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Vascularized Composite Tissue Allografts (VCA): the Policy Side

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Abstract In July 2013, the Secretary of Health amended the National Organ Transplant Act of 1986 to designate vascularized composite tissue allografts (VCAs) as organs. The definition of a VCA as an organ required that all nine criteria published in the Final Rule were fulfilled. VCAs meeting the definition of an organ would henceforth come under the oversight of the Organ Procurement Transplant Network (OPTN) and were required to develop and be in compliance with policies and bylaws as for traditional organ transplantation. The implementation date for the Final Rule modification was July 3, 2014. The OPTN and the United Network of Organ Sharing (UNOS) convened a multidisciplinary VCA committee to spearhead developing the first policies relevant to VCA. Described in this article are the policies that have been developed and the necessary bylaw changes required. These include requirements for OPTN/UNOS membership for VCA programs, specific policies for the authorization of potential donors of VCAs, allocation algorithms for VCA donors, mandatory data submission requirements, and guidance documents for the donation and authorization process, and for potential VCAs from living donors. The OPTN/UNOS Board approved the initial policies and bylaw changes in June 2014 to meet the deadline for implementation of the Final Rule modification. Since then, further modifications of the first policies and bylaws have occurred which are also described.

Keywords Vascularized composite tissue allografts · Definition · OPTN oversight

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Introduction

The initial development of vascularized composite tissue allograft (VCA) transplant programs brought to light operational and regulatory issues that were similar to those faced by the field when "standard" transplants were expanding in the early 1980s. Although organ procurement organizations (OPOs) obviously were comfortable with the donation process, VCAs posed a new set of concerns: How would the recovery of VCAs be coordinated? What special provisions would be required for obtaining authorization for donation? How would patients be listed for transplant? What safeguards would be in place to assure the safety of donated VCA grafts, and the safety of the recipients? To complicate matters, the newly formed VCA transplant teams were largely drawn from the fields of plastic, reconstructive, and orthopedic surgery and had little, if any, familiarity with the organ donation process. Regulatory oversight of VCA transplants also was unclear and seemingly inadequate. The Organ Procurement and Transplantation Network/United Network for Organ Sharing (OPTN/UNOS) had responsibility and authority only for

those organs specifically named in the National Organ Transplant Act (NOTA): kidney, liver, heart, lung, pancreas, and small bowel. VCAs might be considered "tissues" rather than organs and thus are regulated by the Food and Drug Administration (FDA). However, the FDA regulations primarily were focused on the prevention of disease transmission and did not deal with any of the other issues noted above. Moreover, the FDA lacked the infrastructure or history of oversight of the other aspects of organ donation. An analysis of the nature of VCA donation and transplantation clearly indicated that VCAs were much closer to organs than to tissues [1••]. For example, tissues are recovered from asystolic deceased donors, while VCAs are recovered from heart-beating, brain-dead deceased donors. While tissues are heavily processed prior to implantation and can be stored for extended periods, VCAs are transplanted as soon as possible after recovery and without substantive alteration. Finally, VCAs require ABO compatibility and the use of immunosuppressive drugs in the recipient to prevent rejection, neither of which is necessary in tissue transplantation.

Recognizing the dilemma, in March 2008, the US DHHS published a request for guidance on VCA oversight "…seeking feedback from stakeholders and from the public about the advisability of exploring rulemaking to include vascularized composite allografts within this definition of organs [under the Final Rule] as well as the potential ramifications of such a change" [2].

While this process of information gathering and regulatory decision making was underway, OPOs still needed to deal with the small number of VCA programs already in place. This required close collaboration between the OPO and VCA program leadership to assure that introduction of VCA recoveries would not negatively impact the recovery of "standard" organs for transplant. Fortunately, OPOs had the systems and experience of the OPTN/UNOS to provide guidance. Thus in most cases, OPOs simply followed the same procedures as were specified for other organs whenever possible. For example, donor records were shared in the same way, donor ABO and infectious disease testing was identical, and VCA graft packaging, labeling, and handling were identical.

