

**OPTN Board of Directors
Meeting Summary
November 29, 2023
Webex**

**Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, President
Richard Formica, MD, Vice President**

Introduction

The Board of Directors met via Webex on 11/29/2023 to discuss the following agenda items and public comment items:

1. Welcome & Announcements
2. Data Advisory Committee Report to the Board
3. Policy Oversight Committee Report to the Board
4. Executive Committee Report to the Board
5. Membership and Professional Standards Committee Report to the Board

The following is a summary of the Board of Directors discussions.

1. Welcome & Announcements

Dianne LaPointe Rudow, OPTN President, welcomed the Board to the meeting and presented the agenda for the meeting.

2. Data Advisory Committee Report to the Board

Sumit Mohan, Chair of the Data Advisory Committee (DAC), presented the report on behalf of the committee. Dr. Mohan shared that the objective of the committee's presentation was to highlight the DAC's work over the past year and share the key takeaways from the OPTN data quality report. He noted the importance of the OPTN data registry, the Board's prioritization in data quality initiatives, reducing barriers to electronic data submission, and maturing data governance and data sharing. Dr. Mohan stated that the presentation would also share the committee's short and long-term recommendations to the Board.

Dr. Mohan presented the highlights of the data review report. He detailed the summary of OPTN data changes that occur within the different OPTN committees and are required go through OMB approval.

Dr. Mohan highlighted challenges the DAC experiences related to data quality reports. He noted that some of these challenges include discrepancies in data, data quality, and the cadence of data changes.

Dr. Mohan reminded the Board that the OPTN Data Registry impacts operational workflows, is utilized for medical research and practices, and that the registry should conform to clinical data and interoperability standards. He explained that clinical data standards are essential to achieving reliable and accurate information exchange. When discussing the impact of the data registry on operational workflows, he noted that data quality is important because it drives operational workflows. He explained that the OPTN community utilizes the data to benchmark performance and improve clinical practice. Dr. Mohan noted the potential impact data quality can have on OPTN members and on the government stakeholders. Dr. Mohan discussed the desire for new capabilities related to data entry,

abstraction, and reporting, and to focus on information that is needed for transplant care, such as decision support and health promotion.

Dr. Mohan shared information on member interest in OPTN data and how transplant centers are using OPTN data to inform their own clinical practices, choice of protocols, and benchmarking performance. He shared that the demand for OPTN data has increased since the implementation of self-service tools. He noted that recognizing the value data has to individual transplant centers who contribute to the data underscores the importance of the self-service tools and the value of the data.

Dr. Mohan shared that prioritizing data quality initiatives is important and shared how the OPTN can improve data quality. Dr. Mohan stated a need to standardize data elements across organ types, adopt health IT standards and prioritize on the technology roadmap, continuously assess community readiness and priorities, invest in skilled resources to improve data collection, and establish a unified view of a patient record such as consolidating data from different external sources. He emphasized that improving the registry requires engagement of broad expertise.

Dr. Mohan presented on reducing barriers to electronic data submission and noted the interoperability between members and the OPTN Computer System, and the OPTN's need to meet these standards. Dr. Mohan noted the need for continuous improvement and the ability to monitor the data and understand the needs of centers. This implementation should improve time, accuracy, and lower the burden of data collection. Dr. Mohan stated that the OPTN's algorithms depend on the data that the OPTN has and data is utilized by regulators evaluating the status of the system, not just by member type. He emphasized that OPTN data needs to be a well-funded resource within the OPTN and that the DAC recognizes this ongoing effort. Dr. Mohan encouraged the Centers for Medicare & Medicaid Services (CMS) and the Health Resources and Services Administration (HRSA) to share data and have data use agreements (DUAs) in place that allow the OPTN to do more and to act more efficiently.

Dr. Mohan shared recommendations from the committee on improving OPTN data quality. He shared that in the short-term, the DAC suggests the OPTN explore what is causing the unlocking and editing of data, consider innovative ways to test data, rethink data collection principles, consider what the OPTN desires from the data registry, and consider the future role of the DAC. He stated that the OPTN needs to consider opportunities for more efficient data capture. Dr. Mohan stated that in the long-term, the DAC would like support from HRSA and the OPTN Board by committing resources for the contractor to implement and sustain clinical data standards within the OPTN Computer System.

Summary of discussion:

A Board member asked about trends within data locking and unlocking. Dr. Mohan explained that the majority of the changes were made when forms were unlocked were made in the direction of an increased risk adjustment.

