

Briefing Paper


Eliminate the Use of Regions in VCA Distribution

OPTN Vascularized Composite Allograft Transplantation Committee

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Eliminate the Use of Regions in VCA Distribution

Affected Policies: Policy 12.2: VCA Allocation
Sponsoring Committee: Vascularized Composite Allograft Transplantation Committee
Public Comment Period: January 22, 2019 to March 22, 2019
Board of Director's Date: June 10-11, 2019

Executive Summary

The OPTN Final Rule (hereafter “Final Rule”) sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, ability for transplant programs to decide whether to accept an organ offer, avoiding wasting organs, and promoting efficient management of organ placement. The Final Rule also includes a requirement that allocation policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements.¹

On July 31, 2018, the Secretary of Health and Human Services (HHS) found that the use of donation service areas (DSAs) or regions in organ allocation policies cannot be justified under the Final Rule.² OPTN policies for vascularized composite allograft (VCA) allocation use “region” as the first geographic boundary for distribution. In response to the Secretary’s letter, the OPTN Executive Committee directed the OPTN VCA Transplantation Committee (hereafter “the Committee”) to develop a proposal that replaces region with another geographic boundary in VCA allocation policy.³ This proposal would replace use of regions in VCA allocation policies with a 500 nautical mile (NM) concentric circle around a donor hospital. This will allow efficient placement of deceased donor VCAs, help achieve optimal recipient and graft outcomes, and reduce the risk of organs being recovered but not transplanted.

This proposal is consistent with Goal Two of the OPTN Strategic Plan to increase equity in access to transplant. This project aims to implement rational units for geographic distribution that are more consistent with the requirements of the Final Rule.

¹ 42 C.F.R. § 121. https://www.ecfr.gov/cgi-bin/text-x?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121_13. Accessed November 21, 2018.

² George Sigounas, letter to Sue Dunn, OPTN President, July 31, 2018.

³ OPTN Executive Committee meeting August 1, 2018. https://optn.transplant.hrsa.gov/media/2609/20180801_executive_meetingsummary.pdf. Accessed November 21, 2018.

What problem will this proposal address?

The Final Rule sets requirements for allocation policies developed by the OPTN, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, promote patient access to transplant, and to promote efficiency. The Final Rule also includes a requirement that policies “shall not be based on the candidate’s place of residence or place of listing, except to the extent required” by the other requirements of the Final Rule.⁴

OPTN *Policy 12.2 VCA Allocation* currently uses OPTN regions for organ distribution.⁵ Use of regions are a poor proxy for geographic distance between donors and transplant candidates. This is due to variation in size of regions and populations resulting in an inconsistent application for all candidates.⁶ As a result, the use of regions in VCA distribution presents a potential conflict with the Final Rule.

Why should you support this proposal?

The use of a fixed geographic distance for VCA distribution applies a rational and consistently applied unit for distribution that is more consistent with the requirements of the Final Rule. The policy changes described in this document are intended to achieve the best use of donated organs, avoid organ wastage, futile transplants, promote candidate access to VCA transplantation, and promote efficient organ placement.⁷ This is accomplished by focusing the first group of VCA offers to transplant candidates within a geographic area where offers are likely to be accepted and the best long term graft survival achieved. The proposed changes consider available data on cold ischemic time (CIT) and VCA transplant outcomes, published literature on CIT and ischemia reperfusion injury (IRI), and the sound medical judgement of VCA transplant subject matter experts.

How was this proposal developed?

At its December 2018 meeting, the OPTN Board of Directors directed the organ-specific committees to pursue removal of DSA and regions from their allocation systems. This directive was made on the grounds that DSAs and regions, as allocation units, are not rationally determined or consistently applied, and thus may create inequalities in candidates’ access to organ transplantation. The Board directed the committees to replace their use with a rationally determined substitute that could be consistently applied and aligns with the Final Rule. With this charge in mind, the Committee sought to develop a policy which distributes organs as broadly as possible, with any geographic limitations to allocation based specifically on requirements of the Final Rule.

In response to the directive, the VCA Geography Subcommittee (hereafter “the Subcommittee”) considered the current VCA allocation policy and alternatives, 1) national allocation without any geographic consideration or 2) replacing region with mathematical optimization, continuous distribution, or fixed distance models.⁸

Current VCA Allocation Policy

OPTN *Policy 12.2 VCA Allocation* requires organ procurement organizations (OPOs) to offer VCAs from deceased donors to candidates with compatible blood types willing to accept a VCA with similar physical characteristics. OPOs make VCA offers first to candidates within the same region as the deceased donor.

⁴ OPTN Final Rule, 42 CFR 121.8.

⁵ OPTN *Policy 12.2 VCA Allocation*,

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_12. Accessed November 21, 2018.

⁶ OPTN Regions, <https://optn.transplant.hrsa.gov/members/regions/>. Accessed November 21, 2018.

⁷ The considerations of this policy change are based on elements contained with the OPTN Final Rule, 42 CFR 121.8(a) (1-3, 5).

⁸ OPTN Ad-Hoc Geography Committee, “Frameworks for Organ Distribution”,

https://optn.transplant.hrsa.gov/media/2565/geography_publiccomment_201808.pdf. Accessed November 21, 2018.

Considerations of a VCA offer include not only the travel distance and overall CIT, but also complex matching considerations between the donor and potential recipient.⁹ If the offers are refused or the candidate is bypassed, then the OPO makes offers to candidates outside the region where the deceased donor is located. Within each of the above classifications, candidates are ranked based on waiting time from greatest to least.¹⁰ While other organs consider candidate prioritization based on severity of illness, risk of waitlist mortality, or degree of histocompatibility matching, these factors are not included in current VCA allocation policy.

Figure 1 below depicts the allocation for a VCA from a hypothetical deceased donor located in Richmond, Virginia (within Region 11 outlined in red).¹¹

Figure 1: Example of VCA Allocation Using Current OPTN Policy Involving a Hypothetical Deceased VCA Donor in Region 11

