OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Meeting Summary

OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
October 27-29, 2020
Conference Call with GoToTraining

Ian Jamieson, Chair
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Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on October 27-29, 2020, to discuss the following agenda items:

1. Membership Requirements Revision Project
2. Performance Monitoring Enhancement Project
3. Encouraging Self Reporting of Potential Patient Safety Issues
4. Educational Referrals
5. Other Significant Items

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

1. Membership Requirements Revision Project

Staff provided an update on the work that has been completed since the last Committee meeting on the Membership Requirements Revision Project.

The Committee discussed the following topics related to the drafts of Appendix B and D:

- Appendix B: Membership Requirements for Organ Procurement Organizations (OPO): The MPSC previously reviewed a draft document in April 2020, which included changes that removed sections that are out of scope of the OPTN, updated language to reflect current practices and abide by federal regulations, revised language to be consistent, and added a requirement for the OPTN to be notified of location and address changes. There have been changes to the draft since the previous review in April to include clarifying the OPTN membership requirement under the Final Rule, adding requirements for functioning of the OPTN, moving performance and quality requirements into its own section, and adding additional language changes. An additional change was proposed that includes information that is required to be provided on Donation Service Areas (DSA).

  The Committee had no further recommendations regarding Appendix B.

- Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs: The MPSC reviewed a draft of Appendix D. The appendix was previously reorganized to provide clarification on requirements for approval of applications. Many of the requirements within Appendix D have been retained to maintain the requirements of the Final Rule. The MPSC and the Membership Requirements Revision Project subcommittee previously recommended some revisions including the following:
  o removal of the assessment requirement of all program surgeon and physicians
  o simplification of the geographic requirement for transplant hospitals
  o implementation of a 30-day grace period for programs without key personnel

- o changing the language for qualifications for the Clinical Transplant Pharmacist from "should" to "must"
- o removal of the provision for relocation or transfer of a transplant program.

The MPSC reviewed the bylaw language and revisions in the draft of Appendix D and provided the following feedback for the subcommittee to consider during its next review.

- o Simplify the language under the "Additional Services" section in Appendix D: revising the language from "Sufficient quantities of blood from a blood bank" to "Blood banking services".
- o Simplify the language under the "Additional Services" section in Appendix D: revising the language from "Clinical chemistry services" to "Clinical diagnostic laboratory services". Many other MPSC members supported this statement.
- o Review the language under the "Vascularized Organ Transplants Not Covered by OPTN Requirements" section in Appendix D: removing the language "for technical reasons and serves no therapeutic purpose" for inclusion of a pancreas in multi-visceral transplants when a transplant hospital does not have an approved pancreas transplant program.
- o Reword the Clinical Transplant Pharmacist requirements section in Appendix D.
- On Site Definition
  The MPSC discussed the inclusion of a definition for the term "on site" in the bylaws and discussed possible definitions. Staff provided examples of how the term "on site" has previously been applied and provided two options for definitions:
  - o Option 1: *On site means an individual is located in the geographical area of the hospital, readily available to transplant program personnel, and involved in the day-to-day operations of the program.*
  - o Option 2: *based on CMS interpretive guidance: On site means the individual must be immediately available to provide transplantation services when an organ is offered for transplantation defined as being able to be present at the hospital within 60 minutes (or lives within a 60-mile radius of the hospital).*

  Staff also requested feedback from the MPSC on any alternative options for the onsite definition. The MPSC reviewed the possible definitions and provided the following feedback:
  Several members supported Option 1 and made the following comments:

  - o That the primary surgeon/physician should not be required to be present at the hospital within 60 minutes or less, and could still participate in executive decision making from home or another location if needed.
  - o Incorporate a coverage plan requirement and clarify the meaning of the language "geographical area of the hospital".

  Several members supported Option 2 because they agreed that it was important to be in alignment with CMS requirements, in part because it would be less confusing for members. After further discussion, they agreed that the language could be more flexible to meet the needs of the programs. For example, there are other factors to consider when restricting the primary to be present at the hospital within 60 minutes. As long as there is a designated back up for the primary, then there is no patient safety issue. Members suggested that there be a clause in the bylaws incorporating back-up coverage. They also noted that Option 2 is more specific and can easily be applied when the MPSC has to review specific issues.

