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HHS/DoT – Organ Procurement and Transplantation Network (OPTN) Domain 1 - Transformation

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Executive Summary

This Mapping report establishes the blueprint of the OPTN policy process, identifying gaps and challenges through desk review, stakeholder interviews, and regional and committee meeting attendance. Using human-centered design techniques, a comprehensive OPTN policy development service blueprint emerged describing the experience of a committee member proposing, developing, and implementing a policy idea, including all interactions with other OPTN stakeholders. Service blueprints outline in-depth processes, and the related key stakeholder's experience to highlight challenges and make recommendations and action plans to transform the process.

The main body of this report represents the "as is" state of OPTN policy process and is presented in Sections 1 through 6. Section 7 describes the approach used for the forthcoming "to be" Re-Engineering Report and Roadmap. Appendix "A" through Appendix "I" provide the supporting details, including stakeholder feedback and desk review, Process Metric Theme Definitions, and meeting summaries. Appendix "C" provides context for the "as is" state with a step-by-step overview of the OPTN BOD and committee selection and policy development processes while Appendix "E" details our analysis and assessment of the current processes.

The chart below illustrates the current state policy process.

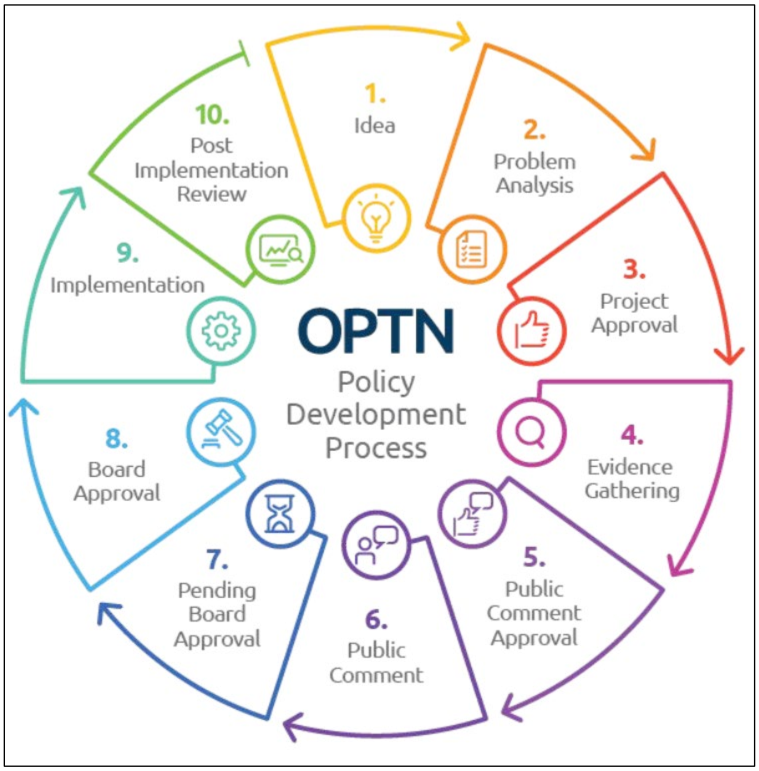

Figure 1: OPTN Policy Development Process

Themes and Key Findings

The following process metrics and policy themes were used to assess the efficiency and performance of the policy development process.

- **Committee and BOD Composition:** The composition of committees and the BOD involved in the policy development process.
- **Engagement & Transparency:** The visibility of the policy development process and the extent of stakeholder participation.
- **Timeliness:** How promptly policies are initiated, developed, and implemented.
- **Data Availability:** The availability and completeness of procurement and transplantation related data for OPTN stakeholders.
- **Prioritization Methodology:** The methods and criteria the OPTN use to prioritize projects and policies.

These themes align with previous reports and investigation including *Realizing the promise of equity in the organ transplantation system* from the National Academies of Sciences, Engineering, and Medicine (NASEM) (2022), *Changes in allocation policies for donated livers and lungs* from U.S. Government Accountability Office (GAO) (2020), *Transforming organ donation in America* from The Bridgespan Group (2020), and others.

The primary issues and challenges identified, broken down by stakeholder segment, will provide a basis for re-engineering recommendations including:

Table 1: Stakeholder Segments & Primary Issues

Stakeholder Segment	Primary Issue
Patients, Families & Caregivers	Support and training to engage with the OPTN effectively.
Community	Consistent, timely updates about OPTN policy to advocate for patients, donors, families and caregivers.
Providers	Diverse representation and data to inform clinical decision-making.
Industry	Representation and ability to provide input on logistical requirements of policy proposals.
Governance (Including Regulatory, OPTN, and Investigation)	Fully defined system and oversight mechanisms to support OPTN's operations and mission.

Data sources, stakeholder interview participants, and investigation methods included in this report are listed below.

Table 2: Data Sources, Stakeholder, Investigation Method Overview

Investigative Type	Data Source	Example
Stakeholder Interviews	**Stakeholder Segment**	**Participants**
	Patients, Families, Caregivers/Community	ORGANIZE Transplant Families American Association of Kidney Patients

Investigative Type	**Data Source**	**Example**
		National Multicultural Action Group
	Providers	Donor Network of Arizona Children's Mercy Hospital American Society of Transplantation Association of Organ Procurement Organizations (AOPO)
	Governance (OPTN)	Policy Oversight Committee (POC) Patient Affairs Committee (PAC) Minority Affairs Committee (MAC) Data Advisory Committee (DAC) Operations and Safety Committee
	Governance (Regulatory)	Health Resources and Services Administration (HRSA) Subject Matter Experts (SMEs)
Desk Review	**Data Source**	**Examples**
	OPTN statutes and regulations	OPTN Final Rule, National Organ Transplant Act (NOTA)
	OPTN Policy Documents	OPTN Bylaws, OPTN Policies
	United Network for Organ Sharing (UNOS) Operating Documents	UNOS Governance and Operations Plan, UNOS Project Management Plan
	Previous Reports about the OPTN	NASEM Report, Bridgespan Report
	Other Secondary Review Sources	Peer-Reviewed Articles, Case Studies, OPTN, UNOS, and Scientific Registry of Transplant Recipients (SRTR) websites, OPTN Committee Meeting Summaries
Meeting Attendance	**Data Source**	**Meeting Types**
	OPTN Committee and BOD Meetings	Virtual attendance at OPTN committee and BOD meetings from November 2024 to April 2025
	2025 Regional Meetings	Virtual attendance at all 2025 Regional Meetings

The overarching policy development gaps and challenges were:

- Lack of clear documentation of criteria and processes
- Transparency and engagement
- Data standardization, collection, and analysis
- Timeliness and efficiency

Conclusion

This report outlines the process used to identify the gaps and challenges in the current OPTN Policy process and provides guidance to drive a patient and family centric policy development and management re-engineering plan. Using a phased implementation, agile methods and service design approaches, OPTN can rapidly build accountability, functionality, and patient outcomes.

The Re-Engineering Report, which is a separate deliverable based on these findings, will outline the transformation of the policy development and management process across models and frameworks, people, processes, and technology. These evidence-based recommendations will be guided by metrics like speed, transparency, access, and health outcomes while ensuring an impartial, efficient, and patient-centered organ procurement and transplantation system.

1 Problem Statement

A current-state assessment of the POC structure, policies, workflows, and operations was conducted. This included reviewing and mapping operations and approaches and recommending best practices to transform patient outcomes, functionality, and accountability.

To support OPTN policymaking re-engineering and putting patients, prospective and registered donors, and donor patient families at the heart of the proposed future policymaking process, a human-centered and service design best practices approach was used to complement the technical mapping process to:

- Identify and capture the voice of the many different audiences the OPTN serves.
- Place the needs of patients and families at the center of design decisions.
- Align patients, donors, and their families’ goals with the strategic priorities of HRSA and the OPTN.
- Identify where the process is failing to advance the interests of key stakeholder groups and deliver stronger patient outcomes.

HRSA identified additional boundaries of the task order including:

- Definition of success – A transformational re-imagining of the OPTN policymaking process, including a reevaluation of the underlying policy instruments.
- Target stakeholder segments – Patients, families, caregivers, those who were unable to get on the waitlist, families of donor patients, and groups that are typically underrepresented.
- Sequencing of the process – Engaging critical voices earlier in the process to avoid delays.
- Patient outcomes – Defining metrics to measure patient outcomes at the policy proposal level and adhering to the NOTA, the OPTN Final Rule, the U.S. Department of Health and Human Services (HHS) Secretarial directives, and the OPTN strategic plan.

Specific metrics and themes were used to evaluate the health of the current policymaking process, focusing on **accountability, functionality,** and **patient outcomes.** Using extensive literature review, OPTN’s Strategic Plan, the NASEM Report, and other previous reports, the metrics and themes below were identified.

The following metrics and themes were used to align the task order categories:

- **Accountability:**
    - **BOD:** How members are selected, the balance of the types of stakeholders involved, and the defined role of the BOD.
    - **Data availability:** Availability of data to assess proposals, conduct post-implementation reviews, and ongoing monitoring. Both internally and externally.
    - **Engagement and Transparency:** Visibility and knowledge of where and how to actively engage in the process and the ability to do so. Both internally (cross-committee) and externally (public).
- **Functionality:**
    - **Committees:** How members are selected, the balance of the types of stakeholders involved, and the defined number and role of the committees.
    - **Timeliness:** Timeliness for policy development, approvals, implementation, and the waiting time in between stages.
    - **Prioritization:** Ability to calculate the potential benefit and estimated cost of a project, and effectively prioritize policies based on benefit optimization and an equitable allocation of cost across stakeholder segments and strategic priorities.
- **Patient Outcomes:** The reimagined process must be transformational, capturing the voices of the diverse audiences OPTN serves. It should place the needs of patients and their families at the center of design decisions, aligning their goals with the strategic priorities of OPTN and HRSA. Additionally, it should identify areas where the process fails to advance the interests of key stakeholder groups and deliver stronger patient outcomes.

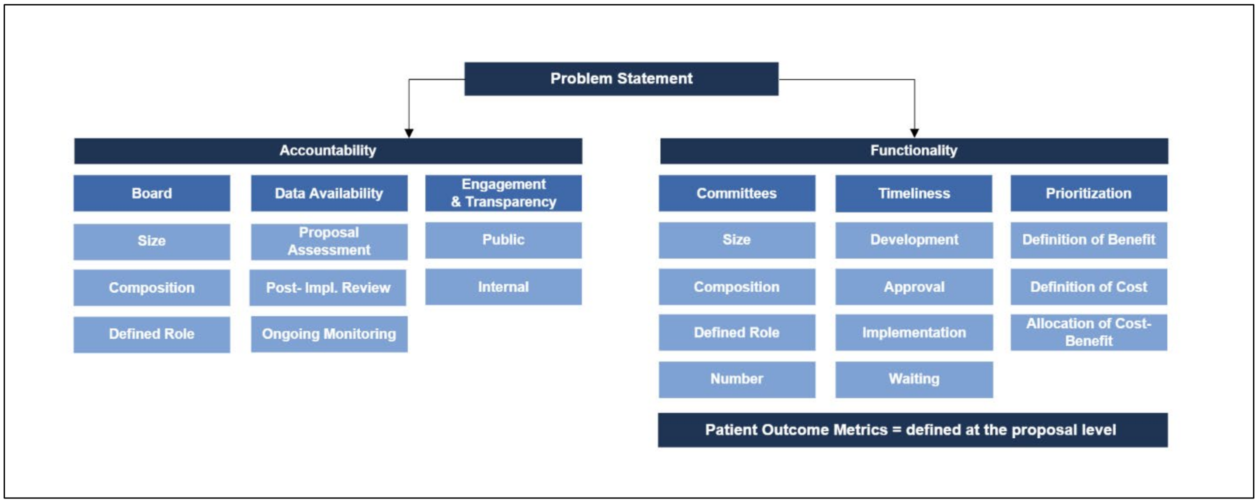

Figure 2: Problem Statement

HRSA set the expectation that metrics to measure patient outcomes need to be defined at the policy proposal level. Patient outcome metrics need to be set at the project proposal level, adhering to strategic priorities set and managed by individual committees, which in turn must adhere to the evolving strategic priorities of the OPTN.

The following summary problem statement drove the current-state mapping and assessment investigation:

How can OPTN identify, develop, and implement policy proposals most likely to better patient outcomes quickly, while providing appropriate oversight, transparency, and engagement into their processes?

Using a human-centered design approach, this report details the current OPTN policymaking process and how it is failing to deliver stronger patient outcomes due to issues with functionality and accountability.

2 Background

The OPTN policy development process evaluation identified opportunities for enhancement and accountability in organ procurement and transplantation. The analysis included mapping the current process, evaluating OPTN statutory and regulatory foundational documents (NOTA, the OPTN Final Rule), OPTN Bylaws, OPTN Policies, OPTN Management and Membership Policies, BOD and committee structures, and examining previous OPTN reports, investigations, and case studies.

2.1 Mapping the Current OPTN Policy Development Process

This Policy Mapping Report examines how the OPTN develops and oversees its policies in compliance with statutes and regulations like NOTA and the OPTN Final Rule. It considers the regulatory oversight roles of entities such as HHS and HRSA. The report analyzes the entire policy process, including committees, workflows, resources, and stakeholder engagement, using a human-centered approach to identify challenges and assess representation for registered/prospective organ donors, recipients, patient families, and underrepresented communities.

A Mapping Plan Charter guided the investigation and ensured HRSA goal alignment. The charter defined how the steps in OPTN's policy development process would be documented, including identification of inefficiencies, gathering of metrics, and alignment of findings with HRSA's strategic aims.

2.2 OPTN Policy Foundation

The OPTN policy development process is informed by OPTN statutory and regulatory requirements, the OPTN Strategic Plan, and OPTN Bylaws and policies. NOTA and the OPTN Final Rule provide a governance framework, but do not fully define operational systems, roles, responsibilities, timeframes, or oversight mechanisms. The OPTN Strategic Plan, adopted by the OPTN BOD every three years, sets priorities. OPTN Bylaws and policies provide further guidance about OPTN procedures but fail to clearly delineate end-to-end OPTN policy processes and workflows.

2.3 Previous OPTN Reports

OPTN operations have been the focus of recent investigations resulting in the OPTN modernization initiative, which aims to enhance accountability, transparency, impartiality, and performance in organ procurement and transplantation. Maximus examined existing literature on current state and stakeholder segment groups to develop an understanding of issues affecting OPTN performance.

For full details on previous reports, please see Appendix A: Previous OPTN Investigation Summaries.

This table compares themes with previous investigations showing alignment. Through this side-by-side view, the table highlights how each investigation's findings align with the themes identified in this mapping report.

Table 3: Theme Alignment Across Previous OPTN Investigations

Theme **Report Title**	**Committee & BOD Composition**	**Engagement & Transparency**	**Efficiency & Timeliness**	**Data Availability**	**Policy Prioritization Patient Outcomes Focus**
Bloom Works Report Findings	✓	✓	✓	✓	✓
Bridgespan Report Findings	✓	✓	✓	✓	
Ernst & Young Redesign Map of Regions	✓	✓	✓	✓	✓
GAO Report Findings	✓	✓	✓		✓
UNOS Hearing Report Findings	✓	✓	✓	✓	✓
NASEM Report Findings	✓	✓	✓	✓	✓
New York Times (NYT) Investigation	✓	✓	✓	✓	✓

Key:

- ✓ indicates the report explicitly discusses or supports that theme.
- *(blank)* means the report is neutral, silent, or does not address the theme.
- **x** indicates the report takes an opposite stance or contradicts the theme (none of these did so).

3 OPTN Current-State Analysis Methodology

3.1 Service Design Approach

The current-state mapping and assessment process was grounded in Service Design and Human-centered Design methodologies:

- **Service Design**: A holistic approach that focuses on creating seamless and efficient service experiences by understanding and addressing the needs of all stakeholders involved.

- **Human-Centered Design (HCD)**: A methodology that places the needs, behaviors, and experiences of people at the forefront of the design process, ensuring solutions are tailored to real-world contexts.

The primary service design artifact guiding the investigation methodology is called a service blueprint – building off the structure of a customer journey, a blueprint explores the customer (or in this case, policymaker) experience through the end-to-end service experience, exploring each step in more detail including the activities, people, policies, and technology at each stage of delivery (not exhaustive).

Service blueprints highlight an existing process at incredible depth, to drive understanding of where challenges exist and drive action plans to transform the experience for all stakeholders involved or impacted.

All investigation activities focused on identifying where the process was failing to deliver stronger patient outcomes and where its functionality and accountability were insufficient to facilitate these outcomes. Further, all insights derived from investigation activities were narrowed down to those most critically impacting the defined process metric themes, with a bias towards uncovering the patient, family, caregiver, and community voices. For a view of the completed current-state service blueprint, including the critical pain points explored in this report and key stakeholder quotes that illustrate the stakeholder experience, we have included a thumbnail and link to the completed service design blueprint.

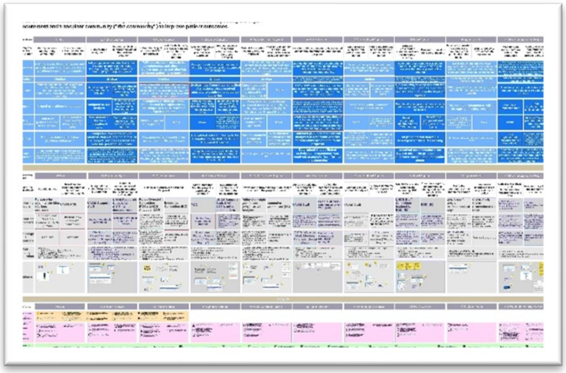

Figure 3: Current State Service Blueprint Icon

Note: The Current State Service Blueprint has been submitted as an attachment with The Mapping Report. Please refer to the Current State Service Blueprint attachment for a detailed view.

The process of mapping and assessing the OPTN policymaking process to get to that finished product involved a comprehensive, collaborative, and iterative approach that prioritized the needs and experiences of all stakeholders, particularly those who are underserved by the current process. Here's a detailed description of the process:

Step 1: Baseline the Current Process

The existing OPTN documentation was investigated to establish a baseline understanding of the current policymaking process. This was achieved by meticulously documenting the end-to-end process in a service blueprint model. The blueprint served as a visual representation of the entire process, highlighting key stages, stakeholders involved, and the flow of activities. This foundational step ensured that a clear and comprehensive understanding of how the current system operated was documented.

Step 2: Gather stakeholder insights

Extensive desk review, stakeholder interviews, and committee and regional meeting attendance were conducted to gain deeper insights and fill in any gaps identified during the initial documentation. This step was crucial for capturing the diverse perspectives and experiences of those directly impacted by the OPTN policies, ensuring that the mapping process was reflective of their experiences and challenges.

Step 3: Analyze and Prioritize findings

Following data collection, the results were analyzed to identify insights, uncover the most critical and impactful challenges, then prioritized based on their presumed impact on the functionality and accountability of the process and enhanced patient outcomes. This step ensured that the most pressing issues surfaced, enabling the most impactful and targeted solutions.

Step 4: Re-engineering Phase

With a deep understanding of the most critical challenges impacting the current process established, the next step is reviewing evidence-based methods to reorient the process around patient outcomes and the patient experience. On completion, findings and recommendations for a future-state service blueprint that maps the ideal policymaking process and addresses HRSA's goals and prioritized success metrics will be delivered.

3.2 Review

The current-state analysis included secondary review, stakeholder interviews, and regional and committee meeting attendance. Secondary review analyses included existing information from sources such as peer-reviewed articles, case studies, reports, OPTN committee meeting summaries, and other published documents to gain insights and support decision-making.

Interviews included stakeholders representing patients, families, and their associated community organizations; providers, including transplant and organ procurement professionals; and governance representatives, including OPTN committee members and HRSA regulatory SMEs (see Appendix F). Observations were gathered through virtual attendance at committee meetings, all regional meetings, and the BOD meetings from November 2024 to present.

3.3 Limitations

Limitations of the Report

Several constraints impacted the scope and depth of the analysis, including:

Data Access: The inability to access specific datasets (e.g., the 'project forms' system, the SharePoint system) hindered our ability to perform detailed evaluations.

Documentation: Delays in receiving documents (e.g., UNOS governance and operations plans, UNOS project management plans, UNOS progress reports, UNOS and OPTN policy development documents) hindered the breadth of our understanding of certain processes and methodologies.

Interview Sample Size: Due to the contract timeline and PRA clearance policy, we limited external interviews to fewer than ten people or groups.

Significant Project Delays: Repeated requests for documents, data, feedback, and the global federal communication pause caused significant barriers to discovery resulting in project delays.

3.4 Process Metrics (Themes)

Process metrics were validated with HRSA and used to measure the efficiency and performance of the policy development process. A service blueprint identified key metrics to evaluate OPTN's current policy development processes, highlighting strengths and challenges.

Stakeholder Quote

> *"In my experience, and I've been on a couple different committees, it's sort of, it's an ad hoc process which is facilitated by the contractor to some degree, but when you take an idea of conception to generate it into a policy, it happens organically, but I'm not sure the rules are super well codified."* – Committee member

The table below outlines the five main themes from the mapping report, with brief definitions. It serves as a quick reference for understanding the focus areas in OPTN policy development and governance.

Table 4: Five Primary Themes Examined in Mapping Report

Theme	Definition
Committee and BOD Composition	The composition of committees and the BOD involved in the policy development process.
Engagement & Transparency	The visibility of the policy development process and the extent of stakeholder participation.
Timeliness	How promptly policies are initiated, developed, and implemented.
Data Availability	The availability and completeness of transplant-related data for OPTN stakeholders.
Prioritization Methodology	The methods and criteria the OPTN uses to prioritize projects and policies.

For more information on these themes, please see Appendix B: Process Metric Theme Definitions.

4 Current-State Mapping

4.1 Current-State Policy Development Process

The current state of the OPTN policy development process was developed through review of OPTN's processes, operations, and the resources required for OPTN policy development and oversight. The findings mirrored previous investigations into OPTN's current state, including:

- Ineffective policy prioritization
- Long timelines for policy implementation
- Failure to define systems and roles, leading to system inefficiencies
- Lack of transparency and role definition in the BOD and committees
- Data quality and availability challenges
- Failure to engage stakeholders.

Stakeholder Quotes:

> *"Science moves fast and so if you wait 18 months to implement something the field may have already changed by that time."* – Transplantation professional

> *"We're presented with a process that takes longer than we're going to even serve on the committee, it's disheartening."* – Committee member

For additional details on the current OPTN policy development process and analysis findings, please see Appendix C: Current-State Mapping.

4.2 Stakeholder Segment Findings

Understanding the stakeholder experience is an essential part of the mapping process. How stakeholder segments currently engage in the policy development process was analyzed based on our Process Metric themes. The table below shows the key stakeholder groups in the OPTN policy development process; patients, families and caregivers; community organizations; providers; industry representatives; and governance bodies; including regulatory, OPTN, and investigation; and summarizes the primary issue each one faces. It provides an overview of how needs and challenges vary among different segments, shaping where policy enhancements and resource investments may be most effective.

Table 5: Stakeholder Segments and Primary Issues

Stakeholder Segment	Primary Issue
Patients, Families & Caregivers	Need additional support and training to engage with the OPTN effectively.
Community	Need consistent, timely updates about OPTN policy to effectively advocate for patients, families, and caregivers.
Providers	Need more diverse representation and help data to inform clinical and policy decision-making.

Stakeholder Segment	Primary Issue
Industry	Need representation and the ability to provide input on logistical requirements of policy proposals.
Governance (Regulatory, OPTN, Investigation)	Need understanding and ongoing engagement with the updated OPTN oversight system to build trust and coordinate efforts.

For more details on these findings, please see Appendix D: Stakeholder Segment Findings.

5 Current-State Assessment

5.1 Theme Gaps & Challenges within the Policy Development Cycle

Across themes, the most frequently cited, overarching gaps and challenges were:

- Lack of clear documentation of criteria and processes
- Lack of transparency and engagement
- Lack of data standardization, collection, and analysis
- Lack of timeliness and efficiency

These issues present different challenges within each theme but in many cases, the issues can be grouped or aligned with solutions that address multiple themes, gaps, and challenges across the ecosystem to increase efficiency of modernization efforts and vastly transform stakeholder experiences.

Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritization.

Stakeholder Quotes:

> *"I think that if it were a more streamlined process, you might be able to get even more engagement from experts knowing that their impact has more direct, expedited effect, because I know that's been a frustration for others as well, so just one thing I would emphasize as well."* – Organ Procurement professional

> *"You know, so you wouldn't know what policies are out there being considered or what policies that you can lend your voice to say if it's bad, good, negative, neutral, whatever, because as the patient, no one tells you that you can actually participate"* – Patient

Subthemes are identified within each theme, contributing useful information about specific stakeholder concerns. Subthemes are presented across data sources identifying high priority issues based on occurrences across multiple sources.

For more details on these findings including excerpts from interviews, desktop review, and meetings of OPTN committees and regions, see Appendix E: Current-State Assessment.

5.1.1 Theme 1: Committee & BOD Composition

OPTN BOD and Committee composition gaps and challenges are related to lack of clarity of existing regulations, guidance, roles, and responsibilities and inadequate public engagement and transparency. Recommendations are based on challenges across stakeholders and sources:

1. Develop clear regulations regarding the nomination and selection processes and required representation from stakeholder groups.
2. Ensure HRSA's role in the nomination and selection process is clearly defined and communicated.
3. Improve public engagement to increase awareness of opportunities to participate in the nomination and committee processes.
4. Increase transparency including information about schedules/timing of nomination, selection, and performance review processes, past and present nominees, and committee members.
5. Define roles, responsibilities, and implementation methods across committees and the policy process.
6. Review the current committees and organizational structures to define committee function and accountability, size, and representation (e.g., geographic, stakeholder group, etc.), and required facilitation support within the modernized OPTN.

The table below highlights subthemes within Theme 1 including BOD composition, BOD size, committee composition, conflict of interest, training and role definition, and transparent nomination process. It shows where each subtheme was identified (i.e., desk review, stakeholder interviews, committee meeting notes, or winter 2025 regional meeting notes) revealing the variation and need for OPTN governing bodies to include a variety of stakeholder groups, especially patients, registered organ donors, prospective donors, and representatives from diverse geographical areas and better policy process engagement.

Table 6: Theme 1: Committee/BOD Composition & Size Subtheme/Stakeholder Group

Committee/BOD Composition & Size Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
BOD Composition: BOD lacks adequate representation from patients, registered organ donors, prospective donors, families, and SMEs, which hampers effective decision-making and stakeholder engagement.	X	X		X

Committee/BOD Composition & Size Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
BOD Size: BOD size is not optimized, leading to challenges in maintaining efficiency and manageability while failing to ensure diverse representation and effective policy development.	X	X	X	X
Committee Composition: Committees lack diverse and adequate representation, including patient and donor representative voices, and suffer from geographic imbalances, which hinder effective policy discussions.	X	X	X	X
Conflict of Interest: Existing conflicts of interest among BOD members undermine fair and transparent policy development.	X	X		
Training and Role Definition: The lack of adequate training for new BOD and committee members, along with unclear definitions of roles and responsibilities, hampers the policy-making process.	X	X		
Transparent Nomination Process: The lack of a clear and transparent process for soliciting nominations for the OPTN BOD and committees, including public solicitations and standardized approaches, undermines trust and effectiveness.	X	X		

5.1.2 Theme 2: Engagement & Transparency

This section lists engagement and transparency gaps and challenges related to the lack of documented criteria for evaluating projects, insufficient stakeholder engagement (especially from patients and underrepresented groups), and transparency concerns throughout the policy development process.

Recommendations are based on challenges across stakeholders and sources:

1. Document criteria and metrics for evaluating and expediting proposed policy projects such as adequacy of evidence, assessment of risks, resources needed, costs, benefits, and outcomes.
2. Define requirements for stakeholder engagement in policy process, (e.g., what stages stakeholder engagement is critical and the process for ensuring input from varied stakeholders including patients, registered organ donors, etc.).
3. Identify responsible individual(s) or develop an accountability matrix to ensure policy proposals are managed through the entire process from idea generation through outcome monitoring.
4. Centralize, track, and provide a dashboard with status of policy proposals through the entire process.

The table below highlights subthemes within Theme 2 including the need for regular engagement and updates, effective communication channels, transparency in decision-making, community involvement, best practices for information sharing, role alignment, accountability systems, defined evaluation criteria, expedited action criteria and variance processes, and resource and implementation concerns. It shows where each subtheme was identified (i.e., desk review, stakeholder interviews, committee meeting notes, or winter 2025 regional meeting notes), providing a cross-sectional view of where each concern was raised and discussed, revealing the range of concerns and the need for consistent, expanded engagement channels and dashboards in line with evolving best practices for stakeholder engagement.

