OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
February 25-27, 2020
Chicago, Illinois

Lisa Stocks, RN, MSN, FNP, Chair
Heung Bae Kim, M.D., Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met at the O'Hare Hilton in Chicago, Illinois on February 25-27, 2020, to discuss the following agenda items:

Addressing Medically Urgent Candidates in New Kidney Allocation Policy (Kidney Committee)

1. Member Related Actions – Applications Guidance on Blood Type Determination and Modify
2. Blood Type Determination and Reporting Policies (Ops and Safety Committee)
3. Modifications to Released Kidney and Pancreas Allocation (OPO Committee)
4. Individual Member Focused Improvement (IMFI)
5. Update on ABO Verification and Living Donor Event Projects
6. Membership Requirements Revision Project
7. Performance Monitoring Enhancement Project
8. Educational Referrals
9. Encouraging Self Reporting of Potential Patient Safety Issues
10. Refusal Code Update
11. Kidney Accelerated Placement (KAP) Project Update
12. Redacting member-identifying information from case packets

1. Addressing Medically Urgent Candidates in New Kidney Allocation Policy (Kidney Committee)

The MPSC received a presentation from the Vice Chair of the Kidney Transplantation Committee on its proposal "Addressing Medically Urgent Candidates in New Kidney Allocation Policy." Following the presentation, MPSC members offered several questions and comments.

- When a candidate has exhausted every access point, then none are left to use during transplant. The policy could require three out of four major access points to be exhausted so one access point remains for transplant.
- Since these candidates are considered medically urgent and the Committee anticipates few of them, why are the candidates not prioritized right behind 100% CPRA candidates?
- Pediatric candidates are prioritized over medically urgent candidates on the match run. If there are multiple pediatric candidates and one is medically urgent, is that candidate prioritized over the other pediatric candidates? Does a medically urgent pediatric patient get more priority than other pediatric patients?
- How will the process for the surgeon and nephrologist to sign off on medically urgent candidates work? Why not have the primary surgeon and physician for the transplant program sign off?
- Medically urgent candidates are likely to have higher EPTS scores and may be higher-risk candidates, and Sequence A is preferentially directed toward candidates with lower EPTS scores and higher

post-transplant survival. Removing the medically urgent status from Sequence A and moving that status higher in Sequences B, C, and D may help gain additional community support for the proposal.
- Dialysis access choices vary between patients. Prospective reviews may be warranted to make sure patients are appropriately prioritized.

The MPSC was polled to determine their support of the proposal, with a result of 6 Strongly Support, 23 Support, 2 Neutral/Abstain, 3 Oppose, and 2 Strongly Oppose.

2. Guidance on Blood Type Determination and Modify Blood Type Determination and Reporting Policies (Ops and Safety Committee)

The MPSC received a presentation from the Vice Chair of the Operations and Safety Committee on its proposals "Modify Blood Type Determination and Reporting Policies" and "Guidance on Blood Type Determination." Following the presentation, MPSC members offered several questions and comments.

- What circumstances might cause someone to have an indeterminate blood type other than a massive blood transfusion or bone marrow transplant?
- In a previous policy proposal, the OPO Committee removed specific lab values and detailed requirements from policies so they wouldn't have to be frequently updated to keep up with new technology. Did the Operations and Safety Committee consider that practice with these proposals?
- How expensive is the DNA-based typing assay mentioned in the guidance document, and would it add significant costs for OPOs? How quickly can results be obtained from that type of assay?
- Since more than one lab may perform typing, did the committee look at discrepancies between different labs that might result from the use of different testing methodologies?
- Since some OPOs are transporting donors to a central recovery facility, it is important to clarify that the requirement to document all blood products received since admission to the donor hospital means from the start of the death event, not when the donor arrives at the OPO recovery facility.
- Did the committee discuss documenting blood products delivered in the field? Did the committee discuss anything about the time that the OPO had a qualified sample?
- Did the committee discuss requiring patient safety event reporting of indeterminate blood typing results in order to track trends and gain a better understanding of these events? Would the committee consider adding that recommendation to the guidance document?

