Introduction

The Membership and Professional Standards Committee met in Chicago, Illinois, on October 16-17, 2018, to discuss the following agenda items:

1. Changes to Hospital-based OPO (HOPO) Voting Privileges
2. CMS Proposal to Lift Unnecessary Regulations and Ease Burden on Providers
3. Collaborative Innovation and Improvement Network (COIIN) Update
4. Member Related Actions
5. Living Donor Events
6. Evaluation of Outcomes Measures Kidney Operational Rule
7. OPO Performance
8. Member Education Opportunities Identified
9. Committee Actions

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

1. **Changes to Hospital-based OPO (HOPO) Voting Privileges**

   Background: The OPTN received a request in February 2018 from the administrative directors of the seven hospital-based OPOs (HOPOs). This request provided reasons for changing the Bylaws to grant HOPOs individual votes on OPTN matters, instead of a single vote that is currently provided for OPOs and transplant hospitals located within the same hospital.

   The MPSC discussed this letter at its next meeting in March and there was general support for making a change and suggested that any changes would need bylaw language that assured separation within the hospital organization between the OPO and transplant programs at the hospital. The chair tasked a work group of the committee with developing a proposal for further consideration. The work group later presented a proposal that the full committee supported and recommended for public comment during August 3, 2018 – October 3, 2018.

   During the public comment period, this proposal received 22 comments on the OPTN website. Comments included input and feedback from the OPTN/UNOS Organ Procurement Organization (OPO) Committee, professional societies, individuals, and regions. The proposal was also presented during a national webinar open to the public on August 6, 2018. All of the commenters voiced support for the proposal as written.

   Of note, the following professional societies provided support for this proposal moving forward to the OPTN/UNOS Board of Directors: the American Society for Histocompatibility and Immunogenetics (ASHI), Association of Organ Procurement Organizations (AOPO), American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), and the American Nephrology Nurses Association (ANNA). All eleven regions considered the proposal on their non-discussion agenda and voted in favor of supporting it.
The Membership and Professional Standards Committee considered this supportive feedback when it met in person on October 16-17, 2018, in Chicago. They voted 35 For, 0 Against, 1 Abstention to send the bylaw proposal to the OPTN/UNOS Board of Directors for consideration during their December 3-4, 2018, meeting.

**RESOLVED, that changes to OPTN Bylaws, Article I: Membership; Appendix B, Membership Requirements for Organ Procurement Organizations (OPOs); and Appendix M: Definitions as set forth below, are hereby approved, effective December 4, 2018.**

### 2. CMS Proposal to Lift Unnecessary Regulations and Ease Burden on Providers

An MPSC work group met on October 16, to discuss reaction to the proposed CMS regulation changes and the full Committee further discussed during its meeting on October 17.

Based on the discussions, the members of the Committee provided the following feedback to the OPTN Executive Committee. The members of the Committee:

- Support the proposed revisions to the CMS regulations and believe it will lead to increased organ utilization leading to better patient access, innovation and cost savings
- Believe that the MPSC’s process of review including working with the program on process improvement will continue to yield positive results for program volume and outcomes.
- Are interested in clarification of
  - The statement that CMS will continue to monitor and assess outcomes through transplant and hospital QAPI programs. What does this mean in practical terms for the program? Will CMS be providing published information/requirements with more detail regarding these reviews?
  - Whether monitoring schedule for CMS surveys of transplant programs will remain the same?
  - Will CMS be using OPTN data as the source of truth or will CMS continue to generate their own data when looking at programs?
  - What circumstances will trigger a review from CMS outside of routine recertification surveys?
  - Are there options available for a program with condition level deficiencies on recertification surveys once the options for mitigating factors applications and system improvement agreements are removed?

### 3. Collaborative Innovation and Improvement Network (COIIN) Update

An update on the COIIN (Collaborative Innovation and Improvement Network) was provided to the Committee during the open session. The update provided a description of the project including the background, structures, and processes deployed for Task 18. Preliminary outcome, process, and relationship measures were shared, and a brief discussion of implications for future collaborative improvement work.