Table 7: Theme 2: Engagement & Transparency Subtheme/Stakeholder Group

Engagement & Transparency Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Regular Engagement and Updates: While documentation demonstrated that social media communications exist, including through newsletters and e-blasts; patients, donors, and family members reported a dearth in regular engagement and comprehensive updates, contributing to a lack of information and involvement in the process.	X	X		X
Communication Channels and Feedback: Current communication channels are insufficient for fostering engagement and collecting feedback from all stakeholders.	X	X		X
Transparency in Decision-Making: The method for integration of public comments into policy decisions and the processes across transplant	X		X	X

Engagement & Transparency Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
centers and OPOs are unclear, undermining fairness and public trust				
Community Involvement and Representation: The weight of patient voices in decision-making is insufficient, and the imbalance in representation undermines public trust and prevents all perspectives from being heard.	X	X		X
Best Practices and Information Sharing: The absence of clear information and updated dashboards, as well as the reluctance among centers to interchange information, and a lack of shared best practices amongst OPTN venues and platforms hampers the transparency, availability, and effectiveness of transplant programs.	X	X	X	X
Role Alignment and Training: Misalignment of individuals' roles with their expertise and insufficient training hinder the effectiveness of the policy development process.	X	X		
Accountability Systems: The absence of robust systems for holding UNOS accountable undermines transparency and trust in the policy-making process.	X	X		
Defined Evaluation Criteria: The absence of documented criteria for evaluating proposed projects leads to inconsistencies and lack of clarity in the evaluation process.	X			
Expedited Action Criteria: The lack of clear, standardized definitions for what constitutes an “emergent public health issue” or “patient safety factor” leads to confusion and delays in action.	X			
Expedited Variance Process: The absence of transparency in the expedited variance process undermines trust and effectiveness.	X			
Resource and Implementation Concerns: The failure to address resource limitations and the inconsistency in monitoring and notification	X			

Engagement & Transparency Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
processes hinder effective policy implementation.				

5.1.3 Theme 3: Timeliness

Timeliness gaps and challenges relate to the need for a more streamlined, transparent, and efficient policy development process.

Recommendations are based on challenges across stakeholders and sources:

1. Ensure timely decision-making and reduce delays by identifying (an) individual(s) or develop an accountability matrix to ensure policy proposals are managed through the entire process from proposal through outcome monitoring.
2. Document criteria and metrics for evaluating and expediting proposed policy projects such as adequacy of evidence, assessment of risks, resources needed, costs, benefits, and outcomes.
3. Standardize proposal submission process, timeline, and requirements for advancing to the next review stage.
4. Develop/document expedited processes for high-priority or time-sensitive policy changes.
5. Provide clear guidance and timeframes for problem analysis and evidence gathering stages including what is required and who is responsible.

The table below highlights subthemes within Theme 3 including delays in policy communication and implementation, long patient wait-times, community input bottlenecks, and overall efficiency concerns. It shows where each subtheme was identified (e.g., desk review, stakeholder interviews, committee meeting notes, or winter 2025 regional meeting notes), providing a cross-sectional view of where each concern was raised and discussed revealing the need to document and set expectations for timing across the policy process as well as dashboards and other tracking methods to ensure and visualize that policies continue to move through the process.

Table 8: Theme 3: Timeliness Subtheme/Stakeholder Group

Timeliness Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Delays in Communication and Implementation: Developing and implementing policies is often slow and not well-coordinated, which leads to	X	X	X	X

Timeliness Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
inefficiencies and delays in addressing important issues.				
Long Wait Times and Complication Rates: The delay in updating policies contributes to prolonged wait times and higher complication rates for patients, negatively impacting outcomes.	X	X		X
Community Input and Delays: The lack of timely and adequate feedback from the community leads to delays in implementing policy changes.	X	X		X
Efficiency in Policy Development: The struggle to balance thoroughness with efficiency in the policy-making process leads to delays in implementation and compromises important steps.	X	X		

5.1.4 Theme 4: Data Availability

Data availability gaps and challenges relate to the lack of data standardization, accountability for data collection, guidance on acceptable data at each stage of the process, and data transparency around public comments.

Recommendations are based on challenges across stakeholders and sources:

1. Clearly define roles for data collection and analysis at each policy development process stage to prevent delays.
2. To support evidence-based decision-making;
   a. Support implementation of consistent data standards across the OPTN ecosystem (e.g., transplant centers and OPOs).
   b. Develop guidance and metrics for long-term data collection on complications, survival, quality of life, and post-transplant healthcare utilization.
3. Develop guidance on acceptable public comment engagement and analyses including addressing and communicating about concerns raised during public comment periods.

The table below highlights subthemes within Theme 4 including fiscal assessment, public feedback metrics, resource limitations, HRSA directives, and challenges in data reporting. It shows where each subtheme was identified (e.g., desk review, stakeholder interviews, committee meeting notes, or winter 2025 regional meeting notes), providing a cross-sectional view of where each concern was raised and discussed revealing the range of concerns and the need for transformed data standardization and clear guidance regarding same.

Table 9: Theme 4: Data Availability Subtheme/Stakeholder Group

Data Availability Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Challenges in Data Reporting: Issues with data accuracy, definitions, and reporting processes hinder effective data collection.	X	X	X	X
Complexity of Data Collection: The lack of standardized and granular data elements increases the burden and reduces the accuracy of data collection.	X	X	X	X
Collaboration and Support: The lack of collaboration among various entities, including transplant centers, OPOs, UNOS, SRTR, HRSA, finance departments, CFOs, IT and communications teams, and stakeholders such as registered organ donors, families, and other underrepresented groups, hampers comprehensive and accurate data collection.	X			X
Proposals for Data Collection enhancements: The current data collection methods are insufficient, leading to gaps in information that hinder effective policy decisions.	X		X	X
Fiscal Assessment: The absence of a clear and consistent process for evaluating the fiscal impact of proposals, including the formation and membership of fiscal workgroups, leads to inefficiencies and uncertainty.	X			
Public Feedback Metrics: The lack of formal methodologies to quantify and evaluate public feedback affects policy decisions.	X			

Data Availability Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Resource Limitations: Challenges faced by smaller OPOs and transplant centers and community-based organizations in complying with new policy proposals due to limited resources.	X			
Monitoring and Review: The absence of clear processes to monitor policy implementation and conduct thorough post-implementation reviews, including long-term data assessment, leads to inefficiencies and gaps in understanding policy impact.	X			

5.1.5 Theme 5: Prioritization Methodology

Prioritization methodology gaps and challenges relate to lack of patient and community input into policy prioritization, clear policy assessment criteria that leads to alignment with strategic priorities, resource allocation, and evidence gathering, and long-term data to evaluate the effect of policy changes on patient outcomes.

UNOS often guides methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise.

A shift in project origination and POC control in Step 3 (Project Approval) describes how policy ideas previously bubbled up from permanent committees to the POC for initial approval, whereas around 2020–2021, the process reversed, with the POC now identifying roughly 80% of new projects and then assigning them to committees for development.

Recommendations are based on challenges across stakeholders and sources:

1. Ensure policy priority decision-making includes various stakeholders, including patients and community.
2. Ensure policy proposals are being generated from a variety of stakeholders to include patients and the community.

3. Develop and implement standardized policy proposal .process that focuses on improving assessment, evidence gathering, and resource allocation practices.
4. Develop and implement plans to use future long-term data on patient outcomes to inform prioritization methods.

The table below highlights subthemes within Theme 5 including standardization of allocation policies, fairness in allocation, operational challenges, community involvement, predictive data models, and strategic oversight. It shows where each subtheme was identified (e.g., desk review, stakeholder interviews, committee meeting notes, or winter 2025 regional meeting notes), providing a cross-sectional view of where each concern was raised and discussed, revealing both the range of concerns and the need for clear, data-driven strategies to ensure impartial, efficient organ allocation.

Table 10: Theme 5: Prioritization Methodology Subtheme/Stakeholder Group

Prioritization Methodology Subtheme	Desk Review	Stakeholder Interviews	Committee Meeting Notes	Winter 2025 Regional Meeting Notes
Standardization of Allocation Policies: The lack of standardized policies for multi-organ donor allocation leads to inequitable and inefficient organ distribution.	X			X
Fairness in Allocation: The current organ allocation system fails to prioritize pediatric and highly sensitized candidates adequately, resulting in unfair access to organs.	X		X	X
Operational Challenges and Efficiency: Persistent operational challenges in organ allocation processes hinder transplant outcomes and place undue burdens on smaller programs.	X		X	X
Community Involvement and Feedback: While there is community involvement in policy discussions, this involvement is not representative of the broader community. This lack of diverse perspectives can lead to policy decisions that do not fully address stakeholder concerns or achieve intended goals.	X	X	X	X

Predictive Models and Data Utilization: The current use of predictive models and data is unreliable and inaccurate, which hampers the evaluation of performance and betterment of organ allocation processes.	**X**		**X**	
Strategic Oversight and Direction: The absence of clear goals, priorities, and strong BOD oversight in policy development leads to ineffective and unfocused decision-making.	**X**	**X**		

6 Re-Engineering the Future State

A complete Re-Engineering Plan and accompanying roadmap based on the findings of this report is a separate deliverable that will be delivered in May 2025 (drafts) and June 2025 (final).

Re-engineering the policymaking process and documenting the plan to implement that transformational vision requires a structured and comprehensive approach aligned with the service design methodology outlined earlier in this report. Building on the deep understanding of the most critical challenges impacting the current process uncovered during the mapping phase of the project, evidence-based methods to reorient the process around patient outcomes and patient experience are being reviewed and considered. Following the delivery of this report, feedback received from HHS/DoT will be considered and incorporated to help guide the re-engineering process.

Developing the future-state vision will involve HHS/DoT and OPTN taking a systems-level view to setting and managing priorities. In practice, this will mean:

- Setting specific, measurable targets that align to and impact strategic goals and adhere to relevant policy.
- Committees setting specific, measurable targets aligning to the strategic priorities and policies.
- Committees developing policies with specific, measurable impact to patients, in alignment with strategic priorities.
- Committees have processes, technology, and expertise for project development, implementation, and performance, with process oversight to ensure accountability over outcomes.
- HHS/DoT and OPTN having processes, technology, and expertise to ensure BOD and committee oversight with accountability over outcomes.

6.1 Steps in the Re-Engineering Phase

The Re-Engineering Plan is a separate deliverable and will be delivered in May 2025 (drafts) and June 2025 (final). The process the team is following through the Re-engineering Phase and to create the Re-Engineering Plan and associated roadmap are defined below:

Step 1: Re-engineering the Process Around Patient Outcomes, Functionality, Engagement, and Accountability

The first step involves re-engineering the policymaking process with a focus on patient outcomes and experiences, addressing the most critical challenges surfaced during the mapping phase of the project. After completing extensive evidence-based review into preferred policymaking methodologies and processes, the most impactful solutions will be prioritized and documented in a future-state service blueprint, like the current-state document delivered in conjunction with this report. This blueprint will emphasize patient outcomes and the overall patient experience, ensuring that the redesigned process is both effective, patient-centered, and addresses the critical challenges discovered around functionality and accountability.

Step 2: Identify the Gaps Between Current and Future-State Processes

Next, an in-depth gap analysis will be conducted to identify what needs to change in terms of people, processes, technology, and policy to guide OPTN stakeholders from the current process to the transformed future state. During this phase, measures of success will be identified such as a reduction in number of days from policy idea submission to approval and increase in engagement of patients, donors, and families in policy development.

Step 3: Document the Implementation Plan

Based on the findings from the gap analysis, a detailed implementation plan will be documented to guide HHS/DoT and OPTN through a successful implementation of the proposed policymaking process. The new proposed process will include a fully defined oversight system, allowing HHS/DoT to be actively engaged in communicating and articulating regulatory authority to OPTN and other communities for the purposes of better enactment and educational understanding of the Modernization program. This plan will outline the necessary steps, resources, and timelines required to transition from the current state to the future state, as well as proactively address key risks and accompanying mitigation strategies. It will serve as a roadmap for all stakeholders, ensuring that everyone is aligned and aware of their roles and responsibilities in executing the transformation.

Step 4: Visualize the Implementation Roadmap

To facilitate clear communication and effective execution, a roadmap visualization that outlines the activities required to transition to the transformed future state will be delivered. This roadmap will provide a clear and concise overview of the implementation journey, highlighting key milestones, timelines, and responsibilities. By visualizing the roadmap, we ensure that all stakeholders have a shared understanding of the process and can work collaboratively towards achieving the transformational vision.

7 Appendix A: Previous OPTN Investigation Summaries

Appendix A compiles key report findings from reviews into the OPTN and the U.S. organ procurement and transplant system, including investigations by Bloom Works, Bridgespan, Ernst & Young, the GAO, the U.S. Senate, NASEM, and the NYT. Each summary highlights critical issues—such as OPO performance gaps, governance challenges, allocation inequities, and oversight deficiencies—and provides recommendations or observations about transforming efficiency, accountability, and fairness in organ transplantation.

7.1 Bloom Works (2025): Finding Ways to Transform the U.S. Organ Donation System

Bloom Works analyzed the current organ procurement and transplantation system to identify challenges that led to over 28,000 viable organs being wasted, whether mishandled, lost in transit, or never recovered from donor patients. The investigation's findings, compiled from interviews, case studies, and published articles, revealed several root causes, including a convoluted governance structure with limited oversight and minimal accountability contributing to poor performance, misaligned financial incentives for organ procurement and placement, outdated technology, and contracting barriers that prevented additional vendors from being awarded OPTN contracts. Together, these issues offer a comprehensive view of the system's breakdowns and the resulting loss of thousands of lives.

7.2 The Bridgespan Group (2020): Transforming Organ Donation in America

The Bridgespan Group identified how OPO performance gaps lead to increased Medicare spending, low procurement of viable organs, and preventable deaths due to long-term stays on organ transplant waiting lists. Factors contributing to poor OPO performance included poor OPO oversight by UNOS, inaccurate data reporting by OPOs, reimbursement model flaws, and OPOs prioritizing for-profit activities like tissue recovery over recovery of lifesaving organs. The findings highlighted the lack of oversight by governing bodies in OPO accountability and performance compliance. Recommendations focused on strengthening these areas with new strategies and outcome metrics.

7.3 Ernst & Young (2021): Redesign Map of the Regions

The OPTN identified a desire to change the makeup of the regional structure due to concerns about inadequate representation and operational inefficiencies. Ernst & Young noted the disproportionate influence of transplant professionals and the one-size-fits-all approach to policymaking. Based on their analysis, Ernst & Young recommended three possible scenarios for redesigning the regional structure:

- Communities of Common Interest: Regional structure would remain the same, but members would be grouped by shared interests rather than geographic boundaries.
- Repurposed Regions: Redraw regional boundaries to promote operational effectiveness.
- Hybrid Cohorts: OPTN members would be grouped by either geographic boundaries or assigned by interest. Each group would elect representatives to a Policy Council that influences policy development.

7.4 GAO (2020): Changes in Allocation Policies for Donated Livers & Lungs

The report details the change in how OPTN manages lung and liver transplant allocations, largely driven by complaints about the inequitable distribution of organs. Liver and lung allocation policies shifted from a regionally based system to one determined by the patient's health and proximity to a donor hospital. The report monitored these changes and noted an increase in the Lung Allocation Score and the average distance to retrieve an organ but found that costs increased due to the greater distance traveled.

7.5 U.S. Senate Finance Committee UNOS Hearing (2020): A System in Need of Repair: Addressing Organizational Failures of the U.S.'s Organ Procurement and Transplantation Network

Senate Finance Committee members conducted a bipartisan investigation into UNOS due to concerns with UNOS's oversight of the OPTN, particularly related to its policy compliance and patient safety activities related to OPOs. Issues identified in the investigation include:

Testing Procedure Errors

Between 2010 and 2020, 104 complaints were submitted to UNOS regarding "testing procedure" errors.

- ABO (ABO blood group system) Incompatibility Case 1 (Donor Network West,[64] San Francisco, CA) – In December 2020, one transplant recipient nearly died after receiving an organ with the wrong blood type and two recipients required the transplanted organs be removed to avoid fatal risks.
- ABO Incompatibility Case 2 (We Are Sharing Hope,[66] Charleston, SC) – On November 28, 2018, a transplant recipient died after receiving an organ with the wrong blood type.
- Cancer Transmission Case 1 (Life Connection of Ohio,[68] Kettering, OH) – On June 4, 2020, during a routine follow up, a transplant recipient was told that he had accidentally received a transplant from a donor with cancer. The recipient was told by his surgeon he "may likely die within 3 years."
- Cancer Transmission Case 2 (LifeQuest Organ Recovery Services,[70] Gainesville, FL) – On February 18, 2018, a transplant recipient contracted cancer unknowingly from a donor. A year later, a germ cell tumor was discovered during a routine transplant follow up appointment.
- Kidney Death Case (Nevada Donor Network,[72] Las Vegas, NV) – On July 14, 2017, two kidney transplant recipients contracted a rare infection after transplant surgery. One recipient died days later.

Transportation Failures

Between 2010 and 2020, 53 complaints were submitted to UNOS regarding "transportation" failures. These complaints include incidents that negatively impact the organ's quality or expected arrival time to the transplant center. Examples of complaints that impacted patient safety include:

- Courier Case 1 (Mississippi Organ Recovery Agency,[75] Flowood, MS) – On February 25, 2017, two incidents were reported to UNOS where the courier service requested by the OPO did not arrive in time to get the organs to their flight. This resulted in three cancelled transplants and one discarded kidney.
- Courier Case 2 (Donor Alliance,[77] Denver CO) – On March 28, 2018, a courier did not pick up all of the organs it was instructed to transport due to a lack of communication. The kidney was subsequently declined by the transplant center due to the delay.
- Airline Case 1 (We Are Sharing Hope,[79] Charleston, SC) – On September 15, 2015, an organ missed two flights, resulting in the transplant center declining the organ due to increased cold ischemic time (CIT). CIT determines whether a kidney remains viable on ice without blood flow.
- Airline Case 2 (We Are Sharing Hope,[81] Charleston, SC) – On March 6, 2017, an organ missed the flight to a transplant center. Due to the delay, the organ experienced such prolonged CIT that the transplant surgeon determined it was not viable and had to be discarded.

Process and Procedure Failures

Between 2010 and 2020, 109 complaints were submitted to UNOS regarding "recovery procedures." Examples of complaints that impacted patient safety include:

- Allocation Error Case (LifeGift Organ Donation Center,[84] Houston, TX) – Multiple instances reported between 2018 and 2019 of an OPO not following the heart lung allocation procedures in place, resulting in one instance of a discarded heart.
- Donation after Circulatory Death Case 1 (Indiana Donor Network,[86] Indianapolis, IN) – On February 24, 2017, an anonymous complaint submitted to UNOS alleged that when the Operating Room team opened the donor surgically, the donor's heart was still beating. Death was not declared until 10 minutes later.
- Donation after Circulatory Death Case 2 (Life Alliance Organ Recovery Agency,[88] Miami, FL) – On November 28, 2018, Life Alliance Recovery Organization (FLMP) in Miami, FL recovered organs from a donor before the donor's heart stopped and against the family's wishes. The family had only consented for Donation after Cardiac Death (DCD).
- Kidney Trash Case (Indiana Donor Network, Indianapolis, IN) – On June 12, 2020, OPO staff accidentally threw a kidney in the trash after procurement, rendering it not sterile and, therefore, not usable.

Other Failures

Between 2010 and 2020, 58 complaints were submitted to UNOS defined as "Other" and 28 defined as "Non-Issue." Below is an example of a complaint categorized as "other."

- Financial Allegations Case (Alabama Organ Center,92 Birmingham, AL) – In February 2011, UNOS received a complaint from a former OPO staff member who alleged the Executive Director (ED) had participated in money laundering and financial improprieties, calling the profits "blood money." These individuals were eventually sentenced to prison.

The investigation found that delays establishing the structure and operation of the OPTN contributed to ongoing systemic issues. The trickle-down effect has led to a gap in oversight for the contractor UNOS, and in turn other parts of the transplant system such as how the OPOs operate. This has had negative impacts on the organ procurement and transplantation system community.

7.6 NASEM (2022): Realizing the Promise of Equity in the Organ Transplantation System

The NASEM Committee on A Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution, developed a consensus report with recommendations for increasing fairness, transparency, and cost-effectiveness in the organ procurement and transplantation system, including recommendations for transforming the OPTN policy-making process. Highlights include:

1. HHS should hold OPTN and HRSA accountable for more expedient and responsive policymaking.
2. There should be contractual deadlines and well-defined priorities.
3. OPTN should be required to obtain expert support from external groups (e.g., the National Quality Forum) to help streamline the policy development process.
4. OPTN should be required to increase racial, ethnic, professional, and gender representation on the BOD and committees responsible for developing OPTN policies

7.7 NYT (2025): Sick and Skipped Over: How we Investigated the Organ Transplant System

An NYT investigation of organ allocation data found that patients high on the waiting list were dying without receiving transplants and that other patients on the list were being skipped. Key takeaways from the report include:

- Increased pressure on OPOs to increase efficiency has led them to prioritize ease over fairness.
- Transplant hospitals have discretion to determine which patients receive organs instead of strictly following the waiting list order.

On August 30, 2024, HRSA sent a critical comment letter to the OPTN regarding the allocation of organs out of sequence. In the letter, HRSA requested the following:

1. The process that the OPTN uses to review and adjudicate reports made to the Membership & Professional Standards Committee (MPSC) and/or to the OPTN regarding Allocation Out of Sequence (AOOS), non-compliant, and/or “expedited” allocation events, including:
    a. The OPTN committees that receive information about the nature and number of AOOS event reports.
    b. Which OPTN committees and/or OPTN staff/teams review reports of AOOS events
        i. For each committee, please include the cadence at which the committee receives reports, and any associated data analysis generated regarding AOOS events, individually or in aggregate.
        ii. For each OPTN staff/team, please include the cadence at which the staff/team receives reports and any data analysis generated regarding AOOS events, individually or in aggregate.
2. All data reporting generated for the OPTN since 2019 that tracks or otherwise monitors the frequency, nature, or any other descriptive statistics regarding AOOS events at the OPTN member organization level.
3. All data reporting generated for the OPTN since 2019 that tracks or otherwise monitors the frequency, nature, or any other descriptive statistics regarding AOOS events at the OPTN system level.

On February 21, 2025, after reviewing the information provided by the OPTN, HRSA sent a letter to the OPTN instructing the organization to:

- Provide a detailed remediation plan to improve OPTN allocation policy requirements and policy definitions by March 31, 2025.
- Propose a detailed, prospective OPTN compliance plan to ensure OPTN members come into compliance with the regulatory wastage provision and otherwise comply with statutory and regulatory requirements for the allocation of organs.
- Create transparency into the submission, approval, and performance of protocols under the OPTN expedited placement variance to ensure government oversight, increase patient awareness and public transparency of variances, and increase patient access to transplants.
- Propose a tool to provide public transparency into how frequently patients are excluded from access to organs for which they have been matched as a consequence of AOOS.

On March 5, 2025, HRSA directed the OPTN to submit the following by April 30, 2025:

- Proposed OPTN policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for Organ Procurement Organizations

(OPO) using Normothermic Regional Perfusion (NRP) in patients from whom organs may be procured.

- Proposed OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured.

8 Appendix B: Process Metric Theme Definitions

Appendix B outlines the five primary themes used to evaluate the OPTN policy development process:

1. Committee & BOD Composition (how committees and the BOD are structured, including membership requirements)
2. Engagement & Transparency (stakeholder participation and visibility of the process),
3. Timeliness (efficiency and speed in policy creation and implementation)
4. Data Availability (availability and comprehensiveness of transplant-related data)
5. Prioritization Methodology (how the OPTN balances costs, benefits, and strategic goals when setting policy priorities)

Each theme includes definitions, relevant guidelines (like required committee composition or data systems), and specific concerns that emerged from stakeholder input—ranging from unstructured data standards to the need for formal processes in prioritizing projects. This section gives a framework for understanding and assessing how well the current OPTN policy development process meets its stated objectives and addresses the needs of diverse stakeholders.

8.1 Theme 1: Committee & BOD Composition

Theme 1 assesses the composition of committees and BODs involved in the policy development process. This includes

- **Committee composition:** Representation of the organ procurement and transplantation community/ stakeholder subgroups.
- **Optimal BOD size**: Target for the total BOD size.
- **Stakeholder balance:** The make-up of the BOD members (demographics, stakeholder group, etc.).

Understanding these structures is essential even before Step 1 begins.

Committee Composition

Each standing committee within the OPTN must have at least one representative from each of OPTN's geographic regions. In addition to regional representation, committees should also include members from the following groups:

- Transplant hospitals
- OPOs
- Transplant coordinators

- Transplant candidates, recipients, donors, or their family members

Committee appointments are made by the OPTN Vice President, who selects members from nominations submitted by regional councillors. Efforts should be made to ensure diverse racial and gender representation, reflecting the populations served by the OPTN.

Ideally, committee members are appointed to only one standing committee, though the OPTN Vice President may assign individuals to multiple committees based on OPTN needs and to foster communication.

BOD Composition

Historically, the OPTN BOD consisted of 42 voting members. The OPTN Final Rule allows OPTN flexibility to determine the appropriate size for its BOD. However, the BOD must adhere to certain composition guidelines:

- Approximately 50% of the BOD must be comprised of transplant surgeons or transplant physicians.
- At least 25% must include transplant candidates, recipients, organ donor, and family members.
- The remaining members should represent a variety of key stakeholders, including representatives from OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.

These members should reflect the variability of the populations served by the OPTN to an extent practicable, including race, ethnicity, and gender.

8.2 Theme 2: Engagement & Transparency

Theme 2 assesses how both external and internal OPTN stakeholders participate in the policy development process and how knowledgeable they are about it, based on the available metrics.

Engagement refers to participation from various stakeholder subgroups and whether there is a collaborative effort during the policy development process.

Transparency is defined by the visibility of the policy development process for both internal and external stakeholders.

8.3 Theme 3: Timeliness

Theme 3 examines how long it takes for a policy to move through the entire OPTN development process and whether policies are initiated in a timely and efficient manner. Three main factors affect the timeline:

- Stakeholders:

  - Variability in stakeholder composition or lack thereof can lead to a broad range of goals. To mitigate misalignment, it is important to identify and prioritize key goals and objectives.
  - Stakeholders must also be clear on their roles and responsibilities to work effectively.
- Data:
  - Stakeholders access various types of data during the policy development process. This can be literature, public comments, and information given by SMEs, etc. Stakeholders can ask for additional data at any time.
  - The time from committee project approval to BOD approval varies and there is limited information and analysis on the implementation timeline. A new process, continuous distribution, has shown to shorten the policy and project timelines.
- Extraneous Factors:
  - Changes in oversight leadership.
  - Policies can be placed on hold due to litigation and public comment.

8.4 Theme 4: Data Availability

Theme 4 examines how accessible and transparent transplant-related data are for the diverse stakeholders within the OPTN.

The UNOS secure transplant network system (UNet℠) is a secure, online database that manages data for the U.S. organ procurement and transplant system. UNOS considers the UNet℠ platform to be closed, meaning there is no clear visibility into how the system is architected or built. The OPTN collaborates with the SRTR to analyze and report on transplant outcomes, organ allocation, and policy impacts. This trademarked system consists of several interconnected subsystems that work together to support the entire organ procurement and transplantation process:

1. Waitlist℠
   a. Used by transplant hospitals to manage information about patients waiting for a transplant.
   b. Algorithms developed in collaboration with the OPTN are employed to calculate the urgency of transplants and predict potential benefits for patients.
2. DonorNet®
   a. Provides OPOs with the interface to add, update, or remove donor data, execute match runs, and make organ offers.
   b. Transplant hospitals use this system to view posted donor information and record organ acceptance or refusal decisions.
3. TIEDI® (Transplant Information Electronic Data Interchange)
   a. Enables OPTN members to access and complete donor, candidate, and recipient-specific electronic data collection records.
   b. This includes a series of forms that are required throughout the transplant process.
4. Transnet℠

    a. A system used to create labels for packaging and labeling donor patients' organs and specimens for transplant or review.
    b. Transplant hospitals use this system to electronically check in or match the organ to the recipient.
5. The UNet℠ Application Programming Interfaces (APIs)
    a. A relatively new addition, UNOS identifies APIs as a separate product.
    b. These APIs enable the interface of data about donors, candidates, and recipients between validated Electronic Health Record (EHR) systems and the UNet℠ system.
    c. "Validated" is subject to UNOS' interpretation.

Committee members can submit a formal data request through the UNOS Service Portal. Requests usually involve specifying the type of data needed, the period it should cover, and the intended use for the data.

An inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements.

Long-term data such as complications, survival, quality of life, and post-transplant healthcare utilization are often lacking.

