

OPTN Board of Directors

Briefing Summary

March 29, 2021

Conference Call

David Mulligan, MD, Chair
Matthew Cooper, MD, Chair

Introduction

The Board met via teleconference on 03/29/2021 to discuss the following agenda items:

1. Transplant Center Performance Metrics
2. Winter 2021 Public Comment Proposals
3. Upcoming Items for Board Consideration

The following is a summary of the Board's discussions.

1. Transplant Center Performance Metrics

Dr. Matthew Cooper introduced Dr. Richard Formica, Chair of the Membership and Professional Standards Committee (MPSC) Performance Monitoring Subcommittee. Dr. Cooper explained that everyone on the Board recognizes there has been much discussion around transplant center metrics. This update will show how the MPSC has focused on developing a more comprehensive system for evaluating transplant centers. The MPSC has begun to discuss ways to make the evaluation process more collaborative, cohesive, and thorough.

Dr. Formica began his update by sharing the overall goals of the performance monitoring enhancement project, noting that there will be a more in-depth update at the June Board of Directors meeting. Dr. Formica explained the components of good metrics, noting that the most important aspect is that the metric used should be understandable to the monitored entity. The MPSC is striving to develop metrics that will be both easy to explain and easy to understand. When considering new metrics, the MPSC anticipates a 3-5 year timeline until implementation. Dr. Formica explained that there are many metrics for which reliable data exists, but many of those are not under the purview of the OPTN or transplant centers cannot reasonably impact the metrics. The metrics should be risk adjusted to avoid the unintended negative consequence of greater organ discard. The MPSC started this project by wanting to shift the frame of reference from "transplant program versus transplant program" to "transplant program versus disease". The proposed metrics are: offer acceptance ratio, waitlist mortality ratio, 90-day patient and graft survival, conditional one-year patient and graft survival, and additional aspirational or experimental metrics (to be determined). Dr. Formica emphasized that the metrics will be iterative, and project needs to emphasize self-monitoring, self-examination, and self-improvement.

One member of the Board commented that they support this project, and noted that the MPSC can only hold transplant centers accountable for the factors that they control. He also suggested that the MPSC continue to share information from improvement projects with the larger community.

2. Winter 2021 Public Comment Items

Dr Mulligan explained that the Board would hear an overview of public comment proposals on today's call. The next opportunity for group engagement will be Board Policy Groups in mid-May. In the interim,

Board members are encouraged to review proposals and reach out to Committee Chairs, Committee staff, and fellow Board members. UNOS Policy and Community Relations staff shared sentiment overviews from public comment, noting that all proposals were either supported or strongly supported at regional meetings. Regional meeting sentiment was based on 1244 sentiment scores. The mean was 3.9 across all proposals. There were also over 200 sentiment scores from patients, with a mean score of 4.6.

There was some opposition on select proposals, but the comments represented a small group when compared to all comments. One Board member inquired about controversial proposals in the past, and UNOS staff explained that the OPTN works towards consensus wherever possible, and the policy development process ensures that input is gathered from a variety of stakeholders.

