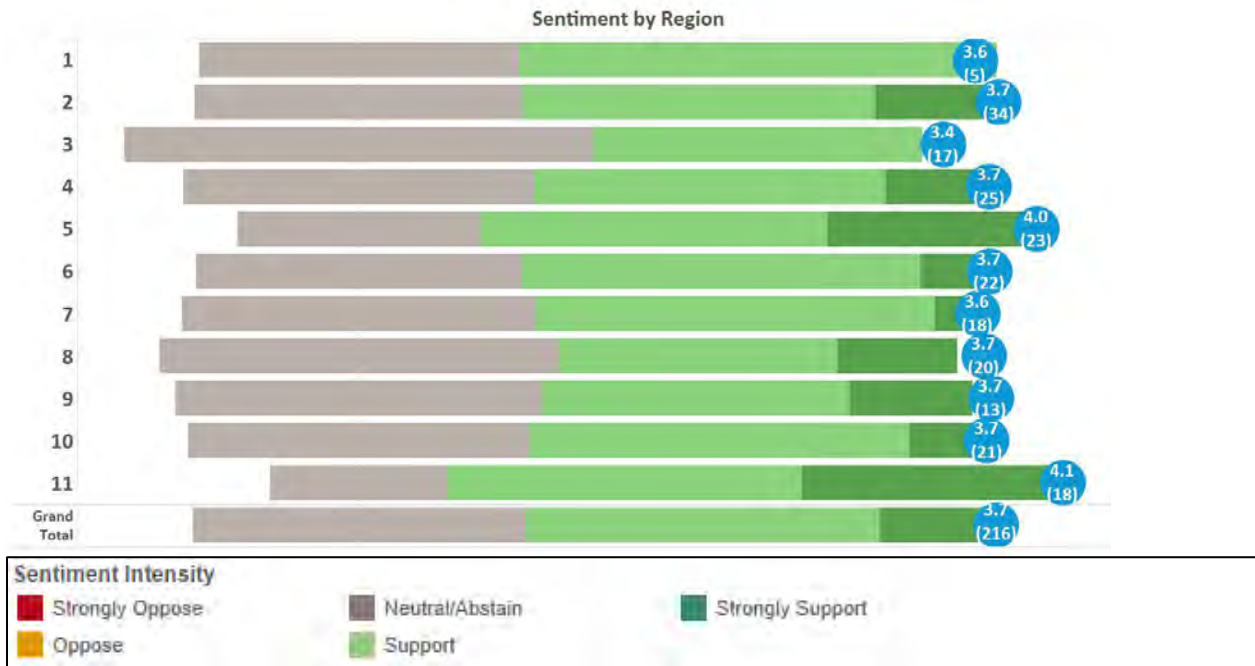


⁴ Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support).

⁵ The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

Figure 2 shows the sentiment broken down by region. Region 11 showed the most support and all member types indicated strong support, support, or neutral/abstaining sentiment.

Figure 2: Sentient by Region for Update Guidance on Optimizing VCA Recovery⁶



Public Comment Themes and Considerations

In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Responses are submitted by members of the public at large, as well as on behalf of regions and committees.

Of the 230 responses submitted, only 8 contained a substantive, written comment. These comments were provided by OPTN Committees, stakeholder organizations, and organ procurement organizations. A lower number of substantive comments is to be expected, as the guidance was on the non-discussion agenda at regional meetings and because the field of VCA transplantation is smaller than that of solid organ transplantation.

Comments covered three main topics:

- Access and Education
- Credit and Costs
- VCA in the Media and Family Considerations

Access and Education

The proposed guidance requested feedback on additional effective VCA recovery practices. Some comments explained that the infrequency of events involving VCA affects member readiness to perform

⁶ The circles after each bar indicate the average sentiment score and the number of participants in is in the parentheses.

VCA recovery and transplant. These comments indicated that the irregularity of VCA also impacts OPOs and transplant programs' ability to become confident and proficient in the field.

The Committee agrees with public comments related to access and education. In response to these comments, the Committee has added a recommendation for OPOs to designate a VCA champion coordinator to develop policies and procedures, provide training, and collaborate with transplant programs. The Committee has also added a clarification that the recovery of VCA grafts should never compromise solid organ recovery.

Credit and Cost

The proposed guidance requested insight on what barriers and challenges are keeping the transplant community from becoming involved with VCA. Comments from the American Society of Transplant Surgeons (ASTS) and the OPTN OPO Committee expressed that there may be challenges in finding interest in VCA from OPOs because CMS metrics for programs do not consider VCA transplants. Comments indicated that lack of insurance coverage for VCA transplantation and uncertainty regarding costs may also deter OPOs and transplant programs from engagement with VCA.

While the Committee agrees with comments pertaining to credit and cost, it is not within the purview of the OPTN to provide guidance on CMS metrics, insurance coverage, or VCA transplantation costs.

VCA in the Media and Family Considerations

The proposed guidance asked the community about the experiences of donors, recipients, and their families with media and public relations strategies. Some comments spoke to the how VCA stories of success can educate the public and promote VCA donation. The Association of Organ Procurement Organizations (AOPO) spoke to the need for OPO staff to carefully consider donor family dynamics on a case-by-case basis before approaching for VCA authorization. Gift of Life Michigan emphasized the importance of disclosing VCA recovery to donor families to make them aware of how VCA recovery will affect the appearance of their loved one.

The Committee agrees with public comments related to Media/Public Relations and Family Considerations. In response to these comments the Committee has added recommendations for building VCA awareness and considerations that should be made before approaching a potential donor family for VCA authorization.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this updated guidance on optimizing VCA graft recovery under the authority of the National Organ Transplant Act (NOTA), which requires the OPTN to "provide information to physicians and other health professionals regarding organ donation."⁷ This updated guidance is also authorized by the OPTN Final Rule, which requires any member procuring an organ to "assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any

⁷ 42 US 274 (B)(2)(H)

contraindications for donor acceptance, in accordance with policies established by the OPTN,"⁸ and requires transplant programs to "establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated."⁹ This guidance document provides guidance on laboratory tests, such as screening for infectious disease. It also makes recommendations for clinical examinations, like on-site visual inspection of the donor and intra-operative assessments. Additionally, this updated guidance suggests considering acceptance criteria when identifying and evaluating a potential VCA donor, such as history of organ dysfunction and cold ischemic time.

OPTN Strategic Plan

Per alignment with the OPTN Strategic Plan, this guidance seeks to increase the number of VCA transplants by informing OPOs and transplant programs of collaborative, effective VCA graft recovery practices.

Conclusion

This updated guidance document advises on effective practices for identifying and evaluating potential VCA donors, authorizing VCA donation with the donor family, recovery and post-recovery processes, and strategies for honoring donor family and transplant recipient confidentiality when media is involved. Minor post public comment changes were made to emphasize the importance of increased awareness of VCA and thoughtful assessment of a potential VCA donor family. Other changes include the recommendation for designating a VCA champion coordinator and clarification that recovery of VCA grafts should never compromise solid organ recovery.

⁸ 42 CFR 121.6(a).

⁹ 42 CFR 121.6(c).

Guidance Document

Proposed new language is underlined (example).

1 **Guidance on Optimizing VCA Recovery from Deceased Donors**¹⁰

2 Repealed.

3 **Guidance on Optimizing VCA Recovery (2023 Version)**

4 **VCA Background**

5 VCA transplantation is the transplantation of a composite tissue that may include skin, muscle, bone,
6 and nerves and that requires blood flow to function after the transplant.¹¹

7 **The First VCA Transplantations**

8 The first successful VCA transplant in the world was a larynx transplant in Cleveland, Ohio in 1998.¹²
9 Later that year, the first unilateral hand transplant was performed in Lyon, France.¹³ This event marked
10 the recognition that VCAs are the logical next step in reconstructive microsurgery and that surgical
11 techniques used in conventional reconstructive microsurgery can be successfully utilized in VCA
12 transplantation. This landmark case ushered in the era of “restorative surgery.” Although “higher” on
13 the “reconstructive ladder,” by utilizing the exact missing composite tissues from a deceased donor, VCA
14 transplantation offered the recipient the possibility of fewer reconstructive surgeries and more natural
15 function and physical appearance. VCA recipients require immunosuppression to prevent immune
16 rejection of allografts, but in exchange, would be spared the morbidity and possible disfigurement of
17 conventional reconstructive procedures that required the use of tissue(s) from elsewhere on the
18 patient’s body. The first successful unilateral hand transplant in the United States, and to date, the
19 longest lasting in the world, was performed in Louisville, Kentucky in 1999.¹⁴ The recipient lost his
20 dominant hand in a fireworks accident 13 years earlier.¹⁵

21 **Face Transplantation**

22 In 2005, the world's first partial face transplant was performed in Amiens, France. The
23 recipient underwent surgery to replace her original face, after she was mauled by a dog.¹⁶

¹⁰ This proposal would repeal the old guidance and replace with this new version. The 2018 version can be found on the OPTN website at https://optn.transplant.hrsa.gov/media/2503/vca_guidance_201806.pdf.

¹¹ OPTN. (2014, November 11). The status of vascularized composite allograft allocation.

<https://optn.transplant.hrsa.gov/news/the-status-of-vascularized-composite-allograft-allocation/>

¹² Strome M, Stein J, Esclamado R, Hicks D, Lorenz RR, Braun W, Yetman R, Eliachar I, Mayes J. Laryngeal transplantation and 40-month follow-up. *N Engl J Med.* 2001 May 31;344(22):1676-9. doi: 10.1056/NEJM200105313442204. PMID: 11386266.