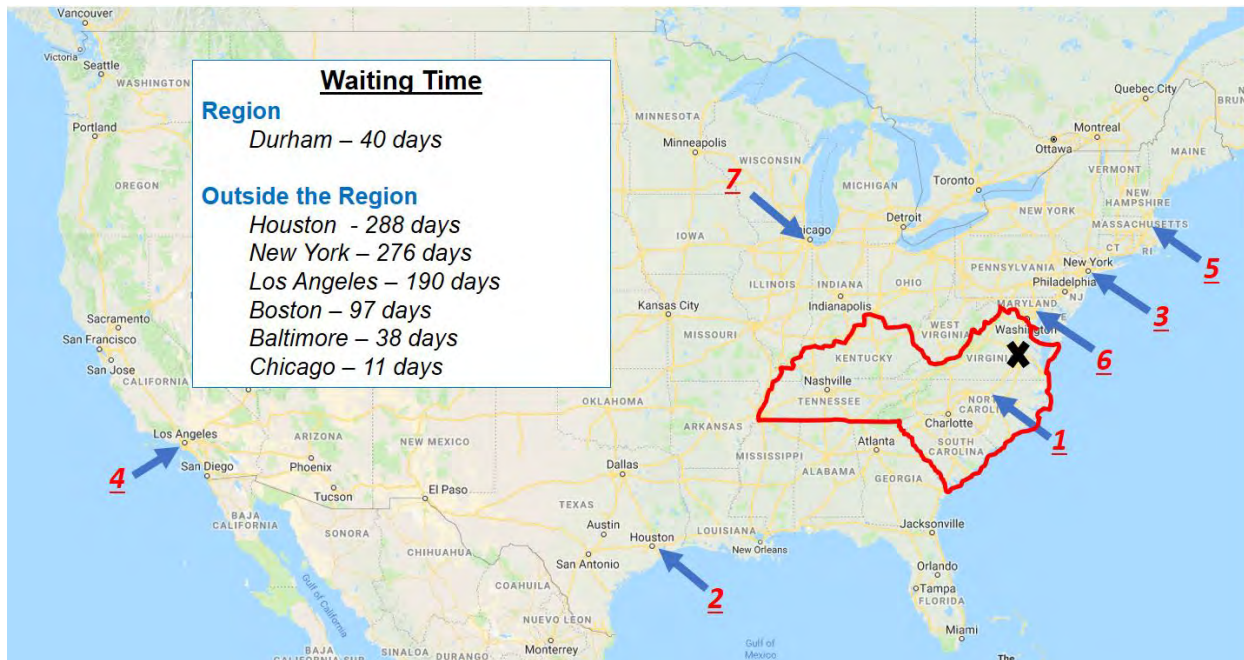


Figure 1 shows the first offer to a VCA candidate in Durham, NC located within the same region as the deceased donor. If the offer to the candidate in Durham is refused or the candidate is bypassed, subsequent offers are made to candidates outside Region 11 in the following sequence:

2. Houston
3. New York
4. Los Angeles
5. Boston
6. Baltimore
7. Chicago

⁹ Donor and potential recipient matching considers blood type and histocompatibility, anatomic size match, vascular quality, skin color, the presence or absence of tattoos, piercings, scars, or other distinguishing features, and hair color/texture/thickness.

¹⁰ OPTN Policy 12.2 VCA Allocation.

¹¹ Region 11 includes the states of Kentucky, North Carolina, South Carolina, Tennessee, and Virginia. <https://optn.transplant.hrsa.gov/members/regions/>. Accessed November 21, 2018.

National Allocation with no Geographic Consideration

The first model considered by the Committee included ranking all VCA candidates in the U.S. based on their waiting time from greatest to least. This model would not be based on proximity to a donor hospital. Members indicated this would be the simplest policy change to execute and would promote the broadest distribution of VCAs. Figure 2 below depicts how this may work.

Figure 2: Example of VCA Allocation Using National Distribution Involving a Hypothetical Deceased VCA Donor in Richmond, Virginia

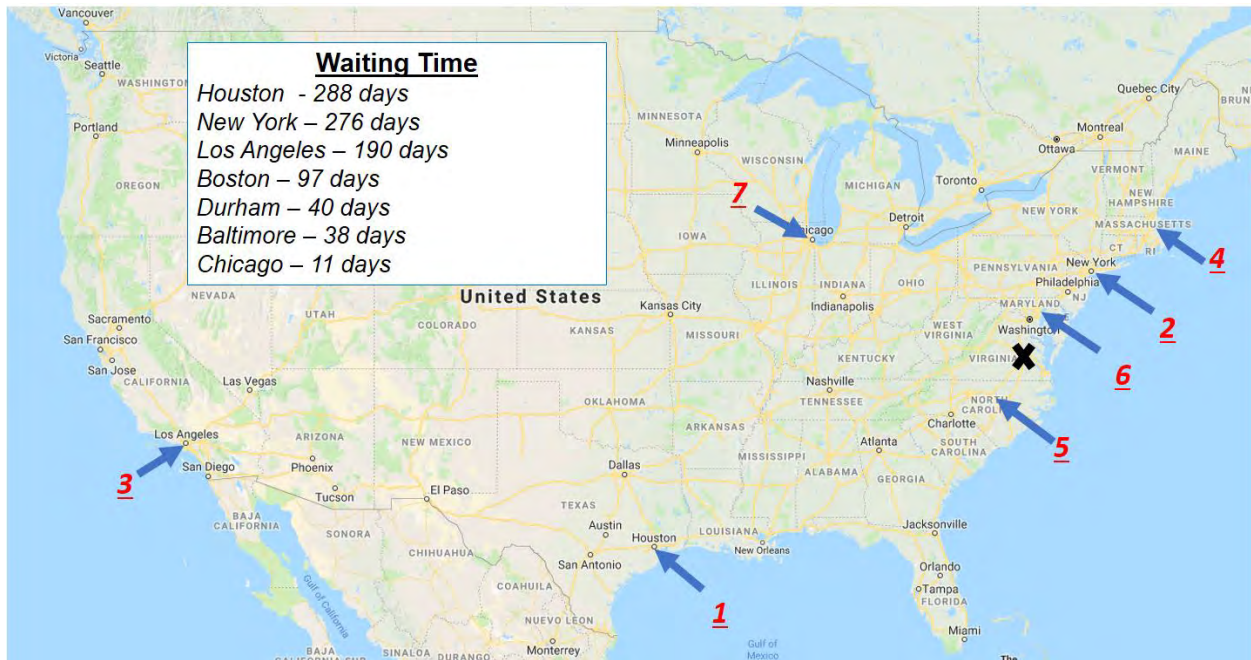


Figure 2 shows the first offer to a VCA candidate in Houston, Texas, as this candidate has the greatest amount of waiting time in the U.S. If the offer to the candidate in Houston was bypassed subsequent offers would be made to candidates in the following sequence:

2. New York City
3. Los Angeles
4. Boston
5. Durham
6. Baltimore
7. Chicago

As Figure 2 depicts, such a policy would mean that a VCA candidate with greater waiting time and an extended distance from the donor hospital may receive an offer before a VCA candidate closer to the donor hospital. The Committee was concerned that an increase in VCA offers from extended distances may compel a transplant program to unnecessarily push the limits of ischemic times at the risk to transplant outcomes or donated VCAs not being transplanted. The Committee agreed this approach would promote wider VCA distribution. However, the Committee noted there was an absence of data firmly correlating CIT with VCA transplant outcomes, as well as consensus in the field on the same.¹²

¹² Amin, K., Wong, J., and Fildes, J., "Strategies to Reduce Ischemia Reperfusion Injury in Vascularized Composite Allotransplantation of the Limb", *Journal of Hand Surgery* 42, no 12, (2017): 1019-1024, doi.org/10.1016/j.jhssa.2017.09.013. Accessed November 21, 2018; Caterson, EJ, Lopez, J, Medina, M, Pomahac, B, and Tullius, SG, "Ischemia-Reperfusion Injury in Vascularized Composite Allotransplantation," *Journal of Craniofacial Surgery* 24 no. 1, (2013), 51-56, DOI: 10.1097/SCS.0b013e31827104e1. Accessed November 21, 2018; Levinson,

Therefore, the Committee was concerned that national distribution of organs would not result in the best use of donated organs, may risk organs being recovered but not transplanted, or result in futile transplants.

The Committee also considered the efficiency of organ placement under this model. The current VCA allocation system is based outside of UNetSM and requires manual notifications from OPOs to VCA transplant programs. Using this distribution model to make VCA offers to distant candidates prior to geographically closer candidates would be time consuming for OPO staff. Several examples of deceased donors screened for VCA donation that do not proceed to successful donation, could deter OPOs from screening *any* deceased donors for VCA donation. This was a substantial concern for the Committee as a current need to grow VCA transplantation is to screen *more* deceased donors for VCA donation.

As a result, the Committee determined national VCA allocation was not an appropriate alternative, because it would not promote the efficient management of organ placement, would not achieve the best use of donated organs, could risk organs being recovered but not transplanted, or may result in futile transplants.

