

Briefing to the OPTN Board of Directors on

Programming VCA Allocation in UNet

OPTN Vascular Composite Allograft Transplantation Committee

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Programming VCA Allocation in UNet

<i>Affected Policies:</i>	<p>2.2: OPO Responsibilities</p> <p>3.6: Waiting Time</p> <p>5.3.B: Infectious Disease Screening Criteria</p> <p>5.4.B: Order of Allocation</p> <p>5.6.A: Receiving and Reviewing Organ Offers</p> <p>5.6.B: Time Limit for Review and Acceptance of Organ Offers</p> <p>12.2: VCA Allocation</p> <p>18.1.B: Timely Submission of Certain Data</p> <p>18.3: Recording and Reporting the Outcomes of Organ Offers</p>
<i>Sponsoring Committee:</i>	Vascular Composite Allograft Transplantation
<i>Public Comment Period:</i>	August 4, 2020 – October 1, 2020
<i>Board of Directors Date:</i>	December 7, 2020

Executive Summary

The purpose of this proposal is to update policy language to enable the programming of Vascular Composite Allograft (VCA) allocation and data collection in UNetSM, including DonorNet[®] and WaitlistSM. 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 of this exclusion, the allocation and data collection for VCAs are conducted using a separate process. As the VCA field has grown, especially for uterus procedures, the VCA committee recommends programming VCA allocation and data collection in UNet.² Policy language modifications will be required to integrate VCA in UNet.

Programming VCA in UNet will enable all VCA recipients to be identified as potential recipients by the OPTN computer match program. This will also allow communication of that matching to occur directly in the system. This programming will promote a more unified system for identifying VCA recipients and will align with matching processes currently used for all other major organs. Following programming and implementation, transplant hospitals, Organ Procurement Organizations (OPO), and histocompatibility laboratories that carry out VCA procedures will be required to use UNet.

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).

² May 13, 2020, Vascular Composite Allograft Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

Background

On July 3, 2014, the Department of Health and Human Services (HHS) added VCAs to the definition of organs covered by the OPTN Final Rule.³ The expansion of this definition required the OPTN to match VCA donor organs to potential recipients and develop VCA policies consistent with the OPTN Final Rule. The addition of VCAs to the OPTN's purview also required hospitals wishing to perform VCA procedures to become OPTN members and comply with the OPTN Final Rule, policies, and data submission requirements.⁴

UNet is an electronic network comprised of multiple systems, designed to link transplant hospitals, OPOs, and histocompatibility laboratories on one platform.⁵ This secure data sharing platform allows transplant professionals to list patients for transplant, match candidates with potential donors, and submit OPTN required data. UNet applications include DonorNet, Waitlist, and TIEDI®.⁶ This network promotes standardized and efficient organ offer and acceptance procedures.

When OPTN VCA oversight began, the BOD elected not to program VCA in UNet.⁷ There were relatively few VCA transplants in 2014. The BOD was also uncertain about the future of VCA and did not anticipate the rapid evolution this field has seen in the past four years. VCA was specifically excluded from OPTN policies that would require reporting in UNet. The VCA committee agreed to circle back to programming VCA in UNet for consideration at a later date.

In lieu of the OPTN computer match system and UNet, a separate VCA matching process is administered.⁸ The current system requires transplant programs to register VCA candidates by submitting a form by secure email to the OPTN. The Organ Center Operations team maintains the VCA candidate list by registering, modifying, and removing VCA candidates based on the forms received from transplant hospitals. The lists are organized by VCA type and are classified by distance and waiting time. The OPOs have access to their individual list through Secure Enterprise, within UNet. Once the OPOs allocate the VCAs, the OPO communicates the disposition of those organs (bypass, refusal, acceptance) to the Organ Center Operations Team.