¹³ J.M. Dubernard, E. Owen, G. Herzberg, *et al.* Human hand allograft: report on first 6 months *Lancet*, 353 (1999), pp. 1315-1320

¹⁴ Jones JW, Gruber SA, Barker JH, Breidenbach WC. Successful hand transplantation. One-year follow-up. Louisville Hand Transplant Team. *N Engl J Med.* 2000 Aug 17;343(7):468-73. doi: 10.1056/NEJM200008173430704. PMID: 10950668.

¹⁵ *Ibid.*

¹⁶ Petruzzo P, Testelin S, Kanitakis J, Badet L, Lengelé B, Girbon JP, Parmentier H, Malcus C, Morelon E, Devauchelle B, Dubernard JM. First human face transplantation: 5 years outcomes. *Transplantation.* 2012 Jan 27;93(2):236-40. doi: 10.1097/TP.0b013e31823d4af6. PMID: 22167048.

24 Three years later in 2008, the first partial face transplant, in the United States, was performed in
 25 Cleveland, Ohio.¹⁷ The first full face transplant performed in the United States was done in Boston,
 26 Massachusetts on a construction worker in 2011.¹⁸ The recipient suffered from a high-voltage electrical
 27 burn.

28 Sixteen years after the hallmark case in France, there have been at least 160 upper extremity and 50
 29 face VCAs transplants performed from deceased donors worldwide.¹⁹

30 **Uterine Transplantation**

31 Uterus transplantation for women with absolute uterus factor infertility began in the early 2000s.²⁰ In
 32 2014, the first baby was born to a uterus transplant recipient in Gothenburg, Sweden.²¹ The recipient
 33 had a congenital uterine agenesis. The first uterus transplant performed in the United States took place
 34 in Cleveland, Ohio in 2016.²² The deceased donor transplant failed and was removed within 2 weeks
 35 post-transplant. That same year the first successful uterus transplant in the United States was
 36 performed from a living donor in Dallas, Texas. The recipient was born without a uterus and delivered a
 37 healthy baby boy in 2017.²³ The first baby born after a deceased donor uterus transplant in the United
 38 States was in Cleveland, Ohio in 2019.²⁴ As of 2023, there have been more than 100 cases of uterus
 39 transplantation performed worldwide and 40 cases in the United States.²⁵ More than 60 babies have
 40 been born after uterus transplant worldwide including 30 in the United States.²⁶

41 **Penile Transplantation**

42 The first penis transplantation was performed in 2006 in China.²⁷ The patient had sustained the loss of
 43 most of his penis in an accident. Although reported as a surgical success, the graft was removed 15 days
 44 later. In 2014, the first successful penis transplant was performed in South Africa.²⁸ The patient had lost

¹⁷ Arno A, Barret JP, Harrison RA, Jeschke MG. Face allotransplantation and burns: a review. J Burn Care Res. 2012 Sep-Oct;33(5):561-76. doi: 10.1097/BCR.0b013e318247eb06. PMID: 22274632; PMCID: PMC3438348.

¹⁸ Singhal, Dhruv M.D.; Pribaz, Julian J. M.D.; Pomahac, Bohdan M.D. The Brigham and Women's Hospital Face Transplant Program: A Look Back. Plastic and Reconstructive Surgery 129(1): p 81e-88e, January 2012. | DOI: 10.1097/PRS.0b013e31823621db

¹⁹ Ibid.

²⁰ Castellón LAR, Amador MIG, González RED, Eduardo MSJ, Díaz-García C, Kvarnström N, Bränström M. The history behind successful uterine transplantation in humans. JBRA Assist Reprod. 2017 Jun 1;21(2):126-134. doi: 10.5935/1518-0557.20170028. PMID: 28609280; PMCID: PMC5473706.

²¹ Brännström M, Johannesson L, Bokström H, Kvarnström N, Mölne J, Dahm-Kähler P, Enskog A, Milenkovic M, Ekberg J, Diaz-Garcia C, Gäbel M, Hanafy A, Hagberg H, Olausson M, Nilsson L. Livebirth after uterus transplantation. Lancet. 2015 Feb 14;385(9968):607-616. doi: 10.1016/S0140-6736(14)61728-1. Epub 2014 Oct 6. PMID: 25301505.

²² Flyckt R, Kotlyar A, Arian S, Eghtesad B, Falcone T, Tzakis A. Deceased donor uterine transplantation. Fertil Steril. 2017 Mar;107(3):e13. doi: 10.1016/j.fertnstert.2016.12.009. Epub 2017 Feb 8. PMID: 28189293.

²³ Testa G, McKenna GJ, Gunby RT Jr, Anthony T, Koon EC, Warren AM, Putman JM, Zhang L, dePrisco G, Mitchell JM, Wallis K, Klintmalm GB, Olausson M, Johannesson L. First live birth after uterus transplantation in the United States. Am J Transplant. 2018 May;18(5):1270-1274. doi: 10.1111/ajt.14737. Epub 2018 Apr 12. PMID: 29575738.

²⁴ Flyckt R, Falcone T, Quintini C, Perni U, Eghtesad B, Richards EG, Farrell RM, Hashimoto K, Miller C, Ricci S, Ferrando CA, D'Amico G, Maikhor S, Priebe D, Chiesa-Vottero A, Heerema-McKenney A, Mawhorter S, Feldman MK, Tzakis A. First birth from a deceased donor uterus in the United States: from severe graft rejection to successful cesarean delivery. Am J Obstet Gynecol. 2020 Aug;223(2):143-151. doi: 10.1016/j.ajog.2020.03.001. Epub 2020 Mar 7. PMID: 32151611.

²⁵ Johannesson L, Richards E, Reddy V, Walter J, Olthoff K, Quintini C, Tzakis A, Latif N, Porrett P, O'Neill K, Testa G. The First 5 Years of Uterus Transplant in the US: A Report from the United States Uterus Transplant Consortium. JAMA Surg. 2022 Sep 1;157(9):790-797. doi: 10.1001/jamasurg.2022.2612. PMID: 35793102; PMCID: PMC9260640.

²⁶ Ibid.

²⁷ Weillie H, Jun L, Lichao Z, et al. A preliminary report of penile transplantation. Eur Urol 2006; 50:851–853.

²⁸ Bateman, C. (2015). World's first successful penis transplant at Tygerberg Hospital. SAMJ: South African Medical Journal, 105(4), 251-252.

45 his penis as a result of a botched circumcision procedure he underwent at age 18. In 2015, the recipient
 46 announced that he had successfully fathered a child. In 2016 in Boston, a team performed a transplant
 47 on a 64-year-old man in remission of squamous cell carcinoma.²⁹ In 2018, The Johns Hopkins Hospital
 48 performed the world's first total penis and scrotum transplant.³⁰ As of 2023 there have been less than
 49 10 penis transplants worldwide.³¹

50 **OPTN Purview of VCA Organs**

51 In 2014, the Health Resources and Services Administration (HRSA) designated VCAs as organs under the
 52 purview of the OPTN.^{32, 33} **Table 1-1: VCA types and covered body parts** below lists the VCA types and
 53 identifies the covered body parts specific to each VCA organ.

²⁹ Cetrulo, Curtis L. Jr MD*; Li, Kai MD†; Salinas, Harry M. MD*; Treiser, Matthew D. MD, PhD*; Schol, Ilse BS*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD*; Ehrlichman, Richard J. MD*; Holzer, Paul W. BS*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD*; Lellouch, Alexandre G. MD*; Kurtz, Josef M. PhD*; Austen, William G. Jr MD*; Winograd, Jonathan M. MD*; Bojovic, Branko MD*; Eberlin, Kyle R. MD*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS*,†. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

³⁰ Nitkin, K. (2018, April 23). *First-Ever Penis and Scrotum Transplant Makes History at Johns Hopkins*. John Hopkins Medicine. <https://www.hopkinsmedicine.org/news/articles/first-ever-penis-and-scrotum-transplant-makes-history-at-johns-hopkins>

³¹ Cetrulo, Curtis L. Jr MD*; Li, Kai MD†; Salinas, Harry M. MD*; Treiser, Matthew D. MD, PhD*; Schol, Ilse BS*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD*; Ehrlichman, Richard J. MD*; Holzer, Paul W. BS*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD*; Lellouch, Alexandre G. MD*; Kurtz, Josef M. PhD*; Austen, William G. Jr MD*; Winograd, Jonathan M. MD*; Bojovic, Branko MD*; Eberlin, Kyle R. MD*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS*,†. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

³² U.S. Department of Health and Human Services, Final Rule, "Organ Procurement and Transplantation Network." *Federal Register* 78, no. 128 (July 3, 2013): 40033, <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf>

³³ Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)," Public Comment Proposal, OPTN, accessed May 4, 2023, https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.

Table 1-1: VCA types and covered body parts³⁴

<u>Type</u>	<u>Covered VCA</u>
<u>Upper limb</u>	<u>Any group of vascularized body parts from the upper limb</u>
<u>Head and neck</u>	<u>Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck</u>
<u>Abdominal Wall</u>	<u>Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis</u>
<u>Uterus</u>	<u>Uterus, cervix, vagina</u>
<u>External male genitalia</u>	<u>Penis and scrotum</u>
<u>Other genitourinary organ</u>	<u>Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder</u>
<u>Vascularized gland</u>	<u>Vascularized gland</u>
<u>Lower limb</u>	<u>Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb</u>
<u>Musculoskeletal composite graft segment</u>	<u>Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin</u>
<u>Spleen</u>	<u>Spleen</u>

55

56 **Benefits of VCA Transplantation**

57 The field of VCA transplantation has existed for more than two decades, and the benefits and challenges
 58 are becoming apparent to larger and wider groups of patients, clinicians, and families. Public attitudes
 59 toward VCA donation are reported as favorable, and much of this is based on media reports of

³⁴OPTN Policy 1.2: Definitions ‘Covered Vascularized Composite Allograft body parts (covered VCAs)’. This language reflects the most recent language approved by the OPTN Board in December of 2021. This language will be implemented pending approval of designated uterus, external male genitalia, and other genitourinary organ transplant programs, currently slated for review at the December 4, 2023 meeting of the OPTN Board of Directors. See Establish Membership Requirements for Uterus Transplant Programs Policy Notice, available at https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf.

