

Briefing to the OPTN Board of Directors on

Regional Review Project

OPTN Executive Committee

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Regional Review Project


<i>Sponsoring Committee:</i>	<i>Executive</i>
<i>Public Comment Period:</i>	<i>June 29, 2020 – October 1, 2020</i> <i>August 3, 2021 – September 30, 2021</i> <i>January 27, 2022 – March 23, 2022</i>
<i>Board of Directors Date:</i>	<i>June 27, 2022</i>

Executive Summary

The OPTN launched the Regional Review project in 2020 pursuant to OPTN Contract Task 3.3.3: Review of OPTN regional process¹ to evaluate OPTN regions and their functions. The OPTN collected community feedback related to the roles and effectiveness of regions over three public comment periods between 2020 and 2022 and engaged a third party vendor, EY, in 2021 to conduct an independent review and analysis of the OPTN regional structure and processes. Most recently, the vendor’s final report was shared with the public in conjunction with a concept paper entitled *Redesign Map of OPTN Regions*.² This report summarizes the overall findings from the Regional Review project, including public comment feedback on the concept paper, and actions being taken in response. Overall, the Executive Committee directed several actions to optimize OPTN governance and operational effectiveness, including actions to enhance patient engagement across the OPTN and to promote consistency in regional meetings and nominations processes. The Committee recommends maintaining the current regional map for now, but resolved to commit to a regular review of the regional map boundaries to assess whether they align with working relationships between transplant hospitals and organ procurement organizations (OPOs).

¹ The current OPTN Contract requires the OPTN Contractor to “develop a plan to review and analyze the existing OPTN regional process for soliciting and collecting OPTN member opinion and comments on OPTN policy proposals. The Contractor shall objectively review the current process to determine strengths, weaknesses, and effectiveness of the current process in supporting OPTN policy development consistent with the OPTN final rule. The Contractor shall utilize technical experts in systems/operations design to evaluate the current process and develop a recommendation for continuing, changing and improving, or eliminating the existing regional process. The Contractor shall include with the recommendation a rationale supporting the contribution of the proposed process to ensuring OPTN policy is developed consistent with the requirements of NOTA and the OPTN final rule.” Organ Procurement and Transplantation Network; HSH250201900001C: Task 3.3.3: Review of OPTN regional process.

² “Redesign Map of OPTN Regions,” OPTN, Concept Paper, accessed April 15, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/redesign-map-of-optn-regions/>.

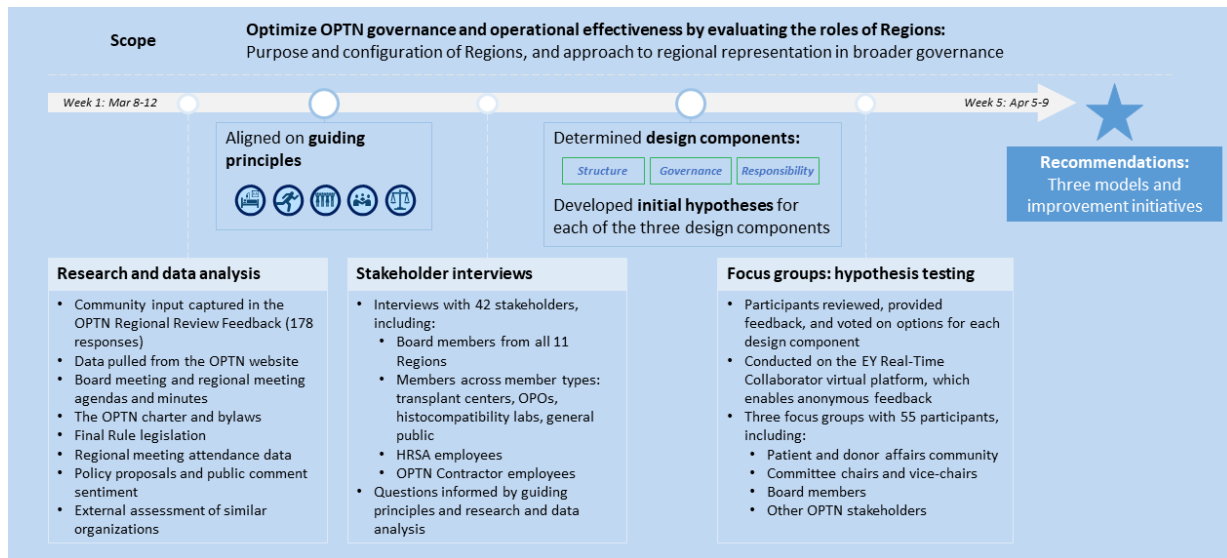


Background

The purpose of the OPTN Regional Review project³ was to optimize OPTN governance and operational effectiveness by evaluating the roles of regions in the OPTN structure.⁴ Planning for the OPTN Regional Review project began in 2019 and an initial request for community input on the role and purpose of OPTN regions was shared with the transplant community from June 29 – October 1, 2020.⁵ This questionnaire, called the OPTN Regional Review Feedback,⁶ asked respondents to describe the current OPTN regional structure; advantages and disadvantages of this structure; barriers and challenges that should be considered over the course of the Regional Review project; and to offer suggestions for designing a new approach.

In October 2020, the OPTN issued a Request for Proposal for a third party vendor to perform an independent, objective review and analysis of OPTN regional structures and processes. In February 2021, consulting firm Ernst and Young (the vendor) was selected to perform this work, which included a review of the OPTN Regional Review Feedback, as well as soliciting and collecting additional OPTN member opinions and comments on OPTN policy development, Board of Directors (BOD) and committee structure, and data reporting. The vendor completed the first phase of this work in April 2021 as outlined in **Figure 1**.

Figure 1. Overview of First Phase of Vendor Work



³ "OPTN Regional Review," OPTN, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/members/regions/optn-regional-review/>.

⁴ The current OPTN Contract requires the OPTN Contractor to "develop a plan to review and analyze the existing OPTN regional process for soliciting and collecting OPTN member opinion and comments on OPTN policy proposals. The Contractor shall objectively review the current process to determine strengths, weaknesses, and effectiveness of the current process in supporting OPTN policy development consistent with the OPTN final rule. The Contractor shall utilize technical experts in systems/operations design to evaluate the current process and develop a recommendation for continuing, changing and improving, or eliminating the existing regional process. The Contractor shall include with the recommendation a rationale supporting the contribution of the proposed process to ensuring OPTN policy is developed consistent with the requirements of NOTA and the OPTN final rule." Organ Procurement and Transplantation Network; HSH250201900001C: Task 3.3.3: Review of OPTN regional process.

⁵ "OPTN Regional Review: Community Input – Summer 2020 Public Comment," OPTN, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/media/4149/optn-regional-review-feedback-summary-summer-2020.pdf>

⁶ Ibid.

The vendor’s preliminary findings and options for the OPTN to consider were released with the *Update on OPTN Regional Review Project* request for feedback from August 3 – September 30, 2021.⁷ These options included three potential models for a new OPTN structure. The public was encouraged to provide feedback on advantages and disadvantages of these three models.

In October 2021, the vendor completed the second phase of their work and delivered their final report to the Executive Committee (enclosed in **Appendix 1**), including a review of the comments submitted on the request for feedback. Overall, comments indicated strong support for gathering with members within their geographic area for multidisciplinary discussions, with some support for redrawing regional boundaries to balance representation across the country.⁸ Additionally, comments highlighted the importance of promoting collaboration between transplant hospitals and OPOs that work together frequently. However, no clear consensus was reached on modifying the OPTN regional structure or restructuring the BOD and committees.

To determine next steps based on the vendor’s report, the Executive Committee took an informal survey to provide feedback on priority action items. The Committee reviewed the survey results in November 2021 and decided to establish two workgroups: one to develop recommendations on the regional nominations process, and one to develop recommendations on patient engagement within the OPTN.⁹ In December 2021,¹⁰ the Executive Committee developed the concept paper *Redesign Map of OPTN Regions*¹¹ to gather more detailed feedback from the community as to whether the regional map and corresponding regional representation on the BOD and committees should be modified. This report summarizes the public comment feedback received on the concept paper as well as the Executive Committee’s actions and recommendations to improve the operational effectiveness of the OPTN.

Concept Paper

Purpose

The concept paper served two purposes. First, the concept paper requested community feedback on the Executive Committee’s proposed options for modifying OPTN regions, including example maps to illustrate how regional boundaries could be redrawn to be more equal. Second, the concept paper delivered the vendor’s final report to the public.

Authority

The National Organ Transplant Act (NOTA) established the OPTN to maintain a national registry for organ matching and called for the network to be operated by a private, non-profit organization under federal contract. In 2000, HHS implemented the OPTN Final Rule establishing a regulatory framework for the structure and operations of the OPTN. Neither NOTA nor the Final Rule define regions, nor do they mention “regions” with regard to the OPTN BOD composition or other governance processes; however, the current OPTN Bylaws include a provision requiring the BOD to “include regional councilors who are

⁷ “OPTN Regional Review,” OPTN, accessed November 4, 2021, <https://optn.transplant.hrsa.gov/members/regions/optn-regional-review/>.

⁸ OPTN Executive Committee, Meeting Summary for October 26, 2021, accessed April 29, 2022, https://optn.transplant.hrsa.gov/media/10211026_executive-committee_summary.pdf.

⁹ OPTN Executive Committee, Meeting Summary for November 19, 2021, accessed April 29, 2022, https://optn.transplant.hrsa.gov/media/10211119_executive-committee_summary.pdf.

¹⁰ OPTN Executive Committee, Meeting Summary for December 5, 2021, accessed April 29, 2022, https://optn.transplant.hrsa.gov/media/10211205_executive-committee_summary.pdf.

¹¹ “Redesign Map of OPTN Regions,” OPTN, Concept Paper, accessed April 15, 2022, <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/redesign-map-of-optn-regions/>.

representatives chosen by the voting members and member electors of each of the 11 geographic regions in the United States.” The OPTN launched the Regional Review project pursuant to the current OPTN Contract, Task 3.3.3 Review of OPTN regional process.

Questions asked of the Community

The concept paper included several maps for consideration, including a map of the 11 current OPTN regions;¹² a map of the 10 U.S. Department of Health and Human Services (HHS) regions;¹³ three maps with 11 more equal regions; and a map each showing options for 8, 6, and 4 more equal regions. All of the maps pictured contiguous regions. With the exception of the current regional map, which splits Virginia across Region 2 and Region 11, all of the maps followed state boundaries. The maps depicting “more equal” regions were more equal than the current OPTN regions in terms of percentage of population, donors, OPTN members, recipients, and transplants.

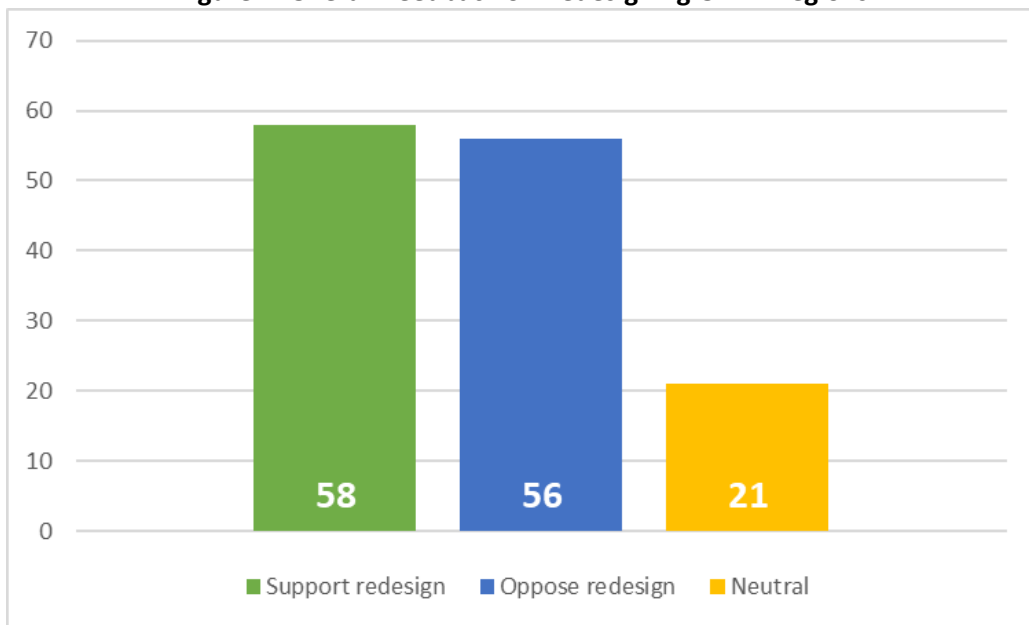
The Executive Committee requested feedback on the following questions:

- Which regional redesign map would best serve the OPTN or should the current map be maintained? Why?
- Which metric(s) should the OPTN consider for reconfiguring regional boundaries?
- Should the OPTN use one consistent regional design for governance, structure, and data reporting functions or select specialized regional designs for each? Why?

Summary of Public Comment Feedback

The Executive Committee received 135 comments on the concept paper. Comments were coded according to whether they were overall in support of a redesign, opposed to a redesign, or neutral, as pictured in **Figure 2**. The number of comments that supported redesign and opposed redesign were about equal, and about 15% of the comments were neutral.

Figure 2: Overall Feedback on Redesigning OPTN Regions

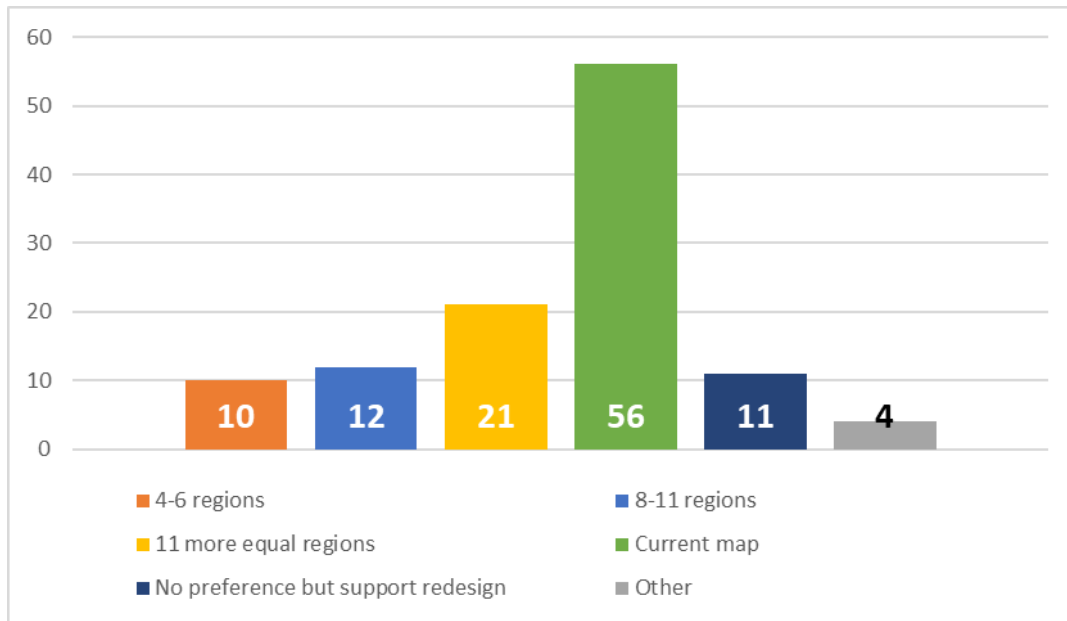


¹² “Regions,” OPTN, accessed April 29, 2022, <https://optn.transplant.hrsa.gov/about/regions/>.

¹³ “HHS Regional Offices,” U.S. Department of Health and Human Services, accessed April 29, 2022, <https://www.hhs.gov/about/agencies/iea/regional-offices/index.html>.

Most comments indicated either a preference for one of the maps featured in the concept paper, or a preference for the current regional map. More comments (56) indicated a preference for retaining the current regional map than any other option, as shown in **Figure 3**. Designing 11 more equal regions was the second most popular option, supported by 21 comments, followed by 8-11 regions with 12 comments, and 4-6 regions with 10 comments. About 20 comments expressed concerns about shifting to fewer, larger regions. Eleven additional comments generally supported redesign but did not indicate a preference for the number of regions, and four comments supported alternate options (two were in favor of greater than 11 regions, and two were in favor of creating 11 more equal regions as an interim step to 4 regions).

Figure 3: Feedback on Options for OPTN Regional Map



Themes in Comments

Public comment feedback covered many different topics, including the following themes:

- Support for retaining current regional map
 - Current system works well
 - Regions represent historic relationships that should not be disrupted
 - Size of regional meetings promotes collaboration and discussion
- Opposition to changing regional map
 - No value to changing regions/benefit is unclear
 - Changes would not improve representation
 - Changes would not advance OPTN strategic goals
 - Not clear it is worth expending additional resources
 - Concerns about timing
- Support for redesigning the regional map
 - Sensible for regions to be more equal based on proposed metrics
 - Current regions provide unequal representation
 - Opportunity for organizational improvement

- No rationale to current structure
- Regional design for governance, structure, and data reporting
- Number of regions
 - Support for 4-6 regions
 - Concerns about fewer, larger regions
 - Support for 8-11 regions
 - Support for 11 more equal regions
 - Support for 11 more equal regions as an interim step to 4 regions
 - Support for more than 11 regions
- Recommended changes to map
- Feedback to consider if changing the map
 - Preserve representation
 - Recommendations for re-drawing boundaries
 - Metrics to use if changing the map
 - Displaying map in public comment proposal

All of the comments received are provided in **Appendix 2**, organized by theme.

Support for retaining current regional map

About 20 comments indicated support for retaining the current regional map. Common themes were that the current system works well and there is no need to fix a system that is not broken; regions represent historic relationships that should not be disrupted; and the current regional map facilitates regional meetings that are a good size for promoting collaboration and discussion. Some respondents felt that they have good collaboration within their regions and worry that changing regional boundaries will interfere with relationships that have been built over the years.

Opposition to changing regional map

Over 50 comments either opposed changing the regional map or expressed uncertainty as to whether changing the regional boundaries would provide value or benefits over the current regional map, particularly since the regions are no longer tied to allocation. Other common themes included concerns that changes would not improve representation; changes would not advance OPTN strategic goals; and that this is not the appropriate time to change regions. Some comments indicated that the OPTN should not expend resources on redesigning regions as there is no clear benefit to patients, and the OPTN should instead focus on its strategic goals, like increasing the number of transplants. Region 6 in particular was opposed to changing the regional map given the unique geographic constraints of their region, which includes both Alaska and Hawaii, as the proposed maps in the concept paper would greatly expand the size of their region. Region 6 members thought that making their region larger would dilute their voice within the OPTN and impose additional challenges for regional meetings by requiring longer travel distances and consideration of additional time zones. Some comments indicated that now might not be the appropriate time to make large changes to OPTN regions, given the ongoing shift to continuous distribution allocation systems and recent regulations from the Centers of Medicare and Medicaid Services that may re-shape the donation service areas of organ procurement organizations.

Support for redesigning the regional map

About 30 comments expressed support for redesigning the regional map. Common includes general support for redesign (e.g., it is time to change the maps), support for regions to be more equal based on the proposed metrics, support for redesign as an opportunity for organizational improvement, and concerns that current regions do not provide equal representation and there is no rationale to the current structure. Comments indicated that since regions are no longer used for allocation, a redesign would allow the OPTN to optimize regions for their current purposes, namely, bringing members together to collaborate at regional meetings and to promote dialogue and feedback. Region 5 in particular supported redesigning the regional map to make California its own region and better equalize the regions by population-based metrics.

Regional design for governance, structure, and data reporting

Of the 9 comments received regarding whether different regional designs should be considered for governance, structure, and data reporting, most comments (5) supported one consistent regional design, though one comment suggested that data reporting should ideally be more fluid. Two comments questioned whether a regional design is necessary now that regions are not used for allocation.

Number of regions

About 65 comments provided feedback on the number of regions, including 10 comments in support of 4-6 regions; 20 comments expressing concerns regarding fewer, larger regions; 12 comments in support of 8-11 regions; 14 comments in support of 11 more equal regions; 2 comments in support of 11 more equal regions as an interim step to four regions; and 2 comments in support of having more than 11 regions. There were five additional comments regarding the number and size of regions.

Members who supported 4-6 regions said that those maps were more aligned with current allocation practices, and that it would be more cost efficient for the OPTN to hold fewer regional meetings. These members indicated that virtual attendance options could mitigate travel challenges associated with larger regions. Members who opposed fewer, larger regions were concerned about losing regional representation on the Board of Directors, “diluting” regional representation, and the additional logistical challenges of in-person meetings with attendees traveling longer distances or crossing multiple time zones. Members who supported 8-11 regions thought that these maps struck a balance between updating boundaries to reflect changing working relationships without causing too much disruption to existing relationships. Members who supported 11 more equal regions thought that this approach would allow for updates to the regional boundaries while maintaining the same level of regional representation and keeping the regions a reasonable size.

Recommended changes to map

Four comments provided specific recommendations for changes to the regional map. One comment recommended placing New Mexico in the same region as Colorado and Arizona, as many patients travel from New Mexico to those states to receive transplants. Currently, New Mexico and Arizona are both in Region 5, but Colorado is in Region 8. Similarly, one comment recommended placing Utah, Idaho, and Wyoming in the same region as many patients travel from Idaho and Wyoming to Utah for transplant. Currently, these states are in three different regions. One comment said that Region 5 is too big and California should be its own region. Finally, one comment said that northwest Indiana should be in the same region as Illinois to consolidate the Chicagoland area in one region.

Feedback to consider if changing the map

About 60 comments, including comments that supported, opposed, and were neutral regarding whether the map should be redesigned, provided feedback for the Executive Committee to consider if moving forward with the redesign. Common themes included not reducing regional representation on the Board (14 comments); ensuring there is a voice for minority populations (6 comments); suggestions for re-drawing boundaries, including metrics (16 comments), administrative factors (4 comments), travel and meeting logistics (6 comments), and number of states within a region (4 comments); and how to display a new proposed map if a public comment proposal is forthcoming (2 comments).

Preserve representation

Many comments emphasized that if the map of OPTN regions changes, then the OPTN should preserve regional representation on the BOD. Comments indicated that if the OPTN reduces the number of regions, then the OPTN should consider providing regions more than one representative to the BOD so that regional representation on the BOD is not reduced. Respondents were concerned that reducing the number of regional representatives would dilute the voice of pediatric representatives and rural OPTN members who serve larger geographic areas. A few comments suggested increasing the number of regional representatives provided to existing regions to improve representation, rather than changing the boundaries of the regions. One comment provided additional suggestions for improving representation without changing regions, including implementing term limits for committee and BOD service (with exceptions for points of view with a limited pool of representatives, like intestinal transplant surgeons), creating “early career” positions for each committee similar to the structure of the AST Communities of Practice, or creating another pipeline program for members to explore participation without directly appointing them to Committees.

Additional comments emphasized the importance of ensuring there is a voice for underrepresented populations, including rural communities; American Indian/Alaskan Native populations; disadvantaged patient populations; patients, donors, and donor families broadly; and smaller transplant centers and OPOs.

Re-drawing boundaries

Several comments offered suggestions for metrics and administrative and logistic factors to consider if re-drawing the regional boundaries. One comment suggested following state lines, whereas a few comments suggested following OPO donation service area boundaries. Comments recommended considering ease of travel (e.g. airport access) across large distances, and to avoid crossing multiple time zones to facilitate meeting scheduling. While some members of Region 5 supported making California its own region, other respondents recommended grouping multiple states together to encourage collaboration. Members of Region 2 emphasized that the Washington, D.C., metropolitan area should remain in one region as it is today.

Respondents suggested considering the following metrics:

- Population as a proxy for patients with end stage organ failure with limited access to waiting list
- Number of transplant candidates and transplant recipients
- Pediatric transplant candidates, pediatric transplant programs, and pediatric transplants performed over a 1-3 year period
- Number of transplant programs
- Number of OPOs
- Working relationships between transplant programs and OPOs

- Regional meeting attendance
- Regional characteristics, including:
 - Population density
 - Socioeconomic factors
 - Waitlist access for vulnerable populations
 - Similarity in patient demographics
 - Patient referral patterns
 - Types of specialty centers available
 - Transplant program and OPO performance
 - Allocation and organ acceptance patterns
 - Geographic challenges (e.g. transport times)

Comments also recommended showing the distribution of pediatric transplant centers as well as transplant programs by organ type for any new map proposed by the Executive Committee.

Action Items

Based on feedback received throughout the Regional Review project, the Executive Committee identified actions to improve OPTN governance. The OPTN has already taken action on the following:

- Standardize regional meeting agendas
- Improve access to meetings by adopting hybrid format (both in-person and virtual attendance)
- Clarify how sentiment and public comment feedback are used during regional meetings
- Provide education opportunities for public comment proposals and policy implementation
- Increase cross-committee collaboration prior to public comment

Moving forward, the Executive Committee has directed the OPTN to:

- Add collaborative sessions and discussions at regional meetings
- Enhance OPTN data dashboards

The workgroups sponsored by the Executive Committee on patient engagement and the regional nominations process met from February – April 2022. Additional action items based on the workgroup recommendations are summarized below.