- 2021-2024 OPTN Strategic Plan – Executive Committee: Dr. Mulligan explained that the Executive Committee focused on streamlining the goals in the plan, moving initiatives from Goal 3 (Promote efficiency in donation and transplant) to Goal 1 (Increasing the number of transplants). Task-oriented initiatives from the 2018-2021 plan were reduced by half in favor of more strategically focused initiatives. The proposal was strongly supported in regional meetings and public comment. There was broad support for the plan, with specific support for Goal 1. The plan was supported by various policy development committees. The Patient Affairs Committee requested that the document be made more user-friendly by explaining acronyms. There were comments that the metrics should remain patient centered, while focusing on efficiency and innovation. Following the presentation, one Board member commented that it is important to emphasize support for living donor transplants.
- Calculate Median MELD at Transplant Around Donor Hospital and Update Sorting Within Liver Allocation – Liver and Intestinal Organ Committee: Dr. James Trotter explained that this is a two-part proposal, including both a calculation change and a sorting update. The calculation change will increase equity by aligning the geographic units used in MMaT calculation with the geographic units used in liver allocation. The calculation change will then require a sorting update. In the current calculation, transplant programs in close geographic proximity can have different MMaT scores and therefore candidates with the same exception diagnoses can have different exception scores. This proposal would calculate MMaT for each donor hospital based on transplants performed within 150 NM of the donor hospital. Additionally, exception candidates will be ranked by time since submission of first approved exception. Dr. Trotter shared that the majority of public sentiment shows support for the proposal, with a minority opposed. Support for the proposal included alignment of geographic units and increased equity. Concerns focused on data related to acuity circles and that the proposal is complicated and hard to explain. There was feedback from the pediatric community that the proposed change may decrease pediatric access to adult donor offers, and the Liver Committee continues to work with this group and anticipates minimal impact on pediatric candidates. Additional data will be presented to the Pediatric Committee on March 30. One Board member asked about using natural lab scores as a tiebreaker, and Dr. Trotter explained that this idea has not gotten a lot of traction. Another Board member asked about pediatric patients, noting that the priority system seems complicated for a small number of patients. Dr. Trotter noted that it may be difficult to address that issue in this proposal.
- Update National Liver Review Board (NLRB) Guidance Documents and Policy Clarification – Liver and Intestinal Organ Committee: The purpose of this proposal is to improve the NLRB based on feedback and experience since it was originally released two years ago. Sentiment for this proposal was overwhelmingly positive with a few comments in opposition. There are no post-public comment changes anticipated.

- **Revise General Considerations in Assessment for Transplant Candidacy – Ethics Committee:** Dr. Keren Ladin explained that this project is a revision of an existing whitepaper to address concerns associated with the use of psychosocial, non-medical criteria in listing evaluations. The revisions will specifically address life expectancy, potentially injurious behavior, adherence, repeat transplantation, incarceration status, immigration status, and social support. The proposal received overwhelmingly positive support with a few comments in opposition. Post-public comment changes include consideration of factors outside of original scope but raised during regional meetings: access to transplantation, financial considerations, disabilities, pediatrics, and the roles of social workers. One Board member asked about stakeholder feedback, and Dr. Ladin shared that the committee has received feedback from AST, ASTS, and many other organizations. A Board member shared that ASTS has additional comments and will meet with Dr. Ladin separately. One Board member asked about the use of quantitative data in this project, and Dr. Ladin noted that this project has illuminated a need for additional data.
- **Clarify Multi-Organ Policy – OPO Committee:** Ms. Diane Brockmeier explained that this proposal is designed to be a first step in addressing multi-organ policies by clarifying policy 5.10.C. The proposal specifically revises the requirements for offering second organs to heart and lung candidates by establishing additional medical criteria. It also expands the required sharing threshold to 500 NM. Public sentiment was positive across the country. In public comment there was some concern about the impact on liver and kidney alone candidates. There were recommendations to include congenital heart candidates (status 4) and include pediatric candidates (lung ages 0-11 and heart status 2). There was broad support for the 500 NM distance the improved clarity for OPOs. Post-public comment changes may include considering additional heart and lung statuses for eligibility of the required allocation of a kidney or liver with the heart of lung. One Board member asked how the committee determined order, and Ms. Brockmeier replied that the committee did not explicitly state if heart or lung should be first. This proposal is a first phase, and additional clarity will be added in future proposals.
- **Modifications to the Deceased Donor Registration (DDR) – OPO Committee:** The purpose of this proposal is to promote consistent and accurate data collection and provide OPO staff with improved direction and clarity when entering deceased donor data on the DDR. This proposal was strongly supported with very little objection to the modifications. There was support for retaining the citizenship question, changes to history of drug use, change to report transfusion volume, removal of recovery date, and collecting more granular information on Chagas and TB. Based on responses to the feedback questions, the committee may align drug use data with DRAI questions, collect more granular information on Chagas, TB, and clinical infection confirmed by culture.
- **Require Notification of HLA Typing Changes – Histocompatibility Committee:** Dr. John Lunz explained that this proposal will require early notification of critical HLA typing changes to prevent adverse events and increase patient safety. The sentiment was generally supportive throughout public comment. There was specific support for OPO discretion in deciding whether a match run should be re-executed. The committee is considering automatic electronic notification and aligning post-procurement timeframes with current OPO timeframes for post-procurement culture reporting.
- **Develop Measures for Heart Primary Graft Dysfunction (PGD) Request for Feedback – Heart Committee:** Dr. Shelley Hall explained that this request is designed to engage the community early in the project timeline. The Committee specifically requested feedback about potential data elements. There was general support for data collection addressing PGD, as long as collection doesn't overburden centers. There was support for collecting inotrope data. There was support for collecting data only when it is clearly associated with PGD. One Board member

