Public Comment Proposal

Eliminate the Use of Regions in VCA Distribution

OPTN/UNOS 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*

Executive Summary

The OPTN/UNOS Final Rule (hereafter Final Rule) sets requirements for allocation polices developed by the OPTN/UNOS, 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"[1] by the other requirements.

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. OPTN/UNOS policies for vascularized composite allograft (VCA) allocation use "region" as the first geographic boundary for distribution.[2] In response to the Secretary's letter, the OPTN/UNOS Executive Committee directed the VCA Transplantation Committee (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 750 nautical mile (NM) concentric circle around a donor hospital. This will address the Secretary's findings by allowing efficient placement of deceased donor VCAs, help achieve optimal recipient and graft outcomes, and to reduce the risk of organs being recovered but not transplanted.

This proposal is consistent with Goal Two of the OPTN/UNOS 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.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee encourages all interested individuals to comment on the proposal in its entirety. Members are asked to comment on both the immediate and long-term impact on budgets and other resources that may be required if this proposal is approved; this information assists the Board in considering the proposal and its impact on the community. The Committee requests specific feedback on the following items:

1. Members are asked if they would recommend an alternative distance for VCA distribution, versus the proposed distance of 750 NM? If so, what distance do you recommend and what evidence justifies this distance?

[1] 42 C.F.R. § 121. https://www.ecfr.gov/cgi-bin/text-idx?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/UNOS President, July 31, 2018.

[3] OPTN/UNOS Executive Committee meeting August 1, 2018. https://OPTN/UNOS.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 polices developed by the OPTN/UNOS, including sound medical judgement, best use of organs, the ability for centers to decide whether to accept an organ offer, to avoid wasting organs, 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 Rule.[4]

OPTN/UNOS Policy 12.2 *VCA Allocation* currently uses OPTN/UNOS regions (regions) for organ distribution.[5] Use of regions are not a good proxy for geographic distance between donors and transplant candidates due to variation in size of regions, shapes, and populations result 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. 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?

On July 31, 2018, the Secretary found that the use of DSAs or regions in organ allocation policies cannot be justified under the Final Rule.[8] OPTN/UNOS Policies for VCA allocation use "region" as the first geographic boundary for distribution. In response the Secretary, the OPTN/UNOS Executive Committee directed the VCA Committee to develop a proposal that replaces "region" with another geographic boundary in VCA allocation policy.[9]

In response to the Executive Committee directive, the VCA Geography Subcommittee (Subcommittee) considered the current VCA allocation policy and alternatives:1) national allocation without any geographic consideration, or 2) replacing region with either mathematical optimization, continuous distribution, or fixed distance models.[10]

Current VCA Allocation Policy

OPTN/UNOS Policy 12.2 *VCA Allocation* requires 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. Considerations

[4] OPTN/UNOS Final Rule, 42 CFR 121.8.

[5] OPTN/UNOS Policy 12.2 *VCA Allocation,* *https://OPTN/UNOS.transplant.hrsa.gov/media/1200/OPTN/UNOS_policies.pdf#nameddest=Policy_12*. Accessed November 21, 2018.

[6] OPTN/UNOS Regions, https://OPTN/UNOS.transplant.hrsa.gov/members/regions/. Accessed November 21, 2018.

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

[8] George Sigounas, letter to Sue Dunn, OPTN/UNOS President, July 31, 2018.

[9] OPTN/UNOS Executive Committee meeting August 1, 2018.

[10] OPTN/UNOS Ad-Hoc Geography Committee, "Frameworks for Organ Distribution", https://OPTN/UNOS.transplant.hrsa.gov/media/2565/geography_publiccomment_201808.pdf. Accessed November 21, 2018.

of a VCA offer include not only the travel distance and overall CIT, but also complex matching considerations between the donor and potential recipient.[11] 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.[12] 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 one below depicts the allocation for a VCA from a hypothetical deceased donor located in Richmond, Virginia (within Region 11 outlined in red).[13]

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

Figure 1 describes the first offer to a VCA candidate in Durham, located with the same region as the deceased donor. If the offer to the candidate in Durham is refused or the candidate bypassed, subsequent offers are be made outside Region 11 in the following sequence until acceptance or the waiting list is exhausted:

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

[11] 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.

[12] OPTN/UNOS Policy 12.2 *VCA Allocation.*

[13] Region 9 includes the state of New York and Western Vermont. https://OPTN/UNOS.transplant.hrsa.gov/members/regions/. Accessed November 21, 2018.