However, some things required special forms and processes as the OPTN/UNOS system was simply not designed with VCAs in mind. For example, there was no way to list a patient as waiting for a VCA graft. Fortunately, with only a handful of VCA transplant candidates, issues around priority for transplant were always mooted by the need to match blood type, HLA, graft size, skin tone, and other factors in the donor/recipient match. Authorization presented a challenge as well. Although a rapidly increasing percentage of US donors had authorized their own donation premortem on a state registry, it was unlikely that donors had envisioned the removal of their face or a limb when signing up. Thus special, supplemental authorization forms needed to be developed and used.

Public comment indicated strong support for VCAs being regulated as organs recognizing that the early development of VCA in the USA generally adhered to the already established principles and practices of more traditional solid organ transplantation. Thus, the lessons learned from solid organ transplantation could be applied to the regulatory, ethical, and clinical pathway VCA transplantation. DHHS agreed and in July 2013, VCAs were added to the definition of human organs [3••] with an effective date of July 2014. Unlike traditional solid organs, the amended Final Rule did not list each type of VCA that would be included. Instead, it created a list of nine characteristics which, if met, would define a VCA graft as being included under the jurisdiction of the OPTN and its contracted operations entity, UNOS.

Implementation of the OPTN Oversight of VCA

Several OPTN/UNOS policy and bylaw changes were required prior to the July 3, 2014 effective date to allow for programs performing VCAs to be in compliance with OPTN requirements. To develop these new bylaws and policies, OPTN/UNOS convened a VCA committee of 18 members. Seven of the members were reconstructive surgeons who had pioneered the VCA programs in the USA and were founding members of the American Society of Reconstructive Transplantation (ASRT). The ASRT is a relatively new society that was formed in 2008 for the purpose of creating a forum for the development of VCA in the USA. Members include reconstructive surgeons, transplant physicians and surgeons, ethicists, psychiatrists, and basic science researchers. The VCA committee also included members representing the military, a VCA transplant recipient, an ethicist, two senior leaders representing organ procurement organizations in the USA, and senior members of the solid organ transplant community. The diversity of experience in reconstructive transplant surgery, and traditional transplant surgery and medicine, was felt to be essential to provide policies and bylaws consistent with the requirements of the OPTN and UNOS.

In order to provide the appropriate oversight and structure for VCA procurement, allocation, and transplantation, the first proposals made to the OPTN/UNOS board in June 2014 established the following: (1) a definition of VCA; (2) membership criteria for VCA programs in the OPTN; (3) a VCA allocation algorithm; and (4) specific policies governing donor authorization to recover VCA (each of these four proposals is addressed in detail below.) The short time frame between the enactment of the revised Final Rule and its implementation required that these new policies be developed and implemented without the usual public comment period. Instead, the policies were adopted by the OPTN/UNOS Board of Directors with a "sunset" date provision of 1 year, then distributed for public comment and subsequently revised.

Definition of a VCA

As noted above, the 2013 Final Rule contained nine criteria all of which must be met for a graft to be considered a VCA (Table 1). Note that similar to traditional donated organs, the composite tissue graft required a surgical anastomosis for viability; the graft was susceptible to ischemia and therefore could only be stored for short periods and not cryopreserved, and was susceptible to allograft rejection generally requiring immunosuppression.

After careful deliberation, the VCA committee made no objection to the definition as put forward in the Final Rule by the Secretary of Health and Human Services. The committee noted, as was also discussed in the Final Rule, that the nine criteria applied only to the organ and made no distinction as to the donor source. Therefore, the criteria listed also could be applied to a graft from a living VCA donor. The possibility of a living VCA donor was addressed by the Secretary of Health and Human services in public comment, who also opined that oversight of living donors, regardless of the organ, comes under the auspices of the OPTN. While the Final Rule definition intentionally did not prohibit the possibility of living VCA donors, it also became apparent to the committee that cases of live VCA donation had already occurred. Specific examples included the already reported use in Sweden of living donors for uterine transplant [4••], and in the USA, the use of abdominal wall tissue transplanted from one identical twin to another for breast reconstruction following mastectomy for breast cancer [5]. Other possible living donor VCAs could include currently performed autologous free tissue transfers such as skin and muscle flaps.