Patient Engagement

The recommendations of the Patient Engagement Workgroup are enclosed in **Appendix 3**. The Executive Committee has directed the OPTN to:

- Include at least two patient and donor affairs representatives on each OPTN policy development committee beginning with the 2022-2023 committee term starting on July 1.
- Update the OPTN patient information letter¹⁴ to inform patients about opportunities to volunteer with the OPTN at the time of registration on the waiting list for transplant.
- Explore options for sponsoring patient travel to regional meetings, either via the OPTN or OPTN members, in a way that is consistent across regions

¹⁴ OPTN Patient Information Letter, accessed April 28, 2022, https://optn.transplant.hrsa.gov/media/2921/optn_patient_info_letter.pdf.

Regional Nominations Process

The recommendations of the Regional Nominations Workgroup are enclosed in **Appendix 4**. The Executive Committee has directed the OPTN to disseminate the recommendations to the regional and Board nominating committees in advance of the 2023-2024 nominations cycle. In particular, the Committee agrees that regional councillors and associate councillors should recruit new volunteers and develop leaders within their regions. To advance that aim, regional councillors should provide more feedback to individuals who volunteer for committee service as to why they were not selected and how they can improve their chances of being selected in the future. To support the regional councillors in this effort, the OPTN should seek more detail from volunteers regarding their interests so that the regional councillors have a smaller pool of stronger candidates to consider for each open position. The Committee holds that hybrid meeting options may help increase attendance from those less involved with the OPTN but also emphasized the importance of in-person meeting attendance so that prospective volunteers can introduce themselves to regional representatives and members of the regional nominating committees.

Regional Map

The Executive Committee recommends retaining the current regional map for now as public comment feedback highlighted the importance of having a regional structure that reflects working relationships between OPTN members, and the value of maintaining existing regional representation. Comments indicated that the current regions represent historic working relationships that should not be disrupted at this time. The Committee agrees with comments noting that allocation practices will continue to change as each organ-specific committee considers shifting to a continuous distribution allocation framework, so now may not be the right time to adjust regional boundaries. However, the Committee noted that data following implementation of continuous distribution allocation systems may indicate that working relationships are shifting, and that updates to regional boundaries would be appropriate to enhance regional collaboration. Accordingly, the Committee resolved to commit to a regular review of the regional map boundaries based on the most current available data, with the first review to take place by April 25, 2025.¹⁵

Conclusion

Based on feedback received throughout the Regional Review project, the Executive Committee has directed the OPTN to take several actions to optimize OPTN governance and operational effectiveness, including actions to enhance patient engagement across the OPTN and to promote consistency, transparency, and fairness in the regional nominations process. The Executive Committee recommends maintaining the current regional map for now but will review the regional boundaries again no later than April 2025.

¹⁵ OPTN Executive Committee, Meeting Summary for April 25, 2022, <https://optn.transplant.hrsa.gov/about/committees/board-of-directors-executive-committee/>.

Appendix 1: Vendor's Final Report

OPTN REGIONAL REVIEW

Vendor's Final Report

October 2021

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Preface

The project team has collaborated with the United Network for Organ Sharing (UNOS), to analyze public sentiment commentary in response to the OPTN Regional Review – Preliminary Recommendations, which were submitted in May of 2021. The public comment received came from a variety of stakeholders including regions, committees, procurement organizations, OPTN board members and patients. This preface reflects the input received from public comment and represents the final recommendation on regions for OPTN consideration.

Public Comment Themes

The public comment was consistent with the initial observations in the preliminary report, and broadly re-enforced the assessment performed during the spring of 2021. EY has identified common themes from public comments of UNOS stakeholders to guide the future definition of governance model. Overall, members support adjustments to structure and governance but stress careful, fact-based analysis before implementing changes. Any changes should be made with guiding principle of increased transplants / donations at its core.

Theme from Comment	Description
 <i>Maintain a Region-based grouping format</i>	Regional structures and cohorts overwhelmingly supported
 <i>Integrate geography and interest groupings (hybrid)</i>	Support exists for the incorporation of national interest committees to sustain regional groupings
 <i>Redraw geographic bounds</i>	General agreement exists regarding the imbalance of number of transplant centers covered
 <i>Ensure the Board has a representative makeup</i>	Members seek to have a Board ensuring representation for all members
 <i>Promote allocation equity</i>	Desire to create equitable transplant access across regions and differing populations
 <i>Fortify a voice for minority members</i>	Often, members of less dominant groups feel disengaged from discussions
 <i>Prevent communication silos</i>	Concern exist over possible communication silos for solely interest based grouping
 <i>Continue engagement and education at meetings</i>	Members re-iterate the importance of continued engagement at regional gatherings

The public comment can be classified into themes, which have been grouped in the following categories:

Structure

	Regions	Committees	Procurement Organizations	OPTN Board / Committee	Patients
Total Entries	10	8	3	4	4
Maintain a Region-based grouping format					
Integrate geography and interest groupings (hybrid)					
Redraw geographic bounds					

Public comment themes by stakeholder group

- **Maintaining geographic groupings:** Stakeholders feel confident in the benefits of regional groupings. According to the public comment, gatherings within regions allow for communication during member meetings, and create the opportunity for multiple stakeholders to have a voice.
- **Combine geographic and interest groupings:** The hybrid cohorts structure was best received in the public comment, with respondents noting support in being able to join like-minded regional groups. Since geography dictates certain variables (transplant time, wait list practices), stakeholders who are proximate geographically share interests and should have a voice to express geographic concern.

- **Redraw geographic bounds:** Members appreciate that Regional boundaries seem arbitrary and need updating from model developed more than 30 years ago, given the widespread consensus that exists in the discrepancy of number of transplant centers in each region.

Governance

	Regions	Committees	Procurement Organizations	OPTN Board / Committee	Patients
Total Entries	10	8	3	4	4
Representative Board makeup					
Allocation Equity					

Public comment themes by stakeholder group

- **Ensure the Board has a representative makeup:** Members emphasize the importance of having a board that is representative, giving all the member representatives a voice in voting for policies and raising issues. However, comments appear split on what the appropriate size of the Board is moving forward. While several comments noted that the board is very large, others maintain that the large size of the board is necessary to ensure accurate representation of regions and interests.
- **Promote allocation equity:** Strong sentiment exists for creating an equitable system for organ allocation, reducing waitlists, and promoting patient outcomes. Patients and OPTN board members showed the most interest in the topic within the public comment.

Responsibility

	Regions	Committees	Procurement Organizations	OPTN Board / Committee	Patients
Total Entries	10	8	3	4	4
Voice for minority members					
Concerns for communication silos					
Engagement and education at meetings					

Public comment themes by stakeholder group

- **Fortify voice for minority members:** Concerns exist amongst members that the current structure overshadows the voices of members such as patients or committees in favor of transplant surgeons and other physicians. National interest cohorts are welcomed as a solution for these members to have a space for discussion and representation.
- **Prevent communication silos:** Some members reflected in the public comment their concern over creating siloes if interest cohorts completely replaced the regions. Members within regions and committees agreed on the importance of retaining geographical segmentation to avoid these siloes.
- **Continued engagement and education at meetings:** Meetings create engagement of the different stakeholders and are viewed by members as opportunities for all to be educated. Committee and patient participant appear to be most excited by educational and engagement opportunities

Together, these themes all map closest to **Archetype 3, Hybrid Cohorts**, supporting the recommendations around the structural maintenance of regions, and introduction of interest cohorts to help prevent communications silos.

The one substantial deviation from the recommendations around archetype 3 in the main report (see below, page 15) concerns governance. The comment supports the continuation of the Policy Oversight Committee rather than a replacement governing body (described as an elected “Policy Council”).

Change Principles

The proposed changes introduced by the working team in this report should follow a certain principles or guidelines to abide by to make the introduction of any modifications as smooth as possible. These change principles include:

- **“Do no harm”:** Governance structures and initiatives that are currently functioning should be maintained
- **Gradual change:** Modifications should be implemented gradually rather all at once, in order to prevent disruptions within the organization
- **“Strawman” Proposed map:** A proposed recommendation of a single new map (rather than a series of maps) may elicit clearer directional feedback on final structure
- **Change Champions:** Identify advocates from within the stakeholder population who can help communicate change and take ownership of adoption

Next Steps

Over the past months, the working team has conducted activities such as aligning on common themes, devising no-regret initiatives, and determining the most fitting archetype. Considering the feedback received in the public comment as well as the change principles that have been identified, the working team believes that there are tangible next steps that can be taken by leadership to finalize a region structure:

1. **Determining the structure for the new regional breakdown:** The most critical factors to reallocate regions must be established, and metrics including number transplant centers, volume of transplants, and population should be considered among others. Reorganization of regions should emanate from a teleological framework and consider all guiding principles, as well as possibility of increasing number of transplants and donors.
2. **Conduct in-depth geographic analysis in anticipation of re-drawing regional boundaries:** These include population and demographic shifts, impacts of the new allocation model in OPO/transplant program working patterns, as well as creating evenly distributed regions.
3. **Finalizing the preferred hybrid structure and how communities of interest can integrate better into regional settings.**
4. **Determine the final impact of region number or boundaries for Board structure:** This would answer the question of would the size of the Board should be larger, smaller or remain the same.
5. **Develop a change management framework for transitioning to the selected model:** Other issues included in this framework would address communication and identification of stakeholder change champions.

Introduction

The Organ Procurement and Transplantation Network (OPTN) and the broader donation and transplant community, as well as the allocation policies, principles and practice of organ transplantation, have evolved significantly since the OPTN Regions were created in 1989. To modernize and streamline its governance structure and processes, the OPTN is leading the Regional Review to analyze the roles of Regions and recommend changes. The OPTN engaged a third-party vendor, Ernst & Young, LLC (EY), to review and analyze the OPTN regional structure and processes. The project team analyzed numerous sources of information¹⁶ to develop the following series of recommendations for the OPTN Board of Directors and members to consider.

Vision of this project. The previous and ongoing implementation of new organ allocation rules creates an opportunity to transform the role of the OPTN Regions. This new OPTN governing construct should promote transparency and accountability, support inclusivity and equity, and enhance communication channels while delivering consistent and efficient operational support for organ transplantation across the United States. This concept paper includes three proposed archetypes that transform the scope and composition of the OPTN Regions in the future. Each of the three archetypes seeks to address challenges in the regional structure today while retaining strengths and benefits:

Archetype 1, Communities of Common Interest, replaces Regions with like-interested communities while maintaining policy sentiment gathering and Board representation

Archetype 2, Repurposed Regions, resizes and redraws geographic boundaries, elevates policy to national forums, and focuses regional responsibility on operational effectiveness

Archetype 3, Hybrid Cohorts, maintains regional cohorts for practitioners while grouping non-practitioner members by interest, replacing an appointed policy committee with an elected one

Additionally, there are functional improvements OPTN can make irrespective of final decisions regarding the configuration and scope of any new governing construct. These initiatives aim to improve representation, communications, operations, process, and data.

Guiding Principles

UNOS and the project team collaborated to align on guiding principles for the future state design. These guiding principles assisted the project team in establishing a shared understanding of the purpose and intent of any governing construct of the OPTN, such that the regional or alternative organizing structure would improve the function of the network. The three proposed archetypes incorporate design elements reflective of the chosen guiding principles.

¹⁶ Data sources include: OPTN community input captured in the OPTN Regional Review Feedback, data reports pulled from the OPTN website, Board meeting and Regional meeting agendas and minutes, the OPTN charter and bylaws, Final Rule legislation, Regional meeting attendance data, policy proposals and public comment sentiment, as well as external assessment of similar organizations

Through primary research and interviews with UNOS staff and OPTN Board members, the project team identified five guiding principles for the OPTN Regional Review Project:



Maximize Benefit – Increase the number of and access to transplants, improve patient outcomes and promote safety for donors and recipients

Accountability and Effectiveness – Advance the mission of the organization transparently and with accountability and develop, promulgate, and govern policies that ensure quality, efficiency, effectiveness, and consistency in membership, data analysis, and operations

Community Engagement – Bring together medical professionals, transplant recipients, and donor families; promote professional networking and community education

Inclusive Participation – Provide a meaningful voice within OPTN to all stakeholders, inclusive of transplant professionals, recipients, and donor families, reflective of the diversity of the population

Allocation Equity – Promote equitable organ allocation to patients registered on the national waiting list, based on need, demographics and geography

Focus group sessions with OPTN members captured sentiment regarding the relative importance of the guiding principles. Overwhelmingly, focus group participants felt that **Maximize Benefit** should be the most important principle driving regional transformation, followed by **Allocation Equity** and **Accountability and Effectiveness**. Focus group participants felt that the new constructs should advance the OPTN mission and purpose, while continuing to bring together the community and provide members a voice in policy.

Because Regions no longer have direct influence in organ allocation,¹⁷ the frequency at which **Allocation Equity** was identified as an important principle may seem at odds with the current policy and practice. However, focus group participants repeatedly emphasized that serving patients, and pursuing equity on their behalf, is the primary purpose of OPTN and that this mission should continue to be promoted by local level governance. Each of the three archetypes proposes ways to harness local engagement to promote the national mission of the OPTN.

Background and assessment of current state

Understanding OPTN Regions today

Membership by Region today

Congress passed the National Organ Transplant Act in 1984, which called for a national network to coordinate the allocation of organs and collect clinical data about organ donors, transplant candidates, and transplant recipients. The United Network for Organ Sharing (UNOS) was awarded the initial contract in 1986. In 1989, eleven Regions, which were created from groupings of Donation Service Areas (DSAs), were established to help determine the allocation sequence of abdominal organs.

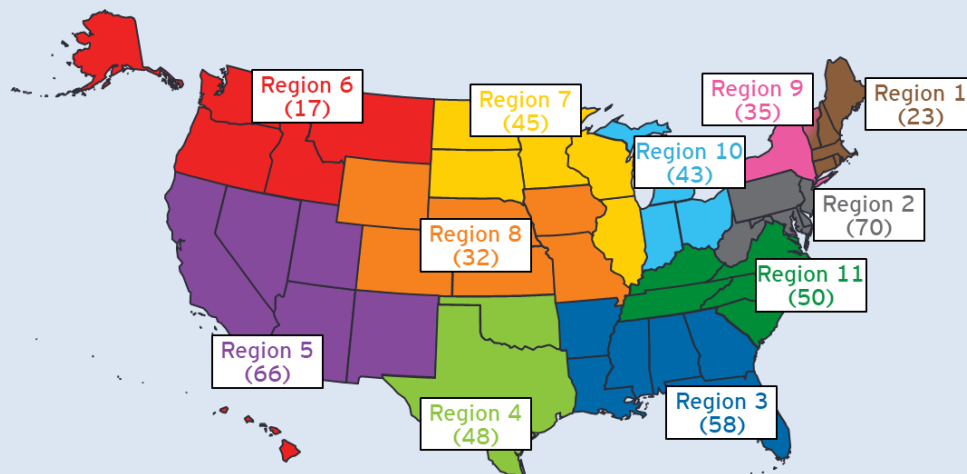
These regional boundaries reflected patient referral and organ sharing patterns when they were created. Since that time, some regional boundaries have been adjusted to account for new relationships between Organ Procurement Organizations (OPOs) and transplant centers or to balance populations. Regions are not uniform in size or population.

DSAs and Regions largely determined U.S. organ allocation until recently, as revised policies have been implemented to bring allocation in compliance with the final rule implemented by HHS in 2000.¹⁸ These revised policies have effectively removed DSAs and regional boundaries as factors that guide organ allocation.

¹⁷ “Policy Notices”, *Organ Procurement and Transplantation Network*, optn.transplant.hrsa.gov/governance/policy-notice

¹⁸ National Organ Transplant Act, 42 U.S.C. § 273 (2000). [ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-K/part-121](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121)

As of April 2021, there were 488 registered active members of OPTN, divided into eleven Regions (numbers in parentheses are the total count of registered members within each Region). Each Region has a representative serving on the OPTN Board of Directors and on most committees to ensure thorough consideration of how transplant policy may affect people and institutions in the United States.



Observations on the primary functions of Regions: initial data review

On its website, OPTN describes the primary functions of OPTN Regions to be the following:¹⁹

Representation

- Electing Regional Councillors who represent and convene their constituents at regional meetings, as well as serve on the OPTN Board of Directors
- Electing regional representatives on OPTN Committees
- Staffing regional heart review boards

Communication & Feedback

- Hosting biannual member meetings in each Region to express feedback on policy proposals and conduct other OPTN activities as a Region

Operations

- Creating policy variances to support special allocation and operational situations for specific Regions

Data Analysis

- Describing geographic differences in transplant data at the regional level

Regions vary in effectiveness at performing their core functions. In the summary report titled OPTN Regional Review Feedback,²⁰ “Representation” was commonly mentioned as an advantage of the OPTN regional structure. Members responded that “this structure allows regional differences to be represented and ensures voices from across the country are heard.” However, other members disagreed and reported that “there is a lack of community and patient engagement in the current structure.” Regions today provide a channel for members to connect to OPTN, but not all participants feel welcome or encouraged to participate, especially new attendees and non-medical professionals.

Effective representation today is complicated by the process of casting sentiment about policy, and how sentiment is ultimately incorporated in decision-making. Currently, Regions discuss and debate policy, then call a “vote” to aggregate collective sentiment of the Region. These “votes” are registered in aggregated public comment on a policy and considered by sponsoring committees. Regional Councillors are not obligated to vote on a policy according to regional sentiment; in fact, fiduciary responsibility to the Board and OPTN can sometimes demand

¹⁹ “OPTN Regional Review”, *Organ Procurement and Transplantation Network*, optn.transplant.hrsa.gov/members/regions/optn-regional-review.

²⁰ OPTN issued a request for community input on the Regional Review Project in Summer 2020, which is summarized in the report: *Organ Procurement and Transplantation Network. (2020), OPTN Regional Review Feedback*, optn.transplant.hrsa.gov/media/4149/optn-regional-review-feedback-summary-summer-2020.pdf

that Councillors vote in opposition to regional sentiment. The general public may also post public comments through the UNOS website or via email, which results in some members expressing and amplifying their opinions through additional channels. Sponsoring Committees consider all public comments; there is no counting or weighting of sentiment. However, the process sows confusion because members incorrectly believe that they are casting an actual vote in regional meetings and providing direct influence on policy outcomes.

Although Regions are effective in communicating with members and creating a community of professionals, there are still existing gaps in communication and feedback. Two benefits echoed repeatedly in [OPTN Regional Review Feedback](#) were that Regions facilitate relationship-building and sharing of best practices. Several members indicated that communication and collaboration with colleagues does not happen frequently, effectively, or consistently, often due to a packed agenda focused on presenting policy with little time for open discussion. Overall, Regions serving as a forum for member engagement is seen as a core strength of today's Regions; however, the consistency and effectiveness of regional meeting execution is a challenge.

Regions could perform better regarding policy implementation guidance and operational effectiveness. Although one stated responsibility of Regions is to create policy variances that reflect regional differences, this topic was not mentioned in [OPTN Regional Review Feedback](#). Conversations with UNOS staff indicate that this practice has decreased over time. Feedback comments, however, voiced frustration with “cookie-cutter” approaches of OPTN policies, both across Regions where geographic differences exist and within Regions where needs of patients, transplant centers, and OPOs may vary due to local demographic and other perceived differences.

There is an opportunity to track performance at a regional level. Data provided on OPTN's website is robust and easy to access, and reports can be pulled by Region. However, there was little mention of how effectively Regions analyze or use data in [OPTN Regional Review Feedback](#). Reviewing regional data did not appear to be a priority for participants in this review. Multiple members expressed that Regions have an opportunity to better use data to “show where transplant hospital[s] and OPOs could improve in terms of performance.”

Stakeholder interview themes

The project team conducted interviews with various stakeholders to better understand the benefits and challenges of the current regional structure. The team spoke with HRSA and UNOS employees and OPTN Board members, which included members from all Regions representing transplant hospitals, OPOs, histocompatibility labs, and patients and living donors. These interviews offered a wide variety of perspectives across Regions and member types to provide a holistic picture of the current structure.

Interview questions were loosely structured around the four primary functions of OPTN Regions: (1) representation, (2) communication and feedback, (3) operations, and (4) data analysis. Themes captured in these interviews, highlighted below, informed initial hypotheses and final design of the proposed archetypes.²¹

Representation

Interviews reiterated that Regions offer members a way to participate in OPTN, but they are less effective in ensuring active participation of *all* members.

The project team observed three categories of challenges in representation:

Dissimilar views within Regions: Members with different perspectives within Regions often struggle to be heard. This is specifically a challenge faced by patients and donor families, as well as smaller centers or programs with fewer staff who regularly attend meetings.

Barriers to participation and involvement: Several participation barriers include logistical or financial barriers (mainly related to travel), lack of transparency around committee involvement, and obstacles to understanding and feeling comfortable expressing opinions on highly technical topics.

Inclusivity challenges: Regions, national OPTN committees, and the Board struggle to reflect the racial and gender diversity of the transplant donor and recipient population. Difficulty getting patients and donor families to be more involved on a regional level is a contributing factor. It is also challenging for junior clinicians to find ways to meaningfully participate on committees and other forums and initiatives, as they frequently switch Regions early in their careers.

²¹ Further detail, including specific insights captured in the interviews, can be found in the [Appendix](#).

Communication and Feedback

Members frequently shared that Regions are most helpful as a forum for networking and community building with colleagues in their geographic area:

Community building and networking: Regional meetings promote strong working relationships, but newcomers often have difficulty navigating meetings, as people who know each other tend to congregate. Additionally, recent changes in allocation rules have realigned some working relationships, such that transplant centers are often working with OPOs outside their Region. There were mixed perspectives on effectiveness of Regions, particularly around feedback and communication pertaining to policy. Responders expressed that communication often seems one-directional, in that OPTN reports out to members without much two-way dialogue and Regions rarely communicate with members outside of formal meetings.

Highly technical topics: Policy topics, which dominate the meeting agenda, can be highly technical and esoteric. This creates another barrier to inclusive discussion for non-clinical stakeholders. For clinical stakeholders, if the topic is outside their focus area, they can find discussion boring (e.g., an abdominal transplant surgeon attending a presentation on HLA lab policy) and subsequently disengage.

Operations

Discussions about effectiveness, structure, and activities within Regions revealed several ways in which Regions could be better organized and better serve members:

Regional boundaries: Many commentators reported how arbitrary regional boundaries had become since the new allocation rules were put in place.

Inconsistent meeting practices: Members shared anecdotes on pre-meeting activities at their own regional meetings, such as collaboratives to discuss implementation challenges or breakfasts for specific member types that precede the official meeting. These practices are not standardized across Regions. This finding led to the observation that some Regions may have more effective meetings than others, presenting an opportunity for OPTN to provide consistency in governance.

Unaddressed implications of the national organ sharing system: Members stated their concerns about applying fully standardized approaches to a national organization with vastly different challenges across geographies. In addition, they felt that policy implementation is not discussed as much as it should be.

Data Analysis

Regions can better use data in support of OPTN Strategic Goals. The following theme emerged across interviews:

Inconsistent data analysis and interpretation: Many interviewees struggled to articulate if and how Regions use data at all. Some shared examples of dashboards being used to monitor performance in specific Regions, but most expressed that across Regions, there is no universally accepted way to leverage metrics.

Initial hypotheses: three design levers

Methodology

The process of designing alternative regional models begins with identifying unique design levers that may define a new regional construct. The five guiding principles informed three overarching questions about the future role and responsibility of the Regions:

Community Engagement – How do we organize members into smaller forums to achieve more effective participation?

Participation and Allocation Equity – How do we ensure all members have a voice in policy?

Maximize Benefits and Accountability and Effectiveness – How should Regions (or an alternate construct) serve members and enable OPTN's strategic goals going forward?

These questions informed the three design levers: *Structure*, *Governance*, and *Responsibility*. For each of these levers, the team identified current deficiencies of the Regions to be addressed and benefits to preserve. Initial hypotheses consisted of multiple alternative options for each design lever. The team then solicited feedback on these options to inform the creation of three recommended archetypes.

Structure: How do we organize members into smaller forums to achieve more effective participation?

Effectively organizing the large member population into smaller forums will be key to successful governance regardless of the role Regions assume going forward.

In the context of regional design, structure refers to the number and physical boundaries of Regions, in addition to the organization of members into forums of communication and association. The structural lever is especially critical given the size and diversity of OPTN membership. Currently, OPTN membership includes more than 480 institutional members, many of which have dozens of staff attending regional meetings, along with many individual and business members who also actively participate.

In [OPTN Regional Review Feedback](#), many members voiced opinions about the existing delineation of Regions. A substantial portion of feedback concerned the guiding principle of Community Engagement, which was perceived by some to be inconsistent and sometimes ineffective in terms of policy development and information sharing. This feedback together with Board interviews revealed benefits and drawbacks of the regional structure.

In summary, benefits of the current structure included:

- Regional meetings encourage meaningful discussion, which both fosters long-term relationships across the field of transplantation and yields better policies through debate;
- Regional structure ensures geographic representation to OPTN Board and committees; and
- OPTN is the only organization in the transplant discussion that brings together perspectives across procurement and transplantation.

The following drawbacks of the current structure were also noted:

Existing boundaries of Regions do not encourage cross-regional relationships;

Regional meetings are overwhelmingly attended by transplant surgeons and are often dominated by the same voices; and

The current geographic representation model doesn't reflect differences in population density or the number of transplant centers across Regions.

Virtual meetings provide opportunities to improve community engagement and imply that geographic proximity may not need to be a structural driver of OPTN governance in the future.

Analysis of attendance reports for the three most recent regional meetings²² showed a 37% increase in total attendance from in-person to virtual regional meetings across the eleven regions. Even more noteworthy was the 106% increase in patients and donor families, voices often under-represented at in-person regional meetings. More than 2000 individuals attended Winter 2021 virtual regional meetings, validating the importance of maintaining a forum for members to engage and voice opinions. It also indicates that virtual meeting options could encourage greater participation and involvement than the traditional in-person regional meeting structure.