National Allocation without Any Geographic Consideration

The first model considered by the Committee included ranking all VCA candidates in the U.S. based on their waiting time. This model would not use any 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

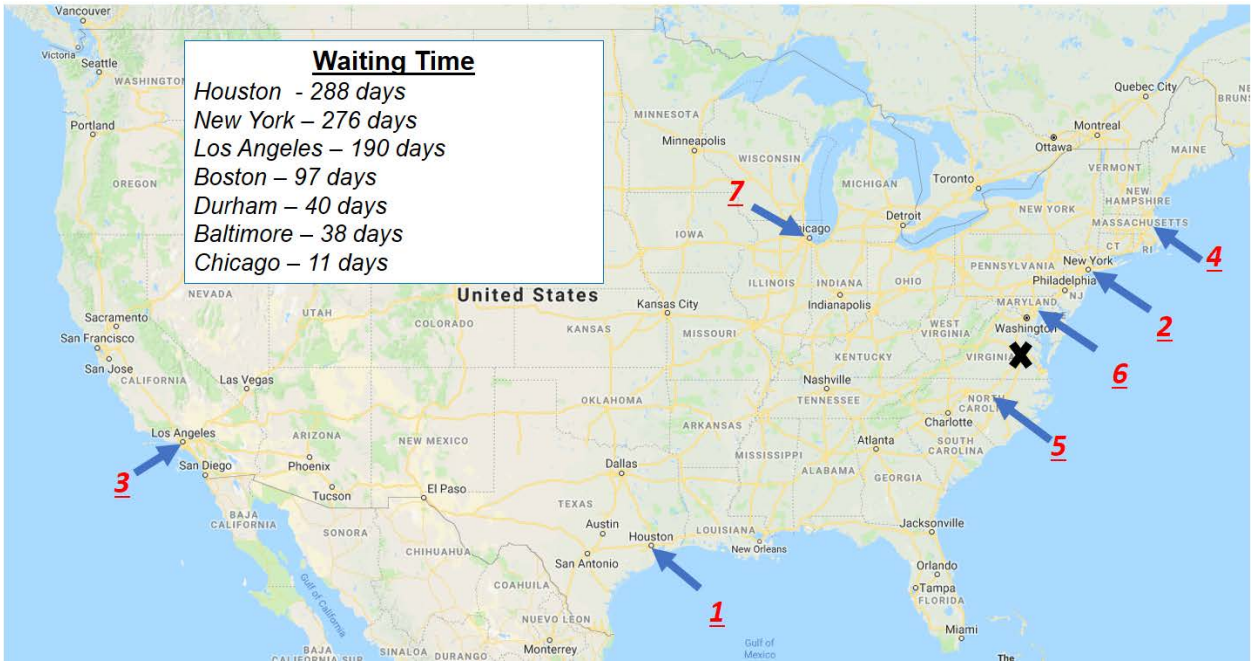

Figure 2 describes the first offer to a VCA candidate in Houston, Texas, as this candidate has the highest amount of waiting time in the U.S. If the offer to the candidate in Houston was refused, subsequent offers would be made in the following sequence until acceptance or the waiting list was exhausted:

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 longer 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.[14, 15, 16, 17, 18, 19, 20, 21]

The Committee also considered the efficiency of organ placement under this model. The current VCA allocation system is based outside of UNet[SM] and requires manual notifications from OPOs to VCA transplant programs. Using this distribution model to make VCA offers to distant candidates (that will likely decline due to distance) prior to geographically closer candidates would be time consuming for OPO staff. Several encounters with deceased donors screened for VCA donation that do not proceed to successful donation could dis-incentivize OPOs to screen *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.

Replacing with Mathematical Optimization, Continuous Distribution, or Fixed Distance

The Committee carefully reviewed the three organ distribution frameworks developed by the OPTN/UNOS Ad-hoc Geography Committee. The frameworks included a Mathematical Optimization, Continuous Distribution, and Fixed Distance models.[22] The Committee reviewed each model, noting simplicity in a model was very relevant for VCA currently due to the lack of available data correlating CIT and VCA transplant outcomes, and short time period prescribed to amend OPTN/UNOS policy.[23]

Mathematical Optimization

The Committee discussed the mathematical optimization model and expressed the complexity of this model was not well-suited for VCA at this time. 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.[24] Members shared this model

[14] 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.jhsa.2017.09.013. Accessed November 21, 2018.

[15] 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.