8.5 Theme 5: Prioritization Methodology

Theme 5 evaluates how the OPTN sets priorities for projects and policies to balance benefits to the OPTN community with overall cost. Current assessments rely on:

1. Project Benefit Score:
    a. This appears to be a calculation based on a multiple-choice impact questionnaire. This is meant to assess which and how many vulnerable populations will be affected by proposed policies.
    b. This is later used in a cost benefit analysis or comparison scatter plot.
2. Technical Implementation:
    a. There is an unknown methodology used to calculate the technical hours for proposed policies. This appears to be how cost is considered during the proposal process.
    b. This is later used in a cost benefit analysis or comparison scatter plot.
3. Strategic Plan Alignment
    a. Proposed policies should align with NOTA and the Final Rule.
    b. The policy development process aligns with four major strategic plan initiatives:
4. Increasing transplantation:
    a. Providing fairness in access to transplantation.
    b. Transforming procurement and transplantation community outcomes.
    c. Promoting living donor and transplant recipient safety.

5. Discussion:
    a. The POC leads conversations to determine timing, sequences, a reassessment of priorities and any external risks in collaboration with the BOD.

9 Appendix C: Current-State Mapping

Appendix C provides a step-by-step overview of the OPTN's processes for BOD and committee selection and policy development.

9.1 Preliminary Steps in BOD and Committee Selection Process

This section details the BOD and committee selection process for the OPTN, including who is responsible and how they coordinate tasks like identifying vacancies, posting calls for nominations, and ensuring federal requirements are met. It explains the annual composition reviews, ED performance evaluations, and timelines for nominations and elections (e.g., posting open positions in August, meeting in October–November). The section also covers how committees are formed, from needs assessments and calls for nominations to final appointments and describes the Board Support facilitator's ongoing role in supporting the BOD and its committees (e.g., maintaining rosters, providing meeting materials, and adhering to federal regulations).

The BOD selection process involves both the Board Support role and the Nominating Committee. The Board Support role tasks include annual composition reviews, ED performance evaluations, and public calls for nominations, while the Nominating Committee identifies upcoming vacancies, releases call for nominations, organizes elections, and ensures the BOD meets federal requirements and reflects diverse representation.

1. Open BOD Positions (August)
    a. Prior to the Nominating Committee's fall meetings, upcoming BOD positions are posted on the OPTN website.
    b. Regional councilors also notify members during regional meetings.
    c. The Committee solicits input and nominations from the entire OPTN membership.
2. Nominating Committee Meetings (October–November)
    a. The Nominating Committee convenes in October and November, ahead of the November BOD meeting, to propose a slate of nominees (directors and officers) for the BOD.
    b. In preparation for the annual meeting of members (usually in March), the form of proxy and ballot is sent to each OPTN member institution's representative.
    c. Candidates are elected by a majority vote of a quorum of the entire voting membership.

By following this timeline, the BOD selection process remains transparent, inclusive, and aligned with OPTN's mission and regulatory requirements.

Note: As of July , 2024, the former OPTN BOD has been renamed INVEST (Independent Network of Volunteers for Equitable and Safe Transplants). INVEST now serves as the OPTN BOD under HRSA's designation and oversight, in compliance with federal laws and regulations. Its bylaw now known as the Bylaws of Independent Network of Volunteers for Equitable and Safe Transplants, Inc., were most recently updated in December 2024.

9.1.1 Board Support Role Tasks

The Board Support Role Activity table summarizes the key tasks performed each year to manage the BOD—including annual composition reviews, ED performance evaluations, and developing public calls for nominations.

Table 11: Current State Mapping Board Support Role Tasks

Board Support Role Activity	Key Tasks
Annual BOD Composition Review	• Five days after any changes in BOD or Executive Committee (EC) membership Ensures the BOD meets § 121.3 The OPTN Board of Directors of the Part 121 - Organ Procurement and the Transplantation Network ○ Reviews the BOD's composition to confirm compliance with federal regulations. ○ Identifies any gaps in representation (e.g., missing professional roles or communities). ○ Considers how regional councilors are nominated and factors this into the overall composition review.
ED Annual Performance Review	• Conducts a performance review of the ED. • Provides that performance review to the Contract Officer Representative (COR) before the BOD decides on re-appointment.
Reporting & Planning	• Provides a report on the findings of the annual composition review to the COR, by a date mutually agreed upon by the Contractor and COR. • Uses the annual composition review findings to develop an annual BOD recruiting plan targeting disparities in representation identified in the composition review. • Includes in the annual BOD recruiting plan recommendations or guidance to OPTN regions to encourage regional nominations that assist in targeting disparities. • Provides the annual BOD recruiting plan to the Nominating Committee to guide the annual BOD nominations process. • Submits the annual BOD recruiting plan to the COR for review 20 business days prior to the beginning of the annual BOD nominations process.

Board Support Role Activity	**Key Tasks**
Support for Nominating Committee	• Uses the findings from the annual composition report to create an annual BOD recruiting plan aimed at closing representation gaps. • Includes recommendations or guidance for OPTN regions to help fill these gaps through regional nominations.
Nominations, Announcements, and Collections	• Gives the annual BOD recruiting plan to the Nominating Committee so they can guide the BOD nomination process. • Submits this plan to the COR 20 business days before BOD nominations begin. • Supports the Nominating Committee by finding candidates for open BOD positions. • Publicly announces the BOD nomination process annually, including on the OPTN website. • Asks for nominations from the procurement and transplantation community and the public; collects and verifies nominee information. • Sends the final list of nominees to the COR within 10 business days after nominations end.
Roster Updates	• Provides updated rosters to the COR: ○ Within five days after the end of the Effective Date of Contract (EDOC), and/or ○ Five days after any changes in BOD or EC membership. • Gives the COR a list of new BOD members and their qualifications after the yearly nominations and elections. • Provides an analysis of how the new BOD makeup meets the composition requirements in the OPTN Final Rule.

9.1.2 Nominating Committee Tasks

The Nominating Committee Tasks table outlines the core responsibilities of the Nominating Committee, such as identifying BOD vacancies, releasing calls for nominations, and reviewing applicants to ensure compliance with the OPTN Final Rule.

Table 12: Nominating Committee Tasks

Nominating Committee Activity	**Key Tasks**
Identifies Vacancies & Recruitment Needs	Following the volunteer needs assessment:

Nominating Committee Activity	Key Tasks
	• Reviews upcoming BOD vacancies and the OPTN Final Rule requirements. • Develops recommendations for recruiting new BOD members. • Reviews potential nominees recruited by Board Support Role contractor
Releases Call for Nominations	• Publishes the “Call for Nominations” each July. • Collects applications through September 15th.
Meetings & Selection	• Meets biweekly in September and November to review applicants and ensure they meet the OPTN Final Rule requirements and the BOD’s needs. • Presents proposed list of nominees at December BOD meeting. • Holds a national election in January; all eligible OPTN members may vote.

9.1.3 Committee Selection Process

The Committee Selection Process explains how committees are selected each year—from identifying which seats are open and asking for nominations, to reviewing candidates and finalizing appointments—so the right people fill each role. The selection process includes the following:

1. **Needs Assessment:**
    a. The nominating committee conducts an annual committee needs assessment.
    b. The nominating committee meets biweekly from March to April to perform a committee volunteer needs assessment.
    c. Reviews upcoming vacancies in conjunction with requirements of the OPTN Final Rule.
    d. Develops recruitment recommendations.
    e. Develops the annual “Call for Nominations.”
2. **Call for Nominations:**
    a. A “Call for Nominations” is released to the public in July detailing each vacancy on the BOD and committees.
    b. All applicants must submit a biography form by September 15th to be considered for positions beginning July 1st the following year.
3. **Review & Recommendation:**
    a. Committee applicants for at-large positions are reviewed by the leadership of the BOD and Committees in conjunction with OPTN Final Rule requirements and the BOD’s annual needs assessment.
    b. Committee applicants for regional representatives to committees are reviewed by the Region’s nominating committee.
    c. Recommendations are made to the OPTN President-Elect.
4. **Appointment:**

a. The OPTN President-Elect looks at the recommendations and makes final committee appointments.

9.1.4 Ongoing UNOS Committee-Related Tasks

UNOS's ongoing responsibilities for managing BOD committees—ensuring they follow federal regulations and providing administrative support—include:

- **Establish & Manage BOD Operating Committees:**
  - Provide agendas and meeting materials to the COR 10 business days prior to each operating committee meeting.
  - Provide rosters of all committee members to the COR one month prior to the beginning of new committee terms.
  - Identify individuals for each operating committee, the role of each member, and reasons for any simultaneous service on different groups.
  - Ensure that operating committee membership is consistent with the requirements of the OPTN Final Rule 42 Code of Federal Regulations (CFR) §121.3(a)(4).
  - Notify the COR in writing when members and chairs of governance groups change.
- **Compliance with OPTN Final Rule:**
  - Ensure each committee follows 42 CFR §121.3(a)(4) of the OPTN Final Rule.
  - Tell the COR in writing when committee members or chairs change.
- **Administrative & Logistical Support:**
  - Provides administrative and logistical support to the OPTN BOD and governance groups to perform their functions under the OPTN contract.
- **Establish Communication and Coordination**
  - Assist with communication and coordination among OPTN committees, subcommittees, and ad hoc groups during policy development.

The OPTN Policy Development Process, from initial idea generation (Step 1) to post-implementation review (Step 10), describes how new policy ideas are gathered, which committees and stakeholders analyze them, how public comments are incorporated, and how final approval and implementation occur. The appendix also points out gaps—like unclear timelines or responsibilities—and highlights key interactions among the POC, EC, and the BOD. Through this step-by-step breakdown, readers can see where decisions are made, who is involved, and how policies move from concept to adoption and ongoing review.

9.2 OPTN Policy 10-Step Development Process

9.2.1 Step 1: Idea

Summary

The Idea step explains how new project and proposal policy ideas enter the system, what information they include, and how they are reviewed and prioritized.

Key Steps

1. **Submitting an Idea to UNOS:**
    a. According to the OPTN policy development process explanatory document, the Policy and Community Relations (PCR) Department logs incoming ideas—originating from a wide range of sources such as BOD and committee members, COR representatives, UNOS staff, transplant conferences, innovation events, the community, the HHS Secretary, Congress, and HRSA—into an electronic system called "project forms."
    b. The "project form" is created and updated in the electronic system by UNOS PCR staff.
2. **Information Included:**
    a. Each idea is required to have the source of the idea, the problem it aims to solve, and any potential solutions.
3. **Review & Prioritization:**
    a. PCR leadership and OPTN Committee leadership review ideas regularly to see which offers the most benefit to the organ procurement and transplantation community, aligns with support of OPTN's strategic goals, and fits under OPTN's scope.
    b. The problem/idea identified and prioritized in this step (Step 1: Idea) is assigned to a committee for analysis.
    c. If selected, the idea goes to an OPTN committee for further analysis.

9.2.2 Step 2: Problem Analysis

Summary

At the Problem Analysis step, committees analyze each approved idea in detail, define a clear problem statement, and confirm compliance with NOTA and the OPTN Final Rule. However, there are gaps in how ideas transition from Step 1 and unclear guidelines about timing and responsibilities.

Key Steps

1. **Define & Analyze the Problem:**
    a. Committees clarify the scope of the problem and create a written problem statement.
    b. UNOS collects evidence and analyzes the problem in depth through an "evidence-based problem analysis."
2. **Update the Project Form:**
    a. UNOS attaches the evidence, a project plan (including a stakeholder collaboration plan), alignment with the Strategic Plan, and estimated resources.
    b. UNOS develops meeting materials (using the updated project form, evidence, and any authority statements) to support the POC when evaluating and recommending the proposal in the next step.
3. **Create an Authority Statement:**

   a. UNOS references the NOTA/Final Rule Checklist—deciding if each requirement is "Applicable" or "Not applicable"—but this process happens behind the scenes, offering limited visibility into how these determinations are reached or documented.
   b. The authority statement documents compliance with NOTA and the OPTN Final Rule. It is unclear where this is documented.
   c. Staff consult with UNOS counsel and HRSA if alignment issues with NOTA and the OPTN Final Rule come up.
4. **Formalizing the Problem Statement:**
   a. The Problem Statement is a statement that describes the problem the policy proposal or project is trying to solve. This is documented on the project form.
   b. This step concludes when UNOS staff updates the project form with a written problem statement.

9.2.3 Step 3: Project Approval

Summary

The Project Approval step shows how project proposals move through the approval process—first through the POC and EC, then the COR—and highlights missing details about timelines, HHS Secretary review, and who is responsible at each step.

Key Steps

1. **POC Evaluation:**
   a. The POC checks if the project aligns with strategic goals, has the right collaborators, and whether potential risks and costs have been considered.
      i. Alignment with the Strategic Plan and Policy Priorities
      ii. Involvement of relevant collaborating committees
      iii. Project sequencing within committee and overall OPTN efforts
      iv. Measurability of the intended effects and identification of key metric(s)
      v. Potential risks or unintended consequences
      vi. Technical implementation resources required
      vii. Overall assessment of cost and benefit
2. **Checklist Analysis:**
   a. A UNOS analyst analyzes the proposed model against the checklist.
   b. If concerns are identified, staff discuss them with the sponsoring committee and HRSA.
   c. A summary of the analysis is included in the public comment proposal.
3. **COR Review:**
   a. Any changes to policies or bylaws must be reviewed by the COR before going to the full BOD. However, the steps for ensuring that COR review occurs and is documented are not clear.
4. **EC Review:**

    a. The EC reviews the POC’s recommendation and decides if the project can move forward.

5. **HHS Review:**
    a. All proposed policies require HHS Secretary review and approval prior to public comment.

9.2.4 Step 4: Evidence Gathering

Summary

The Evidence Gathering step focuses on gathering detailed evidence, consulting relevant experts, and checking each policy proposal against NOTA and the OPTN Final Rule—though the process lacks clarity on exactly when committees begin gathering evidence, how long it should take, and how much input is required.

Key Steps

1. **Committee Analysis:**
    a. Committee members assigned to the policy proposal gather evidence and build potential solutions.
    b. Committee members may use data analysis, Inferential modeling from the SRTR, wireframe models from UNOS information technology (IT), review policy language, or hold conferences.
2. **Stakeholder Input:**
    a. UNOS staff seek feedback from other OPTN committees or community members who have relevant expertise.
    b. If more expertise is needed, they may bring additional SMEs onto the committee.
    c. HRSA and general counsel are consulted if issues arise.
3. **Check Against NOTA and the OPTN Final Rule:**
    a. UNOS staff use a checklist to ensure each policy proposal meets all legal requirements. The HHS Office of General Counsel can override the contractor’s interpretation of alignment with NOTA and the OPTN Final Rule.

9.2.5 Step 5: Public Comment Approval

Summary

In the Public Comment Approval step, the committee’s final policy proposal goes to the POC and EC to confirm it is ready for public comment—though it is unclear who manages the review process, how long each review should take, and exactly when evidence gathering ends and public comment approval begins.

Key Steps

1. **Committee Vote:**

    a. Sponsoring committee members, with support from UNOS, draft the public comment policy proposal—including the policy language and a summary of the analysis.
    b. The committee finalizes its solution and votes to send it out for public comment.
2. **POC & EC Review:**
    a. The POC and the EC review the policy proposal again against the same factors required for approval in Step 3 (Project Approval) as well as checking that it had enough stakeholder input, that the proposed solution is aligned to the problem, and that the solution meets fiscal requirements.
        i. Whether ample stakeholder engagement occurred
        ii. Whether the solution is tailored to the problem
        iii. Whether the project meets high-level fiscal implications
        iv. All factors from Step 3 (Project Approval)**:**
            1. Alignment with Strategic Plan and Policy Priorities
            2. Involvement of relevant collaborating committees
            3. Project sequencing within committee and overall OPTN efforts
            4. Measurability of intended effects and identification of key metric(s)
            5. Potential risks or unintended consequences
            6. Technical implementation resources required
            7. Overall assessment of cost and benefit
3. **Public Comment Decision:**
    a. If the POC and EC vote to approve it, the policy proposal can be distributed to the public for comment.
    b. After the POC and EC approve for public comment, the UNOS Communication Department notifies the public (through the OPTN website, social media, mailings, etc.).

9.2.6 Step 6: Public Comment

Summary

At the Public Comment step, the policy proposal is published for public feedback—UNOS staff notify stakeholders, gather comments, and coordinate a fiscal impact review—though it is unclear how each type of feedback is tracked and evaluated, who decides whether comments change the policy proposal, and how long the entire public comment process should last.

Key Steps

1. **Notifications:**
    a. UNOS staff,
        i. Posts a notice on the Public Comment OPTN website.
        ii. Posts notification at regional meetings and committee meetings.
        iii. Emails all OPTN members and uses additional tools—such as social media or targeted mail—to notify relevant stakeholder organizations, including both

    transplant professionals and patient groups. This approach varies based on the specific policy under review and aims to ensure all affected stakeholders receive timely information.
   b. Performs targeted communication to specific stakeholder groups based on specific policy.
   c. OPTN requests public comments at least twice per year.
2. **Collects & Review Comments:**
   a. UNOS staff record comments in an electronic system and check for any that might violate set principles outlined in the OPTN policy development document.
   b. Applicable OPTN committees also review comments and provide feedback (including SMEs like ethics, minority, pediatrics, and patient affairs).
   c. An OPTN workgroup reviews fiscal impacts and shares their analysis with the committee and the BOD.
3. **Public Comment Timing:**
   a. Public comment periods are usually 45 days, but this can vary (such as 55 or 56 days for certain cycles).
4. **Some Policy Proposals Do Not Require Public Comment**, including:
   a. Proposals that clarify or correct existing policy without changing its intent.
   b. Proposals that reflect administrative or other non-substantive procedural changes.
   c. Emergency Policy Changes: Approved and enacted prior to public comment but must be submitted for public comment within six months of approval and for at least 30 days.
   d. Expedited Policy Changes: May take effect after a 30-day comment period, unless a threshold number of objections is received

9.2.7 Step 7: Pending BOD Approval

Summary

UNOS staff will analyze and summarize public comment feedback, which will be provided to the sponsoring committee and the POC along with the collected data. Based on this analysis, the committee may adjust the policy proposal to meet policy proposal goals and, if necessary, resubmit it for further public comment before voting to send the updated policy proposal to the BOD.

Key Steps

- **Public Comment Analysis:**
  - UNOS reviews each set of public comments, organizes the feedback, and then shares it primarily with the sponsoring committee, the group that originally proposed the policy. Other relevant committees may also be involved, depending on the policy proposal’s focus (e.g., specific organs, safety issues, or ethical considerations). After examining UNOS’s analysis, the sponsoring committee

    determines whether the policy aligns with broader OPTN goals and available evidence, deciding if any revisions are necessary before moving forward.

- **Committee Review of Public Comments:**
    - The sponsoring committee examines the feedback/analysis of public comments from UNOS and considers how stakeholder input may affect or transform the proposed policy.
    - The sponsoring committee reviews the final policy proposal, ensuring it meets all necessary criteria and addresses identified issues.
- **Approval or Revision:**
    - The relevant committee votes on the updated policy language—which incorporates findings from the public comment analysis—and, if approved, sends it to the BOD for final approval. If the policy proposal does not meet required standards or needs further changes, the committee may request revisions or even reject it.

9.2.8 Step 8: BOD Approval

Summary

BOD Approval involves final approval by the BOD after reviewing the completed policy proposal, public comment feedback, and any necessary revisions. BOD's approval is required for the policy proposal to be formally adopted and implemented, ensuring that it aligns with the organizational goals and adhering to legal and regulatory standards.

Key Steps

1. **Policy Proposal Final Review:**
    a. The BOD conducts a review of the finalized policy proposal, incorporating any revisions based on public comments, committee feedback, and data analysis.
    b. The BOD discusses the proposed policy in detail, ensuring it meets all relevant legal, clinical, and ethical standards.
2. **Policy Proposal Approval or Rejection:**
    a. The BOD votes on the policy proposal.
        i. If approved, then the policy proposal moves forward to be implemented.
        ii. If rejected, then the policy proposal will be sent back for further revisions or even reconsideration.
    b. The decision, along with the rationale for approval or rejection, is documented and made publicly available under recent updates of the Policies page on the OPTN website.
3. **Post-Approval Implementation Planning:**
    a. Once the BOD approves the policy proposal, preparations for implementation begin, including any necessary training, system updates, and stakeholder communication.

9.2.9 Step 9: Implementation

Summary

Implementation of the approved policy is rolled out. This step involves updating systems, training stakeholders, and ensuring that all parties involved are informed and prepared to follow the new policy guidelines.

Key Steps

- **Engagement to Transplant Centers, OPOs, and Other Key Groups**
  - Transplant centers, OPOs, and other involved parties are notified about the new policy and provided with detailed information on how it will affect their operations.
- **Training and Education for Transplant Personnel:**
  - Training sessions and educational resources are provided for relevant personnel to ensure they understand the policy's requirements and are equipped to apply them.
- **OPTN Data System Updates:**
  - UNOS staff make necessary updates to OPTN data systems, tools, and infrastructure to accommodate the new policy and ensure it can be effectively executed.

9.2.10 Step 10: Post-Implementation Review

Summary

Post-Implementation Review involves the evaluation of the effectiveness of the newly implemented policy. This stage includes gathering feedback, analyzing data on policy outcomes, and identifying any areas that require further adjustments or enhancements to ensure the policy is meeting its objectives.

Key Steps

- **Data and Feedback Collection:**
  - Gathering data on the policy's performance, including any challenges, successes, and impacts on procurement and transplantation outcomes and operations.
  - Collecting feedback from transplant centers, patients, families, caregivers, and OPOs to assess how the policy is functioning in practice.
- **Evaluating Policy Proposal Effectiveness:**
  - Analyzing the gathered data and feedback to determine whether the policy is achieving its intended goals, such as transforming patient outcomes or optimizing organ allocation.
  - Identifying any unintended consequences or barriers to successful implementation, including operational or logistical challenges.
- **Reporting and Recommendations:**
  - Documenting the results of the review and communicating any changes or next steps to transplant centers, patients, families, caregivers, and OPOs, ensuring transparency and continued alignment with policy objectives.

  - Based on the results review, making recommendations for necessary adjustments, revisions, or updates to the policy to address any identified issues and enhance its effectiveness.

10 Appendix D: Stakeholder Segment Findings

Appendix D presents stakeholder-specific findings from the OPTN mapping effort. It outlines key challenges for each group; Patients, Families, and Caregivers; Community; Governance; including regulatory, OPTN, and review; Providers, and Industry; and demonstrates how differences in representation, engagement, data access, timeliness, and policy prioritization affect each segment:

- Patients, Families, and Caregivers call for more inclusive BOD/committee structures, plain-language explanations of policies, and quicker updates to alleviate long wait times and disparities.
- Community organizations (such as advocacy groups) want regular policy updates and more transparent data to effectively champion patient needs.
- Governance stakeholders, including regulatory and OPTN stakeholders, emphasize the need for understanding and ongoing engagement with the updated OPTN oversight system to build trust and coordinate efforts.
- Providers seek robust data, diverse representation (including rural and underrepresented clinicians), and a streamlined policy process that considers real-world clinical and logistical constraints.
- Industry stakeholders (e.g., technology, insurance, supply chain) highlight insufficient representation in committee discussions, needing better data flows, and a more comprehensive approach to the operational, financial, and technical aspects of organ procurement and transplantation policy implementation.

By detailing each group’s perspective, Appendix D underscores the complexity of balancing multiple priorities—such as equitable access, efficient processes, reliable data, and collaboration across the OPTN.

10.1 Patients, Registered Organ Donors, Families & Caregivers

Need additional support and training to engage OPTN.

- **Issues Related to Board and Committee Composition:**
  - Lack of minority representation, including racial and ethnic minorities.
  - Failure to create an inclusive environment on the BOD and committees inhibiting patient and family voices.
  - Insufficient training on ways to engage in the policy-making process.
  - Proposals are often too technical for patients/families.
  - Many of the policies and committee meetings are tailored toward medical professionals with highly technical language.
  - The size of the BOD is too large to be effective.

- **Issues Related to Engagement and Transparency:**
    - Lack of transparency/awareness about the OPTN policy-development process.
    - Insufficient communication informing patients, families, caregivers how to participate.
    - The policy development process can be communicated in a manner that is too technical for laypeople.
    - Limited opportunities for patient and family engagement in each phase of the process.
    - Failure to communicate outcomes of previously solicited feedback to patients, families, and caregivers.
- **Issues Related to Data Availability:**
    - Inconsistencies in data collection methods across organizations results in failure to accurately report all data across the OPTN ecosystem in a uniform manner. This means that patients and families do not have direct access to the complete range of data necessary to make fully informed decisions.
    - Available data is too technical to be understandable.
    - Key information, like organ allocation patterns, waiting list statistics, or disparities in access to transplantation, may not always be presented in a way that is immediately actionable for patients, families, and caregivers.
    - Even if data is made available to patients, families, and caregivers, interpreting it in the context of procurement and transplantation policy and understanding its real-world implications can be challenging.
    - Data dashboards do not clearly define the data categories and/or targeted audience by labeling fields in a standardized manner.
- **Issues Related to Timeliness:**
    - The policy-making process is too long and rigid. It needs to be more agile so it can respond to immediate needs and evolving medical information.
    - Patients often face long waiting times on transplant lists or encounter unfairness in the allocation system, but changes to transform these aspects can take years to be implemented.
    - The OPTN Final Rule hinders making enhancements quickly.
    - Patients' lives depend on making enhancements. They do not have time to wait years for enhancements.
- **Issues Related to Prioritization:**
    - Significant gaps in patient-related policies include policies ensuring equitable access, reducing wait times, providing clearer communication, and offering financial and emotional support.
    - Policies that disadvantage people of color should be assessed and updated ASAP. Any policy or practice that disadvantages any group should be fast-tracked for review as a matter of principle and fairness.

10.2 Community

Need consistent and timely updates about OPTN policy to effectively advocate and support patients, families, and caregivers.

- **Issues Related to BOD and Committee Composition:**
  - The BOD is too large to be effective.
  - Community/advocacy groups work to ensure that policies reflect the experiences of patients from various socioeconomic backgrounds, ethnicities, genders, ages, and geographic locations, as well as those with different medical conditions.
- **Issues Related to Engagement and Transparency:**
  - Need to be informed about new policies so they can advocate for patients, families, and caregivers.
  - Lack of transparency/awareness about the OPTN policy-development process.
- **Issues Related to Data Availability:**
  - Transparent data is essential to allowing advocacy groups to push for evidence-based policies that reflect real-world patient needs.
  - Making data publicly available is necessary for advocacy groups to evaluate the impact of existing policies, understand transplant trends, and advocate for changes where necessary.
- **Issues Related to Timeliness:**
  - Delays in policy development or decision-making can limit the ability of advocacy groups to mobilize their communities and advocate for changes before critical decisions are made.
  - Issues like delays in receiving information, slow decision-making in committees, and extended policy development cycles can hinder community organizations' ability to engage in the process and with their members and then respond accordingly.
- **Issues Related to Prioritization:**
  - Community organizations advocate for policies that prioritize better health outcomes, access, and fairness, often highlighting issues like disparities in organ allocation, financial barriers, or gaps in post-transplant care.
  - Community organizations provide essential feedback on proposed policies, ensuring they reflect the experiences and concerns of those directly affected by transplantation.
  - Organizations advocate for OPTN to address disparities and barriers to ensure that all patients are truly prioritized.

10.3 Governance (Including Regulatory, OPTN, and Review)

Need understanding and ongoing engagement with the updated OPTN oversight system to build trust and coordinate efforts.

- **Issues related to Transparency:**
  - Lack of coordination and differing requirements between regulatory agencies.
  - Misinformation and lack of trust in the OPTN system.

  - Lack of clarity about roles and oversight.
- **Issues Related to Efficiency/Timeliness:**
  - Recently revised legislation requiring changes to regulations, OPTN Bylaws, and HRSA's OPTN oversight responsibilities which result in governance system reengineering .
- **Issues Related to Data:**
  - Lack of standardized data
  - Methodology
- **Issue related to Impact:**
  - OPTN's purview begins when patients are added to the waitlist. We are missing an opportunity to engage people until too late.

10.4 Provider

Need diverse representation and data for clinical decision-making.

