

OPTN Membership and Professional Standards Committee (MPSC)

Meeting Summary

July 21-23, 2020

Conference Call with GoToTraining

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Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call via Citrix GoToTraining on July 21-23, 2020, to discuss the following agenda items:

1. HRSA Introduction
2. Appendix L: Post-Implementation Review
3. Member Quality Strategic Plan
4. SRTR Presentation
5. Performance Monitoring Enhancement Project
6. Membership Requirements Revision Project
7. Update on ABO Verification Project
8. Update on Living Donor Event Project
9. Encouraging Self Reporting of Potential Patient Safety Issues
10. Educational Referrals - Discussion of New Topics

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

1. HRSA Introduction

HRSA provided an overview of the partnership between the Health Resource and Service Administration (HRSA) and the Organ Procurement Transplantation Network (OPTN) and its relationship to the MPSC. They explained that HRSA is the primary federal entity responsible for the oversight of solid organ transplant system in the United States. HRSA regulates the contract that helps guide the OPTN through policymaking. HRSA's oversight is exercised according to statutory requirements, federal regulation, and federal contracts. The National Organ Transplant Act (NOTA) enables the OPTN to do its work and grants authority for the SRTR and UNOS to assist the OPTN. The OPTN Final Rule guides the OPTN's operations and functions. As an operating committee, the MPSC is responsible for overseeing the system, monitoring patient safety, and evaluating compliance. UNOS is required to assist MPSC members in meeting requirements outlined in the OPTN Final Rule. HRSA stressed that this system would not work without the involvement of the members of the transplant community.

2. Appendix L: Post-Implementation Review

The Committee sponsored a proposal to revise Appendix L of the OPTN Bylaws and it went through public comment January 22-March 23, 2018. Appendix L of the OPTN Bylaws details actions that the OPTN, through the MPSC and Board of Directors, may take when OPTN members fail to comply with OPTN Obligations. Appendix L also outlines members' rights when the MPSC or Board of Directors is considering taking certain actions. The Committee intended the change to improve the OPTN review

process and describe the process in a way that is more detailed and easier for members to understand. The Board of Directors approved the proposal on June 13, 2018.

To evaluate whether the changes were successful, the Committee stated that it would monitor whether the changes yield unanticipated consequences, and review data on types of member interactions with the Committee. At the meeting, staff provided a post-implementation update for the MPSC. The Committee has seen an increase in informal discussions with members and a decrease in interviews and hearings. This change in member interactions is what the Committee expected to see based on the Bylaw changes. In addition, the MPSC continues to review and evaluate patient safety risks, and has quickly reacted to issues with members by asking them to perform specific actions to mitigate potential risk. The Committee has not seen an increase in member noncompliance or repeated review of the same members. Staff also gathered information from members and the Committee on the process and benefit of the informal discussions, interviews, and hearings. The responses show that the process changes have been beneficial.

The Committee determined that the proposal had met its objectives and voted 35 Yes, 0 No, and 0 Abstentions to consider this project complete.

3. Member Quality Strategic Plan

An assistant director of Member Quality (MQ) provided a departmental strategic plan update to the Committee, which included an overview of the department and functional areas. The purpose of MQ is to collaborate with members to promote patient safety and system integrity within the transplant community through monitoring and education. The staff displayed a diagram showing how the key functional areas of MQ support the MPSC.

The MQ staff shared that the MPSC was previously seen as the enforcer in the transplant community. In 2015, a strategic approach was taken to transform the MPSC into an improvement partner. These initiatives included the following:

- merging the former department of evaluation and quality with the membership department
- incorporating new leadership with specific skills in quality and performance improvement
- supporting the Collaborative Innovation and Improvement Network (COIIN), a 3-year contract task
- supporting bylaw changes to Appendix L, which allowed the MPSC the flexibility to better support the needs of the transplant community.