The definition of a VCA was presented to the OPTN/UNOS Board in June 2014 and was approved. During the subsequent public comment period (September 29 to December 5, 2014), several comments were submitted specifically objecting to the possibility of the use of a living VCA donor. The VCA committee carefully considered these comments and sought collaboration with the UNOS/OPTN Living Donor Committee and OPTN/UNOS ethics committees to develop a guidance document with the specific purpose of educating the transplant community and general public about the concept of a living donor VCA, and under what circumstances this might occur. The VCA committee was aware of the precedent for developing guidance documents in the field of living kidney and liver donation. This approach is well-established within the OPTN/UNOS as an appropriate mechanism to not only educate but to also provide specific and detailed guidance and to request important information to better inform the future development of appropriate policies.

The Living Donor VCA Guidance Document that resulted from a consensus of all three committees addresses general considerations regarding the VCA types that might be considered suitable from a living donor, the principles of protecting donor safety, recommendations for informed consent process, medical and psychosocial evaluation of living VCA donors, and criteria for living VCA recovery programs. While the VCA committee felt that it was too early to try and develop specific policy and bylaws governing living donor VCA, the guidance document is closely modeled on the current Living Donor Policy that covers all other living donors, but had specifically excluded VCA living donors [6].

The guidance document was presented to the OPTN/UNOS board on June 2, 2015 and was accepted. It is now posted on the OPTN website [7] and is open for public review.

Table 1 Definition of a VCA

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2. Containing multiple tissue types;
3. Recovered from a human donor as an anatomical/structural unit;
4. Transplanted into a human recipient as an anatomical/structural unit;
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7. Not combined with another article such as a device;
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Data from ref [3••]

Membership Requirements for VCA Programs

To allow enactment of the Final Rule governing VCA on July 3, 2014, the VCA committee proposed a minimum set of membership criteria to allow VCA programs currently active to be able to continue their work under the new oversight of the OPTN. This first VCA membership requirement bylaw required that the VCA program must be located in a hospital that was a member of the OPTN/UNOS and have an approved traditional solid organ transplant program. Furthermore, the application required a letter of intent that stated that the local OPO would provide VCA organs, and identified the surgical, medical, and administrative directors who would be responsible for the VCA program. The letter of intent had to be signed by the surgical and medical directors and the chief administrative officer of the institution. It is important to note that the first VCA Membership Bylaws did not contain any training or experience requirements for VCA program key personnel. The membership requirements were passed by the board in June 2014 with the provision they would "sunset" in

September of 2015 so that the committee could develop more specific requirements.

In the intervening year, the VCA committee worked diligently on improved VCA membership requirements aligning new proposals with established OPTN/UNOS membership criteria for traditional solid organ programs that emphasize objective credentialing standards and training and experience requirements for both the medical and surgical leaders of traditional transplant programs. The committee felt it was essential to apply to the new and innovative field of VCA the same standards of all other organ transplant program whose overarching intent has always been to promote patient safety by being certain that minimum requirements are met by the medical and surgical leaders of the program, and to enhance accountability to the OPTN/UNOS.

The VCA committee chose to develop specific criteria for the three VCAs most commonly performed currently in the USA: upper limb, head and neck, and abdominal wall. In addition, a fourth category of "other" was described to encompass other VCAs not yet commonly performed (for example vascularized joints, larynx). For all four categories, a VCA program needed to identify (1) a program director, (2) a primary reconstructive transplant surgeon, and (3) a primary transplant physician responsible for the medical management of the patient. Tables 2, 3, 4, 5, and 6 describe the details of the requirements for the primary reconstructive transplant surgeon for upper limb, head and neck, abdominal wall, and the category other, respectively. It can be seen that for upper limb, head and neck, and abdominal wall primary surgeons, there were appropriate board certification requirements but also experience pathways designed to allow pioneers in the field to continue to contribute their experience to advance their programs until appropriate board certification was obtained either by themselves or another surgeon. Note that the experience pathway option expires on September 1, 2018. Also, for each of the three major categories of VCAs, the primary surgeon needed to document appropriate fellowship training or could qualify by an experience pathway. For example, a VCA upper limb primary surgeon must meet one of the following fellowship training criteria: complete an ACGME-approved hand surgery fellowship or a similar fellowship program, or an experience pathway in lieu of fellowship training is allowable. The experience pathway requires the surgeon to meet all of the