- **Issues Related to BOD and Committee Composition:**
  - The OPTN Final Rule stipulates that the majority of the BOD and committee members must be providers.
  - Providers on the BOD tend to be older and more established in their field.
  - Many providers on the BOD represent hospitals, organizations, or laboratories in urban, affluent areas potentially impacting which policies get approved.
  - Younger providers and providers from more rural areas are underrepresented on the BOD and committees.
  - Need to ensure consistent provider representation on the BOD and committees from OPTN's diverse geographic regions, as well as diverse minority and gender representation.
- **Issues related to Transparency:**
  - Providers need accurate information for clinical decision-making even though it can be too technical for patients, families, and caregivers to understand when presented in proposals and meetings.
  - Providers emphasized the need for donor and patient centered language and graphics to help communicate complex information to patients.
  - Providers have expressed a desire for the OPTN to be more transparent in defining its goals and aligning its performance metrics. During public comments regarding the updated Strategic Plan, many providers noted that the plan lacked specificity in measuring its success:

> *"There is some concern that the pillars of the strategic plan did not explicitly mention metrics around safe and effective patient care outcomes which are integral to the work of the OPTN. The Committee [OPTN Transplant Administrators Committee] suggests incorporating metrics related to system costs, such as OPO costs, decline rates, and transportation modes, when considering policies."*

  - Insufficient communication to providers in rural areas or from centers with less funding leads to inadequate provider engagement.
- **Issues Related to Data:**
  - Need for better data quality, data definition, and data and metric standardization between stakeholders (OPOs, transplant centers, OPTN, Centers for Medicare & Medicaid Services (CMS)) to accurately define the scope of problems, prevent misalignments among providers, and foster efficient policy development. Need for better data tools across the OPTN eco-system and better integration within the policy development process (e.g., Digital platforms can facilitate a timely and accurate exchange of information among transplant centers and OPOs, reducing the potential for human error).
  - Need for more automated data collection with electronic medical record (EMR) integration across platforms so that policy changes requiring new data collection will not create undue burden or adversely impact center operations. While UNOS has created multiple API tools, many members don't use them.
  - Inadequacies in UNOS's IT infrastructure resulted in untimely and inaccurate data and undermined practice review and policy development
  - Accurate data are necessary so that policy development simulations will be more representative of expected changes and, therefore, allow for appropriate decision making.
  - Gaps in data make it difficult to make decisions, especially for more disadvantaged demographics.
  - Need for data analysts to assist with understanding data nuances so perceptions during policy development are not skewed .
  - Need for continuous data monitoring and alignment with real-world patient populations.
  - Need to ensure that transplant demographics match local population demographics (e.g., African American representation in a region).
- **Issues Related to Efficiency/Timeliness:**
  - Providers recommend implementation of artificial intelligence (AI), integrated EMRs, and data-sharing to reduce manual burdens.
  - Providers suggest using AI to streamline organ allocation processes and enhance patient matching.
  - Concern about the amount of time it takes to implement a proposed idea given how many stakeholders and committees are involved in the policy approval process.
  - A report by the NASEM criticized the OPTN for this slow process, noting that the "consensus-drive nature of the OPTN policy development process can create slowness and policy implementation challenges can further delay the process".
  - On the other hand, some providers worry about the tradeoff of expediting policy development at the expense of other priorities like patient safety.
- **Issues Related to Prioritization:**

  - OPTN regions can vary significantly along economics and race and some policies may be difficult to implement for providers, especially in rural areas that do not have sufficient resources. One OPTN member was quoted in a report stating that:

    > *"Every program is in a different place in the United States with a different ethnic makeup of its patients, different races, and gender distribution. It would seem reasonable to have one of our outcomes be "are you transplanting the patients you are representing?" In other words, do the demographics of your transplant population reflect the demographics of those in need in your location. If your kidney population is 50% African American, is your transplant population 50% African American?"*

  - Providers have reported that while they are technically part of stakeholder engagements, their feedback is not always substantively reflected in final policies—particularly when those policies affect clinical operations or impose new burdens without sufficient feasibility review.. Criticism has been levelled against a one-size-fits-all approach to policymaking and not addressing issues relevant to stakeholders outside urban, affluent areas. Policies should recognize the regional differences between hospitals, transplant centers, OPOs, and labs when considering idea proposals.
  - The impact of policy changes on transplant centers, including costs of implementation, should be considered as part of proposed policies.
  - Logistics of policy proposals need to be considered.

10.5 Industry

Need representation and ability to provide input regarding logistical requirements for policy proposals.

- **Issues Related to Board and Committee Composition:**
  - A lack of industry representation on committees and during the policy development process means practical issues they could highlight often are overlooked. As a result, policies may lack "teeth" when it comes to handling real-world logistics.
  - Failure to conduct targeted communication to industry members or their involvement as committee members.
- **Issues Related to Transparency:**
  - Lack of process to notify or involve industry members (like private insurers or health data companies) in policy proposals. Businesses and organizations may not even realize a new policy that could affect them is being considered. Consequently, they risk being left out of important discussions and decisions that could significantly impact their operations
- **Issues Related to Data:**
  - Industry could play a major role in transforming data flows if the OPTN adopted modern technology (open-sourced, cloud-based technology from government-approved providers with advanced, user-friendly systems).

  - Need for a central data warehouse under an OPTN entity to standardize metrics.
- **Issues Related to Prioritization:**
  - Failure to obtain Industry input when considering resources and steps needed to make policies work in practice.
  - Failure to obtain industry input when considering the cost and operational impact of policy ideas on transplant centers to ensure they can be implemented.
  - Language within the OPTN Strategic Plan 2024-2027 is too vague (data metric goals are not specific or measurable) so it will be difficult to determine success.
  - Need to conduct impact evaluations to ensure rural or resource-poor centers are not left behind.
- **Issues Related to Efficiency/Timeliness:**
  - Without a thorough evaluation of the resources and steps needed to make policies work in practice policies can lack "teeth" to make them work.
  - Need to factor in cost and operational impact of policy ideas on transplant centers to ensure they can be sustainably implemented.
  - There is insufficient attention to logistical challenges.
  - Need to speed up or optimize certain processes through cross-collaboration among OPTN, CMS, and hospitals.
  - Need to allow third-party innovators to create effective software that meets the needs
  - of OPOs.

11 Appendix E: Current-State Assessment

Appendix E represents our analysis and assessment of the OPTN's current state based on our five process metric themes. Across these themes, the most frequently cited, overarching gaps and challenges were:

- Lack of clear documentation of criteria and processes
- Lack of transparency and engagement
- Lack of data standardization, collection, and analysis
- Lack of timeliness and efficiency

These gaps and challenges, identified in stakeholder interviews, desk review, and meeting attendance, are discussed by theme below.

11.1 Theme 1: Committee & BOD Composition Assessment

11.1.1 Interviews Assessment

Note on Reporting Language

Interview findings are reported when at least three separate participants noted a similar response. Each finding includes a mix of stakeholders unless otherwise noted. Reporting language includes "a few" (n=3-4), "some" (n=5-8), "half" (n=9), "more than half" (n=10–13), "most" (n=14–17), "all" (n=18).

Some stakeholders cited BOD member conflict of interest with corporate or clinical interests as one of the key challenges with the overall policy development process. A few stakeholders felt the BOD and committee selection process is not opaque or understandable.

Interview Insights

> *"And they have OPTN and BOD and policymaking people that are just on the take from medical device companies."* – Patient Advocacy Organization

> *"There are certain committees that really benefit from certain representation and that those committees actually work to make sure that's maintained. It's well done in the background. I just don't think people realize it happens."* – Committee Member

Half of the interview participants cited lack of patient participation as a challenge to committee and BOD composition. Others felt the number of people, size of the committees, and BOD were ineffective, with a few pointing to too many people on the BOD and a few others to too many committees.

Interview Insight

> *"When you have a board or group that's making decisions or coming up with policies and procedures. And you have everyone with the same background. You want to get the same responses."* – Community Donation Education Program

Strengths

As a counterpoint, some interview participants reported that the mix of participation was a key strength to the overall process, which extends to the committee and BOD composition. When specifically asked about composition, some found the committee composition and a few separately the BOD composition to be adequate. They cited the mix of different types of participants in the process, including providers and patients.

Interview Insight

> *"So, we were intentional during the next period when we were given a slate of potential candidates to make sure that we were filling those voices and that we stay balanced. And I'm sure all of the other committee leaders are doing the same as making sure that you have the right expertise in your committee to be able to move forward good work."* – Current Committee Co-Chair

11.1.2 Desk Review Assessment

The OPTN BOD establishes and maintains transplant policies, bylaws, and management and membership policies that govern OPTN. Committees work to address concerns of the organ procurement and transplantation community. Ensuring that the OPTN governance structure is comprised of a diverse group of experts and stakeholders who are free of conflicts of interest is essential for maintaining strategically focused and efficient decision-making. However, several issues contribute to failures within the BOD and committee selection process.

Unclear regulations arise because both NOTA and the OPTN Final Rule are silent in terms of the process for soliciting nominations for the OPTN BOD and committees.

Another concern is the lack of direct HRSA oversight of committee appointments, as HRSA does not formally review or approve committee composition or appointments. Additionally, there is a lack of consensus in the OPTN Vice President's committee selection process. Under the "OPTN Management and Management Policies" (updated March 6th, 2025), the OPTN Vice President independently selects committee members from a list of candidates, rather than holding a formal vote. This lack of a consensus-based process raises concerns about potential limited stakeholder input in determining committee composition.

Unclear annual timelines and scheduling further complicate matters. While August is identified as the month when upcoming BOD positions are posted, and October–November is set for Nominating Committee meetings, it remains unclear how other key tasks fit into the overall timeline. Specifically, there is no mention of when the annual composition review or the ED performance review begin, nor how long each task takes. It is also unclear whether the BOD selection process has a consistent annual kickoff or how the annual BOD recruiting plan aligns with the posting of open positions and committee meetings.

Public solicitations for committee nominations remain unclear, aside from posting a 2024–2025 "Call for Nominations" on the OPTN website, there is no formal mechanism to keep the general public informed of new nomination opportunities. While potential sources for publicizing these calls (e.g., Federal Register notices, professional societies like the American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), AOPO, or transplant forums such as TransplantPro or TransplantConnect) could broaden communication and engagement, there is no definitive evidence these channels are routinely used to reach a wider audience. It remains unclear how individuals are nominated for committees and how individuals can request to join. There is an informal "let us know" or recommendation-based system, raising concerns about public availability and transparency. In some cases, UNOS proactively contacts candidates to encourage them to apply, but there is no evident, standardized approach for meeting composition requirements or informing interested individuals.

Another gap concerns the storage of preliminary BOD and committee selection documents, as it remains unclear where or how these documents are maintained. There is also no accessible database of past, present, and nominated members, leaving stakeholders unable to view changes in membership overtime. Finally, unclear committee appointment deadlines and approvals pose yet another challenge, since there is no clear mention of time requirements (i.e., firm deadlines) for committee appointments.

The OPTN Final Rule outlines requirements for the size and composition of the BOD. The OPTN Final Rule requires that the BOD have at least 34 but not more than 42 voting directors. The OPTN Bylaws allow the BOD to only meet twice a year and permit the EC, comprised of only 12 individuals, to continue the work of the BOD throughout the year without needing to convene the entire BOD.

Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritization.

Provider-heavy committees can also influence which projects the POC approves, given their technical expertise, alignment with OPTN's clinical goals, and understanding of the nuances required to move policies through the process.

While expert perspectives are essential to the OPTN policy-making process, the current committee and BOD structure fails to adequately balance clinical viewpoints with patient and family perspectives. Providers often approach problems from a medical or operational standpoint, which can lead to the unintentional neglect of patient and family perspectives. To develop effective solutions, it is essential to include diverse viewpoints and gather feedback from all relevant stakeholders when examining issues and formulating solutions.

Providers—such as doctors and transplant professionals—have a strong presence in the OPTN's policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories. Since providers dominate in representation on the BOD, committees, and conference participation, they submit more ideas than patients, families, or donors.

Ideally, there should be a balance of people involved in proposing ideas. However, this can be difficult for people who do not have a formal medical education and can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. Additionally, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the organ procurement transplantation system. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Additionally, neither NOTA, the OPTN Final Rule, nor the OPTN Bylaws delineate the number of individuals required for minority and gender representation or whether a single person can count as representation for multiple groups (e.g., a Black female transplant surgeon). It is important to ensure each distinct perspective is represented by a separate voice, potentially undermining the goal of genuine variability.

A lack of role and structure definition also contributes to failures throughout the policy-making process. The BOD and committee members must be clear on their roles and responsibilities to work effectively. However, OPTN fails to train new BOD and committee members about the policy-making process, including strategies for proposing ideas, how and when to access available/required resources, and requirements for moving policies through all stages of the process. Adequate training is essential for informing committee and BOD members how to contribute their diverse viewpoints to ensure that all stakeholder voices are heard throughout the process and to avoid delays in a policy's progression.

Clearly defined roles also contribute to ensuring a policy moves forward as expected. However, the OPTN policy development process documents fail to fully define the roles and responsibilities at each step of the process. For example, in Steps 2 (Problem Analysis) and 4 (Evidence Gathering) of the policy-development process, when data collection is required, committee members need to know the kinds of data that can be requested, the amount budgeted for the request, and how to submit the request. However, newly onboarded committee members are not consistently informed about the requirements for this process.

Additionally, during Steps 2 and 4, the UNOS liaison coordinates resources and logistics by notifying relevant resources (such as SRTR, UNOS IT, and the UNOS Research Department). Liaisons also manage schedules, set meeting agendas, and oversee workgroup progress. However, it remains unclear who informs committee members of the liaison's responsibilities and who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track.

There is also no clearly defined responsibility for the data collation necessary in Steps 2, 4, 7 (Pending BOD Approval), and 10 (Post-Implementation). Although meeting minutes capture the discussion points and issues raised, it remains unclear who specifically compiles and organizes the data once it is collected. There appears to be no formal process to determine who consolidates these findings into a cohesive format, leaving an ambiguity around how data is integrated and documented.

Because of variations in committee makeup and the types of policies they approve, there is no standardized methodology for policy implementation (Step 9), including requirements for stakeholder notification of new policy rollouts and post-implementation monitoring (Step 10). There is no clear mechanism for how UNOS staff inform all relevant stakeholders—beyond general announcements—about new policy requirements, leaving it uncertain whether key parties receive timely and accurate updates.

11.1.3 Meeting Notes Assessment

Meeting Notes Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to board composition and size, and committee composition and size within the policy development cycle.

Table 13: Theme 1: Committee/BOD Composition & Size

Committee/BOD Composition & Size Sub-Theme	**Evidence**	**Source**
BOD Composition	Region 1 attendees pointed out the crucial representation of donor families on the BOD for more compassionate and effective organ allocation practices.	Regional Meeting Notes
BOD Composition	Region 2 attendees stressed the importance of ensuring patient advocacy groups have a role and adequate representation on the BOD.	Regional Meeting Notes
BOD Composition	Region 1 and 2 attendees highlighted the importance of regional and OPO representation on the BOD to ensure diverse perspectives in policy development. They noted that it’s disproportionately high physician and surgeon representation; low OPO representation.	Regional Meeting Notes
BOD Composition	Region 6 attendees pointed out the need for regional representation on the BOD for underrepresented groups like pediatrics and rural populations. Decisions on allocation have disparate impacts on different parts of the country and densely populated regions might be disproportionately impacted by allocation changes. They stressed the importance of focusing on patient experience and equitable organ allocation.	Regional Meeting Notes
BOD Composition	Region 6 attendees shared that there's great value in having industry representation to complement regional representation because of the complexity of how states and regions have different population, geographic, and logistical challenges. And those association perspectives can often highlight either disparities or strengthen ties to policy.	Regional Meeting Notes
BOD Composition	Presenter of Region 9 emphasized the importance of getting true leaders who understand the OPTN and who understand the community so that they can help influence modernization in a positive way.	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	**Evidence**	**Source**
BOD Composition	Region 9 Patient Representative in the BOD expressed the importance of maintaining patient and donor family representation on the BOD.	Regional Meeting Notes
BOD Composition	Region 9 attendees raised concerns on the lack of pediatric representation on the Transitional Nominating Committee and the need for adequate representation on the BOD	Regional Meeting Notes
BOD Composition	Region 10 attendees supported the inclusion of committee leadership and SMEs in BOD discussions to provide inputs and clarity on certain specialty subjects. They will just be on an advisory capacity and non-voting members. The attendees also highlighted the importance of ensuring that stakeholders' inputs are heard and considered in BOD decisions.	Regional Meeting Notes
BOD Size	Regions 1 and 3 attendees expressed that a larger BOD provides greater safeguards in policy development.	Regional Meeting Notes
BOD Size	PAC Presenter of Region 2 suggested that a manageable BOD size is 10-15 members and should have diverse representation including patients, donors, PAC members, lawyers, finance, and IT professionals. He also suggested incorporating a Patient Bill of Rights into the Final Rule, or wherever appropriate and must include, among other things, patients' rights pre-transplant on the waitlist.	Regional Meeting Notes
BOD Size	Regions 5 and 11 attendees considered current BOD as too large, which consists primarily of physicians/surgeons/providers who are very busy, leading to inefficiencies.	Regional Meeting Notes
BOD Size	Majority of attendees in Region 10 believed that the BOD appears to be unwieldy because it's fairly large but also admitted not knowing the correct size. For them the size is meaningful, but perhaps secondary. What matters is optimizing representation of patients, donor families, and relevant stakeholders as well as ensuring better interaction and	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	Evidence	Source
	communication between the BOD and the committees. They also emphasized that the BOD's size should reflect its function and the priority of representing the organ procurement and transplantation community.	
BOD Size	Regions 9 and 10 attendees expressed caution about significantly reducing the size of the BOD, fearing that it could limit the voice of patients, donor families, and the broader community.	Regional Meeting Notes
BOD Size	During the PAC meetings in early 2025, members expressed concerns about the large size of the BOD, questioning its ability to be agile and responsive to changing times.	PAC Meeting Notes
Committee Composition	PAC Presenters believed that PAC is well represented and consists of diverse members including living donors, recipients of various organs, and family caregivers.	Regional Meeting Notes
Committee Composition	Region 1 attendees stressed the need for more voices and perspectives in committees, especially for out-of-sequence organ allocation.	Regional Meeting Notes
Committee Composition	Region 2 attendees raised concerns on regional representation and suggested having a rotating ability to sub-in individuals with relevant expertise across specialties. They also emphasized the importance of representing diverse areas within the region to avoid having everyone from the same place.	Regional Meeting Notes
Committee Composition	Region 2, 3, and 8 attendees emphasized the need for at least one PAC member or patient and donor representatives on OPTN organ-specific committees to provide patient perspectives in policymaking and enhance engagement.	Regional Meeting Notes
Committee Composition	Region 5 attendees highlighted the need for sub-committees dedicated to vulnerable and underrepresented populations (e.g., pediatrics, rural folks).	Regional Meeting Notes

Committee/BOD Composition & Size Sub-Theme	**Evidence**	**Source**
Committee Composition	Region 6 attendee expressed concerns about geographic imbalances in committee representation, particularly noting the lack of West Coast representation on the Pancreas Committee. Other attendees supported the need for adequate regional representation to ensure diverse perspectives in policy discussions.	Regional Meeting Notes
Committee Composition	Region 9 attendee suggested the need for membership category for certain groups within the MPSC to hold them accountable.	Regional Meeting Notes
Committee Composition	Region 9 and 10 attendees emphasized the importance of patient, donor family, and community representation in committees and also their participation in policy discussions.	Regional Meeting Notes
Committee Composition	Region 10 and 11 attendees suggested a reevaluation of regional representation in light of continuous distribution allocation system. They expressed the need for representation from all regions and stakeholders to ensure all voices are heard.	Regional Meeting Notes
Committee Composition	Region 5 and 6 attendees noted that committee size is reasonable, but not all regions are equitably represented. Some regions are less well-represented and there's less of a voice compared to others.	Regional Meeting Notes
Committee Composition	During an Operations and Safety Committee meeting on 02/20/2025, members discussed the roles and expertise of key personnel involved in the NRP process, highlighting the importance of including trained recovery surgeons and Advanced Practice Providers (APPs) in the guidance document.	Operations and Safety Committee Meeting Notes

11.2 Theme 2: Engagement & Transparency Assessment

11.2.1 Interviews Assessment

More than half of interview participants cited lack of patient awareness or engagement as the key pain point of the overall process. When specifically asked about engagement and transparency, participants cited the key issues as: lack of patient awareness and engagement in the process, lack of transparency throughout the process, loud voices advancing personal agendas and crafting outcomes, and roles being misaligned with skills.

Half of stakeholders felt that general public patients, families, and caregivers are not aware of how to get involved in the policy development process. Even if they do become involved, such as sitting on a committee, their voice is not valued as highly as other stakeholders. Some felt this was exasperated by health literacy barriers like complex medical terminology.

Interview Insights

> *"*Like if you're just like an independent patient that's not involved with TRIO or you're not with the American Kidney Foundation, you may not be getting any information at all. So, what policies and procedures are being made? How do how do we get that point of view from that patient to voice their opinion? So, it's there. But how do I know it's there?" – Donor education organization
>
> *"They use patients just as like mascots that they don't listen to."* – Patient advocacy organization

Some felt that a select few "loudest voices" were driving the policy making process and drowning out the voices of others. Some others felt that those savvy to the process tried to control the process to produce their desired outcomes.

Interview Insights

> *"...this singular expert on the committee who has a large voice, you know, particularly if they are the loud voice in the room. You know what they say usually goes and it's not as much of a robust discussion."* – Transplant professional
>
> *"And so, when I see and interact with members on the BOD, and I can't speak to the BOD when I get to go to the BOD meetings twice a year as [redacted], I'm not allowed to speak at those meetings. What you just see is sort of something that to me looks choreographed because I've been around business long enough to know when I'm going to get turned down for a bank loan. That decision has already been made well in advance of me going in the door."* – Committee member

Some thought that there was role misalignment between the responsibilities of individuals in the process and their expertise. Examples included physicians making policy decisions and patients being expected to know how to participate in the policy development process. Some identified a need for training to better fulfill their roles, while others saw a need for a better facilitator role to drive policy forward. Additionally, some found a lack of collaboration avenues both between committees and with external stakeholders, causing missed opportunities for efficient and effective problem solving.

Interview Insights

> *"But really sometimes federal agency officials, with all due respect to HRSA, and medical professionals, with all due respect to their professions and their terminal degrees, it's not a deep well of people that implement policy."* – Patient advocate organization

> *"But as it's currently structured, I don't know of a whole lot of conscious effort to inform the community. I think there's probably a general expectation that people have some literacy about that when they're coming into the discussion."* – Transplantation professional

> *"It's hard to keep track of what's going on and making cohesive policy decisions without knowing what the different organ groups or the different other groups are going on. And it would be nice if there were a way where a topic could be early identification of relevant stakeholders, because I have had experience where different committees are kind of working on something related without information."* – Committee member

And finally, many thought that there was a lack of systems in place to hold the contractor (UNOS) accountable for their work.

Interview Insight

> *They didn't feel comfortable bringing it to UNOS because they thought this would just get buried, they'd face retaliation, and I can't say people's names but a lot of people that brought a complaint to UNOS got run out of industry.* – Patient Advocacy organization

Strengths

Some felt there was adequate representation of stakeholders in the policy development process.

- Some pointed to OPTN committee and BOD members commitment to contribution, dedicating time and effort into the policy development process
- A few thought there was transparency in the process with stakeholders and the public.

11.2.2 Desk Review Assessment

One major issue is the lack of documented criteria for evaluating proposed projects found in Step 3 (Project Approval). There are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there clear guidelines for evaluating the measurability of outcomes, potential risks, technical resource needs, costs, or overall benefits. Without these standards, it's unclear how proposals are judged before moving forward.

A related concern involves no defined measures for stakeholder involvement in Steps 2, 3, 4, and 6. There is no documented process for measuring how stakeholders, including donors, families, and other underrepresented groups, are included in Step 2 (Problem Analysis). Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. In addition, there is no clear guidance on how committees formalize or execute collaboration strategies with stakeholders.

Another gap centers on defining "enough" evidence in Step 4 (Evidence Gathering). Documents do not specify how much stakeholder input or review is required before moving on to the next step. This creates ambiguity about when a committee can confidently transition from information gathering to proposal development.

Further, there is a shortfall in quality standards in Step 5 (Public Comment Approval), as there are no official criteria for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Compounding this, the process lacks metrics to measure stakeholder engagement (also in Step 5). There are no clear measures for how well Step 5 involves donors, families, and the underrepresented, or how effectively it communicates transparency.

Finally, there is a persistent issue of lacking metrics to measure stakeholder engagement and transparency in Step 6 (Public Comment). OPTN solicits public comments twice per year but does not provide any metric to gauge the proper level of engagement. There is a goal to increase participation from donors and families at regional meetings and in online public comments—for example, a member from the PAC suggested that a public comment question be "designed to ensure the living donor perspective is represented." The POC wants more pediatric patient families to share their views as well, but there is no official measure of how much feedback is considered "enough." Without metrics or best practices for measuring engagement and transparency at the public comment stages, it is difficult to gauge whether the policy development process is truly inclusive. Reports highlight the disproportionate participation of providers at regional meetings and through the online public comment forum. With no specific metrics or practices established by the OPTN, measuring successful engagement and transparency remains a challenge throughout policy development.

Submitting an idea is an unclear process in Step 1 (Idea). Although regional meetings include open mic sessions where attendees can speak directly with OPTN BOD members, there is no formal online form or clearly advertised process for public idea submissions. Moreover, there appears to be no known annual call for ideas, leaving the public uncertain about how—or even whether—they may officially submit proposals for consideration. There is no documented system or formal instructions letting OPTN stakeholders know if or how they may submit new policy ideas. Anyone who is not already "in the know" has no clear path to propose ideas, and it remains unclear whether any submissions go through OPTN or directly to UNOS. This lack of transparency leaves many potential contributors unaware that they can even offer suggestions. The OPTN does not appear to offer a public-facing submission process—such as an annual call for ideas or a Federal Register notice—beyond open-mic sessions at regional meetings. Consequently, it remains unclear how (or whether) suggestions submitted via email, fax, mail, or phone are formally evaluated and tracked.

A lack of ideas from diverse sources in Step 1 further compounds these challenges. Ideally, there should be a variability of people involved in proposing ideas. However, this can be difficult for people who do not have a formal medical education. Since providers dominate in representation on the BOD, committees, and participation in conferences, they will submit more ideas than patients or donors.

Some OPTN members have asked for more perspectives from people who are not typically involved or who represent overlooked problems. POC meeting notes show that proposals—especially in the early "idea" phase—need more diverse viewpoints and "recommended more patient feedback and involvement." Meanwhile, committees such as the MPSC focus on transplant success metrics and do not measure how well they engage the public or share information openly. The OPTN has no set process or metric to ensure that donors, families, or other underrepresented groups have a voice early on. Without official guidelines or measures of engagement, it's hard to know if the process is truly transparent or successfully inviting all relevant perspectives.

Providers—such as doctors, reviewers, and transplant professionals—have a strong presence in the OPTN's policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories. Because providers make up so many committees, they tend to submit the majority of new policy proposal ideas. However, this can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. In addition, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the organ procurement and transplantation system. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Provider-heavy committees can influence which projects the POC approves, given their technical expertise and alignment with OPTN's clinical goals.

No central oversight or tracking for idea submissions in Step 1 remains a barrier, since there is no documented process for collecting, reviewing, and entering them into the system. Additionally, there is no established mechanism or oversight to ensure that every idea is logged, processed, and followed up on, which raises concerns about potential gaps in capturing stakeholder input. While a policy-related Tableau dashboard (owned by UNOS) exists, there is no known comprehensive system for logging, monitoring, and following up on new proposals. Although the PCR Department logs ideas into the "project forms" system, there is no standardized form or procedure to ensure each idea is submitted with the necessary details (such as the source of the idea, the problem it aims to solve, and potential solutions). It remains unclear who in PCR gathers this information or how consistently those requirements are met—leaving many proposals without the crucial data needed for proper evaluation.

Ambiguous criteria for expedited action in Step 1 is yet another issue. There is no clear, standardized definition of what constitutes an "emergent public health issue" or "patient safety factor." Instead, HRSA and the OPTN exercise broad discretion in determining when expedited action is warranted—for example, issuing an advisory on NRP after patient safety concerns arose. It remains unclear whether the BOD formally defines these criteria or how alternate pathways are chosen. Additionally, HRSA issued a directive for OPTN to improve allocation policy requirements and policy definitions in response to a critical comment letter concerning the activities related to "expedited" allocation of organs.

Similarly, an expedited variance process lacks transparency in Step 1. There is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked. The problem is compounded by the subjective definition of "non-controversial" proposals in Step 1, since no formal or consistently applied criteria exist for classifying a proposal as "non-controversial." It appears to be a subjective term without a clear, written definition—underscoring the need to investigate if any official guidance on this designation is provided.