60 transplant outcomes.³⁵ There is increased acceptance outside the VCA transplant community that the
61 therapeutic goal of VCA transplantation is functional restoration and bodily integrity, not only cosmetic
62 restoration.³⁶

63 The benefits of VCA transplantation include increased quality of life and social integration. For example,
64 the ability to hold someone’s hand, return to near normal appearance after severe trauma, experience
65 gestation and childbirth, being able to speak, write and smile, and regain independence in activities of
66 everyday living. The Committee hopes this document provides the transplant community with
67 knowledge that will contribute to the increased utilization of the precious resources for the patients and
68 families that can benefit.

69 **Considerations for the Identification and Initial Evaluation of the** 70 **Potential VCA Donor**

71 As with solid organ transplantation, there are transplant program-specific criteria utilized for the
72 evaluation of VCA organs from deceased donors; and in the case of uterus transplant, both living and
73 deceased donors. The criteria and tools used to evaluate potential VCA donors will differ by VCA type.
74 Minimal criteria for acceptance of all VCAs are based on guidelines for solid organ transplantation, with
75 additional criteria to ensure the best possible outcomes of the VCA transplant. Additional considerations
76 are specific to the type of VCA graft needed. The decision to include or exclude VCA from deceased
77 donors based on these criteria should be left to the individual VCA transplant programs. All deceased
78 donors should be considered for VCA, and a match run should be generated.

79
80 Once a match run is generated, communication between the VCA program and the OPO for further
81 screening, including preliminary virtual and/or flow crossmatch, feasibility, and additional
82 considerations should occur early in the allocation process. Depending on the VCA type, additional
83 donor imaging (x-rays, CT scans, vascular ultrasound) may be requested, as well as photographs to
84 ensure donor-recipient suitability. **Table 1-2: Examples of VCA type-specific evaluation considerations**
85 below reflects some examples of VCA type specific considerations for the initial evaluation of the
86 potential VCA donor:

³⁵ Rodrigue, J, 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.

³⁶ Caplan, A., “An Ethics Infrastructure for VCA”, presentation at the Evolving Issues of Vascularized Composite Allograft Transplantation, Baltimore, MD September 19, 2017.

87

Table 1-2: Examples of VCA type-specific evaluation considerations³⁷

	<u>Limb (Upper or Lower, Unilateral or Bilateral)</u>	<u>Head and Neck</u>	<u>Penile</u>	<u>Uterus</u>
<u>Physical attributes</u>	<u>Skin tone, scars, tattoos, distinguishing marks, mechanism of injury, sex/gender, body habitus, height, weight, limb length, laterality (if unilateral)</u>	<u>Tattoos, scars, piercings, skin tone, distinguishing marks, mechanism of injury, sex/gender, anatomic abnormalities</u>	<u>Anatomic abnormalities, distinguishing marks</u>	<u>Anatomic abnormalities</u>
<u>Medical and surgical history considerations</u>	<u>Mechanism of injury/death, vascular access placement, history of limb dysfunction/paralysis</u>	<u>Mechanism of injury/death, history of facial paralysis/dysfunction</u>	<u>Mechanism of injury/death, History of organ dysfunction</u>	<u>Mechanism of injury/death, reproductive history</u>
<u>Additional work-up</u>			<u>Additional infectious testing (e.g., chlamydia, gonococcus, etc.)</u>	<u>Additional infectious testing (e.g., chlamydia, gonococcus, Papanicolaou (PAP), etc.),</u>

88

89 Consistent with solid organ donor evaluation, medical and surgical history review should also specifically
 90 include: any history of malignancy, current or recent sepsis, disseminated intravascular coagulation
 91 (DIC), diabetes, 2020 Public Health Service (PHS) Medical and Social Donor Risk Criteria, and other
 92 factors that may impact form and function of the VCA.

93 After acceptable donor and recipient characteristics are determined, recovery and case-specific needs
 94 can be discussed. Once VCA authorization is obtained, an OPO team member should speak with the VCA
 95 surgeon to thoroughly understand VCA recovery. This knowledge is essential to inform the donor’s
 96 family, funeral home, medical examiner/coroner, and/or law enforcement representatives of the VCA
 97 donation.

98 Other considerations related to the donor procurement process include:

- 99 • Donor allografts must be recovered and transported within transplant program acceptable limits
 100 of cold ischemic time. The amount of allowable ischemic time will vary by transplant program,
 101 type of VCA and size of the allografts. As with other transplanted organs, short ischemic times
 102 are desired.
- 103 • Transfer to transplant hospital for simultaneous donor/recipient surgeries may be requested.
- 104 • As with the practice in solid organ donation, on-site visual inspection of the donor, prior to
 105 recovery, and intra-operative assessments are the final components of VCA donor suitability
 106 evaluation prior to removal of the allografts.
- 107 • Prosthetics/reconstruction of the donor post recovery should be planned to preserve the
 108 integrity and respect of the donor.

³⁷ Table 1-2 is not an all-inclusive list of VCA type specific evaluation considerations.

- 109 • Evaluation of living donors for VCA will follow *OPTN Policy 14: Living Donation*

110 Emerging types of VCA transplants may require additional consultations or testing beyond existing
 111 standards. OPOs and transplant programs are strongly encouraged to review VCA educational materials
 112 on the OPTN Learning Management System in addition to developing protocols and relationships with
 113 VCA programs that intend to transplant emerging VCA types.

114 **Family Considerations**

115 With the advancement of VCA transplants, some donor families can now make an additional gift apart
 116 from solid organ and tissue donation. VCA authorization requestors need to be knowledgeable, skilled
 117 advocates for VCA donation. OPOs should also develop a standard practice around authorization for VCA
 118 donation.

119 **Preparing Staff for VCA Discussion**

121 Preparation for VCA authorization is key to a successful outcome. VCA transplant surgeons should be
 122 engaged with OPO requestors to articulate the need for VCA transplantation and the recovery process.
 123 VCA specific considerations should be explained to OPO staff to ensure potential donor families are
 124 aware of additional testing, longer operating room time, possible transfer of the donor to a recovery
 125 center, reconstruction of the donor site, potential face masks or prosthetics, and funeral home or
 126 medical examiner needs. OPOs that have successfully procured VCAs report benefit of rehearsal
 127 conversations with OPO staff. These OPOs can also provide suggested scripts and VCA authorization
 128 documents. Learning about outcomes of past VCA transplants helps requestors facilitate the approach
 129 and become advocates for VCA transplant candidates.

130
 131 Approaching families for a potential VCA donation should be carefully considered on a case-by-case
 132 basis. OPO staff should use their expertise in evaluating donor family dynamics to ensure that an
 133 approach for VCA donation does not jeopardize potential solid organ donation.

134 **Authorizing a VCA Donor**

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

141
 142 Authorization for VCA recovery must be documented carefully and cannot be assumed from general
 143 organ donation authorization or registry information. *OPTN Policy 2.14.E: Deceased Donor Authorization*
 144 *Requirement* states that OPOs must document the specific authorization for VCA donation from
 145 deceased donors.³⁸ Effective VCA authorization practices show that VCA authorization should occur after
 146 authorization for organ and tissue donation.³⁹ Further, any discussion on VCA authorization should only
 147 occur after identifying a potential recipient. This approach ensures that VCA authorization does not
 148 dissuade next-of-kin from life-saving organ donation decisions. Families should be offered the

³⁸ OPTN Policy 2.14.E: Deceased Donor Authorization Requirement.

³⁹ OPO Guidance on VCA Deceased Donor Authorization, <https://optn.transplant.hrsa.gov/resources/guidance/opoguidance-on-vca-deceased-donor-authorization/>. Accessed May 19, 2023.

149 opportunity for VCA donation once a potential recipient has been identified, regardless of whether they
 150 have authorized eye or tissue donation. Prospective crossmatching between potential donors and
 151 recipients varies between transplant programs and even between different VCA programs at the same
 152 transplant hospital. Crossmatch timing and determining if the crossmatch will be virtual or physical must
 153 be determined between the OPO, histocompatibility lab, and transplant program early in the process.
 154 This is because the crossmatch could determine if VCA donation is offered to a donor family.

156 **Helping Families Understand the Need for VCA Transplants and Empowering Them to**
 157 **Make a Decision**

158 VCA donation is a unique and rare opportunity to make a life-changing donation to a VCA candidate.
 159 OPOs should be conscientious in how they approach VCA donation with different donor families. Donor
 160 families require accurate information about VCA donation opportunities to understand the impact of
 161 the donation, such as the potential benefits the donation could bring to a recipient. When a donor
 162 family feels a connection to the potential recipient, they are more likely to overcome the hesitancy
 163 some have with considering donation of a face, limb, uterus, or penis. That connection between a donor
 164 and recipient represents a facet of VCA donation that is unlike many gifts: VCA transplant offers a
 165 unique continuation of a deceased donor's life through that connection to the potential recipient.
 166 Before sharing any information about a potential recipient, the OPO must abide by all applicable federal
 167 and state privacy laws and should consult their own attorneys and confer with transplant programs prior
 168 to sharing any information.

170 Throughout the discussion, the family needs to be assured of the mutual commitment from the OPO
 171 and VCA transplant program to treat the donor with the utmost respect and integrity. Also, the OPO
 172 must disclose the potential for media coverage, potential identification of the recipient by the transplant
 173 hospital, and how the OPO will protect the donor's identity and confidential information.

175 Finally, there needs to be transparent communication about the impact of VCA donation on the entire
 176 donation process. Additional testing will be needed to understand the quality of the VCA being
 177 considered and, as a result, additional time may be required to thoroughly evaluate and coordinate the
 178 donation.

