

Request for Feedback

Update on OPTN Regional Review Project

OPTN Executive Committee

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Update on OPTN Regional Review Project

Sponsoring Committee: Executive
Public Comment Period: August 3, 2021 – September 30, 2021

Executive Summary

The purpose of the OPTN Regional Review project is to optimize OPTN governance and operational effectiveness by evaluating the roles of Regions in the OPTN structure.¹ The OPTN engaged a third party vendor to perform an independent, objective review and analysis of OPTN regional structure and processes. The vendor has completed the first phase of their work, and the purpose of this request for feedback is to gather input from the transplant community on the vendor's initial findings and suggested options for changes to the regional structure.

In this first phase of work, the vendor performed research and data analysis on OPTN Regions and governance structures; conducted stakeholder interviews; and facilitated focus groups to gather feedback from OPTN members. Using this feedback, the vendor created options designed to address various challenges in the current OPTN regional structure. The OPTN is not limited to selecting any of the options as the future governance structure, but can use the three models developed by the vendor and the individual elements of each model to evaluate and discuss what the OPTN governance structure should look like in the future, and what role geography should play within this structure.

This paper is not a public comment proposal, but instead a request for feedback. The feedback received will be used to develop a future proposal on the OPTN structure 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*.

¹ "OPTN Regional Review," OPTN, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/members/regions/optn-regional-review/>.

Background

The purpose of the OPTN Regional Review project² is to optimize OPTN governance and operational effectiveness by evaluating the roles of Regions in the OPTN structure.³ Planning for the OPTN Regional Review project began in 2019 and an initial request for community input on the role and purpose of OPTN Regions was shared with the transplant community between June 29 - October 1, 2020.⁴ This questionnaire, called the [OPTN Regional Review Feedback](#),⁵ asked respondents to describe the current OPTN regional structure; advantages and disadvantages of this structure; barriers and challenges that should be considered over the course of the Regional Review project; and to offer suggestions for designing a new approach. In total, 112 respondents completed the questionnaire and provided a wide range of feedback, which is described in more detail below.

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. In February 2021, consulting firm Ernst and Young (the vendor) was selected to perform this work, which included review of the OPTN Regional Review Feedback, as well as soliciting and collecting additional OPTN member opinions and comments on OPTN policy development, Board and Committee structure, and data reporting. Questions that the vendor was asked to answer in this work included, but were not limited to:

- What are the OPTN Regions expected to accomplish - for the OPTN, for members, and for patients?
- What is the basis for geographic regions in the governance of OPTN in an era of broader geographic sharing?
- Does the current OPTN Regions approach work? If so, how? In what way do the regions “work” for the OPTN, for the members in the region, and for patients in the region? What about other stakeholders? And by what objective metrics do they and should they work?
- Is the current configuration of regions optimal? If so, how? In what ways are they “optimal”? And by what objective metrics should the configuration be evaluated?
- What other regional configurations might be considered? How many regions should there be? What basis (or bases) might be considered for reconfiguration? (For example: population density patterns, End Stage Organ Disease patterns, number/distribution of organ-specific transplant centers, specialist-tertiary referral patterns, OPO/population geographic distribution, specific geographic features (mountains, water bodies), etc.).

² “OPTN Regional Review,” OPTN, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/members/regions/optn-regional-review/>.

³ The current OPTN Contract requires the OPTN Contractor to “develop a plan to review and analyze the existing OPTN regional process for soliciting and collecting OPTN member opinion and comments on OPTN policy proposals. The Contractor shall objectively review the current process to determine strengths, weaknesses, and effectiveness of the current process in supporting OPTN policy development consistent with the OPTN final rule. The Contractor shall utilize technical experts in systems/operations design to evaluate the current process and develop a recommendation for continuing, changing and improving, or eliminating the existing regional process. The Contractor shall include with the recommendation a rationale supporting the contribution of the proposed process to ensuring OPTN policy is developed consistent with the requirements of NOTA and the OPTN final rule.” Organ Procurement and Transplantation Network; HSH250201900001C: Task 3.3.3: Review of OPTN regional process.

