

**OPTN Policy Oversight Committee
Meeting Summary
October 20, 2023
Detroit, Michigan**

**Jennifer Prinz, BSN, MPH, Chair
Erika Lease, MD, FCCP, Vice Chair**

Introduction

The Policy Oversight Committee (“Committee”) met in Detroit, MI on 10/20/2023 to discuss the following agenda items:

1. Efficiency Efforts
2. Continuous Distribution Updates and Discussion
3. Efficiency Group Report-Outs
4. Multi-Organ Transplant Policy Updates
5. New Project Review: OPO Performance Enhancements
6. Open Discussion

The following is a summary of the Committee’s discussions.

1. Efficiency Efforts

Staff provided an update on the Executive Committee’s efforts to promote efficiency within the system. The Committee also heard an update from the task force Expeditious: Organ Usage through Placement Efficiency.

Presentation summary:

The Executive Committee discussed the strategic plan with a focus on three main goals: increase organ acceptance, decrease organ non-utilization, and improve efficiency and allocation. The Executive Committee considered incorporating a separate patient-specific goal into the plan but decided to integrate patient-related aspects into all goals.

Through their discussion, metrics for organ acceptance were a focal point, with an emphasis on redefining and refining offers. In addition, capacity planning and incorporating transportation into contracts were discussed to enhance efficiency.

Finally, present throughout all the discussion was the need for improved transparency, best practices, and alternative allocation schemas for high-risk organs.

Summary of discussion:

The Committee will continue discussing and reviewing the existing portfolio to identify areas for efficiency improvements.

A member inquired if allocation variances were being examined as a route for alternative placement schemas. Staff replied that they were, but they would need to be foundationally based on data, some of which may not be currently collected. A second member supported the idea of variances, but emphasized the need for handling variances efficiently, ensuring adherence to the framework, and

soliciting feedback on the proposed approach in the policy development lifecycle. They added that each area of the country does not handle placement in the same fashion, which would have to be captured in different variance frameworks. Finally, there was support for holding special public comment cycles to ensure the recommendations from the taskforce can be implemented as quickly as possible.

Another member shared concerns about the potential challenges of having multiple public comment cycles for different policies, particularly for smaller populations without direct representation. Members agreed, noting the importance of incorporating input from diverse population groups affected by policies and ensuring transparency and communication during policy development. However, other members expressed concerns about the slow response of the current policy development process and the balance between the benefits of the existing schedule and the need for timely reactions to emerging issues. Staff from the task force acknowledged the complexity of breaking the cycle and expressed a commitment to weighing the pros and cons for effective decision-making.

The discussion also addressed historical examples of variances, including split liver, and members emphasized the need for improvements in the structure of variance processes. Specifically, they felt it needed to be able to more dynamically update once data from the variance was gathered.

Next steps:

The Committee will review the existing portfolio and identify potential areas for efficiency improvements.

2. Continuous Distribution Updates and Discussion

The Committee discussed the most recent updates to Kidney, Lung, Heart, and Liver continuous distribution.

Summary of discussion:

No decisions made during this discussion.

Concerns were raised about the measurability and limitations of the current transportation system's capacity in relation to continuous distribution (CD) and how it might affect CD moving forward. In addition, members noted that themes from public comments and in-person meetings reflected the shift from equity towards efficiency and utilization of hard-to-place organs. CD, they felt, highly prioritized equity in a transplant system with already elevated levels of non-utilization. The Vice-Chair of the kidney committee emphasized the need for a coordinated, strategic effort to address intersecting factors and define efficiency goals in building a CD framework. For example, emphasizing placement efficiency could more highly prioritize efficiency within the CD framework. A member agreed, highlighting the importance of addressing non-use more directly, understanding the distance kidneys travel, improving allocation pathways for hard-to-place organs, and tackling fundamental limitations in infrastructure (e.g., courier limitations and airport closing times). To support improving this, it was suggested to capture metrics to understand logistical impacts, consider variances that correspond allocation difficulty with transportation capacity based on geography, and shared decision-making supported by navigable patient discussions.

A member shared their concerns over the impact of biopsy requirements on organ acceptance, challenges in transportation hindrances, concerns about pumping and not pumping, and the need for cultural competency in information dissemination. They felt that there were increased requirements for procurement, which in turn would make it easier for programs to refuse the organ if that information were missing or lacking.