Replacing with Mathematical Optimization, Continuous Distribution, or Fixed Distance

The Committee noted simplicity in a model for VCA distribution was very relevant due to the lack of available data correlating CIT and VCA transplant outcomes. The Committee carefully reviewed the three organ distribution frameworks developed by the OPTN Ad-hoc Geography Committee.¹³

Mathematical Optimization

In this framework, one or more objectives (minimize effect of geography, pre-transplant deaths, etc.) and possible constraints (amount of travel, supply and demand, etc.) are used to create the optimal distribution system.¹⁴ The Committee discussed this and expressed the complexity of this model was not well suited for VCA at this time. In principle, VCA transplantation is not considered a life-saving transplant. As a result, the concept “medical urgency” in this model is not entirely applicable in VCA transplantation. VCA candidates would potentially be ranked within the geographic area according to clinical factors and waiting time. The size of the geographic area could be influenced by the population density of the area. Members agreed the body of data to make informed decisions on this complex model was still accumulating and these data would help support considerations on a scoring or ranking system for VCA candidates.¹⁵ Members shared this model appeared to have the same risk as current DSA and

H., Garcia R.M., Miller, K. J., Levin, L. S., “Major hand replantation after extended search for the missing part”, *Current Orthopedic Practice* 25, no. 3 (2014): 302-304, DOI: 10.1097/BCO.000000000000098. Accessed November 21, 2018; Fletcher, C., “Case report and literature review of the outcome following reimplantation of the arm”, *Trauma Surgery & Acute Care* 2 (2017); doi: 10.1136/tsaco-2017-000124. Accessed November 21, 2018; Brazio, P. S., Rodriguez, E. D., Bartlett, S. T., Barth, R. N., “Reconstructive Transplantation: What Can We Learn from Solid Organ Transplantation?”, *The Science of Reconstructive Transplantation* (New York: Humana Press, 2015): 33-44, doi.org/10.1007/978-1-4939-2071-6_3. Accessed November 21, 2018; Tasigiorgos, S., Kollar, B., Krezdorn, N., Bueno, E. M., Tullius, S.G., and Pomahac, B., “Face transplantation—current status and future developments,” *Transplant International* 31, no. 7, (2018): 677-688, doi-org.proxy.library.vcu.edu/10.1111/tri.13130. Accessed November 21, 2018; Brannstrom et al., “First clinical uterus transplantation trial: a six-month report”, *Fertility and Sterility* 101, no. 5 (2014): 1228-1236, http://dx.doi.org/10.1016/j.fertnstert.2014.02.024. Accessed November 21, 2018; Bajaj, A., Perez, V., Dickinson, M., Hadley, D., and Punjabi, A., “Penile Replantation: How Much Ischemia Time is too Much?”, presentation at the American Society for Plastic Surgery Annual Scientific Meeting, San Antonio, Texas, November 3, 2002. Accessed November 21, 2018.

¹³ OPTN Ad-Hoc Geography Committee, “Frameworks for Organ Distribution”.

¹⁴ OPTN Ad-Hoc Geography Committee, “Frameworks for Organ Distribution”.

¹⁵ Additional considerations of a scoring or ranking system for VCA candidates may include candidate medical urgency (e.g.: whether a candidate in need of bilateral upper limbs is of higher medical urgency than a candidate in need of a unilateral upper limb), the role of candidate sensitization (what role should histocompatibility matching or

regional boundaries: the potential for a transplant candidate inside a boundary to have higher priority despite a lower disease severity/score than a transplant candidate outside the boundary with a greater disease severity/score, even if only separated by a few miles.¹⁶ Also, this model could create problems for a VCA transplant program in proximity to an OPO that does not consistently screen deceased donors for VCA donation, or that may be under performing (e.g., low conversion rates).¹⁷ These two circumstances may create inequities in organ distribution and therefore not promote candidate access to transplant. As a result, the Committee did not pursue this distribution model.

Continuous Distribution

The framework of organ distribution without geographic boundaries incorporates proximity of candidates to a donor through an algorithm designed to account for the Final Rule principles below (e.g. outcomes, discards, efficiency), rather than their location inside or outside a boundary.¹⁸ The Committee discussed this model and also expressed concern it was not well suited for VCA at this time. In principle, VCA transplantation is not considered a life-saving transplant. As a result, the concept “medical urgency” in this model is not entirely applicable in VCA transplantation. Members agreed the body of data to make informed decisions on this complex model was still accumulating and these data would help support considerations of candidate medical urgency (e.g.: whether a candidate in need of bilateral upper limbs is of higher medical urgency than a candidate in need of a unilateral upper limb), the role of candidate sensitization (what role should histocompatibility matching or donor specific antibodies play), and VCA candidate prioritization (should pediatric candidates be prioritized over adult candidates), or should a candidate have higher priority if their individual waiting time is greater than the median waiting time for the same VCA type. Pending the accumulation of data supporting these decisions, the Committee decided to pursue Fixed Distance as an interim step.

Fixed Distance

This framework utilizes a system of fixed geographic units based on the distance from the donor hospital to the candidate’s place of listing.¹⁹ Of the three distribution models from the Geography Committee, members agreed it appeared to hold the most potential for VCA transplantation.

Members appreciated the need to base any geographic distances for VCA distribution on data from the OPTN and other sources and agreed that it was premature to develop different distances for each VCA type (e.g., upper limb or uterus). There was wide agreement amongst members on the desire to keep CIT as short as possible due to the potential impact of CIT on post-transplant outcomes. The VCA transplant community considers the clinical similarities of ischemia reperfusion injury (IRI) on skeletal and cardiac muscle. These data support the rationale that VCAs can tolerate similar CIT as heart transplants.

Committee members reviewed available OPTN data on VCA acceptances, and the distance between the host OPO and transplant programs.²⁰ Figure 3 below profiles the distances traveled by VCA recovery teams, reported CIT, and graft status.

donor specific antibodies play), and VCA candidate prioritization (should pediatric candidates be prioritized over adult candidates, or should a candidate have higher priority if their individual waiting time is greater than the median waiting time for the same VCA type).

¹⁶ This concern was noted in the Geography Committee’s Recommendations Report on Geographic Organ Distribution Principles, https://optn.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf. Accessed November 21, 2018.

¹⁷ OPO donor conversion rate is used to measure the number of eligible deaths identified by OPOs and whether an organ is recovered for transplant. <https://www.srtr.org/about-the-data/guide-to-key-opo-metrics/opoguide/articles/donor-conversion/>. Accessed November 21, 2018.

¹⁸ OPTN Ad-Hoc Geography Committee, “Frameworks for Organ Distribution.”

¹⁹ OPTN Ad-Hoc Geography Committee, “Frameworks for Organ Distribution.”

²⁰ Unpublished report to the VCA Committee on October 12, 2018. Based on OPTN/UNOS data as of October 5, 2018.