Table 2 General membership requirements

VCA program must
• Complete an application for:
Upper limb
Head and neck
Abdominal wall
Other VCAs not commonly performed
• Identify the following key personnel:
Program director
Primary transplant physician
Primary transplant surgeon

Table 3 General membership requirements for VCA program director, primary surgeon, and physician

- A physician or surgeon who is a member of the transplant hospital staff
- Responsible for transplant program coverage plan
- Same individual can be the program director for multiple VCA programs
- M.D., D.O., or foreign equivalent, and current license to practice medicine
- Accepted on a hospital's medical staff and be onsite
- Vetted by the transplant hospital's credentialing committee
- Completed a medical or surgical transplant fellowship

Table 4 Specific requirements for upper limb primary surgeon

Board certification	
• American Board of Plastic Surgery	
• American Board of Orthopedic Surgery	
• American Board of Surgery	
• Foreign equivalent	
Experience pathway	
• Observe two multiorgan procurements	
• Primary or first assistant surgeon on 1 VCA procurement	
• Evaluation of at least three upper limb transplant patients	
• Primary surgeon of at least one upper limb transplant	
• Posttransplant follow-up on one upper limb recipient for at least 1 year	
• Expires September 1, 2018	
Fellowship training	
• ACGME-approved hand surgery fellowship	
• Similar fellowship program outlined in Appendix J	
Experience pathway	
• 2 years consecutive and independent practice of hand surgery	
• American Society for Surgery of the Hand and their Subspecialty Certificate in Hand Surgery	
• Additions for microvascular experience	
Type of procedure	Minimum number of procedures
Bone	20
Nerve	20
Tendon	20
Skin or wound problems	14
Contracture or joint stiffness	10
Tumor	10
Microsurgical procedures free flaps	10
Non-operative	6
Replantation or transplant	5

Table 5 Specific requirements for head and neck primary surgeon

Board certification	
• American Board of Plastic Surgery	
• American Board of Otolaryngology	
• American Board of Oral and Maxillofacial Surgery	
• Foreign equivalent	
Experience pathway	
• Observe two multiorgan procurements	
• Primary or first assistant surgeon on 1 VCA procurement	
• Evaluation of at least three head and neck transplant patients	
• Primary surgeon on at least one head and neck transplant	
• Posttransplant follow up on one head and neck recipient for at least 1 year	
• Expires September 1, 2018	
Fellowship training	
• ACGME-approved otolaryngology, plastic, oral and maxillofacial, or craniofacial surgery fellowship	
• Similar fellowship program outlined in Appendix J	
Experience pathway	
• Two years of consecutive and independent practice of head and neck surgery	
• Minimum number of surgical procedures	
Type of Procedure	Minimum number of procedures
Facial trauma with bone fixation	10
Head or neck free tissue reconstruction	10

following: (1) 2 years of consecutive and independent practice of hand surgery, (2) procedure requirements from the American Society for Surgery of the Hand and their subspecialty certificate in hand surgery, (3) additions to these procedures relevant to microvascular experience. A log is required showing the type of procedure and the minimum number of procedures for each of the three major categories.