The MPSC was polled on their support of the policy proposal "Modify Blood Type Determination and Reporting Policies" with a result of 14 strongly support, 20 support, 2 neutral/abstain, 0 oppose, and 0 strongly oppose.

The MPSC also was polled on their support of the guidance document "Guidance on Blood Type Determination" with a result of 18 strongly support, 17 support, 0 neutral/abstain, 0 oppose, and 0 strongly oppose.

3. Modifications to Released Kidney and Pancreas Allocation (OPO Committee)

The MPSC received a presentation from the UNOS Policy Analyst for the Organ Procurement Organization (OPO) Committee on it proposal "Modifications to Released Kidney and Pancreas Allocation." Following the presentation, MPSC members had several comments for consideration when drafting the final policy language.

- Kidney and Pancreas allocation do not have equivalent problems. The major difference being ischemic time for the pancreas. Time is an extremely critical component when a pancreas is flown to

a recipient center. A 250NM share is totally unreasonable for that because time is of the essence. If a program flies the organ in, they should be able to keep it at their center.

- Once an organ is at a program, time is not our friend. When the original policy approved at the last Board meeting for removing DSA went from 500NM to 250NM, we realized that the more cooks there are and people involved, the more challenges there are and the likelihood of discards increases. We should be discussing smaller circles or something more locally directed and then evaluate the data to see if it's working and then expand to a larger geography. Concerns still exist around discards. If we are eliminating DSA, we are expanding allocation. If we are demonstrating that this is a success for allocation and reallocation and if we have the ability to discuss limitless geography, we could really create a tremendous disincentive and major pushback from the community. If we find out that the numbers indicate more organs are not being transplanted, which will happen, and if that reason is cold time, it will be because of the allocation policy. There is no downside to making kidney reallocation circles smaller and pancreas reallocation circles as small as possible.
- The committee should consider looking at population density to determine different circle sizes for different geographic areas. 250NM creates a problem in a dense population with 100 transplant centers being offered an organ at one time where 500NM might be okay for others.
- From an OPO perspective, the proposal makes sense for reallocation of a kidney because it gives the Host OPO flexibility and keeps them involved where as another OPO may not even be aware that that kidney is coming in. For pancreas, there are significant concerns that we are making policy because someone across town "might" have an interest. Last year, six thousand organs were recovered for transplant and ultimately discarded. We have to stop making policy around the notion that someone might have an interest and everyone wants to get all offers. Practicality is that if we take a pancreas and fly it out from Oklahoma to Florida, sight unseen, and something goes wrong with the intended recipient, by the time this is figured out it'll be too late to reallocate it to someone off of the list or even across town. The two proposals need to be functionally different.
- If an OPO in Region 5 sends a kidney to Florida, regardless of it they or the Organ Center (OC) reallocates, there would be coordinators trying to place a kidney somewhere where they don't know the centers. The kidney is just too far away. In this case, we would pass it to the OC and that takes more time.

The MPSC decided to vote separately on the two proposals as one of the members felt that if they voted together, the results for the kidney proposal would be contaminated by the vote for the pancreas proposal. The sentiment vote for Kidney was 7 Strongly Support, 19 Support, 3 Neutral/Abstain, 6 Oppose, and 1 Strongly Oppose. And for the Pancreas proposal, 2 Strongly Support, 7 Support, 9 Neutral/Abstain, 7 Oppose, and 9 Strongly Oppose.

4. Individual Member Focused Improvement (IMFI)

The Committee was introduced to the new initiative, Individual Member Focused Improvement (IMFI), the purpose of which is to monitor and improve member performance through the use of quality and performance improvement (QAPI) tools and engagements custom designed for the member and their unique needs. This proposed improvement partnership aims to increase collaboration with members, and share the transplant community's effective practices. The initiative is currently in the very early discovery and planning phase of what is projected to be a 3 year discovery and design. The program will facilitate partnership with individual members that will entail customized coaching, resources and/or training needed to help said member work toward a defined project aim. IMFI will be another tool on

the path for improvement, it will eventually be open to all members and is meant to be a value add. Additionally, IMFI will not replace any current monitoring, processes or policies.