In 2016, the number of uterus transplants started to grow with donations from both deceased and living donors. To date, there have been 12 deceased uterus donors and 19 living uterus donors.⁹ These numbers are expected to continue to rise with the availability and success of the procedure. As VCA allocation volume continues to increase, particularly for uterus transplantation, the VCA committee considers that programming VCA in UNet will allow greater access and efficiency for VCA transplant programs to consider VCA offers, and provide a platform that will better integrate with upcoming and concurrent data collection projects.

³ Federal Register, Department of Health and Human Services, July 2013, <https://www.federalregister.gov/documents/2013/07/03/2013-15731/organ-procurement-and-transplantation-network> (accessed May 27, 2020).

⁴ Ibid.

⁵ UNet, United Network for Organ Sharing, 2020, <https://unos.org/technology/unet/> (accessed May 27, 2020).

⁶ Ibid.

⁷ 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).

⁸ Ibid.

⁹ OPTN Policy 12.2 VCA Allocation. Available at [https://optn.transplant.hrsa.gov/10OPTN/Data/as/of/06/24/20](https://optn.transplant.hrsa.gov/10OPTN>Data/as/of/06/24/20).

Purpose

The purpose of this proposal is to update policy language to enable the programming of VCA allocation in UNet, including DonorNet and Waitlist. The current VCA matching process is inconsistent with the allocation and data collection system used for other organs. This inhibits operational and programming efficiencies as well as data integration with the organ types.

Significant changes to VCA data collection were recently passed by the OPTN Board. These changes will impact data collection for deceased donor VCAs of all types including head and neck, upper limb, and uterus transplant recipients. Programming the recently approved requirements in the current system would be inefficient and miss an opportunity to integrate VCA with other organs. The VCA Committee also sponsored the *Modify Data Collection on VCA Living Donors* proposal this public comment cycle. This proposal would require data collection specific to living VCA donors on the Living Donor Registration (LDR) and Living Donor Follow-up (LDF) data collection instruments. This highlights the need for this programming VCA in UNet as it addresses inefficiencies in the current system for deceased donor VCA processes.

The Committee submits the proposal for Board consideration under the authority of the National Organ Transplant Act (NOTA), which requires the OPTN to establish a national transplant candidate waiting list in addition to “a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs”.¹⁰ *OPTN Policy 1.1.C: Reporting of Information to the OPTN* requires members to report requested information to ensure compliance with OPTN policies and gives the OPTN the authority to determine the method and format for required reporting.¹¹

Sentiment from Public Comment

The VCA committee submitted their proposal *Programming VCA Allocation in UNet* to the OPTN Summer 2020 public comment period. Overall, the proposal garnered supportive sentiment.¹²

This proposal was on the non-discussion agenda for regional meetings and supported by the majority in all 11 regions. Across all regions, 169 (67.88%) members supported or strongly supported the proposal, 79 (31.73%) members remained neutral or abstained, and only 1 (.40%) member opposed the proposal. The overall regional sentiment score was 3.8.¹³

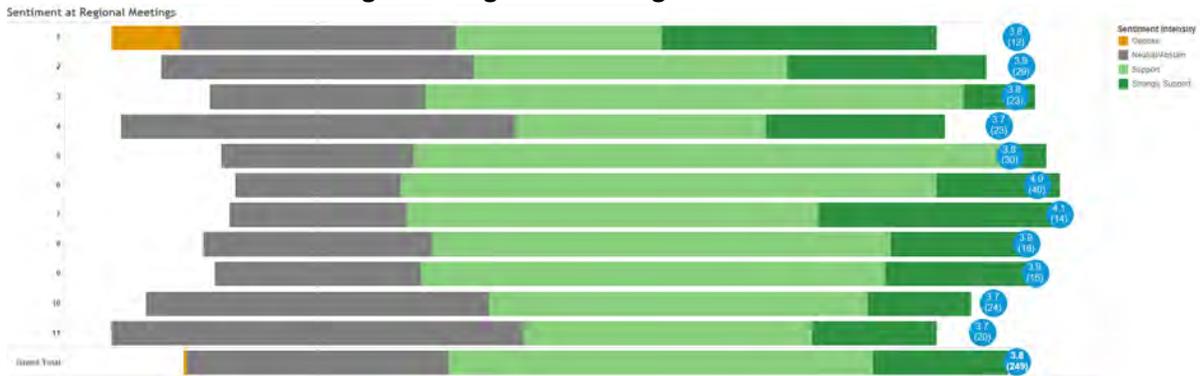
¹⁰ National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(A).