A representative from HRSA stated that HRSA supports the contractor exploring a path to move the OPTN data from the current structure into a different structure that will allow data to be shared more consistently. They stated that the DAC may need to make recommendations to the Board on where the committee observes a need in the system and bring their formal recommendation to the Board. Dr. Mohan explained that this will require resources and a timeline, and that the quality of the data is essential to all aspects of the OPTN.

A Board member stated that one way to achieve better data will be through API adoption. Dr. Mohan shared that APIs and utilizing electronic medical records (EMRs) can pose a significant burden for transplant centers, and there is a desire for EMR companies to standardize collection. He noted that

conversations with CMS about data capture and standardization could be beneficial in accelerating the adoption of API usage.

A Board member enquired if the DAC considered opportunities in improving donor referral data. The Board member stated that there is a gap in donor referral data, which presents an opportunity for APIs between transplant hospitals and the OPTN to obtain more information about the availability of donors. The Board member suggested the DAC consider this gap in their future work to better connect transplant hospitals with the donor pool.

A Board member enquired about best practices to standardize data entry while encouraging the utilization of APIs throughout the transplant community. Dr. Mohan referred to other data registries that the OPTN could utilize in improving the OPTN data registry and that partners at HRSA and CMS could assist in encouraging transplant centers to invest in technology that is necessary for standardizing data.

A Board member asked about the cost associated with changing data practices and if the DAC considered how members would fund these changes. Dr. Mohan shared that some data collection is already paid for through organ acquisition. He also stated that data capture is important in understanding what is happening to patients throughout the transplantation process.

The DAC Vice Chair discussed data that is collected outside of the field of transplant still touches transplant patients, and the committee is looking to leverage this data. They mentioned how important the OPTN's partnership with HRSA and HHS could be in utilizing this data to improve care.

3. Policy Oversight Committee Report to the Board

Jennifer Prinz, Chair of the Policy Oversight Committee (POC), presented the committee's report to the Board. Ms. Prinz shared that the POC's presentation will detail the committee's role in the policy development process, the project review process, project portfolio evaluation, the strategic policy priorities, and the policy development process metrics.

Ms. Prinz shared that the POC's role in the policy development cycle is to review OPTN committee projects, evaluate the OPTN project portfolio, and develop and assess progress on the policy priorities of the OPTN. She explained the three points at which the POC engages with projects: project approval, public comment, and post-implementation review. Ms. Prinz explained the project approval process, and noted that the committee has reviewed and recommended approval on four projects since June 2023. Ms. Prinz explained the public comment approval process and shared that the POC previewed, reviewed, and recommended fourteen projects for summer 2023 public comment.

Ms. Prinz then explained the post-implementation evaluation process and shared that the post-implementation monitoring subcommittee was created in 2022 to help standardize post-implementation review. Ms. Prinz shared that the subcommittee has formalized their review process and identified which projects need to be reviewed and the criteria by which to review them. Ms. Prinz presented the POC's project portfolio evaluation process, which is utilized to ensure projects maximize benefit to the community, increase sequencing, and enhance future planning capabilities. The POC also utilizes a project benefit scoring metric, cost-benefit analysis, project bundling, and continues collaboration with the Membership and Professional Standards Committee (MPSC).

Ms. Prinz presented the project work and strategic policy priorities that are recommended by the POC to the committees. She reminded the Board that the priorities are: continuous distribution, more efficient donor/recipient matching to increase utilization, and improved equity for multi-organ and single organ candidates. Ms. Prinz noted that the committee has considered the recommendations from the NASEM report on system improvements, projects developed to address this priority, future collaboration

between the POC and the Expeditious Task Force, and other ways the committee can ensure efficiency efforts are prioritized. Ms. Prinz shared requirements noted in the OPTN Contract and noted that the POC analyzes 17 policy development metrics, and shared the metrics and their progress to date.

Summary of discussion:

A Board member asked how the new 2024-2027 OPTN Strategic Plan may impact the work of the POC. Ms. Prinz shared that the POC evaluates projects in relation to the OPTN Strategic Plan and with a new strategic plan there is an opportunity for the POC to act more efficiently and effectively in aligning policy projects. Maureen McBride, OPTN Executive Director, commented that the new strategic plan will not have weights associated with each goal in order for the OPTN to have more flexibility. The Board discussed ways the POC could become more selective in their project approval process and how the POC should prioritize effort. Some Board members suggested developing a decision matrix that could assist with project prioritization.

4. Executive Committee Report to the Board

Dianne LaPointe Rudow, Chair, presented the report from the Executive Committee. Dr. LaPointe Rudow reminded the Board of the Executive Committee's purpose to develop and assess progress of the OPTN Strategic Plan, consider emergency or clarifying policy actions, approve OPTN comment on federal or national issues, approve public comment documents for release each cycle, consider urgent member actions, and take action on new OPTN projects. She noted that the Executive Committee is empowered to take action on behalf of the Board of Directors in between meetings.