During the current community feedback and requirements gathering phase, staff are conducting key informant interviews with select members, seeking community feedback in a variety of venues and modalities and will ultimately refine the IMFI framework based on the trends and insights learned through this discovery process. The discovery phase will also be used to estimate time and resources needed and how many improvement projects can be undertaken simultaneously. All of the learnings from the community feedback and requirements gathering phase will be used to develop a pilot project and plan for large scale deployment to all members. There has been a potential pilot project identified.

The engagements with members will be customized based on the scope of the problem, estimated length of time of the engagement, and resources needed. There are two pathways by which members can get involved with IMFI: 1) Members contact the OPTN Contractor with a QAPI issue with which they would like help; 2) Staff and the Committee can use IMFI as another tool in the toolbox to help members improve when the data is showing they are having an issue.

The Committee later discussed a potential IMFI pilot project with a member who has requested assistance.

5. Update on ABO Verification and Living Donor Event Projects

At previous meetings, the Committee has discussed increasing MPSC transparency by publishing information about some of the issues it has reviewed. Topics under consideration were blood type determination and living donor events. The MPSC determined these issues are timely and the MPSC should proceed with these projects.

6. Membership Requirements Revision Project

The Committee continued its work on this project. Staff provided an update on the work completed by the Membership Requirements Revision and MPSC/Histocompatibility Advisory Subcommittee since the last Committee meeting. Committee small groups considered four topics based on either a request from the subcommittee for guidance from the full Committee or on the amount of discussion during the small group sessions at the November meeting. The topics discussed in small groups and a summary of the committee's recommendations follows:

- *OPTN Bylaws, Appendix A, A.1.F. Geographically Isolated Transplant Program Applications*:
  Following discussion in small groups and among the full Committee, the Committee supported removing this section from the bylaws. The Committee requested that the removal be delayed until an exception that could be applied to other situations can be developed in conjunction with revisions to the organ-specific membership requirements. The Committee supported including provisions for close monitoring of programs that are granted an exception. The Committee will consider incorporating an exception into conditional approval provisions in organ specific appendices or in Appendix D.

- *OPTN Bylaws, Appendix D, D.7. Transplant Program Key Personnel and D.8.A. Surgeon and Physician Coverage – On-site Definition and Coverage Plan provisions*:
  Following discussion in small groups and among the full Committee, the Committee supported leaving the "on-site" language to allow for flexibility for different types of programs. The Committee also supported continuing to allow simultaneous on-call in the coverage plan but could not come to agreement on whether to keep the 30 miles or to use minutes. A question

will be included in public comment document as to whether miles or minutes are the most appropriate.

- *OPTN Bylaws, Appendix D, D.6. Transplant Program Director*:
  Following discussion in small groups and among the full Committee, the majority of the Committee supported eliminating this position as duplicative with no clear responsibilities enumerated in the bylaws.

- *OPTN Bylaws, Appendix D, D.9. Changes in Key Transplant Program Personnel – inactivation language for lack of key personnel*:
  Following discussion in small groups and among the full Committee, the Committee supported enforcing the inactivation provisions when transplant program does not have key personnel positions filled. If a program is staffed by a single surgeon or physician, if the surgeon or physician departed, the program would need to immediately inactivate. For programs with additional surgeons or physicians, there can be a 30 day grace period. If the program cannot submit a complete application within 30 days, include an option for the program to submit a plan to fill the position within a reasonable time that will need to be reviewed and approved by the MPSC.