Governance: How do we ensure all members have a voice in policy?

Regional governance reform presents an opportunity to enhance inclusivity and equity in OPTN elections, policymaking, and member participation.

Whereas the structure lever applies to organizing a large group into more manageable forums, the governance lever seeks to ensure forums have opportunity to contribute to policy proposals. As per the Final Rule, voices of the entire transplant community should be considered in developing policy, including voices which reflect the diversity of the impacted population. The current regional governing system is complex and has been challenged by some members²³ as lacking accountability and transparency. Board interviews helped to raise and clarify the benefits and shortcomings of the current governance elements of OPTN regional participation.

In summary, the benefit of the current governance model, echoed in most interviews, was that OPTN members generally seem satisfied by committee representation of regional interests and expertise in developing policy.

The following drawbacks of the current governance model were also noted:

²² Charts and key takeaways from the attendance reports of the Winter 2020, Summer 2020, and Winter 2021 Regional meetings can be found in the [Appendix](#).

²³ It should be noted that in issues of governance, some interviewees struggled to separate challenges with broader Board and OPTN governance from region-specific governance. This may point to a need for a broader review of governance across OPTN which is not in the scope of this assessment.

- Regional Councillors who hold Board seats are perceived as advocates for regional interests, partially because of the practice of “voting” on sentiment at regional meetings. This conflicts with their fiduciary responsibility as a Board member to represent the entire OPTN membership;
- The nomination and election process to the Board and appointment process to committees lacks transparency, and may be impeding new members from getting involved;
- The regional “casting of sentiment” resembles a vote but in fact does not govern policy. This process confuses some members and adds to the impression of opacity in current governance.
- Regional policy discussions end with the “casting of sentiment,” but there is little to no communication back to the Regions pertaining to either the rationale behind a final Board vote on a policy or how members should implement that policy; and

Analysis of Public Comment sentiment validated interview responses indicating that some voices are more prominently heard than others.

The project team analyzed three policies²⁴ across 2019-2020 to better understand how sentiment is captured in regional meetings and compare this with general public comment. The overall sentiment of Regions appears nearly identical to sentiment from transplant hospitals, which indicates that transplant hospital voices may dominate the record of sentiment on a regional level. Because of the relative volume of these comments, perspectives of other members such as OPOs, histocompatibility labs, and patients and donor families may be overshadowed. The latter three groups combined account for fewer than half the participants of transplant hospitals at regional meetings. Public comments appear to capture more varied perspectives; however, participation in the public comment process is low relative to participation in regional meetings. Analysis also revealed that some members registered sentiment in multiple places: at regional meetings, through the web-based public comment platform, and in committee meetings. This could appear to be an attempt to stack the deck with “votes” on a policy position, even though committees weigh the body of public commentary by counting comments in favor or against a particular aspect of policy. Taken as a whole, these issues suggest an opportunity to transform how Regions apply governance of public comment to become more transparent and inclusive.

Responsibility: How can these smaller forums serve members and enable OPTN’s strategic goals?

Our final lever, responsibility, seeks to define the purpose of the Regions going forward, and to what extent it should be driven by the guiding principles of *Maximize Benefit and Accountability and Effectiveness*.

As noted above, with the evolution of Regions away from historical responsibility over allocation, this project was launched to validate or transform the identity of OPTN Regions. The project team observed a potential disconnect between the current purpose and function of Regions and OPTN strategic goals.²⁵ Several internal stakeholders and Board interviewees saw no connection today, nor any need for a connection in the future, to these strategic goals. Yet the project team’s external benchmarking analysis indicates that high performing governing bodies within organizations typically have some responsibility to implement or at least advance the mission and vision of the organization. After making this observation and sharing it with interviewees, some Board members did agree that the principles driving overall OPTN performance should be directly aligned with the Regions’ responsibility and remit.

The third design lever, responsibility, considers ways to ensure Regions or an alternate construct effectively serve members and enable OPTN’s strategic goals.

The following drawbacks were noted from interviews:

- While allocation policy no longer belongs under the jurisdiction of Regions, many respondents struggled to define an alternate purpose for Regions, but agreed there should be regional responsibility to maximize benefit on behalf of patients;
- Regions could be more proactive at ensuring equal representation of local membership: today, some hospitals participate in greater numbers than others and representation heavily favors the medical community over patients and donor families;

²⁴ Charts and key takeaways from public comment analysis can be found in the [Appendix](#).

²⁵ 2021-2024 OPTN Strategic Goals: Increase the number of transplants, increase equity in access to transplants, promote living donor and transplant recipient safety, and improve waitlisted patient, living donor, and transplant recipient outcomes, optn.transplant.hrsa.gov/governance/public-comment/2021-2024-optn-strategic-plan

- Travel to regional meetings can be costly, creating high barriers to participation for individuals and members from smaller programs, further affecting representation; and
- There is little to no ongoing communication from Councillors to members within their Region outside of regional meetings.

Focus group participants had an opportunity to review the five guiding principles and rank them in order of importance. As previously mentioned, *Maximize Benefit* was ranked first across all three focus groups, followed closely by *Allocation Equity* and *Accountability and Effectiveness*. This response from the community emphasizes stakeholders' widely held desire to delegate responsibilities and tasks to the Regions that are connected to and supportive of the core mission of the OPTN. In addition, Regions should continue to serve as a forum for all stakeholders to learn about, question, and voice sentiments about proposed policy changes and come to understand their potential downstream implications.

Hypothesis testing through focus groups

The project team built multiple hypothetical models to test the levers of structure, governance, and responsibility across potential future regional constructs.²⁶ For structure, the team considered four ways to organize members: one aligned to geography, another aligned to similar interests, and two different hybrid structures. For governance, two alternative models were designed, one which offered a *representative* voice in policy and one which provided a *direct* voice in policy. For responsibility, the team compared member feedback to initiatives within the 2021-2024 OPTN Strategic Goals and developed possible activities in which the new regional constructs could engage.

OPTN Board members, committee chairs and vice chairs, patients and donor families, and other stakeholders were invited to participate in focus groups conducted anonymously and virtually, in which these hypotheses were presented for feedback. Participants commented on benefits and issues of each option and voted on preferred structure, governance, and responsibility options. The project team analyzed these reactions and distilled the final recommendation into the three proposed archetypes.²⁷

Proposed archetypes to replace Regions today

The project team designed three archetypes as alternative structures to the eleven Regions today. Each archetype is intended to address various challenges highlighted throughout this report while maintaining those core elements of the Regions that work well today. No single archetype is recommended above the other two, however each emphasizes certain guiding principles over others and is designed to produce distinct outcomes, which should be considered during public comment.

Archetype 1: Communities of Common Interest – Regions would be replaced with similarly-interested communities, such as non-academic transplant centers, or rural OPOs. Policy debate and sentiment-gathering at community meetings would look much like what happens at regional meetings today, but communities could focus on policies of greatest interest to their respective group. Communities would elect Councillors, who would hold seats on the Board.

Archetype 2: Repurposed Regions – OPTN members would still be divided along geographic lines, but regional boundaries would be redrawn based on factors such as population and OPTN membership count. These Regions would no longer debate and provide sentiment on policy proposals. Instead, policy debate would be elevated to a national forum, inviting interested members to express opinions in a series of debates organized by committees. Regions would continue to elect regional leaders, who would form a regional advisory body to the Board to raise concerns specific to Regions.

Archetype 3: Hybrid Cohorts – This archetype maintains geographically-defined cohorts for transplant centers, OPOs, and histocompatibility labs, which regularly work with each other in organ procurement and transplantation and donor and recipient care and screening. The boundaries of the Regions for these cohorts would be redrawn to better reflect new allocation rules and practices. Other member types, such as patients and donor families, would be grouped into national cohorts. Cohorts would elect

²⁶ Descriptions of initial models, as well as focus group feedback, can be found in the [Appendix](#).

²⁷ A flowchart capturing the team's process of engaging with OPTN stakeholders can be found in the [Appendix](#).

Councilmembers to sit on a Policy Council, which would replace the existing Policy Oversight Committee²⁸ as an approval body in the cycle of policy development.

One potential outcome of this restructuring is that each of these archetypes has the potential to decrease the number of seats on the OPTN Board:²⁹

In Archetype 1, elected Councillors represent different member types and as a result, fewer at-large seats would be needed to fill specific member requirements and the Board could be reduced in size by as many as 11 seats

Archetype 2 and Archetype 3 eliminate Board seats currently reserved for Regions, reducing the Board by 11 seats

Archetype 1: Communities of Common Interest

This archetype would operate similarly to Regions today in function, but rather than by geographic boundaries, members would be grouped by shared interests.

Structure – In this archetype, members would be organized into communities by member type and interest, for example:

Transplant hospitals clustered by organs transplanted, size, and/or type (e.g., academic vs. non-academic)
OPO by setting (e.g., rural, suburban, urban)
Histocompatibility laboratories by type (e.g., academic vs. non-academic)
Medical/scientific community and public organizations
Business members
Individuals, including patients and donor families

Responsibility – Similar to today, in this new construct, each community would focus predominantly on policy discussion and debate by:

- Disseminating, discussing, and debating policy in virtual and/or rotating-location meetings
- Providing collective sentiment on new policies during the public comment period
- Discussing the potential impacts and path to implementation of approved policies
- Sharing effective practices and learning from one another
- Proposing new policy initiatives to national committees
- Recruiting new participants from member organizations and cultivating a volunteer pipeline for eventual committee and Board roles

Governance – Similar to Regions today, communities would elect a Councillor to lead the community and serve on the Board, and Councillors would oversee the process of nominating committee members to represent interests of the community. Because Councillors represent different member types, the Board may be able to decrease in size, as at-large seats would no longer be needed to fill specific member type gaps. However, in order to ensure geographic representation, the Board should consider adding geographic diversity requirements to Board and committee compositions.

Meetings – To preserve the opportunity members have today to congregate with neighboring organizations, OPTN should establish nationally organized meetings in multiple locations throughout the U.S. in conjunction with implementing this archetype. The meetings would be staggered throughout the calendar year and all members would be invited to attend. Meetings would focus on items such as policy implementation and effective practice sharing, reports on national performance against strategic goals, and geographic-specific variance discussions and policy proposals.

Benefit and Challenges

OPTN benefit

²⁸ Note – public comment was opposed to change to the Policy Oversight Committee. It is now recommended that other mechanisms be considered for incorporating cohorts into governance without replacing the existing governing body

²⁹ Organ Procurement and Transplantation Network. (2020). *OPTN Bylaws effective December 7, 2020*. optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf

Nationally organized meetings create additional opportunities to engage members and inform them about approved policy changes

Decreasing the number of Board seats may streamline the decision-making process

Member benefit

Meeting with members facing similar challenges should lead to more productive policy proposal discussions and sharing effective practices

Networking and relationship-building will be easier among similarly interested members not limited by geography

Risks and Challenges

Interdisciplinary discussions may be lost as policy discussion moves to like-minded communities

More vocal or prominent voices within communities may continue to dominate debates and discussions

Councillors on the Board could face similar challenges as those faced by Regional Councillors today, such that fiduciary responsibility to OPTN and the Board may not reflect community interests

Board nomination and committee appointment processes would need to include parameters ensuring geographic diversity

Questions for feedback in public comment

1. Would Archetype 1, Communities of Common Interest, improve upon the current regional model in achieving the strategic goals set forth by the OPTN?
2. What factors should be considered when implementing this archetype?
3. What operational concerns or barriers are critical considerations for the OPTN Board adoption and implementation?

Archetype 2: Repurposed Regions

This archetype proposes reassessing and redrawing regional boundaries. The new Regions would focus on operational effectiveness, while policy debate and sentiment would be elevated to a national forum.

Structure – This archetype maintains geographic boundaries but would redraw Regions. Whereas Regions today are largely defined by state borders, the new boundaries would be based on a combination of factors, such as:

Geographic proximity, informed by concentric circles; and/or

U.S. population density; and/or

Number of transplant centers

Responsibility – Unlike today, in this new construct, Regions would focus predominantly on enabling OPTN strategic goals by:

Discussing impact and implementation of approved policies

Sharing effective practices and learning from one another

Monitoring regional performance against strategic goals

Proposing new policy initiatives to be brought to national committees

Developing and piloting projects at a regional level before scaling nationally

Recruiting new participants and cultivating a volunteer pipeline for OPTN committee roles

Governance – Regions elect two leads to convene and direct regional activities. Leads sit on a Regional Advisory Committee that meets with the Board twice a year to raise issues of regional concern. Other details related to governance:

One lead cannot be a physician or surgeon; leads have set term-limits and cannot serve consecutively; terms would be staggered to allow for continuity

Regions maintain committee recommendations and all committee appointments would continue to be approved by the Board

Region leads do not hold Board seats or cast formal votes on policy

National Policy Debates – The OPTN would introduce nationally organized policy debates through a series of virtual and in-person forums to encourage all members interested in specific policies to engage in debate and express opinions. The policy debates would be hosted by the proposed policy sponsoring committee throughout the year, and all members would be invited to participate. There would no longer be a “voting” process, and all feedback and debate would be given consideration.

Benefit and Challenges

OPTN benefits

New policy debate structure should allow for the expression of more opinions and perspectives on policy at the nationally organized policy debates, virtually and in-person

Regional Advisory Committee preserves a forum to hear unique regional perspectives

Decreased number of Board seats may streamline decision making

Member benefit

Maintenance of regional structure preserves interdisciplinary relationships with neighboring organizations

The Regional Advisory Committee is a dedicated forum to express regional concerns

Multiple nationally organized policy debates may be a better platform for members who feel they have less of a voice in regional meetings

Regions would have more opportunities to discuss implementation of policies, effective practices, pilot projects, and other initiatives outside of policy debate

Risks and Challenges

Region leads may feel that their voices carry less weight without a seat on the Board

Meeting attendance may suffer if participants are not debating policy

Board nomination process would need to include parameters ensuring geographic diversity

Regional members may feel that policy debates should remain local to discuss Region-specific impact

Possibility of increased number of members on each committee

Questions for feedback in public comment

1. Would Archetype 2, Repurposed Regions, improve upon the current regional model in achieving the strategic goals set forth by the OPTN?
2. What factors should be considered when implementing this archetype?
3. What operational concerns or barriers are critical considerations for the OPTN Board adoption and implementation?

Archetype 3: Hybrid Cohorts

In this archetype, members would be organized using a hybrid approach: some will be placed in cohorts by geographic boundaries and others assigned to cohorts by interest. Cohorts would elect representatives to sit on a Policy Council that influences policy development, thus creating more of a democratic representative voice than today.

Structure – In this archetype, those members that frequently work together within a geographic area would be organized into cohorts aligned by geography. The new boundaries would be redrawn to reflect how recent allocation policies have changed working relationships. Other members would be clustered into cohorts by member type:

Transplant centers, OPOs, and histocompatibility labs would be clustered into cohorts by geographic proximity, informed by concentric circles

Other member types, including the medical/scientific community, public organizations, business members, and patients and donor families, would be clustered into cohorts by member type

Responsibility – Similar to today, in this new construct, each cohort would focus predominantly on policy discussion and debate by:

Disseminating, discussing, and debating policy in virtual and/or rotating-location meetings

Providing collective sentiment on new policies during the public comment period

Discussing the potential impacts and path to implementation of approved policies

Sharing effective practices and learning from one another

Proposing new policy initiatives to national committees

Recruiting new participants from member organizations and cultivating a volunteer pipeline for eventual committee and Board roles

Monitoring cohort performance and identifying areas for improvement

Governance³⁰ – A key change in this archetype is the establishment of a cohort-elected Policy Council, which would replace the Policy Oversight Committee. Currently, the Policy Oversight Committee members include UNOS Board members as well as non-Board members with subject matter expertise as non-voting Advisors. The Policy Council would operate differently: Cohorts would elect two councilmembers to sit on the Policy Council. The Policy Council would assume responsibility of the Policy Oversight Committee, and therefore have the authority to move policy forward to Board vote or push back to committees for revisions. Other details of the Policy Council include:

One councilmember per cohort cannot be a physician or surgeon

Councilmembers have set term-limits and cannot serve consecutively; terms would be staggered to allow for continuity

Cohorts maintain committee recommendations and all committee appointments would continue to be approved by the Board

Councilmembers do not hold Board seats

Meetings – To encourage relationship building across different member types (e.g., transplant hospitals and patients), OPTN would establish a nationally organized, bi-annual conference to be held in conjunction with the Board meeting in conjunction with implementing this archetype. The conference would be open to all members and offer an opportunity to discuss major issues, share leading practices across Regions, and promote community building and education across member types.

Benefit and Challenges

OPTN benefit

- The model is very similar to Regions today, resulting in easier implementation
- Bi-annual member conferences would encourage national dialogue
- A decrease in the number of Board seats may streamline decision making

Member benefit

- Geographic relationships between transplant Centers, OPOs, and histocompatibility labs would remain and may strengthen
- Stakeholders without clinical knowledge would be in the same cohorts, and therefore may have more engaged and productive policy discussions
- Councilmembers can represent their cohorts' interests without also having to weigh their fiduciary responsibility to the Board

Risks and Challenges

- Councilmembers may feel that their voices carry less weight without a seat on the Board
- The transition from the current Policy Oversight Committee to the future Policy Council may present additional implementation challenges
- Robust education and communication of the changes would be necessary to explain the difference to all members, as some members today do not fully understand that they do not currently have a vote on policy through Regions, but that what they consider to be voting consists merely of casting sentiment
- Policy Council may not be best positioned as independent oversight committee to think broadly about all policies and all organs and to prioritize alignment with the OPTN strategic plan

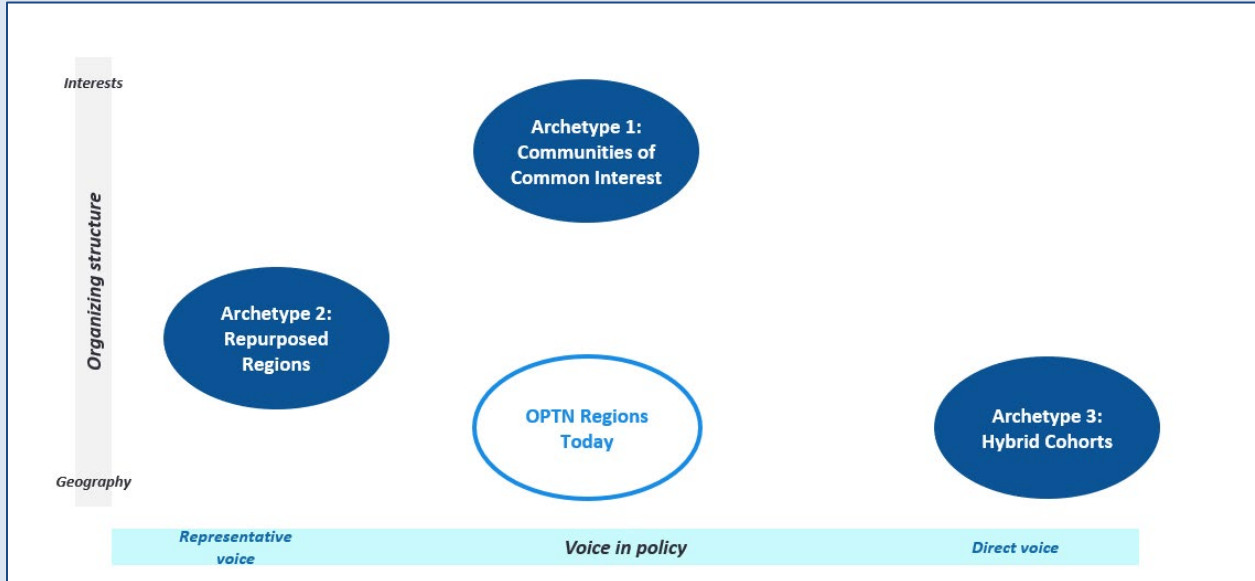
Questions for feedback in public comment

1. Would Archetype 3, Hybrid Cohorts, improve the current regional model in achieving the strategic goals set forth by the OPTN?
2. What factors should be considered when implementing this archetype?
3. What operational concerns or barriers are critical considerations for the OPTN Board adoption and implementation?

³⁰ See note 13 above on policy oversight committee – changes from public comment




Difference between Regions today and three archetypes

The most apparent changes to the OPTN Regions are visible in two of the design levers: structure and governance, or specifically, how voices are captured in policy. To help illustrate how these three archetypes differ from the OPTN Regions today, each is plotted on a 2x2 visualization: the structure Y-axis depicts organizing members by either geography or interests; the policy X-axis depicts a representative voice in policy or a direct voice in policy.



Additionally, elements of the regional structure today have been listed in a specifications table, in which changes between today and the three archetypes are represented as no change (=), some change (Δ), or a new concept (★).

OPTN Regions Today	Archetype 1: Communities of Common Interest	Archetype 2: Repurposed Regions	Archetype 3: Hybrid Cohorts
'Regions' defined by geographic boundaries	★ Eliminate geographic boundaries and create like-interest cohorts	Δ Re-draw geographic boundaries	Δ Create hybrid cohorts considering geography and like-interests
Regionally-elected representatives	Δ Cohorts elect Councillors	Δ Regions elect Region Leads	Δ Cohorts elect policy councilmembers
Board includes designated Region seats	Δ Cohort Councillors replace Region Councillor Board seats (opportunity to decrease total # of Board seats)	★ Region Leads do not hold Board seats; form a regional advisory body	★ Councilmembers do not hold Board seats; Policy Council replaces Policy Oversight Committee
Regions recommend representatives to serve on committees	= Cohorts nominate committee members	= Regions nominate committee members	= Cohorts nominate committee members
Most committees have designated Region seats	= Committees have evenly distributed cohort representation	= Committees have evenly distributed region representation	= Committees have evenly distributed cohort representation
Primary purpose of meetings is policy debate	Δ Policy debate is central to cohorts; add nationally-organized meetings for community and OPTN objectives	★ Regional meetings focus on community and OPTN objectives	= Policy debate is central to cohort meetings
Regional Councillors have fiduciary responsibility to Board; do not vote in line with regions	= Cohort Councillors have fiduciary responsibility to Board	Δ Regions Leads can advocate for regional interests, but have no direct vote	Δ Councilmembers directly represent interests of cohorts
Members encouraged to express public comment through Regional Meeting sentiment	Δ Members encouraged to express public comment through Cohort meeting sentiment	★ Members encouraged to express public comment through national policy debate channels	= Members encouraged to express public comment through Cohort meeting sentiment
Regional meetings are held twice a year	Δ Cohorts hold policy meetings; OPTN/UNOS hosts District Meetings aligned to regions throughout the year	Δ Sponsoring Committee hosts policy debate sessions; Regions host meetings which do not include public comment vote	Δ Cohorts hold policy meetings; OPTN hosts bi-annual member conferences, open to all members

 No change from today
  Similar, but slight change from today
  Different than today

Improvement initiatives to consider

In addition to the potentially significant transformation represented by each archetype, the project team has identified ways the OPTN can address some regional governance challenges without altering their current structure, responsibilities, and governance. Representation, communications, operations and process improvements, and data usage can all be improved in a way that would improve stakeholder experience and network outcomes OPTN should consider both immediate actions to take and longer-term initiatives to implement along with a new structure, regardless of what that structure looks like.

Immediate actions to improve governance

1. Raise awareness about the OPTN to increase national interest in participation in OPTN policy development processes, particularly among patients, donor families, and junior members of the transplant community;
2. Clarify and streamline the public comment process; ensure members understand that the casting of sentiment does not constitute a vote, and encourage members to participate fairly and constructively (i.e., not casting sentiment multiple times through multiple channels in the hopes of affecting actual votes);
3. Encourage committees to share draft proposals with other committees to gather initial input/feedback, rather than obtaining such initial feedback through the public comment process;
4. Clarify committee nomination and appointment processes, removing barriers to entry for new volunteers to participate; and
5. Ensure that all meetings conducted under the auspices of the OPTN dedicate time to best-practice sharing and collaboration in meetings, either through standardized collaborative sessions or through designated agenda topics.

Initiatives to implement with new structure

1. Introduce monthly/quarterly communication cadence from Regions (or alternate construct) to members in order to engage members outside of just public comment period;
2. Enhance educational opportunities for physicians/surgeons and non-clinical members, including programming related to policy proposals and onboarding materials for new participants; and
3. Introduce performance monitoring dashboards at the level of the Regions or alternate constructs to track performance against OPTN Strategic Goals and encourage dialogue around performance improvement.

Questions for feedback in public comment

1. Would these OPTN initiatives improve the regional governance model, regardless of final decisions around structure, responsibility, and governance? Are there others that were not included that you would suggest?
2. What factors should be considered when conceiving and selecting improvement initiatives that can be implemented, regardless of final decisions around structure, responsibility, and governance?
3. What operational concerns or barriers should be considered as new initiatives are considered for OPTN board action and implementation?

Conclusion (including all public comment questions)

The practice of organ procurement and transplantation has significantly evolved over the past 25 years and continues to improve with continued innovation in clinical practice, technology, and logistics. The OPTN Regional Review Project is an opportunity to think about how regional constructs can serve the OPTN and its members today and be adaptable for the future.

The project team looks forward to receiving public comments on the archetypes that can be incorporated into a final proposal for Board consideration in November 2021.

All Questions for feedback in public comment (restated)

Archetype 1: Communities of Common Interest

- Would this archetype improve the current regional model in achieving the strategic goals set forth by OPTN?
- What factors should be considered when implementing this archetype?
- What operational concerns or barriers should be considered as this archetype is being prepared for OPTN Board action and implementation?