The priorities of MQ and the MPSC are to protect patient safety, help members improve, and encourage self-reporting. A primary focus of the department is to change the perception of the MPSC. The MQ staff discussed the potential results of the change in the community's perception of the committee. The change could potentially result in

- added value to members, system, and community as a result of monitoring,
- increased member and volunteer engagement,
- increased self-reporting, and
- lead to OPTN policy making committees having a deeper understanding of the MPSC and its purpose

The staff emphasized the importance of receiving support, suggestions, and feedback from the MPSC.

4. SRTR Presentation

The Director of the Scientific Registry of Transplant Recipients (SRTR) presented the SRTR plans for longer-term post-transplant outcomes reporting. The SRTR plans to integrate five-year post-transplant outcomes into the program specific reports. The transition will include a move to a period-prevalent cohort rather than an incident cohort and a 2-year cohort window rather than the current 2.5-year cohort window. The SRTR can continue to provide the MPSC with 1-year post-transplant evaluations. However, the proposed 2-year cohort window does not align with the current OPTN Bylaws reference to a 2.5-year cohort window. In his presentation, the Director explained the difference between period-prevalent and incident cohorts and provided illustrations of the differences in 1-year post-transplant evaluations in the 2-year period-prevalent cohort versus the current 2.5-year incident cohort. The evaluation shows the 2-year cohort is strongly correlated with the 2.5-year cohort although there is some variability in the hazard ratios for some programs. The new method will allow the SRTR to provide longer-term outcome evaluations if it is of interest to the MPSC. If the MPSC wants to continue to review the 1-year outcomes, the SRTR could still provide the MPSC with 1-year post-transplant outcomes using the period prevalent method. The SRTR could also provide other time ranges if MPSC is interested.

The Director answered questions from Committee members:

- Under the period prevalent approach, if a patient who was transplanted in the last 5 years died prior to the 2-year window, that patient would not be included in the report. The event for that patient would have been recorded in a previous report that included the 2-year period during which the event occurred. The SRTR would be using the most recent 2-year experience to derive the failure rates for the program. SRTR is using this methodology to evaluate longer-term outcomes while attempting to reflect the experience of patients for whom the program is recently providing care rather than assessing events that occurred more than two years ago.
- Post-transplant outcomes reports would still be produced every six months and every sixth month report would reflect a different 2-year interval. As the reports roll forward, the evaluations would catch the events that were in the 2-year window. The patients who died or lost their grafts would fall out because they are no longer being followed but the reports would reflect more recent experience while measuring longer-term outcomes.
- The Director stated that the models would be redeveloped under the new framework but would be adjusted using the same data points currently used including the listing factors and donor factors that were known before the transplant occurred. The SRTR would not include additional data points from the follow-up forms. In that aspect, the modeling is not going to change. The Committee member suggested investigating whether including only pre-transplant information without incorporating data from the follow-up forms would be relevant when looking at 5-year outcomes.
- A Committee member asked how meaningful the measure would be if under the prevalent model, patients have to survive to be included in the 2-year cohort resulting in a measurement of conditional survival, which tends to be quite high even in thoracic transplants. The new model is trying to address the criticisms that 1-year transplant outcomes are no longer of primary concern to the transplant community while also addressing a method to provide the most relevant longer-term data to patients. The Director mentioned that the MPSC may want to consider even shorter-term outcomes, e.g., 90-day outcomes, to evaluate survival during that early period.
- In response to a Committee member question, the Director noted that a determination on how to handle patients whose follow-up care is transferred has not been made.