180 Mock runs can help programs learn what improvements can be made in their recovery processes. These
 181 practice exercises include approaching donor families for VCA authorization and recovery of the graft,
 182 but do not include transplantation of the VCA graft to a living recipient. Transplant programs should
 183 educate the OPO staff, so they are able to convey the importance of donation that promotes the
 184 advancement of the VCA field when making this specific type of authorization ask.

186 **Recovery Considerations**

187 Coordinating the recovery of VCAs and solid organs for transplant requires collaboration and
 188 communication between the OPO and all transplant hospitals involved in the recovery and transplant of
 189 organs from the deceased donor. Considerations include the timing of VCA recovery and solid organ
 190 recovery, OPO staffing during the recovery, and plans for unexpected donor instability. A conference call
 191 between all recovery teams and the OPO in advance of the recovery procedure allows all parties to
 192 discuss the procurement process and sequence.

193 **Specialized Considerations for VCA Recovery**

194 Given the complexity of procurement needs associated with VCA transplants, some transplant programs
 195 have opted to move the donor to a specialized or centralized recovery center. The OPO has a lead role in
 196 coordinating these activities among various procurement teams, and it is recommended that VCA
 197 transplant programs discuss needs regarding procurement location as early as possible with OPO staff.

198 For those OPOs seeking more involvement with VCA procurement, designating a VCA champion
 199 coordinator is recommended. The duties of this staff members could include developing policies and
 200 procedures, providing training, and collaborating with transplant programs.

201 **Timing and Sequence of VCA graft recovery**

202 The addition of VCA recovery to thoracic and/or abdominal organ recovery may add various amounts of
 203 time to the donor procurement. OPOs and transplant programs should thus plan for recoveries that may
 204 be of extended length. This will include assigning primary OPO staff and relief staff to the recovery, and
 205 frequent communication with the donor hospital's operating room when booking the organ recovery.
 206 While recovery of VCA grafts should be performed whenever possible, non-VCA grafts must be
 207 prioritized if donor instability intervenes. During the pre-procurement team huddles, it is advisable to
 208 make plans between procurement teams and OPO staff about the events that will occur should a
 209 deceased donor become unstable. The recovery of VCA grafts should never compromise solid organ
 210 recovery.

211 This guidance document emphasizes the value of a pre-recovery huddle between all participants,
 212 inclusive of surgeons and OPO staff. Details of procurement timing, sequence, and preservation should
 213 be discussed and agreed upon prior to initiation of recovery.

214 **General Timing Guidelines by VCA Type**

215 Each type of VCA graft has unique criteria for recovery. A brief review of timing considerations for some
 216 of the VCA types follows. Individual cases may vary significantly from these estimates.

217 **Upper Limb**

218 The recovery of upper extremities can be performed with or without a tourniquet. The timing of the
 219 removal of the donor graft may occur prior to or after cross-clamp to optimize the recovery of non-VCA
 220 organs. In general, recovery procedures take 30 minutes per extremity.⁴⁰

221 **Facial Allografts**

222 Oftentimes, recoveries from the head and neck precede the thoracic and/or abdominal organ recovery.
 223 The operating room may be arranged with anesthesia at the foot of the donor instead of the head,
 224 providing enough space for the VCA recovery team to perform the facial recovery. If a sentinel flap is
 225 being recovered from the donor's forearm, the arms can be outstretched for this procedure. Elective
 226 tracheostomy may have to be performed on the donor in advance of the recovery to avoid obstruction
 227 of the airway during facial recovery. The length of the procedure will be dictated by the size and

⁴⁰ Mendenhall SD, Lutfy J, Graham E, Overschmidt B, Levin LS, Neumeister MW. Technique for Rapid Hand Transplant Donor Procurement Through the Elbow. Hand (N Y). 2021 May;16(3):391-396. doi: 10.1177/1558944719863127. Epub 2019 Jul 23. PMID: 31331207; PMCID: PMC8120581.

228 complexity of the graft. Recovery times for facial allografts vary but in general are complex.^{41, 42}
 229 Depending on the type of face allograft, recovery times may vary widely from 2-12 hours. Much of this
 230 recovery can be done prior to the administration of heparin and cross-clamp of thoracic and abdominal
 231 organs.

232 **Uterus Allografts**

233 Multiple uterus recovery approaches have been successful. Most of the uterus dissection occurs prior to
 234 cross-clamp, in conjunction with the dissection and evaluation of other organs. The sequence of uterus
 235 dissection can occur at any point but is often performed after dissection of the vital abdominal organs is
 236 complete. In some circumstances, the uterus has been removed prior to cross-clamp and mimics the
 237 approach in a living donor hysterectomy. If the uterus is to be removed after cross-clamp, all vital organs
 238 can be removed first with uterus recovery occurring last. Dissection of the uterus prior to cross-clamp
 239 can be performed in approximately 2-3 hours. Depending on recovery sequence and order of dissection,
 240 minimal time or up to 2 hours may be added to the total recovery time for all organs.

241 **Abdominal Wall Allografts**

242 In many cases, abdominal wall grafts will be recovered in conjunction with the abdominal organs (liver,
 243 small bowel). Dissection of the abdominal wall graft can be performed before cross-clamp, and the flap
 244 can remain connected to blood supply until cross-clamp is performed.⁴³ Recovery time will also depend
 245 on the size of the graft, but in general will add 30 minutes to recovery of the abdominal organs.

246 **External Male and Other Genitourinary Allografts**

247 As with many VCA grafts, types of genitourinary grafts can vary widely. The graft may include a
 248 combination of the penis, scrotum, thigh tissue, and lower abdominal wall, or penis alone.⁴⁴ In complex
 249 cases, the recovery can commence prior to cross-clamp to allow more time for dissection of the
 250 abdominal wall, exposing the blood vessels. At that point, the recovery of other solid organs may
 251 proceed prior to cross-clamp, if so desired and coordinated with the VCA genitourinary recovery
 252 team. Once cross-clamp has occurred, procurement teams may proceed removing organs with the VCA
 253 genitourinary team going last. In this scenario, the total recovery time is minimally impacted by the
 254 recovery of even a complex urogenital graft.

⁴¹ Bueno J, Barret JP, Serracanta J, Arnó A, Collado JM, Valles C, Colominas MJ, Diez Y, Pont T, Salamero P, Martinez-Ibañez V. Logistics and strategy of multiorgan procurement involving total face allograft. Am J Transplant. 2011 May;11(5):1091-7. doi: 10.1111/j.1600-6143.2011.03489.x. Epub 2011 Mar 28. PMID: 21443675.

⁴² Brazio PS, Barth RN, Bojovic B, Dorafshar AH, Garcia JP, Brown EN, Bartlett ST, Rodriguez ED. Algorithm for total face and multiorgan procurement from a brain-dead donor. Am J Transplant. 2013 Oct;13(10):2743-9. doi: 10.1111/ajt.12382. Epub 2013 Aug 5. PMID: 23915309.

⁴³ Erdmann D, Atia A, Phillips BT, Mithani SK, Avashia YJ, Hollister BA, Cendales LC, Ravindra KV, Sudan DL. Small bowel and abdominal wall transplantation: A novel technique for synchronous revascularization. Am J Transplant. 2019 Jul;19(7):2122-2126. doi: 10.1111/ajt.15370. Epub 2019 Apr 15. PMID: 30913367.

⁴⁴ Lopez CD, Girard AO, Lake IV, Oh BC, Brandacher G, Cooney DS, Burnett AL, Redett RJ. Lessons learned from the first 15 years of penile transplantation and updates to the Baltimore Criteria. Nat Rev Urol. 2023 Jan 10:1–14. Doi: 10.1038/s41585-022-00699-7. Epub ahead of print. PMID: 36627487; PMCID: PMC9838304.

255 **Tracheal/Esophageal Allografts**

256 In the most recent reported recovery of a tracheal allograft, the transplant team simultaneously
 257 prepared the abdomen for liver procurement. Time from cross-clamp to graft retrieval was 26 minutes.⁴⁵
 258 Recovery of this graft can occur in conjunction with other organs and does not significantly impact the
 259 total length of recovery time for all organs.

260 **Summary of Recovery Times for VCA Grafts**

261 These estimates are provided only to give an idea how long VCA graft recoveries may take. As in all
 262 donor recoveries, there will be variability in the timing and sequence of VCA recoveries alongside other
 263 thoracic and abdominal organs. In some cases, the VCA recovery has occurred before the thoracic
 264 and/or abdominal organ recovery. In other circumstances, the VCA and thoracic and/or abdominal
 265 organ recoveries began at the same time with each recovery team given the amount of time necessary
 266 to complete any warm dissection prior to cross-clamp while the other procurement teams wait.⁴⁶ In the
 267 cases of teams working together, the VCAs may be removed before cross-clamp, then the thoracic
 268 and/or abdominal organ teams are able to cannulate in preparation for cross-clamp in the standard way.

269 **Specialized Needs of the VCA Recovery Team**

270 VCA recovery may require specialized surgical equipment not available at all hospitals. If a VCA recovery
 271 team will be traveling to a donor hospital, the recovery team is responsible for bringing any specialized
 272 equipment that may be required to complete the recovery. If the VCA recovery is complex, the VCA
 273 transplant program and OPO should consider the risks and benefits of transporting the VCA donor to the
 274 transplant hospital where the VCA program is located, or other centralized recovery center as
 275 mentioned above.

276 If the VCA team accepting the graft is traveling from farther away, the team may need support with
 277 ground transportation to and from the donor hospital. If the VCA team is flying-in, the timing of the
 278 recovery may also impact the duty time of the aircraft crew involved in the trip.