Dr. LaPointe Rudow shared that since June 2023, the committee has approved three new OPTN projects. Dr. LaPointe Rudow then shared the fourteen public comment items that were approved for the Summer 2023 Public Comment cycle.

Dr. LaPointe Rudow presented the strategic planning process to-date and the work of the Executive Committee since June 2023 in developing the 2024-2027 OPTN Strategic Plan. She shared that the first step in the strategic plan development process occurred at the June 2023 Board meeting when a brainstorming session was held to consider the next goals of the OPTN. Then, during the summer 2023 regional meetings, community feedback was sought on ideas for the next strategic plan, while the Executive Committee worked to draft a framework for the new plan. Dr. LaPointe Rudow shared that next, the committee will submit the plan for Winter 2024 Public Comment, and after public comment, the Executive Committee will consider feedback and finally, the full Board will take action on the plan during the June 2024 Board of Directors meeting. Dr. LaPointe Rudow shared that the committee focused on goals that are intentionally broad and ambitious, high-level outcomes and achievements to serve as guideposts for decision making, and resource allocation to inform the development of more specific actions. She shared that the three draft goals for the 2024-2027 OPTN Strategic Plan are improve offer acceptance rate, optimize organ use, and enhance OPTN efficiency.

Dr. LaPointe Rudow presented on the development of the Expeditious Task Force. She shared that in the summer of 2023, discussions among the Board and other stakeholders guided initial planning and the creation of the task force. Dr. LaPointe Rudow shared that in October 2023, the composition of the task force was finalized, and volunteer appointments were made. During this time, communications and outreach were performed to the community. She shared that in December 2023, the task force will meet in-person to continue discussions on bold aims and a variance proposal. Dr. LaPointe Rudow shared that in 2024, the Executive Committee will continue to work closely with the Expeditious Task Force.

Dr. LaPointe Rudow shared that planned work for the Executive Committee in 2024 includes considering Winter 2024 Public Comment items, continuing collaboration with the Expeditious Task Force, and continuing work on the next OPTN Strategic Plan.

Summary of discussion:

A Board member enquired how the implementation of HRSA's Modernization Initiative and use of multiple vendors may affect the OPTN Strategic Plan. Dr. LaPointe Rudow explained that based on conversations between Board Leadership and HRSA Leadership, there will be a clear transition with a new contractor, and contractors will be required to support the strategic plan the Board has approved. Dr. LaPointe Rudow also stated that it is the job of the OPTN Board of Directors to ensure the contractor or contractors follow through the plans and goals set within the OPTN Strategic Plan. A representative from HRSA commented that the contractor or contractors must support the Board and what the Board is trying to accomplish.

5. Membership and Professional Standards Committee (MPSC) Report to the Board

Scott Lindberg, Vice Chair of the Membership and Professional Standards Committee (MPSC), presented the MPSC's report to the Board. Dr. Lindberg shared that the update from the committee would include updates on committee projects, policy improvement, increasing public disclosure, monitoring activities, and improvement activities.

Dr. Lindberg shared the projects the MPSC has been working on to address transplant program performance monitoring. He noted that the MPSC previously monitored programs by outcomes, however, the MPSC is seeking to take a more balanced approach. He noted that one of the MPSC's first efforts was to monitor programs and analyze pre-transplant outcomes and post-transplant outcomes. Dr. Lindberg explained that the MPSC split outcomes into 90-day graft survival and 1-year graft survival conditional on 90-day survival. He noted that there are different patterns for graft and patient loss in the very early period after transplant, as compared with the period after transplant. Dr. Lindberg explained that the MPSC implemented these standards after the Board approved the new monitoring metrics. Dr. Lindberg noted that the third metric the MPSC implemented was the offer acceptance rate ratio which pertained to pre-transplant metrics. He noted that this data is collected for one year to analyze program acceptance in relation to other programs across the country. The MPSC has chosen to include this metric to encourage improved waiting list management activities and incentivize more aggressive offer acceptance practices. Dr. Lindberg noted that the last metric that will be implemented in July 2024 and focuses on the pre-transplant mortality rate ratio. Dr. Lindberg explained that the MPSC balanced both pre-transplant and post-transplant metrics and analyzing these metrics before and after transplant is important in evaluating a program more holistically.

Dr. Lindberg explained that the MPSC believes there this is an important enhancement to programs from a patient-centered perspective. He noted that the metric will be a risk adjusted model and the SRTR is calculating the per patient risk while analyzing multiple factors.