Unclear roles and responsibilities affect the entire 10-step policy development process. From Step 1 to Step 2, the process does not clarify how an idea transitions from initial submission to being formally assigned to a specific committee. It is also unclear who determines which committee will sponsor and address the problem, leaving a gap in transparency and responsibility at this critical handoff. It is not spelled out who does each task, when, or what level of analysis is required (e.g., literature review, formal study, etc.). Moving from Step 3 (Project Approval) to Step 4 (Evidence Gathering), the process does not clearly define how the committee is informed that a project is approved and can start collecting evidence. During Step 4, staff liaisons coordinate resources and logistics once a proposal is approved for evidence gathering. The staff liaison—not the volunteer committee members—typically notifies relevant resources (such as SRTR, UNOS IT, and the UNOS Research Department), manages schedules, sets meeting agendas, and oversees workgroup progress. However, it remains unclear who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track.

In terms of the HHS Secretary review in Step 3, it is unclear whether committees designate a policy as "mandatory" vs "non-mandatory" at this step, when policies are sent to the HHS Secretary for review, how that gets done, or how long it takes. Further complicating matters is the lack of documented criteria for evaluating proposed projects in Step 3. There are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there clear guidelines for evaluating the measurability of outcomes, potential risks, technical resource needs, costs, or overall benefits. Without these standards, it's unclear how proposals are judged before moving forward.

No defined measures for stakeholder involvement in Steps 2, 3, 4, 6 adds another layer of complexity. There is no documented process for measuring how stakeholders, including registered organ donors, families, and other underrepresented groups, are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. No clear guidance on how committees formalize or execute collaboration strategies with stakeholders. This intersects with defining "enough" evidence in Step 4, where documents do not specify how much stakeholder input or investigation is required before moving on to the next step. The NOTA/OPTN Final Rule Checklist Used Behind the Scenes in Step 4 further complicates things: while the NOTA/OPTN Final Rule checklist states that proposals move forward if no concerns are raised about compliance with its requirements, the checklist does not fully define the steps for this analysis. However, UNOS process documents indicate that a spreadsheet is used to document whether the authority and/or applicability of one or more requirements is not clearly established or there are different interpretations as to applicability. The process documents fail to indicate when and by whom the spreadsheet is implemented.

At Step 5, quality standards remain undefined. No official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Step 5 also lacks metrics to measure stakeholder engagement, providing no clear measures for how well to involve donors, families, and the underrepresented or communicate transparency. Meanwhile, Step 6, which lacks metrics to measure stakeholder engagement and transparency, is equally problematic. OPTN solicits public comments twice per year but does not provide any metric to gauge the proper level of engagement. There is a goal to increase participation from donors and families at regional meetings and in online public comments. A lack of metrics and best practices to measuring engagement and transparency, particularly at the public comment stages. Reports have highlighted the disproportionate participation of providers during regional meetings and through the online public comment forum. Without any specific metrics or practices by the OPTN, it is difficult to measure successful engagement and transparency during policy development.

Step 6 further illustrates these weaknesses as there is no clear monitoring or responsibility for public notifications. While the Public Comment OPTN website posts public comment announcements and staff or committee liaisons may share them via email or newsletters, it remains unclear how or whether social media channels are used. Moreover, there appears to be no formal process to verify that these notifications reach all stakeholders or to confirm that the step has been completed. Public comment details (also Step 6) are likewise undefined, as the OPTN policy process documents do not explain step-by-step how each kind of feedback (online, in-person, email) is gathered and tracked to ensure that every comment is included in the public comment analysis. The policy process documents also do not clarify who decides if comments can alter the proposal or how that decision is made. OPTN requests public comments at least twice per year and may also hold special comment periods for various reasons but currently lacks a metric to gauge whether participation is sufficient.

Virtual meetings and public comment engagement in Step 6 shows some promise. A study by Ernst & Young found that attendance at winter regional meetings between 2020-2021 increased by 37% and 106% for patients, families, and caregivers when they could participate virtually indicating a possible path to more balanced engagement. The Ernst & Young study indicated that virtual meetings provided more proportional representation during these regional meetings; transplant hospitals and other medical professionals tend to drive public comments online and at meetings. There was a noted tendency to cast votes through multiple forums, skewing perceptions for or against a policy proposal. Virtual meetings increased participation among patients, families and caregivers, and a further study by an OPTN committee provided a potential baseline for the appropriate amount of participation among stakeholders. Yet, without any specific metrics or best practices by the OPTN, it is difficult to measure successful engagement and transparency during policy development. This lack of metrics and defined targets, particularly at the public comment stage, further hinders the ability to ensure consistent and thorough stakeholder involvement. Reports have highlighted the disproportionate participation of providers during virtual regional meetings and through the online public comment forum. It was noted that regional meeting engagement did skew towards providers relative to patients, families, and caregivers. The Ernst & Young report specified that transplant hospitals tended to dominate these discussions over other groups including OPOs and labs. A transition to hosting virtual regional meetings increased participation among all groups. However, there is a lack of metrics and defined targets to measuring engagement and transparency, including at the public comment stage. The policy development process tends to be tailored to medical professionals, making it difficult for patients, families, and caregivers to fully engage with the ideas being discussed. This creates a burden for physicians trying to properly educate their patients. At a Kidney Transplantation Meeting discussing statistics from the SRTR, one member remarked that the “Committee and community may need to hear this information a few times in order to fully appreciate the nuances.”

Provider Dominance in Public Comment in Step 6 is a recurring theme, as many public comments come from medical professionals, overshadowing the patient/donor viewpoint. There were recommendations to include more representatives from OPOs and pediatrics. Many OPTN providers also tend to be older and more established in their fields and come from urban areas.

Concerns about the limited impact of public feedback in Step 7 (Pending BOD Approval) then arise. While public comments are reviewed, there may be instances where stakeholder input does not significantly alter the final policy proposal, leading to concerns that the process could be more responsive to public support, suggestions, and concerns. This raises the question about potential bias in donor, family, advocacy, and small organization representation where clinical perspectives outweigh patient voices. During the public comment period, medical professionals and clinicians may exert greater influence than donors, families, or advocacy groups. This imbalance can lead to concerns that clinical viewpoints are prioritized over the firsthand experiences of those most directly affected by organ procurement and transplantation policies.

An unclear comment review and tracking process in Step 7 exacerbates the issue. It remains unknown who specifically reviews each public comment for compliance with OPTN public comment principles and how any potentially violative comments are escalated to UNOS leadership. There is no documented process detailing who tracks these reviews, how follow-up occurs, or whether comments are returned to the general queue. Neither HRSA's role in this screening nor the UNOS's or BOD's exact responsibilities are clearly defined, leaving a major gap in transparency and accountability. No formal process for incorporating public comment concerns pre-BOD approval in Step 7 makes it unclear how—or even whether—feedback from the public comment period is systematically addressed before proposals reach the BOD. There is no documented mechanism to ensure that stakeholder concerns are resolved, leaving uncertainty as to whether significant objections or suggestions are truly considered or merely set aside. Additionally, influence of larger organizations in Step 7 arises because larger transplant centers and well-funded institutions may have more resources to devote to policy discussions, thereby overshadowing smaller transplant centers or community-based organizations. This disparity can create an uneven playing field, potentially affecting the variability and balance of input that shapes final policy outcomes.

Finally, resource and implementation concerns appear in the later steps. Limited resources in Step 9 (Implementation) are an issue for some OPTN transplant centers, smaller transplant centers, and community-based organizations may lack the resources (such as funding, staff, time, etc.) to fully comply with the new policy proposal, potentially leading to unequal implementation across the system. Ongoing monitoring of policy proposal rollout (in Steps 9 and 10) is unclear, making it difficult to determine how the implementation process is tracked and potentially affecting early detection of issues. This lack of clarity can hinder a policy's successful rollout. Additionally, there is no documented process for stakeholder notification of new policy implementation. No clear mechanism for how UNOS staff consistently informs all relevant stakeholders—beyond general announcements—about new policy requirements, leaving it uncertain whether key parties receive timely and accurate updates. Finally, insufficient long-term data in Step 10 (Post-Implementation) completes the picture of missing elements. Some policies may require more time to fully assess their long-term impact, and post-implementation reviews may not always account for the full range of effects over time. The UNet system is closed, so it is difficult to understand the methods of analysis that are being conducted, and qualitative data is often overlooked in favor of quantitative data. These gaps collectively illustrate the complexities and shortcomings within the OPTN's 10-step policy development process, highlighting the need for more transparent guidelines, robust stakeholder engagement, and clear accountability measures across all 10-steps.

11.2.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to engagement and transparency within the policy development cycle.

Table 14: Theme 2: Engagement & Transparency

Engagement & Transparency Sub-Theme	Evidence	Source
Regular Engagement and Updates	Region 1 and 8 attendees expressed the need for regular engagement and more comprehensive updates with patients, donors, and family members.	Regional Meeting Notes
Communication Channels and Feedback	Region 2 and 5 attendees shared the need for better communication among members within the region and suggested creating a listserv or moderated forum for interregional and intraregional communication. Other communication channels like community town halls, national public campaigns, grassroots engagement through local OPOs and transplant centers were suggested to foster better engagement and transparency.	Regional Meeting Notes
Communication Channels and Feedback	Region 4 attendees discussed the need for better communication and feedback across transplant centers. They also pointed out the importance of involving the community in discussing policy outcomes and identifying impacted groups.	Regional Meeting Notes
Communication Channels and Feedback	Region 5 and 7 attendees recommended keeping virtual options for those who cannot attend in-person meetings to enhance engagement. They also encouraged procurement and transplant professionals to promote OPTN volunteering opportunities.	Regional Meeting Notes
Transparency in Decision-Making	Region 3 attendees questioned how effectively public comments were integrated into final policy decisions, expressing a need for greater transparency in how feedback influences outcomes. There were also concerns on whether all stakeholders, including smaller transplant centers and OPOs, had equal access to the public comment process.	Regional Meeting Notes
Transparency in Decision-Making	Region 5 attendees suggested the use of the OPTN safety portal in reporting unexpected disease transmission events and to incorporate standardized national guidelines into hospital protocols. They also emphasized the need for clear, uniform processes across OPOs and	Regional Meeting Notes

Engagement & Transparency Sub-Theme	Evidence	Source
	transplant centers to promote transparency, consistency and fairness.	
Transparency in Decision-Making	A Region 6 attendee wanted some clarifications on how one measures whether the BOD or the committee is achieving the goals of the OPTN and how these goals can become part of the metric of effective operation of either the BOD or the committee.	Regional Meeting Notes
Transparency in Decision-Making	Region 8 and 9 attendees raised concerns about transparency in OPTN leadership activities despite the creation of new conflict of interest policies.	Regional Meeting Notes
Transparency in Decision-Making	A Region 9 attendee expressed feelings of deception and disrespect regarding the temporary nature of BOD appointments, highlighting the lack of transparency in the communication process regarding OPTN Modernization. Other attendees also expressed concerns that patients are not well informed about changes in policies and how these changes might affect them. They stressed the importance of transparent communication and education for patients.	Regional Meeting Notes
Transparency in Decision-Making	During the PAC meetings in early 2025, members raised concerns about the transparency of the transition process, with some feeling that there has been a lack of clear communication and inclusion in critical discussions.	PAC Meeting Notes
Transparency in Decision-Making	A PAC member said there is a lack of transparency around policy projects and how sponsoring committees incorporate feedback from other committees into their policies.	PAC Meeting Notes
Community Involvement and Representation	Attendees from Regions 3, 4, 8, and 9 emphasized the importance of ensuring patient voices and experiences are heard by the BOD and committees. They also raised the need for patients' involvement in the decision-making process as well as receiving comprehensive updates from OPTN leaders.	Regional Meeting Notes

Engagement & Transparency Sub-Theme	**Evidence**	**Source**
Community Involvement and Representation	A Region 9 attendee pointed out the need for balanced representation and transparency in congressional hearings related to OPTN Modernization.	Regional Meeting Notes
Community Involvement and Representation	Region 10 attendees emphasized the value of regional breakout meetings for understanding policy impacts and ensuring regional representatives are well-informed. They also stressed the importance of elevating alternate voices to ensure all perspectives are heard, especially those outside the mainstream conversation. The attendees also suggested including content experts as non-voting members in BOD discussions to ensure informed decision-making.	Regional Meeting Notes
Community Involvement and Representation	Region 11 attendees pointed out the importance of transparency and formalizing allocation practices to maintain public trust, highlighting the need for community input.	Regional Meeting Notes
Best Practices and Information Sharing	During an MPSC meeting on 02/21/2025, members highlighted the need for transparency for candidates regarding the updated notification requirements, noting that the retrospective notification process could be burdensome on transplant programs.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During a MPSC meeting on 02/21/2025, members stressed the importance of sharing best practices and engaging the PAC to ensure the process works best for both programs and patients.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During a MPSC meeting on 02/06/2025, members highlighted the importance of sharing effective practices between OPOs and ensuring that performance measures are complementary to CMS metrics to aid in identifying opportunities for enhancement.	Membership & Professional Standards Committee Meeting Notes
Best Practices and Information Sharing	During an MPSC meeting on 12/13/2024, members highlighted the importance of providing clear information for programs about the performance enhancement zone, as	Membership & Professional Standards Committee Meeting Notes

Engagement & Transparency Sub-Theme	**Evidence**	**Source**
	feedback from previous processes indicated confusion among some members.	
Best Practices and Information Sharing	During Living Donor Committee (LDC) meetings in the month of March 2025, members highlighted the importance of clarifying options and adding definitions to the forms to ensure transparency and comprehensiveness in capturing relevant data.	LDC Meeting Notes
Best Practices and Information Sharing	During an LDC meeting on 03/06/2025, members highlighted the importance of providing clear information to programs about the data collection process, as feedback indicated confusion among some members.	LDC Meeting Notes
Best Practices and Information Sharing	During a MAC meeting on 12/16/2024, members emphasized the importance of updating the Equity in Access dashboard with a rolling 10-year window for better availability and transparency for the public and other OPTN Committees.	MAC Meeting Notes
Best Practices and Information Sharing	During a MAC meeting on 11/18/2024, members emphasized the importance of including the requirement for all candidates registered on or after January 4, 2024, to receive proposed education, eligibility, and outcome notifications in the public comment proposal to ensure transparency and community feedback.	MAC Meeting Notes
Best Practices and Information Sharing	During a MAC meeting on 10/16/2024, members emphasized the importance of including what constitutes a notification in the evaluation plan to ensure clarity and transparency for transplant programs.	MAC Meeting Notes
Best Practices and Information Sharing	During an Operations and Safety Committee meeting on 02/20/2025, members highlighted challenges in engagement and transparency, emphasizing the importance of involving all key personnel in pre-procurement huddles to ensure clear communication and decision-making.	Operations and Safety Committee Meeting Notes

11.3 Theme 3: Timeliness Assessment

11.3.1 Interviews Assessment

Some felt the overall policy-making process was too long. Most feedback was about the length of the overall process, a few specifically identified the amount of time to receive data and the length of public comment as two bottlenecks. Although there was a consensus the process was too long, many also mentioned that length was necessary to get through all the important steps in the process.

Interview Insights

> *"Are you out of your minds that you're going to crawl along a 10-step process that's multiple years when literally people are dying?"* — Committee member

> *"I think that if it were a more streamlined process, you might be able to get even more engagement from experts knowing that their impact has more direct, expedited effect, because I know that's been a frustration for others as well, so just one thing I would emphasize as well."* – Organ Procurement professional

> *"Science moves fast and so if you wait 18 months to implement something the field may have already changed by that time."* – Transplantation professional

Strengths

A few pointed out that there have been times when the policy process moved fast, such as during the COVID pandemic or when there was a high priority directive.

Interview Insight

> *"When it's a little more focused and HRSAs and OPTN are very interested in making things happen quickly, they do."* – Committee member

11.3.2 Desk Review Assessment

Failures and extraneous factors affect timeliness throughout the 10-step process. Submitting an idea is an unclear process in Step 1 (Idea). Although regional meetings include open mic sessions where attendees can speak directly with OPTN BOD members, there is no formal online form or clearly advertised process for public idea submissions. Moreover, there appears to be no known annual call for ideas, leaving the public uncertain about how—or even whether—they may officially submit proposals for consideration. There is no documented system or formal instructions informing OPTN stakeholders if or how they may submit new policy proposal ideas. Anyone who is not already "in the know" has no clear path to propose ideas, and it remains unclear whether any submissions go through OPTN or directly to UNOS. This lack of transparency leaves many potential contributors unaware that they can even offer suggestions. The methods for submitting an idea to OPTN are unclear. Consequently, it is unknown how (or whether) email, fax, mail, or phone submissions are formally logged, evaluated, and tracked.

No central oversight or tracking for idea submissions in Step 1 also poses a significant gap. There is no documented process for collecting, reviewing, and entering them into the system. Additionally, there is no established mechanism or oversight to ensure that every idea is logged, processed, and followed up on, which raises concerns about potential gaps in capturing stakeholder input. While a policy-related Tableau dashboard (owned by UNOS) exists, there is no known comprehensive system for logging, monitoring, and following up on new proposals. Although the PCR Department logs ideas into the "project forms" system, there is no standardized form or procedure to ensure each idea is submitted with the necessary details (such as the source of the idea, the problem it aims to solve, and potential solutions). It remains unclear who in PCR gathers this information or how consistently those requirements are met—leaving many proposals without the crucial data needed for proper evaluation.

No formal process for revisiting unprioritized policy proposals in Step 1 further complicates matters. Although the POC should periodically re-evaluate previously submitted ideas, prioritize them, and communicate any updates to the original submitters, there is no evidence that this happens. The absence of a defined schedule or clear feedback loop leaves the fate of unselected proposals in a "black box," making it unclear if they are ever reviewed again.

No standardized process for committee assignments in Step 1 adds another layer of inconsistency.

Decisions about which committee handles a given policy proposal appear to rest largely with the POC, which has the discretion to create ad hoc committees as needed. There is no consistent, documented approach for similar proposals, resulting in variability and a lack of transparency in how assignments are made. Meanwhile, the expedited variance process lacks transparency in Step 1 (also seen in Theme 2: Engagement & Transparency), given that there is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked. Additionally, there is no formal definition for "critical constituency" involvement in Step 1 (again, also seen in Theme 2: Engagement and Transparency). It remains unclear who designates a "critical constituency" for a given policy proposal and how those groups are formally brought into the process. While it appears the POC chair may play a key role in identifying these stakeholders, there is no documented procedure governing their selection or engagement.

A gap between Step 1 and Step 2 (Problem Analysis) underscores the problem of unclear transitions. The process does not clarify how an idea moves from initial submission to formal assignment within a specific committee. It is also unclear who determines which committee will sponsor and address the problem, leaving a gap in transparency and responsibility at a critical handoff. Unclear timing in Step 2 remains an issue, as there is no standard timeframe for turning an approved idea into a complete problem statement and updated project form.

Inconsistent data standards in Steps 2, 4,7, 9, and 10 is another obstacle as inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements.

Unclear roles and responsibilities in the entire 10-steps and specifically Step 2 further hinder efficient progress. It is not spelled out who does each task, when, or what level of analysis is required (e.g., literature review, formal study, etc.). This lack of clarity extends to complexities in SRTR Data Requests and Resource Allocation in Steps 2 and 4. Committee members cannot make data requests to SRTR directly; requests must go through UNOS staff or potentially involve HRSA as an intermediary. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues.

No clear process for determining required resources in Step 2 and Step 4 (Evidence Gathering) compounds these delays. It remains unclear how committees decide what resources, financial, technical, or expertise—are needed for developing and implementing a proposal. UNOS often guide methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise. This creates a risk that committees receive solutions shaped more by the UNOS' understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed.

No formal guidance on problem analysis tools and timeframes in Steps 2 and 4 highlights another gap. It remains unclear which tools or resources committees use to analyze a problem, or how members are informed of their availability. There is no documented process specifying a timeframe for completing an analysis or guidelines for documenting and reviewing the results, leaving committee members uncertain about best practices and next steps. Likewise, there are no defined measures for stakeholder Involvement in Steps 2, 4, and 6. There is no documented process for measuring how stakeholders, including donors, families, and other underrepresented groups are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. Similarly, no clear guidance on how committees formalize or execute collaboration strategies with stakeholders.

The unclear processes in Step 3 (Project Approval) also contribute to timeline failures because there is no documented process or monitoring system to ensure all reviews occur as required or to prevent projects from getting stuck in any review stage. It remains unclear who is responsible for each step or how much time is required for each review. Moreover, the HHS Secretary review is not well defined in Step 3. It is not clear which policies must be sent to the HHS Secretary for review, how that gets done, or how long it takes. It is unclear whether committees designate a policy as "mandatory" vs "non-mandatory" at this step and whether this is the step that requires mandatory policies to undergo review by the HHS Secretary.

COR Involvement in Step 3 lacks transparency as well since the contract says the COR reviews changes first, but the public OPTN documents do not mention how or when this occurs. Moving forward, there is no standard timeline in Step 4 to guide how long evidence gathering should take, and transition from Step 3 to Step 4 is not clearly defined in terms of how the committee is informed that a project is approved and can start collecting evidence. The timeframe from project approval to completion of evidence gathering is unclear. There are no guidelines for how long evidence gathering should take. The timeframe between committee vote and POC feedback in Step 4 similarly remains unclear, as it largely depends on the POC's meeting schedule and can be affected by requests for additional information or documentation. Further, defining "enough" evidence in Step 4 is an unresolved issue, given that documents do not specify how much stakeholder input or review is necessary before advancing to the next step. This leads to a highly variable timeframe for evidence gathering in Step 4: if a proposal requires minimal deliberation, the committee may proceed quickly, while more complex cases can significantly prolong this stage. Further, it is unclear if drafting the proposal is considered part of Step 4 or Step 5 (Public Comment Approval).

Staff liaisons coordinate resources and logistics in Step 4 by notifying relevant resources such as SRTR, UNOS IT, and the UNOS Research Department. Liaisons also manage schedules, set meeting agendas, and oversee workgroup progress. However, it remains unclear who, if anyone, is responsible for monitoring the liaison to ensure the project stays on track. There is a need for clarity in Step 4. The boundary between finishing evidence gathering and drafting the public comment proposal is not clearly defined.

Focusing on roles and timeframes in Step 5 reveals that it is unclear how long the POC and EC each have to complete their review. Once the POC is notified of a policy's readiness, the vote can occur at its next meeting, which varies from a few weeks to a couple of months. After the POC approves a proposal, the BOD typically considers it in the following meeting cycle. The typical timeframe for drafting and releasing public comment proposals in Step 5 is also subject to batching cycles that occur two to four times a year, making the scheduling neither fixed nor transparent.

Varying timelines in Step 6 (Public Comment) reflect the exact length of the public comment window differs and is not strictly documented, and some policy changes (e.g., emergency or expedited) skip or shorten this phase. Variable timeframes and no formal Federal Register Notice in Step 6 further highlight how OPTN relies on general announcements via email blasts, newsletters, regional meetings, and mailing list signups, rather than a standard Federal Register Notice. The public comment window itself typically lasts 45 to 60 days, though it can vary depending on interest or other factors, without a single fixed duration. This lack of formal structure can lead to concerns about time regarding how long the entire process takes (weeks or months) and Step 7 (Pending BOD Approval) similarly offers no specific guidance on analyzing public comments in a timely manner, particularly comments that criticize the OPTN policy development process.

An implementation gap in Step 8 (BOD Approval) arises when the time required for policy proposal review and approval creates a lag between approval and actual implementation, potentially affecting the timely adoption of crucial changes. Finally, the lack of standardization in Step 9 (Implementation) becomes evident because variations in committee makeup and the policies they approve result in no standardized methodology for implementation. This inconsistency, coupled with earlier gaps in process definition and data management, underscores the overall timeliness challenges plaguing the policy development cycle.

11.3.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to timeliness within the policy development cycle.

Table 15: Theme 3: Timeliness

Timeliness Sub-Theme	Evidence	Source
Delays in Communication and Implementation	Region 1 attendees raised concerns regarding the timeliness of the policy development process. Specifically, during the discussion on Continuous Distribution of Kidneys, a member expressed concern that broader sharing of organs has resulted in an increase in non-use, with allocation taking too much time, especially for medically complex kidneys. They emphasized that any additional complexity should be accompanied by efforts to increase efficiency, highlighting the need for timely and efficient policy development to address these issues. This ensures that policies are effective and responsive to the challenges faced in the allocation process.	Regional Meeting Notes
Delays in Communication and Implementation	Region 2 attendees raised concerns about the complexity of the Multi-Organ Allocation Policies proposal and how allocation staff will interpret and apply it, especially in urgent situations.	Regional Meeting Notes
Delays in Communication and Implementation	Region 4 attendees discussed delays in communication and implementation, highlighting updates on various proposals and initiatives, including the timeline for the special election and the HRSA modernization contract strategy.	Regional Meeting Notes
Delays in Communication and Implementation	Region 11 attendees expressed concerns about the untimely and uncoordinated policy development process for estimated Glomerular Filtration Rate (eGFR) monitoring requirements. These requirements were introduced separately from the policy change, causing confusion and an administrative burden on	Regional Meeting Notes

Timeliness Sub-Theme	Evidence	Source
	transplant programs as they had to adapt retroactively. Multiple members suggested that a more synchronized approach would have been beneficial. The lack of timely implementation led to difficulties, highlighting the need for better planning and execution in policy development.	
Delays in Communication and Implementation	During a MPSC meeting on 02/21/2025, members expressed concerns related to timeliness, emphasizing the importance of adding a 30-day time frame for reporting the third notification requirement to patients.	MPSC Meeting Notes
Delays in Communication and Implementation	During a MPSC meeting on 12/13/2024, members expressed concerns related to timeliness, noting the high level of effort required to follow the current process for performance enhancement zone notifications.	MPSC Meeting Notes
Delays in Communication and Implementation	During LDC meetings in the month of March 2025, members expressed concerns related to timeliness, noting the need to streamline the workflow for aborted procedures to ensure timely and accurate data collection.	LDC Meeting Notes
Delays in Communication and Implementation	During the PAC meetings in early 2025, members noted that the current policy development process often leads to delays in implementing necessary changes, emphasizing the need for a more efficient approach.	PAC Meeting Notes
Delays in Communication and Implementation	A PAC member said the issue is not the committee structure but rather that the policy development process is cumbersome and takes too long.	PAC Meeting Notes
Delays in Communication and Implementation	During an Operations and Safety Committee meeting on 02/20/2025, members expressed concerns related to timeliness, noting that the policy development process often faces delays due to the need for extensive reviews and approvals by multiple committees.	Operations and Safety Committee Meeting Notes
Long Wait Times and Complication Rates	Region 9 attendees discussed the timeline for the potential enactment of a proposal for the escalation of status for time on Left Ventricle Assist Devices (LVAD), with implementation anticipated in 2026 if approved, highlighting the lengthy process involved.	Regional Meeting Notes
Long Wait Times and Complication Rates	Region 5 attendees emphasized ongoing issues with long wait times and complication rates. They stressed	Regional Meeting Notes

Timeliness Sub-Theme	**Evidence**	**Source**
	the need for establishing consistent timeframes for unexpected events to clarify reporting requirements for transplant programs. Recommendations included policies to direct the match run for highly prioritized candidates, aiming to transform efficiency and equitable distribution. These points underscore the need for timely adjustments to policy for better patient outcomes and reduce the risks associated with long wait times and complications.	
Community Input and Delays	Region 11 attendees addressed a request for feedback on a complex multi-organ allocation proposal. Multiple opportunities for community input were noted to prevent delays, although the controversial nature of the proposal could still lead to significant delays. Additionally, attendees supported clarifying requirements for reporting unexpected disease transmissions to OPO operations.	Regional Meeting Notes
Community Input and Delays	Region 5 and 11 attendees raised concerns about the proposed 5–7-year period for escalation of status for time on LVAD, suggesting earlier escalation. Attendees also discussed modifying lung donor data collection and establishing a comprehensive multi-organ allocation policy, focusing on operational issues and tracking mechanisms.	Regional Meeting Notes
Community Input and Delays	Region 7 attendees pointed out the need for timely feedback from the community, with public comment periods of 30 and 60 days. Region 3 attendees felt that the time allocated for public comments was insufficient for thorough review and feedback on complex proposals.	Regional Meeting Notes

11.4 Theme 4: Data Availability

11.4.1 Interviews Assessment

More than half of participants thought data was inaccessible on some level. This included not being user-friendly, difficult to retrieve, understand or share. Although UNOS data is publicly accessible and HRSA has its own data request portal, obtaining these documents can be challenging and may involve a fee.

Interview Insight

> *"You know I see it, but they're not allowed to release it, or they're not allowed they get told they can't post it or HRSA blocks that process. And I don't understand it when it's there."* – Committee member

Some felt there was a lack of robust data, including data requested being limited or not available.

Interview Insight

> *"Every time we asked like, hey, we need more specific information about demographics or about specific conditions, it was always no, that's a data burden."* – Former Committee member

Strengths

Some felt OPTN data was available and accessible.