Table 6 Requirements for "other" VCA primary surgeons

Board certification
• American Board of Medical Specialties or foreign equivalent in a specialty relevant to the VCA type
Experience
• Independent surgical practice in the specialty over a consecutive 5 year period
• Observe at least two multiorgan procurements
• Preoperative evaluation of at least three potential VCA transplant patients
Program infrastructure
• Multidisciplinary surgical team including other specialists necessary to perform the VCA transplant
• Must include member with extensive microvascular experience
• Demonstrated planning for the type of VCA transplant
Documentation
• Letter from hospital identifying type(s) of VCA
• Signed by presiding institutional executive
• Identify team members and their roles
• Logs documenting cadaveric rehearsals

The proposal for the new membership requirements for VCA transplant programs went out for public comment in the spring of 2015. With minor revisions, the OPTN/UNOS Board approved the new VCA membership requirements which became effective September 1, 2015. With the passage of the new, more extensive policies for membership, previously OPTN/UNOS-approved VCA programs were required to reapply for OPTN membership.

VCA Allocation

From its inception, the VCA committee adopted a strong mandate to increase access to VCA organs. Although the number of VCA recipients awaiting transplantation is not large, many of the established programs have reported long waiting times, particularly for sensitized patients. Further, the need to achieve a good match for skin color and size particularly for upper limb and head and neck transplants can limit donor choices. Therefore, the VCA committee decided to establish an allocation policy that would allow the broadest sharing of donors within the limits of cold ischemia time as individually judged by accepting surgeons (the limits of cold ischemia times are not yet known for VCAs and may differ among VCAs). The new policy, therefore, proposed allocating donor organs based on blood type and physical characteristic compatibility with the first level of allocation being to regional programs followed by offers to all programs nationally. The usual algorithm of offering local donors to local candidates first was discarded in the interest of increasing access and broader sharing of VCA

grafts. The committee did consider prioritization based on other factors such as sensitization, zero ABDR match, and geographic parameters to limit ischemia time, but found that there was insufficient data to justify adding these elements into current policy. Data to be collected will help inform decisions for future VCA allocation policies.

The initial VCA organ allocation system was first approved in June of 2014 and was reapproved by the OPTN/UNOS board unchanged in June of 2015.

VCA Donor Authorization Policy

The VCA committee felt strongly that separate authorization for VCA donation should be obtained. A policy requiring a separate authorization specific for a VCA donation did not violate the Uniform Anatomic Gift Act which permits consideration of a further gift, therefore allowing OPOs to seek authorization for VCA donation separately in the setting of a potential donor's premortem authorization for organ donation on a general registry. The policy also did not conflict with state laws or the efforts of the donation community. The authorization requirement stated "recovery of a vascularized composite allograft for transplant must be specifically authorized from individual(s) authorizing donation whether that be the donor or a surrogate donation decision maker consistent with applicable state law." The specific authorization for VCA must be documented by the host OPO.

Following public comment, the policy was amended to clarify that authorization for VCA donation from surrogate decision makers was only for deceased VCA donors. The committee however declined to recommend prohibiting living VCA donation as this prohibition would require a change to the Final Rule as noted above.

The committee felt strongly that education of OPO staff, donor hospital staff, requestors, and general public was essential to ensure full understanding of the request for VCA donation and that consent would not be assumed unless specifically documented by the potential donor. Also, it was strongly emphasized that approaching a family for authorization for VCA donation should not jeopardize their authorization for life-saving solid organ donation. These principles were formalized in a guideline for VCA authorization document that was approved in December 2014 and is now posted on the OPTN website [8].

The OPOs also have an important responsibility in order to participate in the donation process. OPOs must ensure their staff has access to the UNOS Secure Enterprise website to obtain the OPTN VCA candidate list (VCA candidates while listed with UNOS are not yet part of the standard transplant candidate listing system.) If a suitable donor becomes available, they must obtain and document separate authorizations for procuring the VCA. VCA grafts only can be allocated from the VCA candidate list according to the rules of VCA allocation. The OPOs also are required to record refusal and bypass reasons from similar to those for traditional solid organ transplantation, and this data must be completed and returned to the OPTN through the secured email site.

The first four policies and bylaw changes governing VCA transplantation resulted in practical implementation procedures for both VCA transplant programs and OPOs. Note that none of these policy and bylaw requirements have yet had time to be incorporated into the UNOS IT computer systems. Therefore, it has been necessary to create a secure website and to develop standardized forms to be submitted both by transplant programs and OPOs. Hospitals wishing to perform VCA transplants must obtain OPTN approval for a VCA transplant program before they can register a VCA candidate. Once their program has been approved, the hospital must request the VCA worksheets from UNOS that allows all of the VCA candidate characteristics to be documented and returned to UNOS by a secured email site.

