Concept Paper

Redesign Map of OPTN Regions

OPTN Executive Committee

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Redesign Map of OPTN Regions

Sponsoring Committee: Executive
Public Comment Period: January 27, 2022 – March 27, 2022

Executive Summary

The OPTN Regional Review project serves as an opportunity to optimize the governance and structural effectiveness of OPTN regions.1 As the sponsoring committee, the OPTN Executive Committee (the Committee) considered all public comment feedback and vendor recommendations to develop the proposals presented in this concept paper. Your feedback will assist the Committee in further developing these recommendations for the Board of Directors (Board) to consider.

This paper is not a public comment proposal, but instead a concept paper. The feedback received will be used to develop a future proposal that will be released for a subsequent public comment period prior to action by the OPTN Board of Directors. The OPTN launched the Regional Review project pursuant to OPTN Contract Task 3.3.3: Review of OPTN regional process.2

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2 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; HHS/250201900001C: Task 3.3.3: Review of OPTN regional process.
Background

The purpose of the OPTN regional review project\(^3\) is to optimize OPTN governance and operational effectiveness by evaluating the roles of regions in the OPTN structure.\(^4\) In October 2020, the OPTN issued a formal Request for Proposal to engage a third party vendor to perform an independent, objective review and analysis of OPTN regional structures and processes. The vendor completed the first phase of this work in March and April 2021, and their preliminary findings and options for the OPTN to consider were included with the Update on OPTN Regional Review Project request for feedback sent to the August 3 – September 30, 2021 public comment period.

At the conclusion of the summer 2021 public comment period, the OPTN and the vendor performed independent analyses on the community input received. The Committee considered all public comment feedback and vendor recommendations as they built consensus on potential modifications to OPTN regions that are presented in this concept paper.

Purpose

This concept paper serves two purposes. The first is to seek community feedback on the Executive Committee’s recommendations for potential modifications to OPTN regions and, second, to deliver the final vendor report to the community. It will also provide example maps to illustrate how regional boundaries could be redrawn to be more equitable. Your feedback will aid the Board in considering potential changes to OPTN regional structure and processes.

Recommendations for Potential Modifications to OPTN Regions

The Committee has come to consensus regarding the preservation of contiguous regions, but recommends they are resized to promote balanced boundaries and equitable representation.\(^5\) This has been a consistent request from some members of the transplant community for many years and was also identified in the EY analysis. If we compare the current OPTN regions to congressional districts, Region 6 receives one Board representative for 4% of active members while Region 5 also receives one Board representative for 14% of active members. By changing the regional boundaries, we can more closely achieve equal representation based upon population. The Committee considered the following metrics for reconfiguring regions:


\(^4\) 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; HHSH250201900001C: Task 3.3.3: Review of OPTN regional process.

\(^5\) See November 19, 2021 OPTN Executive Committee meeting (unpublished).
• Number of transplant centers
• Volume of transplants
• U.S. population
• Number of waitlisted patients, by home state
• Number of waitlisted patients, by transplant hospital state
• Geographic area
• Volume of all OPTN members
• Historical volume of public comments

Of these choices, the Committee favors number of transplant hospitals and number of transplant patients. They also prefer to use state lines when considering new regional boundaries as some states have specific laws that affect transplantation.

The OPTN’s current regional design is used for governance (Board and Committees), structural (regional meetings), and data reporting functions. The Committee considered selecting specialized regional designs for each of these functions, but determined there was no need for the additional complexity. They recommend one consistent regional design for all three functions.

Alteration to the number of regions or boundaries within the OPTN regional design will impact governance, structural, and data reporting functions. OPTN Bylaws require that the Board and each of the permanent standing OPTN committees include representation from each of the OPTN geographic regions. For this reason, changes to the regional design will impact regional representation on the OPTN Board and Committees. The OPTN Bylaws also require each region to hold biannual meetings to discuss public comment items in the OPTN policy development process, nominate regional and associate regional councilors, and to collaborate with other members within that region. Modifications to the OPTN regional design will impact which members will attend each regional meeting. Changes to the OPTN regions will also impact regional aggregate data reporting, although the OPTN could segment data in various ways for comparison to other data sources, such as data relating to the geographic prevalence of end stage renal disease or cancer.