- A Committee member commented that this method does tend to have conditional bias for the survivors and the event rates would be significantly lower. He suggested that one could consider peri-operative survival for one process including candidate selection, donor selection and execution and then the second process is medical management of the patient from 3 or 6-months post-transplant forward. Looking at the two of them could give a program good information on where the problems are and what processes need work. The Director noted that the SRTR currently provides 1-month outcomes but the numbers are lower with corresponding loss of power compared to the 1-year outcomes. The SRTR could explore that with MPSC if there is interest.
- The vice-chair noted that the MPSC would like to know more information on which programs would be significantly changed under the new model and why. Why would a particular program have a high hazard ratio under the current method and have a somewhat significantly lower hazard ratio under the new method or vice versa. The MPSC is generally looking at any programs that would be above a hazard ratio of 1.5 on either axis in the graph on slide 17. The Director responded that it may not be possible to determine why a program's hazard ratio significantly changed from one method to another. It could just be based on events being included/excluded due to the cohort dates.
- One Committee member suggested the appropriate metrics to be used to evaluate different organs may be different. The SRTR will help the MPSC investigate the use of different metrics for different organs.
- General comments were provided supporting the new approach and the longer 5-year outcome measure. One Committee member noted that this method is reasonable way for a measurement of long-term outcomes to reflect the current program. The common criticism of longer-term outcomes is that would be a measurement of outcomes from another program era. This method gives the ability to look at longer-term outcomes that reflects the quality of the program when the patient comes into a program. To the extent that policy can modify practice, many recognize that the 1-year benchmark now used is not as meaningful since programs can get many patients through the first year without doing anything meaningful for them. The five-year outcomes moves away from the one-year benchmark that may lead to behaviors that are not necessarily in the patient's best interest.

5. Performance Monitoring Enhancement Project

The Committee is in the early stages of a project to evaluate and enhance its transplant program and organ procurement organization performance monitoring. During the meeting, staff provided background on the project and reviewed the results of a survey completed by Committee members prior to the meeting. This project flows from recommendations of the OPTN Ad Hoc Systems Performance Committee (SPC). The SPC, established in spring 2018, was charged with seeking common standards for and understanding transplant system performance. The executive summary provided to the OPTN Board of Directors in June 2019 noted that the committee considered the metrics and elements that could be universally accepted as performance standards for OPOs, transplant programs, and the system as a whole and identify ways the OPTN can support system performance. The SPC noted in the executive summary that it is critical for each organization to participate and contribute to the health of the system. Each organization has an impact on the system, whether favorable or unfavorable. The key areas discussed by the SPC were stewardship, data sharing as a key area in which transparency and accountability can be leveraged, and cultivating a community of partnerships, through enhanced relationships and collaboration.

The SPC included performance monitoring enhancement as one of the four areas under which they provided specific recommendations:

- Holistic approach to evaluation of transplant hospital and OPO performance.
- Could be achieved by developing a balanced scorecard
- Transplant hospitals, OPOs, and the OPTN can use to monitor performance and identify members with opportunity for improvement.

The SPC further acknowledged the need for more input and work to identify and define appropriate metrics for scorecards and accordingly, referred this topic for further work to the MPSC.

Previously, the Committee received presentations on the work of the SPC and considerations in determining a good metric. In addition, during its February meeting, the Committee discussed the goals of performance monitoring. At its July meeting, the Committee established a goal timeline for the project in anticipation of the project review by the OPTN Project Oversight Committee and the OPTN Executive Committee.

The Committee also discussed what metrics or data should be investigated for inclusion on a transplant program balanced scorecard to reflect a more holistic view of the performance of transplant programs. In evaluating the metrics and data, the Committee is considering the question “what are the characteristics of a healthy transplant program?” During the discussion, the Committee completed several polls to get initial thoughts regarding three categories: metrics that currently exist, possible metrics where data is available but no metric developed, possible metrics where there is no OPTN data collected or insufficient data collected, and additional data or metrics suggested by Committee member respondents on the pre-meeting survey.

The first poll asked Committee members to check all metrics that currently exist that they think should be considered for inclusion on a balanced scorecard. The results of the poll are provided in the percentage of the respondents that supported the investigation of each metric:

Table 1: Percentage of survey respondents that supported investigation of each currently existing metric for inclusion in a balanced scorecard

Patient/graft survival – multiple time periods	Survival from listing	Transplant rate	Offer acceptance rate	Waitlist mortality rate
92%	62%	51%	46%	51%

The second poll asked Committee members to check all possible metrics where data is available but no metric developed that they think should be considered for inclusion on a balanced scorecard. The results of the poll are provided in the percentage of the respondents that supported the investigation of each metric:

Table 2: Percentage of survey respondents that supported investigation of each metric for which data exists for inclusion in a balanced scorecard

Time to Transplant	Active vs Inactive on Waiting list	Offer Response Time	Length of Stay	None of these
32%	30%	16%	14%	46%