Archetype 2: Repurposed Regions

- Would this archetype improve the current regional model in achieving the strategic goals set forth by OPTN?
- What factors should be considered when implementing this archetype?
- What operational concerns or barriers should be considered as this archetype is being prepared for OPTN Board action and implementation?

Archetype 3: Hybrid Cohorts

- Would this archetype improve the current regional model in achieving the strategic goals set forth by OPTN?
- What factors should be considered when implementing this archetype?
- What operational concerns or barriers should be considered as this archetype is being prepared for OPTN Board action and implementation?

Improvement Initiatives

- Would these OPTN initiatives improve the regional governance model, regardless of final decisions around structure, responsibility, and governance?
- What factors/considerations should be considered when thinking of improvement initiatives that can be implemented, regardless of final decisions around structure, responsibility, and governance?
- What operational concerns or barriers should be considered as these initiatives are being prepared for OPTN board action and implementation?
- What alternative improvement initiatives will improve the regional governance model, regardless of final decisions around structure, responsibility, and governance?

Appendix

Detailed insights captured in interviews

Detailed themes and insights captured in interviews are provided below, organized by the four primary functions of OPTN Regions: representation, communication & feedback, operations, and data analysis.

Representation

Dissimilar viewpoints within Regions are often unheard:

- Patients' and donor families' voices have been historically underrepresented

- Transplant hospitals do not send the same numbers of attendees to regional meetings, often leading to a few centers with a greater presence dominating discussions

- A dominant share of voice by MDs (50% of board members mandate, more likely participants in meetings) can be intimidating to non-clinical professionals

- Physicians swear an oath to their patients first and this can create a tension with being stewards of the OPTN system and the population as a whole

Barriers to participation and involvement:

- Travelling to regional meetings can be costly, creating high barriers to participation for individuals and members from smaller programs
- The process of Board elections, regional elections, and committee appointments lack transparency and seem to be heavily influenced by who you know
- Members without clinical knowledge struggle to understand some important policy discussions
- Councillors today direct the regional meetings and have less opportunity to share their opinions, compromising their ability to maintain neutrality

Inclusivity challenges:

- Racial diversity is lacking in regional meetings, on committees, and on the Board, and does not reflect the diversity of the patient population
- The nominating committee's ability to ensure diversity and representation on the Board is made more challenging since eleven seats are guaranteed to regional representatives
- Committee positions tied to Regions are not conducive to the participation of junior physicians who are more likely to switch Regions early in their careers

Communication and Feedback

Value of community building and networking:

- Regional meetings are helpful for networking and building long-term relationships between neighboring transplant centers, OPOs, and other professionals
- Regional meetings can be tough to navigate for newcomers as they are not as familiar with long-standing members
- The new allocation model has led to transplant centers working with OPOs outside their Regions where longstanding relationships don't exist
- Councillors do not communicate with members in Region outside of meetings
- Communication feels one-way, rather than bi-directional, between OPTN and members
- Regions rarely report on rationale behind final Board decisions
- Regional meetings are driven by the correction of policies, rather than building connections between various members

Highly technical and esoteric meeting topics:

- Regional meeting presentations are dominated by discussions on the clinical aspects of the transplantation process, rather than the impact on patients and donor families

- The technicality of topics can be boring

- Some transplant professionals do not fully understand all the technicalities of many proposals outside their realm of expertise, e.g., a kidney transplant surgeon may not necessarily be familiar with HLA policies

- Medical presentations can be met with skepticism when presented by a medical professional not well-known within the Region

Operations

Arbitrary regional boundaries:

- Regional boundaries are outdated since they are no longer needed for organ allocation
- Advancements in technology in terms of transporting organs while maintaining viability effectively expands regional boundaries
- Having a relationship with program partners (e.g., centers and OPOs) lessens the burden of administrative tasks and enables better collaboration and better patient outcomes

Inconsistent practices across Regions:

- Significant regional variation in operation of meetings, population density, transportation of organs, socioeconomic status, etc.
- Breakout pre-meetings, such as Collaboratives or member-type breakfasts, are greatly valued as an opportunity to discuss operational challenges not otherwise covered in regional meetings, but these do not happen at all regional meetings
- Concern over the cookie-cutter approach used for implementing policies across areas with vastly different challenges
- Lack of transparency in the committee nomination process as it varies by Region, the path from nomination to appointment at Board level is often unclear

Unaddressed implications of the National Organ Sharing model:

- Practitioners are concerned about the redistribution of organs within their Region, including the functionality of organs that have traveled further distances
- Increased costs associated with transporting organs further distances have not been widely discussed
- Operational aspects of a new policy are often an afterthought, at the expense of smooth implementation

Data Analysis

Inconsistent interpretation and utilization of data across Regions:

- Members are unsure if and how Regions utilize available data today
- Regions interpret data differently depending on their unique circumstances and may miss opportunities to effectively use the data to fulfill OPTN's mission
- The Board relies exclusively on data presented by the SRTR and could benefit from the opinions of other statisticians

Initial hypotheses and focus group feedback

Detailed feedback captured in focus groups is shared below, organized by questions asked related to each of the three design levers: structure, governance, and responsibility.

Structure

Participants voted and provided feedback on two questions related to structure.

Q: How do you feel about the number of Regions as currently constructed?

Feeling	Just Right	Too Many	Too Few
Vote (n=34)	17 (50%)	10 (29%)	7 (21%)
Comment	<i>Since people are used to interacting with their other regional centers, I think continuity would be helpful Based on individual experience on attendance at regional meetings</i>	<i>The Regions have such a dramatic variation in number of transplant Centers and OPOs that voices have disproportionate impacts for no reasons other than imbalance...fewer would allow better balance Since allocation is moving to a continuous system, don't need so many This will depend, to a great degree, on what structure is chosen</i>	<i>Large Regions create too few opportunities for disparate voices within the Region to be heard Due to geographic sizes of some Regions Perhaps 20 to 25 may allow more of a platform for folk to participate and contribute</i>

Q: Which of the following do you believe best aligns to how regional constructs should be defined?

Presented options:

Re-draw map – Keeps the basic construct of Regions; however, it proposes re-drawing the Regions based on one or more of the following factors:

- By geographic proximity, informed by concentric circles
- By number of waitlisted patients
- By number of transplant centers
- By U.S. population density

Cohorts by interest – Organize members based on interest. Cohorts would be based on similar interest/ member type: non-academic kidney and pancreas centers and urban OPOs in large population-dense areas for instance. There are several ways in which to establish cohorts, for example:

- Transplant hospitals clustered by organs served and size (small, medium, large)
- OPO by setting (rural, suburban, urban)
- Histocompatibility laboratories by setting (rural, suburban, urban)
- Medical/scientific community + public organizations + business members
- Individuals (patients and donor families)

Hybrid cohorts – Blended cohorts considering geographic proximity and like-interests. Cohorts would potentially be organized partially by geography, informed by concentric circles, and partially organized by member type:

- Cohorts organized partially by geography: Transplant centers, OPOs, and histocompatibility labs clustered by geographic proximity (informed by concentric circles)
- Cohorts organized partially by member type: medical/ scientific community + public organizations + business members; individuals (patients and donor families)

Matrixed model – Cohorts are organized by member type and task forces. Member types, such as transplant centers, OPOs, and histocompatibility labs will be vertically aligned. Those cohorts will then create task forces that cut across the verticals to collaborate around unique challenges (e.g., Rural communities; pediatric transplantation; living donors)

Options	Re-draw map	Cohorts by interest	Hybrid cohorts	Matrixed model
Vote (n=51)	15 (29%)	4 (9%)	25 (50%)	6 (12%)
Comment	<i>Each Region should represent the same number of people... This would give each individual equal representation Concept of Regions hasn't worked well--need more flexibility Larger geographic area with more centers and more patients, based on population rather than listed patients or number of centers</i>	<i>I like the idea of like-minded individual coming together as a resource. Eliminating boundaries allows for larger discussions of what may be happening outside your own area</i>	<i>I think a mix of both would help get important feedback while also keeping the medical experts with their own colleagues and keeping donor families / recipients grouped. But there also needs to be a way to incorporate the patient / family perspective into all [vote against] Like 'senate' and 'house of representatives', offers different means of representing the same voices</i>	<i>Conceptually this is the best organization method. However, I would prioritize the function of the cross-functional teams over the type groups</i>

Governance

Participants reviewed details of two alternative models, provide detailed reactions and their preference.

Option A: Establish Policy Council

68% voted for this option (n=38)

This option is structured around creating more of a true representative democracy, where elected policy council members act as a stop-gate in the policy development process to ensure 'Regions' have an actual vote. The details shared about this model:

Regions elect two councilmembers, whereby one councilmember cannot be a physician, cannot serve consecutively, and there are set term limits

Councilmembers do not have seats on the Board; responsibility is to represent interests of Regions in policy discussion

Councilmembers serve as a stop-gate to policy development:

Before public comment period: debate proposed/in-flight policy projects, considering Region perspective with binding vote to send policy to public comment

After public comment period: binding vote on whether committees need to revise policy prior to Board vote

Focus group comments – Pros:

- *No consecutive terms served by one individual is great*
- *Replace POC and give a larger group opportunity to contribute to policy development*
- *Creates balance with all those in the transplant field – ensures committee membership is meaningful*
- *I would choose this one due to having a voice that is not an MD. I am a transplant coordinator and sometimes we are not heard*
- *This structure would also benefit our goal of demonstrating concretely that we honor the voice of non-clinicians*
- *I think the 2nd councilmember should be more defined- I see that patients could still be shut out. That 2nd person would still be a professional in the field just not an MD*
- *Formal membership and includes non-physicians. Would need to understand how to incorporate in POC*
- *Gives the Region (or whatever it becomes) a stronger voice*
- *Harmonizes with the tenets of democracy in the country and will require continuous work to maintain*
- *Development of policy left to experts, with voting left to representative responsible for representing 'region'*

Focus group comments – Cons:

- *This elevates the importance of regional meetings in general; but perhaps Region should give way to nation is the locus of emphasis (leaving regional gatherings as primarily a place for discussion, but not a place to directly impact policy)*
- *How do we ensure that the council members have expertise to review all policy?*
- *Puts the voice of the entire Region on 2 individuals. concerns about ability to adequately represent full scope of opinions for the region*
- *I am more concerned about the regional councillor's role in nominations*
- *It does take some time to get up to speed with policy and process. Having term limits can be challenging because you may be rolling off just when you're up to speed*
- *Increases the complexity by which policies would go out for public comment. Already the process is slow moving and regional objections could further slow the process*
- *Sounds like a junior board based solely on Regions. This complicates policy process unnecessarily*
- *I am opposed to eliminating board seats for the Regions*
- *If Regions have no board representation that is a major step backward*

Option B: Create 'Policy Roadshows' and focus new structure around community-building

32% voted for this option (n=38)

The 'Policy Roadshow' model will allow Regions to become a construct for community building, information/best-practices sharing, education, and member recruitment to OPTN. There will be a mandate that committees host policy debates (in person and virtually) and proactively reach out to OPTN membership for informed comment on proposals.

The details of this model are listed below:

Regions exist for communications, data gathering, networking, volunteer-pipeline (no policy debate)

- Meetings focus on implementation of approved policies, discussing challenges and sharing best practices
- No mandated regional reps on committees or Board
- Regions continue to cultivate and recommend nominee members

- All committee appointments go through Board Nominating Committee
- Institute more Board composition parameters to ensure broad representation (e.g., geographic representation, transplant center size representation)

Expand nationally coordinated member communications to drive policy debate to open public comment forum

- Ensure announcements about proposed policy are clear, succinct, and comprehensible by all member types
- Explain effects and impacts to all member types of proposed policy
- Assign committee members to proactively engage with specific member organizations
- Host virtual policy debates off-cycle as part of public comment period led by committee members
- All members invited, so members can self-select into areas of interest
- Build in mechanisms to ensure inclusion for any members with Wi-Fi/access limitations

Focus group comments – Pros:

- *Board representation would be key and would need to be balanced ensuring representation of all stakeholders*
- *Less politically driven*
- *Makes it easier for DF/P to learn but there is still a challenge of educating people the road shows exist*
- *Community engagement will lead to more involvement by patients/DF as they will feel more apt to participate in this more ‘welcoming’ setting*
- *Developing and truly supporting efforts such as this to cultivate more community volunteer engagement is vital*
- *Simpler; more transparent; Regions are more a place to discuss and understand; emphasis for policy development is at the national level*
- *Less ‘sterile’ environment which will naturally promote conversation and ideas*
- *No policy debate would eliminate a lot of arguing at regional meetings. Would probably get more done in the area of increasing transplants, advocacy and education*
- *Policy developers will have more direct interaction with regional players*

Focus group comments – Cons:

- *National committees may be too powerful*
- *A show and tell function would have little value... the engagement is in creating an opportunity for dialogue and debate*
- *Concerned about regional representation in policy*
- *This would severely reduce the influence of the Regions on policies which they will live with*
- *What happens to the voting concept of 1 vote/member in this model; so, at what point would the member vote on policy?*
- *Removes the voice of the people (vote) in the Region in terms of a vote and may lead to disinterest on the regional level*
- *Attraction to participation is policy development... we may lose interest if we do not join policy to collaboration*
- *If the only goal of Regions is to advocate, recruit and share, they will be poorly supported. ASTS and AST function well in this role*
- *Feels like we are removing an important part of our community and its voice; Concerned with no regional reps. No Regions having a voice*
- *You need regional policy debate. How else will you know what is going on in each region? Regions will feel they have no voice in the process*
- *There will be more cronyism and policy will be dictated by more prominent programs which may not include smaller or less prominent Regions*

Responsibility

Participants selected and commented on a list of possible activities in which Regions could engage.

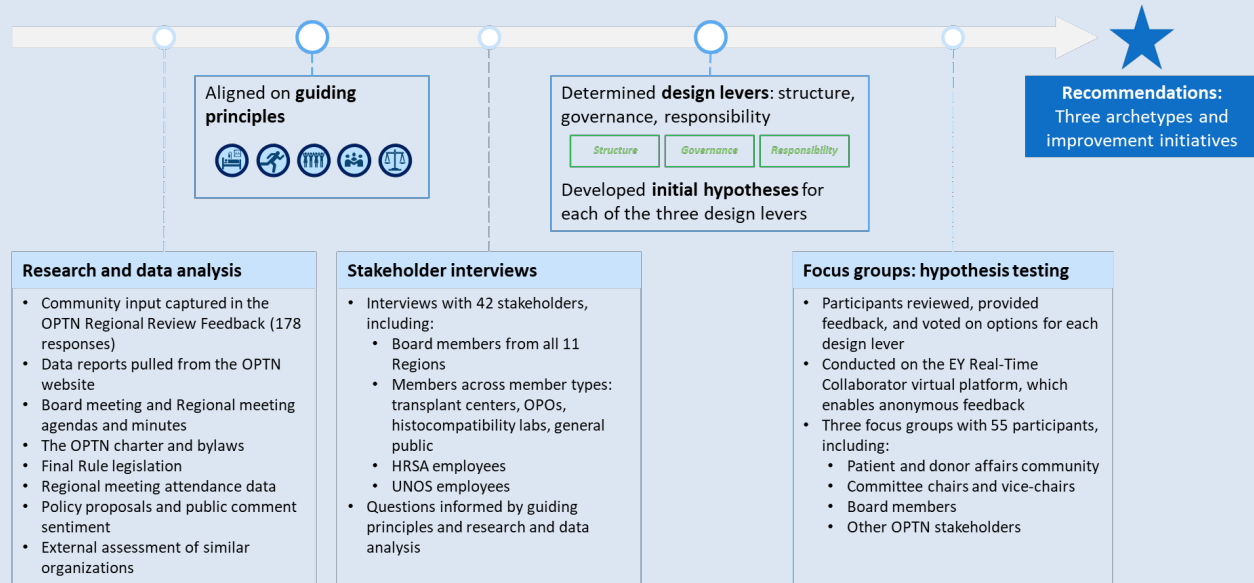
Q: Which of the following responsibilities most aligns to your perspective on the role of a regional structure and is most likely to enable OPTN’s strategic goals?

Possible Action	Vote n=51	Comments
Create structure within meetings to ensure all voices are heard (e.g., member-cohort breakouts for discussion)	40 (78%)	<i>Due to the time constraints of the meetings, discussion is often too brief or dominated by the same voices Agree, however patient and family representation needs to increase, we do not have a good structure for representation of minorities</i>
Dedicate more time in meetings to sharing best practices and discussing implementation challenges	38 (75%)	<i>Critical importance Fosters broader experiential learning</i>
Partner with other organizations in transplant community around efforts to increase donation	38 (75%)	<i>The more local donors, the more total transplants Regional partners can participate in paired exchanges....set up their own network</i>
Performance monitoring	28 (55%)	<i>This effort can further highlight how our performance is intended to be transparent Having reporting of performance would be helpful and allow local comparison but would need to link to national benchmarks. Ensure the integrity of the system is maintained - promote transparency</i>
Run meetings quarterly in which 2 meetings per year are virtual	27 (53%)	<i>All meetings should provide for virtual attendance in addition to in-person attendance Unsure we need more frequent meetings- more virtual would be good</i>
Introduce educational programming to meeting agendas	26 (51%)	<i>Would help with best practice dissemination</i>
Develop and disseminate new-member onboarding materials	16 (31%)	<i>Mentoring new members would be useful</i>
Recruit new members to OPTN	14 (27%)	<i>The Regions need to be small enough to allow knowing each other as this is the best way to recruit new members</i>
Write in Option:		
Conduct improvement projects as a region		

Project methodology and analysis

Overview of project methodology and OPTN stakeholder input into process

The project team incorporated input from more than 260 OPTN stakeholders, including OPTN Regional Review Feedback (178), interviews (42), and focus group sessions (55). The process for developing recommendations is depicted below.

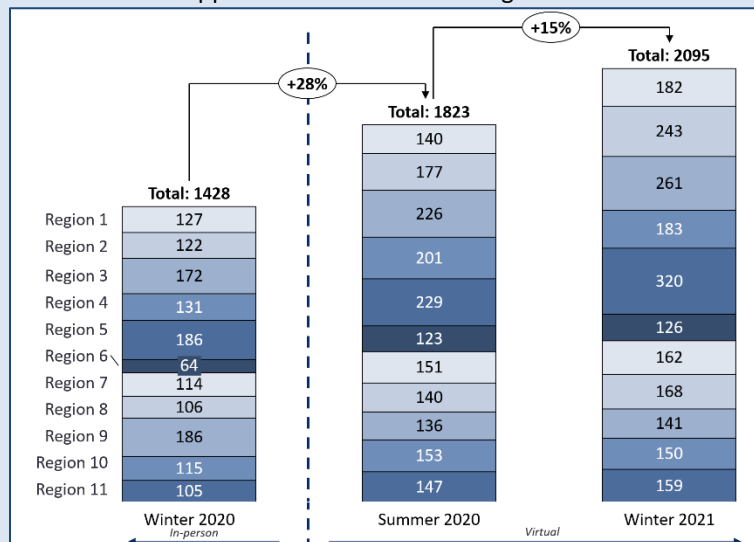


Analysis of regional meeting attendance data

The team analyzed regional meeting attendance data from three recent meetings: Winter 2020, Summer 2020, and Winter 2021. Winter 2020 was the last series of in-person meetings prior to the pandemic; Summer 2020 and Winter 2021 were both virtual meetings.

Key takeaways:

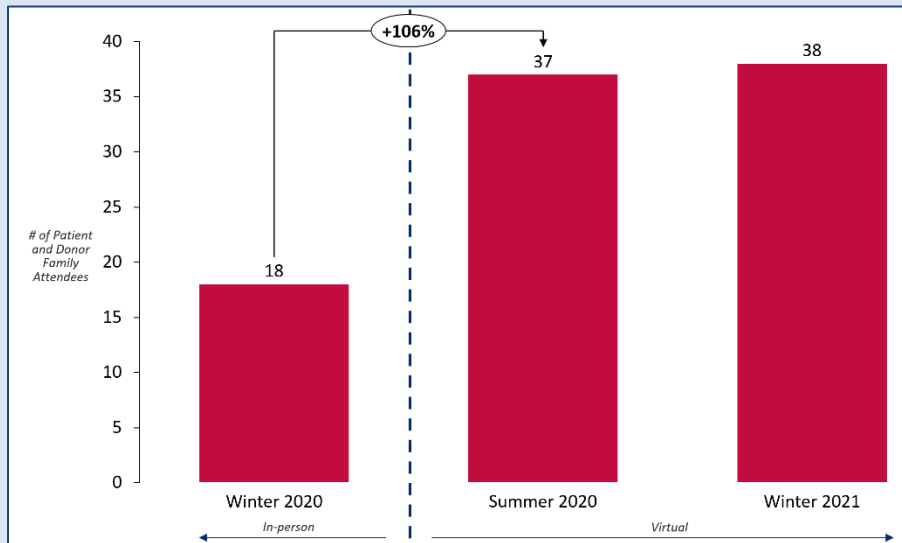
- Total attendance increased by approximately **37%** from in-person to virtual regional meetings
- This increase in attendance is apparent across all eleven Regions



Key takeaways:

- The number of attendees who identify as **patients and donor families** increased by **106%** from the in-person Winter 2020 to the virtual Summer 2020 regional meetings

- A similar level of attendance by patients and donor families can be seen in both cycles of virtual meeting series



Analysis of selected public comment data

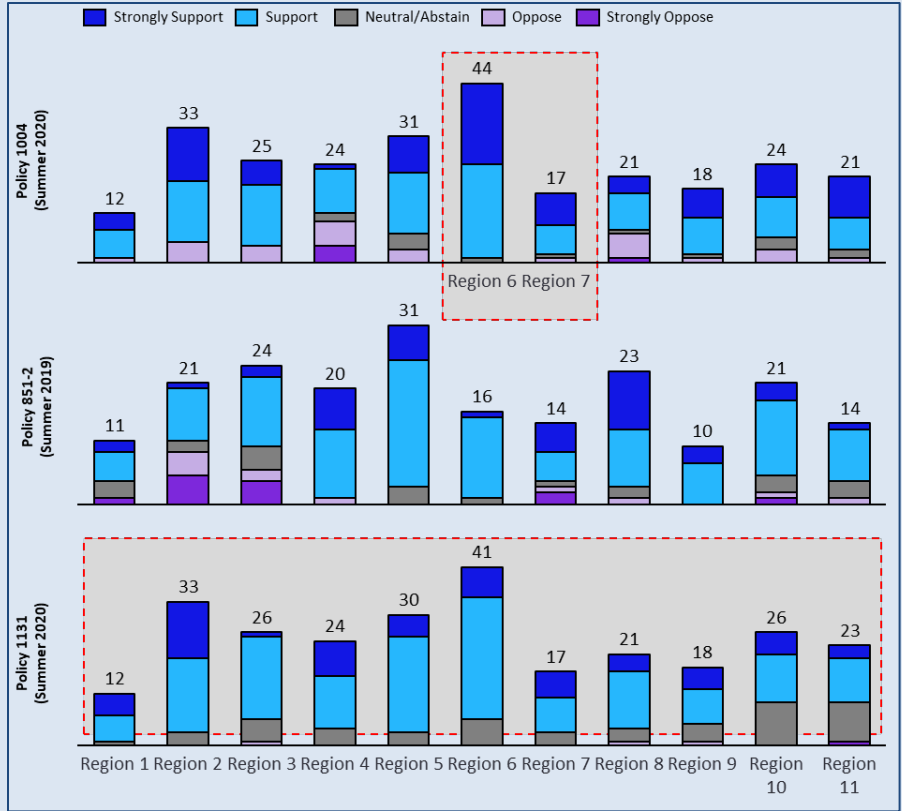
The project team analyzed three policies across 2019-2020:

- Policy 1004: Align OPTN Policy with U.S. Public Health Service Guideline, Summer 2020 (optn.transplant.hrsa.gov/media/3933/align_policy_with_phs_guideline_2020_pc.pdf)
- Policy 851: Expedited Placement of Livers, Summer 2019 (optn.transplant.hrsa.gov/media/3106/opo_publiccomment_201908.pdf)
- Policy 1131: Further Enhancements to the National Liver Review Board, Summer 2020 (optn.transplant.hrsa.gov/media/3927/further_enhancements_nlr_b_pc.pdf)

To better understand how sentiment on policy is recorded in regional meetings and through the web-based public comment, the team analyzed sentiment by member type, Region, and sentiment (strongly oppose, oppose, neutral, support, strongly support).