Regional Designs for Consideration

The Committee recommends new regional boundaries that result in regional populations that are more balanced than the current OPTN regions. The Committee does not recommend any maps with non-contiguous regions as this design could present collaboration and networking challenges. Similarly, the Committee recommends that states not be split between regions. The Committee presents the following example regional designs to illustrate how OPTN regions could be restructured.

The Committee considered, but does not recommend the End-Stage Renal Disease (ESRD) Network map because they found it no better balanced than the current OPTN regional structure.

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6 See November 19, 2021 OPTN Executive Committee meeting (unpublished).
7 See October 26, 2021 OPTN Executive Committee meeting summary https://optn.transplant.hrsa.gov/
8 The OPTN Final Rule requires that regional statistics are reported by each region, but does not define regions.
9 See November 19, 2021 OPTN Executive Committee meeting (unpublished).
10 OPTN Bylaws
11 Ibid.
Maintain Current OPTN Regional Design

Currently the OPTN divides the U.S. into 11 regions. These regions have not been evaluated for governance and operational effectiveness since they were created in 1986.12 This regional review project provides an opportunity to reevaluate OPTN regional boundaries. Figure 1 shows, the current regional boundaries are not optimized for any of the stated metrics. For each set of maps, the country is divided into a set number of regions. Each region is represented by a specific color and number. Below each map, there are six of the metrics that the Executive Committee discussed. Each region is represented by a vertical bar for each of the metrics. The values are a percentage of the country. For example, the first metric shows the percentage of the national population in each of the 11 current OPTN regions.

Figure 1: Current OPTN Regional Design

United States Department of Health and Human Services (HHS) Regions

Figure 2 shows the current HHS regional offices. These 10 regional offices are used to directly serve state and local organizations that address the needs of communities and individuals served through HHS programs and policies.13 Similar to the current OPTN regions, these regions are not optimized for any of the stated metrics.

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Figure 2: United States Department of Health and Human Services (HHS) Regions

Figure 3, Figure 4, and Figure 5 use 11 regions like the OPTN’s current regional structure, but draws regional boundaries that are more equitable according to the first five metrics (population, donors, members, recipients, and transplants). Due to differences in population density and the desire to keep states together, it is difficult to equalize the total area across the regions when including Alaska.

Figure 3: 11 More Equitable Regions
Figure 4: 11 More Equitable Regions
Less Regions

The Executive Committee also discussed the possibility of creating a map with less than the current 11 regions. Decreasing the number of regions has several impacts:

- It increases the size of each region compared to the current regional map.
- It makes it easier to have consistently sized regions.
- It increases the distance that some members will need to travel for in-person, regional meetings.
- It decreases the number of regional representatives on the Board and Committees (assuming one representative per region).

Figures 6-8 show how boundaries could be drawn to create four, six, or eight regions.

**Figure 6: Four Regions**
NOTA and Final Rule Analysis

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. The only mention of “regions” in NOTA and the Final Rule is in regard to how data is aggregated for certain analyses. Neither NOTA nor the Final Rule define regions, nor do they mention “regions” with regard to the OPTN Board composition or other governance processes; however, the current OPTN Bylaws include a provision requiring the Board to “include regional councilors who are 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.

Conclusion

The OPTN Regional Review project aims to optimize the effectiveness of OPTN regions for the first time since they were created in 1986. This concept paper presents the Committee’s proposed actions and recommendations.