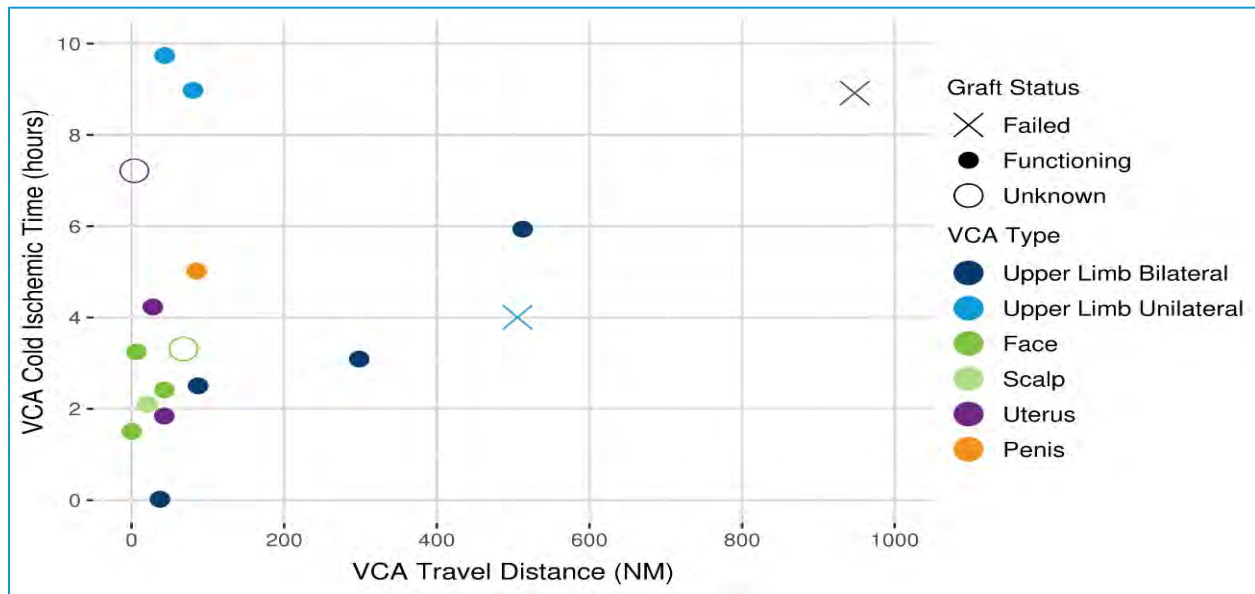
Figure 3: Distance and CIT for VCA Transplants since July 2014²¹

Figure 3 highlights that 18 of 24 VCAs transplanted (75%) since July 2014 were recovered within 200 NM of the VCA transplant program. 21 of 24 VCAs transplanted (87.5%) were recovered within 500 NM of the VCA transplant program. While this is informative data, CIT does not appear to be correlated with all VCA transplant outcomes. Members discussed available literature reports of CIT in VCA transplantation, but these papers also did not report finding correlations between CIT and VCA transplant outcomes.²²

Members did however report there was some use in considering current clinical guidance from limb replantation/reconstruction that did correlate CIT with post-surgical outcomes.²³ Though not a direct correlation with VCA transplantation, members felt this was a clinically suitable surrogate to consider.²⁴ As in transplantation of other organs, the available literature and research show the least amount of CIT generally supported better outcomes. The Committee adopted as a first unit of distribution for VCA organs a fixed distance from the donor hospital, due to the potential effect of CIT on post-transplant outcomes, to

²¹ Ibid. The data reflected here represents TIEDI forms that have been received by the OPTN. Forms for some VCA transplants are not yet due to be submitted.

²² Literature review: Amin, K., Wong, J., and Fildes, J., "Strategies to Reduce Ischemia Reperfusion Injury in Vascularized Composite Allotransplantation of the Limb"; Caterson, EJ, Lopez, J, Medina, M, Pomahac, B, and Tullius, SG, "Ischemia-Reperfusion Injury in Vascularized Composite Allotransplantation"; Levinson, H., Garcia R.M., Miller, K. J., Levin, L. S., "Major hand replantation after extended search for the missing part"; Fletcher, C., "Case report and literature review of the outcome following reimplantation of the arm"; Brazio, P. S., Rodriguez, E. D., Bartlett, S. T., Barth, R. N., "Reconstructive Transplantation: What Can We Learn from Solid Organ Transplantation"; Tasigiorgos, S., Kollar, B., Krezdorn, N., Bueno, E. M., Tullius, S.G., and Pomahac, B., "Face transplantation—current status and future developments"; Brannstrom et al., "First clinical uterus transplantation trial: a six-month report"; Bajaj, A., Perez, V., Dickinson, M., Hadley, D., and Punjabi, A., "Penile Replantation: How Much Ischemia Time is too Much?"

²³ Datta, N., et al, "Prolonged cold ischemia time results in local and remote organ dysfunction in a murine model of vascularized composite transplantation," *American Journal of Transplantation*, 17 no.10, (2017): 2572-2579, XXXX. Accessed November 21, 2018. Sabapathy, S.R., Venkatramani, H., Bharathi, R., and Bhardwaj, P., "Replantation Surgery", *The Journal of Hand Surgery* 36 no. 6, (2011): 1104-1110, doi.org/10.1016/j.jhssa.2011.03.039. Accessed November 21, 2018. Boulas, J.H., "Amputations of the Fingers and Hand: Indications for Replantation", *Journal of the American Academy of Orthopaedic Surgeons* 62 no. 2 (1998): 100-105. Accessed November 21, 2018.

²⁴ There is frequently high energy trauma preceding limb replantation, and this is not a factor in VCA transplantation. Preservation solutions are used in VCA transplantation, and these solutions are not used in limb replantation/reconstruction.

ensure the best use of donated organs, and to avoid the risk of organs being recovered but not transplanted,

The Committee in preparation for public comment, discussed three distances from a donor hospital; 250 NM, 500 NM, and 750 NM. There was a difference in opinions about which distance from a donor hospital may be appropriate. A 250 NM distance would keep initial offers close to a donor hospital and promote the optimal chance of VCA being accepted and transplanted with low CIT, thus resulting in the best use of donated organs and minimizing the potential for organ wastage or futile transplants. Members shared that this was an option, but VCA programs reported good transplant results with broader distribution, including 250 NM. A 500 NM distance was also discussed and was supported by the Committee. This distance was approximately equal to one hour of flight time²⁵ and members felt this would not substantially contribute to overall CIT in VCA transplants.²⁶ Figure 4 below depicts how VCA allocation within a 500 NM fixed distance may work.

Figure 4: Example of VCA Allocation Using a 500 Nautical Mile Radius Involving a Hypothetical Deceased VCA Donor in Richmond, Virginia



As shown in Figure 4 above, the first offer would be made to a VCA candidate in New York, NY as this candidate has the greatest amount of waiting time within the 500 NM distance from the donor hospital. If the offer to the candidate in New York was refused, subsequent offers would be made to candidates in the following sequence within the 500 NM distance:

2. Boston
3. Durham
4. Baltimore

If offers to the candidates in Boston, Durham, and Baltimore were refused, subsequent offers would be made until acceptance or the waiting list was exhausted:

5. Houston

²⁵ OPTN heart allocation policy changes in 1988 adopted fixed distances for organ distribution between a heart transplant program and the location of a deceased donor. These distribution zones were established to facilitate efficient organ allocation and minimize CIT. Each zone was 500 NM increments and based on how far a charter jet could fly in approximately one hour. Actual travel times vary based on time of day, air traffic conditions, weather, etc...