⁴ “OPTN Regional Review: Community Input – Summer 2020 Public Comment,” OPTN, accessed April 21, 2021, <https://optn.transplant.hrsa.gov/media/4149/optn-regional-review-feedback-summary-summer-2020.pdf>

⁵ Ibid.

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 are enclosed in this request for feedback. These options include three potential models for a new OPTN structure, but each of these models should be viewed as a conglomerate, or menu, of ideas, rather than a limited set of recommendations from which one must be selected. For example, the OPTN could choose to bundle various elements from each of the three models. Additional feedback gathered after the vendor completed their first phase of work will be included in a report to the Board in December 2021 with public feedback gathered during this August 3 – September 30, 2021, public comment period.

Purpose

The purpose of this request for feedback is to gather input from the transplant community on the vendor’s initial findings. Your feedback will aid the OPTN Board of Directors (BOD) in considering potential changes to OPTN regional structure and processes. This paper is not a public comment proposal, and any proposed changes to the OPTN structure will be released for a subsequent public comment period prior to BOD action. Additionally, certain potential changes in the regional structure would require changes to the OPTN Bylaws (for example, regional representation on the Board and Committees). Since any change to one portion of the OPTN structure may create interdependencies that were not within the scope of the vendor’s work, a future public comment proposal may include proposed changes not described within this paper. Accordingly, the OPTN welcomes feedback on the structure of the OPTN beyond the bounds of what is described in this paper.

Authority

The National Organ Transplant Act (NOTA) established the OPTN to maintain a national registry for organ matching and called for the network to be operated by a private, non-profit organization under federal contract.⁶ In 2000, HHS implemented the OPTN Final Rule establishing a regulatory framework for the structure and operations of the OPTN.⁷ Neither NOTA nor the Final Rule define regions, nor do they mention “regions” with regard to the OPTN BOD composition or other governance processes; however, the current OPTN Bylaws include a provision requiring the BOD to “include regional councilors who are representatives chosen by the voting members and member electors of each of the 11 geographic regions in the United States.”⁸ The OPTN launched the Regional Review project pursuant to the current OPTN Contract, Task 3.3.3 *Review of OPTN regional process*.⁹

Summary

The OPTN Regional Review project serves as an opportunity to optimize the governance and operational effectiveness of the OPTN by evaluating the roles of Regions in the OPTN structure. This paper explains the analysis completed by an independent vendor to date and their preliminary suggestions for alternate models that the OPTN could use instead of the current structure, as well as suggestions for changes that could be incorporated into the current structure. Your feedback is needed to aid the BOD in deciding whether to propose changes to the OPTN structure, and if so, what a new OPTN structure should look like. A new OPTN structure could look like one of the three models described in the vendor report; it could combine components of the three models; or it could introduce new components not

⁶ 42 U.S.C. §274

⁷ 42 CFR §121

⁸ OPTN Bylaws, Article 2.1.B. https://optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf (Accessed on July 8, 2021).

⁹ Organ Procurement and Transplantation Network; HHS250201900001C: Task 3.3.3: Review of OPTN regional process.

described in this paper. Any proposed changes will be released for a subsequent public comment period prior to action by the BOD.

Community Feedback

Today, OPTN Regions have four primary functions:

- **Representation**, including electing regional representatives to the OPTN Board of Directors and OPTN Committees
- **Communication and feedback**, including gathering sentiment on policy proposals;
- **Operations**, including discussions about shared operations and effective practice; and
- **Data analysis**, including describing geographic differences in transplant data at the Regional level

The OPTN is seeking your feedback on how Regions, or an alternate construct, can best fulfill these functions for OPTN members and stakeholders. You can provide your feedback on the questions below via the [Summer 2021 OPTN Regional Review Feedback Form](#).¹⁰

Representation

Per the OPTN Final Rule, the OPTN Board of Directors must include clinical experts (transplant surgeons or transplant physicians); operational experts (representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals); and patient and donor affairs representatives (transplant candidates, transplant recipients, organ donors and family members).¹¹ The OPTN values diversity and strives for Board and committee membership that reflects the professionals, patients, donors, and families that make up the donation and transplantation community.

