Update on OPTN Regional Review Project

OPTN Executive Committee
Purpose

- OPTN, donation and transplant community, and organ allocation policies have undergone significant change since OPTN Regions were created.
- Purpose of the review is to evaluate the structure, processes, performance, and effectiveness of Regions.
- Review considers current and future needs of the nation’s donation and transplant community.
## Regional review roadmap

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>2020</td>
<td>Request for community input</td>
<td>Summer</td>
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<td>2020</td>
<td>Issued RFP for external vendor to conduct the project</td>
<td>Fall</td>
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<td>2021</td>
<td>Selected external vendor (EY) to lead project</td>
<td>Winter</td>
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<td>2021</td>
<td>EY reviewed community input, studied OPTN system, conducted interviews, and prepared recommendations for Board of Directors</td>
<td>Spring</td>
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<tr>
<td>2021</td>
<td>OPTN Board of Directors receives and reviews recommendations</td>
<td>Summer</td>
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<tr>
<td>2021</td>
<td>Consultant recommendations issued for community feedback</td>
<td>Summer</td>
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<tr>
<td>2022</td>
<td>Board of Directors considers community feedback and develops public comment proposal</td>
<td>December</td>
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<td>2022</td>
<td>Proposal released for public comment</td>
<td>Winter</td>
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<tr>
<td>2022</td>
<td>Board of Directors considers public comment and approves OPTN structure</td>
<td>June</td>
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<tr>
<td>2022</td>
<td>Implementation begins of Board-approved OPTN structure</td>
<td>Summer</td>
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Considerations

- OPTN launched the Regional Review project pursuant to OPTN Contract Task 3.3.3: *Plan to Review and Analyze the OPTN Regional Process*

- Selected EY as vendor as an impartial, national consulting firm with no previous affiliation with UNOS or other transplant stakeholders

- EY presents three models, but there are a myriad of potential options
In a five-week sprint, EY project team developed three potential models to replace Regions today, incorporating OPTN member input.

Optimize OPTN governance and operational effectiveness by evaluating the roles of Regions:
Purpose and configuration of Regions, and approach to regional representation in broader governance

Scope

Research and data analysis
- Community input captured in the OPTN Regional Review Feedback (178 responses)
- Data 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
- External assessment of similar organizations

Stakeholder interviews
- Interviews with 42 stakeholders, including:
  - Board members from all 11 Regions
  - Members across member types: transplant centers, OPOs, histocompatibility labs, general public
  - HRSA employees
  - UNOS employees
  - Questions informed by guiding principles and research and data analysis

Focus groups: hypothesis testing
- Participants reviewed, provided feedback, and voted on options for each design component
- Conducted on the EY Real-Time Collaborator virtual platform, which enables anonymous feedback
- Three focus groups with 55 participants, including:
  - Patient and donor affairs community
  - Committee chairs and vice-chairs
  - Board members
  - Other OPTN stakeholders

Aligned on guiding principles

Determined design components:
- Structure
- Governance
- Responsibility

Developed initial hypotheses for each of the three design components

Recommendations:
Three models and improvement initiatives

Week 1: Mar 8-12

Week 5: Apr 5-9
EY project team created three options for the new structural model, each of which solves multiple challenges with today’s regional system.

