At-a-Glance

Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)

- **Affected/Proposed Policy:** OPTN Policies 18.1 and 18.2

- **Vascularized Composite Allograft (VCA) Transplantation Committee**

  There is no systematic data collection for VCA transplants in the U.S. The current proposal addresses the new data collection for VCA transplants. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. The intervals for data collection were drawn from those intervals for other organ-specific Tiedi® forms. As an interim solution, VCA recipient data will be collected outside of UNet℠. The database used to collect this information will be managed by UNOS and can be queried to assess member compliance with OPTN policies and bylaws. The proposed updates to OPTN Policies 18.1 and 18.2 add specific data submission requirements for VCA candidate list, registration removal, transplant recipient registration, and transplant recipient follow-up information.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates

- **Number of Potential Candidates Affected**
  In February 2014, all OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. The survey also indicated that five of the 11 centers already having performed a VCA transplant had plans to expand their program to additional VCA graft types, and nine additional transplant centers indicated their plan was to begin performing VCA transplants. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal meets two of the six goals outlined in the OPTN Strategic Plan:

  Goal 3: Improve survival for patients
  Goal 4: Promote transplant patient safety

Establishing VCA data collection and submission requirements:

- Provides consistency and structure to VCA data collection in the U.S.
- Centralizes data collection to a single source to broadly assess:
  - Recipient post-transplant outcomes.
  - Effectiveness of VCA allocation policy.
- Allows for collection of data on VCA transplants that have occurred historically in the U.S., thereby increasing the data available for this transplant field.
- Addresses the advancing field of transplantation by responding to a new area of transplant clinical practice.

Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)

Affected/Proposed Policy: OPTN Policies 18.1 (Data Submission Requirements) and 18.2 (Timely Submission of Data)

Vascularized Composite Allograft (VCA) Transplantation Committee

Public Comment Response Period: September 29, 2014 to December 5, 2014

Summary and Goals of the Proposal:

To date, there is no systematic, centralized data collection for VCA transplants in the U.S. The current proposal addresses the first attempt to collect transplant and follow-up data on VCA recipients for the immediate purposes of evaluating outcomes and ensuring patient safety. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. As the data collection evolves, data elements may be added, amended, or deleted in the future based on input from the transplant community.

Additionally, this proposal updates OPTN data submission requirements. The proposed policies contain the following:

- Specific data elements to be collected on VCA recipients at transplant and follow-up
- Members responsible for submitting VCA organ transplant candidate, recipient, and donor data
- The time period that VCA organ transplant candidate, recipient, and donor data must be submitted to the OPTN

Background and Significance of the Proposal:

On July 3, 2014, the OPTN Final Rule (42 CFR part 121) was amended to add VCAs under the definition of an "organ"[1], thereby granting the OPTN oversight over VCA recovery, allocation, and transplantation. Under the Final Rule, the OPTN shall:

I. Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
II. Maintain records of all transplant candidates, all organ donors and all transplant recipients;
III. Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested;
IV. In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.

Additionally, the OPTN is required by statute to:

I. Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary.

[1] U.S. Government Printing Office, Electronic Code of Federal Regulations, 42 CFR part §121.2, August 14, 2014, http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl

II. Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

In order to properly fulfill the requirements set forth by the Secretary of Health and Human Services, the OPTN Final Rule, and the National Organ Transplant Act (NOTA), the VCA Committee recommended a list of data elements to collect on VCA candidates and recipients. The goals of this data collection include:

- Centralizing data collection on all VCA transplants performed in the U.S. in order to:
    - Support the scientific advancement of VCA transplantation in the U.S.
    - Comply with requirements of the OPTN Contract
- Aligning VCA data submission requirements with requirements for other, non-VCA organs

The VCA Data Subcommittee ("the Data Subcommittee") met on May 28, 2014 to review data elements to be collected on the VCA Registration and Removal worksheets outside of Tiedi®. Additionally, the Data Subcommittee reviewed the VCA Candidate List that contained donor and potential recipient matching for VCA organ allocation to be implemented outside of DonorNet®. UNOS staff developed an interim solution for data linkages between the worksheets and VCA organ allocation lists to promote wider access to VCA organs while maintaining the security of the VCA candidate list. This interim solution for VCA waiting list and allocation has been effective since July 3, 2014.