Dr. Lindberg presented the MPSC's monitoring activity over the last three SRTR report cycles and noted that the metrics have stayed relatively consistent over the last three cycles. Dr. Lindberg presented transplant performance resources, including the OPTN Performance Metrics Toolkit and the OPTN Post-Transplant Graft Survival Dashboard.

Dr. Lindberg shared the new OPTN MPSC Transplant Metrics Dashboard and noted that the tool is available by the OPTN and is informed by the work of the MPSC. Dr. Lindberg noted that the dashboard utilizes data on outcomes and provides a forum for programs to easily understand the information. The

MPSC has looked to include tools for programs to visualize their own data and understand where opportunities lie in their program's performance.

Dr. Lindberg presented the MPSC's efforts on allocation monitoring and noted that the MPSC observed a large increase in allocations out of sequence (AOOS) and began targeted review of how AOOS are monitored. He explained that the MPSC's Allocations Review Subcommittee has been evaluating data to identify potential improvements to monitoring and inform recommendations for policy and data collection. Dr. Lindberg explained that the MPSC is analyzing allocations out of sequence to better understand why they happen and how to correct them. Dr. Lindberg shared events that AOOS often coincide with and that the MPSC determined that in most instances individual AOOS seem appropriate to ensure organs are successfully transplanted. Dr. Lindberg stated that the MPSC would like to capture AOOS in policy and have a strong policy for late turndowns, as almost half of AOOS donor organs involve a turndown.

Dr. Lindberg shared how the MPSC is evaluating potential changes to OPO performance monitoring. He acknowledged the new OPO performance metrics enacted by CMS and how the OPTN needs separate metrics from CMS, however the metrics should be complimentary. Dr. Lindberg shared that the OPTN has a unique role due to its regulatory role over OPOs and transplant centers, and their more focused measures of the donation process contribute to CMS' donation and transplantation rate. Dr. Lindberg shared that the desired OPO performance metrics from the MPSC will measure OPO activities that are clearly within OPTN authority, include metrics that OPOs can impact and are responsible for, and have a clearly desired outcome while also being risk adjusted. He noted that standardizing critical OPO processes and consistent data definitions are essential to improve member performance, effective data collection, and efficiency of the system. Dr. Lindberg explained that the MPSC is considering developing a committee to analyze standardization of critical processes by potentially submitting a data collection tool and submitting a white paper during a future public comment period.

Dr. Lindberg shared that the MPSC will submit a concept paper for the Winter 2024 public comment cycle to receive feedback on the data requirements for collecting potential donors and donor referral data in the OPO electronic donor record (EDR) systems. He noted that the concept paper would collect data through a module in the OPO EDR that incorporates logic, standard processes, and consistent definitions for essential data points for the referral to authorization phases of the donation process.

Dr. Lindberg presented that the MPSC has been analyzing ways to improve quality across the system and has developed recommendations for policy improvements. He noted that most policy proposals do not fall under the authority of the MPSC, however, the MPSC is looking for ways to improve the process. He stated that the MPSC may recommend a policy change when the MPSC finds the policy is no longer applicable or lacking necessary elements based on changes in practice, is confusing to members, is difficult to monitor, is difficult to enforce, or can be improved to address known safety or efficiency issues. He shared that recent changes should improve the flow of these recommendations through the policy development process. He noted that the MPSC has been collaborating with the POC to help bridge the gap in authority.

Dr. Lindberg then presented the MPSC's efforts to increase public disclosure. He shared that the MPSC would like to make more information available to the public, and the committee is actively developing pathways to share appropriate information with the community. He explained that there is a large push for more presentations to the community on the actions of the MPSC and their authority. Dr. Lindberg shared that another way the MPSC has worked to increase public disclosure is through community messages from the Chair of the MPSC. He explained that the OPTN Executive Committee granted the MPSC the authority to distribute messages about important findings from MPSC reviews. Dr. Lindberg shared that members have suggested the MPSC provide broader access to MPSC presentations and

provide process maps for events that are reported to the OPTN Patient Safety Reporting Portal. He noted that is still a significant amount of information the MPSC is unable to share publicly due to patient specific details.

Dr. Lindberg then presented the monitoring activities of the MPSC, including performance reviews, compliance reviews, allocation reviews, site surveys, investigations, and membership. Dr. Lindberg explained that half of the MPSC's work is analyzing performance outcomes, and that the number of members flagged for post-transplant outcomes has decreased. Dr. Lindberg explained the compliance review process and that reviews involve more administrative actions and may lead to investigations. Dr. Lindberg then discussed site surveys, noting that they are a tool utilized by the MPSC for member monitoring. He explained that the site survey team is conducting continuous monitoring based on specific triggers in the OPTN Computer System. Dr. Lindberg explained the MPSC's involvement in membership applications and noted that a total of 676 applications were reviewed by the MPSC during 2023.