<table>
<thead>
<tr>
<th>Model 1: Communities of Common Interest</th>
<th>Model 2: Repurposed Regions</th>
<th>Model 3: Hybrid Cohorts</th>
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<tbody>
<tr>
<td><strong>Structure</strong></td>
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<td>- Eliminate geographic Regions and organize members into like-interested communities</td>
<td>- Resize and re-draw geographic Regions</td>
<td>- Organize membership into cohorts using a hybrid approach:</td>
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<td>- Members grouped by member type and interest (e.g., non-academic transplant programs, rural OPOs, patients)</td>
<td>- Members grouped by combination of factors: population size, number of transplant centers, geographic proximity</td>
<td>- Geographic proximity for procurement and transplantation organizations</td>
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<td><strong>Governance</strong></td>
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<td>- Maintain policy debate and sentiment, similar to Regions today</td>
<td>- Elect Region Leads who do not hold Board seat; have national advisory role</td>
<td>- Like-interests for other stakeholders</td>
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<td>- Elect Councillors who continue to serve on Board, but represent community</td>
<td>- Policy debate and discussion moved from Regions to national forums</td>
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<td><strong>What challenges does this model solve?</strong></td>
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<td>Diminished relevance of physical territory in increasingly virtual and community-driven world</td>
<td>Desire to maintain some physical presence, recognizing Region lines today are outdated</td>
<td>Balance between grouping members likely to work together and those with similar challenges</td>
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<td>More productive policy debates among members with similar experiences and challenges</td>
<td>Elevates policy to wider national audience, avoiding local politics</td>
<td>More representative democratic engagement with direct influence on policy development</td>
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<td>Desire to maintain direct member-elected voice on Board</td>
<td>Expands other activities of Region to support OPTN mission and purpose</td>
<td>Empowers reps to advocate for cohort without conflicting interests</td>
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OPTN has an opportunity to improve governance and deliver better outcomes starting today

Next steps for Regional Review Project

- **Board Review and Initial Public Feedback**
  - May - Oct
- **Final EY Report**
  - Nov - Dec
- **Public Comment**
  - Jan 2022

Activities to start in conjunction with public comment period:
- Conduct analysis on effective organization of like-interest community structures
- Develop change management framework for transitioning to whichever model is selected (e.g., plan for re-sizing Board)

Initiatives OPTN can consider outside of public comment

**Immediate actions to improve governance**
- Raise awareness about the OPTN to increase national interest in participation
- 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
- Encourage committees to share draft proposals with other committees to gather initial input/feedback
- Clarify committee nomination and appointment processes, removing barriers to entry for new volunteers to participate
- Ensure that all meetings conducted under the auspices of the OPTN dedicate time to best-practice sharing and collaboration in meetings

**Initiatives to implement with new structure**
- Introduce monthly/quarterly communication cadence from Regions (or alternate construct) to members
- Enhance educational opportunities for physicians/surgeons and non-clinical members
- 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
Use models to think about the structure and function of the OPTN

Structure – how do we organize members into smaller forums?

Governance – how do we ensure members have a voice in policy?

Responsibility – how can Regions (or alternate construct) serve members and enable OPTN’s strategic goals?

Geography – what is the role of geography in each of these categories?
Discussion - Structure

- Should the OPTN retain geographic Regions in some form?

- Should Regions be defined by historic boundaries or be redrawn to be the same “size” as defined by some measure?
  - Ex: Population, number of transplants performed per year, number of transplant centers

- Should the OPTN establish other Communities of Common Interest or Hybrid Cohorts?
  - If so – how should these groups be defined?
  - Should the way in which these groups are defined vary based on purpose (e.g. policy development vs. implementation or effective practices)?
Discussion - Governance

- For recruiting quality and diverse candidates to the Board and committees, what role should Regions, Communities of Common Interest, or Hybrid Cohorts play?
- How should regional sentiment be collected and reported?
Discussion - Responsibility

- For discussions about policy development, is it best to organize around:
  - A) members that interact together frequently
  - B) different member types (Ex: OPOs vs. kidney programs vs. histocompatibility labs)
  - C) something else (Ex: national discussions)

- For discussions about shared operations and effective practice, is it best to organize around:
  - A) members that interact together frequently
  - B) different member types (Ex: OPOs vs. kidney programs vs. histocompatibility labs)
  - C) something else

- Are there other functions that Regions, or an alternative construct, should fill?
Discussion - Geography

- Are there other roles that Regions currently fill that have not been captured in this discussion?
- Are there other ways in which geography should influence OPTN structure, governance, or responsibility?