The VCA Committee discussed VCA recipient data collection. As the area of VCA transplantation is emerging, the Committee views all of the proposed data elements as critically important. Central to this was adherence to the OPTN Principles of Data Collection that were approved by the OPTN/UNOS Board of Directors in 2006. The primary goal of these principles is to improve patient outcomes by:

- Developing transplant, donation, and allocation policies,
- Determining if institutional members are complying with policies,
- Determining member-specific performance,
- Ensuring patient safety when no alternative sources of data exist, and
- Fulfilling the requirements of the OPTN Final Rule

The Committee asked the VCA Data Subcommittee to identify any additional VCA-specific data elements that should be collected on recipients. The Data Subcommittee met on July 18, 2014 and recommended additional VCA-specific data elements for collection, including general physical and mental health, VCA organ functions, and major complications. The Subcommittee also recommended collecting data at intervals identical to those for other, non-VCA organs (at discharge or six weeks post-transplant, whichever is first; at the six month anniversary; and annually thereafter).

Since OPTN data collection forms must be reviewed and approved by the Office of Management and Budget (OMB). The draft list of data elements was submitted to HRSA on July 31, 2014 for OMB review. Data submission on VCA transplants performed prior to July 3, 2014 will be optional. Data submission on VCA transplants performed after July 3, 2014 will be mandatory.

Prior to July 3, 2014, data collection and data submission for VCA candidates and recipients was not possible due to technical limitations of the existing electronic infrastructure used by the OPTN. As such, a policy waiver was implemented by the OPTN/UNOS Board of Directors for VCA data

submission. Because of the pending statutory change at the time, these policy changes were approved by the OPTN/UNOS Board of Directors during its June 23-24, 2014 meeting with a "sunset" date on September 1, 2015. Those initial policies, including the waiver in Policies 18.1 and 18.2, are being released for public comment at the same time as this proposal. Due to time constraints, the proposal will be considered by the Executive Committee on behalf of the BOD at the end of March 2015 or early April 2015.

Mechanism for Data Collection

Programming a new organ type into the existing electronic infrastructure used by the OPTN is a significant endeavor. In light of the time available before the regulatory change and the anticipated low number of VCA transplants that may occur annually, it was determined that high level data integration was not possible at this time. In collaboration with the VCA Committee, UNOS staff developed VCA candidate registration/removal, allocation, and transplant data collection that would function in a system outside of DonorNet®, Wait List℠ and Tiedi®. The transplant data collection will be managed through an Access database and will only be accessible to VCA transplant program staff through a secure SharePoint website.

In addition to the changes above, this proposal includes a cleanup of the introductory text in Policy 18.1 that is consistent with the principles used to draft the 2013 plain language rewrite; these changes do not substantively change the requirements of Policy 18.1.

Supporting Evidence:

A survey of Organ Procurement Organizations (OPOs) was conducted in February 2014. The purpose of this survey was to assess the number of VCA transplants performed in the U.S. The survey results identified 28 hand and face transplants performed at 11 transplant hospitals since 1999[2]:

- 6 face transplants
- 7 bilateral upper limb transplants
- 14 unilateral upper limb transplants
- 1 multiple VCA transplant – a face and a bilateral upper limb

A literature review identified 15 VCA grafts used in the reconstruction of the abdominal wall have been transplanted at two transplant hospitals[3]. However, the time period for these procedures is unknown. In each case, the authors report the abdominal wall transplants were performed in recipients who received intestinal transplants. It is anticipated the actual number of VCA grafts used in the reconstruction of the abdominal wall to be much higher.

Given the reported 43 instances of known VCA transplants in the U.S. and in the absence of outcomes and patient safety information following VCA transplants, it is critically important to have a centralized data collection system.

[2] Organ Procurement and Transplantation Network, Unpublished report, February 25, 2014.

[3] Selvaggi, G., Levi, D.M., Cipriani, R., Sgarzani, R., Pinna, A.D., and Tzakis, A.G., "Abdominal Wall Transplantation: Surgical and Immunologic Aspects", *Transplantation Proceedings*, (2014): 521.