- What is the best way to recruit quality and diverse clinical experts to the OPTN Board of Directors and OPTN Committees?
- What is the best way to recruit quality and diverse operational experts to the OPTN Board of Directors and OPTN Committees?
- What is the best way to recruit quality and diverse patient and donor affairs representatives to the OPTN Board of Directors and OPTN Committees?
- Currently, Regions elect Regional Councillors who serve on the OPTN Board of Directors.
 - What, if any, would be the advantages of electing regional representatives to a Regional Advisory Committee instead of the Board of Directors?
 - What, if any, would be the disadvantages of electing regional representatives to a Regional Advisory Committee instead of the Board of Directors?
- Are there other functions that Regions, or an alternative construct, should fill related to representation?

¹⁰ Link:

https://empir.force.com/surveys/survey/runtimeApp.app?invitationId=0Ki3n00000TZVI&surveyName=regional_review_survey_summer_2021&UUID=f7ecc457-87ab-472b-8750-ef83fb76f64e.

¹¹ 42 CFR §121.3(a)

Communication and Feedback

- What is the best way to organize members for discussions about policy development?
- Currently, the OPTN accepts public comment from anyone but collects sentiment on policy proposals from designated representatives of OPTN member organizations. Sentiment on policy proposals is reported to the Board of Directors by Region and by member type.
 - From whom should member sentiment on policy proposals be collected?
 - How should member sentiment on policy proposals be collected?
 - How should member sentiment on policy proposals be reported to the Board of Directors?
- How should the OPTN educate stakeholders and the public about OPTN work?
- How should the OPTN gather feedback on proposed policies?
- Are there other functions that Regions, or an alternative construct, should fill related to communication and feedback?

Operations

- What is the best way to organize members for discussions about shared operations and effective practice?
- Are there other functions that Regions, or an alternative construct, should fill related to operations?

Data Analysis

- Regions are used to describe geographic differences in transplant data, for example, progress toward the OPTN strategic goals and specific allocation policy proposals.¹² Moving forward, how should transplant data be reported with respect to geography?
- Are there other functions that Regions, or an alternative construct, should fill related to data analysis?

Vendor Report

Enclosed below are the vendor's preliminary findings from their review of the OPTN regional structure along with options for alternative OPTN structures. The report is enclosed in full so as to reflect the independent nature of the vendor's analysis. The contents of the report reflect the views of the vendor and not the OPTN or HRSA, and inclusion of the report does not constitute endorsement of the vendor by the OPTN or HRSA.

¹² 42 C.F.R. §121.8(c)(3)



OPTN REGIONAL REVIEW

Preliminary Recommendations

March – April 2021

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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 information¹³ 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 models that transform the scope and composition of the OPTN Regions in the future. Each of the three models seeks to address challenges in the regional structure today while retaining strengths and benefits by varying how like-minded groups are organized and how they participate in the policy development process.

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 models incorporate design elements reflective of the chosen guiding principles.

¹³ 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, NOTA and the OPTN Final Rule, 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,¹⁴ 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 models 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