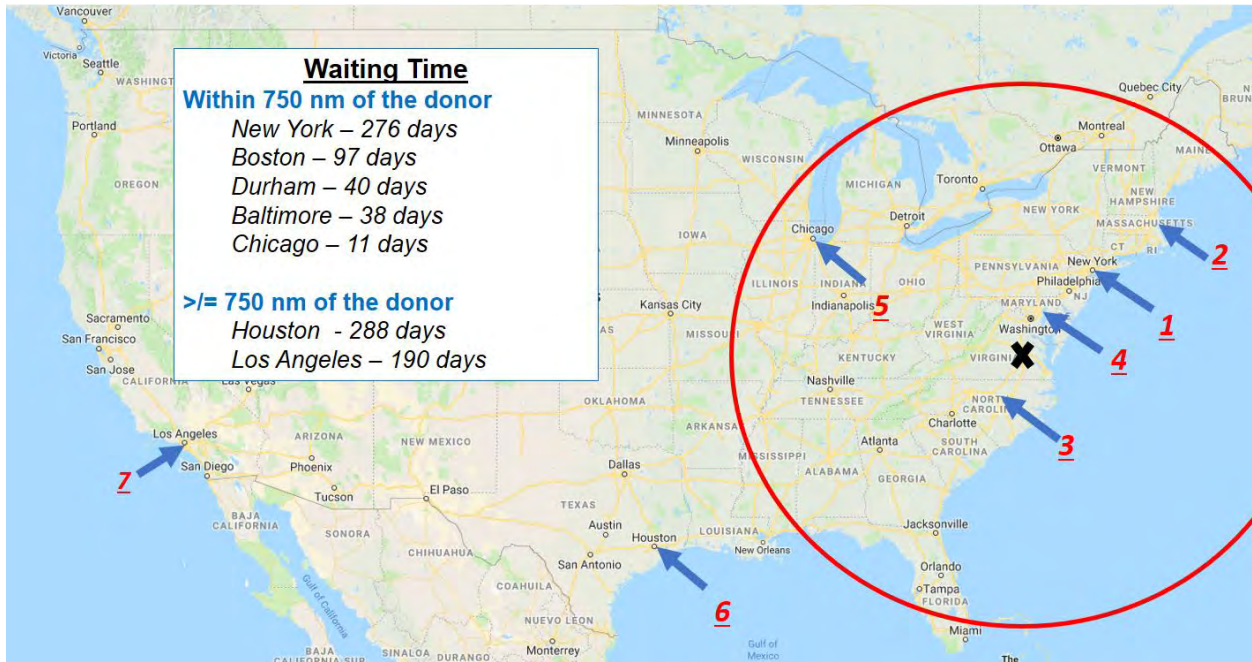
²⁶ Colvin-Adams, M., et al., "Lung and Heart Allocation in the United States," *American Journal of Transplantation* 12 no. 12 (2012) 3213-3234, doi.org/10.1111/j.1600-6143.2012.04258.x. Accessed November 21, 2018.

6. Los Angeles
7. Chicago

Some members were concerned that a 500 NM distance from a donor hospital may disadvantage under-populated or coastal areas (should the size of the region be larger than the size of the fixed distance).

In an attempt to balance these size differences, some members of the Committee supported 750 NM, to minimize a potential reduction in deceased donor access. Figure 5 below depicts how VCA allocation within a 750 NM fixed distance may work.

Figure 5: Example of VCA Allocation Using a 750 Nautical Mile Radius Involving a Hypothetical Deceased VCA Donor in Richmond, Virginia



As shown in Figure 5 above, the first offer would be made to a VCA candidate in New York, NY as this candidate has the greatest amount of waiting time within the 750 NM distance from the donor hospital. If the offer to the candidate in New York was refused, subsequent offers would be made to candidates in the following sequence within the 750 NM distance:

2. Boston
3. Durham
4. Baltimore
5. Chicago

If offers to the candidates in Boston, Durham, Baltimore, and Chicago were refused, subsequent offers would be made to candidates until acceptance or the waiting list was exhausted:

6. Houston
7. Los Angeles

Committee members who favored a 750 NM fixed distance noted there was a small increase in CIT when travel by aircraft increased from 500 NM to 750 NM. Their sentiment, based on their professional experience was that a small increase would not measurably impact graft outcomes. However, there was not consensus regarding the 750 NM distance as some members felt 750 NM would contribute to longer CIT and potentially poor transplant outcomes.

The Committee did consider distances greater than 750 NM. However, it was felt a larger fixed distance for VCA allocation would create allocation system inefficiencies by requiring OPOs to make offers to

potential VCA recipients that would, in all likelihood, not be accepted due to distance. Further, such a distribution policy may create a disincentive for OPOs screening deceased donors for VCA donation by being overly complicated and inefficient. This is contrary to the VCA transplant community's goal to identify more potential VCA donors. Further this would not promote access to transplant, would not make the best use of donated organs, and would not promote efficient management of organ placement.

Based on the available data and input from subject matter experts on the Committee, members felt distribution within a 750 NM single fixed distance followed by national distribution was consistent with the Final Rule.²⁷ The Committee did want feedback from the community whether they would support 250, 500, 750 nm, or another distance for VCA distribution, as well as evidence to support such a recommendation. The Committee voted unanimously²⁸ to approve changes to *Policy 12.2* and solicit public comment in January 2019.

How well does this proposal address the problem statement?

The VCA candidate list is comprised of diverse and growing patient types. There are currently 64 OPTN-approved VCA transplant programs located within 28 transplant hospitals.²⁹ However, not every approved VCA transplant program has registered a VCA candidate with the OPTN. Since July 3, 2014, 80 VCA transplant candidates have been registered with the OPTN at 16 separate VCA transplant programs.³⁰

VCAs have been recovered from both living and deceased donors in the U.S. However, changes to *Policy 12.2* would apply to the allocation of VCAs from deceased donors. Table 1 below outlines the number of transplants in the U.S. by VCA procedure type.

Table 1: VCA Transplants by VCA Procedure Type³¹

VCA Procedure Type	N
Abdominal Wall	2
Bilateral Upper Limb	8
Head and Neck: Craniofacial	6
Head and Neck: Scalp	1
Penis	2
Uterus (Living Donor)	13
Uterus (Deceased Donor)	7
Unilateral Upper Limb	4
Total	43

As noted in Table 1 above, 43 VCA transplants have occurred in the U.S. since July 3, 2014. VCAs used in these transplants were recovered from 28 deceased donors by 14 OPOs.

Committee members discussed their respective experiences with VCA donor recoveries to identify any similarities. They assessed whether VCAs have been recovered outside the immediate geographic area of the transplant program. Some members commented that the majority of their donor recoveries occurred within their local DSA, while others shared that they have traveled outside their DSA and regions for VCA recoveries. Table 2 below shows whether deceased VCA donors in the U.S. since July 3,

²⁷ 121.8(a) 1 (based on sound medical judgement), and 121.8(b) 3 (distributing organs over as broad geographic area as feasible), and 121.8(a) 5 (avoid wasting organs, promote patient access to transplantation, and to promote efficient management of organ placement).

²⁸ On October 12, 2018 the VCA Committee voted to recommend to the POC that public comment be sought on the proposed policy language; (yes-13, no-0, and abstain-0).

²⁹ Based on OPTN data as of March 29, 2019. One transplant hospital may have multiple VCA transplant programs.

³⁰ Based on OPTN data as of March 29, 2019.

³¹ For VCA transplants from July 3, 2014 to March 29, 2019. Based on OPTN data as of April 5, 2019.

2014 were distributed locally (to a VCA program within the same DSA as the host OPO), regionally, or nationally.

Table 2: Distribution Type for Deceased Donor VCA Transplants in the US after July 3, 2014

VCA Type	Local	Regional	National	Total
Abdominal Wall	2 (100.0%)	0 (0.0%)	0 (0.0%)	2
Craniofacial	5 (83.3%)	1 (16.7%)	0 (0.0%)	6
Penis	1 (50.0%)	0 (0.0%)	1 (50.0%)	2
Scalp	1 (100.0%)	0 (0.0%)	0 (0.0%)	1
Upper Limb Bilateral	6 (75.0%)	0 (0.0%)	2 (25.0%)	8
Upper Limb Unilateral	1 (25.0%)	1 (25.0%)	2 (50.0%)	4
Uterus	5 (71.4%)	1 (14.3%)	1 (14.3%)	7
Total	21 (70.0%)	3 (10.0%)	6 (20.0%)	30

Based on most recent available information provided by members to the OPTN as of April 5, 2019. Data subject to change based on future data submission or correction.

Table 2 above shows more than two thirds of VCA recoveries occurred within the DSA that serves the VCA transplant program. However, 30% of VCA recoveries occurred outside the DSA of the VCA transplant program, and these were predominantly upper limbs.