Recommendations from the Committee also included expanding offer filters, evaluating different candidate groups, and establishing an accountability process for programs turning down organs late. These recommendations, it was felt, would help the balance between standardization and flexibility in organ allocation processes; a member supported the need for a system-supported decision-making approach to determine the trade-off between conventional allocation and expedited placement when allocating medically complex organs. A second member agreed, emphasizing the difficulty in assessing the overall benefit to the system when various committees approach expedited allocation differently, especially within CD. Members also emphasized the importance of shared decision-making between the OPTN and its members, particularly in cases where local knowledge plays a crucial role in organ placement. These cases spotlight the complexity of the process which is made more so when the organ is medically complex, the pressure to find suitable organ placements, and the changing nature of organ recovery.

The impact of the Centers for Medicare and Medicaid (CMS) pressure on Organ Procurement Organization (OPO) certification and the need for shared policies to align with both UNOS and CMS requirements was discussed, considering the challenges faced by transplant teams in meeting certification deadlines.

A member proposed discussing staffing approaches to improve organ placement, but members felt that one approach would not be universally applicable for each program and may only temporarily solve the problem.

The Committee considered lung continuous distribution. The Vice-Chair of the Lung Committee shared the challenges faced by lung transplant programs with the implementation of the continuous distribution allocation system; specifically, the decrease in overall efficiency, significant increases in the number of organ offers, and changes in travel distance. A member suggested the formation of a long allocation efficiency work group, with a goal to address short-term and long-term efficiency issues. They hypothesized that a key metric for evaluation could be the number of offers sent after the final acceptor. Another member considered other proposed solutions, such as the creation of offer filters, updates to offer notification limits, changes to required lung donor testing, and modifications to donor acceptance criteria. They emphasized the need for collaboration and data collection to inform future lung offers.

A member shared concerns regarding the impact of slowing down offer rates, the availability and necessity of donor testing data, and the challenges of multi-organ allocation. They felt that filters would diminish the overall offers available, thus reducing the number of transplanted organs. In addition, it may breed further confusion for multi-organ candidates who are filtered off the kidney match run.

A question was raised about the increase in travel distances despite the 250-mile allocation limit in the continuous distribution system. A second member explained that the difficulty was in offering to programs that were on different sides of the circle and may not have considered the offer. In the previous system, programs often had candidates adjacent to one another and would be able to streamline organ evaluation efforts for multiple potential recipients. This was felt to be a cause of the inefficiency noted in the Lung monitoring report. However, the Vice-Chair of the Lung Committee acknowledged that while the system is logistically challenging, continuous distribution has shown a decrease in mortality on the waitlist.

The discussion touched on the need for increased staffing resources, the difficulty in hiring experienced coordinators, and the overall stretched nature of the system. A member shared the sense of panic during allocation due to the urgency of identifying recipients for organ offers, considering it one of the primary reasons that organs are allocated out of sequence.

The Vice-Chair provided an update on the Liver and Intestinal Organ Transplantation Committee's progress, focusing on efficiency and equity attributes such as travel efficiency, utilization efficiency, and geographic equity. They outlined the goals, attributes, and metrics for placement efficiency, discussing their committee's approach to measuring success and its efforts to incorporate population density circles. They emphasized the distinction between the committee's efforts in the allocation system and their value addition to the efficiency task force.

In addition, they acknowledged the challenges in defining medically complex liver grafts and noted ongoing collaboration with MIT for rate-based optimization, especially given the promotion of efficiency within allocation. They noted, again, the use of population density circles for geographic equity, recognizing potential inaccuracies in supply and demand metrics.

Members expressed curiosity about population density circles and the importance of considering the broader population beyond the waiting list. The Vice-Chair noted the need to balance allocation policies to prevent unintentional exclusion of patients, especially when considering socio-economic factors.

The Vice-Chair of the Liver and Intestines Committee replied and agreed with the inclusion of socio-economic factors in the committee's future plans.

The Vice-Chair of the Heart Committee provided an overview of the progress on the heart continuous distribution project, acknowledging that the heart is one of the later organs in the continuous distribution effort. They shared positive public comment feedback on the transition to continuous distribution but noted mixed opinions on introducing post-transplant survival as an attribute in the first iteration. Additional considerations noted were adding attributes related to size matching for pediatrics, demonstrating severity of clinical condition, and geographic equity.

There were also comments urging faster changes to pediatric heart statuses and reinforcing the need to address logistical challenges to avoid late turndowns.

They updated the Committee on their work to simplify blood type rating scales and proposed changes to the sensitization scale, such as including a logarithmic scale. This work is being performed in conjunction with efforts to develop a medical urgency scale, focusing on both adult and pediatric patients, and emphasized the need to transition away from specific statuses to allocation points. Staff shared data on waitlist outcomes related to heart support status and mortality, highlighting correlations that inform the development of a logarithmic scale for medical urgency.