asked about predictive heart mass, and Dr. Hall stated that there was general support for including predictive heart mass.

- Update Transplant Program Key Personnel Training and Experience Requirements – Request for Feedback from Membership and Professional Standards Committee (MPSC): Sharon Shepard (UNOS staff) shared that the request for feedback is designed to obtain community input to assist the committee’s consideration of changes to the overall framework used to develop key personnel training and experience requirements. This is part of a broader MPSC review of all membership requirements. Limited feedback was received, but there was general support for changes to the framework. The feedback will be considered in development of future proposals for revision to organ-specific key personnel requirements. The MPSC will collaborate with organ-specific and other stakeholder committees in development of future proposals.

3. Upcoming Items for Board Consideration

Susan Tlusty (UNOS staff) shared that there are additional projects coming before the Board:

- Project to Update Refusal Codes: Originally recommended by the SPC in 2018, the DAC has been reviewing drop down codes for organ refusals. The DAC has solicited feedback from over 12 committees and received over 300 comments through a request for community feedback.
- Clarification on Definition of VCA: This project aims to clarify the definition of VCA, and includes new VCA membership applications.
- Lung Data Fields Special Public Comment: The Committee is modifying data fields to work better with APIs.
- Non-Substantive Clarification of Appendix L: This project removes redundant language in Appendix L regarding hearings and interviews.

The meeting was adjourned.

Upcoming Meeting

- June 14, 2021

Attendance

- **Board Members**
 - David Mulligan, President
 - Matt Cooper, Vice – President
 - Maryl Johnson
 - Robert Goodman
 - Lisa Stocks
 - Mindy Dison
 - Alan Langnas
 - Alexandra Glazier
 - Atsushi Yoshida
 - Celeste Williams
 - Denise Alveranga
 - Earnest Davis
 - James Sharrock
 - Jeff Orłowski
 - Joseph Ferreira
 - Keith Wille
 - Kelly Ranum
 - Laura DePiero
 - Leona Kim-Schluger
 - Marian Michaels
 - Medhat Askar
 - Merry Smith
 - Michael Moritz
 - Pamela Gillette
 - Patrick Healey
 - Pono Shim
 - R. Patrick Wood
 - Randee Bloom
 - Seth Karp
 - Stacey Lerret
 - Valinda Jones
 - William Bry
 - Christopher McLaughlin, HRSA – Ex Officio, Non-Voting
 - Brian Shepard, UNOS - Ex Officio, Non-Voting
- **UNOS Staff**
 - Susan Tlusty
 - Chelsea Haynes
 - Sharon Shepard
 - Susie Sprinson
- **Other Attendees**
 - Shelley Hall
 - James Trotter
 - Richard Formica
 - Keren Ladin
 - Diane Brockmeier

- John Lunz