Expected Impact on Living Donors or Living Donation:

The Secretary of Health and Human Services responded to the possibility of a living VCA donor in the amendment to the OPTN Final Rule. The Secretary affirmed that oversight of living donors was under the auspices of the OPTN. The definition of a VCA in both the OPTN Policies and Bylaws was adopted from the Final Rule. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe[4], however there are no candidates for living VCA donors registered with the OPTN.

Expected Impact on Specific Patient Populations:

This will impact all VCA candidates and recipients.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal meets two of the six goals outlined in the OPTN Strategic Plan:

Goal 3: Improve survival for patients
Goal 4: Promote transplant patient safety

Establishing centralized VCA data collection and data submission requirements:

- Provides consistency and structure to VCA data collection in the U.S.
- Centralizes data collection to a single source to:
    - Develop transplant, donation, and allocation policies
    - Determine if institutional members are complying with policies
    - Determine member-specific performance
    - Ensure patient safety when no alternative sources of data exist
    - Fulfill the requirements of the OPTN Final Rule
- Allows collection of data on VCA transplants that have occurred historically in the U.S.
- Addresses the changing field of transplantation by responding to a new area of transplant clinical practice

Plan for Evaluating the Proposal:

Periodic tabulations of data elements will be provided to the VCA Committee when sufficient data are available, including, but not limited to:

- Patient socio-demographics and clinical characteristics
- General physical and mental health
- Organ function
- Graft and patient survival
- Immunosuppression
- Acute Rejection

[4] Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. "The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome*", American Journal of Transplantation*, (2014): 44, http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf

Additional Data Collection:

Additional data collection will be required as a result of this proposal. Tables 1 and 2 in **Exhibit A** list the justification(s) for each data element to be collected on the TRR and TRF forms according to the OPTN Principles of Data Collection (PODCs). The PODCs were determined based on the immediate purposes of VCA transplant and post-transplant data collection including outcomes evaluation and ensuring patient safety. Because VCA is a life enhancing procedure, collecting data pertinent to the risks of immunosuppression are essential to protect patient safety. As the field advances and more experience is gained, some of the elements may be used for other purposes such as determining allocation policy, payment for insurance coverage (including Medicare coverage) for the procedure and immunosuppressive medications, or determining member-specific performance.

The data elements that are proposed to be collected on the VCA TRR and TRF forms include common data elements already collected on the TRR and TRF forms for other non-VCA organs. Additionally, the TRR and TRF forms will capture information that is particularly relevant to VCA organ transplants such as source of payment for the transplant (including grant and institutional funding), general physical and mental health, and VCA organ functions. Organ functions will be specific to craniofacial and upper limb, most of which will be important to capture on the follow-up forms. In the absence of systematic information about outcomes following VCA transplants in the U.S., the data elements proposed in this policy will be very critical for developing allocation policy and ensuring patient safety when no alternative sources of data exist.

Expected Implementation Plan:

Member OPOs and Transplant Hospitals will need to be familiar with the requirements of OPTN Policies 18.1 and 18.2 pertaining to submission of information on organ donors from whom VCA grafts are recovered, VCA allocation, VCA registration removal, and VCA recipients. Data submission on VCA transplants performed after approval by the OPTN/UNOS Executive Committee will be required. Data submission on VCA transplants performed prior to July 3, 2014 will be optional.

Member transplant programs will:

1. Continue to register and remove VCA candidates by using the worksheets provided by the OPTN as outlined in Table 18-1.
2. Need to complete TRR and TRF forms for VCA recipients and submit completed forms as outlined in Table 18-1.
3. Need to obtain credentials for accessing the VCA database in order to submit TRR and TRF forms.

Member OPOs will:

1. Continue to use DonorNet® to register all donors, including those donors from whom only VCA grafts may be recovered.
2. Continue to complete Donor Feedback and Deceased Donor Registration forms for all donors, including those donors from whom only VCA grafts are recovered as outlined in Table 18-1.
3. Submit completed VCA Candidate Lists to the OPTN as outlined in Table 18-1.