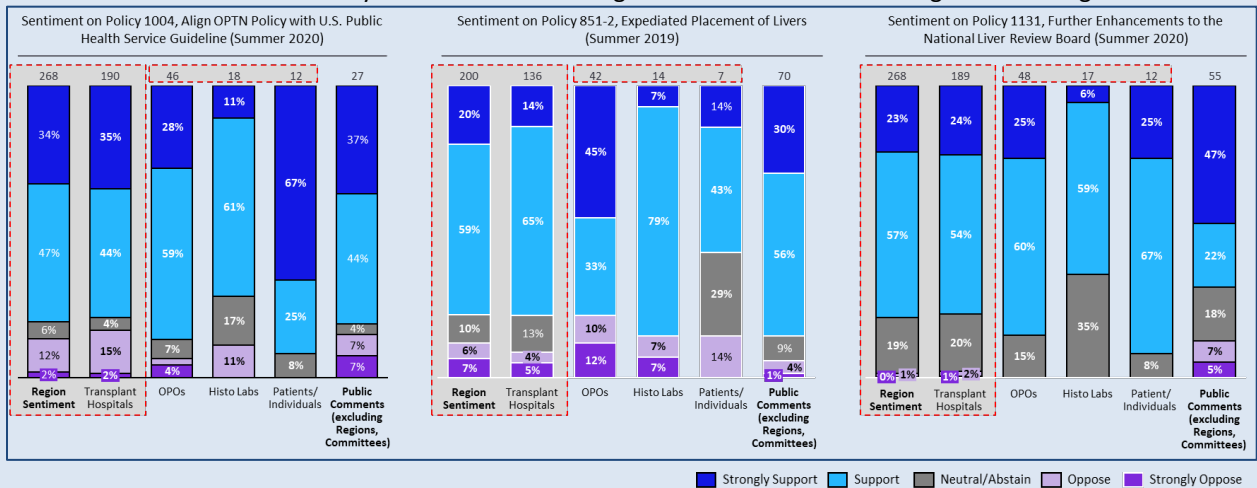
Key takeaways:

- Collective sentiment captured at regional meetings are recorded as one input per Region, however **member participation varies significantly by Region**. For policy 1004, more than twice the number of members recorded a vote in Region 6 compared to Region 7.
- The process of recording sentiment collectively by Region may be **overshadowing dissenters**. For policy 851, sentiment varied within Regions, but the aggregation and reporting of sentiment together as the Region may inadvertently disregard dissenting “votes.”
- Policies will **not always necessitate unique regional considerations**. Sentiment was consistent across Regions for policy 1131, even with high variability in the number of members who participated in each region.



Key takeaways:

- Region sentiment and transplant hospital sentiment appear nearly identical and thus, **transplant hospitals appear to drive Region 'vote'**
- OPOs, histocompatibility labs, and patients/individuals combined to account for less than half the participation of transplant hospitals in regional meetings; **non-transplant hospital voices in policy sentiment may be unheard**
- Public comments appear to capture more varied perspectives, but participation is low, and some comments are written by members who also registered their sentiment in regional meetings



Public Comment

Member Type	Public Comment Moderated Comment	Representative board makeup	Resizing of the board	Maintain geography groupings	Both geography and interest groupings	Voice for minority	Redraw geographic bounds	Engagement and education at	Concerns for communication	Allocation Equity
Stakeholder Organization	<p>A comment was submitted saying the OPTN has an opportunity for the makeup of the Board to be representative of the community with less constant re-education and change while allowing organ specific committee inputs on policy recommendations and maintaining diversity and inclusion. The comment also said that keeping the relationships built with existing regions could be modified to include the centers and OPOs that newer methods of allocation have created. Another member submitted a comment that there is a need to separate grouping based on geography for operational or policy implementation purposes versus for policy review and representation on governance. An attendee commented that when kidney allocation changes, OPOs in New England came together to discuss best practices and consider how they could work most efficient and effectively together, and that when our goals are aligned it adds to discussion and makes a more productive and collaborative environment.</p>	x		x	x					
Stakeholder Organization	<p>An attendee noted that historically, changes among regions have been mainly related to organ allocation, so it may be challenging to realign regions for administrative purposes. The same attendee added the current structure has always worked well for regional meetings.</p>			x						
Stakeholder Organization	<p>AOPO appreciates the opportunity to provide input on the Regional Review Project and agrees that now is the right time to review the definition and purpose of the OPTN regions and how they factor into other OPTN structures including Board membership, Committee membership, public comment review and best practice sharing. AOPO believes that there are elements of each model as described in the study that could be combined to best support the goals of different organizing functions. For example, for best practice sharing, communities of common interest could be most effectively leveraged to ensure that types of members have an opportunity to interact collectively beyond geographic boundaries. This may also be productive and important for some types of policy and public comment review. For example, OPOs would benefit from having a collective opportunity to review OPTN policy proposals that directly impact OPOs rather than the current structure, where OPOs comprise a minority number of the OPTN membership in each Region and, therefore, the discussion of such polices through regional structures maybe less robust.</p> <p>AOPO urges the OPTN to consider whether it would be valuable to have certain types of policy proposals reviewed both in units organized by community of practice as well as through geographic units. For example, some of the efficient matching policy proposals would benefit from regional review as the units of members that will be working together most frequently to implement these policies, as well as review by communities of common interest such as OPOs, transplant administrators, etc., that would provide a focused perspective. For other types of policy proposals, it may make the most sense to only have communities of practice review, such as Histo-compatibility tables reviewed</p>	x			x	x				

	<p>by Histo programs or VCA program requirements reviewed by VCA Program members. And yet, for other policy proposals, the review might be most valuable through geographic regional structures (such as policy proposals involving geographic components that will impact a geographic area in a collective manner).</p> <p>As for how the geographic regions are defined, AOPO recognizes that currently the regions are not drawn in a consistent manner as to size whether measured by population, number of OPTN members, number of waitlist candidates or volume of donors or transplants. This should be considered and perhaps re-defined for more equitable representation of members to the extent geographic units continue to be utilized as the basis for representation on the Board and Committees, which AOPO supports maintaining at this time. While we recognize that alternative governance models could be effective, AOPO recommends that such discussion be deferred into the future after full implementation of the continuous distribution framework at which time members may be more comfortable considering a non-geographic based governance and committee structure model. In the interim, the OPTN could consider organizing regional units in a more equitable manner as identified above, as well as in a manner better aligned with current organ distribution (250nm circles) - however recognizing that overlapping areas make it difficult to accomplish. Alternatively, OPTN members could be invited to join more than one region for purposes of policy review meetings and best practices.</p> <p>AOPO recommends that the OPTN be careful to retain those components of the system that are currently functioning well, including the use of hybrid representation on Committees and the structure of the Policy Oversight Committee with representational membership from each Committee, to ensure the ability to effectively coordinate policy development systemwide. AOPO recommends that the OPTN approach any changes to the use and definition of regional units in a manner that ensures increased equity for all OPTN member types, facilitates increased options for more focused input and collaborative participation, and minimizes stakeholder disruption.</p>								
Organ Procurement Organization	<p>As a past Regional Councilor, I valued the opportunity to come to a Regional Meeting (in person or online) to hear the latest policy proposals and have them explained, perhaps better than in written form, and to hear diverging opinions. That, I think, is the most important part of the meeting; the opportunity to get up and express opinions whether pro or con. I'm not sure that the vote/sentiment of the Region really mattered that much. When it came down to me casting my vote at the board meeting, I had the fiduciary duty to vote for what I thought was best for the organization. I based my opinion on what I heard, learned and read about each issue and the Regional meeting was a good place to get that input. I also value learning about what it is in the, "hopper" so to speak. What are the committees thinking about and dealing with that has not yet come to the policy proposal stage. The Regional meeting is also a good opportunity to learn the Federal perspective and to get an update on UNOS organizational and administrative issues. I also, very much value the input from the patients, donors and donor families. The Regional meeting is more informal than a board meeting and I found that those representatives were more likely to speak in that environment. In my view, the jury is still out on how organ</p>					x			

	<p>allocation will change all of this. While we are in Region 8, most of our organs have been going to Region 7. If the Regional Meeting is designed to help us work more effectively with our organ sharing partners, we should probably wait with a re-design of the regions until we have put Continuous Distribution in place for all of the organ systems AND allowed enough time for new organ sharing relationships to emerge.</p>								
Stakeholder Organization	<p>As a previous and now current member of an OPTN Committee, I think consideration should be given to each of the mentioned entities. Working interactions, professions, proximity, and common roles are all very important within a group. Each brings their own important point of view. A group of representatives with common roles, regardless of their proximity, will be able to evaluate an issue and develop a potential plan for resolution. Given the size and diversity of the United States, proximity should be considered so that the needs of all stakeholders are addressed.</p> <p>Regarding regional groupings, I believe the size and shapes of the regions should be revisited. Region 3 is a good example; Puerto Rico can have very different issues than Arkansas. And Georgia may be able to relate better on issues with Tennessee and North Carolina. Alaska, Hawaii, and Puerto Rico struggle with issues that the contiguous states do not. They may benefit from a grouping together that allows them to work on issues related to the difficulty of their location and proximity to the 48 conjoined states. I am for keeping geographical regions, but feel that it is time that they are amended to better serve its members.</p> <p>I feel the most important function of the membership groups is the evaluation, modification, and finalization of policy proposals. This is so important because it is from here that the Board receives opinions and feedback from specialty committees, regions, transplant centers, and OPOs. This, along with public comments from independent stakeholders, is valuable information considered by the Board when making the final decision on a policy proposal.</p>			x			x		
Transplant Hospital	<p>As a previous Regional Councilor and member of the Board of Directors, I would like to comment on the OPTN Regional Review Project. I'll comment in generalizations only or specifics as to UNOS Region 1 (my Region).</p> <p>In UNOS Region 1 we have a long history of collaboration between 14 transplant centers and two DSA. The states share common geography, similar populations, similar politics, and similar goals. This familiarity enables cooperation and common purpose and usually we reach common ground in areas of organ allocation and policy.</p> <p>I support maintaining this entity as a representative body to UNOS Committees and Board functions. The heart, lung and liver broader sharing areas and the kidney 250 nM circles are defined to optimize patient outcomes and equity. While important, these goals are distinct from the cooperation needed to develop policy and I would not support using patient-centered geographic entities to supplant UNOS Regions and UNOS Region 1 specifically.</p> <p>This will not limit sharing of information ? that can happen at the committee level, but it will limit confusion and controversy in generating areas for discussion prior to Committee work.</p> <p>UNOS Region 1 offers a broad base of programs and interests representing all organs, varied size programs, and academic settings. We have a strong history of involvement at all levels</p>	x		x					

	<p>of OPTN/UNOS. I suggest keeping Region 1 intact as a designated representative area at the OPTN and avoiding expansion to the large metropolitan areas in our geographic south.</p>									
Patient	<p>Based on my 20+ years of experience working on various committees and serving two 3-years terms on the board as a patient representative living 27 years with a transplant heart in Region 2, I welcome the opportunity to support the OPTN Regional Review Project with this public comment. First, let me say with all that experience, I have found the current process to have worked very effectively, offering all constituencies opportunities to participate in open discussions and finally to express their final position with a vote that directly impacts the issue at hand. I feel the current board membership with its representation of each community of interest is effective and should be retained in whatever change may come out of this review process. As to the three models offered, I accept Brian's suggestion in the supporting video (which I compliment as an excellent overview of this comment opportunity) of supporting a combination of the models 2 and 3 EY presented. The current regions should be reviewed to see if a better number or boundary better serves the overall purpose in light of the changes that have certainly taken place since 1986 when these were originally formed. I do not know if there should be fewer, more or the same in number, but support a full review to answer that question based on transplant center geography, patient population and OPO service. Whatever comes out of that review, I feel the current process of electing board members should be retained, maintaining the balance of constituent representation we see today. While a particular topic may seem broad in scope, I certainly have come to recognize regional differences in how that topic is seen and reviewed, especially as it concerns service provision in various parts of the country where the density of patient need and center service support is extremely varied. That has served us well both in the regional meeting discussions and the carrying forward the content of those discussions to the national board level. As a patient I found the regional meetings to be very educational, especially on complex topics as debated and discussed by experts in their fields ?well above my pay grade?, very important to my layman's understanding in forming an opinion that carried on into even further discussion at the board meeting, either confirming or sometimes changing, my final vote as a result of that discussion/debate and voting process. The OPTN committee structure today allows for member engagement in a meaningful way, not only for those directly involved in some topic, but also for indirectly affected parties to learn and express differing opinions often from a totally different viewpoint than the more directly engaged expert practitioners as is most obvious between patients, donor</p>	x		x		x	x	x		x

	<p>family members and medical staff. I very much appreciated the respect those practitioners always had for my views as a patient, often expressed in the phrase "They may have done one, but they never had one?" referring to my own heart transplant.</p> <p>The current process in my experience was very supportive of that open view discussion and fairness I felt in having a vote in the final say on the proposal before me on that board.</p> <p>I hope these remarks address the themes suggested of allocation equity, community engagement, and participation in policy development. My thoughts and experience over these 20+ years don't provide direct answers to many of the considerations under discussion, but I hope they support the discussion myself and so many other thoughtful minds offer in these public comments and in the follow-on discussions that will be held at many levels leading to keeping the best of what has been learned and practiced over the decades of use and change, with yet improved new ideas coming out of this review process. Thank you for this opportunity to reflect and share my experience and thoughts on a complex process that saves so many lives, my own included!</p> <p>As a long-term transplant survivor and spouse to a 'donor mom', I offer a unique perspective of being both recipient and donor family with decades of direct UNOS/OPTN engagement for which I am so thankful.</p>								
Patient	<p>Comments: Members of the region voiced support of maintaining a system that closely mirrors the current regional structure. As the community moves to broader allocation, there has been an erosion of OPO and transplant center relationships. There is concern that if the regional structure is taken away, that will further erode OPO and transplant center relationships. There is benefit to having a structure that allows geographically similar groups to work together as they serve a similar patient population. It was also noted that if we change to a system that only focuses on specific groups, like specific organ groups, then we will become more insular. There is great benefit from sharing best practices and learning from the other organ groups in the current regional structure. There was also concern for a lack of engagement in a silo system if a particular group is unable to feel that their voice is heard. Another member noted that in the current system we do have the benefit of like-minded groups collaborating together in a national setting through the committee system and the regional structure allows for the cross community collaboration. Lastly, with all the changes occurring in organ allocation the strengths of the current regional structure should not be discarded. Now more than ever, relationships need to be maintained.</p>			x					x
Stakeholder Organization	<p>Comments: One attendee stated that regions are helpful in allowing broader sentiment collection, as well as a way to develop a "bench" of individuals who move up to committees and leadership. Regions also provide a larger forum to ensure that the full demographic of transplant is represented - large/small program, across organs, academic/private, health professionals, donors, recipients, and etc. An attendee suggested improvements to the regional representative process to make certain, that the best qualified candidates are available to committees. Another representative added that regions are a really important mechanism for receiving information and being able to provide feedback to the OPTN. It allows members to hear what the issues are for the other organs. During the</p>			x	x	x		x	

	meeting, there was continued discussion on regional representation and suggestion from one attendee on grouping pediatric and adult separately. Another attendee recommended grouping larger and smaller centers separately. One attendee commented that regional meetings allow discussion across organs, different size centers, and between pediatric and adult programs that may not always occur in organ-specific committees. Most attendees agreed that regions are important but may need to consider rebalancing based on shifts in population.								
Stakeholder Organization	First of all, I believe that it is important to retain some degree of geographical determination of regions. My experience with Region 10 was that it provided a forum to discuss regional issues - especially with organ allocation - off-line but in-person that would be lost with the loss of a regional meeting. Expanding the size of the regions makes attendance somewhat more difficult but would be preferable to losing regional meetings entirely. How these regions would look, I believe, is less important again than retaining geographical regions. One of the complaints of regional make-up I have heard in the past has been the discrepancy of (primarily) numbers of transplant centers included in each region. If one felt the need to change the current regional make-up, I would focus on trying to more equitably divide regions by numbers of participating centers. This would tend to increase the number of current regions and thus avoid the concern of travel to a larger region's meeting. If the number of regions increased significantly, board membership eligibility would have to be re-evaluated as, is the current practice, automatically putting each region's councillor on the board would tend to decrease the number of available board positions for specific interest groups (patients, OPO's, etc). I feel it is important that we keep the current number of board positions that are currently allocated to these interest groups.	x		x			x	x	x
Non-Member (General Public)	I beg of you to initiate a program similar to the NKR where patient's family members (that are incompatible blood matches) or friends can secure a voucher for a kidney transplant (or probably the way you'd administer it would be by placing them at the top priority to receive a transplant) by donating on their behalf to the next person which they match with on UNOS's waiting list. Everyone would gain. The next person on the UNOS list would get a living kidney instead of a more inferior cadaver kidney and the living donor will help his beneficiary family member or friend be transplanted in a more prompt fashion (offsetting the lack of compatibility issue)								x
Transplant Hospital	I favor maintaining the current Regional structure. The current system continues to be effective. It provides a modicum of representation from the regions and a mechanism for diverse community voices to be heard and to be effective in policy development. The regions have been effective drivers of change, but have also been extremely valuable to the OPTN as crucibles for policy development. They have provided, at times probably to the chagrin of the OPTN, diverse views and a "reality check" to some of the more problematic policy proposals that have come for community comment. Regional representation on the Board and Committees have been extremely valuable for the OPTN and, in turn, for membership. The deliberative process at the regional level has ultimately protected both the interests of the OPTN and of the greater transplant community. Please maintain the current regionals system rather than expend resources changing a part of the system that is not broken. As a community, lets instead focus all	x		x		x			x

	energy on our shared passion and strategic goal of increasing access to transplantation nationwide.									
Patient	I support making some changes to the regional system that exists today; at the moment I favor a mixture involving Model 3 as the base template. I caution, in general, that we do not want to create new silos that might overshadow the common good that we are all trying to achieve by being more transparent, open to hearing about others experiences, sharing best practices, etc. Our strategic goals of increasing the number of transplants, providing equity in access, promoting efficiency in donation and transplant, promoting patient and donor safety, and improving wait list outcomes cannot be compromised in any way. Discussion is healthy, sharing of ideas is important, debating is often necessary and at the end of the day, we need to do what's right to meet the rigors of our agreed upon strategic goals and hear from all member groups in the transplant community equally.				x				x	x
Patient	i think the new system is giving too many points to pediatric category. the idea that pediatric patients will have longer post transplant time is not necessarily true.									x
Patient	Many attendees had feedback for the committee and provided the following comments: There are many changes happening right now and changing the regions may not be needed. Changes would affect hospital agreements with OPOs, and relationships between hospitals and OPOs. OPTN committees already function to provide interest specific communities. If some are not represented, maybe we need more committees or subcommittees. I believe patients should be better represented at regional meetings, and would support the idea of creating regional patient committees, perhaps led by the regional PAC rep. Several attendees supported leaving the regional system as it currently exists. They commented that the system is working well and there should not be change just for the sake of change. Transplant Centers and OPOs share common issues and even though allocation is broader, the local support between center and OPOs should be maintained. The model of common interests makes little sense to me and re-drawing lines based on population has little effect now that allocation no longer even uses regional boundaries. If you want the OPTN members to have the belief that our voices are heard, we need to function more like a representative system where regional representatives cast a vote representing his/her region then OPTN adapt policy based on the votes of the regions. There remains value in geographic representation and collaboration. There are regional differences in patient populations, shared challenges of logistics and travel, etc. Simultaneously, the diversity of interests within a region brings diversity of perspective to discussions of common importance. A system based only common interest risks isolating groups with different interests in silos, fostering competition rather than collaboration. As many centers will have multiple programs with different interests, it also presents logistical challenges to participation and representation.			x	x	x			x	
Stakeholder Organization	Members of the region expressed interest in the progress of the work as it will be helpful for the donation and transplant community. It was also noted that any future structure should maintain a way for dissimilar groups to meet. The				x				x	

	regional meetings are a great way to learn about different perspectives within the community. For example, a smaller transplant program will have different perspectives and priorities than larger transplant programs, but it is beneficial for both groups to interact in order to learn from each other.								
Stakeholder Organization	One attendee commented that with any of the models submitted, it appears the regions will no longer have regional representation on the Board . Another attendee remarked they support a model where fair representation is maintained .	x							
Stakeholder Organization	One member suggested that it would be helpful to return to a system where transplant centers had a specific liaison with the OPTN . Another member commented that perhaps individuals should be elected based on what platform they support. A member noted that the roles of regions have changed over the years and with a move to broader allocation, regions may not be necessary anymore . The concept of ?Communities of Practice? or of Expertise were considered as one way in which the nation could be distributed regarding action items.	x				x			
Stakeholder Organization	Region 5 supports the OPTN Regional Review Project and provided the following notable comments and suggestions. A member cautioned that some of the proposed changes could produce silos of common interest . Further, grouping by the number of centers doesn't make sense ; rather, the member suggested grouping by equal numbers of people and potential people. This member suggested there should be four to five regions rather than eleven regions . A member suggested that it would be nice to have an option that retains current boundaries just for measuring general sentiment. Further, Model 1 is the least desirable option since there are already ample communities of common interest. A member suggested increasing the number of center interactions for organ offer and placement to achieve optimal efficiency. A member requested more information on the size of regions, specifically, patient size . A member expressed concern over the appointment process and believes that can be addressed as part of the regional review project. Many members support a review of the regional structure . A member strongly supports an update of the regional organization structure but wants to see some continuity with the current structure. The member suggests to update regional structure to better balance patient populations, number of centers, and center/OPOs that routinely work together .			x			x		x

Stakeholder Organization	<p>Region 8 supports the Regional Review Project and the opportunity to provide feedback on it, with specific suggestions below.</p> <p>A member pointed out that the challenge will be what to do with the Board of Directors and its structure (i.e. number of board members, and representation).</p> <p>A member stated that his institution favours maintenance of a regional structure, with participation of all stakeholders at the same meeting. There is a need to make all stakeholders feel more welcome to participate, but we believe that some groups would feel even more marginalized if they met independently and in the absence of relevant data from transplant experts. Further, the member stated that his institution is pleased that the consulting group recognized the distinct disconnect between what the region believes the function of its representative is (to represent the sentiment of the region at Board of Directors votes) versus the actual fiduciary responsibility of the regional representative to the OPTN/UNOS at Board votes. Further, he suggested that the regional representative ought to more accurately represent the "will" of the region so that the function of "representation" actually carries weight. At the very least, this distinction should be made clearly known at every regional meeting (that the regional representative is not bound to vote in the direction the region has voted). Lastly, the members? institution believes that, while it is aware the size of the UNOS/OPTN BOD is somewhat dictated by regulation, its size is too unwieldy to be functional by most standard business measures.</p> <p>A member stated that his institution generally supports the reduction in the size of the OPTN Board of Directors. Because transplantation is a multidisciplinary effort, we recommend caution in regrouping regions primarily based on cohorts. We recommend caution with the proposal to replace the POC (currently made up of committee vice-chairs) with a cohort based Policy Council as on the surface it isn't clear that such a structure could replicate the current functions of that committee.</p> <p>Another member stated that currently Region 8 is not indicative of organ allocation practices and that it would be nice to have the opportunity to formalize these newer networks. The member further stated the importance of ensuring the OPTN Board of Directors size is not overwhelming but representative of all stakeholders.</p> <p>A member appreciated the Regional Review project being taken on and having input in the project. The member stated that representation from Region 8 has been a success for his transplant program and that using this platform to discuss policy proposals, sharing best practices, and data has been fruitful. It would be important to ensure the data comparisons used today for transplant center to region have a similar representation in a new system. In addition, because there is so much variability of transplant programs, types, size within the region that allows opportunity for competing views in discussions, eliminating this and moving towards a grouping of common roles or professions may eliminate robust discussions of competing views.</p>	x	x		x				
Non-Member (General Public)	Test Comment								
Stakeholder Organization	<p>The American Society for Histocompatibility (ASHI) and its National Clinical Affairs Committee (NCAC) appreciate the opportunity to comment on the OPTN Regional Review Project. The histocompatibility laboratory community consists of subject matter experts which generally do not confine to geographical boundaries with regards to national policy development, review, and discussion. This is a complex</p>								

	issue that requires further discussion. ASHI welcomes being a part of this discussion.									
Stakeholder Organization	<p>The American Society of Transplantation appreciates the OPTN's effort to ensure sufficient and effective representation across regions-regardless of where the boundaries are drawn- and disciplines. The purpose of the OPTN Regional Review project is seeking to optimize OPTN governance and operational effectiveness by evaluating the role of regions. Regions were historically created from groupings of Donation Service Areas (DSAs) to help manage the national organ transplant network. These regional boundaries were based on patient referral and organ sharing patterns that were created in 1986. Accordingly, while this is not a concrete proposal, we are supportive of the concept of restructuring UNOS regions with the aim of improving representation and engagement. We acknowledge the diversity of the regions and recognize that merit in similar member-type groups working well for some activities, including the review of policy proposals and sharing best practices.</p> <p>The following thoughts and feedback were offered as our communities of practice considered this update:</p> <p>General Governance Feedback Reducing the size of the OPTN Board of Directors and using other mechanisms such as advisory forums to provide input to a smaller Board from regional and special interest cohorts may allow the Board to be more effective and nimble in its actions.</p> <p>We suggest caution in replacing the current POC structure with the proposed outline.</p> <p>From the Transplant Administrator Perspective We support efforts that seek to better serve the transplant and donation community, as well as our patients. A hybrid model may be able to be constructed to achieve the equally important goals of allocation equity, community engagement and active participation in policy development. We additionally would support solutions that would be fiscally responsible, efficient and easily operationalized. We would not support costly solutions that would be difficult to implement or navigate.</p> <p>From a Kidney Perspective Regions have heterogenous groups with differing voices and usually doesn't lead to effective discussions. Large centers and OPTN power figures dictate the outcome of the discussion. There is a need to redraw the current regions as the new concentric circle distribution model of kidney and pancreas transplants has diminished the significance of regions.</p> <p>With all of the three models, regional representatives will be board members.</p> <p>Model 1- No more regions but communities. It will create groups that will work in their own bubbles. This will help provide voice to smaller programs but the chance to learn and meet colleagues from larger centers will be taken away.</p> <p>Model 2- redrawn Boundaries based on new allocation system and national policy debates. This will take away the</p>	x	x	x	x	x	x	x	x	

sentiments from regions. National meetings will be larger and it will be difficult to have input of smaller programs.

