Notice of OPTN Policy Changes

Programming VCA Allocation in UNet

Sponsoring Committee:	**Vascularized Composite Allograft Transplantation**
Policies Affected:	**2.2: OPO Responsibilities**
	3.6.A: Waiting Time for Inactive Candidates
	5.3.B: Infectious Disease Screening Criteria
	5.4.B: Order of Allocation
	5.6.A: Receiving and Reviewing Organ Offers
	5.6.B: Time Limit for Review and Acceptance of Organ Offers
	12.2: VCA Allocation
	18.1.B: Timely Submission of Certain Data
	18.3: Recording and Reporting the Outcomes of Organ Offers
Public Comment:	**August 4, 2020 – October 1, 2020**
Board Approved:	**December 7, 2020**
Board Amended:	**June 14, 2021**
Effective Date:	**Pending OMB approval, implementation, and notice to OPTN members**

Note: The OPTN Board of Directors approved a clarification to VCA-specific policies and bylaws at its meeting in June 2021. Amendments approved as part of the clarification are noted by a corresponding footnote. For more information regarding this clarification, please contact member.questions@unos.org.

Purpose of Policy Changes

The OPTN is programming allocation and data collection for vascularized composite allografts (VCAs) in UNet[SM], which is the OPTN computer match system. VCA is currently excluded from sections of OPTN policy that pertain to UNet functions. Other policies include requirements specific to VCA because VCA was not programmed in UNet. Accordingly, policy changes are necessary to support programming VCA in UNet.

Proposal History

When OPTN oversight of VCAs began in 2014, the Board of Directors (BOD) elected to exclude VCA from UNet due to the novelty of the field and programming time constraints.[1] As a result, allocation and data collection for VCAs are managed through a separate system. The field of VCA transplantation has

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[1] Report to the Board of Directors, OPTN Vascular Composite Allograft Committee, June 2014, https://optn.transplant.hrsa.gov/media/1335/vca_boardreport_20140616.pdf (accessed May 22, 2020).

continued to develop in subsequent years, especially for uterus transplantation. The OPTN deemed that it would be more efficient to program VCA allocation and data collection in UNet rather than implementing future allocation and data collection changes for this growing field in a separate system.[2] Programming VCA in UNet will also align practices for VCA with that of other organs and streamline workflows for OPTN members, including transplant programs, organ procurement organizations (OPOs), and histocompatibility laboratories.

Summary of Changes

This action removes policy exclusions that allow VCA to be managed outside of UNet, adds VCA to policies required for programming in UNet, and updates VCA organ offer and acceptance requirements to occur in UNet. Additional changes to affected policy language were approved in June 2021 via _Clarification of Policies and Bylaws Specific to Vascularized Composite Allografts_.

Implementation

Transplant hospitals, OPOs, and histocompatibility labs will be required to use UNet for VCA instead of the separate VCA matching system. Transplant hospitals will be required to use the Waitlist, DonorNet, and TIEDI applications for VCA candidates and recipients, just as they are used for all other organs, including for all data collection. Specific requirements include viewing posted VCA donor information and accepting or refusing organs via the DonorNet application in UNet. Transplant hospitals will also be required to complete the Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) in UNet. Transplant hospitals may need to work with their medical record vendor to make any needed system updates. OPOs will be required to enter VCA donor data, complete match runs, make electronic organ offers, and provide supplemental medical donor information through the DonorNet application in UNet. Histocompatibility laboratories will be required to use the UNet system to document all candidate test results, including for VCA.

The OPTN will be responsible for notifying members of new VCA UNet requirements. The OPTN will also provide educational materials to support members' usage of UNet throughout the VCA donation and transplantation process. In order to operationalize allocation via UNet in the same way that the OPTN manages allocation for other organs, some modifications will be made to the Waitlist application for VCA inclusion. These modifications aim to improve data quality, consistency, and clarity. Some UNet data fields that are used for all other non-VCA organs will apply to VCA. Changes to OPTN data collection will be submitted to the Office of Management and Budget for approval under the Paperwork Reduction Act of 1995. This approval process may impact the implementation timeline.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~)

2.2   OPO Responsibilities

The host OPO is also responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.