¹¹ OPTN Policies Effective as of September 10,, 2020. Available at https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

¹² OPTN Public Comment, <https://optn.transplant.hrsa.gov/governance/public-comment/> (accessed October 6, 2020).

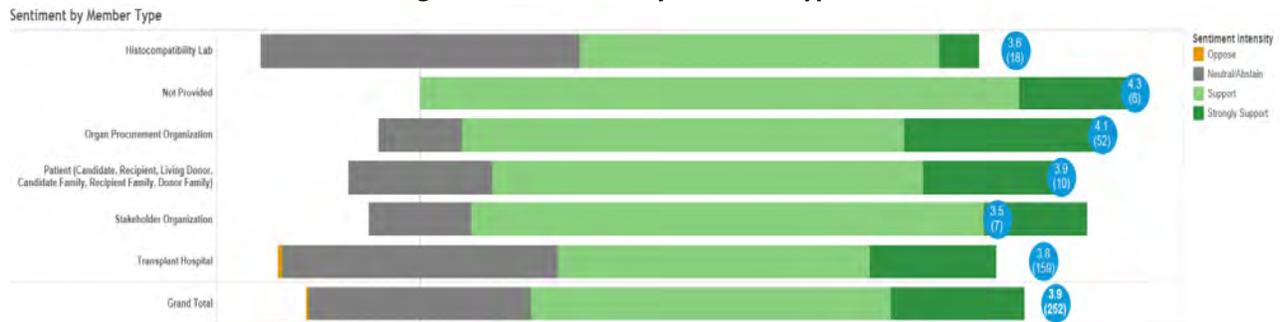
¹³ Ibid.

Figure 1: Regional Meeting Sentiment¹⁴



The proposal received 174 responses from transplant hospitals, 52 responses from OPOs, 18 responses from histocompatibility labs, 10 responses from patients, and 7 responses from stakeholder organizations. Four respondents did not identify their member type. The majority of all member types supported the proposal. The proposal had one opposing member who identified as a transplant hospital. The overall member type sentiment score was 3.9.¹⁵ This member type sentiment is inclusive of the regional sentiment previously presented in the paper.

Figure 2: Sentiment by Member Type¹⁶



The two committees consulted by the VCA committee were the OPTN OPO Committee and OPTN Data Advisory Committee (DAC). Both groups supported the proposal and all members of the OPO committee indicated that they either supported or strongly supported the integration of VCA in UNet.¹⁷

Several stakeholder organizations provided feedback on the proposal. All five of the organizations that submitted public comment expressed support for the programming of VCA allocation in UNet. The American Society of Transplantation (AST) commented that programming VCA allocation in UNet would

¹⁴ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

¹⁵ OPTN Public Comment, <https://optn.transplant.hrsa.gov/governance/public-comment/> (accessed October 6, 2020).

¹⁶ This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

¹⁷ OPTN Public Comment, <https://optn.transplant.hrsa.gov/governance/public-comment/> (accessed October 6, 2020).

provide the community with a more transparent method of data collection. AST also suggested that the OPTN use “flexibility regarding rule out criteria or limitations around organ offers by the listing transplant program due to the fact that VCAs remain part of an IRB with its own limitations.” The American Society for Histocompatibility and Immunogenetics (ASHI) expressed that it would be advantageous for Histocompatibility Laboratories to use the same system for VCA candidate testing as they do for solid organ transplant candidates. The Association of Organ Procurement Organizations (AOPO) strongly supported the proposal, noting the inefficiencies of the current VCA allocation system. Both NATCO and the American Society of Transplant Surgeons (ASTS) indicated that they saw value in the proposed operational change resulting in all organs being managed and allocated in one system.¹⁸