Model 3 is a hybrid model with current regional structure but will have communities of interest. Outline the pros and cons of 3 proposed models that will replace the regions in terms of four functions- representation, communication and feedback, operations, and data analysis.

Report generating/data analysis - will be possible only if some sort of regions is maintained (model 2 and 3). However, model 1 can include communities of practices of redrawn regions.

Representation seems best with model 1, as this model (Model 1) allows members with a common interest to come together, have more effective group discussions which will provide clarity to OPTN when debating on policy matters. For this reason, communication and feedback are best with model 1?

From a Living Donor Perspective
What is the optimal governance structure to best perform OPTN functions?

Based on the information available in the Update document, the LDCOP EC opined that the **hybrid model may be favorable**, based on considerations including:

Ease of implementation by **maintaining geographical relationships** that are important when considering regional differences.

Elevating the voices of patient and donor family stakeholders that would be grouped into national cohorts.

We ask for clarification regarding whether policy discussions would occur at the national or regional levels.

How should the OPTN organize members into smaller forums?

One suggestion is to **create forums of all stakeholders around clusters of transplant centers within 250nm** of each other given current allocation, to group the voice of stakeholders most likely to interact with one another in practice.

How should the OPTN ensure members have a voice in policy?

We suggest a model where **all stakeholders votes are counted at a smaller level (e.g. regional) and are then transmitted to the board by representatives of the various stakeholders.**

We would request a clear definition of advisors to board given the reduced level of representation and size of the board.

What role should geography play in the OPTN structure and functions?

Geography often dictates waiting time for transplant, wait list practices, etc. Stakeholders who are proximate

	<p>geographically will share interests and should have a voice to express geographic concerns?in?policy?discussions.?</p> <p>From the Thoracic Perspective We support the review of models for a new OPTN structure particularly with in the setting of the ongoing institution of continuous distribution models.??There is little detail provided in the proposed structural?changes?so it is difficult to offer detailed comments?and thus we do not endorse a particular model at this time.???</p> <p>Comments on specific suggested models:?</p> <p>Model 1:???</p> <p>Population density, transplant access, and organ availability are quite variable throughout the country.???</p> <p>As geographic factors are de-emphasized in continuous distribution models,?separation into ?alike communities??may improve national focus on equity and access.? However, the ability to identify and respond to specific regional issues would be reduced.???</p> <p>Model 2:?</p> <p>Repurposed regions.? The redrawing of regions based on population and OPTN membership has the potential to further increase disparities by overly empowering areas of greater population density/OPTN membership.???</p> <p>Model 3:?</p> <p>The hybrid model would seem to offer a potential to balance regional and national issues and resources.? Of the three models, this seems to have the greatest potential?for fair representation of interests and flexibility in the setting of ongoing changes in allocation and?access?but full details and renditions would be needed before we could endorse.</p>								
Stakeholder Organization	<p>The Heart Transplantation Committee appreciates the opportunity to provide input on the Executive Committee?s request for feedback document Update on Regional Review Project. The Committee supports this initiative overall. The members did not express a consensus for any specific option identified in the document, but individual members did share their feedback about some of the options. A member commented that they support the idea of the Communities of Common Interest model but noted there are practice patterns tied to regions as well, noting that rural programs face different challenges than urban programs. Another member commented that geography may become less important as continuous distribution is implemented and it will be important to promote communication among all members as opposed to just members within a region. The members value the interactions with various member types (transplant programs, organ procurement organization, etc.) and believe that separating these member types into groups may create silos, potentially decreasing cooperation or cross functional understanding. The members support the structure of regional meetings to facilitate member communication but acknowledge that the way the regions are drawn are arbitrary at this point in time. A member also commented</p>	x		x	x	x	x	x	

	that although the Board of Directors may be large, it does have broad representation.								
Stakeholder Organization	<p>The Kidney Transplantation Committee appreciates the opportunity to comment on the OPTN Regional Review project. Committee members feel any new structure should still include consideration for inherent geographic differences and varied opinions between different regions/areas of the country, especially as OPO policies and practices vary. A committee member commented regions vary by size and population. Additionally, different regions vary in the types of transplant programs available, transplants offered, whether there are MOT programs, the volume of transplants performed, the patient population, and number of candidates on the waiting list. Members felt these were important points of consideration to be evaluated as part of the project. Additionally, a committee member commented in-person regional meetings are very beneficial as they offer a diversity in thought and multi-disciplinary opinions, and would want them to continue. Also, the member said clarity is needed on what a regional sentiment vote means and stressed the importance of having adequate regional representation at the Board level. A committee member expressed concern for potentially creating more silos within the transplant community if representation on committees and the Board are reduced and questioned how decreased representation would accomplish the goal of increased collaboration. Another committee member encouraged more engagement with patient organizations and patient groups to solicit the patient perspective to incorporate into the OPTN's work. The member further expressed that patients are very capable of participating in the OPTN policy process but information on how they can participate is not broadly shared.</p>	x		x		x	x	x	

Stakeholder Organization	<p>The Number 1 Goal of the Strategic Plan is to increase the number of transplants. Any change in regional structure should be designed to result in improved donor rates at OPOs and increased number of transplants. Otherwise, the commitment of the resources necessary to make such sweeping changes is not justified.</p> <p>There is a need more patient participation at regional level. One Patient Affairs Committee member cannot possibly interact with enough people in regional meetings. Most regional meeting participants are full time specialists in one area of transplantation. PAC members are usually not transplant professionals and have no formal training, yet we are asked to represent the patient perspective across the entire range of transplantation. The proposed changes would further isolate PAC members, not make them more effective.</p> <p>The Regional Review Project deals with patient participation issues as if patients were simply one additional interest group of transplant professionals. However, the patient perspective is significantly different than that of the transplant professional.</p> <p>Policy cuts across all organs, OPO performance, MPSC standards, statistical analysis, and every aspect of OPTN activity. If all those disciplines are siloed by activity type, how is any patient or patient group to have access to information and experience necessary to provide an informed opinion? Patients meeting with patients is only useful if it leads to an informed expression of patient concerns to OPTN, or to pertinent parts of OPTN. A single patient on an organ committee is unlikely to have much meaningful to say. A patient group, acting together, like the PAC, must be fully informed to have meaningful input. A major source of information under the current structure is the regional meeting. It provides patients a reasonably accessible place to meet and mix with professionals and not only to hear formal presentations, but also to engage in sidebar discussions.</p> <p>From a patient perspective, a geographic regional structure promotes effective patient representation and interaction. Patients have better opportunity to meet and interact with patients and providers in their geographic area.</p> <p>Many complaints about the existing structure in the Regional Review in the Regional Review previously circulated are really about problems raised by acuity circle allocation, not about regional structure.</p> <p>I suspect providers who have operated for years under the DSA/Regional regime see the current structure primarily as an allocation system, thus they see less value to the current structure as a governance and networking system. As a patient, I was the beneficiary of the DSA/Regional system, but its value in allocation is not a day-to-day experience and is relative unimportant to the issues I have been asked to comment on during the last three years.</p> <p>In a time when we have moved from geographic distribution to circle distribution, and now moving to continuous distribution, a regional restructure project is premature. After a period of operations under acuity circles and/or continuous distribution the OPTN should review data to determine if there are patterns of hospital/OPO interaction</p>	x				x	x	x	x	
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	<p>that suggest how regional restructure might facilitate development of these relationships.</p> <p>Preliminary results indicate some issues with the current structure that may need to be addressed, but restructure is not necessarily the answer. Any proposal to restructure should describe why restructure is necessary to address those issues.</p> <p>We need more information to understand the problems that are suggested with the current structure. We should obtain information comparing regions by various metrics, such as number of transplant programs, number of OPOs, number of transplant surgeons and physicians, number of specialty programs, population, etc. If the regions are unbalanced, we need to see data that supports that conclusion. We know disparities exist, such as the comparison of the northwest to New England, but don't really understand that comparison without some numbers.</p> <p>There may be valid reasons to modify the governance structure to adjust for the significant discrepancies in the population and number of transplant centers in different regions. However, regional differences that are based in culture, shared experience, attitude, and closer working relationships need to be recognized in any governance modification.</p> <p>As a lawyer with more than a passing interest in politics, I see the role of regional meetings as the medical equivalent to town hall meetings, school board meetings, and other opportunities for those concerned to hear and be heard. I believe that is a strength of the system and should be retained in the policy development process.</p> <p>Having participated on both the Liver Committee and the Multi-Organ committee, it is clear to me that the OPTN is in critical need of cross-disciplinary groups. The idea of silos for each group, without the opportunity for each group to have expose to the concerns, issues, and concepts important to other groups will detract from policy development and potentially make it much harder for individuals with different points of view to work closely together. We have too many political silos in governance of the country and our states and it does not lead to collaboration.</p>								
Patient	<p>The Operations and Safety Committee thanks the OPTN Executive Committee for their efforts on the OPTN Regional Review Project.</p> <p>The Committee suggested that the function of the groups should be determined before deciding on a new regional structure. The Committee supported keeping aspects of the current regional structure. The Committee noted the benefit of groups based on regions, given differences among regions such as geography, logistical and travel challenges, and population density and makeup. The Committee noted that groupings based on populations is more beneficial than groupings based strictly on state lines. Additionally, the Committee noted that the current regional structure supports the already established relationships within the transplant community.</p> <p>The Committee suggested the regional review take into consideration organ procurement organization (OPO) regions and the new OPO metrics. The Committee noted that the Centers for Medicaid and Medicare Services (CMS)</p>		x						

	<p>directive for OPOs to influence transplantation rates has led to relationship development within regions to increase utilization, and a potential change to the regional structure would undo a lot of that collaborative work. The Committee also suggested a concept paper that is easily accessible and digestible as it is important for the transplant patient community to understand OPTN regions and their potential impact.</p>									
Stakeholder Organization	<p>The OPO Committee appreciates the opportunity to provide feedback on the Executive Committee's request for feedback on the OPTN Regional Review project and provides the following comments:</p> <p>One member remarked that regional meetings vary region to region, and that it would be nice to maintain current regional relationships, and maximize relationships with new key partners (OPOs and transplant centers) in broader sharing who are outside of the administrative region. Another member agreed, sharing that many OPOs have already begun to reach out to transplant centers that they have begun to share more organs with in broader sharing. The member added that a hybrid model built to optimize these allocation relationships in a more formal way would work best. One member agreed, noting that there has been a fundamental change in how procurement and allocation are organized, and redistributing those relationships within the broader sharing boundaries would be worthwhile.</p>			x	x					
Stakeholder Organization	<p>The OPTN Histocompatibility Committee appreciates the opportunity to comment on the OPTN Regional Review Project. Members emphasized the need to maintain an interdisciplinary forum for policy development in order to ensure stakeholders are properly engaged, and that the current regional system helps foster more productive discussions due to differing viewpoints. One member posed that entirely discarding geography wouldn't be appropriate, especially in regards to programs in close proximity more frequently working with other, and that it may be more appropriate to change the regional structure to reflect changes in populations. A member posed that there should be an effort to incorporate plain language explanations for proposed policies in order to be more accessible to the patient community and to the and general public. A member asked that the Executive Committee consider representation for histocompatibility labs who are part of a transplant hospital, and that currently they don't have their own voice.</p>			x		x	x	x		
Stakeholder Organization	<p>The Pancreas Committee thanks the OPTN Executive Committee for the opportunity to review their public comment proposal. The Committee provides the following feedback:</p> <p>Members agreed that it is important to have different perspectives convening for discussions at the regional level and that they would be worried about creating silos if the regional structure switched to the communities of interest model. A member noted that keeping the geographical component is important from the patient perspective, since patients in the same area will probably be experiencing similar issues.</p> <p>Members suggested that the regional structure should be retained, although it could be resized since transplant volume at certain centers have changed and there are new centers available. Members also noted that hosting the regional meetings in different locations from year to year,</p>			x		x	x	x	x	

	instead of staying in the one regional location, would allow more members to attend and share their perspective.									
Stakeholder Organization	<p>The Pediatric Committee thanks the OPTN Executive Committee for the opportunity to review their OPTN Regional Review Project update. The Committee provides the following feedback:</p> <p>The Committee emphasized the importance of geography in regards to issues that affect patients.</p> <p>The Committee was concerned with the communities of interest model, especially from the pediatric perspective, since it would group members with the same opinions together instead of encouraging discussions among members with different priorities or interests. The Committee stated that these diverse groups are where discussions arise about the impact non-pediatric policies have on children, which are crucial for the work of the Committee.</p> <p>In regards to whether the current regional structure and regional meetings are working, Committee members agreed that they felt there was adequate pediatric representation and that the virtual format has been helpful in allowing more people to share their opinions.</p>	x		x	x	x				
Stakeholder Organization	<p>The VCA Transplantation Committee appreciates the opportunity to comment on the OPTN Regional Review project. A member noted that the OPTN Board of Directors (BOD) is quite large and expressed support for restructuring the BOD. Another member expressed concern that some of the ideas developed by EY, particularly organizing around communities of common interest, might actually result in more silos among OPTN members. The member felt that multidisciplinary forums enrich discussions around OPTN policy. However, since some people do not always feel empowered to voice their opinions in the current OPTN structure, there may be opportunities for improvement in this area.</p>		x						x	

Appendix 2: Public Comment Feedback on *Redesign Map of OPTN Regions*

Support for retaining current regional map

About 20 comments indicated support for retaining the current regional map. Common themes were that the current system works well; regions represent historic relationships that should not be disrupted; and the current regional map facilitates a good size for promoting collaboration and discussion at regional meetings. Some respondents felt that they have good collaboration within their regions and worry that changing regional boundaries will interfere with relationships that have been built over the years. In 5/11 regional meetings, members submitted comments in support of the current system (Regions 3, 4, 6, 7, and 10).

Current system works well

- The current structure has served the OPTN very well (Membership and Professional Standards Committee)
- There is nothing wrong with the current regions except they don't dilute or get rid of the regions you don't want (Region 3)
- This is not a system that is broken (Region 6)
- Comfortable with the current configuration of regions (Region 7)
- The current OPTN regional design is meeting our regional needs and I don't feel that a change is warranted (Tammy Sebers)

Regions represent historic relationships that should not be disrupted

- AOPO would also point out... the need to preserve a strong working relationship that currently and historically exists. (AOPO)
- We eliminated Regions as units of allocation. The Regions are useful as administrative units and for public discourse and debate. Much like US states, the Regions have shifting population numbers, demographics and relative engagement with OPTN. However, within the Regions, we have historic ties and ongoing relationships. The more we consolidate Regions, the more voices we exclude. We benefit from diverse viewpoints and multiple voices. We benefit from the existing relationships within the current Regional framework and the vigorous discourse that comes from the Regions. I advocate keeping the original Regional structure. (Region 4)
- Do not believe a change in regions represents enough quantifiable benefit to patients or providers to justify the sacrifice of decades of working relationships within regions or of region specific process management (elections, physical meeting sites when these resume etc.) (Region 4)
- Currently established regional relationships are important (Operations and Safety Committee)
- Region 6 currently embodies the OPOs and Transplant centers we work closely with based on allocation schemes and it would be such a disservice to lose the collaboration we currently have. (Region 6)
- I worry, as a member of region 6, that the networking and is partnerships would be deleteriously affected. We fight geographic challenges that will only be made worse with any of these changes, making it harder for us to be engaged and innovative (Region 6)
- [A redesign] also impacts the ability for DSAs and TxCs to collaborate (Region 6)

- This would be like breaking up families just because they don't fit into some arbitrary criteria that the administrators have defined. There are people involved with these centers with patient sharing, research collaborations, and networking. We are not just pieces that you move around on a chess board. (Region 6)
- We like the map the way that it is. As you saw on the call, we are a particularly collaborative group. I would think we should only disrupt this if we have a really good reason (Region 10)
- Now that regions are no longer used as units for allocation, there does not seem to be a strong rationale to break apart such a collaborative group. (Region 10)
- Any redesigning should be backed by conclusive data, as, otherwise, working relationships within existing regions may be compromised. (Transplant Administrators Committee)
- Any remapping of OPTN regions should be weighed against the cost of breaking historical collaborations within regions, and at present, there is not enough data to support a redesign. At the heart of the issue is regional collaboration, and facilitating this collaboration should be a key goal of a remapping project. Members recommended that instead of changing the regions and disrupting those existing relationships, the OPTN should instead promote collaboration along the existing regions, since regions today can be a “bubble” and it would be helpful to learn more about practices in other regions. (Transplant Coordinators Committee)
- NATCO believes that a redesign can have potential positive or negative impacts to both organ procurement organizations and transplant centers depending on the design. Reducing the number of regions and consequently increasing the areas of coverage may impact potential collaboration within the regions due to distance. The current model of 11 regions provides a substantial longstanding history of valuable collaboration (Organization for Donation and Transplant Professionals)

Size of regional meetings promotes collaboration and discussion

- The current map allows the regional representative to accurately gauge the membership opinions due to size and personal contacts (Region 10)
- The current regional structure allows for enhanced OPO and transplant center collaboration; the ability to discuss and address challenges that are unique to the region; promotes special interest group collaboration and pilot programs; the ability to provide feedback on policy changes from our unique perspective. Any of the proposed regional redesigns greatly diminishes or eliminates these functions. (Tammy Sebers)
- It seems that the decision for a re-design has been made. If that is the case, I think that an 11 region model is still the best in order to keep the regions as balanced as possible and to have regional meetings in which all members can be heard. (Christopher Anderson)

Opposition to changing regional map

Over 50 comments either opposed changing the regional map or expressed uncertainty as to whether changing the regional boundaries would provide value or benefits over the current regional map. Common themes included concerns that changes would not improve representation; changes would not advance OPTN strategic goals; and concerns that this is not the appropriate time to change regions. In 8/11 regional meetings, members submitted comments opposing changes to the regional map (Regions 2, 3, 4, 6, 7, 8, 9, 10).

No value to changing regions/benefit is unclear

- The AST appreciates the need to periodically review OPTN regional structure; however, we are concerned that OPTN has not sufficiently outlined the anticipated benefits and guiding principles for fair representation. Without this clarity, it is difficult to support any of the proposed maps over the current OPTN regional structure. (AST)
- ANNA needs more information regarding risks and benefits before commenting or choosing an option on this project. (American Nephrology Nurses Association)
- The Committee does not support redesigning OPTN regions over the existing regional structure, at this time. (Patient Affairs Committee)
- Would like to see potential suggestions to consider to determine actual consequences and benefits. (Region 2)
- I have not seen any compelling data to justify any benefit to redesign of OPTN regions. I do not support redesign of OPTN regions without more clear data from modeling. (Region 4)
- Benefits of changing are not well-defined, particularly with the dissociation of regions from organ allocation policy. (Region 4)
- If we must change the Regions, I would keep as many Regional units as feasible. We could easily argue for consolidating US states with the same graphs and maps. Why don't we combine RI and DE? Why are they even states. Yet, we have no credible proposal to do so, and for good reason. (Region 4)
- [There is] a lack of a clearly defined issue with the structure as it currently exists or a clear benefit to another map other than rearranging percentages and patient counts. (Region 4)
- I'm still not sure I understand the purpose of this change. If there is concerns about representation on committees, etc., then perhaps that can be determined separately from the regions (a unique system). The current geographic grouping for regional meetings makes sense for my region as we have similar experiences around patient population, donor procurement, etc. (Region 6)
- I'm unclear that there is really a need for change. Some of the basic assumptions make no sense. Clearly the framers of the constitution struck a balance between population and land mass when they developed the house and senate. (Region 6)
- Now that we have geographic distribution (nautical mile/concentric circle) as a method for organ allocation, do we need to change the current region design? (Region 6)
- Speaking on behalf of Hawaii, redesigning the Map of the Regions is not a simple thing for us. We are usually just an insert on your map and in fact, we are 2500 miles away from everyone. Despite continuous organ distribution, we will not be realistically sharing organs with centers in the midwest or East coast on a regular basis because of sheer geography. You cannot just erase the distance. We have different challenges that distant mainland centers would never understand so making a region that involves a large distance between centers does not make any sense. (Region 6)
- We feel strongly that enlarging Region 6 to increase "members" would not lead to equity and would have a number of unintended consequences; less involvement at regional meetings, decreased input from centers, lower personal involvement within UNOS committees. The changes in kidney/liver distribution abrogates a need for re-drawing the OPTN regions. The current system is not broken, why try to reinvent this? (Region 6)
- Need to establish the goals for doing so and how it will benefit transplant candidates (Region 7)
- I don't know that there is a real advantage. (Region 8)
- I am unsure the benefits to changing the OPTN regional maps. Change for change's sake. I don't object to a change in the map. Just [its] impact beyond current state. (Region 9)

- With a move to remove physical boundaries from allocation it doesn't make sense to change the regions. I'm not resistant to change, but I feel there needs to be a more solid reason but feel it wasn't addressed. (Region 10)
- Some members noted opposition to the possible regional redesign noting the lack of a sufficient reason to change the regions. (Region 10)
- Since regions are not tied to allocation any longer, I don't fully understand the purpose of redesigning them as they still foster member feedback and collaboration. (Christopher Anderson)
- I think it is important to ask the question of "why" the regions exist. I hear a lot about relationships among OPO's and Transplant Centers. Does this directly impact how many patients are transplanted? If it does, I think it is important for this to be a factor. If not, I think there are many opportunities within the OPO and Transplant community to learn from others - regardless of the regional framework. How does the designation of the regional boundaries support the Strategic Plan? (Anonymous)
- I think redesigning the regions is unnecessary. (Douglas Norman)

Changes would not improve representation

- Rather than redesigning the map of OPTN regions, consideration should be given to changing the number of regional board seats allocated to each region, if the driving factor is representation. (Patient Affairs Committee)
- No trust in this executive leadership of UNOS to fairly redesign (Region 3)
- It seems like changing the current regions would be intended to fix a disparity but in practicality, with the removal of Regions from allocation, really the only equity issue would be in representation. It is unclear that any alternative map would improve disparity (real or perceived) rather than simply rearranging it. (Region 4)
- I am strongly opposed to changes to the current OPTN Regions. Reducing the amount of regions limits the amount of unique input provided through committees and the Board. It seems like the goal is to shift from a Senate style governance to a House of Representative style and the problem with that is it dilutes the voice of regions that have different challenges and experiences with policies. Region 6 may not be as populated as other regions, but we experience different challenges with policies based on our size and I feel our unique input is just as important to have [its] own platform as the other more-populated regions. (Region 6)
- Broadening and decreasing regions decreases the voices of smaller areas/population density and specific needs of various regions. It decreases collaboration amongst local centers/region. I strongly oppose suggested models of region redistribution (Region 6)
- I am against this redesign. This does not support the interests of our region. We will lose the ability to provide feedback that is specific to our geographic area and our voice will diminish. (Region 6)
- I fail to see where any of the current maps really improve on the current one. If the goal is to improve the representation, education, etc. (everything but organ allocation) none of the shifts really matter. The representatives currently do not "represent the concerns of the region, but are currently acting "in the best interest of the OPTN" and I imagine that will not change regardless of the map used. Looking at the maps per se, many of them have Iowa in the same reconfigured region as the States of Washington and Alaska. That makes little sense to me from the perspectives of representation or education. I do not see the added value of change here for change sake. The most important change that could occur is to allow the representatives to actually reflect and vote in the interest (with the sentiment) of the region they represent. The second is to reduce the size of

the Board to something more functional (an in line with the models of most highly functioning boards of Governors) and representative of the country as a whole. (Region 8)

- I do not consider the current regions inequitable and I find that my current region is a collaborative group of centers that share best practices and participate significantly in regional meetings and UNOS matters. (Christopher Anderson)
- The central argument of the proposed redesigned maps is that equity should be defined based on the creation of regions that are numerically/proportionally equal based on population, regardless of other factors. This video and the presentation to our region 6 meeting explicitly suggest that landmass is not relevant, and this assumption is a central tenant of the proposed options. I would suggest that there is more to equity than just numbers, and the foundational postulate that landmass is not relevant is in fact false, and is not an acceptable assumption to make when redesigning UNOS regions. We face geographic challenges in our region that are not relevant in more populous/population dense regions with more transplant centers and greater access to transplant care. Furthermore, the presumption that continuous distribution solves this inequity is spurious. Patients who live in remote parts of the country, far away from a transplant center, experience inequities in transplant care which likely will not be solved through continuous distribution. Preserving our region preserves our voice to continue to raise these concerns and advocate on behalf of the patients we serve. (Chris Connelly)
- The proposed changes would significantly negatively affect region 6. The regions were established to provide a forum for discussion among geographically linked transplant center and their patients. There is no mandate to make the regions be of equal population. We know that in a country of 325 million people there will be many different viewpoints. Some of these are based on geography (east coast v. west coast v. mid-west v. southeast v. southwest, etc). It is unlikely that centers, and their patients, in Seattle have the exact same concerns as centers in Iowa, North Dakota, South Dakota. Regional meetings that spanned that geography would be unwieldy and probably under representative. Region 6 has a different way of voting, that would likely change if it expanded greatly geographically. Each organ program is represented by a physician and surgeon who have a vote on policies. Other regions allow only one vote per transplant center. Region 6's way of voting has fostered greater participation from transplant centers, whose representative feel more connected to policy decisions. Please don't change the regions--they are fine, as is. (Douglas Norman)
- Any of the proposed regional redesigns greatly diminishes or eliminates [the current functions of OPTN Regions]. This is especially true of Region 6 which already covers the largest land area and has unique challenges because of this. Adding more states will increase meeting logistical challenges and impact participation. The larger the region the more dilute our voice will be. I am concerned that transplant center, OPO, and true regional interests will not be recognized or supported and that we will lose our ability to provide meaningful feedback. I am not in support of any of the proposed OPTN regional redesign options. (Tammy Sebers)