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[2] May 13, 2020, Vascularized Composite Allograft Committee Meeting Summary. Available at https://optn.transplant.hrsa.gov/.

3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Ensuring the clinical management of the deceased donor.
8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
11. Executing the match run and using the resulting match for each deceased donor organ allocation. ~~The previous sentence does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to *Policy 12.2: Covered VCA Allocation*.~~[3]
12. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased Donor Information,* is reported to the OPTN upon receipt to enable complete and accurate evaluation of donor suitability by transplant programs.
14. Ensuring that documentation for *all* of the following deceased donor information is submitted to the OPTN upon receipt:
    a. ABO source documentation
    b. ABO subtype source documentation
    c. Infectious disease results source documentation
    d. Death pronouncement source documentation
    e. Authorization for donation source documentation
    f. HLA typing source documentation
15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available, for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these samples are available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

3.6.A   Waiting Time for Inactive Candidates

Candidates accrue waiting time while inactive according to *Table 3-3* below. Inactive candidates do not receive organ offers.

Table 3-3: Waiting Time for Inactive Candidates

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Heart	No time
Intestine	Up to 30 cumulative days
Kidney	Unlimited time

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[3] Amended by the OPTN Board of Directors on June 14, 2021.

If the candidate is registered for the following organ…	Then the candidate accrues waiting time while inactive as follows…
Kidney-pancreas	Unlimited time
Liver	No time
Lung and is at least 12 years old	No time
Lung and is less than 12 years old	Unlimited time
Pancreas	Unlimited time
Pancreas islet	Unlimited time
Any covered VCA[4]	Unlimited time
~~All other organs~~[5]	~~Up to 30 days~~

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options[6]

If the donor tests positive for:	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA
Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, VCA

5.4.B Order of Allocation

The process to allocate deceased donor organs occurs with these steps:

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[4] Amended by the OPTN Board of Directors on June 14, 2021.
[5] Ibid.
[6] Ibid.

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential transplant recipients (PTRs) in the order that the PTRs appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update candidates' data with the OPTN. The host OPO must re-execute the match run to allocate the organ.
5. Extra vessels allocated with an organ but not required for its transplant can be shared according to *Policy 16.6.A: Extra Vessels Use and Sharing*.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all PTRs on the match run. Members must submit the *Organ Export Verification Form* to the OPTN prior to exporting deceased donor organs.

~~This policy does not apply to covered VCA transplants; instead, members must allocate covered VCAs according to~~ *~~Policy 12.2: Covered VCA Allocation~~*.[7]

5.6.A   Receiving and Reviewing Organ Offers

Transplant hospitals must view organ offers and respond to these offers through the match system. ~~The previous sentence does not apply to covered VCA transplants.~~[8]

The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including whether deceased donor and candidate blood types (and donor subtype, when used for allocation) are compatible or intended incompatible.

5.6.B   Time Limit for Review and Acceptance of Organ Offers

This policy does not apply to expedited liver offers as outlined in *Policy 9.10.B: Expedited Liver Offers.*

A transplant hospital has a total of one hour after receiving the initial organ offer notification to access the deceased donor information and submit a provisional yes or an organ offer refusal.

Once the host OPO has provided all the required deceased donor information according to *Policy 2.11: Required Deceased Donor Information*, with the exception of organ anatomy and recovery information, the transplant hospital for the initial primary potential transplant recipient must respond to the host OPO within one hour with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

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[7] Amended by the OPTN Board of Directors on June 14, 2021.
[8] Ibid.

All other transplant hospitals who have entered a provisional yes must respond to the host OPO within 30 minutes of receiving notification that their offer is for the primary potential transplant recipient with *either* of the following:

- An organ offer acceptance
- An organ offer refusal

The transplant hospital must respond as required by these timeframes or it is permissible for the host OPO to offer the organ to the transplant hospital for the candidate that appears next on the match run.

~~This policy does not apply to covered VCA transplants.~~[9]

12.2 Covered VCA Allocation[10]

A covered VCA from a deceased donor is allocated to candidates registered for that covered VCA according to *Table 12-1* below.