The COIIN project (Task 18) was a three year HRSA funded project from October 2015 – September 2018 focused on reducing risk-avoidance behavior associated with current performance outcomes monitoring for one-year patient and graft survival. The project sought to develop and test an alternative, data-rich quality monitoring framework, supporting a collaborative approach to performance improvement. The primary aim of the project was to increase the utilization of moderate-to-high KDPI kidneys. This aim was chosen due to the increase in kidney discards over subsequent years.
The project used a collaborative improvement framework developed by the Institute for Healthcare Improvement (IHI) called the Breakthrough Series Collaborative Model in which participants “all teach, all learn”. COIIN focused on identifying Practice Model Organizations who were high accepters of moderate-to-high KDPI kidneys while maintaining favorable patient outcomes. From these organizations, the team developed an effective practice guide called the Intervention Guide for enrolled participants to test using Plan-Do-Study-Act cycles of testing and learning. Project staff provided performance improvement support during the project including conference calls, learning webinars on specific practices, and a virtual learning platform with data transparency, discussion boards, resources, and workspace. Two groups of hospitals were recruited and selected. Cohort A had 19 transplant centers and participated in improvement cycles from January – September 2017. Cohort B had 39 centers and participated in improvement cycles from October 2017 – June 2018.

The project tracked a balanced scorecard of measures including outcome, process, and relationship measures. Preliminary results on transplant rates for Cohort A and Cohort B when compared to centers not participating in COIIN show that Cohort A increase their transplant rate significantly during their participation when compared to the time period prior to joining COIIN. Cohort A saw 14 of 19 centers increase their 50-100% KDPI transplant volumes during COIIN compared to the time period prior. Cohort B saw 22 of 39 centers increase their 50-100% KDPI transplant volumes during COIIN compared to the time period prior to their participation. Other highlights include:

- 33 of 58 centers increase their overall deceased donor volumes
- Cohort A increased their deceased donor volumes by 15%; Cohort B by 3%
- Cohort A increased their 50-100% KDPI volumes by 20%; Cohort B by 9%
- Cohort A increased their acceptance rates by 29%; Cohort B did not appreciate a change

Preliminary process results for Percent Active Candidates on the waitlist showed a decrease for Cohort A and no change for Cohort B. This was particular to the interventions centers worked on. Some centers focused on converting inactive patients to active, while others focused on reducing their waitlist to ensure transplant readiness. The same results were seen for percent candidates consented for high-KDPI. Cohort B did not see a change in median length-of-stay, where Cohort A saw a 1-day increase for high-KDPI transplants (four to five days).

Similarities and differences between the cohorts were discussed. The size of each cohort, entrance criteria, and time periods were different for each. Additionally, this was not a research study, but a quality improvement project.

Relationship results were shared based on Relational Coordination survey results. There were not statistically significant changes in Relational Coordination scores pre- and post-COIIN involvement. Additionally, there was no correlation between high scores and outcomes for patient, graft survival, nor organ and offer acceptance rates. This was likely due to low response rates.

Feedback survey results were shared in which 85% of Cohort A respondents and 60% of Cohort B respondents stated that their center transplanted more moderate KDPI kidneys. When asked if their teams changed their perception on moderate-to-high KDPI kidneys as a result of COIIN, 95% of Cohort A respondents and 80% of Cohort B respondents agreed.

Key factors that contributed to collaboration and potential success were shared. Each cohort ranked the following elements as integral to their work in COIIN: in-person kick-off meetings, the virtual learning site (CLASS), and collaboration with other centers. These factors, in addition to
data transparency, resource sharing, testing and learning, and support from Subject Matter Experts (SMEs) are recommended for future collaborative work.

There were no questions following the presentation of preliminary results. One committee member recommended that well-thought-out study design that mirrors research should be considered to evaluate the results. UNOS staff will use this consideration in project design moving forward.

The discussion then moved onto future collaborative improvement work through the work of discovery projects. To spread the effective practices, the team would like to launch a national collaborative with the learnings from COIIN to invite all kidney programs to “all teach, all learn”. The staff is currently building a better virtual learning platform for more dissemination and learning, as well as updating the resources, tools, and Intervention Guide used in COIIN.