Benefits of a Unified Allocation System

Public comment feedback indicated that programming VCA in UNet would be beneficial for the transplant community. Members discussed the current VCA allocation system’s inefficiencies and expressed the need for one unified allocation system where registrations for potential VCA recipients and donors can be stored. Feedback also indicated that VCA transplant professionals see value in having one platform where they can execute match runs, make and accept offers, and submit data. Members believe that programming VCA allocation in UNet will also support transparent data collection. Overall, the transplant community’s sentiment expressed readiness for an operational shift towards one consistent organ management system.¹⁹

The VCA committee reviewed and discussed the results of public comment and concluded the public sentiment supports sending Programming VCA Allocation in UNet to the BOD with no changes.²⁰

Proposal for Board Consideration

This proposal will update policy language to support programming of VCA allocation in UNet, including DonorNet and Waitlist. This section presents an overview of the proposal and addresses public comment sentiment by region, committee, member type and society. This is followed by discussion on the benefits of a unified allocation system.

Policy Removals

These proposed policy changes will remove language that excludes VCA from programming in UNet. Policy sections with current VCA exclusions and the areas where the VCA exclusion would be removed are displayed in **Table 1** below.

Table 1: OPTN Policy Language with Current VCA Exclusion Proposed for Removal

Policy Section	Current VCA Exclusion to be Removed
2.2 OPO Responsibilities	OPO requirement for executing the match run and using the resulting match for each deceased donor organ allocation
5.4.B Order of Allocation	Requirements for using the match run and released organs

¹⁸ Ibid.

¹⁹ OPTN Public Comment, <https://optn.transplant.hrsa.gov/governance/public-comment/> (accessed October 6, 2020).

²⁰ October 14, 2020, Vascular Allograft Transplantation Committee Meeting Summary. Available at <https://optn.transplant.hrsa.gov/>.

5.6.A Receiving and Reviewing Organ Offers	Transplant hospital requirement to view organ offers and respond to these offers through the match system
5.6.B Time Limit for Review and Acceptance of Organ Offers	Transplant hospital requirement to respond to initial (primary) Potential Transplant Recipient (PTR) offer within one hour and provisional yes within 30 minutes
12.2 VCA Allocation	Separate OPO documentation requirements
18.1.B Timely Submission of Certain Data	Stand-alone VCA donor and candidate reporting data collection instruments (VCA Candidate List and Candidate Removal Worksheet)
18.3 Recording and Reporting the Outcomes of Organ Offers	Requirement for OPOs to report refusal codes on PTR within 30 days and transplant hospitals to confirm or amend within 45 days

Policy Additions

These proposed policy updates will add language that is necessary to align and have VCA function within UNet. The policy sections proposed for addition to OPTN policy are displayed in Table 2 below.

Table 2: New OPTN Policy Language

Policy Section	New Policy to Align with UNet Programming
3.6.A Waiting Time for Inactive Candidates	<ul style="list-style-type: none"> Any VCA candidate will accrue unlimited waiting time while inactive
5.3.B Infectious Disease Screening Criteria	<ul style="list-style-type: none"> Adds ability for transplant programs to select for candidates to be screened off matches for Hepatitis B core antibody and NAT as well as Hepatitis C antibody and NAT. This policy and functionality currently exists for other organs. Adds VCA to HOPE Act screening language. This policy and functionality currently exists for other organs.
18.1.B Timely Submission of Certain Data	<ul style="list-style-type: none"> Adds VCA to required reporting for the UNet recipient histocompatibility (RHS) data collection instrument Adds requirement to complete the Potential Transplant Recipient (PTR) for VCA Adds requirement for completing Waiting List Removal for VCA Adds requirement for completing Transplant Candidate Registration (TCR) for VCA