[16] Levinson, 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.0000000000000098. Accessed November 21, 2018.

[17] 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.

[18] 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.

[19] 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.

[20] 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.

[21] 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.

[22] OPTN/UNOS Ad-Hoc Geography Committee, "Frameworks for Organ Distribution".

[23] The Executive Committee directed the VCA Committee to prepare a proposal for public comment in January 2019.

[24] 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 donor specific antibodies play), and VCA candidate prioritization (should pediatric candidates be prioritized over adult candidates, or should a candidate have higher priority if

appeared to still have the same risk as current the DSA 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.[25] Also, this model could engender 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).[26] These two circumstances may create unintended inequities in organ distribution. As a result, the Committee did not pursue this distribution model. Members felt this model was better suited for organs with greater case volumes and clinical experience.

Continuous Distribution

The Committee discussed the continuous distribution model, and also expressed concern 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. 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). The Committee also acknowledged the VCA transplant community is currently working towards consensus on definitions of success and of outcomes. As a result, the Committee deferred discussions on this advanced model of distribution pending further data and development of consensus in the field.[27]

Fixed Distance

Of the three distribution models from the Geography Committee, members agreed the fixed distance model appeared to hold the most potential for VCA transplantation. Members noted this model may have the most "policy durability"; the expected growth in the VCA transplant field, the evolution in clinical practice, and the inclusion of future technology (e.g.: perfusion technology) could be accommodated by this model and not require frequent policy changes. Members appreciated the need to base any geographic distances for VCA distribution on data from the OPTN/UNOS and other sources to avoid the perception of developing distances that could be seen as arbitrary in nature. Members agreed that it was premature to develop different distances for each VCA type (e.g.: upper limb or uterus) due to the still-developing body of transplant outcome data and the very low case volume of some emerging types of VCA transplants. As a result, it was prudent to develop policy language that applied to all VCAs.

There was wide agreement amongst members on the desire to keep CIT as short as possible. The VCA transplant community accepts there are clinical similarities of IRI on skeletal muscle and cardiac muscle. The latter was the rationale for using heart CIT tolerances of four to six hours.[28] Members also recognized that some VCA programs appeared to be traveling farther distances since the first VCA transplant in 1998 (based on OPTN/UNOS data on VCA acceptances, and the distance between the host OPO and transplant programs).[29] Figure 3 below profiles the distances traveled by VCA recovery teams, reported CIT, and graft status.

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their individual waiting time is greater than the median waiting time for the same VCA type).

[25] This concern was noted in the Geography Committee's Recommendations Report on Geographic Organ Distribution Principles, https://OPTN/UNOS.transplant.hrsa.gov/media/2506/geography_recommendations_report_201806.pdf. Accessed November 21, 2018.

[26] 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/opoguidearticles/donor-conversion/. Accessed November 21, 2018.

[27] This future discussion is consistent with the Board's approval of the Continuous Distribution model in December 2018.

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

[29] 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 2014[30]