  While discussing the options the committee asked for more clarification of the purpose for the definition. Staff responded that the definition will apply to the primary surgeon and physicians and where they must be located. The Final Rule indicates that the primaries must be on site. Staff further advised that the Final Rule states that there has to be a transplant physician and a transplant

surgeon on site, but does not indicate it has to be the primary. The challenge is that the detailed training and experience requirements under the OPTN bylaws are generally targeted towards the primaries, and not additional transplant surgeons and physicians. Staff suggested that the bylaws be drafted to specify any transplant surgeon or physician could be on site as long as they meet the requirements within the bylaws for the primary or the additionals. The primary concern by the MPSC is that the options only apply to the primaries, which puts onus on one individual to comply.

Several MPSC members supported language that would combine elements of Options 1 and 2 and another suggested that the MPSC rewrite the definition to state that it is the primaries responsibility to ensure coverage.

The MPSC was unable to reach a consensus on the appropriate language for the onsite definition. Staff will revise the language based on the MPSC's feedback and will further discuss the proposed changes during its November conference call.

- Transplant Program Key Personnel

  The Membership Requirements Revision Project subcommittee has been working on the transplant program key personnel format. Staff provided an overview of the recommendations previously made by the MPSC and the subcommittee. The MPSC reviewed and provided feedback on the following topics, for which a consensus had not been reached:

  o Foreign Equivalency: The MPSC reviewed background information and the history of the foreign equivalency requirement. The subcommittee recommended retaining board certification as a minimum requirement for primary surgeons and physicians. There have been challenges with application of provisions for foreign equivalency. The subcommittee completed a survey and provided suggestions for implementation of a foreign equivalency requirement. The subcommittee also suggested including a standing subgroup to evaluate application using agreed upon criteria, and requiring the primary to have a continuing Medical Education (CMA) plan and two letters of support from US program primary surgeons. The subcommittee also suggests that the primary must meet all clinical experience requirements at an OPTN approved program and must provide a transplant log from foreign country. The MPSC reviewed the subcommittee's recommendations and provided the following feedback.

  ▪ It is challenging to rely on board certification to prove that an applicant has the experience needed. More individuals are completing foreign training that is equivalent to what they could receive in the United States. As an alternative, logs, letters of reference, etc. could be used when making determinations.
  ▪ It is important for foreign-trained applicants to have experience in the United States and suggests a requirement of CME.
  ▪ If someone has all of their transplant experience outside of the U.S. and Canada, there needs to be a provision in the bylaws stating that they either need to gain experience at a domestic transplant hospital or should have another pathway to approval.
  ▪ There still needs to be experience within the U.S. transplant system regardless of qualifications or experience.

  Staff reported that the MPSC could also use a concept paper to collect feedback from the community to find out how to best structure foreign equivalency requirements. This may provide the committee with more suggestions. The Membership Requirements Revision Project subcommittee chair agrees but emphasizes the importance of asking the community the right

questions. The subcommittee chair also suggests getting feedback from professional organizations like the ASTS, AST, etc.

Next Steps: The Membership Requirements Revision Project subcommittee will work to come up with specific questions to ask in the concept paper. The goal is to have the concept paper ready for public comment in January.

- <u>Experience requirements for primary surgeons and primary physicians:</u>
  The Committee reviewed the current experience requirements for the primary surgeon in the bylaws. Previous discussions by the MPSC supported the inclusion of currency requirements for surgeon, transplant logs, and physician care logs. The MPSC has also previously supported the inclusion of a requirement to demonstrate experience with multiple aspects of transplant patient care and combining experience requirements into one requirement.

  o <u>Primary Surgeon Requirements:</u>
    The subcommittee supported requiring documentation of surgeon experiences with multiple phases of transplant care and provided two options for the bylaws language. The MPSC reviewed the suggestions from the subcommittee for language pertaining to the primary surgeon requirements and provided feedback on these two options:
    - Option 1: *Remove references to a list of specific aspects of care and retain the reference to participation in pre-operative assessment and post-operative care.*
    - Option 2: *Keep the requirement for performance of a certain number of transplants and the direct involvement in transplant care separate.*

    Suggestions made during the discussion included the following:
      o Retaining a log requirement for surgeons because it serves as a way to verify experience.
      o Adding requirements will make it extremely difficult for applicants and the MPSC with reviewing applications.
      o Providing continuity within the bylaws between requirements and specific organs.