7. Performance Monitoring Enhancement Project

In order to determine what would be appropriate metrics for performance monitoring, the Committee must decide what the goals are for MPSC monitoring. Committee small groups participated in a brainstorm session on what the goals of MPSC monitoring should be. The themes that arose from the discussion include:

Patient Centered

- Increasing safe and equitable transplants
- Maximizing organ use
- Recipient quality of life
- Maximum benefit vs. minimum outcomes
- Are you good at keeping people alive?
- Not better or worse – acceptable standard deviation

System Goals

- Ethical stewardship – use of organs
- Relationships in community
- System-wide performance improvement opportunities

Quality

- Collaborative improvement
- Identify members that will benefit from quality improvement
- Holistic review of members
- Support innovation while monitoring quality
- Member resources to prevent negative outcomes
- Identify shifts in performance and alert/help member in “real time”

In a follow-up discussion, Committee members supported the consideration of a scorecard approach that would result in a more holistic review of a program or OPO. Committee members also favored

looking for ways to use more real-time data in evaluations and evaluate whether it is possible to gather data on the disease population rather than just those that are accepted on the waiting list. One Committee member also suggested considering measurements of how areas, regions and/or Donor Service Areas (DSAs) are working together. Another Committee member felt it was important to make sure that any metric chosen did not discourage expansion of the donor pool or increasing transplants. Several Committee members encouraged putting together reasonable metrics that can be adopted in a timely fashion rather than looking for perfect metrics that will delay adoption of new metrics. As a next step, staff will use a survey tool to collect Committee members' evaluation of possible metrics including which are the top metrics to be used as a trigger for review versus metrics that could be reviewed and used during a review.

8. Educational Referrals

Staff discussed the educational initiatives currently taking place and asked for MPSC feedback regarding educational topics to share with the community. There are many MPSC related abstracts and presentations in the works that will be presented at upcoming transplant conferences. Some of these educational initiatives focus on self-reporting, member interactions with the MPSC, multi-organ allocation and performance improvement. The MPSC Chair encouraged staff to follow up with other appropriate OPTN committees about the need for clarity in OPTN multi-organ allocation policies based on the MPSC's review of a number of cases. Staff encouraged committee members to share additional ideas and expertise regarding educational opportunities to share with 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 on the discovery efforts to determine ways to encourage members to self-report potential patient safety issues, including key informant discovery calls, presentations and requests for feedback at regional meetings, and focus groups at conferences to a gather feedback from the community. Staff are also requesting feedback from the community about the improving patient safety portal in UNet^{sm}. One Committee member suggested included an area where a member can provide more detail such as a policy being confusing or the reason something happened. Another Committee member encouraged streamlining the process so it is less of a time burden on members.

The Committee had further discussion on the goal and scope of the project. Staff noted that the overall goal is to find ways to encourage members to self-report issues rather than mediating disputes between members following a complaint. Through increased reporting, the OPTN and MPSC can promote member improvement through assistance in identifying potential patient safety issues and in developing root cause analyses and corrective action plans to mitigate risk, promote general awareness, formal education, and distribution of guidance. It can also help inform the development of appropriate policy requirements. The Committee provided feedback on the scope of the project. The OPTN should encourage members to report

- issues that involve potential noncompliance with OPTN obligations,
- situations that people think the OPTN can act on or that the OPTN system will benefit from knowing about,
- ongoing systemic patient safety issues that are transplant specific,
- situations that result in non-utilization of organ or delay of transplant, and
- member requests for help with issues that are within the scope of OPTN.

Two Committee members noted organizations that have been successful at this have figured out ways to mitigate penalties and made self-reporting part of the evaluation process such as self-reporting is

evidence of a highly developed and successful QAPI process. In addition, a Committee member suggested that we need to emphasize that we are offering help to improve member internal processes to identify issues and not an effort to identify issues in order to penalize members.

The OPTN is also incorporating expanded reporting of data about the reports we receive. The Committee had a brief discussion of the types of data that the Committee would find helpful in a routine periodic report. As an example, the Committee was provided with a report prepared for the Operations and Safety Committee. The Committee was asked to provide feedback on whether they would find this data helpful or if there was any other data, not currently provided, that would be helpful. One Committee member suggested that it would be helpful to know the top 5 violations for each type of action the MPSC takes. Since limited feedback was received, the Chair encouraged members to provide feedback by email to staff. Staff will also consider ways to get additional feedback through a survey or Committee Management post.

Finally, the Committee continued consideration of changes to MPSC processes that may help encourage reporting and decrease the work load of the Committee. Staff provided an update on the feedback received from the Committee in November and the operational rule adopted by the Committee in December. Following introduction of the topic, the Chair requested that staff develop a survey to gather feedback from the Committee to bring back to a future meeting.