Changes would not advance OPTN strategic goals

- A member said that investments of OPTN time and resources should be focused on shortening the waiting list and increasing the number of transplants instead of reorganizing regions (Patient Affairs Committee)
- Several MPSC members questioned whether changing the regions would further any of the OPTN strategic goals. (Membership and Professional Standards Committee)

- We have a lot of work to do to advance diversity, equity and access, and we are all dedicated to those critical goals. However, changing the Regions would not credibly advance those goals. (Region 4)
- To some extent, this sounds like rearranging deck chairs on the titanic. I'm not sure that this will actually advance the practice of transplantation nationwide. (Region 9)

Not clear that it is worth expending additional resources to change regions

- The OPTN needs to carefully weigh the overall returns on investment of redrawing new regions. Any future proposal should provide assurances that such a shift is justified by a quantifiable benefit to patients or OPTN members. Rationale for change should include demonstrated increase to collaboration, decrease in OPTN and OPTN member cost, and improve equitable representation on the OPTN Board and Committees. (AST)
- This is a large undertaking by the OPTN, and consequently, the improvements that stem from regional redesign should be weighed against the same effort applied to proposals that directly impact transplant candidates and recipients. (Patient Affairs Committee)
- I would suggest regional collaboration and communication are essential to our ultimate goal of maximizing the number of transplants performed and decreasing deaths on the waiting list; in the absence of a clear benefit to outcomes, I don't believe this is a good use of our time and energy as a community. (Region 4)
- Strongly oppose - Distance and time zones would pose challenges, increase time out of office etc, travel costs. Most impact for Region 6 due to time zone changes. (Region 6)
- There are huge logistic and cost issues with a change like this. (Region 6)
- Why would UNOS want to spend so much time and \$\$\$\$ reorganizing the regions when relationships have been clearly established already? (Region 6)
- I am not against changing the regions if it improves patient outcomes and access to organs. An estimate of how the implementation would work with respect to time and resources would be helpful to determine if the effort would be worth the potential benefits. There is no doubt that there could be benefits if you balance the region metrics better. But what time, efforts, and resources will it take to do that? What is the cost of [implementation] against the new region benefits? I am generally supportive of this initiative. (Region 7)
- UNOS is [wasting] their time on things which are not important at the end. As it does not change the number of available kidneys. UNOS should spend their time on trying to persuade government to make a kidney donation being a default option (with the deceased family having an option to opt out) — which is a Spanish model — which works! Also non- monetary incentives (paying for funeral, free medical future medical costs, etc) to the immediate family of deceased donors for allowing organ donations. UNOS seem to wrongly conflating incentives for LIVE kidney donations vs cadaver kidney donations. Roughly 50% of potential deceased donor kidneys go to the grave with them — what a waist!! Why deceased kidney family cannot get non-monetary incentives while hospitals and the rest of medical profession including UNOS stuff getting paid over 1 million dollars for each diseased donor organs. UNOS to me is a big bureaucratic machine which only wants to create a perception that they are trying to being helpful to the public — but refuse to address the real issues. Thank you UNOS for doing a “great job”. (Anonymous)

Concerns about timing

- AOPO would also point out that now may not be the right moment for such a drastic change given other significant changes underway. (AOPO)

- With the upcoming allocation changes due to continuous distribution, this action may be premature if new allocation patterns arise following the implementation of continuous distribution (Patient Affairs Committee)
- Members said the timing of this project is interesting given that the OPTN is in the middle of shifting each organ to a continuous distribution allocation model. Members said there is anxiety over the new CMS regulations since it is possible that the lowest 25% of OPOs would get absorbed by other OPOs, which would result in a large change to current DSAs. Any redesigning of the OPTN regions could add unintended complications. (Transplant Administrators Committee)
- It would not be the right moment for large scale regional consolidation given all the other changes happening right now. (Region 1)
- We have concerns related to impending DSA changes as a result of the new CMS regulations which will require the lowest performing OPOS to be absorbed by other OPOs. Having one OPO that sits in more than one region could pose issues. (Region 7)
- One member said that due to all of the other changes occurring in transplant, they recommend not changing the regions at this time. (Region 11)
- I would caution on timing, however, that this proposal is occurring at a time of significant mistrust in multiple regions related to the policymaking process related to eliminating DSA and region in allocation of organs. I would suggest shelving this until the community has moved past that and then consider a realigned 11-region map. (Luke Preczewski)
- I believe the current OPTN Regions should remain intact for now. The changes in broader sharing/allocation that have happened so far are significant and we are not in a final state to fully assess the impact. Changing the OPTN Regional map right now will not allow a clean assessment of the impact of that change. (Pacific Northwest Transplant Bank)

Support for redesigning the regional map

About 30 comments expressed support for redesigning the regional map. Common includes general support for redesign (e.g., it is time to change the maps), support for regions to be more equal based on the proposed metrics, concern that current regions do not provide equal representation and there is no rationale to the current structure, and support for redesign as an opportunity for organizational improvement. In 7/11 regional meetings, members submitted comments in support of redesigning the regional map (Regions 1, 2, 4, 5, 7, 10, 11).

General support for redesign

- Much needed re-alignment of the OPTN/UNOS (Region 4)
- TXDM strongly supports a change in regional distribution although there is a lot to consider. (Region 4)
- It's time the regional maps be updated. The examples presented are interesting and demonstrate a great deal of thought has been exercised in developing the various scenarios. Having just seen the proposal, I am definitely in favor of equalizing the regions, but this undertaking requires more time to study. (Region 5)
- We agree that the centers that work more closely together should be grouped together... So I do support in changing the regions to reflect this. (Region 5)
- Support in redesigning the regional map if it improves patient outcomes and access to organs. (Region 7)

- I think that since we are doing away with UNOS regions and going with distance from the donation/procurement hospital that moving away from the current region system makes sense. (Anonymous)
- Agree that the redesign would be beneficial [in] reducing waitlisted patient death (Anonymous)

Sensible for regions to be more equal based on proposed metrics

- SPLIT supports the concept of resizing to provide “balanced boundaries and equitable representation” as it relates to OPTN governance and operational effectiveness. Although community feedback is sought on which regional design would best serve the OPTN, it is impossible to provide feedback without additional data. (Society of Pediatric Liver Transplantation)
- Excited to see a more even distribution for population. (Region 5)
- Evening out the number of donor, recipients, etc. is a great idea. (Region 5)
- Regions should balance based on population and number of transplant centers (Region 5)
- I support redesign to equalize the criteria listed. % of membership and Recipients being the biggest priority. (Region 10)
- CASD is not opposed to a redesign of the regions with the intent of optimizing the governance and structural effectiveness of the OPTN and generally agrees that the existing regions could be resized to promote balanced boundaries and equitable representation. (UC San Diego Health Center for Transplantation)
- I think going to a more balanced region breakout has merit. The critical point is what aspect to balance. (John Durning)
- As region is removed from allocation policy, the purpose of the regions is primarily the governance of OPTN. With that in mind, a map that more evenly distributes the regions across donors/recipients/population makes sense to give everyone an equal voice. (Rachel Engen)

Current regions provide unequal representation

- We support the redesign of regions to create more equalized representation on committees and the board. The redesign should focus on balancing the number of candidates, transplants, and transplant programs in the region. (Region 1)
- I am a transplant hepatologist in California, which carried nearly 40 million people alone. Region 5 is currently too big and I would support any map that decreases the size of the region to at least California alone, in order to make it more equitable with the rest of the regions (Region 5)
- This work needs to move forward with broader regions of sharing and better representation of stakeholders to the board (Region 5)
- Equity of representation as north star is absolutely desirable; loss of productive relationships and scale/size are uncertain. Is there risk if region is different than DSA boundaries? (Region 8)
- AOPO recognizes that currently, the regions are not drawn consistently as to size, whether measured by population, number of OPTN members, number of waitlist candidates, or volume of donors or transplants. On this basis, AOPO supports a re-design of the OPTN map to better equalize the Regions, particularly as that relates to Board and Committee representation. (AOPO)
- Members supported equal representation on the Board of Directors, particularly for voting on high-impact proposals like changes to organ allocation. (Vascularized Composite Allograft Transplantation Committee)

Opportunity for organizational improvement

- As the only OPO in region 1 (and the only region with only 1 OPO) we have seen very effective aligned collaboration in regard to policy and have harnessed the region structure for driving performance improvement. Nonetheless, current and future allocation reforms will continue to

increase our work and collaboration with OPTN members in NY and elsewhere. We see value in the region being re-organized to include frequent partnerships in clinical activity between OPTN members to further the regions as a performance improvement frameworks as well as representational functions. (Region 1)

- There is value in redesigning the region to include frequent partnerships in clinical activity between OPTN members to assist in performance improvement as well as representational functions. (Region 1)
- The changes in allocation have minimized the relevance of the regions. I like the idea of "like size" OPO's working more closely together, and the strategies that can come from this that can drive improvement. (Region 2)
- Another member noted that the changes in organ allocation have minimized the relevance of regions, and they would support the idea of having similar sized areas working more closely together. The strategies that [come] from that organization can drive improvement. (Region 2)
- The current committee regional representative appointment process varies amongst regions, and there is an opportunity with restructuring to bring consistency in all regions. (Region 7)
- Several members support a change to the regional map and commented that this change is an opportunity for robust quality improvement and overall organizational quality improvement (Region 8)
- One attendee commented that the regions should be optimized for their current purposes – large enough to promote diversity of opinion, but small enough to encourage open, thorough dialogue. (Region 11)
- Since regions have less to do with allocation and more to do with collaborating at regional meetings and appointments to the Board and committees, we should optimize them for their current purposes. (Anonymous)

No rationale to current structure

- The current regional structure is inefficient and ill designed with some areas that already have to operate across regional lines (Region 7)
- A restructuring of the regions makes sense for a number of reasons. There is no rationale for the current structure. Legend has it they were originally drawn on a napkin! (Anonymous)

Feedback on regional design for governance, structure, and data reporting

The Executive Committee sought feedback on whether the OPTN should use one consistent regional design for governance, structure, and data reporting functions or select specialized regional designs for each. Of the 9 comments received in response to this question, most comments (5) supported one consistent regional design, though one comment suggested that data reporting should be more fluid. Two additional comments questioned whether a regional design is necessary now that regions are not used for allocation.

- The OPTN should use one consistent design for governance, structure, and data reporting functions of regions. Considering that there is impetus to remove discrepancies between regions with the redesign map, there should be less impetus to govern them differently. The transplant community is relatively small, and well connected with each other. Implementing differences in governance and regulation between regions will only serve to create rifts in the community. With the newly

implemented allocation changes, the “silos” of regions no longer exists as organs frequently cross regional boundaries at this time. (ASTS)

- We suggest one consistent regional design for governance, structure and data reporting. (NATCO)
- It would be best to keep one consistent regional design for governance, structure, and data reporting. The creation of select specialized regional designs will add complexity without value. (AST)
- SPLIT agrees that, once having met and assured equitable metrics of redesigning the regions, that one consistent regional design be used for the governance, structure and data reporting functions in order to be most efficient. (Society of Pediatric Liver Transplantation)
- Absent any irrefutable evidence of derived benefit, we agree that one consistent contiguous regional design, which follows state lines as boundaries, seems a reasonable and more fiscally responsible approach than selecting specialized regional designs to manage the various functions of governance, structure, and data reporting. Specialized regions seem unnecessarily complex and would likely result in increased administrative costs. Further, retaining geographical segmentation will help ensure that stakeholders who are proximate geographically who generally share interests and have common experiences with their patient populations have a unified voice. (UC San Diego Health Center for Transplantation)
- Ideally, data reporting should be more fluid than regions. For example, the OPO clusters that UNOS developed a few years back have been helpful in performance improvement. (Operations and Safety Committee)
- What is the purpose of UNOS Regions? They have no relation to either organ procurement nor organ allocation. They were created in an era before widespread use of the internet, and served as a means for discussion of issues among nearby transplant professionals. But with modern online communication, is there any need to continue having regions? (Anonymous)
- With the new organ allocation policies, regions seem less necessary today than they were in the early days of the OPTN. And now, with the OPO Tier model and metrics, the OPO map will likely change significantly. Assuming Tier 1 OPOs begin taking over the Tier 3 DSAs, it's conceivable that one OPO could operate several DSAs all across the country. This could support the removal of any contemplated OPTN region map into one single region. (Region 8)
- As long as these regions don't become an impediment to the [paired] exchange program - they focus on administrative functions - then whatever is the most administrative efficient regional mapping should be considered. (John Durning)

Feedback on number of regions

About 65 comments provided feedback on the number of regions, including 10 comments in support of 4-6 regions; 20 comments expressing concerns regarding fewer, larger regions; 12 comments in support of 8-11 regions; 14 comments in support of 11 more equal regions; 2 comments in support of 11 more equal regions as an interim step to four regions; and 2 comments in support of having more than 11 regions. There were five additional comments regarding the number and size of regions.

Members who supported 4-6 regions said that those maps were more aligned with current allocation practices, and fewer regional meetings that offered virtual attendance options would be more cost efficient. Members who opposed fewer, larger regions were concerned about losing regional representation on the Board of Directors, “diluting” regional representation, and the additional logistical challenges of in-person meetings. Members who supported 8-11 regions thought that these maps struck

a balance between updating boundaries to reflect changing working relationships without causing too much disruption to existing relationships. Members who supported 11 more equal regions thought that this approach would allow for changes while maintaining the level of regional representation and keeping the regions a reasonable size.

Support for 4-6 regions

- With the advent of newer procedures not available at the time of the last redesign such as DCD, the constraint in time to implant of the donor organ is now increased. This makes the larger regions more viable; I would recommend the four-region approach [or] something similar along that line. (Peter Fee)
- I would seem to favor the 4 region model since basically divides the U.S. into four larger regions but the only concern I would have is will this lead to better regional meetings or less functional meetings since there will be so many people involved in each region. The current benefit to the smaller regions is that I feel there is better discussion since the size of the group is smaller but not sure how that will change if we go to a larger representation in each region. Overall, I still think the large 4 region plan seems to be the best option. (Anonymous)
- Models 6 and 4 appear to align more with the current allocation structure which will allow for better communication and help drive [process] improvement. (Region 3)
- I am in favor of having fewer large regions, since the regional structure is slowly not being used for organ allocation. I think the optimal number is in the range of 4 - 6. We want to continue to have regional collaboration, but work toward an equitable national organ allocation system. (Hans Gritsch)
- While LifeGift has enjoyed the collaboration and input in the current and historical model, we believe reducing regions to a 4-6 region administrative unit model is more consistent with how we operate in the new environment. Regarding loss of opportunity for collaboration and input, we have all learned that using virtual and electronic communication models allows for many opportunities to communicate and collaborate successfully, regardless of arbitrary lines on a map. Regarding OPO communication across fewer regions, this actually is much more consistent with current practice where the OPO DSA is the USA and all of us in this community interact more than ever with "newer" or non-DSA transplant centers and other OPOs. We also believe this will reduce administrative cost for UNOS and members in travel and meeting expense. (LifeGift)
- As regions are removed from allocation policy, the purpose of regions is primarily for the governance of OPTN. More even distribution across regions makes sense to give everyone an equal voice. There is a benefit to having multiple states within a region, and having fewer (4-6) large regions, to have regional collaboration. (Region 9)
- A member stated support for the six region map, as it provided the most balance between population, donors, members, recipients, and transplants, with the eight region map as their second choice. (Region 11)
- Perhaps fewer regions makes sense, especially if we can do virtual meetings to facilitate more involvement. (Region 7)
- One member noted that fewer regions could be more cost effective to administer. (OPO Committee)
- Support smaller number of regions to promote greater collaboration (Region 5)

Concerns regarding fewer, larger regions

- I think 4 is too few (Region 5)

- 4 is too small (Region 7)
- I am concerned that a 4-region model would result in a regions too large to allow full participation of members at regional meetings and on committees. (Rachel Engen)
- The OPTN suggested that the redesigns should have enough representation from the rural communities so that larger areas don't dilute them. One issue that might occur is that a region could get too big and this could end up resulting in having difficulty managing the given feedback. Having the knowledge and being able to use technology for communication models opens up many more doors for possible ways of communicating. Allowing the 4 regions would divide our country into four sections. While this seems to have both pros and cons, I see one of the cons being that now since there are only 4 sections, each one is going to be very populated. Larger sizes could result in a more difficult time communicating and hearing out all ideas though with a bigger population comes more ideas though it would be more chaotic than a smaller sized population and it would make for a better discussion. (Anonymous)
- AOPO would not support moving to a 4 or 6 region map unless Board membership from each region was increased to ensure appropriate representation. (AOPO)
- AST would not support the regional map models with the most significant consolidation such as 4 or 6 Regions as they would be geographically unwieldy. Because of this, it seems unlikely that regional representatives would be able to fully appreciate and "represent" the needs of their constituencies. It also could be destabilizing to make dramatic changes to the regional representation given all the significant allocation changes underway. (AST)
- We would advise against any redesign that significantly lowers the number of regions without a simultaneous redesign of the committee and Board structure as well... While allocation is no longer a pertinent feature of the regions, if considering a system that aligns with the new distribution models, then the 4 equal regions proposed make sense for patients and transplant programs; 6 equal regions does seem to provide slightly more equity. Whether 4 or 6, again such a significant decrease in regions would require a simultaneous redesign of the committee and Board structure that the community largely agrees upon prior to passage and implementation. (UC San Diego Health Center for Transplantation)
- It seems that 4 and 6 spread too much and takes away the advantages of knowing people in a small region. With such large regions it would be easy for some voices to be lost. (Region 7)
- Reducing to 4 or 6 will dilute representation unacceptably. (Luke Preczewski)
- Models with less than 8 regions become unmanageable geographically as a large portion of the benefit of regions is geographical representation on the Board (the Midwest or Southwest is different from California or the Northeast) and the networking regional meetings provide. If the regions are too large, they start to fail in these regards in my opinion. (Region 8)
- Consideration should be made so that regional meetings/feedback, and collaboration is manageable. If the region gets too big, feedback could be difficult (Operations and Safety Committee)
- Another member supported the redesign project but asked that the community be mindful about the new structure and function of the regions, and to not limit regional representation based on fewer regions since this would negatively impact overall community development by reducing exposure to broader experience and viewpoints. (Region 5)

- The VCA Committee’s discussion included support for fewer regions, but cautioned against making regions too large since it would be difficult to have thoughtful discussion with too many attendees. (Vascularized Composite Allograft Transplantation Committee)
- A member explained that the regions serve as a forum for robust and healthy dialogue for proposed policy. A region should be small enough to encourage open, easy, thorough and comfortable discussion for everyone, and large enough to promote a healthy diversity of opinion. (Region 8)
- As regions grow in size (as reflected in some of the presentation examples), there could be less “close-knit” collaboration between programs. (Transplant Administrators Committee)
- With respect to the discussion around a redesign of the regional map, the question should begin with what are we trying to accomplish? There is little argument to be made that the original regions were designed based on state lines and in a way that fostered relationships amongst centers, OPOs, patients and professionals who were in geographic proximity to one another. They occurred at a time that predates the internet, travel was more challenging, and the overall field of transplantation was still in its infancy. While the organic creation of the regions wasn’t built on scientific data the by-product of the regions has been the creation of community hubs for shared ideas that have advanced the field of transplantation. So while many advances have occurred over the last four decades, when we look at the regional map the question needs to be asked in a slightly different way. What is the role of regions as organ allocation has moved to acuity circle methodology? I would argue that some of the positive byproducts of the original design occurred because there are variable/local issues that transplant centers, OPOs and patients face based on the social, demographic and geographic factors that differ across the country. Shrinking the number of regions may make sense from a modeling perspective but it misses the mark on what the new land mass regions would mean to an area that is acutely expanded. Decreasing the number of regions further dilutes the voice of centers in less populous areas using the current voting model. (David Gerber)
- Several members agreed that fewer regions could challenge productivity of OPTN regional meetings, particularly if regional meeting sizes reach more than 500 members. (OPO Committee)
- Larger and fewer regions risk diluting individual voices within a region. It may be harder for members to represent their unique challenges (e.g., a member serving patients in a sparsely populated region), and it could dilute patient and donor family voices... Another MPSC member expressed concern about losing the ability to meet and discuss local practices in regional meetings if the regions increased in size. (Membership & Professional Standards Committee)
- A number of members also contributed that, as regional size grows in some of the maps, both individual voices could become dilute and travel could be a concern. (Transplant Coordinators Committee)
- Another member stated that smaller regions are better, and if the hope is to increase interaction, the OPTN could alternate how the groups are clustered from time to time. For example, if regions become more homogeneous, some days New Hampshire could cluster with New York and sometimes it could cluster with Pennsylvania. (Region 1)

Support for 8-11 regions

- I liked the Model with 8 regions. May save money in organizing meetings. Gives members more feedback from peers during discussions. This model seems to align centers with many of the same centers with whom they have formed relationships in the old Region map. (Region 3)
- Favor redesigning the map of OPTN regions with 8 or more regions. (Region 7)

- If change must occur the proposed eight region map does best job of continuing those relationships for our region. All proposals make Region 10 "less average". (Region 10)
- 8 Regions would be my second choice [after 11 more equal regions]. (Region 5)
- AOPO supports the 11 or 8 region re-design models as a measured way to proceed without disruption (and AOPO also understands that geographic square mileage is not a factor that needs to be balanced). (AOPO)
- Likely 8-11. (Region 5)
- A member shared support for either eight or eleven regions, to try and balance the need for continuity with the need for acknowledging the new relationships allocations changes create. The member added they were not concerned about regions covering large geographic areas since programs already frequently travel long distances between donor hospitals or OPOs. (Region 11)
- I support a redesign and like the 9-11 regions (Region 5)
- I think roughly 10 seems best. I think that the area should be considered as well, since most centers have a certain nautical mile circumference, collaborating with programs within that area might be valuable. (Region 7)
- Either 11 more equitable regions or the 8 region models can accomplish [more equal representation] while not destabilizing existing strong collaboration between current OPTN members (Region 1)
- Agreeing that no model is perfect I would argue that creating a regional map of 10-11 regions accomplishes a critical mass effect with multiple communities of varying backgrounds empowered to articulate the needs that they and their patients face on a daily basis. (David Gerber)
- Another attendee shared their institution's support of redesigning regions to create more equal representation on committees and the Board of Directors, either with a 10 or 11 region model. (Region 1)

Support for 11 more equal regions

- To promote continued collaboration, we recommend a model that retains the current 11 regions adjusted for some of the key metrics as outlined in this concept paper. (NATCO)
- 11 regions would be ideal. All of those maps show California alone, which is fine with me (being a California OPO). (Region 5)
- We prefer the 11 region maps with California in [its] own region. (Region 5)
- Would strongly favor one of the 11 region models, with equitability metrics balanced. (Region 2)
- COSL supports a larger number of regions (eg. 11) in order to increase the number of voices in the decision making. This also allows better accessibility at times when in-person meetings are necessary. (Region 8)
- An attendee commented that the redesign is needed, but that they did not support fewer than 11 regions, so that the regions can remain a manageable size that allows for more intimate meetings. (Region 11)
- The number of regions should remain the same and the new 11 region model allows for representation of the population demographics, in particular the characteristics of people, hospital systems, classes and academic centers within the population. Appointments should occur by a regional vote of people who nominate for particular position or are nominated by others for these positions. The electoral process needs to be independent of the existing board, UNOS and OPTN influence. At a time when trust in the process of the UNOS is low, this simple change will create trust in the UNOS organization by introducing a democratic process. (Richard Gilroy)

- The American Society of Transplant Surgeons (ASTS) overall supports the portion of the proposal suggesting redesign involving 11 contiguous regions, however we oppose proposed changes to the governance structures. The ASTS commends UNOS for working to balance discrepancies among the various UNOS regions in several important metrics. The Committee has offered several well thought out redesign maps for consideration. The advantages and disadvantages of lesser regions are presented as well. The ASTS believes the number of regions should remain the same at 11, and these regions should remain largely contiguous. This maintains the diversity and constancy of regional representation, and makes it less cumbersome for attending regional meetings by keeping the regions smaller. Among the redesign maps that have been presented, Figure 3(a) appears to hit the average on almost all important metrics. (ASTS)
- Map 11A seems to make the most sense from an equity standpoint, in my opinion. (Region 5)
- I don't see a reason to change the number of regions. I think the 11 equal regions option (A) has the most consistent average % of population, donors, recipients and transplants across all regions (excluding % land area, which I don't feel is very relative to this evaluation). (Region 8)
- I like the 11 equal regions, slide B, idea. (Anonymous)
- I favor 11 regions, option B. If less than 11, I'd suggest 8, but taking into account appropriately broad representation needs to occur. (Anonymous)
- In general, a regional realignment to rebalance the regions is sensible, so long as the number of regions is maintained. (Luke Preczewski)
- Advocate for similarly sized regions so there can be distinct representation. (Region 10)

Support for 11 more equal regions as an interim step to 4 regions

- Option A for 11 regions or going to 4 regions seems to make sense, based on the information provided. Please consider: What would the cost difference be for either of these options? Is there cost savings going to 4 regions? What is the long-term benefit comparison? How will patients benefit from a change? (Anonymous)
- I appreciate the OPTN work on this challenge. I wonder if we can eventually get to the 4 regions map? As an interim step I would start with region map 11 A. (Region 8)

Support for more than 11 regions

- I would support a redesign that adds more regions. This could help meet the goal of equalizing numbers with a focus on continuous distribution or Nautical Mile circles. (Region 6)
- If you insist on change, instead divide the larger population regions into 2 smaller ones, thus increasing the number of regions. (Douglas Norman)

Other

- NEED to change the map. 11 may be too many, but 4 may be too few, please add more options than three different versions of 11 region map (Region 5)
- Not a big fan, but if the EC wants to propose 2 maps for discussion that would be acceptable (Region 5)
- As long as there is a major airport and a virtual component to regional meetings, I don't have strong feelings about the number. The bylaws will need to be rewritten for any change. (Anonymous)
- The Committee feels that the success of virtual regional meetings indicates that representation and attendance from regional members will continue even through any redesign. (Transplant Coordinators Committee)
- Given the success of virtual meetings, the Committee does not feel that larger regions will limit patient access to regional meetings. (Patient Affairs Committee)

Feedback to consider in redesigning any new map

About 60 comments provided feedback that the Executive Committee should consider if moving forward with any new map. Common themes included not reducing regional representation on the Board (14 comments); ensuring there is a voice for minority populations (6 comments); re-drawing boundaries, including metrics (16 comments), administrative factors (4 comments), travel and meeting logistics (6 comments), and number of states within a region (4 comments); and how to display a new proposed map if a public comment proposal is forthcoming (2 comments).