Table 12-1: Allocation of Covered VCAs from Deceased Donors

Classification	Candidates ~~that are~~ registered for the covered VCA at a transplant hospital that is within this distance from a donor hospital:	And are:
1	500 NM	Blood type compatible with the donor
2	Nation	Blood type compatible with the donor

Within each classification, candidates are sorted by waiting time (longest to shortest).

~~When a covered VCA is allocated, the host OPO must document both of the following:~~

~~1.   How the organ is allocated and the rationale for allocation~~

~~2.   Any reason for organ offer refusals~~

18.1.B   Timely Submission of Certain Data

Members must submit data to the OPTN according to Table 18-1.

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[9] Amended by the OPTN Board of Directors on June 14, 2021.
[10] Ibid.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Histocompatibility Laboratory	*Donor Histocompatibility* (DHS)	60 days after the DHS record is generated	Each living and deceased donor <u>This does not apply to living VCA donors</u>
Histocompatibility Laboratory	*Recipient Histocompatibility* (RHS)	60 days after the transplant hospital removes the candidate from the waiting list because of transplant	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas<u>, or covered VCA</u>[11] transplant recipient typed by the laboratory
OPO	*Death Notification Registration (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	All imminent neurological deaths and eligible deaths in its DSA
OPOs	*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	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	Each deceased donor heart, intestine, kidney, liver, lung, ~~or~~ pancreas<u>, or covered VCA</u>[12] that is offered to a potential recipient
~~Allocating OPO~~	~~VCA Candidate List~~	~~30 days after the procurement date~~	~~Each covered deceased donor VCA organ that is offered to a potential covered VCA recipient~~[13]
Host OPO	*Donor Organ Disposition (Feedback)*	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered

[11] Amended by the OPTN Board of Directors on June 14, 2021.
[12] Ibid.
[13] Ibid.

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Host OPO	*Deceased Donor Registration* (DDR)	60 days after the *donor organ disposition (feedback)* form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	*Living Donor Feedback*	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to covered VCA donor organs[14]
Recovery Hospitals	*Living Donor Feedback*	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient
Recovery Hospitals	*Living Donor Registration* (LDR)	90 days after the Recovery Hospital submits the *living donor feedback* form	Each living donor organ recovered at the hospital This does not apply to covered VCA donor organs[15]
Recovery Hospitals	*Living Donor Follow-up* (LDF)	90 days after the six-month, 1-year, and 2-year anniversary of the donation date	Each living donor organ recovered at the hospital This does not apply to covered VCA,[16] domino donor, and non-domino therapeutic donor organs

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[14] Amended by the OPTN Board of Directors on June 14, 2021.
[15] Ibid.
[16] Ibid.

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Transplant hospitals	*Organ Specific Transplant Recipient Follow-up* (TRF)	*Either* of the following: • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or • 30 days from notification of the recipient's death or graft failure	Each recipient followed by the hospital
Transplant hospitals	*Organ Specific Transplant Recipient Registration* (TRR)	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	*Waiting List Removal for Transplant*	1 day after the transplant	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas, or covered VCA[17] recipient transplanted by the hospital
~~Transplant hospitals~~	~~Candidate Removal Worksheet~~	~~1 day after the transplant~~	~~Each covered VCA recipient transplanted by the hospital~~[18]
Transplant hospitals	*Recipient Malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.

[17] Amended by the OPTN Board of Directors on June 14, 2021.
[18] Ibid.

The following member:	Must submit the following instruments to the OPTN:	Within:	For:
Transplant hospitals	*Transplant Candidate Registration* (TCR)	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, ~~or~~ pancreas<u>, or covered VCA</u>[19] candidate on the waiting list or recipient transplanted by the hospital

18.3   Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN may report this information. The OPO or the OPTN must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

~~This policy does not apply to covered VCA organ offers; instead, members must document covered VCA offers according to *Policy 18.1: Data Submission Requirements*.~~[20]

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[19] Amended by the OPTN Board of Directors on June 14, 2021.
[20] Ibid.