The third poll asked Committee members to indicate each area that they would support investigating the development of a dataset for use in any type of monitoring activity. The results of the poll are provided in the percentage of the respondents that supported the investigation of each dataset:

Table 3: Percentage of survey respondents that supported investigation of the proposed data sets for use in any type of monitoring

Listing rate for referred patients	Readmission/complication rate	Survival rate among ESOF patients	Transplant rate among ESOF patients	None of these
24%	41%	41%	32%	35%

In the pre-meeting survey, some Committee members made suggestions for other possible metrics to investigate. Following discussion by the Committee, the fourth poll asked Committee members to indicate if they supported further investigating the development of any of the data sets for use in any type of monitoring activity or review. The results of the poll are provided in the percentage of the respondents that supported the investigation of each dataset:

Table 4: Percentage of survey respondents that supported investigation of the suggested metrics or data sets for use in any type of monitoring

Listed acceptance criteria Vs. actual behavior	Re-transplantation rate	Rejection episodes in first year	Pre-emptive living kidney transplantation rate	None of these
65%	44%	29%	41%	21%

A newly appointed subcommittee will use the results of the polls and Committee discussion to begin detailed work on the project.

6. Membership Requirements Revision Project

The Committee continued its work on this project. Staff provided an overview of the project for the benefit of new committee members and an update on the work completed so far. The Committee was divided into two groups to continue review of potential revisions to the transplant program key personnel format. Staff reviewed the results of a survey completed by the Committee during the project kick-off in November 2019. Feedback was solicited from the groups on the minimum training and experience that should be required to serve as a transplant program primary surgeon and primary physician. The groups discussed and provided feedback on the following general requirements for both primary surgeons and primary physicians:

- MD, DO or equivalent degree from another country
- License to practice medicine in the hospital’s state or jurisdiction
- Acceptance onto the hospital medical staff
- Individual on-site at the hospital
- Documentation from hospital credentialing committee that it has verified state license, board certification, training, and transplant continuing medical education, and that the surgeon is currently a member in good standing of the hospital’s medical staff
- Organ-specific appropriate board certification
- Foreign equivalency option for board certification

- Letter of reference from a supervising person who has been directly involved in documenting the individuals transplant and experience and can speak to the individual's competence or qualifications to direct a program
- Letter of recommendation that outlines overall qualifications to act as primary, as well as the individual's personal integrity, honesty, familiarity and experience with OPTN obligation, and other matters judged appropriate
- Letter of qualification from proposed individual detailing training and experience

Generally, the groups supported the retention of the requirements for a degree, state license and acceptance on the hospital staff and for the individual to be present and available to the program. Some concern was expressed regarding use of the term "on-site" as the general understanding of this term is that the individual is on hospital campus. In addition, the groups recognized the need to further evaluate the documentation needed to demonstrate compliance with these requirements. The groups were more divided on the need for applicable American or Canadian board certification, noting that there is not transplant specific board certification for all roles and organs. The groups overwhelmingly supported a pathway for foreign trained individuals to become primary surgeons or physicians. However, there was disagreement on whether an individual proposed for a primary surgeon or physician position should have some level of experience with the United States transplant system. Concern was expressed over the ability to successfully lead a program without experience within the OPTN system in light of the primary surgeon and physician responsibility to ensure a program's compliance with OPTN obligations. Some suggested the development of a curriculum for all individuals taking on the primary surgeon or physician role for the first time that includes an evaluation to demonstrate understanding of OPTN requirements. Finally, there was little support for retention of letters of reference, letters of recommendation and letters of qualification. Committee members noted that the letters do not add sufficient value to the application, often are templates, and do not generally affect the decision on whether to approve an individual for a primary position. The results of these discussions will be provided to the subcommittee for use in developing the proposed new transplant program key personnel format.