Do not reduce regional representation on the Board

- Should the transplant community support an OPTN map with fewer regions, the Liver Committee asks the Executive Committee to consider having more than one representative in each region to prevent the reduction of regional representation on OPTN Committees and the OPTN Board of Directors. (Liver and Intestinal Organ Transplantation Committee)
- Several members expressed concern that fewer regions could dilute the representation that each organization has on OPTN Committees and the Board of Directors. Members noted that this could particularly lead to over-representation of coastal OPTN members, and dilute the voice of OPOs and transplant programs representing more rural patient populations that cover a larger geographic area. (OPO Committee)
- The Committee expressed concerns regarding representation on the Board and committees if the number of regions were to decrease because that could dilute the pediatric voice in the community. (Pediatric Transplantation Committee)
- Members suggested that larger regions should be provided more representatives [if the OPTN shifts to fewer, larger regions] as members felt it is important not to dilute current representation (Transplant Administrators Committee)
- One member commented that instead of changing regions, the OPTN could allow more councilors per capita in terms of volume of programs in that region. (Region 1)
- Granted change is critical, but remember that the regional reps on UNOS' board are the transplant community's only voice on that body amongst the hand picked by UNOS staff. Don't give up the 11 seats that represents. (Region 2)
- Any change should not lose sight of the 11 board members who are elected by the regions. That representation is important to the community and should not be reduced. (Region 2)
- Generally not opposed to a redesign of the OPTN Regions but need to be mindful about the new structure and function of the regions; UNOS must be careful not to limit regional representation based on fewer regions as this would negatively impact overall community development by reducing exposure to broader experience and viewpoints. (Region 5)
- With fewer regions, one member suggested increasing the number of regional representatives to allow for different perspectives and to ensure geographic diversity within a region. (Region 7)
- A member explained that its institution supports eleven regions because that number of regions increases the number of voices at the Board level. (Region 8)
- We want to preserve regional representation in the model that is chosen. If super regions are utilized we would recommend multiple representatives from the regions in order to ensure that programs have an opportunity to participate in the governance of our transplant community. (Region 9)

- We share the concerns of other commenter’s that decreasing the number of regions would presumably result in less regional representation, members on the Board and Committees (assuming one representative per region). This would likely negatively influence overall community development by reducing exposure to a broad array of valuable experience from our colleagues across the country; particularly in light of the new structure of regional meetings, which no longer seem to facilitate robust conversation around policy proposals but urge members to “share their sentiments” regarding policy proposals... To address some of the themes noted in the concept paper pertaining to a perceived limitation on the ability to participate in the governance process can and should be addressed in other ways. For example implementing term limits for members who continuously rotate on and off of committees or the Board (accounting for some exceptions– for example, it’s well known that there are only a handful of intestinal transplant surgeons across the country – these individuals should not be limited in their appointments so long as there are no other reasonable candidates for consideration), creating “early career” positions for each committee similar to the structure of the AST Communities of Practice, or creating another pipeline program for members to explore participation without directly appointing them to Committees with little to no prior exposure may increase these opportunities. (UC San Diego Health Center for Transplantation)
- Regional representatives make up 25% of the board of directors. It would be fine to increase that % by adding a few more regions. (Douglas Norman)
- We could have fewer regions but multiple regional reps to keep a similar amount of Board members selected by regions. (Anonymous)

Ensure there is a voice for minority populations

- I think rural communities need to ensure they have enough representation. I know the American Indian/Alaskan Native population is not the largest population, but areas in the Dakotas have these as their largest populations. If you expand their region, you cut voices off (for example: if there is equal allocation of representations, such as regional rep) (Operations and Safety Committee)
- Members expressed support for increased consideration of access and equity in the regional redesign project, particularly among disadvantaged patient populations. Members noted that this project will affect patient representation in OPTN Committees and Board of Directors. (OPO Committee)
- Would prefer smaller regions to facilitate attending regional meetings (unless plan is to only do virtual meetings). Having more regions will likely result in more feedback and thoughts on proposals with more voices being heard. (Region 10)
- A member suggested the Committee consider an option that considers equity in underrepresented minority populations. The member added that currently Region 11 serves a similar community with similar demographics and that should also be a consideration... Another attendee expressed concern that small centers and OPOs might get lost in this redesign. (Region 11)
- Any adjustment to the regional maps that dilutes the representation of centers from less dense or distant centers would disadvantage any influence that each of those centers may have at the board level or for policy. Though the idea that population equity would make for “balance” representation that completely misses the fact that the challenges and needs of centers in less dense population areas have unique needs and concerns for our patients that are often not considered in national policy. I would suggest that maintaining a larger number of regions with less dependence on population as a mechanism for division would be preferable. (Cristy Smith)

- How does each proposed design increase the number of transplants and give the best representation to patients, donor families, living donors, OPO's and Transplant Centers? Everyone wants a voice - including the patients and donor families in a structure dominated by professionals. While this is understandable to an extent, I would not be supportive of a structure that in any way decreases patient and donor family/living donor representation. (Anonymous)

Re-drawing boundaries

- Metrics
 - Agree with the proposal to consider the number of transplant hospitals and number of transplant patients (both waitlist and recipients) as the metrics of choice in determining the boundaries. We would also prefer that state lines be used to determine boundaries, to factor in local state practices of the OPO and transplant centers. (ASTS)
 - The metrics used omit the key issue of diversity of representation. They seem to focus more on equality than equity and do not address socioeconomic factors. (Membership and Professional Standards Committee)
 - Some regional redesigns could create regions with only “tier three” or “tier two” programs; therefore, any change in mapping should ensure adequate access to program quality across each region. The Committee agreed working relationships within Organ Procurement Organizations and transplant programs should be examined as a potential basis for regional mapping. (Patient Affairs Committee)
 - A member recommended the Executive Committee consider which centers and OPO work with each other most often, to encourage effective relationship building. Another member similarly noted that isolating certain states, such as Texas or California, could be detrimental to transplant center and OPO relationship building, and reduce learning opportunities between OPTN members... A member remarked that the regions should be representative of the demographics and interests of the patients within the regions; Kentucky, for example, is more aligned with the South or Southeast as far as patient and donor demographics than with Texas or Pennsylvania. A member noted that the proposed maps place too much emphasis on relationships between OPOs and transplant programs over the interests and demographics of the patient populations. (OPO Committee)
 - Consideration should be given to balancing representation from high population density areas and rural areas, as well as the types of specialty centers (e.g thoracic, pediatric) (Transplant Coordinators Committee)
 - When considering changes to the OPTN regional structure, the Liver Committee encourages the Executive Committee to take transplant and OPO performance, waitlist access for vulnerable populations, and allocation patterns into account. The Liver committee also urges the Executive Committee to preserve current transplant center and OPO working relationships. (Liver and Intestinal Organ Transplantation Committee)
 - The balance in the number of members per region in regard to OPOs may be less important than ensuring the number of candidates, transplants and programs. This may be particularly true into the future with anticipated OPO consolidation. (Region 1)
 - To be truly useful, any redesign should account for regional variabilities in practice patterns (of transplant centers and OPOs) (Region 4)
 - We should also consider where patients are coming from with each center to keep those areas in the same region. (Region 5)

- Recognizing the DSAs only exists for the purposes of managing referrals and community engagement; acceptance patterns for organs might be a consideration in redesigning the regions. This could facilitate consistent relationships management for OPOs. Symmetry around logistical hurdles might be another consideration. For those OPOs in cities that have limited commercial airline availability creates constraints. Working in a Region with other OPOS that are addressing similar challenges could provide additional value. (Region 8)
- A member stated that whatever is option is chosen needs to be balanced not just in terms of the metrics already considered, but also in terms of the number of OPOs and transplant programs in each region. (Region 10)
- We note there is no data presented in the concept paper on pediatric transplant populations or on equitable distribution of minority populations or other disadvantaged populations. We urge the OPTN to take this opportunity in redesigning the regional maps to include metrics that specifically describe how new Regions would impact pediatric candidates and transplant centers as a top priority. For example, we recommend describing for new Regions the number, by organ, of (1) pediatric transplant candidates (2) active pediatric transplant centers and (3) pediatric transplants over a 1-3 year period – and comparing these to representation by existing Regions. This transparency would help ensure that a fundamental goal of NOTA- “to recognize the differences in health and organ transplantation issues between children and adults throughout the system and adopt criteria, policies and procedures that address the unique health care needs of children.” Patient and Racial diversity in the redrawn regions should be then reflected in the subsequent Board and committee representation. It will be critical also to transparently define what the purpose and responsibilities of Regions and regional divisions are going forward, since they will no longer figure into organ allocation. Defining what the representation of specialized groups like pediatrics will be in these re-defined regions will also be important for considering the impact on ours and other vulnerable populations. (Society of Pediatric Liver Transplantation)
- Which metric(s) should the OPTN consider for reconfiguring regional boundaries? Number of transplant centers, OPOs, patients on waiting list, attendance at regional meetings (NATCO)
- AOPO recognizes that the functional units of collaboration have changed with the reform of allocation policies and believes there is value in the OPTN Regions consisting of OPTN members that are routinely working together in order to leverage the regional structures as frameworks for systemwide improvement work. With the allocation policies moving to a continuous distribution framework (and acknowledging that the NASEM report recommends that this occurs as rapidly as possible), AOPO suggests that whatever re-design of the map is selected, it takes into account what the near future will look like in terms of close working relationships between OPOs and Transplant programs. (AOPO)
- Concerns were raised about the use of metrics to equalize regions for purposes of representation such as number of transplants, candidates waiting, donors, and OPTN members without including some measure of overall population (as a proxy for patients in end stage organ failure who do not have adequate access to the waitlist). This could be perceived as under-representing areas where the ratio of these metrics to the population of patients potentially in need of transplant are lower. (AST)

- We also believe that it makes sense for centers that have similar geographic challenges (transport times, etc) to be in the same region. Being in New Mexico, we refer patients to Arizona or Colorado for services we cannot provide like liver transplant, and we find when patients move and transfer their long term care, they tend to stay in geographically similar regions. (Region 5)
- In determining, which metrics are most appropriate for reconfiguring the existing regions, an emphasis on number of transplant hospitals and number of waitlisted candidates by (primary) transplant center seems most reasonable to ensure equity. It may be of benefit to analyze the number of transplant hospitals offering each organ transplant type within these newly proposed regions vs simply the total number of transplant hospitals. (UC San Diego Health Center for Transplantation)
- Administrative factors
 - Several of the presented examples break up an OPO designated CMS area and that should be taken into consideration if there is a change to the regional boundaries. (Region 8)
 - Several members expressed support for establishing continuity between donor service areas and OPTN regions. A member agreed, recommending that the regions consolidate OPO DSAs, such that no DSA is split between two regions. (OPO Committee)
 - While some have commented that OPO consolidation may change the configuration of OPO members, AOPO believes the OPTN Regions should be designed taking into account DSAs (versus the location of corporate governance of an OPO) as that locality drives an OPO's clinical and operational collaboration with other OPTN members and reflects the immediate geo-social and healthcare infrastructure environment within which the organ donation services are being delivered. Finally, we also recommend that in designing the new regions, OPTN factor in the geographic areas encompassed by OPO DSAs. Some DSAs encompass multiple states or cross state lines. We believe OPTN should design the new regions to minimize the number of DSAs that are split between regions and ensure OPOs with DSAs split between regions have representation, or some manor of providing input, in each of the regions to which their DSA is assigned. (AOPO)
- Travel and meeting logistics
 - The Committee noticed that most of the regional structure options created a huge region that spanned from Minnesota to Washington and members pointed out difficulties, such as time zone differences and attendance at regional meetings, which could result from the larger regions. (Pediatric Transplantation Committee)
 - Consideration should be given to the convenience of travel versus the actual physical distance (e.g. based on access to airports and airline routes) but noted that larger or different regions would provide a benefit of interacting with new peers. It was also suggested that travel burden for members of the public and patient affairs individuals should be thoughtfully considered since if travel becomes too difficult they are even less likely to attend. With that in mind, the Committee recommends that virtual attendance should remain an option and suggests that the OPTN should consider sponsoring travel for patients. (Vascularized Composite Allograft Transplantation Committee)
 - Several members commented that regional meetings promote networking so member travel convenience should be taken into consideration if there is a change to the regional map. (Region 8)

- The current proposals seem to "discount" land mass. The one aspect where land mass plays is the logistics as a function of land mass. The larger the area the more difficult it may be for the donor and recipients to get together. The distance between the west end of the upper west/mid west regions and the eastern most part can be ~2,000 miles. I don't have a preferred recommendation, just observing some challenges with the proposed options. (John Durning)
- Lumping the norther[n] half of the country together would place a substantial burden on our region. Each UNOS meeting would probably be a 3 day trip with the flights across multiple time zones. Most of the other regions would probably be able to drive to the meeting the same day. Currently we have significant clinical overlap with other programs in our region. The distances in the proposed new region 6 are so vast that we would have very little common ground. (Region 6)
- Most of the proposed redesigns would make it logistically challenging to participate in onsite or virtual meetings due to time zones and distance and would likely reduce the collaboration that currently exists within our region. (Region 6)
- Number of states in a region
 - There is a benefit to having multiple states within a region. (Hans Gritsch)
 - A number of members felt that regions should not exist as a single state (e.g California as an isolated region). (Patient Affairs Committee)
 - Multiple states within a region are beneficial. Even though this redesign proposal will not change organ allocation, hopefully voices will be heard more equally. (Anonymous)
 - We would advise against any redesign that silos a single state to its own region to avoid limiting community building on a broader scale. (UC San Diego Health Center for Transplantation)

Specific geographic recommendations

- New Mexico should be in the same region as Colorado and Arizona. Many New Mexican candidates transplant in those states. (Anonymous)
- I do feel bad for the northwest; in all the new equal region models, that region extends across 3 time zones, Minnesota to Washington. Transit time to attend regional meetings, or even logistics of scheduling virtual regional meetings, will be a problem in that area. (Rachel Engen)
- Several members suggested to see where patients travel from in order to keep the patient population and center in the same region. For example, there are a large number of patients from Idaho that travel to Utah for transplant, but Idaho and Utah are currently in different regions. (Region 5)
- Why is northwest Indiana separate from Illinois, when it is integrated with Chicagoland in a practical sense? (Region 7)
- A center / location specific response. We are at Inova, located in Northern Virginia and are a part of the Washington DC metro region which is consisting of VA/MD/DC. Further, we are residents of the Mid-Atlantic region of the East Coast for so many patient and health care related issues. Proposals that split a single metro area where our patients live and programs work closely together is very disruptive. It has for many years prevented a cohesive regional transplant collaborative to enhance donors and hospitals to work together to benefit recipients. It is also confusing for patients who need transplantation looking for local health care. Thus, from a local perspective we strongly support 11c, followed by support for 8 equal regions and 4 equal regions. The other proposals split Virginia from DC and Maryland which is exactly would we would want to avoid. (Region 2)

- A few members noted that if change is to occur then the new regions should make sure to keep transplant hospitals within the same region as their affiliated OPO. There are some OPOs that cover hospitals in multiple states. Another member noted that it would be important to keep major metropolitan areas within one region, for example the Washington DC metro area extends into Virginia and Maryland. It is disruptive and confusing to patients when the health care system is split into multiple areas. (Region 2)
- If there is a redesign, careful attention needs to be paid to where patients are coming from in relationship to their transplant centers. For example, patients in Idaho and Wyoming are often transplanted in Utah. Currently, these states are in 3 different regions. (Anonymous)

Displaying map in public comment proposal

- It would be helpful to see the distribution of pediatric transplant centers for each organ in the proposed regions - the proposal does not show whether any of the proposed regions have zero or just 1 pediatric transplant center for any of the organs, and this could impact both access to transplant and pediatric representation in the Regional structure that is important to anticipate. (Region 5)
- The Committee would like to see the distribution of pediatric transplant centers stratified by the following to ensure there is no underrepresentation or unintentional dilution of representation across regions: number of centers by organ [and] number of transplants by organ (Pediatric Transplantation Committee)

Appendix 3: Patient Engagement Workgroup Recommendations

Overview

- OPTN should enhance patient engagement by:
 - Continuing to build up the volunteer pipeline
 - Continuing to enhance the volunteer experience
 - Developing new ways to engage patients who are not already connected to the OPTN
 - Incorporating the patient voice more fully throughout the policy development process

Continue to build up the volunteer pipeline

- Expand outreach to groups best positioned to recruit patients via volunteers and Volunteer Coordinator
 - Organ Procurement Organizations (OPOs) – donor families
 - Transplant coordinators (pre-transplant, post-transplant, living donor)
 - Transplant administrators via listserv
 - The Alliance (education programs for transplant & OPO professionals who work with patients)
 - Support groups
 - Society of Transplant Social Workers (STSW)
- Grow patient experience via OPTN committees. Patient representatives are required and included on all OPTN committees, but the following committees in particular may serve as good training opportunities for patient representatives who are new to OPTN service:
 - Patient Affairs Committee (PAC)
 - Minority Affairs Committee (MAC)
 - Living Donor Committee (LDC)
 - Transplant Administrators Committee (TAC)
 - Transplant Coordinators Committee (TCC)
- Establish roles for patients to engage with the OPTN outside of committee service, for example, an OPTN Ambassadors program, or a standard approach for engaging with patients in regional meetings

Continue to enhance the volunteer experience

- Add at least one additional patient representative to each committee so that each committee has a minimum of two patient representatives
 - This will provide more opportunities for patients to serve the OPTN, and will help patient representatives support each other in incorporating their voice into the policy development process
 - Patients are a diverse group, including transplant candidates, transplant recipients, organ donors, and family members, so committees should aim to select patients with different perspectives
 - Committees should consider nominating additional patient representatives to provide different perspectives as needed for committee work
- Continue enhancing the application process
 - Make it easier for applicants to see what skillsets the OPTN is seeking, and continue to engage with those whose skillsets may be needed in the future

- Be mindful that most OPTN volunteers have high educational attainment and ensure that people with lower educational attainment or lower socioeconomic status are included in the application process
- Increase transparency around factors in selection process, including experience that may improve chances of being selected for committee service, like previous volunteer work with other transplant and donation organizations
- Promote culture of bringing in new voices
- Make community aware of Volunteer Coordinator as a resource
- Ensure committees empower patient representatives to be active participants
 - Pair new patient representatives with experienced representatives who can serve as a guide to the OPTN
 - Provide additional support to help new members learn how to engage
 - Encourage committee and Board leaders to hold space for the patient voice, for example, by specifically asking patients for input at meetings
 - Provide training to new representatives on how to be an advocate for all patients
- Fund travel to regional meetings for patient representatives on all committees (not just those on the Patient Affairs Committee)

Develop new ways to engage patients who are not already connected to the OPTN

- Explore the possibility of developing a digital OPTN application that patients could download at the time of registration on the waiting list to receive tailored updates from the OPTN (about volunteer opportunities, about national emergencies like COVID-19, etc.) to better engage patients prior to transplant
- Update the [OPTN Patient Information Letter](#) provided upon registration to notify them of how to engage with the OPTN and explain how volunteering with the OPTN is of value to them
- Encourage transplant programs and organ procurement organizations to sponsor patient attendance at regional meetings

Incorporate the patient voice more fully throughout the policy development process

- The patient voice must not only be heard, but incorporated into policy development
 - OPTN staff should work with committees to gather patient input prior to public comment and include a section in public comment proposals speaking to the patient perspective, which should also be summarized in the At-a-glance
 - Highlight impact of proposed policy on patients
 - Highlight patient-focused questions for public comment
 - When the Policy Oversight Committee reviews projects, the plan for engaging patients in policy development should be clearly outlined
 - OPTN should more clearly define a role for the Patient Affairs Committee in the policy development process prior to public comment
- Engage patients in regional meetings, including any discussions of best practices, as best practices should ultimately be about improving patient care
 - Consider giving patients a role in regional meetings
 - Regional councillors should work with regional PAC representative to engage patients in the region
- Add an “up vote” feature to the public comment website to allow patients and others to indicate support for previously entered comments
- Retain hybrid options for OPTN meetings so that patients can attend remotely

Appendix 4: Regional Nominations Workgroup Recommendations

Overview

- The OPTN should promote consistency, transparency, and fairness in the regional nominations process across Regions by providing recommendations to the regional nominating committees
- The intent of these recommendations would be to provide a framework which Regional Nominating Committees (RNCs) can tailor for their regions; the intent is not to be overly prescriptive
- Such recommendations should advise on composition of the Regional Nominating Committee (RNC) and the process for selecting nominees
- **ACTION:** These recommendations should be issued to RNCs in advance of selections for the 2023-2024 year

Composition of RNCs

- At a minimum, the RNC should include the Region's Councillor, Associate Councillor, and Immediate Past Councillor
- If none of the councillors represents an organ procurement organization (OPO), then RNCs should continue including an OPO representative. This representative could be the region's representative to the OPTN Organ Procurement Organizations Committee, or it could be another person affiliated with an OPO.
- If none of the councillors is a patient/donor affairs (PDA) representative, then a PDA representative should be included in the RNC.
 - The RNC should seek to identify a PDA representative who is empowered to participate in the nominating process.
 - This representative could be the region's representative to the OPTN Patient Affairs Committee.
 - Alternatively, a patient representative who previously served on OPTN committees and/or the OPTN Board, or has professional experience in health care, organ donation, or organ transplantation, may be well prepared to participate in the RNC.
 - Inclusion of a PDA representative on the RNC is particularly important when the RNC is filling a vacancy for a PDA representative on a committee.
- The RNC should be comprised of 4-6 people to ensure appropriate representation while keeping the size of the group manageable to facilitate meeting scheduling.
- The role of the OPTN staff is to ask critical questions to understand why the RNC favors a particular candidate over another, and to ensure RNCs are considering the overall pool of applicants and not just those applicants who are most well-known to the RNC members.

Selecting Nominees – Associate Councillor Elections

- Per the OPTN Bylaws, each region determines the guidelines for electing associate councillors.
 - Generally, the RNC selects two people for the associate councillor ballot
 - Many Regions rotate the associate councillor position between states or other population centers, and the rotations are fairly specific to regional geography and population density

- RNCs should continue to evaluate the geographic distribution of their representatives and decide on a regional basis if, and how, to rotate the associate councillor position
- RNCs should seek to nominate associate councillors who are interested in the role and will be engaged leaders
- Candidates for the associate councillor position should generally have previous experience on an OPTN committee. This should be advertised to the public so that people have an understanding of how they can prepare themselves to fill the associate councillor role and ultimately serve on the OPTN Board of Directors.

Selecting Nominees – Committee Appointments

- OPTN should continue to provide RNCs with committee needs assessments, diversity goals, historic geographic representation (e.g. which member institutions have been represented on the Kidney Committee over the last 10 years)
- If possible, OPTN should also provide RNCs with records of regional meeting attendance, previous committee service, and previous volunteer applications for prospective volunteers
- RNCs should continue to follow an intentional approach to appointing committee members informed by the committee needs assessments, diversity goals, historic geographic representation, and other factors
- RNCs should promote a culture of bringing in new volunteers to grow the volunteer pipeline and develop young leaders, while recognizing that it may be appropriate to nominate members with previous OPTN experience for some committees based on their needs assessment
- While RNCs should continue to evaluate the geographic distribution of their representatives, RNCs may decide on a regional basis if, and how, to rotate committee positions among member institutions. RNCs should share information regarding any committee rotations with their regions for transparency.
- RNCs should seek to nominate committee members who are interested in the role and will be engaged representatives
- Membership elections are not recommended for committee appointments as the RNC is best-suited to assess applicants who will be a good fit to fill committee vacancies as informed by the needs assessments, diversity goals, historic geographic representation, and other factors
- All regional representatives should take an active role in recruiting new volunteers and gauging interest in committee, region, and Board service, including interest in serving on the RNC

Additional Recommendations

- OPTN should seek lessons learned from high-performing organizations on recruiting volunteers and consider updates for the 2023 call for nominations
- OPTN should encourage engagement in regional meetings and other transplant and donation events, as such participation demonstrates interest and provides baseline knowledge to help prepare prospective volunteers for OPTN committee service
- OPTN should continue to enhance the committee needs assessments to highlight the skillsets that the OPTN is seeking, as well as allow applicants to highlight the policy areas they are particularly interested in