Highlighting the emphasis placed on efficiency, especially within the context of kidney continuous distribution, they assured the Committee that they were reviewing efficiency considerations for heart continuous distribution. They acknowledged the complexity of the topic and required any insight from kidney discussions on the topic.

A member expressed concern at the decision against including post-transplant survival in the initial model, highlighting its potential impact on continuous distribution overall. They worried about the accuracy of models predicting post-transplant survival, noting the heavy weighting toward patient age at 5 years. The vice-chair acknowledged the massive change in the heart distribution system, but they and their committee felt it better to avoid breaking the system by changing too many variables simultaneously than try to address all issues in the first iteration.

The member agreed that fixing all problems within the first iteration was unreasonable, but still shared concerns over the medical urgency part and removal of waiting time as a major contingency. The vice-chair suggested seeking insights from lung distribution on concrete variables impacting post-transplant survival. They also recognized the challenges in balancing medical urgency, access to care, and post-

transplant survival for specific patient groups like those with congenital heart disease or pre-sensitized patients.

Next steps:

The committees developing continuous distribution frameworks will continue to provide updates and seek input where required from the Committee.

3. Efficiency Group Report-Outs

Members heard from the Efficiency Task Force and discussed potential next steps in small groups surrounding specific themes.

Presentation summary:

Staff shared updates on the Task Force, emphasizing an innovative approach, collaboration with experts, and leveraging human-centered design, behavioral science, and systematic approaches. Emphasis was placed on the need for real-time feedback from the community and leveraging existing opportunities, such as conferences, to engage stakeholders. In addition, the Task Force plans to involve collaborative improvement staff and integrate effective practices from previous collaboratives in their work. This could include the potential for additional workshops, aiming to leverage existing gatherings within the organ transplant community.

A request was made of the Committee on recommendations for spaces or events where the Task Force could effectively engage with the community.

The themes identified for small group discussion were:

- Organ non-use data
- DonorNet
- Offer Filters
- Virtual Crossmatches
- Late Declines
- Other Themes:
 - Provisional Yes, Predictive Analytics, Multi-Organ Policies, Donor Evaluation, Safety Event Efficiency, Travel Efficiency

Members were asked to find three specific items within these areas to prioritize.

Summary of discussion:

No decisions made during this discussion.

A member inquired about the role of the task force in policy generation, emphasizing the need for updates and communication channels between the task force and individual committees. Staff replied that committees would still be responsible for policy generation, but the Task Force may provide recommendations for areas of focus. A member appreciated this response and shared their hope for a collaborative process between the task force and committees, where information and insights from task force engagements can support policy creation within committees.

A second member highlighted the importance of clear communication between the task force, executive committee, and board to ensure alignment with the strategic plan. Staff agreed.

A concern arose about potential overlaps between committees and duplicating work efforts. Staff replied that the task force will not engage in collaborative or focus groups for specific recommendations on an issue but will instead focus more on operational improvement and best practice sharing.

Staff acknowledged the need for community engagement beyond major national conferences, suggesting forums for specific subgroups to ensure diverse representation. They requested any information on where those spaces may be.

The discussion concluded by encouraging feedback from the Committee on new projects and how they fit into the broader goals and resourcing of the organization.

Group 1 report out

The discussion revolved around late declines and standardizing definitions of various stages in allocation. In addition, they also considered offer filters to improve placement efficiency, and utilizing the recovery and usage maps (RUM) report for accountability. Members of this group felt that the RUM report would help detail how allocation practices vary depending on program-specific practices.

Group 2 report out

The second group emphasized non-use and non-utilization, questioning the usefulness of current utilization metrics, and discussing the need for defining appropriate non-utilization rates. Specifically, what measures are nuanced enough to reflect the variance in organ quality when compared to outcomes, and how should the monitoring be structured to reflect that 100% success rate means a program is not pursuing enough organs.

Group 3 report out

The third group highlighted organ non-use as a major concern, discussing the need for defining late declines, creating an expedited placement pathway, and exploring reasons for organ discards. A member noted a proposed study aims to gather more granular information on organ utilization. Additionally, virtual crossmatching was identified as low-hanging fruit for efficiency improvement, but regulatory and reimbursement issues were noted.

Next steps:

Staff will compile the recommendations and share them with the efficiency task force.

4. Multi-Organ Transplant Policy Updates

Presentation summary:

The Chair of the Multi-Organ Transplant (MOT) Committee shared updates on the conversations they had been having regarding required and permissible organ sharing and the document they intend to send out language for public comment review.