Interview Insight

> *"And by the time the POC sees these policies, we typically, if not always, nearly always have whatever data we might need to consider that policy."* – POC member

11.4.2 Desk Review Assessment

Failures identified within data availability include lack of long-term data in Step 1 (Idea), where long-term data such as complications, survival, quality of life, and post-transplant healthcare utilization are often lacking. Another concern is no formal guidance on problem analysis tools and timeframes in Step 2 (Problem Analysis). It remains unclear which tools or resources committees use to analyze a problem, or how members are informed of their availability. There is no documented process specifying a timeframe for completing an analysis or guidelines for documenting and reviewing the results, leaving committee members uncertain about best practices and next steps.

A further gap is no defined measures for stakeholder involvement in Step 2. There is no documented process for measuring how stakeholders, including donors, families, and other underrepresented groups, are included in Step 2. Because there is no formal metric for stakeholder engagement during this phase, it is not possible to determine whether the process includes all relevant viewpoints. No clear guidance exists on how committees formalize or execute collaboration strategies with stakeholders. Meanwhile, inconsistent data standards in Step 2 add additional obstacles. An inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's regulatory requirements.

Complexities in SRTR Data Requests and Resource Allocation in Step 2 represent another difficulty. Committee members cannot make data requests to SRTR directly; requests must go through UNOS staff or potentially involve HRSA as an intermediary. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues.

There is no clear process for determining required resources in Step 2 and Step 4 (Evidence Gathering) either. It remains unclear how committees decide what resources, financial, technical, or expertise—are needed for developing and implementing a proposal. UNOS often guide methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise. This creates a risk that committees receive solutions shaped more by UNOS' understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed.

No clearly defined responsibility for data collation in Steps 2, 4 and Step 6 (Public Comment) also emerges as a shortfall. Although meeting minutes capture the discussion points and issues raised, it remains unclear who specifically compiles and organizes the data once it is collected. There appears to be no formal process to determine who consolidates these findings into a cohesive format, leaving ambiguity around how data is integrated and documented. Similarly, no standardized threshold for completing analysis in Steps 2 and 4 exists. It appears committees decide that analysis is "adequate" once all their questions are addressed, and any feedback—whether from formal surveys or informal discussions—is sufficiently documented. However, there is no clear, standardized criterion for determining when this point is reached. Committees typically create a slide deck or report to present their findings, but the ultimate decision to move forward hinges on whether the committee deems its write-up thorough rather than following a formal procedural benchmark.

Inconsistent data standards in the entire 10-Step process reappear as an overarching problem. An inconsistency in data standards across transplant centers, OPOs, and other stakeholders leads to challenges. Varying formats for data collection and storage make it difficult to aggregate and analyze information effectively. The observed variation in coding practices across transplant centers indicates a general lack of understanding of OPTN's policy requirements. Quality standards in Step 5 (Public Comment Approval) also remain unclear. No official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement.

Moving on to no clear monitoring or responsibility for public notifications in Step 6 (Public Comment), it remains unclear how or whether social media channels are used for announcements, and there appears to be no formal process to verify that notifications reach all stakeholders or to confirm that the step has been completed. Since there are public comment summaries but no strict threshold for action in Step 6, this reflects a situation in which UNOS and OPTN compiles a response document summarizing public feedback, yet it is unclear whether the BOD or POC routinely reviews this final report. Moreover, there is no formal metric to mandate changes when public concerns are strong; proposals can still advance despite substantial opposition.

An additional complication involves unclear fiscal impact workgroup roles and responsibilities in Step 6. While a fiscal workgroup is reportedly formed to determine whether proposals meet budgetary requirements, it remains unclear who is assigned to this workgroup, whether the same individuals participate across multiple projects, and how the selection process is decided. There is no documented method indicating who makes these choices or how consistency is maintained from one project to the next. Fiscal assessments appear to depend largely on staff consultation with the finance department, chief financial officer (CFO), and relevant teams (e.g., IT or communications) rather than a structured or standing "fiscal workgroup." Membership can rotate based on the proposal's needs, but there is no documented, measurable set of criteria for determining a project's fiscal impact, leaving it unclear how cost estimates are consistently calculated or approved. Although the Finance Committee is presumed to be involved in evaluating a proposal's cost impacts, it remains unknown how the workgroup is formed, which members are selected, or what specific financial metrics are used.

Unknown metrics to measure public concern and critical comments in Step 7 (Pending BOD Approval) also pose a problem. There is no formal or consistent methodology to quantify or evaluate how public feedback influences final policy decisions, leaving it unclear how—or if—the comments meaningfully impact the outcome. The UNOS team's analysis of data from public comments is not made publicly available. Unspecified "Approved" or "Rejected" proposed policy metrics in Step 8 (BOD Approval) indicate that the exact metrics used to either approve or reject a proposed policy are unclear.

Turning to limited resources in Step 9 (Implementation) and Step 10 (Post-Implementation Review), some OPTN transplant centers, smaller transplant centers, and community-based organizations may lack the funding, staff, or time needed to fully comply with a new policy proposal. Smaller transplant centers or community-based organizations with fewer resources may face challenges in effectively participating in the review process or struggle to implement suggested changes, leading to unequal implementation across the system. Ongoing monitoring of policy proposal rollout in Step 9 is another weak point, as it remains unclear how the implementation process is monitored, making it harder to detect issues that may hinder the successful rollout of a policy. Lastly, insufficient long-term data in Step 10 completes the picture. Some policies may require more time to fully assess their long-term impact, and post-implementation reviews may not always account for the full range of effects over time. The UNet system is closed, so it is difficult to understand the methods of analysis being conducted, and qualitative data is often overlooked in favor of quantitative data.

11.4.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to data availability within the policy development cycle. These observations reflect the challenges in data availability and data accuracy within the policy development cycle.

Table 16: Theme 4: Data Availability

Data Availability Sub-Theme	Evidence	Source
HRSA Directives	Attendees in Region 3 discussed the importance of HRSA's directives for OPTN to collect data on patients before they are added to the waitlist and on ventilated patients prior to referral to an OPO. They emphasized that this data is crucial for understanding the total disease burden and potential donor numbers.	Regional Meeting Notes
HRSA Directives	Attendees in Region 5 stressed the need for clear, uniform processes across OPOs and transplant centers to promote consistency, fairness, and transforming health outcomes.	Regional Meeting Notes
Challenges in Data Reporting	Attendees in Regions 1, 3, and 8 expressed concerns about the potential confusion in data reporting due to patients being listed at multiple centers. This issue was expressed as a significant barrier to accurate data collection.	Regional Meeting Notes
Challenges in Data Reporting	Attendees in Region 3 expressed concerns regarding unclear data definitions and ambiguity regarding whether the new diagnostic test status applies to all or only required tests, whether fields can be modified after disposition closure, and whether reasons for incomplete tests (e.g., hospital capability) will be included. They also noted that the absence of an automatic notification system means OPOs must manually alert transplant centers about test results, which does not help efficiency.	Regional Meeting Notes
Challenges in Data Reporting	In Region 6, attendees raised concerns about the increased data reporting burden for OPOs, particularly with the new lung donor data collection requirements.	Regional Meeting Notes
Challenges in Data Reporting	During a MPSC meeting on 02/06/2025, members expressed concerns related to data availability, noting the two-year lag in CDC Multiple Cause of Death data for potential donors and the limitations in variables available for risk adjustment.	MPSC Meeting Notes
Challenges in Data Reporting	During a MPSC meeting on 12/13/2024, members discussed the limitations of the current data, suggesting alternatives such as using newer data or CSM reports to determine which programs may need resources.	MPSC Meeting Notes
Challenges in Data Reporting	During a MAC meeting on 11/18/2024, members discussed the need to retrospectively notify candidates of their eGFR modification eligibility and/or outcome,	MAC Meeting Notes

Data Availability Sub-Theme	**Evidence**	**Source**
	noting that this requirement could be burdensome for programs and confusing from a compliance perspective.	
Challenges in Data Reporting	During a MAC meeting on 10/16/2024, members discussed the need for transplant programs to have a documented process for confirming candidate race and seeking supporting documentation, highlighting the importance of clear and accessible data collection protocols.	MAC Meeting Notes
Challenges in Data Reporting	During an Operations and Safety Committee meeting on 02/27/2025, members discussed issues with the availability of donor data collection and multi-organ allocation data availability, emphasizing that incomplete or outdated data can hinder effective policy formulation.	Operations and Safety Committee Meeting Notes
Complexity of Data Collection	Attendees in multiple regions, including Regions 1, 3, and 6, raised concerns about the complexity of data collection. They emphasized the need for standardized data elements to reduce the burden on coordinators and accuracy. Additionally, attendees in Region 1 emphasized the need for standardized terminology, such as using "cannabis" instead of "marijuana," to streamline data collection and reporting. Attendees in Region 6 expressed the need for specificity in data requests to avoid confusion and ensure accuracy as well as the need for more granular and data-driven approaches to policy adjustments.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 10 also emphasized the need for clear definitions and reporting requirements for lung transplant recipients, implying that there may be gaps or inconsistencies in the available data.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 11 highlighted the need for standardized practices and clearer priorities, questioning the allocation sequence for liver-intestine-pancreas patients and suggested calling out these combinations separately, indicating a need for more detailed data.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 1 and Region 6 noted that implementing new data fields requires modifications to existing systems, adding cost, time, and programming effort. This is crucial to avoid the burden of documenting information in multiple places during the transition period. Attendees in Region 6 raised concerns about the need for standardized data elements to reduce back-and-forth communication.	Regional Meeting Notes

Data Availability Sub-Theme	Evidence	Source
Complexity of Data Collection	Attendees in Region 2 also stated that modifying donor data collection may add an operational burden to the OPO community, which must be balanced against the benefits of better communication. Region 6 attendees emphasized the need for clearer guidance and definitions for reporting requirements to ensure accurate and efficient data collection.	Regional Meeting Notes
Complexity of Data Collection	An attendee in Region 8 pointed out that the efficacy of the Multi-Organ Allocation Policy would depend on whether recipient centers are using the same metrics, as comparisons cannot be made if they are not. Region 6 attendees added that the complexity of multi-organ allocation policies was a significant concern, with attendees pointing out the increased donor case times and the potential for errors due to the need to switch between multiple match runs.	Regional Meeting Notes
Complexity of Data Collection	Region 7 and Region 8 attendees both noted the importance of recipient centers using the same metrics for comparison and the potential for human error in using mathematical equations.	Regional Meeting Notes
Complexity of Data Collection	Attendees in Region 11 expressed concern about donor families being unaware of the donor's tobacco and marijuana use, emphasizing the need for better data collection and communication.	Regional Meeting Notes
Complexity of Data Collection	During LDC meetings in the month of March 2025, members discussed the limitations of the current data collection process, suggesting enhancements to better align with the definition of a living donor and ensure accurate reporting.	LDC Meeting Notes
Complexity of Data Collection	During LDC meetings in early 2025, members discussed the limitations of the current data collection process, suggesting enhancements to better capture barriers at the first in-person appointment.	LDC Meeting Notes
Complexity of Data Collection	During the LDC meeting on 02/20/2025, members discussed the need for more granular data on alcohol consumption, particularly for liver donors, to ensure accurate and relevant data collection.	LDC Meeting Notes
Complexity of Data Collection	During a MAC meeting on 12/16/2024, members discussed the need for alternative graphs on the Equity in Access dashboard to better reflect variability in access to transplantation by race/ethnicity, ensuring the data is more accessible and useful.	MAC Meeting Notes

Data Availability Sub-Theme	Evidence	Source
Complexity of Data Collection	During a MAC meeting on 12/16/2024, members highlighted the limitations of using data over 10 years old, suggesting that a more recent data cohort would better align with current data collection practices.	MAC Meeting Notes
Collaboration and Support	Attendees in Regions 4 and 10 highlighted the need for support and collaboration among community hospitals, OPOs, and other entities. They emphasized that this collaboration is necessary to ensure accurate and comprehensive data collection.	Regional Meeting Notes
Collaboration and Support	Region 3 attendees expressed that a plan to monitor transplant centers' use of the additional data elements is necessary. This requires ongoing collaboration and support from oversight bodies, data analysts, and transplant centers to ensure the data is used effectively and contributes to better decision-making.	Regional Meeting Notes
Collaboration and Support	Region 6 attendees suggested having the ensuing IT solution part of the Multi-Organ Transplantation (MOT) Committee proposal to be able to integrate with DonorNet and to be as interactive as possible for ease of usability for the OPOs.	Regional Meeting Notes
Collaboration and Support	Region 10 attendees pointed out that the Uniform Donor Risk Assessment Interview (uDRAI) does not always capture granular information, reinforcing the need for better data integration and collaboration to ensure comprehensive data availability. System changes would also require collaboration with other organizations to ensure seamless integration and reduce redundancy. Region 10 attendees also commented on the need for OPTN to collaborate with entities like AOPO and the American Association of Tissue Banks (AATB) regarding data collection tools to align lung donor data collection requirements.	Regional Meeting Notes
Collaboration and Support	Attendees in multiple regions, including Regions 1, 3, 6, and 8 suggested using AI chatbots to support waitlisted candidates and personalized decision-making in the organ offer process.	Regional Meeting Notes
Collaboration and Support	Presenter of Region 2 shared that to get data collected within the OPTN, you have to go through the Office of Management and Budget (OMB).	Regional Meeting Notes
Proposals for Data Collection Enhancements	Attendees in Regions 5, 6, and 9 discussed various challenges in data collection, such as modifying donor testing collection data, establishing consistent and	Regional Meeting Notes

Data Availability Sub-Theme	Evidence	Source
	granular data points, and streamlining communication between OPOs and transplant programs.	
Proposals for Data Collection Enhancements	An attendee in Region 5 also suggested defining "hard-to-place kidneys" and creating an algorithm to predict which kidneys will be hard to place. They also recommended developing a protocol for the placement of these kidneys to manage increased costs and geographic distribution challenges.	Regional Meeting Notes
Proposals for Data Collection Enhancements	An attendee in Region 8 suggested including patients' lived experiences in data collection (e.g., struggles, mental health, quality of life).	Regional Meeting Notes
Proposals for Data Collection Enhancements	During the PAC meetings in early 2025, members highlighted the need for more comprehensive and accessible data to inform policy decisions, stressing the importance of having accurate and timely information.	PAC Meeting Notes
Proposals for Data Collection Enhancements	A PAC member recommended that Committee members focus on providing the patient perspective regarding collecting data on patients.	PAC Meeting Notes

11.5 Theme 5: Prioritization Methodology

11.5.1 Interviews Assessment

More than half of participants felt there was inefficient prioritization of policies developed in the process. A few thought that unclear goals and priorities were the key challenges in the overall process. A few felt that there were unclear goals or strategic direction, a few others that the strategic direction is too reactive to events such as public comment or news articles, and a few others that there is a conflict of interest in what gets prioritized. Additionally, some expressed a lack of strong oversight of strategic direction.

Interview Insights

> *"I found the strategic plan was all encompassing in that if anybody had a loud enough voice or sharp enough explanation, anything could fall under the strategic plan."* – Transplant professional

> *"We're running top down with a tiny coterie of people at HRSA who overreact to every critical comment we receive...then it's all hands-on deck and all projects stop."* – Committee member

> *"I think we need to have a little bit of a tighter guardrail on that process. Let's come together earlier on and say, it's not really, the question is not really whatever you want to do to support the plan. Here's the plan. Here's what we really need you to do."* – Committee member

> *"In my experience, and I've been on a couple different committees, it's sort of, it's an ad hoc process which is facilitated by the contractor to some degree, but when you take an idea of conception to generate it into a policy, it happens organically, but I'm not sure the rules are super well codified."* – Committee member

Strengths

Some felt policies were prioritized correctly based on their overall importance.

Interview Insight

> *"I think the committees do a great job with the tasks they are given, you know, in meeting monthly and, you know, we do try to prioritize as we go along, you know, like, okay, is this idea, should we work on this first before we go on to, you know, anything else? And that's the way that, you know, we do it. So, I think that part works pretty well."* – Committee member

11.5.2 Desk Review Assessment

Failures identified with Prioritization begin with the significant decision-making power held by a small group within the OPTN in Step 1 (Idea). Because the EC and the POC can determine which proposals move forward without a full BOD review, a relatively small group exerts substantial influence over policy prioritizations. There is no formal process for revisiting unprioritized policy proposals in Step 1 either, as the POC should periodically re-evaluate previously submitted ideas, prioritize them, and communicate any updates to the original submitters, yet there is no evidence that this happens. The absence of a defined schedule or clear feedback loop leaves the fate of unselected proposals in a "black box," making it unclear if they are ever reviewed again. Adding to these concerns, the expedited variance process lacks transparency in Step 1. There is an expedited pathway for variance proposals that bypasses the usual public comment step and goes directly to a committee for review. It remains unclear whether all approved variances are publicly documented, creating ambiguity in how these proposals are tracked.

A lack of ideas from diverse sources in Step 1 further complicates matters. Ideally, there should be a variability of people involved in proposing ideas. However, this can be difficult for people who do not have a formal medical education. Since providers dominate in representation on the BOD, committees, and participation in conferences, they will submit more ideas than patients or donors. Some OPTN members have asked for more perspectives from people who are not typically involved or who represent overlooked problems. POC meeting notes show that proposals—especially in the early “idea” phase—need more diverse viewpoints and “recommended more patient feedback and involvement.” Meanwhile, committees such as the Membership and Professional Standards Committee (MPSC) focus on transplant success metrics and do not measure how well they engage the public or share information openly. The OPTN has no set process or metric to ensure that donors, families, or other underrepresented groups have a voice early on. Without official guidelines or measures of engagement, it’s hard to know if the process is truly transparent or successfully inviting all relevant perspectives. Providers—such as doctors, investigators, and transplant professionals—have a strong presence in the OPTN’s policy development process. The OPTN Final Rule requires that half of the BOD be transplant surgeons or physicians, with another quarter made up of other provider groups like OPOs, transplant facilities, and laboratories. Most committees also contain a large number of medical professionals—for instance, 15 out of 18 people on the Histocompatibility Laboratory Committee are from laboratories. Since providers dominate in representation on the BOD, committees, and conference participation, they submit more ideas than patients or donors. However, this can leave out voices from smaller or rural centers and other groups, meaning those perspectives may not be heard. In addition, some providers say current policies favor patients with more resources, while people with lower incomes or less support struggle to navigate the organ procurement and transplant system. Critics warn that focusing on well-off patients could worsen inequities in who receives a transplant. Provider-heavy committees can influence which projects the POC approves, given their technical expertise and alignment with OPTN’s clinical goals.

Lastly, there is an unclear evaluation of needs and gap identification in Step 1. There does not appear to be a mechanism in place for ongoing evaluation of needs and gap identification that leads OPTN to investigate ways to fix issues.

UNOS often guides methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise.

Complexities in SRTR data requests and resource allocation in Step 2 (Problem Analysis) and throughout the 10-Step process arise because committee members cannot make data requests to SRTR directly; HHS/DoT holds the SRTR contract and approves data requests as they come through. Additionally, concerns persist about the slow progress in organ modeling (e.g., continuous distribution) and the broader control of data—what is collected, which questions are asked, and how analyses are conducted—potentially contributing to policy stagnation and limiting timely correction of past policy issues. This ties into no clear process for determining required resources in Step 2, as it remains unclear how committees decide what resources—financial, technical, or expertise—are needed for developing and implementing a proposal. **UNOS often guides methodologies and options, but their interpretations may not align with committee priorities, and many lack consistent medical or public health expertise.** This creates a risk that committees receive solutions shaped more by UNOS’ understanding of resource availability than by the actual clinical or operational needs. Additionally, committee liaisons without medical or public health backgrounds may inadvertently misinterpret complex issues and fail to accurately convey the committee's requirements. Although SRTR has a predefined support capacity outlined in its task order, it remains unclear whether this capacity has ever been exceeded or how such constraints are managed. Balancing clinical focus with patient/family perspectives in Step 2 is also challenging. Providers often approach problems from a medical or operational standpoint, which can lead to the unintentional neglect of patient and family perspectives. To develop effective solutions, it is essential to include diverse viewpoints and gather feedback from all relevant stakeholders when examining issues and formulating solutions. The data used to develop project proposals may vary in consistency across transplant centers or OPOs, and geographic disparities in reporting quality, as well as differences in how data is collected and reported, can lead to gaps in the comprehensive data necessary to support proposals.

A shift in project origination and POC control in Step 3 (Project Approval) describes how policy ideas previously bubbled up from permanent committees to the POC for initial approval, whereas around 2020–2021, the process reversed, with the POC now identifying roughly 80% of new projects and then assigning them to committees for development.

The POC meets monthly to review project status and ultimately allows the final approval before proposals advance to the BOD for a final decision, indicating a significant increase in POC oversight and control. Because the POC spans multiple committees, its discussions are broader than the committee-specific focuses—for example, an OPO committee discussion is largely confined to operational issues, whereas the POC reviews cross-cutting topics monthly and allows final approval before proposals move on to the BOD. Unclear Cost Evaluation and Resource audits in Step 3 persist, as there is no clear criterion within the POC's review process for determining acceptable costs or the appropriate level of resource allocation. Additionally, no audits or reconciliations appear to be in place to confirm whether initial cost or resource estimates accurately reflect real expenditures, leaving significant uncertainty about fiscal oversight and accountability. A project's budget is jointly estimated by the working committee and the POC, with committee liaisons providing guidance on available IT hours and total allocated funds. Even if a committee has budget left, UNOS IT resources might already be at capacity, meaning projects requiring significant development or reprogramming may be deferred. This illustrates how both financial and bandwidth factors influence which projects can move forward.

No defined authority for assigning strategic goals in Step 3 creates further ambiguity, as it remains unclear who officially assigns a primary strategic goal to each project. Neither the POC, BOD, nor the EC appears to have a documented process or explicit authority for determining this key designation. Moreover, no documented criteria for evaluating proposed projects in Step 3 exists; there are no formal metrics for assessing whether a project meets essential requirements such as alignment with the Strategic Plan, consistency with OPTN policy priorities, or sequencing among committees. Nor are there guidelines for evaluating outcomes, risks, technical resource needs, costs, or overall benefits. Without such standards, it's unclear how proposals are judged before moving forward. No clear criteria or early visibility for key review factors in Step 3 adds to the problem. While projects are expected to consider alignment with the OPTN Strategic Plan, NOTA and the OPTN Final Rule, resource requirements, and potential risks, there is no transparent process for documenting or assessing these factors. Cost estimates, for instance, are reportedly stored in an internal management system and may not be visible to HRSA until later in the policy development process, after UNOS and the sponsoring committee have conducted analysis. This lack of early insight limits the ability to measure intended effects, identify key metrics, and evaluate trade-offs in a timely manner. Historically, there was possibly a scoring document or framework applied to policies for consistent assessment, but it is unclear whether the same tool remains in use or if the POC currently employs a different method.

Moving to evidence gathering, defining “enough” evidence in Step 4 (Evidence Gathering) is problematic, as documents do not specify how much stakeholder input or investigation is required before moving on to the next step. No standardized threshold for completing analysis in Step 4 compounds this issue, given that committees decide analysis is “adequate” once all their questions are addressed and any feedback is sufficiently documented. There is no clear, standardized criterion for determining when this point is reached, so the ultimate decision to move forward hinges on whether the committee deems its write-up thorough. Meanwhile, the NOTA/Final Rule Checklist used “behind the scenes” in Step 4 indicates that proposals move forward if no concerns are raised about compliance with its requirements, yet this checklist does not define the steps for that analysis. UNOS process documents mention using a spreadsheet to document situations where authority or applicability of requirements may be unclear or subject to differing interpretations, but the process documents fail to indicate when and by whom this spreadsheet is implemented.

Quality standards in Step 5 (Public Comment Approval) remain insufficient, as no official criteria exist for deciding if a proposed solution meets stakeholder requirements or is closely tied to the original problem statement. Later in the policy cycle, public comment summaries but no strict threshold for action in Step 6 (Public Comment) become relevant because UNOS/OPTN compiles a response document summarizing public feedback, yet it remains unclear whether the BOD or POC routinely reviews this final report or if a formal metric mandates changes when concerns are strong. Proposals can still advance despite substantial opposition. The fiscal impact workgroup in Step 6 is another area of uncertainty, as it remains unclear who is assigned to this workgroup, whether the same individuals participate across multiple projects, and how the selection process is decided. Fiscal assessments appear to rely heavily on staff consultation with the finance department, CFO, IT, or communications, rather than on a structured or standing “fiscal workgroup.” Although the Finance Committee presumably evaluates a proposal’s cost impacts, the workgroup’s membership, selection criteria, and specific financial metrics used remain unknown.

Shifting to public comment outcomes, clinical perspectives vs. patient voices in Step 7 (Pending BOD Approval) highlight an imbalance where medical professionals may exert greater influence than donors, families, or advocacy groups, potentially prioritizing clinical viewpoints over firsthand experiences. Potential bias in donor, family, advocacy, and small organization representation emerges, while unknown metrics to measure public concern and critical comments in Step 7 result from having no formal or consistent methodology to quantify the impact of public feedback on final policy decisions. The UNOS team’s analysis of data from public comments is not made publicly available. Adding to this, there is no formal process for incorporating public comment concerns pre-BOD approval in Step 7, leaving it unclear how—or if—feedback is systematically addressed before proposals reach the BOD, and influence of larger organizations in Step 7 continues to pose a risk to balanced input. Committee-based review lacks formal evaluation criteria in Step 7 means decisions hinge largely on stakeholder support or opposition, without a measurable set of criteria, and there is a lack of transparency in logging and reviewing all comments in Step 7 because no clear mechanism guarantees every public comment is entered into a centralized system or reviewed. The unclear comment review and tracking process in Step 7 allows potentially violative comments to go unaddressed, and HRSA's role remains undefined.

Unspecified "Approved" or "Rejected" proposed policy metrics in Step 8 (BOD Approval) then follow, as the exact metrics for final decisions are unclear, and the implementation gap in Step 8 shows that review and approval lags can affect the timely adoption of critical policy changes. Limited resources in Step 9 (Implementation) and Step 10 (Post-Implementation Review) come into play because some OPTN transplant centers, especially smaller ones or those in community settings, may lack the resources (funding, staff, time) to comply with new policies, creating unequal implementation across the system. Resource constraints for smaller transplant organizations in Step 10 expand on this disparity, with challenges in both the review process and policy implementation due to limited capacity. Finally, insufficient long-term data in Step 10 highlights that some policies require more time to assess their true impact, yet post-implementation reviews may not always capture the full range of effects. The UNet system is closed, making it hard to understand how analyses are conducted, and qualitative data is often overlooked in favor of quantitative data.

11.5.3 Meetings Assessment

During the OPTN Winter 2025 Regional Meetings, attendees identified several challenges related to prioritization methodology within the policy development cycle.