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14 42 U.S.C. §274
15 42 CFR §121
16 42 CFR §121.8(c)(3) “For each organ-specific allocation policy, the OPTN shall provide to the Secretary data ... Such data shall be ... aggregated by organ procurement area, OPTN region...”
18 Organ Procurement and Transplantation Network; HHSH250201900001C: Task 3.3.3: Review of OPTN regional process.
seeks feedback on potential modifications to OPTN regions. Your feedback will assist the Committee in further developing recommendations for Board consideration.

**Community Feedback**

The Committee is seeking feedback on the following:

- 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?
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.

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

### Structure

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

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

- **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**

<table>
<thead>
<tr>
<th></th>
<th>Regions</th>
<th>Committees</th>
<th>Procurement Organizations</th>
<th>OPTN Board / Committee</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Entries</td>
<td>10</td>
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<td>3</td>
<td>4</td>
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<tr>
<td>Representative Board makeup</td>
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<tr>
<td>Allocation Equity</td>
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</table>

*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**

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<td>Voice for minority members</td>
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<td>Concerns for communication silos</td>
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*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 silos if interest cohorts completely replaced the regions. Members within regions and committees agreed on the importance of retaining geographical segmentation to avoid these silos.

• **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 information¹ 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.

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¹ 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, 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. These revised policies have effectively removed DSAs and regional boundaries as factors that guide organ allocation.

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2 “Policy Notices”, Organ Procurement and Transplantation Network, optn.transplant.hrsa.gov/governance/policy-notices
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:  

**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*, 5 “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

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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.6

**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.

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6 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 meetings 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 members 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:

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7 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.

8 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 policies 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. 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;

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9 Charts and key takeaways from public comment analysis can be found in the [Appendix](#).
10 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. 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.

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

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11 Descriptions of initial models, as well as focus group feedback, can be found in the Appendix.

12 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 Committee\textsuperscript{13} 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:\textsuperscript{14}

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

\textsuperscript{13} 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

• 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
**Governance** – 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?

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15 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.
<table>
<thead>
<tr>
<th>OPTN Regions Today</th>
<th>Archetype 1: Communities of Common Interest</th>
<th>Archetype 2: Repurposed Regions</th>
<th>Archetype 3: Hybrid Cohorts</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>‘Regions’ defined by geographic boundaries</strong></td>
<td>Eliminate geographic boundaries and create like-interest cohorts</td>
<td>Re-draw geographic boundaries</td>
<td>Create hybrid cohorts considering geography and like-interests</td>
</tr>
<tr>
<td>Regionally-elected representatives</td>
<td>Cohorts elect Councillors</td>
<td>Regions elect Region Leads</td>
<td>Cohorts elect policy councilmembers</td>
</tr>
<tr>
<td>Board includes designated Region seats</td>
<td>Cohort Councillors replace Region Councillor Board seats (opportunity to decrease total # of Board seats)</td>
<td>Region Leads do not hold Board seats; Policy Council replaces Policy Oversight Committee</td>
<td>Councilmembers do not hold Board seats; Policy Council replaces Policy Oversight Committee</td>
</tr>
<tr>
<td>Regions recommend representatives to serve on committees</td>
<td>Cohorts nominate committee members</td>
<td>Regions nominate committee members</td>
<td>Cohorts nominate committee members</td>
</tr>
<tr>
<td>Most committees have designated Region seats</td>
<td>Committees have evenly distributed cohort representation</td>
<td>Committees have evenly distributed region representation</td>
<td>Committees have evenly distributed cohort representation</td>
</tr>
<tr>
<td>Primary purpose of meetings is policy debate</td>
<td>Policy debate is central to cohorts; add nationally-organized meetings for community and OPTN objectives</td>
<td>Regional meetings focus on community and OPTN objectives</td>
<td>Policy debate is central to cohort meetings</td>
</tr>
<tr>
<td>Regional Councillors have fiduciary responsibility to Board; do not vote in line with regions</td>
<td>Cohort Councillors have fiduciary responsibility to Board</td>
<td>Regions Leads can advocate for regional interests, but have no direct vote</td>
<td>Councilmembers directly represent interests of cohorts</td>
</tr>
<tr>
<td>Members encouraged to express public comment through Regional Meeting sentiment</td>
<td>Members encouraged to express public comment through Cohort meeting sentiment</td>
<td>Members encouraged to express public comment through national policy debate channels</td>
<td>Members encouraged to express public comment through Cohort meeting sentiment</td>
</tr>
<tr>
<td>Regional meetings are held twice a year</td>
<td>Cohorts hold policy meetings; OPTN hosts District Meetings aligned to regions throughout the year</td>
<td>Sponsoring Committee hosts policy debate sessions; Regions host meetings which do not include public comment vote</td>
<td>Cohorts hold policy meetings; OPTN hosts bi-annual member conferences, open to all members</td>
</tr>
</tbody>
</table>