Key elements of collaboration will be considered in future work. A discussion of the IHI’s Idealized Design phases was discussed as a part of the discovery work for more collaborative improvement projects. This would entail gathering information and research on a topic, evaluating effective practices, building Improvement Guides, and recruiting small groups of organizations to test and learn. This may result in recruiting a bigger group of organizations to further refine learnings, and culminate in a national deployment for more effective spread.

To select projects, UNOS staff are considering questions such as whether projects address OPTN strategic goals, the desire in the transplant community, potential for large-scale impact, achievability within established timeframes, and the ease of evaluation.

Potential discovery projects identified by the previous committee and COIIN Advisory Council include expanding the donor pool, expanding access to transplantation, young adult transition/transfer, increasing DCD liver utilization, OPO efficiencies, increasing heart transplants/reducing discards, increasing DCD utilization, increasing KPD transplants, and increasing ex vivo lung perfusion.

There were no questions following the presentation. The committee vice-chair and a committee member thanked the participating hospitals as well as the staff who worked diligently on the project.

4. Member Related Actions

The Committee is charged with determining whether member clinical transplant programs, organ procurement organizations, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants.

The Committee reviewed the applications and status changes listed below and will recommend that the Board of Directors take the following actions when it meets in December:

- Approve 1 New transplant program in an existing member hospital
- Approve 4 Renewals for non-institutional members

In addition, the Committee reviewed and approved the following action:

- 6 Changes in transplant program and living donor component personnel

The Committee also received notice of the following membership changes:

- 5 Transplant programs and 1 living donor component inactivated
- 1 Living donor component withdrew
- 1 Change in OPO personnel
The Committee reviewed and approved the membership consent agenda
The full Committee also discussed a key personnel change application for a primary heart transplant physician.
In light of questions raised during this discussion the Committee agreed that it should review the board certification exception language in the Bylaws.
The Committee also received an update on the implementation of the new intestine transplant program membership requirements.

5. Living Donor Events
The Committee reviewed 11 total living donor events at its October meeting, including nine aborted procedures one redirected living donor kidney and one donor death. The Committee closed issues with no action, issued a Notice of Noncompliance for late reporting, or requested an informal discussion to gather additional information for these cases.

6. Evaluation of Outcomes Measures Kidney Operational Rule
The Committee received data an update on the results of use of the Outcome Measures Kidney Operational Rule. UNOS Research and the SRTR provided data analysis of whether there has been an increase in the number of high KDPI donor kidneys transplanted since implementation of the operational rule, a comparison of the odds of placing high KDPI kidneys before and after implementation of the operational rule and a comparison of the odds of accepting an offer for a high KDPI kidney before and after implementation of the operational rule. The MPSC requested additional data in the next evaluation of this operational rule and also encouraged additional publicity of the operational rule to the transplant community.

7. OPO Performance
Consent Agenda: The Committee approved the continuation of monitoring of two OPOs and the release of one OPO that were under review for lower than expected organ yield by a vote of 33 Yes, 0 No, and 0 Abstentions.

8. Member Education Opportunities Identified
Throughout its meeting, MPSC members identified the following topics that require follow up and/or should be addressed in through educational efforts in the transplant community:

The MPSC noted that hospitals continue to use donor vessels in non-transplant procedures. The MPSC suggested refreshing the education on the policy requirements and why the restriction is important.

The MPSC suggested that the Living Donor Committee review psychosocial evaluation requirements to see if they are sufficient to evaluate the potential of suicide in donors, and to evaluate how programs assess family support.

The MPSC requested that the Kidney Committee evaluate kidney paired donation policies and how the OPTN can provide oversight of the National Kidney Registry or other KPD programs.

The MPSC encouraged additional publicity for the current kidney outcomes operational rule.

9. Committee Actions
The Committee unanimously agreed that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

RESOLVED, that the Committee accepts those program specific determinations made during the meeting as UNOS recommendations.
FURTHER RESOLVED, that the Committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted 35 Yes, 0 No, 0 Abstentions

Upcoming Meetings

- November 20, 2018, Conference Call
- January 8, 2019, Conference Call
- February 26-28, 2019, Chicago
- July 16-18, 2019, Chicago
- November 5-7, 2019, Chicago