NOTA and Final Rule Analysis

NOTA requires the OPTN to establish a national transplant candidate waiting list in addition to “a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list, especially individuals whose immune system makes it difficult for them to receive organs”.²¹ The OPTN Final Rule defines the OPTN computer match program as “a set of computer-based instructions which compares data on a cadaveric organ donor with data on

²¹ National Organ Transplant Act (NOTA), as amended, 42 USC §274(b)(2)(A).

transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).²²

Potential transplant recipients must be ranked by the OPTN computer match program by the organ specific allocation criteria. If a donor organ does not meet a transplant program's criteria, transplant candidates of that program will not appear on the ranked list of potential recipients for that organ.²³ The programming of VCA in UNet will allow all VCA recipients to be identified and rank ordered by the OPTN computer match program, as opposed to the current VCA matching process that is separate and does not use the OPTN computer match program. The programming of VCA in UNet will promote a more organized system for identifying VCA recipients and will align with matching process currently used for all other major organs.

The Final Rule also requires that the OPTN maintain records and operate an automated system for managing information on transplant candidates, transplant recipients, and organ donors.²⁴ The OPTN must maintain a computerized list of individuals waiting for transplant.²⁵ While the OPTN has maintained separate computerized system to match VCA donors with potential VCA transplant recipients, programming VCA in UNet will result in one consistent system for management of OPTN records and the transplant candidate waiting list.

Alignment with OPTN Strategic Plan²⁶

Promote the efficient management of the OPTN:

This proposal seeks to provide efficient management of the OPTN by facilitating an operational change that programs VCA allocation in UNet. The alignment of VCA allocation in UNet aims to provide a singular access point for members to consider offers and submit required data. Once programed, the OPTN will have one management and allocation system for all organs. This change will promote more organized data collection and management. Additionally, a unified platform will better integrate with upcoming and concurrent data collection projects.²⁷

Implementation Considerations

Member and OPTN Operations

Transplant hospitals, OPOs, and histocompatibility labs will be required to use UNet instead of the separate VCA matching system for deceased donors. The target implementation timeline for this proposal is June 2022. This implementation timeline is longer than the standard 12-month implementation timeline to allow time for the Office of Management and Budget (OMB) to review and approve the data collection instrument changes. This extended timeline will allow for programming of 8 new organ types across at least three UNet applications within the system.

²² 42 CFR §121.2.

²³ Ibid.

²⁴ 42 CFR §121.11(a).

²⁵ 42 CFR §121.11(a)(1)(i).

²⁶ For more information on the goals of the OPTN Strategic Plan, visit <https://optn.transplant.hrsa.gov/governance/strategic-plan/>.

²⁷ Programming VCA Allocation in UNet, OPTN Vascular Composite Allograft Transplantation Committee, August 2020, https://optn.transplant.hrsa.gov/media/3928/programming_vca_allocation_into_unet_pc.pdf (accessed October 7, 2020).

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. These fields are outlined in Appendix 1.

Operations affecting Transplant Hospitals

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 reporting information in the data fields outlined in Appendix 1. 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 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.

Operations affecting Organ Procurement Organizations

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.

Operations affecting Histocompatibility Laboratories

This proposal will require histocompatibility laboratories to use the UNet system to document all candidate test results, including VCA.

Operations affecting the OPTN

This proposal will require programming changes. The OPTN will be responsible for notifying members of new VCA UNet requirements. OPTN will follow established protocols to inform members of any policy changes through Policy Notices. The OPTN will also provide educational materials to support members' usage of UNet throughout the VCA donation and transplantation process.

Potential Impact on Select Patient Populations

This proposal will impact all VCA candidates and recipients. Programming VCA allocation in UNet will allow for more efficient matching with use of the OPTN computer system. Since 2014, there have been 12 deceased uterus donors and 19 living uterus donors. Eight upper limb bilateral and five upper limb unilateral procedures have also been completed as well as nine head and neck VCA procedures.²⁸ Data reporting from donors and recipients will be necessary to monitor patient safety and outcomes. Programming VCA in UNet will promote more organized data collection and management.