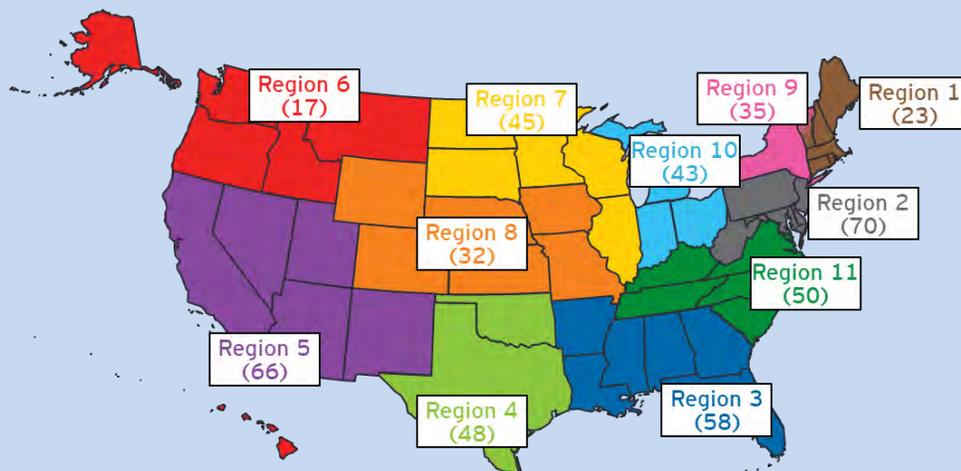
Congress passed the National Organ Transplant Act in 1984, which called for a national network to coordinate the allocation of organs and collect clinical data about organ donors, transplant candidates, and transplant recipients. The United Network for Organ Sharing (UNOS) was awarded the initial contract 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

¹⁴ “Policy Notices”, *Organ Procurement and Transplantation Network*, optn.transplant.hrsa.gov/governance/policy-notice

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 2000.¹⁵ These revised policies have effectively removed DSAs and regional boundaries as factors that guide organ allocation.

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:¹⁶

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

¹⁵ National Organ Transplant Act, 42 U.S.C. §273 (2000). [ecfr.federalregister.gov/current/title-42/chapter-I/subchapter-K/part-121](https://www.ecfr.gov/current/title-42/chapter-I/subchapter-K/part-121)

¹⁶ "OPTN Regional Review", *Organ Procurement and Transplantation Network*, accessed April 12, 2021, optn.transplant.hrsa.gov/members/regions/optn-regional-review.

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](#),¹⁷ “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 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 effective 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

¹⁷ OPTN issued a request for community input on the Regional Review Project in Summer 2020, which is summarized in the report: Organ Procurement and Transplantation Network. (2020), *OPTN Regional Review Feedback*, optn.transplant.hrsa.gov/media/4149/optn-regional-review-feedback-summary-summer-2020.pdf

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 models.¹⁸

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.

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.

¹⁸ Further detail, including specific insights captured in the interviews, can be found in the [Appendix](#).

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 (hosted by UNOS rather than the OPTN) 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 components

Methodology

The process of designing alternative regional models begins with identifying unique design components 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 components: *Structure*, *Governance*, and *Responsibility*. For each of these components, 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 component. The team then solicited feedback on these options to inform the creation of three recommended models.

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 component 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 meetings¹⁹ 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?

¹⁹ 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.

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

Whereas the structure component applies to organizing a large group into more manageable forums, the governance component 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 members²⁰ 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.

The benefit of the current governance model, as 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:

- 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

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

The project team analyzed three policies²¹ 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 do not 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.

²⁰ 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.

²¹ Charts and key takeaways from public comment analysis can be found in the [Appendix](#).

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

Our final component, 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.²² 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.

The third design component, 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 is no longer impacted by the boundaries of the 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;
- 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 components of structure, governance, and responsibility across potential future regional constructs.²³ For structure, the team considered four ways to organize members: one aligned to geography, another aligned to similar interests, and two

²² 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

²³ Descriptions of initial models, as well as focus group feedback, can be found in the [Appendix](#).

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 models.²⁴

Proposed models to replace Regions today

The project team designed three models as alternative structures to the eleven Regions today. Each model is intended to address various challenges highlighted throughout this report while maintaining those core elements of the Regions that work well today. No single model 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.

Model 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.

Model 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.

Model 3: Hybrid Cohorts – This model 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 Councilmembers to sit on a Policy Council, which would replace the existing Policy Oversight Committee as an approval body in the cycle of policy development.