- The MOT Committee focused first on equity, especially for pediatric and multi-organ transplants, but this led to concerns of reduced efficiency in allocation.
- There are issues with multi-organ transplants like lung-liver delaying allocation of livers and kidneys. Centers now allocate only to a certain point on multi-organ lists before moving to single organs.
- Proposed policy changes try to address this by allowing single organ allocation once the surgery order is set, even if it means not giving multi-organ patients higher priority.

- There was a proposal to allocate one kidney from donors to multi-organ/pediatric and one to single-kidney recipients, but objections were raised.
- The committee seeks public comments on further improving efficiency without sacrificing equity across different patient groups in need.

Summary of discussion:

No decisions made during this discussion.

One member noted that there remains a lack of clarity on specific goals or changes to implement, even with the many conversations the MOT committee has had to explore various policy changes. Open questions persist regarding which patient groups should receive priority and in what organ combination scenarios.

Several members agreed on the need to engage the public for comment soon. As suggested by one member, a document outlining concrete options and examples could aid the public in providing meaningful feedback to help guide policy decisions. However, the MOT committee must first decide on the scope and fundamental priorities. For instance, there were disagreements over incorporating considerations for kidney-pancreas (KP) patients into current efforts. As observed by a couple of members, larger unsettled issues exist regarding KP alignment with the new continuous distribution allocation system presently on pause.

The Vice Chair highlighted issues with lung allocation impacting multi-organ transplants when donor organs initially seem available. Often lung is allocated last, but then a liver or other organ becomes committed. A member noted resulting challenges for OPOs in balancing following allocation rules with transplant center timelines when late multi-organ offers occur. Clear guidance could assist with these logistical difficulties.

In conclusion, the path forward remains unclear even to committee members themselves until fundamental priorities and key questions to address are decided upon. Imperfect initial decisions on issues like prioritizing organ combinations and sequencing will need to occur before meaningful public input can help shape balanced policy changes. But broader representation from relevant transplant communities also appears needed to settle open questions.

Next steps:

The Committee will hear further updates about the MOT committee's progress.

5. New Project Review: OPO Performance Enhancements

Summary of discussion:

Unanimous support of the new project:
14 approve, 0 abstain, 0 object.

Members reviewed the project form and answered questions on a RedCap survey relating to the potential benefit of this project.

Next steps:

The project will progress to the public comment stage for feedback from the transplant community.

6. Open Discussion

Summary of discussion:

A member asked for clarification about the question on the RedCap survey which reflects the policy priority of equity between multi-organ and single-organ candidates. Despite frequent discussions on the matter at regional meetings, this member has observed a shift away from this topic. They suggested informing the community about any changes or adjustments in the organization's approach. The Chair responded, stating there has not been a conscious decision to move away from the issue. However, the member referred to a previous meeting where a shift towards efficiency was mentioned, prompting their question on what had replaced the focus on equity. The Chair acknowledged the need to address this concern and proposed regrouping with the Multi-Organ Transplantation Committee to develop a more cohesive approach to the policy priorities.

Upcoming Meetings

- November 9, 2023
- December 14, 2023
- January 11, 2024

Attendance

- **Committee Members**
 - Nicole Turgeon
 - Jennifer Prinz
 - Erika Lease
 - Lisa Stocks
 - Arpita Basu
 - Ty Dunn
 - Lori Markham
 - Molly McCarthy
 - Sanjay Kulkarni
 - Kim Koontz
 - Peter Stock
 - Vijay Gorantla
 - Jason Huff
 - Scott Lindberg
 - Stevan Gonzalez
 - Scott Biggins
 - Oscar Serrano
 - Matt Hartwig
 - JD Menteer
 - Christine Brenner
 - Stephanie Pouch
 - Jesse Schold
 - Rachel Engen
- **HRSA Representatives**
 - Marilyn Levi
 - Shelley Grant
 - Vanessa Arriola
- **SRTR Staff**
 - Ajay Rasani
- **UNOS Staff**
 - Cole Fox
 - Lindsay Larkin
 - Stryker-Ann Vosteen
 - Roger Brown
 - Ann-Marie Leary
 - Leah Nunez
 - Gabrielle Hibbert
 - James Alcorn
 - Kim Uccellini
 - Krissy Laurie
 - Laura Cartwright
 - Sharon Shepherd
 - Laura Schmitt
 - Kaitlin Swanner
 - Kristina Hogan

- Taylor Livelli
 - Meghan McDermott
 - Susan Tlusty
- **Other Attendees**
 - John Lunz