279 Programs with limited VCA recovery and transplantation experience are encouraged to seek mentorship
 280 from more seasoned VCA programs. Experienced VCA programs should support the ever-growing VCA
 281 community by sharing their exemplary practices with recently established programs.

282 **Changes in Donor Hemodynamic Stability**

283 If the VCA recovery is planned to proceed prior to cross-clamp and before the thoracic and/or
 284 abdominal organ recovery, measures should be taken to ensure there is no loss of organs if the donor
 285 becomes unexpectedly unstable during VCA recovery. The thoracic and/or abdominal organ recovery
 286 teams should be available at the donor hospital in case instability occurs and the immediate recovery of

⁴⁵ Genden EM, Laitman BM. Human Tracheal Transplantation. Transplantation. 2023 Feb 14. doi: 10.1097/TP.0000000000004509. Epub ahead of print. PMID: 36782283.

⁴⁶ Brazio, P, Barth, R, Bojovic, B, Dorafshar, A, Garcia, J, Brown, E, Bartlett, S, and Rodriguez, E, "Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor", American Journal of Transplantation no 13: 2743–, (2013). doi:10.1111/ajt.12382.

287 other organs becomes necessary.⁴⁷ Preservation solutions for the thoracic and/or abdominal organ
 288 recovery should be available during the VCA recovery. Blood products for the donor should also be
 289 available in the donor operating room in the event of blood loss from the VCA recovery and the need for
 290 transfusion.

291 **Preservation and Packaging**

292 OPOs and VCA transplant programs should discuss the plans for use of organ preservation solutions and
 293 needs for sterile packaging materials. Sterile packaging needs will be determined by the type and size of
 294 grafts being recovered. Separate packaging will be necessary for multiple VCA grafts recovered from the
 295 same donor. As with all other organs, VCAs must be packaged and labeled in accordance with OPTN
 296 Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage.⁴⁸ The labels are printed
 297 from the OPTN Organ Labeling, Packaging and Tracking System.

298 **Post-Recovery Considerations**

299 For head and neck and upper extremity recoveries, the use of prosthetics is strongly recommended if
 300 allowed by the donor family to preserve donor dignity. After recovery, prosthetics must be secured to
 301 prevent them from being dislodged when the donor is moved.

302 OPOs should prepare to document the recovery of VCAs with practices similar to thoracic and/or
 303 abdominal organ recoveries.

304 **Funeral Home and Medical Examiner Involvement**

305 OPO communication with the donor family's funeral home of choice is an important step in the VCA
 306 donation process, as it is with the standard organ and tissue donation process. This communication
 307 ensures the funeral home understands that extra care of the donor may be necessary due to anatomical
 308 modifications and the nature of the organ recovery. As VCA donation can extend the organ donation
 309 process, this may impact the funeral arrangements including the funeral director's preparations for
 310 memorial services.

311 Similar concerns apply to medical examiners or coroners who may be investigating the donor's
 312 circumstances of death. Coordination with the medical examiner or coroner following VCA authorization
 313 to ensure there are no restrictions that impact the VCA donation is recommended early in the process.

314 **Media and Public Relations Strategies**

315 **Rationale**

316 A media strategy needs to be considered by the transplant program and OPO to protect the privacy of
 317 the recipient, donor, and their families as much as possible. This is to maximize the dissemination of
 318 information while safeguarding the public confidence and transparency for VCA transplantation.

⁴⁷ Datta, N, Yersiz, H, Kaldas, F, Azari, K, "Procurement strategies for combined multiorgan and composite tissues for transplantation", Current Opinion in Organ Transplantation no 20:121-126, (2015), DOI: .1097/MOT.0000000000000172.

⁴⁸ OPTN Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.

319 **Planning**

320 One of the most important first steps, before any media plans are executed, is for the clinicians and
321 public relations team at the transplant hospital to find out whether the recipient and their family are
322 comfortable with media attention and interviews, and to what extent. Media attention could include
323 photography and videography, interviews, and press conferences. This is a dynamic process
324 throughout the transplant experience, which must be revisited regularly for amendment, as necessary.
325 Every program is unique, and decisions must be guided by recipient and donor family preferences and
326 institutional policies.

327 Most of the planning for VCA-related media will fall to the public relations team at the transplant
328 hospital, with support from the OPO. The transplant hospital should establish a direct line of
329 communication with the OPO public relations team. This line of communication should be established
330 as early as possible, ideally before the transplant takes place.

331 A public relations strategy should be developed and include a timeline for any media moments based on
332 transplantation and subsequent patient milestones. Having this plan in place will mitigate any rushed
333 announcements and media events. Development of a working group to establish the strategy and
334 timeline is recommended and should include public relations contacts at all the hospitals involved with
335 the VCA transplant. This working group should determine whether there will be a press conference and,
336 if so, who will host and lead the on-site coordination. In most instances, this responsibility would belong
337 to the transplant program. Ideally, the working group should coordinate any announcements to take
338 place following the transplant to ensure the public the procedure was a success, the patient is recovering
339 well, and to provide an added layer of privacy for the recipient, donor, and donor family.

340 **Confidentiality/Anonymity**

341 Privacy is paramount for the donor, recipient, and their families. Institutional policies should be followed
342 and reinforced to protect their identities, if desired. Transplant program staff should counsel the VCA
343 recipient and recipient family about disclosing information to friends and family and on social media.
344 Some transplant programs do not release the VCA transplant date as an additional layer of protection.

345 **Building VCA Awareness**

346 In select circumstances and with permission of the recipient and donor family, transplant programs
347 might consider sharing these individuals' experiences with the public to build awareness of VCA
348 transplantation after a waiting period defined for that individual. While making information about VCA
349 transplantation more accessible is important, the desires of the recipient and donor family must be
350 honored first and foremost. Additionally, recipients serving as advocates should be fully informed of the
351 possibility of negative feedback.

#

Appendix A: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (example).

Guidance on Optimizing VCA Recovery (2023 Version)

VCA Background

VCA transplantation is the transplantation of a composite tissue that may include skin, muscle, bone, and nerves and that requires blood flow to function after the transplant.¹

The First VCA Transplantations

The first successful VCA transplant in the world was a larynx transplant in Cleveland, Ohio in 1998.² Later that year, the first unilateral hand transplant was performed in Lyon, France.³ This event marked the recognition that VCAs are the logical next step in reconstructive microsurgery and that surgical techniques used in conventional reconstructive microsurgery can be successfully utilized in VCA transplantation. This landmark case ushered in the era of “restorative surgery.” Although “higher” on the “reconstructive ladder,” by utilizing the exact missing composite tissues from a deceased donor, VCA transplantation offered the recipient the possibility of fewer reconstructive surgeries and more natural function and physical appearance. VCA recipients require immunosuppression to prevent immune rejection of allografts, but in exchange, would be spared the morbidity and possible disfigurement of conventional reconstructive procedures that required the use of tissue(s) from elsewhere on the patient’s body. The first successful unilateral hand transplant in the United States, and to date, the longest lasting in the world, was performed in Louisville, Kentucky in 1999.⁴ The recipient lost his dominant hand in a fireworks accident 13 years earlier.⁵

Face Transplantation

In 2005, the world’s first partial face transplant was performed in Amiens, France. The recipient underwent surgery to replace her original face, after she was mauled by a dog.⁶

Three years later in 2008, the first partial face transplant, in the United States, was performed in Cleveland, Ohio.⁷ The first full face transplant performed in the United States was done in Boston,

¹ OPTN. (2014, November 11). The status of vascularized composite allograft allocation.

<https://optn.transplant.hrsa.gov/news/the-status-of-vascularized-composite-allograft-allocation/>

² Strome M, Stein J, Esclamado R, Hicks D, Lorenz RR, Braun W, Yetman R, Eliachar I, Mayes J. Laryngeal transplantation and 40-month follow-up. *N Engl J Med*. 2001 May 31;344(22):1676-9. doi: 10.1056/NEJM200105313442204. PMID: 11386266.

³ J.M. Dubernard, E. Owen, G. Herzberg, *et al*. Human hand allograft: report on first 6 months *Lancet*, 353 (1999), pp. 1315-1320

⁴ Jones JW, Gruber SA, Barker JH, Breidenbach WC. Successful hand transplantation. One-year follow-up. Louisville Hand Transplant Team. *N Engl J Med*. 2000 Aug 17;343(7):468-73. doi: 10.1056/NEJM200008173430704. PMID: 10950668.

⁵ *Ibid*.

⁶ Petruzzo P, Testelin S, Kanitakis J, Badet L, Lengelé B, Girbon JP, Parmentier H, Malcus C, Morelon E, Devauchelle B, Dubernard JM. First human face transplantation: 5 years outcomes. *Transplantation*. 2012 Jan 27;93(2):236-40. doi: 10.1097/TP.0b013e31823d4af6. PMID: 22167048.

⁷ Arno A, Barret JP, Harrison RA, Jeschke MG. Face allotransplantation and burns: a review. *J Burn Care Res*. 2012 Sep-Oct;33(5):561-76. doi: 10.1097/BCR.0b013e318247eb06. PMID: 22274632; PMCID: PMC3438348.

Massachusetts on a construction worker in 2011.⁸ The recipient suffered from a high-voltage electrical burn.