Following the discussion, the committee was surveyed to see which option they supported. The results of the poll indicate that there is majority support for the language provided in Option 1, with 86% in favor.

  o <u>Primary Physician Requirements:</u>
    The MPSC reviewed background information and current working knowledge/direct involvement requirements for the primary physician in the bylaws. Previous discussions by the MPSC and subcommittee supported the insertion of currency requirements, consolidation of current pathways into one pathway, and retaining current working knowledge/direct involvement requirements that include a list of aspects of transplant patient care. The MPSC reviewed options for working knowledge/direct involvement provisions for primary physicians and provided feedback on potential language.

    - Option 1: *Two requirements are separate with a shorter time frame for working knowledge/direct involvement requirement.*
    - Option 2: *Combine working knowledge/direct involvement in transplant patient care requirements into first requirement and require that surgeon document involvement in the various aspects of care for a certain number or percentage of the patients included in the transplant log.*
    - Option 3: *Alternate suggestions to organize the two requirements*

The MPSC reviewed the options and provided the following feedback:

- Supports Option 1. The MPSC member supports the requirement of a log, but also supports inclusion of criteria on what is expected for qualification.
- Supports combining currency and experience logs to demonstrate proficiency.
- Support revising the primary physician requirements language to mimic primary surgeon requirements.
- The role of the primary physician needs to be transparent. "Listing the criteria would be helpful to ensure qualified people are entering into the roles".
- The currency count is low and should be achievable.
- The Project subcommittee chair recommends simplifying the language and agrees that a log is important. However, there is understanding that it is difficult to audit all logs with data currently collected. The subcommittee chair supports listing the aspects of care, but also supports including a requirement for individuals with knowledge of the physicians experience to attest that the physician meets the qualifications.

    Following the discussion, the committee was surveyed to determine which option they supported. The results were 57% in support of Option 1, and 43% in support Option 2.

    In conclusion, the MPSC agreed to move forward with the requirement without the full list of aspects of care for primary physician.

The MPSC will discuss the topic of transplant program inactivation and deactivation during the next MPSC meeting.

2. Performance Monitoring Enhancement Project

Committee leadership and the Performance Monitoring Enhancement project subcommittee chair provided introductory remarks to the Committee, addressed the goals of today's discussion and emphasized that it will be an iterative process while noting the importance of completing a proposal for the summer 2021 public comment cycle. The Committee chair discussed the current metrics used to evaluate OPTN members and encouraged the committee to consider areas that they care most about to recognize the most important metrics to evaluate. The chair also addressed the potential for changes to the review process and mentioned the possibility of alternative pathways based on severity of issue identified at the program. The subcommittee chair noted that the community has expressed dissatisfaction with the current one metric used to evaluate transplant programs so the MPSC needs to decide on something different. The subcommittee chair advised the committee that data is limited by what is currently collected, and the Committee must work with what is available. However, as the Committee works to produce something that can be put in place now, there is always the option in the future to come up with something better. If the Committee wants to produce something that will require additional data collection, that will take time. The subcommittee chair noted that it is important to focus on what we can do now. Questions have arisen regarding whether the inclusion of additional metrics will put transplant programs in more jeopardy. The subcommittee chair requested that the Committee separate the two questions – development of a scorecard that is a more holistic view of a program and development of the triggers that will commence Committee involvement with a program. The subcommittee chair also provided committee members with a timeline, including a total of three stages. Stage 1 would be putting together a scorecard of available metrics that can be put out for the community to provide feedback. In stage two, the Committee can look at other data captured by the OPTN and the SRTR that the Committee believes could be a good marker of performance but has not been developed into a metric. Stage 3 would be a more aspirational discussion of what the Committee might want to evaluate in the future.

- Performance Review Process & Historical Decisions

Staff provided an overview of the current performance review process including a summary of the initial questionnaire provided to OPTN members and some data on the Committee actions in outcomes cases during 2019, and the duration of reviews for kidney programs identified for outcomes review over the five-year period from 2014 to 2018. Staff reiterated that the Committee has the ability to determine what criteria would trigger an inquiry. Historically, the Committee has favored using a broader trigger boundary of approximately 5% of programs as a guide to determine the criteria to identify programs for review. A broader boundary would result in identification of programs that would identify programs that may not be in need of improvement but would be more likely to capture the programs in need of improvement.