The Committee acknowledged that the amount of allowable ischemic time will vary amongst VCA programs, the type of VCA, and the size/tissue composition of the allografts. The VCA transplant community has considered CIT for heart transplantation as a model due to the similar impact of CIT and IRI on skeletal muscle and myocardial muscle.³² The Committee agreed that, in general, a VCA with greater amounts of muscle would be more sensitive to ischemia, and therefore may not be recovered and transported over a far distance.³³ Longer travel times could be possible for some VCA types and may not be realistic for other VCA types due to ischemic time concerns or logistical needs of the team. However, given the lack of available evidence, the committee selected one larger circle (instead of multiple or a smaller sized circle) for all VCA types. This will allow the medical team at each transplant hospital to use their clinical judgment when evaluating each VCA organ offer. The decision to accept or decline an offer would balance the needs of the potential recipient with the transplant team's clinical decision making on acceptable CIT.

As shown in Table 3 below, 23 candidates are waiting for a VCA transplant as of March 29, 2019.

Table 3: Registrations on the Waiting List by VCA Type³⁴

VCA Type	N
Abdominal Wall	2
Bilateral Upper Limb	1
Head and Neck: Craniofacial	4
Head and Neck: Craniofacial; Head and Neck: Scalp	1
Uterus	12
Unilateral Upper Limb	3
Total	23

³² Brazio, PS, Rodriguez, ED, Bartlett, ST, Barth, RN, "Reconstructive Transplantation: What Can We Learn from Solid Organ Transplantation?"

³³ Caterson, EJ, Lopez, J, Medina, M, Pomahac, B, and Tullius, SG, "Ischemia-Reperfusion Injury in Vascularized Composite Allotransplantation," *Journal of Craniofacial Surgery* 24 no. 1, (2013), 51-56, DOI: 10.1097/SCS.0b013e31827104e1. Accessed November 21, 2018.

³⁴ Based on OPTN data as of March 29, 2019.

The OPTN data noted above indicates a small number of VCAs are recovered annually by a small cohort of OPOs. As a result, the operational impact of this proposal is expected to be small. Time spent by OPOs to allocate VCAs may decrease as a result of initial allocation efforts being focused on VCA programs located within the initial geographic boundary.³⁵ This may reduce the length of time spent on donor management and reduce the risk of declining function in organs that are suitable for transplantation.

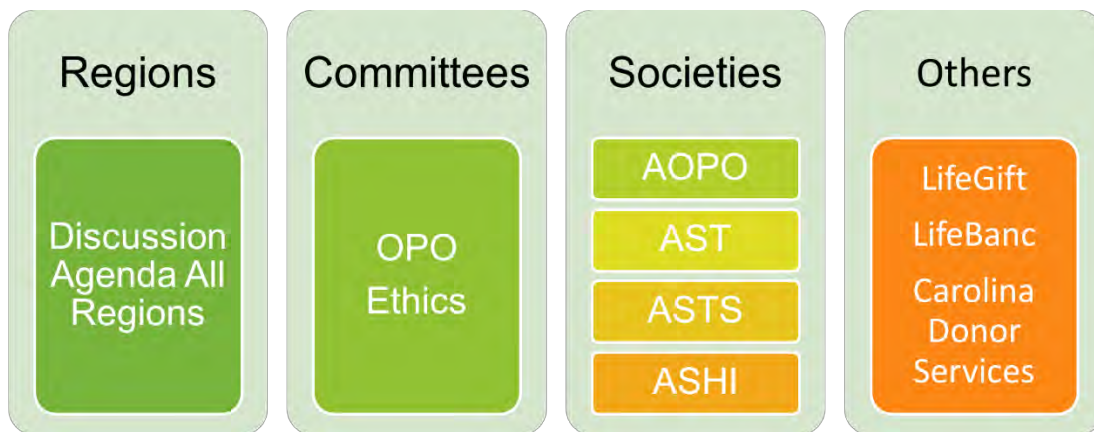
Allocation simulation modeling from the Scientific Registry of Transplant Recipients (SRTR) is often used by OPTN committees to assess how potential allocation changes will function prior to implementation. This modeling is available for heart, kidney, liver, lung, and pancreas transplantation. However, simulation modeling is not available for allocation changes for VCA transplantation. This absence is due to the low case volume for VCA transplantation and the unreliability of statistical regression models that comes with low case volume. This is consistent with other low-volume organ transplants such as intestine transplantation.

The VCA Committee supports the proposed changes as an improvement upon the current allocation policy and to ensure compliance with the Final Rule. The policy changes establish a geographic boundary for VCA distribution that can be consistently applied and is informed by available data and subject matter experts in the field. Further, the proposal does have a high measure of policy durability to apply with expected growth in the VCA transplant field, the evolution in clinical practice, and the inclusion of future technology (e.g., perfusion technology).

Was this proposal changed in response to public comment?

This proposal was broadly supported during a public comment period from January 22, 2019 to March 22, 2019. Figure 6 below profiles the feedback from OPTN regions and committees, transplant societies, and professional groups.

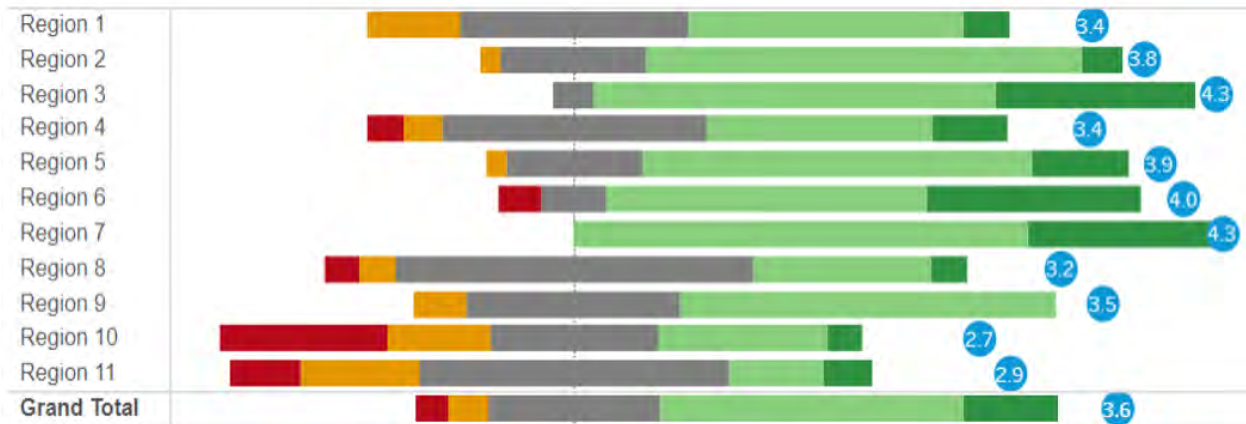
Figure 6: Summary of Public Comment Participation



³⁵ Figure 3 above and Table 3 below note VCA allocation efforts are most often successful within 500 NM of the host OPO. By initiating allocation efforts to VCA programs closer and most likely to accept a VCA, the length of time spent on allocation will be shorter and more efficient.

Sentiment polling was conducted at all 11 regional meetings.³⁶ There was overall support for the proposal. This is shown below in Figure 7.

Figure 7: Proposal Sentiment by OPTN Region



The sentiment was supportive from VCA programs in Regions 1, 2, 4, 5, 7, 9, 10, and 11 that had at least one active candidate since July 2014.³⁷ This is shown in Figure 8 below.

Figure 8: Proposal Sentiment (Mean) by Regions from VCA Programs With At Least One VCA Candidate Registration Since July 3, 2014



Sentiment by OPOs with VCA experience (at least one successful VCA recovery since July 2014) was also supportive of eliminating regions. This is shown in Figure 9 below.