Additional programing in DonorNet®, Wait List℠, or Tiedi® is not anticipated at this time.

Communication and Education Plan:

Since this policy proposal is about data collection of VCA organs transplants, the audience is limited to the transplant teams that have approved VCA programs and OPOs. Thus far, we have reached this audience directly with emails and letters. While the number of VCA programs remains small, this is a good way to reach them. Additionally, online articles will inform the transplant community at large as we begin to collect data on VCA transplants through the OPTN.

Communication & Education Activities

- Policy notice
- E-newsletter/member archive article
- Presentation at Regional Meetings
- Instructional programs as needed
- Articles/Guidance Documents on the Web and Member Archive

Compliance Monitoring:

The following routine monitoring will continue to apply to OPTN members:

At OPOs, site surveyors will review rates of compliance with submission dates for Deceased Donor Registration (DDR) forms submitted to the OPTN within the review timeframe.

The following new routine monitoring may apply to OPTN members:

For each deceased donor VCA organ offered to a potential VCA recipient, UNOS staff will verify that the allocating OPO submitted a VCA candidate list to the OPTN:

- in the required time period
- containing all required refusal, bypass, and acceptance information

Any data submitted to the OPTN may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

18.1 Data Submission Requirements

~~OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.~~

Members must report data to the OPTN Contractor ~~using standardized forms~~ according to~~.~~ *Table 18-1 below*. ~~shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.~~

~~This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.~~

Table 18-1: Data Submission Requirements

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Histocompatibility Laboratory	Donor histocompatibility (DHS)	30 days after the OPO submits the deceased donor registration	~~For e~~Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	Recipient histocompatibility (RHS)	Either of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the recipient feedback	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	Death notification records (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	~~For a~~All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	Monthly Donation Data Report: Reported Deaths	30 days after the end of the month in which a donor hospital reports a death to the OPO	~~For a~~All deaths reported by a hospital to the OPO
Allocating OPO	Potential transplant recipient (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	~~For e~~Each deceased ~~organ~~ donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	Deceased donor feedback	5 business days after the procurement date	All deceased donors

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Host OPO	Deceased donor registration (DDR)	30 days after the deceased donor feedback form is submitted and disposition is reported for all organs	~~For a~~ All deceased donors ~~and authorized but not recovered potential deceased donors~~
Recovery Hospitals	Living donor feedback	The time prior to donation surgery	~~For~~ e<u>E</u>ach potential living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>
Recovery Hospitals	Living donor registration (LDR)	60 days after the Recovery Hospital submits the living donor feedback form	~~For~~ e<u>E</u>ach living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>
Recovery Hospitals	Living donor follow-up (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	~~For~~ e<u>E</u>ach living donor organ recovered at the hospital <u>This does not apply to VCA donor organs</u>
Transplant hospitals	Organ specific transplant recipient follow-up (TRF)	1. 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14 days from notification of the recipient's death or graft failure	~~For~~ e<u>E</u>ach recipient followed by the hospital

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Transplant hospitals	Organ specific transplant recipient registration (TRR)	60 days after transplant hospital ~~submits the recipient feedback form~~ removes the recipient from the waiting list	~~For~~ ~~e~~Each recipient transplanted by the hospital
Transplant hospitals	Liver Post-Transplant Explant Pathology	60 days after transplant hospital submits the recipient feedback form	~~For~~ ~~e~~Each liver recipient transplanted by the hospital
Transplant hospitals	Recipient feedback	~~24 hours~~ 1 day after the transplant	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	Recipient malignancy (PTM)	30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas recipient~~,~~ with a reported malignancy~~,~~ that is followed by the hospital
Transplant hospitals	Transplant candidate registration (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary. *Table* 18-2: Timely Data Collection sets standards for when the member must collect the data from the patient.

~~This policy does not apply to VCA transplants.~~

Table 18-2: Timely Data Collection

Information is timely if this Member:	**Collects this information for this form:**	**Within this time period:**
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first This does not apply to VCA transplants
Recovery hospital	*Living donor follow-up* (LDF)	60-days before or after the six-month, 1-year, and 2-year anniversary of the donation date This does not apply to VCA transplants