The Committee has the ability to design a new review system. However, the Committee must first finalize the aspects of care that the Committee believes are important to evaluate and then, determine the metrics that assess those aspects of care to include in the scorecard.

Staff summarized the goals the Committee has set for the project including the importance of having a holistic review of member performance throughout all phases of transplant, and identifying real-time patient safety issues. Additionally, the Committee emphasized the importance of providing support and collaboration to programs for identified opportunities for improvement, and evaluating any review system to maximize support for increasing transplants, equitable access to transplant and innovation. The Subcommittee has discussed the essential aspects of care including keeping patients alive and well, promoting efficiency in the allocation system, and recognizing the importance of surgical success and long-term outcomes. MPSC committee members provided feedback on the current review process.

A Committee member commented on the requirement for the MPSC to review programs that meet a flagging threshold of 5% and asked if there is data to suggest that the MPSC should still review programs that meet the 5% threshold. The MPSC chair noted that it is possible to revise the threshold. The threshold may have to differ for different types of programs (pediatric programs versus adult programs, heart program versus liver program, small versus large programs). Another MPSC member suggested that 5% may be a reasonable threshold. The subcommittee chair counselled the MPSC to develop a new flagging threshold after deciding what metrics to use.

- Scorecard Framework

Staff discussed scorecard development and advised the Committee to think about which aspects and dimensions of care the Committee wants to address. Staff addressed the difference between a measure and a dimension. The Committee reviewed the scorecard framework/diagram. Staff provided the Committee with examples on the diagram, including the dimensions of Waitlist Management and Post-Transplant Outcomes as the essential aspects of transplant program performance. Staff encouraged the Committee to think about any aspects of transplant program performance that are missing from the diagram. The diagram should represent the aspects of care that will inform our working definition of what makes a healthy program or a program that may need performance improvement.

Staff also provided examples of different sub-dimensions that may fall within the dimensions of Waitlist Management and Post-Transplant Outcomes. Under Waitlist Management, the sub-dimensions previously discussed by the subcommittee are Waitlisted Patient Care and Offer Acceptance Practices. The sub-dimensions mentioned for Post-Transplant Outcomes include Perioperative Care and Postoperative Care. Lastly, staff provided examples of metrics that could be used to measure the sub-dimensions or aspects of care including waitlist mortality rate ratio, offer acceptance rate ratio, 1-month patient/graft survival rate ratio, and 1-year patient graft survival rate ratio. Staff noted that if the Committee can determine what aspects of care matter, then there are only so many metrics that can

measure each aspect. From there, deciding on a metric becomes easier. Staff requested feedback from the Committee regarding what dimensions or sub-dimensions may be missing from the example diagram that are critical to proper program functioning. The following comments were made during the discussion:

- o A Committee member noted that the referral process is missing from the diagram. Transplant program performance starts with the patient referral process, and essential areas should include how long it takes a patient to get from referral to evaluation and how long it takes from evaluation to being placed on the waiting list. All of these things affect patient outcomes. Staff responded that referrals are crucial to program performance; however, the data is limited in relation to patient referrals and questions arise about the OPTN's scope of authority to monitor that area. The subcommittee chair agrees that the patient referral process is essential, but we also want to make sure that the criteria are measuring aspects that are under the control of the program.

- o Another Committee member suggested that the Committee consider the metrics that are already being monitored as well as the unintended consequences of creating new metrics and the downstream effects. Transplants are increasing, in part, because of decreased regulatory evaluation.

- o One Committee member was hesitant about creating new metrics but supports changing the current metric from 1-year graft survival to 3-year graft survival. The Committee member noted that metrics are used for purposes for which the metrics were not intended. The waiting list and referral times are challenging to manage. Programs are working to reduce wait times, but wait times are highly dependent on things that are out of the program's control. Patients' access to transplant is often dependent on the state in which the patient lives. The Committee member suggested keeping the metrics used to flag programs simple but develop a separate dashboard to identify what contributed to the lower survival rates once identified.