10. Refusal Code Update

Staff presented an overview of the Refusal Code Project and requested MPSC feedback. The project entails a comprehensive review of the PTR refusal codes, which were last updated in 2004. The community has requested that the codes be updated and specifically that code 830 “Donor Age/Quality”, be broken up to improve the data quality and decision making, and to better understand why organs are being refused or not utilized. In 2018, Donor Age/Quality was used as the refusal reason nearly 70% of the time. The proposal includes renaming refusal reasons, improving the selection drop downs on the screen, and increasing the number of categories from 23 to 31. Staff are requesting feedback from the community at this time and a draft list was shared with the committee.

A committee member asked about the plan to encourage transplant hospitals to use the new codes instead of continuing to use a “default code”. Staff tried to make the new refusal codes as simple as possible, including short descriptions, and avoiding a new catch all code. Staff explained that this initiative was effectively tested through UNOS labs in 2018, but we have refined it more since then. An MPSC member suggested providing a code report out or scorecard to individual programs and OPO’s on a regular basis. If programs could see the information more readily, it would be easier for them to self-monitor.

Staff responded to multiple committee member questions regarding choosing several categories. There will be an option to choose a primary and secondary refusal code, and a comment box to provide more information. A committee member suggested allowing more refusal options. Staff explained that the intent was to not overwhelm members by adding too many refusal codes. Committee members suggested adding an abnormal donor function code, unable to meet OPO needs code, and splitting the organ anatomical damage or defect. MPSC members also suggested separating the refusal codes based on organ type to better track and capture data.

The MPSC Chair encouraged committee members to reach out to staff if they had specific questions about categories/refusal codes. There will be more education coming out about this proposal. Staff thanked the MPSC for their valuable feedback and encouraged them to reach out with any questions.

11. Kidney Accelerated Placement (KAP) Project Update

Staff presented an overview and first quarter update of the Kidney Accelerated Placement (KAP) project. The project focuses on increasing placement of extremely hard-to-place kidneys through the Organ Center. The concept involves using data to identify donor "triggers" for accelerated placement and detecting transplant hospitals that utilize hard-to-place kidneys in order to accelerate offers of hard-to-place kidneys to programs more likely to accept and transplant them, while continuing to offer to all programs. The goals from the onset are 3-fold and include decreasing placement time, which will hopefully improve the organ quality, and increased utilization.

Donors have to meet three triggers in order to apply for kidney accelerated placement. They must be an adult donor that has a KDPI of >80% at the time of match submission and it is only applied on a match once all offers at the local and regional level have been refused and it is coming to the Organ Center for placement. Research identified several key donor characteristics that differentiated accepting or declining high-KDPI, national offer kidneys from the Organ Center to create the algorithm of qualifying transplant programs. This is implemented based on all kidney transplants performed in the prior two years, updated monthly. Transplant programs qualify if they have transplanted a kidney from a donor with similar characteristics as the current donor on the match. Another key element is determining each specific match in real-time at the time of allocation. Age, peak serum creatinine, history of diabetes, history of IV drug use, and donation after circulatory death were determined to be most predictive characteristics of organ acceptance for these kidneys and make up the transplant program qualification algorithm along with KDPI.

The President signed an executive order on July 10, 2019, to increase access to kidney transplants. This project was implemented on July 18, 2019, as a year-long project with ongoing evaluation. Updates have been posted on the OPTN website and presented at Regional Meetings. Staff recognized the five individuals on the Data and Safety Monitoring Council who have contributed to this effort. The group was charged with reviewing and finalizing stop/pause criteria, determining measures of success for the project, reviewing evaluation of the project to identify areas of concern, and providing recommendations at the end of the project regarding next steps and broader uses of this methodology for other organs/policy.