Projected Fiscal Impact

Projected Impact on Transplant Hospitals

The only anticipated fiscal impact to transplant hospitals is associated with time and resources required for training staff in UNet. However, many staff that would require training currently use UNet when managing allocation for other organ types. Moving all allocation processes to a single system will reduce the need to train employees in multiple systems.

Projected Impact on Organ Procurement Organizations

There is minimal expected fiscal impact to OPOs.

²⁸ OPTN Data as of 10/09/20.

VCA allocation is currently managed outside of UNet by the UNOS Organ Center, requiring OPO members to use a separate application. If VCA volume increases, particularly for uterus transplants, programming VCA allocation in UNet will allow for greater access and efficiency for VCA transplant programs to consider VCA offers. This standardization with how other organs are allocated also provides a platform for VCA to integrate with future or concurrent data collection projects.

OPOs may be required to work with their medical record vendor to make any needed updates. OPO reporting systems may also require updates. All work would now be completed in UNet, which would likely be more efficient than using separate systems for VCA and other deceased donors, as is done currently. Staff education on different types of VCA programs, including VCA authorization, evaluation, and recovery may also be needed. These items may be a cost to OPOs.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

This project is estimated to require a large effort from Policy and Community Relations (PCR). PCR is estimated to spend 390 hours developing and 520 hours implementing UNet requirements. This project will require an enterprise level effort from IT with 500 development, 10,600 implementation and 890 ongoing hours. IT efforts involve programming and testing system changes to add the eight VCA organ types to at least three UNet applications. Member Quality is estimated to spend 400 implementation hours attending meetings and training staff in addition to 200 ongoing hours on site survey and allocation reviews, dependent upon the number of VCA transplant programs and annual volume of VCA transplants. Professional education is estimated to spend 300 hours developing UNet trainings. Research is estimated to spend 200 hours attending meetings and reviewing materials and 50 ongoing hours on monitoring efforts

Post-implementation Monitoring

Member Compliance

Integrating VCA allocation in UNet will permit integration of VCA data into routine compliance monitoring processes. Any data entered in UNet may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The OPTN will report the number of VCA candidate additions and removals, VCA donors, and VCA transplants entered in UNet routinely after implementation.

Conclusion

This proposal aims to update policy language to allow the programming of VCA in UNet for deceased donors. The presented policy additions and removals will allow for VCA organ matching and management processes to be carried out in UNet. While the OPTN has maintained records for VCA through a separate system, programming VCA in UNet will result in one comprehensive system for the

management of OPTN records and the transplant candidate waiting list. Upon implementation, transplant hospitals, OPOs, and Histocompatibility labs will be required to utilize UNet for VCA processes and procedures. The programming of VCA in UNet will promote more efficient organ placement and data reporting on one consistent system.

Appendix 1: Applying Existing Data Fields to VCA²⁹

Add or Update a VCA Candidate Registration in Waitlist	Remove VCA Candidate from Waitlist
Center's patient ID	
State of permanent residence	
Permanent ZIP code	
Accept VCA if procured by another procurement team?	
Number of previous VCA organ transplants	
	Were extra vessels used in the transplant procedure?
	Vessel Donor ID
	Did the patient receive any other organ transplant at this time?
	Recipient Histocompatibility Laboratory
	Did the patient go to the operating room and receive anesthesia for transplant prior to death?
	Was anastomosis initiated?