- 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 relationship 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?**

<table>
<thead>
<tr>
<th>Feeling</th>
<th>Just Right</th>
<th>Too Many</th>
<th>Too Few</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vote (n=34)</td>
<td>17 (50%)</td>
<td>10 (29%)</td>
<td>7 (21%)</td>
</tr>
</tbody>
</table>

**Comment**
- 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
- 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
- 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
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)

<table>
<thead>
<tr>
<th>Options</th>
<th>Re-draw map</th>
<th>Cohorts by interest</th>
<th>Hybrid cohorts</th>
<th>Matrixed model</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vote (n=51)</td>
<td>15 (29%)</td>
<td>4 (9%)</td>
<td>25 (50%)</td>
<td>6 (12%)</td>
</tr>
<tr>
<td>Comment</td>
<td>Each Region should represent the same number of people... This would give each individual equal representation. The 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.</td>
<td>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.</td>
<td>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/recipient groups. 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.</td>
<td>Conceptually this is the best organization method. However, I would prioritize the function of the cross-functional teams over the type groups.</td>
</tr>
</tbody>
</table>

**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 takes 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?
<table>
<thead>
<tr>
<th>Possible Action</th>
<th>Vote n=51</th>
<th>Comments</th>
</tr>
</thead>
</table>
| Create structure within meetings to ensure all voices are heard (e.g., member-cohort breakouts for discussion) | 40 (78%) | 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 |
| Dedicate more time in meetings to sharing best practices and discussing implementation challenges | 38 (75%) | Critical importance  
Fosters broader experiential learning |
| Partner with other organizations in transplant community around efforts to increase donation | 38 (75%) | The more local donors, the more total transplants  
Regional partners can participate in paired exchanges....set up their own network |
| Performance monitoring                                                        | 28 (55%) | 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 |
| Run meetings quarterly in which 2 meetings per year are virtual               | 27 (53%) | All meetings should provide for virtual attendance in addition to in-person attendance  
Unsure we need more frequent meetings- more virtual would be good |
| Introduce educational programming to meeting agendas                         | 26 (51%) | Would help with best practice dissemination |
| Develop and disseminate new-member onboarding materials                       | 16 (31%) | Mentoring new members would be useful |
| Recruit new members to OPTN                                                    | 14 (27%) | The Regions need to be small enough to allow knowing each other as this is the best way to recruit new members |
| **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 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_nlrb_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

<table>
<thead>
<tr>
<th>Member Type</th>
<th>Public Comment Moderated Comment</th>
<th>Representing Board makeup</th>
<th>Resizing of the board</th>
<th>Maintaining Geography groupings</th>
<th>Both geography and interest groupings</th>
<th>Voice for minority redrawing geographic bounds</th>
<th>Engagement and education about new methods of allocation</th>
<th>Concerns for communication and allocation equity</th>
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<tbody>
<tr>
<td>Stakeholder Organization</td>
<td>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.</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Stakeholder Organization</td>
<td>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.</td>
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<td>x</td>
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<tr>
<td>Stakeholder Organization</td>
<td>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. 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.</td>
<td>x</td>
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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).