Sixteen years after the hallmark case in France, there have been at least 160 upper extremity and 50 face VCAs transplants performed from deceased donors worldwide.⁹

Uterine Transplantation

Uterus transplantation for women with absolute uterus factor infertility began in the early 2000s.¹⁰ In 2014, the first baby was born to a uterus transplant recipient in Gothenburg, Sweden.¹¹ The recipient had a congenital uterine agenesis. The first uterus transplant performed in the United States took place in Cleveland, Ohio in 2016.¹² The deceased donor transplant failed and was removed within 2 weeks post-transplant. That same year the first successful uterus transplant in the United States was performed from a living donor in Dallas, Texas. The recipient was born without a uterus and delivered a healthy baby boy in 2017.¹³ The first baby born after a deceased donor uterus transplant in the United States was in Cleveland, Ohio in 2019.¹⁴ As of 2023, there have been more than 100 cases of uterus transplantation performed worldwide and 40 cases in the United States.¹⁵ More than 60 babies have been born after uterus transplant worldwide including 30 in the United States.¹⁶

Penile Transplantation

The first penis transplantation was performed in 2006 in China.¹⁷ The patient had sustained the loss of most of his penis in an accident. Although reported as a surgical success, the graft was removed 15 days later. In 2014, the first successful penis transplant was performed in South Africa.¹⁸ The patient had lost his penis as a result of a botched circumcision procedure he underwent at age 18. In 2015, the recipient announced that he had successfully fathered a child. In 2016 in Boston, a team performed a transplant

⁸ Singhal, Dhruv M.D.; Pribaz, Julian J. M.D.; Pomahac, Bohdan M.D. The Brigham and Women's Hospital Face Transplant Program: A Look Back. *Plastic and Reconstructive Surgery* 129(1): p 81e-88e, January 2012. | DOI: 10.1097/PRS.0b013e31823621db

⁹ Ibid.

¹⁰ Castellón LAR, Amador MIG, González RED, Eduardo MSJ, Díaz-García C, Kvarnström N, Bränström M. The history behind successful uterine transplantation in humans. *JBRA Assist Reprod.* 2017 Jun 1;21(2):126-134. doi: 10.5935/1518-0557.20170028. PMID: 28609280; PMCID: PMC5473706.

¹¹ Brännström M, Johannesson L, Bokström H, Kvarnström N, Mölne J, Dahm-Kähler P, Enskog A, Milenkovic M, Ekberg J, Diaz-Garcia C, Gäbel M, Hanafy A, Hagberg H, Olausson M, Nilsson L. Livebirth after uterus transplantation. *Lancet.* 2015 Feb 14;385(9968):607-616. doi: 10.1016/S0140-6736(14)61728-1. Epub 2014 Oct 6. PMID: 25301505.

¹² Flyckt R, Kotlyar A, Arian S, Eghtesad B, Falcone T, Tzakis A. Deceased donor uterine transplantation. *Fertil Steril.* 2017 Mar;107(3):e13. doi: 10.1016/j.fertnstert.2016.12.009. Epub 2017 Feb 8. PMID: 28189293.

¹³ Testa G, McKenna GJ, Gunby RT Jr, Anthony T, Koon EC, Warren AM, Putman JM, Zhang L, dePrisco G, Mitchell JM, Wallis K, Klintmalm GB, Olausson M, Johannesson L. First live birth after uterus transplantation in the United States. *Am J Transplant.* 2018 May;18(5):1270-1274. doi: 10.1111/ajt.14737. Epub 2018 Apr 12. PMID: 29575738.

¹⁴ Flyckt R, Falcone T, Quintini C, Perni U, Eghtesad B, Richards EG, Farrell RM, Hashimoto K, Miller C, Ricci S, Ferrando CA, D'Amico G, Maikhor S, Priebe D, Chiesa-Vottero A, Heerema-McKenney A, Mawhorter S, Feldman MK, Tzakis A. First birth from a deceased donor uterus in the United States: from severe graft rejection to successful cesarean delivery. *Am J Obstet Gynecol.* 2020 Aug;223(2):143-151. doi: 10.1016/j.ajog.2020.03.001. Epub 2020 Mar 7. PMID: 32151611.

¹⁵ Johannesson L, Richards E, Reddy V, Walter J, Olthoff K, Quintini C, Tzakis A, Latif N, Porrett P, O'Neill K, Testa G. The First 5 Years of Uterus Transplant in the US: A Report from the United States Uterus Transplant Consortium. *JAMA Surg.* 2022 Sep 1;157(9):790-797. doi: 10.1001/jamasurg.2022.2612. PMID: 35793102; PMCID: PMC9260640.

¹⁶ Ibid.

¹⁷ Weillie H, Jun L, Lichao Z, et al. A preliminary report of penile transplantation. *Eur Urol* 2006; 50:851–853.

¹⁸ Bateman, C. (2015). World's first successful penis transplant at Tygerberg Hospital. *SAMJ: South African Medical Journal*, 105(4), 251-252.

on a 64-year-old man in remission of squamous cell carcinoma.¹⁹ In 2018, The Johns Hopkins Hospital performed the world's first total penis and scrotum transplant.²⁰ As of 2023 there have been less than 10 penis transplants worldwide.²¹

¹⁹ Cetrulo, Curtis L. Jr MD†; Li, Kai MD†; Salinas, Harry M. MD*; Treiser, Matthew D. MD, PhD*; Schol, Ilse BS*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD*; Ehrlichman, Richard J. MD*; Holzer, Paul W. BS*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD*; Lellouch, Alexandre G. MD*; Kurtz, Josef M. PhD*; Austen, William G. Jr MD*; Winograd, Jonathan M. MD*; Bojovic, Branko MD*; Eberlin, Kyle R. MD*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS*,†. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

²⁰ Nitkin, K. (2018, April 23). *First-Ever Penis and Scrotum Transplant Makes History at Johns Hopkins*. John Hopkins Medicine. <https://www.hopkinsmedicine.org/news/articles/first-ever-penis-and-scrotum-transplant-makes-history-at-johns-hopkins>

²¹ Cetrulo, Curtis L. Jr MD†; Li, Kai MD†; Salinas, Harry M. MD*; Treiser, Matthew D. MD, PhD*; Schol, Ilse BS*; Barrisford, Glen W. MD†; McGovern, Francis J. MD†; Feldman, Adam S. MD, MPH†; Grant, Michael T. MD†; Tanrikut, Cigdem MD†; Lee, Jeffrey H. MD*; Ehrlichman, Richard J. MD*; Holzer, Paul W. BS*; Choy, Garry M. MD, MBA‡; Liu, Raymond W. MD‡; Ng, Zhi Yang MD*; Lellouch, Alexandre G. MD*; Kurtz, Josef M. PhD*; Austen, William G. Jr MD*; Winograd, Jonathan M. MD*; Bojovic, Branko MD*; Eberlin, Kyle R. MD*; Rosales, Ivy A. MD§; Colvin, Robert B. MD§; Ko, Dicken S. C. MD, FRCSC, FACS*,†. Penis Transplantation: First US Experience. *Annals of Surgery* 267(5):p 983-988, May 2018. | DOI: 10.1097/SLA.0000000000002241

OPTN Purview of VCA Organs

In 2014, the Health Resources and Services Administration (HRSA) designated VCAs as organs under the purview of the OPTN. ^{22, 23} **Table 1-1: VCA types and covered body parts** below lists the VCA types and identifies the covered body parts specific to each VCA organ.

Table 1-1: VCA types and covered body parts²⁴

Type	Covered VCA
Upper limb	Any group of vascularized body parts from the upper limb
Head and neck	Face, larynx, vascularized parathyroid gland, scalp, trachea, vascularized thyroid, and any other vascularized body parts from the head and neck
Abdominal Wall	Abdominal wall, symphysis pubis, and any group of vascularized skeletal elements of the pelvis
Uterus	Uterus, cervix, vagina
External male genitalia	Penis and scrotum
Other genitourinary organ	Internal male genitalia; external and internal female genitalia other than uterus, cervix, and vagina; and urinary bladder
Vascularized gland	Vascularized gland
Lower limb	Pelvic structures that are attached to the lower limb and transplanted intact, gluteal region, vascularized bone transfers from the lower extremity, toe transfers, and any group of vascularized body parts from the lower limb
Musculoskeletal composite graft segment	Spine axis, chest wall, and other composite graft of vascularized muscle, bone, nerve, or skin
Spleen	Spleen

²² U.S. Department of Health and Human Services, Final Rule, “Organ Procurement and Transplantation Network.” Federal Register 78, no. 128 (July 3, 2013): 40033, <https://www.govinfo.gov/content/pkg/FR-2013-07-03/pdf/2013-15731.pdf>

²³ Implement the OPTN’s Oversight of Vascularized Composite Allografts (VCAs),” Public Comment Proposal, OPTN, accessed May 4, 2023, https://optn.transplant.hrsa.gov/media/1118/05_vca_implementation.pdf.

²⁴ OPTN Policy 1.2: Definitions ‘Covered Vascularized Composite Allograft body parts (covered VCAs)’. This language reflects the most recent language approved by the OPTN Board in December of 2021. This language will be implemented pending approval

Benefits of VCA Transplantation

The field of VCA transplantation has existed for more than two decades, and the benefits and challenges are becoming apparent to larger and wider groups of patients, clinicians, and families. Public attitudes toward VCA donation are reported as favorable, and much of this is based on media reports of transplant outcomes.²⁵ There is increased acceptance outside the VCA transplant community that the therapeutic goal of VCA transplantation is functional restoration and bodily integrity, not only cosmetic restoration.²⁶

The benefits of VCA transplantation include increased quality of life and social integration. For example, the ability to hold someone's hand, return to near normal appearance after severe trauma, experience gestation and childbirth, being able to speak, write and smile, and regain independence in activities of everyday living. The Committee hopes this document provides the transplant community with knowledge that will contribute to the increased utilization of the precious resources for the patients and families that can benefit.