Table 17: Theme 5: Prioritization Methodology

Prioritization Methodology Sub-Theme	**Evidence**	**Source**
Standardization of Allocation Policies	There is currently no OPTN policy instructing OPOs on multi-organ donor allocation. OPOs have differing allocation practices and laborious efforts to create allocation plans. The MOT Committee proposed a new policy to standardize the allocation order and balance the needs of single and multi-organ candidates. The proposal includes multi-allocation tables to standardize the order in which OPOs allocate organs across match runs, ensuring a more equitable and efficient allocation process.	Regional Meeting Notes
Standardization of Allocation Policies	Attendees in almost all of the regions agreed on the multi-organ allocations for liver/kidney and heart/kidney be prioritized based on the highest risk of death on the waiting list to ensure that the most critical patients receive timely transplants.	Regional Meeting Notes
Standardization of Allocation Policies	Region 1 and 8 attendees noted that the multi-organ allocation policies for liver/kidney and heart/kidney are	Regional Meeting Notes

Prioritization Methodology Sub-Theme	**Evidence**	**Source**
	cumbersome, and the requirement for lung chest X-rays from donor patients is not feasible for smaller donor hospitals. They also pointed out the need for clear and transparent prioritization frameworks to ensure fair and efficient organ allocation processes.	
Standardization of Allocation Policies	Region 2 attendee suggested adopting a flexible policy for the development of policies by all committees. The flexible policy will replace the "Policy Development Wheel" which has been unnecessarily time-consuming.	Regional Meeting Notes
Fairness in Allocation	Region 2, 4, 5, and 10 attendees expressed concerns about fairness of organ allocation, particularly for pediatric and highly sensitized candidates who face challenges in receiving high-quality kidneys. They usually receive the lowest offers and should be prioritized higher in the allocation tables.	Regional Meeting Notes
Fairness in Allocation	Region 6 attendees raised concerns on prioritization between pediatric kidney candidates and kidney-pancreas recipients, and the need for additional guidance to address operational challenges.	Regional Meeting Notes
Fairness in Allocation	Region 6 and 9 attendees raised concerns on the complexity and impact of the multi-organ allocation policies on different regions. They emphasized the importance of considering post-transplant survival and patient survival on the waiting list.	Regional Meeting Notes
Fairness in Allocation	During a MAC meeting on 11/18/2024, members highlighted the importance of assessing every kidney transplant candidate for eligibility regardless of waiting time criteria or waiting list status, including those registered for MOT, to ensure fair and consistent prioritization.	MAC Meeting Notes
Fairness in Allocation	During a MAC meeting on 10/16/2024, members highlighted the need to assess MOT candidates for eGFR waiting time modifications, emphasizing the importance of fair and consistent prioritization for all candidates.	MAC Meeting Notes
Operational Challenges and Efficiency	Region 1, 3, and 8 attendees suggested allocating organs closer to donor hospitals to reduce cold ischemic time and to assist transplant outcomes and efficiency.	Regional Meeting Notes
Operational Challenges and Efficiency	Region 9 attendee mentioned the difficulty in implementing policies operationally, especially for smaller programs that may struggle with regulatory	Regional Meeting Notes

Prioritization Methodology Sub-Theme	**Evidence**	**Source**
	burdens compared to larger centers with more resources.	
Operational Challenges and Efficiency	The Modify Lung Donor Data Collection Project of the Lung Committee was prioritized because the OPTN BOD recently approved a policy to promote efficiency in lung donor allocation, and the committee saw an opportunity to enhance this goal with data collection.	Regional Meeting Notes
Operational Challenges and Efficiency	During a LDC meeting on 03/12/2025, members expressed concerns about the variation in evaluation processes among programs, suggesting that a standardized approach could help prioritize and address barriers more effectively.	LDC Meeting Notes
Operational Challenges and Efficiency	During the LDC meeting on 02/26/2025, members discussed the balance of considerations for the start point of data collection, emphasizing the need to prioritize the most effective and least burdensome approach for transplant programs.	LDC Meeting Notes
Operational Challenges and Efficiency	During an Operations and Safety Committee meeting on 02/20/2025, members emphasized the need for clear prioritization of tasks and responsibilities within the NRP guidance document, particularly in terms of pre-operative and intra-operative communication standards.	Operations and Safety Committee Meeting Notes
Community Involvement and Feedback	Region 3 and 4 attendees highlighted the importance of assessing whether policies achieve their intended goals and involving the community in discussing policy outcomes and in identifying groups who might have been impacted as bystanders.	Regional Meeting Notes
Community Involvement and Feedback	Region 3 and 4 attendees raised concerns about the allocation of resources to different policy initiatives, highlighting the need for a balanced approach that addresses both urgent and long-term needs. Attendees also emphasized the importance of clear criteria and processes for how policies are prioritized, ensuring that stakeholders understand the decision-making process.	Regional Meeting Notes
Community Involvement and Feedback	Region 10 Presenter highlighted the MPSC’s efforts to prioritize and address issues early and ensure the best interest of the transplant community and the committee’s goal to help rather than be punitive.	Regional Meeting Notes
Community Involvement and Feedback	During the PAC meetings in early 2025, members discussed the complexity of multi-organ allocation and	PAC Meeting Notes

Prioritization Methodology Sub-Theme	Evidence	Source
	the need for clear prioritization methodologies to ensure fair and equitable access to transplants.	
Predictive Models and Data Utilization	During a MPSC meeting on 02/06/2025, members discussed the need for a reliable predictive model to account for the lag in data, emphasizing that the current model has a broad confidence interval and may not be suitable for evaluating individual OPO performance.	MPSC Meeting Notes

12 Appendix F: Stakeholder Interview Participants

External: Patients, Families, and Caregivers/Community

- ORGANIZE
- Transplant Families
- American Association of Kidney Patients
- National Multicultural Action Group

External: Providers

- Donor Network of Arizona
- Children's Mercy Hospital
- American Society of Transplantation
- AOPO

Internal: Governance

- OPTN
    - POC
    - PAC
    - MAC
    - DAC
    - Operations and Safety Committee

Regulatory

- HRSA SMEs

13 Appendix G: Regional Meeting Summaries

13.1 Regional Meeting Summaries

Each regional meeting focuses on key issues central to the OPTN policy development process. Committee/BOD Composition & Size examines the makeup of governing bodies, emphasizing balanced representation and diverse perspectives. Engagement covers efforts to involve stakeholders, such as patients, donor families, and transplant professionals, in shaping policies and ensuring transparency. Timeliness addresses how quickly and effectively policies are implemented or updated, while Data Availability looks at the collection, sharing, and use of data to inform policy decisions. Prioritization Methodology reviews the frameworks used to determine which transplant recipients or processes should receive attention first, aiming for fairness and efficiency. Finally, Additional Information (Pain Points/Recommendations) provides space for participants to highlight persistent challenges and propose new ideas for strengthening the organ procurement and transplantation community.

Collectively, these topics guide regional discussions, helping to identify areas where OPTN policies can better serve patients and donors nationwide. By focusing on representation, transparency, data-driven decision-making, and ongoing community feedback, each region contributes to the overall mission of ensuring equitable and effective organ procurement and transplantation practices.

13.1.1 Region: 1

Date: March 11th, 2025

1. Committee/BOD Composition & Size

- Martha Pavlakis, M.D., and Christopher Curran, CPTC, CTBS, CTOP, serve as Councillor and Associate Councillor respectively.
- The importance of regional representation and OPO representation on the BOD was discussed by Martha Pavlakis, M.D., and Raymond Lynch, M.D., representative from HRSA's Division of Transplantation. Ensuring diverse perspectives in policy development was emphasized.
- The PAC is well-represented with various recipients and family caregivers. John Sperzel, member of the PAC, and a 2017 heart transplant recipient, shared his personal story and commitment to the PAC.
- The Transitional Nominating Committee will select new members for the OPTN BOD through a special election in Spring 2025. Anyone who is interested in serving on the BOD can self-nominate and the criteria is posted on the website.
- There is a consensus that a larger BOD provides greater safeguards in policy development.
- The discussion emphasized the need for more voices and perspectives in the decision-making process, particularly for out-of-sequence organ allocation.
- It was highlighted that the donor family perspective is crucial and needs more representation on both committees and the BOD. This ensures that policies consider the experiences and needs of donor families, which can lead to more compassionate and effective organ allocation practices.

2. Engagement

- The BOD approved bylaw revisions to ensure independence from OPTN contractors. Despite new conflict of interest policies, concerns about transparency regarding OPTN leaders' activities remain.

- Ensuring more patient voices are heard by the BOD and committees is crucial. Ginny McBride, ED of OurLegacy Florida, the OPO in east central Florida, expressed concerns about decision-making transparency and the need for more comprehensive updates for patient donors and family members.
- Grassroots communication to engage patient and family partners could involve hosting information sessions at local OPOs and transplant support groups. This approach aims to foster better engagement and communication within the community.
- The importance of regular engagement with patient donors and family members was emphasized to ensure their voices are heard and their perspectives are considered in policy development.

3. Timeliness

- No specific points discussed.

4. Data Availability

- HRSA issued directives for OPTN to collect data on patients before they are added to the waitlist and on ventilated patients prior to referral to an OPO. Richard Formica, M.D., highlighted the importance of these directives in understanding the total disease burden and potential donor numbers.
- The importance of accurate and usable data collection was emphasized to ensure effective policy development and decision-making.

5. Prioritization Methodology

- Multi-organ allocations for liver/kidney and heart/kidney should be prioritized based on the highest risk of death on the waiting list. This approach aims to ensure that the most critical patients receive timely transplants.
- Reducing cold ischemic time by allocating organs closer to donor hospitals was suggested to better transplant outcomes and efficiency.
- The complexity of MOT policies was discussed, with concerns about the feasibility of certain requirements for smaller donor hospitals. The need for streamlined and efficient policies was emphasized.
- The importance of clear and transparent prioritization frameworks was highlighted to ensure fair and efficient organ allocation processes.

6. Additional Information (Challenges/Recommendations)

- The importance of evaluating whether policies achieved their intended goals and involving the community in discussions was emphasized. This approach aims to identify and address any unintended impacts on bystander groups.

- Concerns about the Conflict of Interests and the 10-year disqualification period were raised by Alexandra Glazier, President and CEO of New England Donor Services (NEDS), one of the largest OPOs in the United States. The need for transparency and clarity in these policies was discussed.
- Glazier also verified with Dr. Lynch, if there's any truth that anyone who has raised concerns about any aspect of the OPTN process will be viewed as not supporting the Modernization Act and wants reassurance that the First Amendment right to voice concerns will not negatively impact individuals being considered for nomination on the BOD. Dr. Lynch responded that whoever voiced that opinion is misinformed.
- The need for more pediatric representation on the BOD was highlighted by Kevin Daly, M.D., Heart Transplantation Committee member, emphasizing the importance of considering the needs of vulnerable populations.
- The need for resources and support from the BOD for committees to advance policies was noted by Dr. Daly, the importance of providing adequate resources for effective policy development was discussed.
- The significance of patient and family input in policy development was emphasized by attendees John Hodges, a past public representative of the OPTN BOD, and Nahel Elias, M.D., Ensuring that patient voices are heard and considered in decision-making processes was highlighted.
- Dr. Formica shared the good news that the DCD donors is growing at a rapid rate. While these transplants are great to get people transplanted, these transplants require more work. Hence, OPTN is very conscious of the capacity issues as it tries to push the volume particularly in the context of DCD donation.

13.1.2 Region: 2

Date: March 10th, 2025

1. Committee/BOD Composition & Size

- Steven Weitzen, Region 2 PAC representative and 2019 heart transplant recipient, emphasized the need for a manageable BOD size, suggesting between 10 and 15 members. He proposed including diverse representatives on the BOD such as patients, donors, PAC members, attorneys, finance, and IT professionals. He also suggested having at least one PAC member to be a member of certain key committees of OPTN.
- Dr. Raymond Lynch explained the transitional nominating committee's role in creating a BOD compliant with NOTA and the Final Rule with competitive roles across 11 different slates for regional representation.
- The OPTN BOD has become independent as of March 31, 2024, with new bylaws out for public comment.
- HRSA and Transitional Nominating Committee are accepting applications for new BOD members, with voting slated for Spring 2025.

- Concerns were raised about the level of physician and surgeon representation being disproportionately high while OPO representation is disproportionately low. Suggestions included having a rotating ability to sub-in individuals with relevant expertise.

2. Engagement

- The OPTN modernization initiative aims to ensure patient voices are heard directly by the BOD and committees. Suggestions included hosting information sessions at local OPOs and transplant support groups.
- Concerns were raised about transparency and the need for regular communication between PAC and contractors related to OPTN.
- Dr. Lynch highlighted the importance of understanding the lived patient experience and ensuring patient advocacy groups have a role in the board. He also shared that unlike a year ago, HRSA's response to critical comments are now posted on the OPTN website. In addition to the critical comments, HRSA is taking an active role in making sure that the MPSC has what it needs to investigate and correct patient safety concerns.
- Deborah MacRann, Region 2 MPSC representative, Infinite Legacy, shared the following MPSC updates:
    - Increased public disclosure and continues to support efforts to share some of the lessons learned by the committee.
    - Launched the "MPSC Chair Emails" to allow greater sharing of information with the community and an opportunity to send notifications about potential issues in a more expedited manner. These emails are documented on the MPSC Resource page.
    - Uses peer visits and informal discussions to interact with members and provides support before issues become severe. Provides feedback to the members about their corrective action plans and the importance of clear communication.
- Weitzen expressed the need for better communication among patients within the region and suggested creating a listserv or moderated forum for interregional and intraregional communication.
- Emily Blumberg, M.D., Director of Transplant Infectious Diseases at the University of Pennsylvania, emphasized the importance of representing diverse areas within the region to avoid having everyone from the same place.

3. Timeliness

Not applicable (N/A).

4. Data Availability

- HRSA issued a directive for OPTN to collect data on patients before they are added to the waitlist and ventilated patients prior to referral to an OPO. Public comment periods were held, and feedback is being reviewed.

- Continuous distribution of lung transplants has shown stable utilization, encouraging the system to move forward with liver and heart distribution.
- Dr. Richard Formica discussed the increase in lung transplants and the importance of continuous distribution for organ allocation. Regarding the Data Directive Update, he shared that to get data collected within the OPTN, you have to go through the OMB.

5. Prioritization Methodology

- The MOT Committee proposed a comprehensive multi-organ allocation policy to standardize organ allocation, addressing both single and multi-organ candidates.
- The Heart Committee discussed increasing opportunities for adult candidates supported by LVADs without worsening waitlist mortality rates.
- The Lung Transplantation Committee addressed challenges in collecting donor smoking history and proposed modifications to lung donor data collection.
- Eman Hamad, M.D., of Temple University Hospital, and Eric Messick, Heart Transplantation Committee member discussed the proposed changes for LVAD-supported candidates.
- Dennis Lyu, M.D., Vice-Chair of the OPTN Lung Transplantation Committee, addressed concerns about the feasibility of collecting detailed smoking history from donor families.
- Concerns were raised about the fair access of organ allocation, particularly for pediatric candidates. Namrata Jain, M.D., pediatric nephrologist with Hackensack Meridian Health, highlighted the challenges faced by pediatric candidates in receiving high-quality kidneys.

6. Additional Information (Challenges/Recommendations)

- Dr. Lynch emphasized the need for rational ways to elevate non-urgent communications through the committee structure.
- Concerns were raised about the representation of pediatric candidates and the need for equal representation across specialties.
- Kyle Soltys, M.D., pediatric liver transplant surgeon at UPMC Children’s Hospital of Pittsburgh, and Namrata Jain, M.D., highlighted the challenges faced by pediatric candidates in organ allocation.
- Michael Slipowitz, OPTN PAC member suggested that a smaller BOD could still ensure diverse perspectives by bringing in experts as needed.
- Charlie Alexander, CEO of Infinite Legacy (OPO) and Dr. Blumberg discussed the importance of patient advocacy groups and adequate patient representation on the BOD.
- Weitzen recommended the following:
    - Need for changes to make the system more patient-centric, focusing not just on the pre-transplant patients but also on post-transplant patients.
    - Allow for regular required meetings or other communications between PAC and contractors related to OPTN.
    - Incorporate a Patient Bill of Rights into the OPTN Final Rule, or wherever appropriate. The Patient Bill of Rights must include, among other things, patients' rights to the pre-transplant on the waitlist.

- Have a flexible policy for the development of policies by all committees, including PAC. The flexible policy will replace the concept of the ‘Policy Development Wheel’ which he believes has been unnecessarily time consuming.
- Concerns were raised about the current process for raising questions about disadvantaged populations and the need for better communication channels.

13.1.3 Region: 3

Date: February 21st, 2025

1. Committee/BOD Composition & Size

- Calvin Henry is the Region 3 representative in the PAC. The PAC is a well-represented committee, consisting of three living donors, three kidney recipients, three heart recipients, two lung recipients, two liver recipients, one multi-organ recipient, and three family caregivers. The PAC recommends allowing one patient representative on OPTN organ-specific committees to provide insights during discussions into new policies, which would then foster enhanced engagement.
- Dr. Richard Formica explained the BOD's collaboration with American Institutes for Research (AIR). He explained that the BOD has a five-year investigative contract for support. UNOS facilitates the BOD's nomination and election process, supports governance, oversight, management, and strategic planning, and assists in updating the OPTN structure, composition, policies, and processes.
- The Transitional Nominating Committee will select new members for the OPTN BOD through a special election. The timeline is as follows: applications were opened in December 2024, committee members will be announced in January 2025, and the special election will take place in Spring 2025.
- During the conversation among meeting attendees, the consensus was that a larger BOD provides greater safeguards in the policy development process.
- Out-of-sequence organ allocation requires broader representation on both committees and the BOD. Additionally, the donor family perspective needs more representation on these committees.

2. Engagement

- In December 2024, BOD approved bylaw revisions ensured BOD's independence from OPTN contractors. Despite newly enacted conflict of interest policies, there may still be lingering concerns about whether OPTN leaders’ activities are transparent enough.
- Patient voices directly heard by the BOD and committees serve as an important fail-safe. Patient donors and family members must be regularly engaged and receive more comprehensive updates than they currently do. A potential opportunity for grassroots communication to engage patient and family partners could involve hosting information sessions at local OPOs and transplant support groups.

> *"I don't know who is making the decisions and setting authorities as an EC member. I don't feel privy to that knowledge"* - Ginny McBride, OPO ED of "OurLegacy Florida".

3. Timeliness

Not applicable (N/A).

4. Data Availability

- In February 2024, HRSA issued a Secretarial directive for the OPTN to collect data on patients before they are added to the waitlist, as well as on ventilated patients prior to their referral to an OPO. From November 4, 2024, to January 3, 2025, there was a 60-day public comment period. On December 13, 2024, the OPTN submitted its response. Looking ahead, HRSA will review the feedback during an additional 30-day comment period before finalizing the directive.
- Henry envisions the use of AI chatbots to support waitlisted candidates and advocates for personalized, shared decision-making in the organ offer process.
- An attendee commented that when transplant programs report data for referrals and evaluations, having patients listed at multiple centers could potentially confuse the data. They also mentioned that one of the biggest barriers is the staff at community hospitals and the need to maintain clear pathways for becoming a donor. Any action that CMS can take regarding the conditions for participation would be greatly appreciated.

5. Prioritization Methodology

- Multi-organ allocations for liver/kidney and heart/kidney should be prioritized based on the highest risk of death on the waiting list. One potential solution to reduce CITis to allocate organs closer to the donor hospitals.
- When discussing policies that slow down allocation or hinder efficiency, one group commented that the MOT policies for liver/kidney and heart/kidney are cumbersome. They also noted that the policy requiring lung chest X-rays from donor patients is not feasible for smaller donor hospitals.

6. Additional Information (Challenges/ Recommendations)

- An attendee stated,
    - *"We need to build on our current approach by asking whether the policy achieved its intended goals. Did it work for the intended group, and who might have been impacted as bystanders? I believe it's important to involve the community in discussing these findings and to help guide us in identifying the bystander groups that we should be focusing on."*

13.1.4 Region: 4

Date: March 3rd, 2025

1. Committee/BOD Composition & Size

- The meeting was attended by various committee members including Michael Kwan, M.D. (Councillor), Shelley Hall, M.D. (Associate Councillor), and several BOD members such as Brittany Clayborne, A. Osama Gaber, M.D., F.A.C.S., F.A.S.T., Kelley Hitchman, M.S., Ph.D., D.B.H.I., Michael Kwan, M.D., and Tara Storch, a representative of the BOD.
- The PAC represented by Cody Reynolds from the Chickasaw Reservation in Oklahoma and parent of a pediatric transplant recipient, shared personal experiences and emphasized the need for collaboration and consistency across transplant centers.
- Macey Levan, Ph.D., J.D., provided updates on OPTN modernization initiatives and the role of the AIR in supporting the OPTN BOD.
- The Transitional Nominating Committee was discussed, highlighting the special election process for new BOD members. A question was raised about whether individuals who publicly questioned or opposed OPTN modernization would be considered for a BOD seat. The response clarified that being for or against the OPTN modernization does not determine whether someone can or cannot join the BOD and is viewed as a positive. The criteria for BOD membership exists independently of one's stance on OPTN modernization.

2. Engagement

- The importance of patient and family engagement was emphasized, with suggestions for grassroots engagement through local OPOs and transplant support groups.
- Reynolds shared his experiences as a parent of a pediatric transplant recipient, highlighting inconsistencies and challenges faced during the donor testing process. He stressed the need for better communication and feedback from transplant centers to avoid time wastage and frustration.
- Levan discussed the need for more patient voices in the decision-making process, serving as an important fail-safe. She suggested that patient donors and family members should be regularly engaged and receive more comprehensive updates than they currently do.
- The need for transparency and comprehensive updates from OPTN leaders was discussed, with concerns about whether there is sufficient transparency regarding their activities.
- The meeting also included a discussion on the importance of involving the community in discussing policy outcomes and identifying groups that may be impacted as bystanders.

3. Timeliness

- Updates on various proposals and initiatives were provided, including the timeline for the special election and the HRSA modernization contract strategy.

4. Data Availability

- HRSA issued a directive for OPTN to collect data on patients before they are added to the waitlist and on ventilated patients prior to their referral to an OPO.

- The meeting also discussed the challenges faced by community hospitals in collecting data, highlighting the need for support and collaboration to ensure accurate and comprehensive data collection.

5. Prioritization Methodology

- Multi-organ allocations for liver/kidney and heart/kidney should be prioritized based on the highest risk of death on the waiting list.
- The need for a clear and consistent allocation system was emphasized, with examples of how prioritization is performed between candidates. The current policy does not clearly direct the order in which organs are allocated, leading to inconsistencies and potential inequities in organ distribution.
- The proposed changes include developing multi-organ allocation tables to standardize the order in which OPOs allocate organs across match runs, ensuring a more equitable and efficient allocation process.
- The committee sought feedback from the community on the proposed changes, emphasizing the importance of community input in refining the policy.
- Concerns were raised about the impact on pediatric patients, with suggestions to prioritize them higher in the allocation tables to ensure they receive the best kidneys.
- The proposed changes aim to streamline the allocation process by providing a consistent plan for OPOs to follow, reducing variability and potential for out-of-sequence allocations.

6. Additional Information (Challenges/ Recommendations)

- The challenges faced by pediatric patients in receiving the best kidneys were highlighted, with concerns about the impact of multi-organ allocation policies.
- The need for feedback from the pediatric community was emphasized to ensure that children are not disadvantaged.
- The importance of involving the community in discussing policy outcomes and identifying groups that may be impacted as bystanders was discussed.

13.1.5 Region: 5

Date: February 13th, 2025

1. Committee/BOD Composition & Size

- The current BOD size composition is deemed too large, particularly because there many physicians and providers—who are already too busy—hold seats. The committee size is considered reasonable, but there is concern that not all regions are presented in some of the committees. Consequently, there is a need to review the structure to ensure broader representation and the opportunity to develop subcommittees dedicated to vulnerable and underrepresented populations (e.g., pediatrics) where equitable issues persist.

2. Engagement

- There is a need to keep the virtual option for meetings for those that cannot attend in person to enhance engagement. A recommendation for community town halls and having written communication correspondence (e.g., list serves for announcements, national public campaigns to counterbalance negative media, etc.) would be a great opportunity for ongoing engagement and transparency. Getting patients, families, and caregivers (the community) involved in committee and regionals meetings to get their perspective is crucial, alongside promoting any volunteer opportunities for engagement. Recommendations were also made to create standardized national guidelines for inclusion of hospital protocols, ensuring transparency and consistency. Additionally, to maintain ongoing transparency unexpected transmission events should be reported to the OPTN safety portal.

3. Timeliness

- Establishing consistent timeframes for unexpected events clarifies the reporting requirements for transplant programs. Long wait times and complication rates (e.g., graft failure) are ongoing. For example, some patients may age out of eligibility, which significantly increases their risk of complications. To address these issues, recommendations include establishing policies that direct the match run for highly prioritized candidates (i.e., recipients) where multi-organ offers can be made and viewed from an allocation table. This donor specific allocation plan creates efficiency and timeliness while promoting equitable distribution.

4. Data Availability

- Recommendations were made to establish policies after investigating mortality data on MOT patients. For example, modifying the donor testing collection data, donor patient registration, and the waiting list is a possible solution to promote efficiency and can assist in streamlining communication and information sharing between OPOs. It would require OPOs to provide additional data on donor patients, particularly for lung organs, and ensure that staff is educated on any new wait list features (e.g., lung offer filters). It is currently difficult to locate information in the OPTN donor data and matching system; therefore, a recommendation was made for updating the tools.
- In 2024, HRSA issued a data directive for OPTN to collect information on patients prior to being added to the waitlist and for ventilated patients referred to an OPO. Gathering additional and up-to-date data along with accuracy and increased granularity is crucial to making decisions on organ offers, such as lung transplants.

5. Prioritization Methodology

- Attention must be given to pediatric patients (i.e., candidates) and highly sensitized patients (i.e., recipients with high levels of anti-HLA antibodies), because they typically receive the fewest offers from donor patients. This is especially important for lung and kidney allocation. Therefore, it is crucial to “not takeaway” an organ from patients (i.e., candidates) who were allocated an organ outside the normal match run, only for them to be bypassed by MOT candidates.

- As of today, there is no priority policy (e.g., liver organ match). It currently depends which organ match run is used first. A recommendation was made to establish a policy outlining the allocation order for MOT. An attendee also suggested reducing variation in organ allocation by creating an algorithm that would enable organ centers to accept marginal organs and allocate them quickly.

6. Additional Information that is Key (Challenges/Recommendations)

- The patient population wants to see independent oversight of the changes made with the OPTN modernization plan. A suggestion was made on creating a legally independent OPTN corporation. Initial feedback from OPOs on the MOT Committee's proposed system solution to guide allocation included several points:
  - Differing OPO- specific allocation practices
  - Laborious efforts to create allocation plans
  - Allocation plans are non-linear
  - Need for policy and system solution that reduce complexity
  - Requests for system level guidance specific to each donor patient
  - Identification of potential contingencies that should be considered

13.1.6 Region: 6

Date: March 14th, 2025

1. Committee/BOD Composition & Size

- Scott Naugler, M.D., Professor of Medicine, Division of Gastroenterology and Hepatology, Oregon Health & Science University (OHSU), raised concerns about the organization of the next regional meeting and the support for committees. Jennifer Muriett, Secretary OPTN BOD, Donor Alliance, clarified that UNOS has an extended contract for supporting regional meetings, while AIR supports the BOD but not the committees.
- Dr. Raymond Lynch discussed the need for continuity in committee membership and the potential for volunteers to extend their roles to provide stability during BOD transitions. He emphasized that the Associate Councilor role in the MPSC will now be an elected position starting in July.
- Shehzad Rehman, M.D., Region 6 Representative Pancreas Transplantation Committee, Transplant Nephrologist, Oregon Health & Science University (OHSU), raised concerns about geographic imbalances in committee representation, particularly noting the lack of West Coast representation on the Pancreas Committee. Some regions are less well-represented and there's less of a voice compared to others. He also emphasized that decisions on allocation have disparate impacts on different parts of the country.
- Catherine Kling, M.D., Region 6 Councilor OPTN BOD, University of Washington Medical Center, emphasized the importance of regional representation on the BOD, highlighting

concerns about underrepresented groups such as pediatrics and rural populations. She expressed fears that a smaller BOD might lead to inadequate representation for these groups.

- Dr. Kling inquired on how some openings on certain committees are going to be handled to which Dr. Lynch replied that it’s being addressed by the Transitional Nominating Committee, but it will be handled through the BOD.
- Chris Blosser, M.D., Transplant Nephrologist, Chair, Center for Innovation in Cancer and Transplant shared that there's great value in having association representation to complement regional representation because of the complexity of how states and regions of the country have different population, geographic, and logistical challenges. And those association perspectives can often highlight either disparities or strengthen ties to policy.

2. Engagement

- Dr. Lynch stressed that modernization efforts should focus on patient experience and equitable organ allocation. He highlighted the importance of ensuring effective operation for patients, including those neurologically injured, living donors, and those suffering from organ failure.
- Dr. Kling echoed the need for adequate regional representation to ensure diverse perspectives in policy discussions. She mentioned that densely populated regions might be disproportionately impacted by allocation changes.

3. Timeliness

- Fred Tibayan, M.D., Cardiothoracic Surgeon, Professor of Surgery and Associate Chief, Division of Cardiothoracic Surgery, Oregon Health & Science University (OHSU), commented that while there are understandable concerns about the Heart Committee’s proposal, this policy change is expected to have a longer feedback loop and has been thoughtfully implemented to minimize drastic swings in policy.

4. Data Availability

- Siddhartha Kapnadak, M.D., Region 6 Representative Lung Transplantation Committee, University of Washington Medical Center, discussed the proposed data collection enhancements for OPO transplant programs, emphasizing the need for consistent and granular data points to reduce the burden on coordinators. He mentioned that discrete data points like smoking history and predictive total lung capacity would help streamline the process.
- Rytaro Hirose, M.D., Interim Chief, Pediatric Transplant, Seattle Children's Hospital, and Lauren Land, an attendee, highlighted the importance of clear definitions and technical compatibility for data collection systems. Dr. Hirose emphasized the need for specificity in data requests to avoid confusion and ensure accuracy.
- Concerns were raised about the increased data reporting burden for OPOs and the need for standardized data elements to reduce back-and-forth communication.

5. Prioritization Methodology

- Zoe Stewart Lewis, M.D., Chair MOT Committee, University Hospitals of Cleveland, presented on the need for standardized multi-organ allocation policies to ensure equitable and efficient organ distribution. Dr. Stewart Lewis discussed the gaps in existing policies and the importance of having a real-world efficient solution that can actually work for OPOs and the system.
- The discussion included concerns about the impact of allocation policies on different regions and the importance of considering post-transplant survival and patient survival on the waiting list. Dr. Stewart Lewis emphasized that the system needs to be transparent and meet the goals of better health outcomes.
- Concerns were raised about prioritization between pediatric kidney candidates and kidney-pancreas recipients, and the need for additional guidance to address operational challenges.