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.

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.

<table>
<thead>
<tr>
<th>Organ Procurement Organization</th>
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<tbody>
<tr>
<td>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, &quot;hopper&quot; 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</td>
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</tbody>
</table>
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.

| Stakeholder Organization | 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. 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. 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. x x |
| Transplant Hospital | 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). 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. 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. 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. 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 x x |
| Patient | 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 | x | x | x | x | x | x | x |
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.
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.

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!

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.

Patient 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 hear. 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.

Stakeholder Organization 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
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 - offline 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. |
| 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’ 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) |
| 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, let’s instead focus all
<table>
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<tr>
<th>Role</th>
<th>Comments</th>
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<tr>
<td>Patient</td>
<td>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.</td>
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<td>Patient</td>
<td>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.</td>
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<tr>
<td>Patient</td>
<td>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.</td>
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<td>Stakeholder Organization</td>
<td>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</td>
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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.

<p>| 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 |</p>
<table>
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<tr>
<th>Stakeholder Organization</th>
<th>Region 8 supports the Regional Review Project and the opportunity to provide feedback on it, with specific suggestions below. 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). A member stated that his institution favors 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 &quot;will&quot; of the region so that the function of &quot;representation&quot; 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 member stated that his 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. 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. 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. 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.</th>
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<td>x</td>
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<tr>
<td>Non-Member (General Public)</td>
<td>Test Comment</td>
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<td>Stakeholder Organization</td>
<td>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</td>
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issue that requires further discussion. ASHI welcomes being a part of this discussion.

### Stakeholder Organization

The American Society of Transplantation appreciates the OPTN’s efforts 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.

The following thoughts and feedback were offered as our communities of practice considered this update:

#### 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.**

  We suggest caution in replacing the current POC structure with the proposed outline.

- **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.**

- **From a Kidney Perspective**

  Regions have heterogeneous groups with differing voices and usually don’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.**

  With all of the three models, regional representatives will be board members.

- **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.

- **Model 2**

  - Redrawn Boundaries based on new allocation system and national policy debates. This **will take away the**
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
geographically will share interests and should have a voice to express geographic concerns?

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.

Comments on specific suggested models:

Model 1:
Population density, transplant access, and organ availability are quite variable throughout the country.

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.

Model 2:
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.

Model 3:
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.

Stakeholder Organization
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...
that although the Board of Directors may be large, it does have broad representation.

| Stakeholder Organization | 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. | x | x | x | x |
| Stakeholder Organization | 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.

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.**

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.**

Policy cuts across all organs, OPO performance, MPSC standards, statistical analysis, and every aspect of OPTN activity. If all those disciplines are **siliced** 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.

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.

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.

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.

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.
that suggest how restructure might facilitate development of these relationships.

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.

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.

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.

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.

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 exposure 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.

Patient The Operations and Safety Committee thanks the OPTN Executive Committee for their efforts on the OPTN Regional Review Project.

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.

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)
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.

| Stakeholder Organization | 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:

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.

| Stakeholder Organization | 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.

| Stakeholder Organization | The Pancreas Committee thanks the OPTN Executive Committee for the opportunity to review their public comment proposal. The Committee provides the following feedback:

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.

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,
| Stakeholder Organization | 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:

The Committee emphasized the **importance of geography in regards to issues that affect patients**.

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.

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. |
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<tr>
<th>Stakeholder Organization</th>
<th>The VCA Transplantation Committee appreciates the opportunity to comment on the OPTN Regional Review project. A <strong>member noted that the OPTN Board of Directors (BOD) is quite large and expressed support for restructuring the BOD.</strong> Another member expressed concern that some of the ideas developed by EY, particularly organizing around communities of common interest, might actually result in <strong>more silos</strong> 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.</th>
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