7. Update on ABO Verification Project

At previous meetings, the Committee has discussed increasing MPSC transparency by publishing information about some of the issues it has reviewed, and decided one topic will be blood type determination. A workgroup consisting of OPO, blood bank, and HLA subject matter experts is drafting an article to submit to a professional journal, which will review issues regarding causes of blood type discrepancies and methods to address conflicting and indeterminate blood type results. The article will detail what happened in each case, and will then address what should have happened. It will provide guidance for OPOs in reviewing their procedures to make sure they have the right ones in place, and how they can establish working relationships with blood centers. Guidance for surgeons will detail how to look for massive transfusions in donors and when surgeons should question donor ABO.

8. Update on Living Donor Event Project

A second project for increasing MPSC transparency by publishing information about some of the issues it has reviewed is starting for living donor events. Staff asked for volunteers, who are subject matter experts, to begin drafting an article to submit to a professional journal. The Committee has access to previously reported and reviewed living donor events, and the first decision of the work group will be to determine the focus of the paper. Living donor deaths and aborted procedures are the most common case types available for review, and may provide the most helpful information for the community.

9. Encouraging Self Reporting of Potential Patient Safety Issues

The Committee received an update from staff on this OPTN/HRSA contract task. Staff updated the Committee the progress on the following initiatives under this contract task:

- **Discovery in the Community:** The plans for community discovery efforts included key informant discovery calls and focus groups at conferences to gather feedback from the community. Staff placed these efforts on hold due to the cancellation of conferences and concerns regarding participant availability during the COVID-19 pandemic. Staff requested feedback from the Committee on whether it was appropriate to move forward with these efforts. Members of the Committee recommended staff should resume contacting members during the pandemic but advised to tread carefully and watch for member staff cues, as the pandemic remains widely and wildly variable. The Committee mentioned that communication with members is vital to elicit the voluntary self-reporting and project feedback required for building valuable programs.
- **Member Reporting Innovations:** Staff will be evaluating changes to the patient safety portal in UNetsm. The target date for completing these changes is the third quarter of 2021, which coincides with the submission of the patient safety portal data collection instrument to HRSA for OMB clearance.
- **Data Reporting:** The OPTN is also incorporating expanded reporting of data about the incident reports we receive. It is also currently designing an aggregate report for the Committee to use in evaluating progress on the project, consistency in decision making, whether changes that have been or should be made to MPSC processes, and areas for additional education or potential policy changes. The Committee reviewed and provided feedback on a draft report.
- **Changes to MPSC Processes:** Some of the changes to MPSC processes that were being considered have been temporarily implemented due to COVID-19. Staff is developing data on these process changes that will be reviewed by the Committee at future meetings to evaluate whether any of the process changes should be adopted permanently.
- **Member Assistance:** Over the summer, UNOS staff have been participating in training sessions on root cause analyses and corrective action plans. Additional training sessions are planned later this year.

10. Educational Referrals - Discussion of New Topics

As previous meetings, the Committee ended with the Educational Referrals session. The purpose of the session was to receive ideas and feedback from committee members regarding any topics for which it would be beneficial to further educate or communicate about to members. The educational recommendations from committee members can take a number of different forms, including but not limited to traditional training, online course or module, an online article or announcement via newsletter, or a conference presentation. The Committee was also updated about four recent and successful community education efforts that resulted from the Committee's previous recommendations.

When asked, "From your perspective, on what topics do members need additional education or clarification?" and "What education or information will be valuable for the transplant community?" multiple committee members volunteered ideas and recommendations. The Committee recommended education on the Simultaneous Liver Kidney (SLK) organ eligibility and listing policy. One committee member advocated for an OPTN primer tailored for new primary program administrators (PPA) to help them navigate policies and bylaws, and others supported that suggestion by recommending some sort of OPTN onboarding tool for new PPAs. Lastly, there was a referral regarding streamlining allocation.

Staff will continue work on these educational opportunities and will report to the Committee about progress.

Upcoming Meetings

- August 25, 2020, 2-4:00pm ET
- September 29, 2020, 2-4:00pm ET
- October 27-29, 2020, Chicago, IL
- November 9, 2020, 2-4:00pm ET
- December 15, 2020, 1-3:00pm ET
- February 23-25, 2021, Chicago
- July 20-22, 2021, Chicago