Data Collection and Submission Requirements for VCA

Once the basic work of the VCA committee that developed policy and bylaws that allowed for implementation of the Final Rule was complete, the committee turned its attention to another pressing problem. Unlike solid organ transplantation, there was no requirement for data collection or submission for VCA. In fact there was no form of centralized data collection available on VCA transplant recipients in the USA. Under the Final Rule that regulates NOTA, one of the requirements of the OPTN was to maintain and operate a data collection system for all organ transplant candidate recipients and donors in the USA. This data was to be used to respond to public data requests, provide data to OPTN members, analyze transplant outcomes, and provide data necessary to make changes in policy. The VCA committee felt strongly that not only was a centralized data collection system a requirement to be in compliance with the requirements of the OPTN contract, but that it also was essential to support the scientific advancement of VCA transplantation in the USA. Accordingly, the VCA committee adopted, with necessary modifications, the same data submission requirements for other non-VCA organs. Moreover, unique data elements specific for VCA were added to the requirements. Just as for traditional solid organ transplantation, transplant recipient registration and transplant recipient follow-up forms were developed. In place already were data submission requirements (as outlined above) for candidate listing and the candidate removal worksheets. The rationale for the proposal's stipulation for detailed data collection was to answer critical questions, currently unknown, that will guide the development of VCA transplantation. These include essential information on patient safety and outcome, patient and graft survival, and functional restoration in VCA recipients.

The data elements that were retained for VCA and are currently collected for other organs include demographic information, insurance and payment information, functional status, diagnosis, medical condition, infection detection, previous or *de novo* malignancy, acute rejection, and immunosuppression. The important new data elements were related to VCA organ function. Objective measures of function were chosen such as disability scores currently used for upper limb functional assessments and specifically also for upper limb transplant (e.g., the DASH score). Sensory tests, motor function, and speech capabilities for cranial/facial transplants were also added. The proposal for data collection for VCA went out for public comment in the fall of 2014 and were presented and approved by the OPTN/UNOS Board on June 1, 2015.

Conclusion: Looking to the Future

Over the last 17 years, vascularized composite allotransplantation has taken its place among organ transplants offering major life-enhancing advances to patients for whom conventional reconstructive techniques fall short in reaching functional as well as aesthetic goals. In fact, VCA currently is the highest rung on the reconstructive ladder [9]. The ladder serves as the concept that guides reconstructive surgeons in their approach to reconstructive surgery [10]. Low rungs are simple techniques such as skin grafts and local "flaps." Higher rungs include reconstructive microsurgical procedures such as autogenous tissue transplantation. The most complex technique currently available for restoration of form and function following loss of body parts such as hand, arm, or face is vascularized composite allotransplantation [11•]. Clearly, the VCA community has embraced and is being guided by the regulatory history and patient safety principles that have allowed solid organ transplant to expand to its current state. Optimism regarding the future of vascular composite allotransplantation must be tempered by the ethics, logistics, and regulations that will no doubt come under scrutiny as techniques advance and the creative application of different VCAs is explored such as the consideration of living-related donation and pediatric VCA [12]. The challenge for the regulation of this diverse field of transplantation will be to develop policies that allow for responsible innovation, with transparency and public accountability. Balancing surgical expertise and creativity with patient safety will require the ability to collect the data regarding how programs are developed, the procedures themselves, and both medical and surgical outcomes—both short and long-term. It will be important to recognize that evidence-based policy recommendations will likely not be possible for some time, and that the expertise residing in the transplantation community as a whole—including its newest member, the reconstructive transplantation community—will be essential to move this new frontier of transplantation responsibly forward.

Compliance With Ethical Standards

Conflict of Interest S.V. McDiarmid and Richard S. Luskin declare that they have no conflict of interest.

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Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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