Figure 9: Proposal Sentiment by OPOs That Participated With At Least One VCA Procurement Since July 3, 2014



Number of responses in each category (yellow – oppose, gray – abstain/neutral, light green – support, dark green – strongly support)

Comments submitted in response to the proposal supported the effort to broaden the reach of VCA distribution. However, comments did express concern over the lack of sufficient data to inform a policy decision at this time. This resulted in diversity of support for the 750 NM distance proposed, with alternative distances of 250 NM and 500 NM suggested.

³⁶ Sentiment polling was conducted across a five point Likert scale – Strongly Support, Support, Abstain/Neutral, Oppose, or Strongly Oppose.

³⁷ Oversight of VCA transplantation came under the auspices of the OPTN on July 3, 2014.

Data Review

The transplant community also recognized that the data concerning VCA experience and outcomes is sparse at this time, and the field is still in its infancy, relative to organ transplantation. The Committee is very cognizant of these considerations and they were carefully considered during development of this proposal. The Committee was also aware of the need to make an as informed a decision as possible based on sound medical judgment.

The Committee is committed to monitoring the effectiveness of this proposal and gathering additional VCA transplant outcomes data. Initiatives, both within the OPTN and larger VCA transplant community, are underway to define success in VCA transplantation and gather more specific information on VCA transplant outcomes. These initiatives will be critical to the further development of the field.

Alternative Distances Considered

The Committee received feedback on the public comment proposal regarding alternative distances for VCA distribution. This feedback was based on the data presented in the proposal depicting increased graft failures once outside of 500 NM from the donor hospital. Also, available data and acceptance patterns did not suggest that VCA candidates would be negatively affected by the distribution distance of 500 NM. As a result, decreasing the distance from 750 NM to 500 NM would allow for efficient management of VCA placement, and avoid unnecessary or inefficient time-consuming organ offers.

Feedback was also received regarding a 250 NM alternative. This was based on one organization's perspective that a 250 to 500 NM range may be more appropriate at this early stage in VCA transplantation and in keeping with current practice. Another organization shared the perspective that a 250 NM distance would help minimize CIT times.

The Committee discussed both a 250 NM and 500 NM distance under the framework of a single fixed-distance circle around a donor hospital. The Final Rule requires as broad organ distribution as possible.³⁸ Members felt the available data, literature, and clinical experience did not inform reducing the first area of VCA distribution to a single 250 NM distance. However, the Committee did feel that reducing the first area of VCA distribution to a single 500 NM fixed distance circle was appropriate. The Final Rule does permit basing organ distribution on a distance that considers efficient management of organ placement. Further, available OPTN data does generally show increased graft function if transplanted in a recipient located within 500 NM of a donor hospital.³⁹ As a result, the Committee supported amending the proposal to replace the 750 NM distance with a 500 NM distance.

Other Considerations

Members discussed the potential of a three-tier distribution framework during the post-public comment period. This concept included 250, 500, and 750 NM tiers, as well as separate distances for each different VCA type. However, the Committee previously decided that distances for different VCA types at this juncture was premature due to lack of available data.

The VCA Committee adhered to a transparent, deliberative and, to the best of their experience with the data available, an evidence-based policy making approach. The Committee believes this recommendation conforms with the Final Rule, specifically §121.8 *Allocation of Organs* and the equitable allocation of organs among potential recipients, with an emphasis on:

- Sound medical judgement
- Best use of donated organs
- Preservation of the ability for programs to accept or decline offers

³⁸ OPTN Final Rule, 42 CFR 121.8.

³⁹ See Figure 3 above.

- Specific to for each organ type or combination, in this case VCAs, to be transplanted
- Avoidance of any circumstance of recovery and not eventual transplant; promote patient access to transplantation and efficient management of VCA placement⁴⁰

Which populations are impacted by this proposal?

At the time of implementation, this proposal will impact current and future VCA transplant candidates, VCA transplant programs, and OPOs.⁴¹

In addition to compliance with federal regulation, the Committee considered the impact of this proposal on minority and vulnerable populations, and geographically isolated donor hospitals.

Minority and Vulnerable Populations

The Committee discussed whether the proposed changes may impact minority or vulnerable populations waiting for a VCA transplant from a deceased donor. Members were sensitive to the need to ensure these candidates are not disadvantaged by the changes. Members agreed that the intent of broader distribution of VCAs will enhance donor access for minorities waiting for a VCA transplant. The Committee will monitor the impact of this policy change on minority and vulnerable populations.

Geographically Isolated Donor Hospitals

The Committee specifically discussed whether the proposed changes should apply to potential VCA donors identified at hospitals located in Alaska, Hawaii, and Puerto Rico. These areas are located more than 1,000 NM from the U.S. mainland and present their own logistical challenges for organ distribution. As it pertains to VCA transplantation, the leading challenge to VCA recoveries in these areas stems from contribution of travel time to overall CIT. The Committee noted there are no VCA transplant programs located in these areas, and no VCA recoveries have occurred in these areas to-date.⁴² The Committee agreed that VCA donation was still possible in these areas, but would require substantial logistical coordination, the right deceased donor, and the right potential VCA recipient. The Committee noted that a wide range of clinical information is considered with each organ offer (inclusive of distance between a deceased donor and potential recipient). The final decision to accept or decline an offer rests with the individual VCA transplant team and considers the totality of this information.

Consistent with the recommendations from the Geography Committee, the Committee did not derive policy changes to apply exclusively to these areas. Further, the Committee was comfortable with VCAs from deceased donors in these areas being allocated under the umbrella of national allocation in the existing and proposed policies.⁴³

Living Donation

This proposal addresses changes to OPTN policy that only impacts allocation of VCAs from deceased donors. This policy change will not have any impact on living VCA donors or those VCA candidates waiting for an organ from a living donor (e.g.: uterus transplant). This proposal is not addressing any issues pertaining to living VCA donation.

⁴⁰ At the conclusion of the deliberation on March 29th, 2019, the Committee voted to recommend the amended proposal to the Board (Yes – 13, No – 0, Abstain – 1).

⁴¹ See Tables 1-3 above for number of VCA candidates currently waiting, number of deceased VCA donors, and VCA transplant volume.

⁴² Based on OPTN data as of April 5, 2019.

⁴³ Once VCA offers are declined or potential recipients bypassed within the region, VCA allocation extends to potential recipients waiting beyond the regional boundaries where the deceased donor is located. With the replacement of region with a fixed distance from the deceased donor, allocation outside this fixed distance would continue to occur with potential recipients ranked based on respective waiting time.

How does this proposal comply with the Final Rule?

A critical objective of the Final Rule is to achieve the most equitable and medically effective use of donated human organs.⁴⁴ Towards that goal, the Final Rule directs the OPTN to overcome as much as possible arbitrary geographic barriers that restrict the allocation of organs to patients with the greatest medical urgency.⁴⁵ In developing this proposal, the Committee considered the Final Rule's equitable allocation criteria as set forth in Section 121.8 as follows:

- **Shall be based on sound medical judgement:** The Committee based its decisions on evidence including the clinical and operational experience of committee members and input from stakeholder committees.
- **Shall seek to achieve the best use of donated organs:** The Committee strives to monitor the impact on waitlist and the volume of transplants.
- **Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate:** The Committee reviewed the available evidence concerning the clinical differences applicable to the various types of VCA organs. Given the lack of available evidence, the committee selected one larger circle (instead of multiple or a smaller sized circle) for all VCA types. This will allow the medical team at each transplant hospital to use their clinical judgment when evaluating each VCA organ offer.
- **Shall be designed to avoid wasting organs:** The Committee considered variations with distribution distances that reflect limits on clinical ischemic times when necessary and monitoring the impact on the number of organ transplants.
- **Shall be designed to promote patient access to transplantation:** The Committee monitored the impact on waitlist mortality and waiting time.
- **Shall be designed to promote the efficient management of organ placement:** The Committee strived to limit travel distance based on data indicating when the distribution method shifts from driving to flying.
- **Shall not be based on the candidate's place of residence or place of listing:** The Committee aims to implement a rational unit for geographic distribution that is more consistent with the requirements of the Final Rule, improve equity in transplant opportunities, and apply principles of geographic distribution to allocation policies across all organ systems.