Considerations for the Identification and Initial Evaluation of the Potential VCA Donor

As with solid organ transplantation, there are transplant program-specific criteria utilized for the evaluation of VCA organs from deceased donors; and in the case of uterus transplant, both living and deceased donors. The criteria and tools used to evaluate potential VCA donors will differ by VCA type. Minimal criteria for acceptance of all VCAs are based on guidelines for solid organ transplantation, with additional criteria to ensure the best possible outcomes of the VCA transplant. Additional considerations are specific to the type of VCA graft needed. The decision to include or exclude VCA from deceased donors based on these criteria should be left to the individual VCA transplant programs. All deceased donors should be considered for VCA, and a match run should be generated.

of designated uterus, external male genitalia, and other genitourinary organ transplant programs, currently slated for review at the December 4, 2023 meeting of the OPTN Board of Directors. See Establish Membership Requirements for Uterus Transplant Programs Policy Notice, available at https://optn.transplant.hrsa.gov/media/gapkro1m/policy-notice_establish-membership-requirements-for-uterus-transplant-programs_december-2021.pdf.

²⁵ Rodrigue, J, 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.

²⁶ Caplan, A., "An Ethics Infrastructure for VCA", presentation at the Evolving Issues of Vascularized Composite Allo-transplantation, Baltimore, MD September 19, 2017.

Once a match run is generated, communication between the VCA program and the OPO for further screening, including preliminary virtual and/or flow crossmatch, feasibility, and additional considerations should occur early in the allocation process. Depending on the VCA type, additional donor imaging (x-rays, CT scans, vascular ultrasound) may be requested, as well as photographs to ensure donor-recipient suitability. **Table 1-2: Examples of VCA type-specific evaluation considerations** below reflects some examples of VCA type specific considerations for the initial evaluation of the potential VCA donor:

Table 1-2: Examples of VCA type-specific evaluation considerations²⁷

	Limb (Upper or Lower, Unilateral or Bilateral)	Head and Neck	Penile	Uterus
Physical attributes	Skin tone, scars, tattoos, distinguishing marks, mechanism of injury, sex/gender, body habitus, height, weight, limb length, laterality (if unilateral)	Tattoos, scars, piercings, skin tone, distinguishing marks, mechanism of injury, sex/gender, anatomic abnormalities	Anatomic abnormalities, distinguishing marks	Anatomic abnormalities
Medical and surgical history considerations	Mechanism of injury/death, vascular access placement, history of limb dysfunction/paralysis	Mechanism of injury/death, history of facial paralysis/dysfunction	Mechanism of injury/death, History of organ dysfunction	Mechanism of injury/death, reproductive history
Additional work-up			Additional infectious testing (e.g., chlamydia, gonococcus, etc.)	Additional infectious testing (e.g., chlamydia, gonococcus, Papanicolaou (PAP), etc.),

Consistent with solid organ donor evaluation, medical and surgical history review should also specifically include: any history of malignancy, current or recent sepsis, disseminated intravascular coagulation (DIC), diabetes, 2020 Public Health Service (PHS) Medical and Social Donor Risk Criteria, and other factors that may impact form and function of the VCA.

After acceptable donor and recipient characteristics are determined, recovery and case-specific needs can be discussed. Once VCA authorization is obtained, an OPO team member should speak with the VCA surgeon to thoroughly understand VCA recovery. This knowledge is essential to inform the donor’s family, funeral home, medical examiner/coroner, and/or law enforcement representatives of the VCA donation.

²⁷ Table 1-2 is not an all-inclusive list of VCA type specific evaluation considerations.

Other considerations related to the donor procurement process include:

- Donor allografts must be recovered and transported within transplant program acceptable limits of cold ischemic time. The amount of allowable ischemic time will vary by transplant program, type of VCA and size of the allografts. As with other transplanted organs, short ischemic times are desired.
- Transfer to transplant hospital for simultaneous donor/recipient surgeries may be requested.
- As with the practice in solid organ donation, on-site visual inspection of the donor, prior to recovery, and intra-operative assessments are the final components of VCA donor suitability evaluation prior to removal of the allografts.
- Prosthetics/reconstruction of the donor post recovery should be planned to preserve the integrity and respect of the donor.
- Evaluation of living donors for VCA will follow *OPTN Policy 14: Living Donation*

Emerging types of VCA transplants may require additional consultations or testing beyond existing standards. OPOs and transplant programs are strongly encouraged to review VCA educational materials on the OPTN Learning Management System in addition to developing protocols and relationships with VCA programs that intend to transplant emerging VCA types.

Family Considerations

With the advancement of VCA transplants, some donor families can now make an additional gift apart from solid organ and tissue donation. VCA authorization requestors need to be knowledgeable, skilled advocates for VCA donation. OPOs should also 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 recovery process. VCA specific considerations should be explained to OPO staff to ensure potential donor families are aware of additional testing, longer operating room time, possible transfer of the donor to a recovery center, reconstruction of the donor site, potential face masks or prosthetics, and funeral home or medical examiner needs. OPOs that have successfully procured VCAs report benefit of rehearsal conversations with OPO staff. These OPOs can also provide suggested scripts and VCA authorization documents. Learning about outcomes of past VCA transplants helps requestors facilitate the approach and become advocates for VCA transplant candidates.

Approaching families for a potential VCA donation should be carefully considered on a case-by-case basis. OPO staff should use their expertise in evaluating donor family dynamics to ensure that an approach for VCA donation does not jeopardize potential solid organ donation.

Authorizing a VCA Donor

When alerted to a donor referral, OPO staff should check the OPTN Computer System 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 as 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 2.14.E: Deceased Donor Authorization Requirement* states that OPOs must document the specific authorization for VCA donation from deceased donors.²⁸ Effective VCA authorization practices show that VCA authorization should occur after authorization for organ and tissue donation.²⁹ Further, any discussion on VCA authorization should only occur after identifying a potential recipient. This approach ensures that VCA authorization does not dissuade next-of-kin from life-saving organ donation decisions. Families should be offered the opportunity for VCA donation once a potential recipient has been identified, regardless of whether they have authorized eye or tissue donation. Prospective cross-matching between potential donors and recipients varies between transplant programs and even between different VCA programs at the same transplant hospital. Crossmatch timing and determining if the crossmatch will be virtual or physical must be determined between the OPO, histocompatibility lab, and transplant program early in the process. This is because the crossmatch could determine if VCA donation is offered to a donor family.

Helping Families Understand the Need for VCA Transplants and Empowering Them to Make a Decision

VCA donation is a unique and rare opportunity to make a life-changing donation to a VCA candidate. OPOs should be conscientious in how they approach VCA donation with different donor families. Donor families require accurate information about VCA donation opportunities to understand the impact of the donation, such as the potential benefits the donation could bring to a recipient. When a donor family feels a connection to the potential recipient, they are more likely to overcome the hesitancy some have with considering donation of a face, limb, uterus, or penis. That connection between a donor and recipient represents a facet of VCA donation that is unlike many gifts: VCA transplant offers a unique continuation of a deceased donor's life through that connection to the potential recipient. Before sharing any information about a potential recipient, the OPO must abide by all applicable federal and state privacy laws and should consult their own attorneys and confer with transplant programs prior to sharing any information.

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 the OPO will protect the donor's identity and confidential information.

Finally, there 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 and, as a result, additional time may be required to thoroughly evaluate and coordinate the donation.

²⁸ *OPTN Policy 2.14.E: Deceased Donor Authorization Requirement*.

²⁹ *OPO Guidance on VCA Deceased Donor Authorization*, <https://optn.transplant.hrsa.gov/resources/guidance/opoguidance-on-vca-deceased-donor-authorization/>. Accessed May 19, 2023.

Mock runs can help programs learn what improvements can be made in their recovery processes. These practice exercises include approaching donor families for VCA authorization and recovery of the graft, but do not include transplantation of the VCA graft to a living recipient. Transplant programs should educate the OPO staff, so they are able to convey the importance of donation that promotes the advancement of the VCA field when making this specific type of authorization ask.

Recovery Considerations

Coordinating the recovery of VCAs and solid organs for transplant requires collaboration and communication between the OPO and all transplant hospitals involved in the recovery and transplant of organs from the deceased donor. Considerations include the timing of VCA recovery and solid 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 all parties to discuss the procurement process and sequence.

Specialized Considerations for VCA Recovery

Given the complexity of procurement needs associated with VCA transplants, some transplant programs have opted to move the donor to a specialized or centralized recovery center. The OPO has a lead role in coordinating these activities among various procurement teams, and it is recommended that VCA transplant programs discuss needs regarding procurement location as early as possible with OPO staff.

For those OPOs seeking more involvement with VCA procurement, designating a VCA champion coordinator is recommended. The duties of this staff members could include developing policies and procedures, providing training, and collaborating with transplant programs.

Timing and Sequence of VCA graft recovery

The addition of VCA recovery to thoracic and/or abdominal organ recovery may add various amounts of time to the donor procurement. OPOs and transplant programs should thus plan for recoveries that may be of extended length. 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. While recovery of VCA grafts should be performed whenever possible, non-VCA grafts must be prioritized if donor instability intervenes. During the pre-procurement team huddles, it is advisable to make plans between procurement teams and OPO staff about the events that will occur should a deceased donor become unstable. The recovery of VCA grafts should never compromise solid organ recovery.

This guidance document emphasizes the value of a pre-recovery huddle between all participants, inclusive of surgeons and OPO staff. Details of procurement timing, sequence, and preservation should be discussed and agreed upon prior to initiation of recovery.

General Timing Guidelines by VCA Type

Each type of VCA graft has unique criteria for recovery. A brief review of timing considerations for some of the VCA types follows. Individual cases may vary significantly from these estimates.

Upper Limb

The recovery of upper extremities can be performed with or without a tourniquet. The timing of the removal of the donor graft may occur prior to or after cross-clamp to optimize the recovery of non-VCA organs. In general, recovery procedures take 30 minutes per extremity.³⁰

Facial Allografts

Oftentimes, recoveries from the head and neck precede the thoracic and/or abdominal organ recovery. The operating room may 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 facial recovery. If a sentinel flap is being recovered from the donor's forearm, the arms can be outstretched for this procedure. Elective tracheostomy may have to be performed on the donor in advance of the recovery to avoid obstruction of the airway during facial recovery. The length of the procedure will be dictated by the size and complexity of the graft. Recovery times for facial allografts vary but in general are complex.^{31, 32} Depending on the type of face allograft, recovery times may vary widely from 2-12 hours. Much of this recovery can be done prior to the administration of heparin and cross-clamp of thoracic and abdominal organs.