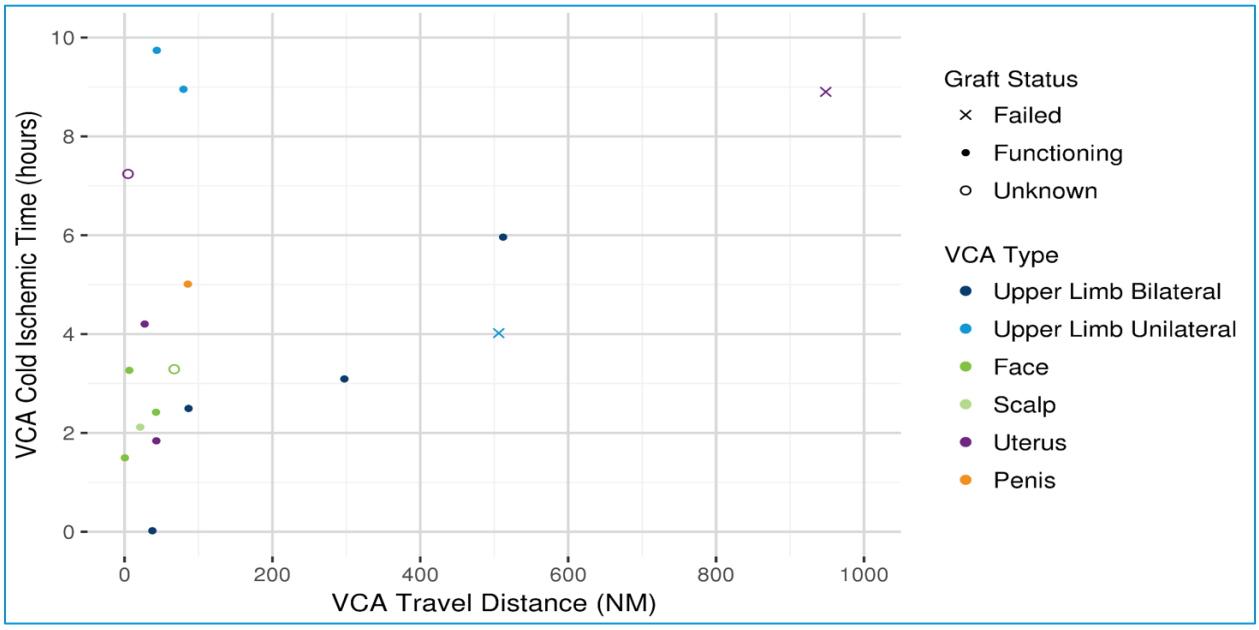


Figure 3 highlights that 18 of 24 VCAs transplanted (75%) since July 2014 were recovered within 200 NM of the VCA transplant program. 21 of 24 VCAs transplanted (87.5%) were recovered within 500 NM of the VCA transplant program. While this is informative data, CIT does not appear to be correlated with 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.[31]

Members did report there was some use in considering current clinical guidance from limb replantation/reconstruction that did correlate CIT with post-surgical outcomes.[32] Members recognized weakness in direct correlation with VCA transplantation; the presence of high energy trauma preceding replantation and the absence of the same in VCA transplantation, and the use of preservation solutions in VCA transplantation and the absence of the same in replantation/reconstruction. As in transplantation of other organs, the available resources showed the least amount of CIT generally supported better outcomes.

The Committee discussed three distances from a donor hospital; 250 NM, 500 NM, and 750 NM. There was diversity 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

[30] Ibid.

[31] 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?"

[32] 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.jhsa.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.

accepted and transplanted with low CIT. Members shared that this was an option, but VCA programs reported good transplant results at distances greater than 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 time and members felt this would not substantially contribute to overall CIT in VCA transplants.[33, 34] 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 City, as this candidate has the highest amount of waiting time within the 500 NM distance from the donor hospital. If the offer to the candidate in New York City was refused, subsequent offers would be made 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:

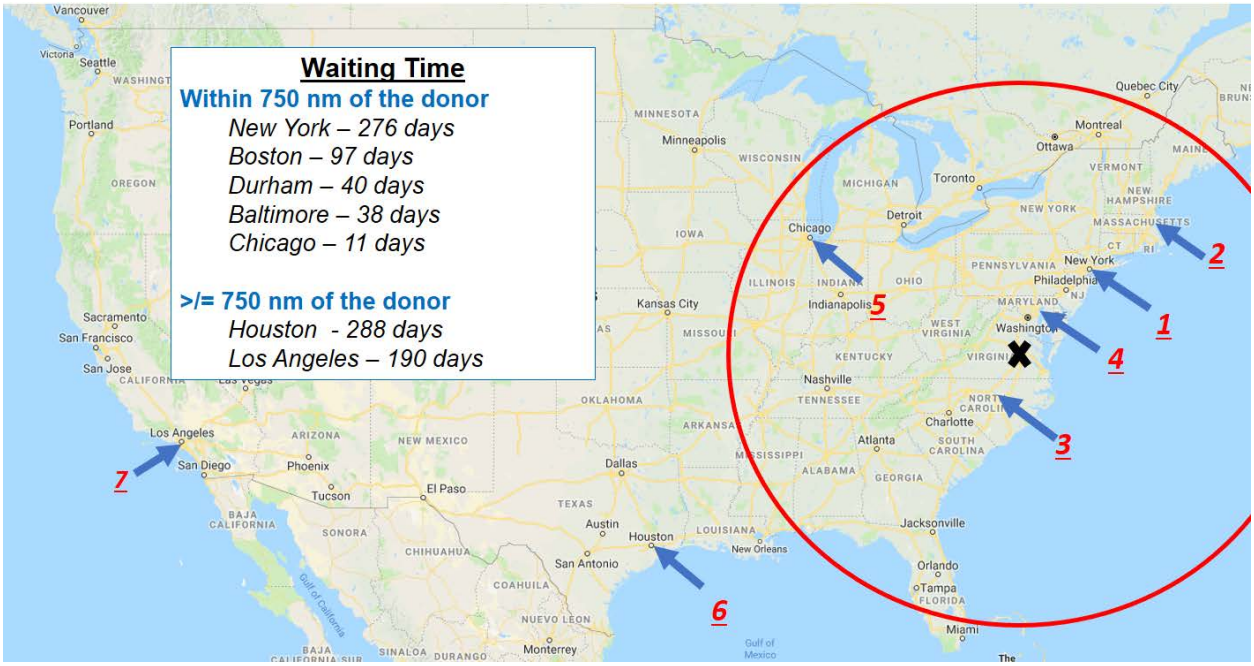
5. Houston
6. Los Angeles
7. Chicago

The Committee discussed 500 and 750 NM distances from a donor hospital. Under-populated or coastal areas were discussed as being potentially disadvantaged with decreased access to VCA offers (should the size of the region be larger than the size of the fixed distance). In an attempt to balance the differences, some members of the Committee supported 750 NM in an attempt to minimize a potential reduction in deceased donor access. Figure 5 below depicts how VCA allocation within a 750 NM fixed distance may work.

[33] OPTN/UNOS 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.

[34] 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.

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 City, as this candidate has the highest amount of waiting time within the 750 NM distance from the donor hospital. If the offer to the candidate in New York City was refused, subsequent offers would be made 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 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 was this small increase would not measurably impact graft outcomes. However, there was not consensus regarding the 750 NM distance as some members felt it was excessive.

The Committee did consider distances greater than 750 NM. However, it was felt a larger fixed distance for VCA allocation would engender allocation system inefficiencies by requiring OPOs to make offers to potential VCA recipients that would, in all likelihood, not accept due to distance. Further, such a distribution policy may create a dis-incentive 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.

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

Final Rule.[35] 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 to approve changes to OPTN/UNOS Policy 12.2 and solicit public comment in January 2019 (yes – 13, no – 0, abstain – 0).

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/UNOS approved VCA transplant programs located within 27 transplant hospitals.[36] However, not every approved VCA transplant program has registered a VCA candidate with the OPTN/UNOS. Since July 3, 2014, 74 VCA transplant candidates have been registered with the OPTN/UNOS at 16 separate VCA transplant programs.[37]

VCAs have been recovered from both living and deceased donors in the U.S. However, changes to OPTN/UNOS 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. using VCAs from deceased donors.

Table 1: VCA Transplants by VCA Procedure Type[38]

VCA Procedure Type	N
Abdominal Wall	2
Bilateral Upper Limb	7
Head and Neck: Craniofacial	6
Head and Neck: Scalp	1
Penis	2
Uterus	
Living Donor	10
Deceased Donor	4
Unilateral Upper Limb	4
Total	**36**

As noted in Table 1 above, 36 VCA transplants have occurred in the U.S. VCAs used in these transplants were recovered from 25 deceased donors by 14 OPOs.

As shown in Table 2 below, 26 candidates are waiting for a VCA transplant as of November 23, 2018.

[35] 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).

[36] Based on OPTN/UNOS data as of December 7, 2018. One transplant hospital may have multiple VCA transplant programs.

[37] Based on OPTN/UNOS data as of December 7, 2018.

[38] For VCA transplants from July 3, 2014 to November 23, 2018. Based on OPTN/UNOS data as of December 7, 2018.

Table 2: Registrations on the Waiting List by VCA Type[39]

VCA Type	N
Abdominal Wall	2
Bilateral Upper Limb	3
Head and Neck: Craniofacial	4
Head and Neck: Craniofacial; Head and Neck: Scalp	1
Uterus	14
Unilateral Upper Limb	2
Total	**26**

The OPTN/UNOS 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.[40] This may reduce the length of time spent on donor management and reduce the risk of declining function in organs that were suitable for transplantation.

Allocation simulation modeling from the Scientific Registry of Transplant Recipients (SRTR) is used by OPTN/UNOS 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 feels the proposed changes are an improvement upon the current allocation policy and achieve the goal of compliance with the Final Rule. The policy changes establish a geographic boundary for VCA distribution that can be consistently applied, and was informed by available data and subject matter experts in the field. Further, the proposed 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).

Which populations are impacted by this proposal?

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 the local DSA, while others shared that they have traveled outside their DSA and region for VCA recoveries. Table 3 below shows whether deceased VCA donors in the U.S. since July 3, 2014 were distributed locally (to a VCA program within the same DSA as the host OPO), regionally, or nationally.