Although the framework variations outlined in this briefing paper address certain aspects of the Final Rule listed above, Committee discussions did not demonstrate impacts on the following aspects of the Final Rule:

- Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e);
- Shall be designed to avoid futile transplants;
- Shall be reviewed periodically and revised as appropriate;
- Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve the equity in access to transplants:* The Final Rule requires that allocation policies "shall not be based on the candidate's place of residence or place of listing." This project aims to

⁴⁴ Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,650 (October 20, 1999).

⁴⁵ Organ Procurement and Transplantation Network, 64 Fed. Reg. 56,651 (October 20, 1999).

implement a rational unit for geographic distribution that are more consistent with the requirements of the Final Rule, improve equity in transplant opportunities, and apply principles of geographic distribution to allocation policies across all organ systems.

3. *Improve waitlisted patient, living donor and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

What are the potential costs associated with this proposal?

Member

Increasing the distribution of VCAs up to 500 miles impacts both transplant hospitals and OPOs. Additional transportation cost and staff time to coordinate more complex procurements at a greater distance causes an increase in cost per transplant. Longer flight time per transplant and more frequent flying of organs may occur with an increase in distance.

Since VCAs are matched through a manual process, OPOs and transplant hospitals may need more time to coordinate compared to matching on the electronic match-run. OPOs will charge hospitals for its additional transportation or staff time.

While cost increase is likely with extended travel, this change will not financially impact VCA programs much overall. VCAs are rare because they require a very specific match. If VCAs are procured and transplanted locally, instead of flying the recovery team, the cost of transplant can be lower. However, if VCAs are flown more frequently, this may reduce waiting time for those VCA candidates.

This proposal can be implemented quickly with staff communication and education. One month implementation time is estimated for transplant hospitals and OPOs.

This proposal is not anticipated to impact histocompatibility laboratories.

UNOS

The VCA allocation system is separate from the electronic systems used to allocate other organs maintained by the IT department (DonorNet® and WaitlistSM). As such, the UNOS Research Department will oversee changes and monitoring associated with the modification of VCA allocation. Approximately 700 hours (medium effort) is attributed to proposal development through post implementation. Should VCA allocation become electronic, the UNOS Information Technology department would maintain this system.

Additional significant hours associated with this proposal included proposal development by the Policy and Community Relations department staff in committee work, conference calls, and policy analysis. Development hours were estimated at 150 hours. Implementation hours are estimated to be at 100 hours.

How will the OPTN implement this proposal?

Enhancements to the VCA candidate registration/removal and VCA allocation system will be needed in order to sort potential recipients based on distance from a donor hospital. Additional enhancements will also be made based on feedback from OPOs to reduce administrative burden to OPOs and the OPTN.

This project work can be performed within the scope of a “small” classification of project. This proposal will not require programming in UNet as the VCA candidate registration/removal and VCA allocation system exists outside of UNet.

Changes to OPTN *Policy 12.2* will be a small educational effort.

How will members implement this proposal?

Transplant Hospitals

VCA transplant programs will continue to receive offers from OPOs, while some VCA transplant programs may receive offers from OPOs that they have not received offers from in the past. VCA transplant programs may need to develop working relationships with any OPO within what the VCA program believes is an acceptable travel distance in order to obtain needed donor information and coordinate VCA recovery. This should include specialized pre-recovery imaging or testing, intraoperative needs including any additional time to recover VCAs, and post recovery considerations (e.g., post-mortem or mortuary considerations). VCA programs should discuss any potential VCA acquisition costs with OPOs *before* any VCA recoveries.

Changes are not being made to policy language describing how VCA candidates accrue waiting time. Registered VCA candidates will retain their accrued waiting time, continue to accrue waiting time in the same manner, and continue to be matched with deceased donors based on ABO compatibility. Future registered VCA candidates will begin accruing waiting time from their respective date of registration with the OPTN and also be matched with deceased donors based on ABO compatibility.

OPOs

OPOs will continue to allocate VCAs from the VCA candidate list. This proposal could change who OPOs contact with VCA offers. OPOs that are committed to supporting VCA donation may need to develop working relationships with VCA programs in order to share needed donor information and coordinate VCA recovery. This should include availability of specialized pre-recovery imaging or testing, intraoperative needs including any additional time to recover VCAs, the needs of other recovery teams, and post recovery considerations (e.g.: medical examiner/coroner or post-mortem considerations).

OPO costs may change as a result of this proposal. Increases in intra-operative time may be seen if OPOs allocate VCAs. Decreases in donor management times may be seen from more efficient VCA allocation. However, this is likely to be small given the low numbers of VCA donors. OPOs should discuss any potential VCA acquisition costs with VCA programs *before* any VCA recoveries.

Histocompatibility Laboratories

This proposal will not impact histocompatibility laboratories.

Will this proposal require members to submit additional data?

This proposal will require VCA transplant programs to submit a small amount of additional data to the OPTN when registering a VCA candidate. This would include a maximum distance the transplant program is willing to travel to recover a VCA for a given candidate, and whether they are willing to travel more than 500 NM to recover a VCA for a given candidate.

OPOs will need to submit a very small amount of additional data on VCA candidate lists. This would include entering an existing Potential Transplant Recipient (PTR) bypass code and completing a text field

to include the rationale for bypassing the VCA candidate. However, OPOs already perform this routinely and the frequency of use for VCA allocation is expected to be very low.

This proposal is consistent with the OPTN Principles of Data Collection as these data will be used to assess patient safety and inform future allocation policy decision making.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current routine monitoring of OPTN members. Any data submitted to the OPTN Contractor may be subject to OPTN review, and members are required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

Using pre versus post comparisons, analyses will be performed post-implementation at approximate 6-month intervals as appropriate to identify trends and potentially unanticipated consequences of the policy. Analysis of post-transplant outcomes will be performed after sufficient follow-up data has accrued, which is dependent on submission of follow-up forms. Analyses will include:

- Number of deceased donor VCA transplants
- Size and composition of the waiting list, and waiting
- Waiting list removals
- Transplant recipient demographics (e.g.: age, sex, ethnicity)
- Post-transplant patient and graft survival
- Organ travel distance, and CIT

Policy Language

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

1 **12.2 VCA Allocation**

2 ~~The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with~~
 3 ~~similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:~~

- 4
 5 ~~1. Candidates that are within the OPO's region~~
 6 ~~2. Candidates that are beyond the OPO's region~~

7
 8 VCAs from deceased donors are allocated to candidates in need of that VCA according to *Table 12-1*
 9 below.

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

<u>Classification</u>	<u>Candidates that are registered at a transplant hospital that is within the distance from a donor hospital:</u>	<u>And are:</u>
<u>1</u>	<u>500 NM</u>	<u>Blood type compatible with the donor</u>
<u>2</u>	<u>Nation</u>	<u>Blood type compatible with the donor</u>

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

12
 13 When a VCA is allocated, the host OPO must document both of the following:

- 14
 15
 16 1. How the organ is allocated and the rationale for allocation
 17 2. Any reason for organ offer refusals

18
 19 #