Uterus Allografts

Multiple uterus recovery approaches have been successful. Most of the uterus dissection occurs prior to cross-clamp, in conjunction with the dissection and evaluation of other organs. The sequence of uterus dissection can occur at any point but is often performed after dissection of the vital abdominal organs is complete. In some circumstances, the uterus has been removed prior to cross-clamp and mimics the approach in a living donor hysterectomy. If the uterus is to be removed after cross-clamp, all vital organs can be removed first with uterus recovery occurring last. Dissection of the uterus prior to cross-clamp can be performed in approximately 2-3 hours. Depending on recovery sequence and order of dissection, minimal time or up to 2 hours may be added to the total recovery time for all organs.

Abdominal Wall Allografts

In many cases, abdominal wall grafts will be recovered in conjunction with the abdominal organs (liver, small bowel). Dissection of the abdominal wall graft can be performed before cross-clamp, and the flap can remain connected to blood supply until cross-clamp is performed.³³ Recovery time will also depend on the size of the graft, but in general will add 30 minutes to recovery of the abdominal organs.

³⁰ Mendenhall SD, Lutfy J, Graham E, Overschmidt B, Levin LS, Neumeister MW. Technique for Rapid Hand Transplant Donor Procurement Through the Elbow. *Hand (N Y)*. 2021 May;16(3):391-396. doi: 10.1177/1558944719863127. Epub 2019 Jul 23. PMID: 31331207; PMCID: PMC8120581.

³¹ Bueno J, Barret JP, Serracanta J, Arnó A, Collado JM, Valles C, Colominas MJ, Diez Y, Pont T, Salameo P, Martinez-Ibañez V. Logistics and strategy of multiorgan procurement involving total face allograft. *Am J Transplant*. 2011 May;11(5):1091-7. doi: 10.1111/j.1600-6143.2011.03489.x. Epub 2011 Mar 28. PMID: 21443675.

³² Brazio PS, Barth RN, Bojovic B, Dorafshar AH, Garcia JP, Brown EN, Bartlett ST, Rodriguez ED. Algorithm for total face and multiorgan procurement from a brain-dead donor. *Am J Transplant*. 2013 Oct;13(10):2743-9. doi: 10.1111/ajt.12382. Epub 2013 Aug 5. PMID: 23915309.

³³ Erdmann D, Atia A, Phillips BT, Mithani SK, Avashia YJ, Hollister BA, Cendales LC, Ravindra KV, Sudan DL. Small bowel and abdominal wall transplantation: A novel technique for synchronous revascularization. *Am J Transplant*. 2019 Jul;19(7):2122-2126. doi: 10.1111/ajt.15370. Epub 2019 Apr 15. PMID: 30913367.

External Male and Other Genitourinary Allografts

As with many VCA grafts, types of genitourinary grafts can vary widely. The graft may include a combination of the penis, scrotum, thigh tissue, and lower abdominal wall, or penis alone.³⁴ In complex cases, the recovery can commence prior to cross-clamp to allow more time for dissection of the abdominal wall, exposing the blood vessels. At that point, the recovery of other solid organs may proceed prior to cross-clamp, if so desired and coordinated with the VCA genitourinary recovery team. Once cross-clamp has occurred, procurement teams may proceed removing organs with the VCA genitourinary team going last. In this scenario, the total recovery time is minimally impacted by the recovery of even a complex urogenital graft.

Tracheal/Esophageal Allografts

In the most recent reported recovery of a tracheal allograft, the transplant team simultaneously prepared the abdomen for liver procurement. Time from cross-clamp to graft retrieval was 26 minutes.³⁵ Recovery of this graft can occur in conjunction with other organs and does not significantly impact the total length of recovery time for all organs.

Summary of Recovery Times for VCA Grafts

These estimates are provided only to give an idea how long VCA graft recoveries may take. As in all donor recoveries, there will be variability in the timing and sequence of VCA recoveries alongside other thoracic and abdominal organs. 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 given the amount of time necessary to complete any warm dissection prior to cross-clamp while the other procurement teams wait.³⁶ In the cases of teams working together, the VCAs may be removed before cross-clamp, then the thoracic and/or abdominal organ teams are able to cannulate in preparation for cross-clamp in the standard way.

Specialized Needs of the VCA Recovery Team

VCA recovery may 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 bringing 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, or other centralized recovery center as mentioned above.

If the VCA team accepting the graft is traveling from farther away, the team may need support with ground transportation to and from the donor hospital. If the VCA team is flying-in, the timing of the recovery may also impact the duty time of the aircraft crew involved in the trip.

³⁴ Lopez CD, Girard AO, Lake IV, Oh BC, Brandacher G, Cooney DS, Burnett AL, Redett RJ. Lessons learned from the first 15 years of penile transplantation and updates to the Baltimore Criteria. *Nat Rev Urol.* 2023 Jan 10:1–14. Doi: 10.1038/s41585-022-00699-7. Epub ahead of print. PMID: 36627487; PMCID: PMC9838304.

³⁵ Genden EM, Laitman BM. Human Tracheal Transplantation. *Transplantation.* 2023 Feb 14. doi: 10.1097/TP.0000000000004509. Epub ahead of print. PMID: 36782283.

³⁶ Brazio, P, Barth, R, Bojovic, B, Dorafshar, A, Garcia, J, Brown, E, Bartlett, S, and Rodriguez, E, “Algorithm for Total Face and Multiorgan Procurement from a Brain-Dead Donor”, *American Journal of Transplantation* no 13: 2743–, (2013). doi:10.1111/ajt.12382.

Programs with limited VCA recovery and transplantation experience are encouraged to seek mentorship from more seasoned VCA programs. Experienced VCA programs should support the ever-growing VCA community by sharing their exemplary practices with recently established programs.

Changes in Donor Hemodynamic Stability

If the VCA recovery is planned to proceed prior to cross-clamp and 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.³⁷ Preservation solutions for the thoracic and/or abdominal organ recovery should be available 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. As with all other organs, VCAs must be packaged and labeled in accordance with *OPTN Policy 16: Organ and Extra Vessel Packaging, Labeling, Shipping, and Storage*.³⁸ The labels are printed from the OPTN Organ Labeling, Packaging and Tracking System.

Post-Recovery Considerations

For head and neck and upper extremity recoveries, the use of prosthetics is strongly recommended if allowed by the donor family to preserve donor dignity. After recovery, prosthetics must be secured to prevent them from being dislodged when the donor is moved.

OPOs should prepare to document the recovery of VCAs with practices similar to thoracic and/or abdominal organ recoveries.

Funeral Home and Medical Examiner Involvement

OPO 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 anatomical modifications and the nature of the organ recovery. As VCA donation can extend the organ donation process, this may impact the funeral arrangements including the funeral director's preparations for memorial services.

³⁷ Datta, N, Yersiz, H, Kaldas, F, Azari, K, "Procurement strategies for combined multiorgan and composite tissues for transplantation", *Current Opinion in Organ Transplantation* no 20:121-126, (2015), DOI: .1097/MOT.0000000000000172.

³⁸ *OPTN Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.

Similar concerns apply to medical examiners or coroners who may be investigating the donor's circumstances of death. Coordination with the medical examiner or coroner following VCA authorization to ensure there are no restrictions that impact the VCA donation is recommended early in the process.

Media and Public Relations Strategies

Rationale

A media strategy needs to be considered by the transplant program and OPO to protect the privacy of the recipient, donor, and their families as much as possible. This is to maximize the dissemination of information while safeguarding the public confidence and transparency for VCA transplantation.

Planning

One of the most important first steps, before any media plans are executed, is for the clinicians and public relations team at the transplant hospital to find out whether the recipient and their family are comfortable with media attention and interviews, and to what extent. Media attention could include photography and videography, interviews, and press conferences. This is a dynamic process throughout the transplant experience, which must be revisited regularly for amendment, as necessary. Every program is unique, and decisions must be guided by recipient and donor family preferences and institutional policies.

Most of the planning for VCA-related media will fall to the public relations team at the transplant hospital, with support from the OPO. The transplant hospital should establish a direct line of communication with the OPO public relations team. This line of communication should be established as early as possible, ideally before the transplant takes place.

A public relations strategy should be developed and include a timeline for any media moments based on transplantation and subsequent patient milestones. Having this plan in place will mitigate any rushed announcements and media events. Development of a working group to establish the strategy and timeline is recommended and should include public relations contacts at all the hospitals involved with the VCA transplant. This working group should determine whether there will be a press conference and, if so, who will host and lead the on-site coordination. In most instances, this responsibility would belong to the transplant program. Ideally, the working group should coordinate any announcements to take place following the transplant to ensure the public the procedure was a success, the patient is recovering well, and to provide an added layer of privacy for the recipient, donor, and donor family.

Confidentiality/Anonymity

Privacy is paramount for the donor, recipient, and their families. Institutional policies should be followed and reinforced to protect their identities, if desired. Transplant program staff should counsel the VCA recipient and recipient family about disclosing information to friends and family and on social media. Some transplant programs do not release the VCA transplant date as an additional layer of protection.

Building VCA Awareness

In select circumstances and with permission of the recipient and donor family, transplant programs might consider sharing these individuals' experiences with the public to build awareness of VCA transplantation after a waiting period defined for that individual. While making information about VCA transplantation more accessible is important, the desires of the recipient and donor family must be

honored first and foremost. Additionally, recipients serving as advocates should be fully informed of the possibility of negative feedback.

#