One potential outcome of this restructuring is that each of these models has the potential to decrease the number of seats on the OPTN Board:²⁵

In Model 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

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

²⁴ A flowchart capturing the team's process of engaging with OPTN stakeholders can be found in the [Appendix](#).

²⁵ Organ Procurement and Transplantation Network. (2020). *OPTN Bylaws effective December 7, 2020*. optn.transplant.hrsa.gov/media/1201/optn_bylaws.pdf

Model 1: Communities of Common Interest

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

Structure – In this model, 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 model. 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
- 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

Model 2: Repurposed Regions

This model 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 model 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

Model 3: Hybrid Cohorts

In this model, 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 model, 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 model is the establishment of a cohort-elected Policy Council, which would replace the Policy Oversight Committee. Currently, the Policy Oversight Committee (POC) members is comprised of the Vice Chairs of each of the policy development committees, as well as the Vice Chairs of the Membership and Professional Standards Committee and the Data Advisory Committee. Each POC member is a voting member. 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 model. 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

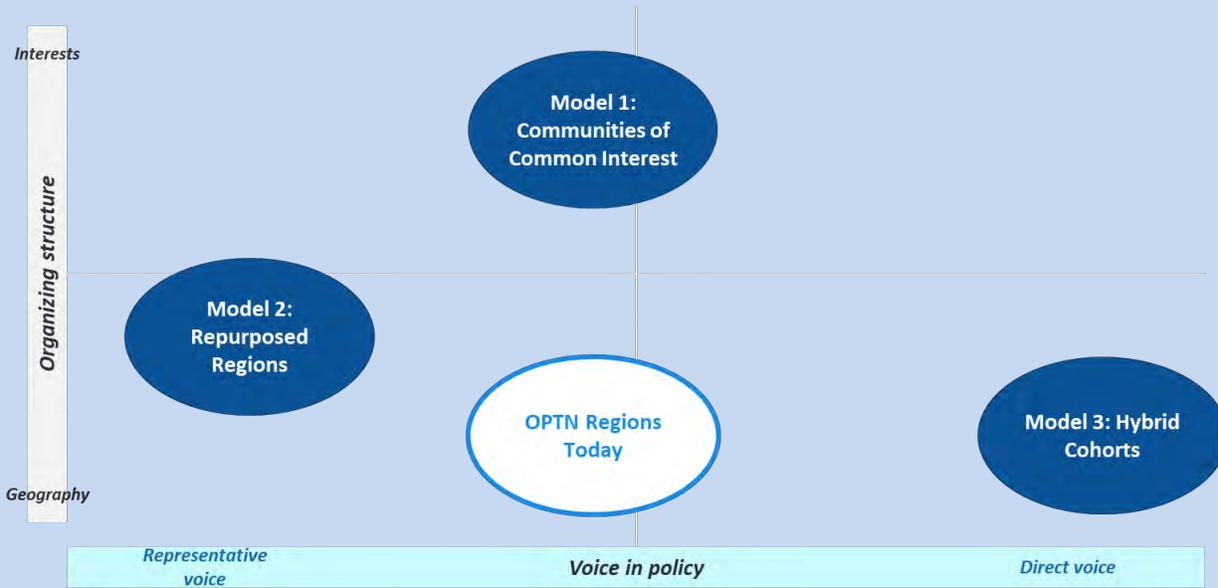
- Geographic relationships between transplant Centers, OPOs, and histocompatibility labs would remain and may strengthen
- Stakeholders without clinical knowledge would be in the same cohorts, and therefore may have more engaged and productive policy discussions
- Councilmembers can represent their cohorts'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

Difference between Regions today and three models

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



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

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

= No change from today Δ Similar, but slight change from today \star Different than today

Improvement initiatives to consider

In addition to the potentially significant transformation represented by each model, 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 continue to 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. Continue to encourage, or increase the degree to which, committees 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.

Conclusion

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 models that can be incorporated into a report for Board consideration in December 2021.