²⁹ These data elements are not new additions to the UNet system and are already collected for other non-VCA organs in Waitlist

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 2.2 OPO Responsibilities

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

- 3
- 4 1. Identifying potential deceased donors.
- 5 2. Providing evidence of authorization for donation.
- 6 3. Evaluating deceased donors.
- 7 4. Maintaining documentation used to exclude any patient from the imminent neurological death
- 8 data definition or the eligible data definition.
- 9 5. Verifying that death is pronounced according to applicable laws.
- 10 6. Establishing and then implementing a plan to address organ donation for diverse cultures and
- 11 ethnic populations.
- 12 7. Ensuring the clinical management of the deceased donor.
- 13 8. Ensuring that the necessary tissue-typing material is procured, divided, and packaged.
- 14 9. Assessing deceased donor organ quality.
- 15 10. Preserving, labeling, packaging, and transporting the organs. Labeling and packaging must be
- 16 completed using the OPTN organ tracking system according to *Policy 16: Organ and Vessel*
- 17 *Packaging, Labeling, Shipping, and Storage*.
- 18 11. Executing the match run and using the resulting match for each deceased donor organ
- 19 allocation. ~~The previous sentence does not apply to VCA transplants; instead, members must~~
- 20 ~~allocate VCAs according to *Policy 12.2: VCA Allocation*.~~
- 21 12. Documenting and maintaining complete deceased donor information for seven years for all
- 22 organs procured.
- 23 13. Ensuring that all deceased donor information, according to *Policy 2.11: Required Deceased*
- 24 *Donor Information*, is reported to the OPTN Contractor upon receipt to enable complete and
- 25 accurate evaluation of donor suitability by transplant programs.
- 26 14. Ensuring that documentation for *all* of the following deceased donor information is submitted to
- 27 the OPTN Contractor upon receipt:
 - 28 a. ABO source documentation
 - 29 b. ABO subtype source documentation
 - 30 c. Infectious disease results source documentation
 - 31 d. Death pronouncement source documentation
 - 32 e. Authorization for donation source documentation
 - 33 f. HLA typing source documentation
- 34 15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as
- 35 available, for each deceased donor for at least 10 years after the date of organ transplant, and
- 36 ensuring these samples are available for retrospective testing. The host OPO must document the
- 37 type of sample in the deceased donor medical record and, if possible, should use qualified
- 38 specimens.
- 39

40 3.6 Waiting Time

41 3.6.A Waiting Time for Inactive Candidates

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

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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
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
<u>Any VCA</u>	<u>Unlimited time</u>
All other organs	Up to 30 days

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47 5.3.B Infectious Disease Screening Criteria

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

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Table 5-1: Donor Infectious Disease Screening Options

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, <u>any VCA</u>
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, <u>any VCA</u>
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, <u>any VCA</u>
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, <u>any VCA</u>

<p>Human Immunodeficiency Virus (HIV); Organs from HIV-positive donors may only be recovered and transplanted according to the requirements in the Final Rule.</p>	<p>Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas, <u>any VCA</u></p>
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5.4.B Order of Allocation

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

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 Contractor. 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 Contractor prior to exporting deceased donor organs.

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

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 VCA transplants.~~

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.

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

- 94
- 95 • An organ offer acceptance
- 96 • An organ offer refusal

97
 98 All other transplant hospitals who have entered a provisional yes must respond to the host OPO
 99 within 30 minutes of receiving notification that their offer is for the primary potential transplant
 100 recipient with *either* of the following:

- 101
- 102 • An organ offer acceptance
- 103 • An organ offer refusal

104
 105 The transplant hospital must respond as required by these timeframes or it is permissible for the
 106 host OPO to offer the organ to the transplant hospital for the candidate that appears next on
 107 the match run.

108
 109 ~~This policy does not apply to VCA transplants.~~

110

111 12.2 VCA Allocation

112 VCAs from deceased donors are allocated to candidates in need of that VCA according to *Table 12-1*
 113 below.

114

115

Table 12-1: Allocation of VCAs from Deceased Donors

Classification	Candidates that are registered 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