Staff gave an overview of the first 90 days of the KAP project. There were a total of 3,348 kidney match runs during this time and 746 of these donors were KAP-eligible donors. The Organ Center attempted placement of 339 of these donors at KAP-eligible sequences (national level sequences). There were 66 kidneys placed during the accelerated portion of KAP, 56 (17%) of donors had a KAP related acceptance, and 5 kidneys were placed after all accelerated hospitals refused the organ. Staff noticed an increased utilization (conversion from acceptance to transplant) during the first three months. There was no decrease in time spent offering kidneys or associated cold ischemia time. Staff also mentioned that the kidneys were offered to and accepted by candidates at considerably more aggressive centers.

Staff wrapped up the presentation by discussing key findings and next steps. The methodology is allocating to hospitals more likely to accept and transplant hard-to-place kidneys. Accepting candidates received the kidney transplant more often, rather than another candidate at the same hospital or different hospital, and there is no decrease in time spent offering kidneys or associated cold ischemia time. The Data & Safety Monitoring Council has no concerns with the project at this stage and will continue to monitor match offer time and cold ischemia time. Staff asked for MPSC feedback.

Several MPSC members mentioned the new allocation policies and suggested adjusting time limits for future accelerated placement initiatives. A Committee member recommended creating a dashboard to display this data. Staff explained that a new "alert message" on the match run shows that accelerated

placement is in process and a hyperlink will display more information. Several Committee members mentioned having some level of flexibility in the accelerated placement criteria to avoid organ discard. A Committee member, who is also on the Data and Safety Monitoring Council, provided further clarification. Staff thanked the MPSC for their valuable feedback and said there will be more updates to come.

12. Redacting Member-Identifying Information from Case Packets

Staff introduced the next topic to the MPSC in order to gather feedback and help streamline case review processes. The item for discussion is whether staff should continue redacting member-identifying information from MPSC case packets. Examples of member identifying information include member name, logo, four-letter member code, member location, and the names of member employees. This would not include PHI, staff will continue to redact PHI. Staff explained that the current process was developed to protect the integrity of the peer review process. Some advantages to why this process was implemented is that it may promote unbiased decision-making. Redacting member identifying information provides an additional layer of patient confidentiality during review and if information was ever released. It also protects MPSC reviewers. For example, if there were ever a case where a member asked about a particular situation, the MPSC reviewer could simply say "I don't know because the case packets are blinded."

There are also many disadvantages to this process. There is conversely a potential for less informed decision making. Knowing all the facts may help reviewers make their decisions in an appropriate way. In addition, MPSC reviewers can often identify the member based on compliance history or other information within the packet. Furthermore, member identity may ultimately be revealed during interactions such as informal discussions. There is also minimal risk to the organization if information is accidentally missed.

Currently, the redacting process is not applied the same way across all MPSC review types. Member identifying information is redacted for all compliance case packets, until member identity is known through interactions with member. The compliance cases take approximately 237.5 hours per meeting cycle to redact and QA (95 cases X 2.5 hours). The Performance Team does not redact member identifying information for the initial posting in Committee Management; however, they redact case packets posted to the discussion agenda for full MPSC review. Membership does not redact member identifying information because the material is necessary for case review. Staff need to implement a consistent process regarding Performance and Compliance cases. The question is, should staff redact all or no member identifying information in compliance and performance case packets.

The Committee discussed the pros and cons of redaction and providing unbiased opinions during the case review process. Staff mentioned that UNOS General Counsel is fine with not redacting member identifying information because redaction doesn't necessarily provide complete protection. The Committee discussed conflicts of interest and recusing themselves if they feel that they cannot make an unbiased decision. The MPSC Chair emphasized the amount of hours staff spend redacting case packets when ultimately the information is revealed during member interactions. A Committee member mentioned the fact that they can typically identify a member, despite staff's redaction efforts, so it seems like a waste of valuable time.

After further discussion, the Committee voted to stop redacting member identifying information from MPSC case packets. Staff will provide further information for the Committee before any permanent changes are made.

Upcoming Meetings

- April 14, 2020, Conference Call, 2-4pm, ET
- May 21, 2020, Conference Call, 2-4pm, ET
- June 29, 2020, Conference Call, 2-4pm, ET
- July 21-23, 2020, Chicago, IL
- October 27-29, 2020, Chicago, IL