6. Additional Information (Challenges/Recommendations)

- Jill Gelow, M.D., Region 6 Representative Heart Transplantation Committee, Providence St. Vincent Medical Center, and other attendees discussed the unintended consequences of allocation policies on clinical practices, particularly for LVAD patients. They emphasized the need for more granular and data-driven approaches to policy adjustments. Dr. Gelow mentioned that the proposal aims to correct some of the unintended consequences of previous allocation changes.
- Kevin Koomalsingh, M.D., Region 6 Representative MPSC, Providence St. Vincent Medical Center, addressed concerns about out-of-sequence allocations and the ongoing efforts of special work groups to handle these issues. He acknowledged the importance of addressing these allocations to ensure fairness and transparency.
- Dr. Hirose wanted some clarifications on how one measures whether the BOD or the committee is achieving the goals of the OPTN and how these goals can become part of the metric of effective operation of either the BOD or the committee.
- There was a suggestion to have the ensuing IT solution part of the MOT Committee proposal to be able to integrate with DonorNet and to be as interactive as possible for ease of usability for the OPOs.

13.1.7 Region: 7

Date: February 14th, 2025

1. Committee/BOD Composition & Size

- Every OPTN committee has at least two patient and donor affairs representatives.

2. Engagement

- Patients, families, and caregivers can submit a volunteer interest form on the OTPN website year-round.

- Procurement and transplant professionals are encouraged to promote OPTN volunteer opportunities to people with a personal connection.

3. Timeliness

- The public comment periods that were mentioned were 30 and 60 days.

4. Data Availability

- OPTN is to collect data on patients prior to being added to waitlists and ventilated patients being referred to an OPO.

5. Prioritization Methodology

- “Values Prioritization Exercise” has been used to help build the clinical consensus on organ allocation priorities. Participants compared 16 sets of candidates to determine priority
- Question that was asked by participants:
    - “Can statistical models help estimate impact of changes?”

13.1.8 Region: 8

Date: March 7th, 2025

1. Committee/BOD Composition & Size

- Robert Johnson, the Region 8 PAC representative, was acknowledged for his contributions. The PAC consists of diverse members including living donors, recipients of various organs, and family caregivers. The PAC emphasizes the importance of patient perspectives in policymaking and recommends allowing patient representatives on OPTN organ-specific committees.
- Dr. Richard Formica discussed the BOD's collaboration with the AIR, which supports governance, strategic planning, and updates to OPTN policies. The Transitional Nominating Committee will select new BOD members through a special election.
- Meeting attendees shared the consensus that a larger BOD provides greater safeguards in policy development. Additionally, attendees agreed that greater representation from donor patient families and committees is needed.

2. Engagement

- Andrea Tietjen, M.B.A., CPA, Treasurer of the OPTN BOD, explained that in December 2024, the BOD approved revisions to ensure independence from OPTN contractors.
- Despite new conflict of interest policies, Ginny McBride, ED of OurLegacy (OPO) in east central Florida, voiced concerns about transparency and whether there is sufficient transparency regarding the activities of OPTN leaders.
- Lorrinda Gray-Davis, Vice Chair of PAC, emphasized the importance of ensuring patient voices are heard by the BOD and committees. Grassroots communication to engage patient

and family partners was suggested, including hosting information sessions at local OPOs and transplant support groups.

- Rexanah Wyse Morrissette, Interim ED of OPTN, highlighted the need for more comprehensive updates and engagement with patient donors and family members. Ensuring transparency in decision-making processes is essential.

3. Timeliness:

Not applicable (N/A).

4. Data Availability:

- An attendee raised concerns about patients listed at multiple centers potentially confusing data. Clear pathways for becoming a donor are needed, and any action by CMS regarding conditions for participation would be appreciated.

5. Prioritization Methodology:

- An attendee suggested that liver/kidney and heart/kidney allocations should be prioritized based on the highest risk of death on the waiting list. Allocating organs closer to donor hospitals could reduce cold ischemic time. MOT policies for liver/kidney and heart/kidney are cumbersome, and the requirement for chest X-rays for lung donors from donor patients is not feasible for smaller donor hospitals.

6. Additional Information (Challenges/Recommendations):

- A meeting attendee said it is important to evaluate whether policies achieve their intended goals and involve the community in discussions to identify impacted groups. Ensuring that policies work for the intended group and identifying bystander groups that may be affected is crucial.
- Gray-Davis suggested the following:
  - A clear roadmap to help patients navigate the transplant process
  - Include in data collection patients' lived experiences (struggles, mental health, quality of life, etc.)
  - Patients need a lifelong plan and not just a transplant
  - Also mentioning these challenges
    - Access to transplant is not equal – some patients face geographic barriers, financial burdens, or systemic discrimination
    - Health insurance has a strong say in the patient's transplant journey

13.1.9 Region: 9

Date: March 13th, 2025

1. Committee/BOD Composition & Size

- Nancy Metzler, Region 9 Councilor and the ED of Transplant Services at Strong Memorial Hospital, University of Rochester Medical Center, provided updates on the Councilor activities and the composition of the OPTN BOD. The BOD includes representatives from various medical and patient communities.
- Elizabeth Devivo, OPTN PAC member, a heart and double lung transplant recipient 22 years ago. She shared insights from PAC and being a social worker who worked in a dialysis center for a number of years as well as working as behavioral coach for people with chronic illness makes her actively involved in PAC initiatives. She emphasized the importance of patient and donor family representation in policy discussions.
- Dianne LaPointe Rudow, Ph.D., Immediate Past President OPTN BOD, shared that in order to have this future modernization state, some changes to the OPTN some changes had to be made to the OPTN. The OPTN BOD became an independent OPTN BOD. A new corporation called INVEST was created in July 2024 and designated by the Secretary of HHS as the OPTN. She discussed the challenges faced during the transition to an independent OPTN BOD and the role of the Transitional Nominating Committee in selecting new BOD members. She emphasized that in this time of transition, it's really important for us to try to get true leaders who understand the OPTN, who understand the community into these important leadership roles so that they can help to influence modernization in a positive way.
- Dr. Raymond Lynch highlighted the temporary nature of the Transitional Nominating Committee and its role in presenting a slate of candidates to the Secretary of HHS. all spots on the BOD will be up for election. For the regional spots instead of being advanced by the regional nominating committee, they will be individuals who will be voted by the OPTN members in the region.
- Concerns were raised by Neha Ami Bansal, M.D., Pediatric Cardiologist from Mount Sinai Hospital and Vice Chair of the Pediatric Transplantation Committee, about the lack of pediatric representation on the Transitional Nominating Committee and the need for adequate representation on the BOD.
- Denise Abbey, At Large Patient and Donor Affairs Representative, and LaPointe Rudow stressed the importance of maintaining patient and donor family representation on the BOD, fearing that reducing the size of the BOD could limit patient voices.

2. Engagement

- An attendee emphasized the importance of patient voices in the decision-making process, with suggestions for grassroots communication to engage patient and family partners.
- Attendees raised concerns about the transparency of OPTN leadership activities and the need for more comprehensive updates to patient donors and family members.
- Abbey expressed feelings of deception and disrespect regarding the temporary nature of her appointment to the BOD, highlighting a lack of transparency in the communication process regarding OPTN Modernization.

3. Timeliness

- Jondavid Menteer, M.D., Chair of the OPTN Heart Transplantation Committee, discussed the timeline for the potential enactment of the proposal for the escalation of status for time on LVAD. He mentioned that if the proposal is approved and not changed after the public comment period, it will go to the BOD in the next several months, with implementation anticipated sometime in 2026.

4. Data Availability

- HRSA issued a secretarial directive for OPTN to collect data on patients before they are added to the waitlist and on ventilated patients prior to referral to an OPO. The committees have worked on this for over a year now and they have come up with what these new data elements should be. They were required to go to the OMB and be on the Federal Register for people to comment.

- Joseph Tusa, Lung Transplantation Committee member and Director of Organ Procurement, with LiveOnNY (OPO), discussed the lung committee's proposal to modify data collection for diagnostic testing to streamline communication between OPOs and transplant programs.

5. Prioritization Methodology

- Lisa Stocks, Co-Chair OPTN Ad Hoc MOT Committee, presented the MOT Committee’s proposal for a new policy that aims to standardize the allocation order to provide clearer guidance to OPOs and balance the needs of single and multi-organ candidates, including pediatric and high-priority patients.
- Attendees expressed concerns about the complexity of the proposed multi-organ allocation policy and how it would impact the efficiency of the allocation process. Questions from attendees included inquiries about the differences between current multi-organ policies and the upcoming policy proposal, the complexity of the new policy, and how it would help streamline the allocation process.
- Stocks discussed that multi-organ allocations should prioritize candidates based on the highest risk of death on the waiting list. She hopes the policy proposal will have a positive impact on patients and donor families as it will provide a fair, equitable, and systematic organ allocation system.

6. Additional Information (Challenges/Recommendations)

- Metzler suggested the need for a membership category for certain groups within the MPSC to hold them accountable. Additional feedback was provided by Nancy Metzler on the need for balanced representation and transparency in congressional hearings related to OPTN modernization.
- Metzler also mentioned the difficulty in implementing policies operationally, especially for smaller programs that may struggle with regulatory burdens compared to larger centers with more resources.

- The importance of maintaining patient and donor family representation on the BOD was emphasized by Denise Abbey, a patient representative, with concerns about the impact of a 100% turnover of the BOD.
- LaPointe Rudow concurred with Denise Abbey's sentiment and thinks that the patient group on the BOD feels the same way as Denise regarding transparency and "perceived conflict of interest". She hopes that as OPTN moves forward to figure out how to get past these concerns since this is going to be a big relations problem for HRSA.
- Stocks discussed the complexity of the proposed multi-organ allocation policy and the need for clear guidance to OPOs to ensure fair and efficient allocation.
- An attendee raised concern to further enhance patient safety, especially with the anticipated growth of living donation through IOTA model, a solution for living donor verifications comparable to that provided for deceased donor patients would be appreciated. Dr. Sander Florman, MPSC Region 9 Rep, agreed and will take the concern back to the committee.

13.1.10 Region: 10

Date: March 12th, 2025

1. Committee/BOD Composition & Size

- Macey Levan, J.D., Ph.D., Vice President for Patient/Donor Affairs, OPTN BOD, shared insights on OPTN's transplant performance, exclusion, and screening criteria for the new BOD and HRSA's Special Election webinar. The criteria and webinar were posted on the OPTN website.
- Dr. Raymond Lynch explained the competitive election slate and the standard composition and size of the BOD and regional representation. He also noted that the mandate of the Transitional Nominating Committee is to give a NOTA and Final Rule compliant BOD slate and not to reimagine the BOD size or how governance is done.
- Kenneth McCurry, M.D., Region 10 Councilor, The Cleveland Clinic Foundation, expressed caution about significantly reducing the size of the BOD, emphasizing the importance of representing the broader community.
- Dorrie Dils, At Large Nominating Committee (BOD), President and CEO Gift of Life Michigan (OPO), highlighted the need for greater participation of OPOs and donor patient families, stressing the importance of SMEs in BOD discussions.
- Silas Norman, M.D., At Large Nominating Committee (BOD) Representative, University of Michigan Medical Center, emphasized that the BOD's size should reflect its function and the priority of representing the transplant community, suggesting a reevaluation of regional representation considering continuous distribution.
- Most of the attendees believe that the size of the BOD is large and appears to be unwieldy but also admit to not knowing the right answer. For them the size is meaningful, but perhaps secondary. What matters is optimizing representation of patients and donor patient

families and relevant stakeholders as well as ensuring better interaction and communication between the BOD and the committees.

2. Engagement

- Levan highlighted the economic value of volunteers in supporting OPTN policy development, emphasizing the importance of recognizing their contributions.
- Chad Denlinger M.D., At Large MPSC Representative, Indiana University Health, reported a slight uptrend in recent months in informal discussions and peer visits to catch problems a bit earlier in their development before they become a larger problem.
- Chris Sonnenday, M.D., At Large MOT Committee Representative, University of Michigan Medical Center, supported the idea of including committee leadership in BOD discussions to help communication and interaction.
- Dean Kim, M.D., At Large Pancreas Transplantation Committee Representative, Children's Hospital of Michigan, emphasized the importance of patient and community representation in committees and the need for transparency in BOD decisions.
- Dr. Sonnenday and Dr. Kim discussed the importance of ensuring stakeholder input is heard and considered in BOD decisions, emphasizing transparency and responsiveness in the OPTN modernization process.
- Dr. Lynch and Dr. Sonnenday discussed the value of regional breakout meetings for understanding policy impacts and ensuring regional representatives are well-informed.
- Dr. Lynch emphasized the importance of elevating alternate voices to ensure all perspectives are heard, especially those outside the mainstream conversation. Also suggest including content experts as non-voting members in BOD discussions to ensure informed decision-making.

3. Timeliness

Not applicable (N/A)

4. Data Availability

- Levan mentioned HRSA's plan to open up the 30-day Public Comment period for the revised data directive this spring. Updates on the data directive will be posted on the OPTN website under the Disease Transmission Advisory Committee (DTAC) page.
- Bruce Nicely, VP – Donation Optimization, Gift of Life Michigan (OPO), expressed concerns that the information collected is getting lost in translation and feels that the effort is duplicative, suggesting that attention to the uDRAI tool could address this issue.
- Wayne Tsuang, M.D., Region 10 Representative Lung Transplantation Committee, The Cleveland Clinic Foundation, and Kelley Poff, UNOS contact in the Lung Transplantation Committee, clarified that the uDRAI tool does not fall under UNOS or OPTN's purview, making it difficult to align or make changes through the usual policy development process, as it is a tool used by OPOs outside of OPTN.

- Attendees discussed the need for OPTN to collaborate with concerned entities such AOPO and AATB regarding data collection tools like DonorNet, uDRAI to align the lung donor data collection requirements as this will simplify the process and avoid duplication of efforts.

5. Prioritization Methodology

- Dr. Sonnenday highlighted that there is currently no OPTN policy or guidance that instructs OPOs how to allocate organs and organize their match runs from a multi-organ donor. The MPSC developed a proposal to standardize allocation for donor patients with more than one organ available by inserting multi-organ allocation tables into policy. The proposal will eliminate complexity by providing system-level solution that will provide clear guidance to the OPOs.
- Dr. Denlinger highlighted the MPSC's efforts to address issues early and ensure the best interests of the transplant community and the committee's goal to help rather than be punitive.
- An attendee questioned the reason behind the prioritization of the project to modify lung donor data collection. Dr. Tsuang explained that the Lung Transplantation Committee pursued this policy now because the OPTN BOD recently approved a policy to promote efficiency in lung donor allocation, and the committee saw an opportunity to enhance this goal with data collection.

6. Additional Information (Challenges/Recommendations)

- Gabriel Maine, Ph.D., At Large DTAC Representative, Histocompatibility Laboratory at Corewell Health William Beaumont University Hospital, discussed the definitions and challenges in reporting expected disease transmissions and Dr. Sonnenday raised concerns about the mandate to report all post-transplant infections for lung patients.
- Dr. Sonnenday questioned the scope of MPSC's potential case investigations identified in the allocation reviews, which is larger than any OPTN committee can possibly cover. He also raised concerns about thorough vetting and feedback to complainants. Dr. Dellinger agreed that the scope is really tremendous like 2,000 a year, and the need for a broad discussion and multidisciplinary approach to help ensure that organ placements are done most appropriately.
- Jennifer Hartman, Region 10 Representative Heart Transplantation Committee, Corewell Health Grand Rapids Hospitals, reported that there is still increased risk of complications, such as stroke, infection, and bleeding the longer a device is implanted. As a result, LVADs have now been referred to as a "bridge to nowhere". She also addressed questions about the impact of proposed changes on the Heart Committee's effort to develop a continuous distribution allocation system.

13.1.11 Region: 11

Date: March 4th, 2025

1. Committee/BOD Composition & Size

- BOD and committee size remains a topic of concern.
- The large BOD consists primarily of physicians and surgeons who are very busy. While the BOD and committees need to have representation from all regions and stakeholders to ensure all voices are heard, their size leads to inefficiencies. Although the need to restructure the BOD and committees was discussed, no optimal solution was reached.

2. Engagement

- Regional meetings are meant for stakeholders to engage and participate with OPTN. After the Trump Administration's communication pause was lifted, this year's regional meetings were changed to virtual. There were 167 attendees at this regional meeting. However, it was not possible to determine each attendee's stakeholder type. It is unclear whether attendance increased or decreased from last year's regional meeting.
    - During the councillor update, the presenter explained how to submit feedback.
    - All feedback will be submitted as public comment
    - Only one submission per institution will be submitted per institution
    - All comments will be included in the region's public comment summary
- The Heart Transplantation Committee's presentation was high-level and not easily understandable for laypeople. Although there were multiple questions and comments, none appeared to come from laypeople.
- The Lung Transplantation Committee's presentation was more accessible and understandable. There were minimal comments in response to this proposal.

3. Timeliness

- The MOT committee presented a request for feedback for an upcoming policy proposal for multi-organ allocation. The proposal presented is complicated with a different classification system for each type of donor patient. The purpose of the proposal is to promote better health outcomes and facilitate consistent and efficient allocation. The presenter noted that the committee required certain data points to make prioritization decisions (candidate waitlisted mortality and outcomes, post-transplant survival, candidate access and time without an offer, and match run efficiency). The presenter noted that multiple opportunities for the community to provide input about the proposal would prevent delays in moving the policy forward. However, the complicated and controversial nature of the proposal would likely lead to delays.

4. Data Availability

- The MOT committee's upcoming policy proposal for multi-organ allocation requires certain data points for prioritization decisions (e.g., candidate waitlisted mortality and outcomes, post-transplant survival, candidate access and time without an offer, and match run efficiency). The presenter noted ongoing efforts to obtain accurate data from all regions.

5. Prioritization Methodology

Not applicable (N/A).

6. Additional Information that is Key (Challenges/Recommendations)

- The agenda included a feedback session on OPTN modernization hosted by HRSA. However, the session was cancelled at the last minute due to an emergency, causing the regional meeting to end an hour early. Because it was a virtual meeting, there was no opportunity for networking.

14 Appendix H: Acronyms & Abbreviations

Table 18: Acronyms and Abbreviations

Acronym	Full Name & Definition
AATB	American Association of Tissue Banks An industry association organization that accredits tissue banks in the United States (and internationally). Established in 1976, the AATB sets standards and best practices to ensure the safety, quality, and ethical sourcing of human tissue used for transplantation, investigation, and education. Its accreditation program involves rigorous inspections and compliance checks, helping to maintain high standards for donor patient screening, tissue recovery, processing, storage, and distribution. The AATB provides educational resources, training, and advocacy efforts to advance the field of tissue banking. By working closely with regulatory agencies such as the Food and Drug Administration (FDA), as well as with clinicians, researchers, and tissue banks, the AATB promotes responsible tissue donation and facilitates continuous improvements in tissue-related services and transplant outcomes.
ABO	ABO Blood Group System A classification system for human blood based on the presence or absence of antigens A and B on the surface of red blood cells. The main blood types are A, B, AB, and O.
AI	Artificial Intelligence Technology enabling computer systems to perform tasks that typically require human intelligence, such as pattern recognition, decision-making, or predictive modeling.
AIR	American Institutes for Research Current OPTN BOD support contractor that conducts social science and behavioral research, including work in education, health, and workforce development.
AOOS	Allocation Out of Sequence The practice of allocating an organ out of the waitlist order as defined by OPTN policy, typically to prevent the organ from going unused.
AOPO	Association of Organ Procurement Organizations A national trade association representing the federal contractors known as Organ Procurement Organizations (OPOs) responsible for organ procurement, preservation, and transportation.
API	Application Programming Interface A set of rules allowing different software applications to communicate and share data, often enabling seamless integration and automation.
APP	Advanced Practice Providers

Acronym	**Full Name & Definition**
	APPs typically refer to healthcare professionals—such as nurse practitioners (NPs), physician assistants (PAs), and sometimes clinical nurse specialists (CNSs)who have advanced clinical training and can perform many of the same diagnostic and treatment functions as physicians. They often play key roles in patient evaluation, post-transplant follow-up, coordinating care, and managing chronic conditions in transplant recipients.
AST	American Society of Transplantation A professional organization supporting transplant professionals and promoting review, education, and public policy to better patient outcomes.
ASTS	American Society of Transplant Surgeons A professional society representing transplant surgeons and related surgical professionals, focused on advocacy, education, and review in transplantation.
BOD	Board of Directors The governing body of an organization, responsible for major decisions, strategic direction, and overall oversight.
CIT	Cold Ischemic Time The time between the chilling of an organ after its blood supply has been reduced or cut off and the time it is warmed by having its blood supply restored. This period is crucial in determining the viability of the organ for transplantation.
CFR	Code of Federal Regulations The official record of all rules and regulations issued by federal agencies in the United States.
CMS	Centers for Medicare & Medicaid Services A federal agency under the Department of Health and Human Services (HHS) that administers Medicare, Medicaid, and other health programs.
COR	Contract Officer Representative An individual who manages and oversees contractual obligations, ensuring the contractor meets performance requirements.
DTAC	Disease Transmission Advisory Committee A specialized committee that focuses on identifying and reducing the risk of disease transmission through organ transplantation.
DCD	Donation after Cardiac Death DCD refers to patients who donate organs after their heart has permanently stopped beating and circulation has ceased, as opposed to brain-dead donor patients whose

Acronym	Full Name & Definition
	hearts are still beating with the aid of mechanical support. DCD donor patients offer a critical source of organs, helping to expand the donor pool and save more lives. However, the process involves careful coordination and decision-making around withdrawal of life support, confirmation of cardiac death, and rapid organ recovery to maintain organ viability. DCD donor patients typically provide kidneys, liver segments, lungs, and, in some cases, other organs, all governed by ethical guidelines and medical protocols designed to ensure respect for the donor patient and the donor patient's family, as well as the safety and efficacy of transplanted organs.
EC	Executive Committee A condensed leadership group in a larger organization, such as a BOD, is typically authorized to make decisions on behalf of the entire BOD or membership..
ED	Executive Director The individual in charge of day-to-day operations and ensuring organizational goals and regulatory requirements are met. Annual performance reviews of the ED are part of UNOS's tasks alongside composition reviews and public calls for nominations.
EDOC	Effective Date of Contract The date the contract goes into effect.
eGFR	estimated Glomerular Filtration Rate A calculation used to gauge how well the kidneys are filtering waste from the blood. eGFR is a critical measure for assessing kidney function, diagnosing the stage of chronic kidney disease (CKD), and determining the urgency of a transplant.
EMR	Electronic Medical Record A digital version of a patient's paper chart, used by healthcare providers to store clinical data and track patient information.
GAO	Government Accountability Office An independent, nonpartisan agency that works for Congress to evaluate federal programs, auditing how taxpayer dollars are spent.
HCD	Human-Centered Design A service design methodology that places the needs, behaviors, and experiences of people at the forefront of the design process, ensuring solutions are tailored to real-world contexts.
HHS	U.S. Department of Health and Human Services The federal department responsible for protecting the health of all Americans and providing essential human services.
HRSA	Health Resources and Services Administration

Acronym	**Full Name & Definition**
	An agency within the U.S. Department of Health & Human Services (HHS) responsible for bettering healthcare access for people who are geographically isolated or economically or medically vulnerable. HRSA (now HHS/DoT) oversees the Organ Procurement and Transplantation Network (OPTN) and enforces federal requirements governing organ donation, procurement, and transplantation.
INVEST	Independent Network of Volunteers for Equitable and Safe Transplants The former BOD for the OPTN has been renamed INVEST. Under the designation and oversight of HRSA, INVEST now serves as the OPTN BOD consistent with federal law and regulations, including NOTA. As such, INVEST's newly updated bylaws (most recently amended on December 24, 2024) also function as the bylaws of the OPTN whenever INVEST is acting as the OPTN BOD. Meanwhile, related policies were most recently updated on March 5, 2025.
IT	Information Technology The use of systems (computers, hardware, software, networks) for processing, storing, and exchanging electronic data.
LDC	Living Donor Committee Responsible for developing, reviewing, and monitoring policies related to the procurement of organs from living donor patients (e.g., kidney, liver lobes). The LDC helps maintain high standards of safety, ethics, and efficacy in living organ donation, advancing policies that support donor patients and recipients throughout the procurement and transplantation process
LVAD	Left Ventricle Assist Device A mechanical pump that supports the left ventricle—the heart's main pumping chamber—when it can no longer function effectively on its own. LVAD plays a crucial role within the U.S. transplant system by keeping heart failure patients stable and extending survival during the sometimes-lengthy wait for a suitable donor heart.
MAC	Minority Affairs Committee The MAC focuses on ensuring that racial, ethnic, and other minority populations receive equitable access to organ procurement and transplantation services. Ensures that the OPTN upholds fairness in organ procurement and transplantation, reducing barriers and bettering outcomes for minority patients across the United States.
MOT	Multi-Organ Transplant The transplantation of more than one organ into a single recipient, such as liver-kidney or heart-lung transplants.
MPSC	Membership & Professional Standards Committee

Acronym	Full Name & Definition
	The OPTN committee with delegated authority from the OPTN BOD responsible for reviewing and monitoring member performance, compliance, and professional standards.
NASEM	National Academies of Sciences, Engineering, and Medicine A private, nonprofit institution that provides independent, expert advice on scientific, technological, and medical matters to federal agencies and other organizations. In the context of HRSA and the OPTN, NASEM’s reports and recommendations often influence policy decisions and enhancements in organ transplantation practices.
NEDS	New England Donor Services One of the largest OPOs in the United States.
NOTA	National Organ Transplant Act A U.S. federal law that established the Organ Procurement and Transplantation Network and prohibited the sale of human organs.
NRP	Normothermic Regional Perfusion A technique used to preserve organs by perfusing them at normal body temperature after circulatory death.
NYT	The New York Times A prominent American daily newspaper based in New York City, known for its comprehensive coverage of domestic, national, and international news, as well as opinion pieces, investigative reports, and reviews.
OMB	Office of Management and Budget A White House office that oversees federal budgetary matters and reviews regulations and information collection requests.
OPO	Organ Procurement Organization A federal contractor designated to coordinate organ procurement in a specific area, responsible for surgical recovery, preservation, and transportation of donated organs.
OPTN	Organ Procurement and Transplantation Network A nationwide system established by federal law and overseen by the Health Resources and Services Administration (HRSA) that matches donated organs with patients on the national waiting list, develops organ allocation policies, and collects and analyzes transplant data to better outcomes and ensure fairness.
PAC	Patient Affairs Committee

Acronym	Full Name & Definition
	A body within the OPTN that ensures patient, donor patient, and family perspectives are incorporated into the development, review, and revision of organ procurement and transplantation policies. Members often include transplant recipients, living donor patients, donor patient families, and patient advocates who contribute firsthand experiences, helping to promote transparency, impartiality, and patient-centered decision-making throughout the organ procurement and transplant system.
PCR	Policy and Community Relations (Department) A department (within UNOS or related structure) focusing on policy development, communication, and community contact.
POC	Policy Oversight Committee A committee responsible for guiding the policy agenda, ensuring proposals align with strategic goals, and monitoring policy development progress.
SME	Subject Matter Expert An individual with in-depth knowledge or expertise in a particular area, often consulted to inform decisions or guide project work.
SRTR	Scientific Registry of Transplant Recipients The SRTR is a federally funded database that tracks transplant statistics. The program is managed under a contract awarded to a single entity. Currently, Hennepin Healthcare Research Institute (HHRI) serves as the contractor responsible for data collection, analysis, and reporting on transplant outcomes, organ allocation, and policy impact.
TIEDI	Transplant Information Electronic Data Interchange Enables OPTN members to access and complete donor patient, candidate, and recipient-specific electronic data collection records.
uDRAI	Uniform Donor Risk Assessment Interview A standardized version of the Donor Risk Assessment Interview (DRAI), designed to ensure that all OPOs ask essentially the same questions in the same way. uDRAI was developed to meet OPTN policy requirements and align with HRSA and CDC guidelines. uDRAI aims to minimize variability or gaps in donor patient history collection and improve overall safety and consistency nationwide.
UNet	The UNOS secure transplant network system A suite of online systems maintained by UNOS to manage transplant data, match organ donor patients to recipients, and ensure secure information exchange.
UNOS	United Network for Organ Sharing

Acronym	Full Name & Definition
	A private, nonprofit organization contracted by the federal government to manage the OPTN.

15 Appendix I: References

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