116

117

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

119

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

121

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

123

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

124
125
126
127

18.1.B Timely Submission of Certain Data

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

Table 18-1: Data Submission Requirements

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Histocompatibility Laboratory	<i>Donor Histocompatibility (DHS)</i>	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	<i>Recipient Histocompatibility (RHS)</i>	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 VCA</u> transplant recipient typed by the laboratory
OPO	<i>Death Notification Registration (DNR)</i>	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	<i>Monthly Donation Data Report: Reported Deaths</i>	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	<i>Potential Transplant Recipient (PTR)</i>	30 days after the match run date by the OPO or the OPTN Contractor	Each deceased donor heart, intestine, kidney, liver, lung, or pancreas, <u>or VCA</u> 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	<i>Donor Organ Disposition (Feedback)</i>	5 business days after the procurement date	Individuals, except living donors, from whom at least one organ is recovered

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Host OPO	<i>Deceased Donor Registration (DDR)</i>	60 days after the <i>donor organ disposition (feedback)</i> form is submitted and disposition is reported for all organs	All deceased donors
Recovery Hospitals	<i>Living Donor Feedback</i>	The time prior to donation surgery	Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	<i>Living Donor Feedback</i>	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	<i>Living Donor Registration (LDR)</i>	90 days after the Recovery Hospital submits the <i>living donor feedback</i> form	Each living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	<i>Living Donor Follow-up (LDF)</i>	Either: <ul style="list-style-type: none"> 90 days after the six-month, 1-year, and 2-year anniversary of the donation date As determined possible by the transplant hospital during the COVID-19 emergency. 	Each living donor organ recovered at the hospital This does not apply to VCA, domino donor, and non-domino therapeutic donor organs Non-submission of the full LDF is acceptable during the COVID-19 emergency.

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
Transplant hospitals	<i>Organ Specific Transplant Recipient Follow-up (TRF)</i>	<p><i>Either of the following:</i></p> <ul style="list-style-type: none"> • 90 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure or as determined possible by the transplant hospital during the COVID-19 emergency • 30 days from notification of the recipient's death or graft failure 	<p>Each recipient followed by the hospital</p> <p>Non-submission of the full TRF is acceptable during the COVID-19 emergency; however notifications of recipient's death or graft failure are still required during the COVID-19 emergency.</p>
Transplant hospitals	<i>Organ Specific Transplant Recipient Registration (TRR)</i>	90 days after transplant hospital removes the recipient from the waiting list	Each recipient transplanted by the hospital
Transplant hospitals	<i>Liver Post-Transplant Explant Pathology</i>	60 days after transplant hospital removes candidate from waiting list	Each liver recipient transplanted by the hospital
Transplant hospitals	<i>Waiting List Removal for Transplant</i>	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas, or VCA recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	<i>Recipient Malignancy (PTM)</i>	<p><i>Either:</i></p> <ul style="list-style-type: none"> • 30 days after the transplant hospital reports the malignancy on the <i>transplant recipient follow-up</i> form or • As determined possible by the transplant hospital 	<p>Each heart, intestine, kidney, liver, lung, or pancreas recipient with a reported malignancy that is followed by the hospital.</p> <p>Non-submission is acceptable during</p>

<i>The following member:</i>	<i>Must submit the following instruments to the OPTN Contractor:</i>	<i>Within:</i>	<i>For:</i>
		during the COVID-19 emergency.	the COVID-19 emergency.
Transplant hospitals	<i>Transplant Candidate Registration (TCR)</i>	90 days after the transplant hospital registers the candidate on the waiting list	Each heart, intestine, kidney, liver, lung, or pancreas, <u>or VCA</u> candidate on the waiting list or recipient transplanted by the hospital

128

129 **18.3 Recording and Reporting the Outcomes of Organ Offers**

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

136
 137 If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to
 138 validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant
 139 hospital report different refusal codes, then the OPTN Contractor will use the transplant hospital's
 140 refusal code for data analysis purposes.

141
 142 If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the
 143 refusal code.

144
 145 ~~This policy does not apply to VCA organ offers; instead, members must document VCA offers according~~
 146 ~~to *Policy 18.1: Data Submission Requirements*.~~

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148

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