Dr. Lindberg concluded by noting the improvement activities underway and the MPSC's involvement in these activities. He noted that these activities include individual member focused improvement (IMFI), webinars and member outreach on eGFR waiting time modifications, and offer acceptance and DCD lung transplant collaboratives.

Summary of discussion:

A Board member asked what percentage of AOOS occur after a later turndown. Dr. Lindberg shared that the MPSC is unable to view whether a late turndown has occurred before an allocation out of sequence has occurred because there is no standardized definition on what qualifies as a late turndown.

A Board member asked why the MPSC chose to send the OPO Data Collection Project to Winter 2024 Public Comment as a concept paper and not as a policy proposal because of the delay this would cause in members being able to collect this data. Dr. Lindberg shared that the MPSC desired more community input, and the MPSC is performing other efforts in parallel to strengthen their efforts and understanding.

A Board member enquired if an increase in allocations out of sequence could be connected to allocation policies. Dr. Lindberg explained that based on the MPSC's analysis, there is not one thing that has led to the increase in allocations out of sequence. He noted that the increase in AOOS is likely due to many different factors, and that the MPSC has not been able to identify one root cause.

A Board member asked if the community had observed a higher acceptance rate from transplant programs following the implementation of offer filters. Another Board member encouraged the MPSC to collaborate with the Organ Procurement Organization (OPO) Committee to analyze late turndowns. The Board member commented that the OPO Committee could have insight into the efficiencies and logistics that OPOs experience. Dr. Lindberg agreed that including the OPO and transplant center perspective in the conversation is important to understand late turndowns and multiple committees are collaborating on understanding late turndowns.

A Board member enquired how the MPSC planned to monitor the policy proposal from the Heart Transplantation Committee to Amend Adult Heart Status 2 Mechanical Device Requirements if approved at the December Board meeting. Dr. Lindberg explained that the Heart Transplantation Committee will primarily be responsible for monitoring the policy while the MPSC will monitor it at a program level. A Board member enquired if there is a way for the MPSC to develop metrics for OPO's to highlight the work they are doing well. Dr. Lindberg explained that the MPSC is monitoring OPOs to observe how they are capable of helping them improve and which metrics the OPTN should measure.

A representative from HRSA enquired how the MPSC plans to take action on centers that are noncompliant with the eGFR waiting time modifications due on January 3, 2024. Dr. Lindberg explained that the MPSC will make recommendations to the Board on how to proceed. Contractor staff noted that the OPTN will be inquiring with programs not in compliance on January 4, 2024 and the MPSC will review responses on a program by program basis.

6. Closed Session

The committee met in a closed session.

The meeting adjourned.

Attendance

- **Board Members**
 - Alan Langnas
 - Andrea Tietjen
 - Andrew Kao
 - Christopher Jones
 - Colleen McCarthy
 - Daniel Yip
 - Dianne LaPointe Rudow
 - Emily Blumberg
 - George Surratt
 - Ginny McBride
 - Jennifer Lau
 - Jerry McCauley
 - Jim Sharrock
 - Julie Spear
 - Kelley Hitchman
 - Kenneth McCurry
 - Laura Butler
 - Laurel Avery
 - Linda Cendales
 - Lloyd Ratner
 - Luis Hidalgo
 - Manish Gandhi
 - Mark Barr
 - Maryjane Farr
 - Meg Rogers
 - Melissa McQueen
 - Michael Kwan
 - Nicole Hayde
 - Reginald Gohh
 - Richard Formica
 - Silas Norman
 - Wendy Garrison
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
 - Daniel Thompson
 - Frank Holloman
 - Jacqueline Rodriguez
 - Manjot Singh
 - Suma Nair
- **UNOS Staff**
 - Anna Messmer
 - Betsy Warnick
 - Cole Fox
 - Emily Womble

- Eric Messick
- Jacqui O’Keefe
- James Alcorn
- Krissy Laurie
- Lindsay Larkin
- Liz Robbins Callahan
- Maureen McBride
- Morgan Jupe
- Nadine Hoffman
- Roger Brown
- Ryan Ehrensberger
- Sevgin Hunt
- Sharon Shepherd
- Susie Sprinson
- Tony Ponsiglione
- **Other Attendees**
 - Ajay Israni
 - Jennifer Prinz
 - Jesse Schold
 - Jon Snyder
 - Scott Lindberg
 - Sumit Mohan