[39] Based on OPTN/UNOS data as of December 7, 2018.

[40] Figure 3 above and Table 5 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.

Table 3: 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	5 (71.4%)	0 (0.0%)	2 (28.6%)	**7**
Upper Limb Unilateral	1 (25.0%)	1 (25.0%)	2 (50.0%)	**4**
Uterus	2 (50.3%)	1 (25.0%)	1 (25.0%)	**4**
Total	**17 (65.4%)**	**3(11.5%)**	**6 (23.1%)**	**26**

Based on most recent available information provided by members to the OPTN/UNOS as of December 7, 2018.
Data subject to change based on future data submission or correction.

Table 3 above shows that two thirds of VCA recoveries occurred within the DSA serving the VCA transplant program. However, 33% of VCA recoveries occurred outside the DSA of the VCA transplant program, and these were predominantly upper limbs.

The Committee acknowledged 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 as myocardial muscle.[41] 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.[42] 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. The decision to accept or decline an offer would balance the needs of the potential recipient and the transplant team's clinical decision making on acceptable CIT.

In addition to compliance with federal regulation, the Committee considered the impact of this proposal on minority and vulnerable populations, geographically isolated donor hospitals, and potential changes in donor access for VCA programs.

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 broader distribution of VCAs will enhance donor access for minorities waiting for a VCA transplant.

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.

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

[42] 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.

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, and no VCA recoveries have occurred in these areas.[43] 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 VCA Committee did not derive policy changes to apply exclusively to these areas. Further, the VCA 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.[44]

Potential Changes in Donor Access for VCA Programs

While the proposal achieves greater compliance with the Final Rule, the issue remains for the potential of decreased access to VCA donors for those candidates registered, 1) at VCA transplant programs in proximity to U.S. coastal or border areas, or 2) at VCA transplant programs located in an area with a theoretical decrease based on population density (transitioning from a larger region to a smaller fixed distance).

Regardless of the size of the fixed distance around a donor hospital, distances extending over U.S. coastal and boarder areas include varying amount of square miles with no potential deceased donors. However, U.S. population centers are located in proximity to coastal areas and may off-set areas with no donor potential.

The Committee acknowledged and discussed these issues. They decided a future option for VCA allocation consistent with the Geography Committee's "continuous distribution" model would mitigate potential reduction in access to deceased donors.[45] However, such a proposal required substantially more time than currently available and a still-accumulating body of transplant outcome data to inform decision-making. The Committee is committed to working towards a future allocation policy that is both in compliance with the Final Rule, and considers additional donor and potential recipient data to ensure the broadest distribution possible.

Living Donation

This proposal addresses changes to OPTN/UNOS policy that only impacts allocation of VCAs from deceased donor. 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.

How does this proposal impact the OPTN/UNOS Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal
2. *Improve 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 implement

[43] Based on OPTN/UNOS data as of November 23, 2018.

[44] 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.

[45] OPTN/UNOS Ad-Hoc Geography Committee, "Frameworks for Organ Distribution.

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/UNOS:* There is no impact to this goal

How will the OPTN/UNOS implement this proposal?

Enhancements to the VCA candidate registration/removal and VCA allocation system will be needed in order 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/UNOS. This project work can and 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/UNOS Policy 12.2 will be considered within a larger educational offering to the transplant community that addresses changes to organ distribution.

How will members implement this proposal?

Transplant Hospitals

VCA transplant programs will continue to receive offers from OPOs. VCA transplant programs may receive offers from OPOs they have not historically. 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. Currently 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/UNOS 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 recover 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/UNOS 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 750 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/UNOS 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/UNOS members. Any data submitted to the OPTN/UNOS Contractor may be subject to OPTN/UNOS 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 list removals
- Transplant recipient demographics (age, gender, diagnosis, ethnicity, socioeconomic factors as available for analysis)
- Post-transplant survival rates
- Organ travel distance, and CIT
- Other metrics deemed relevant and necessary to the evaluation of the policy by the Committee analysis

Policy or Bylaws Language

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

12.2 VCA Allocation

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

1. Candidates that are ~~within the OPO's region~~ less than 750 nautical miles from the donor hospital.
2. Candidates that are ~~beyond the OPO's region~~ equal to or more than 750 nautical miles from the donor hospital.

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

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

1. How the organ is allocated and the rationale for allocation
2. Any reason for organ offer refusals

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