- o The Vice President advised that the words used to describe this effort are very important to this effort. The conversation around "good and not so good" programs is not really the purpose of this effort. What the community has communicated is that programs that may not be doing so well on one metric should not be punished, and we should not prohibit ingenuity or innovation that result in more transplants. The metrics should provide a full picture of a transplant program. Programs want to be recognized not just for outcomes, but for all of the things they are doing such as serving an underserved population, high acceptance rate for organs that would otherwise be discarded, or transplanting patients that might not be accepted by other programs. They also want to be recognized for all the things they are aggressively doing to make sure no patient is lost and no transplantable organ goes unused. Another important area that is more difficult and aspirational is defining where bad stewardship lies like late turndowns for organs or extended patient evaluation that delays listing or not efficiently using filters. These areas are important to look at since the OPTN's focus has been broader distribution and making sure no organ is wasted. We are not looking for more metrics to put programs in jeopardy. We are trying to make sure that one metric alone is used to define a program that may be doing important things as far as waiting list management, for example. We are looking for a system that does not focus on one metric alone and fails to recognize the good work a program may be doing in another area of transplant care. We need to recognize that this is a very complex system and ensure that stewardship is evaluated. We need to take the conversation away from trying to determine what a good or bad program is and focus on trying to measure in a universal

way, a program that is not being well evaluated by one-year patient and graft survival and still try to improve upon other aspects that could make a really big difference.

- o A Committee member commented that there are metrics collected in all hospitals. Some metrics include infection rates, unplanned returns to the OR, length of time on a ventilator, and ICU stay. At her hospital, these are the metrics discussed in addition to waiting list management and post-transplant outcomes. Most of those conversations involve what are the areas of improvement within the hospital, which are things that are important to patients. One-year and three-year survival are important, but there are many factors that contribute to those metrics, not all of which are under full control of the program.

- o Another Committee member asked if there were thoughts on using some of the other metrics that are available from outside the OPTN surrounding quality, safety, and patient satisfaction to give a more holistic view of the program. The Chair noted that data sources outside the OPTN are on the table and part of the aspirational goal.

- o The subcommittee chair commented that there are still a lot of questions about the trigger for flagging. He encouraged the Committee to step outside of the flagging frame of reference because the Committee can decide to flag fewer programs. The Committee needs to separate the ideas for how it can best measure performance at a program from the flagging.

- o A Committee member noted that often the discussion has focused on those things that are easy to control. She disagrees with focusing on what is easy and already established metrics. She advocated for a focus on a holistic approach, and addressing disparities and issues with underserved patients that are challenging for hospitals. If we change the metrics, then the transplant hospitals will change practices and innovate to better serve the underserved populations and deal with the disparities. This focus may better serve the greater good, rather than focusing on the piece that currently programs have the most control over.

- Performance Monitoring Metrics

The Director of the Scientific Registry of Transplant Recipients (SRTR) provided a synopsis of the discussions during the Performance Monitoring Enhancement Project subcommittee meetings. The SRTR Director noted that the Committee must clearly define the goals of monitoring before the Committee can determine the best metrics to meet that goal. The Committee is evaluating metrics to monitor and improve transplant program performance. At the subcommittee meeting, the subcommittee looked at data currently available, data that exists with no current metric and possible metrics for which no data exists yet.

The SRTR Director presented a performance monitoring metrics illustration and addressed the difference between a system performance metric and a program/OPO performance metric. To illustrate the differences, the SRTR Director used the example of Transplant Rate for Listed Patients, which describes a systems interaction between multiple entities within the system such as waitlist experience, OPO donor conversion, and offer acceptance practices. Transplant rate describes a system interaction between transplant processes but does not represent the aspects that are under the transplant program's control. The program performance metrics measure aspects of care that are within the program's control as opposed to the system performance metrics. If the Committee were to look at transplant rate as a metric, it would need to tease out which of the individual program or OPO aspects were the issue. The SRTR Director provided another example of a system performance metric, Overall Survival from Listing, which is a very good metric from the patient perspective. However, it is even broader than the transplant rate metric, which would make it difficult for the Committee to address the underlying components that influence this metric. A final example addressed by the SRTR Director was

the OPO Deceased Donor Yield, which is currently used to evaluate OPOs. An OPO performance metric that contributes to the Deceased Donor Yield is the Death to Donor Conversation. The SRTR Director suggested the Committee focus on performance metrics that are more directly under the program or OPO control rather than metrics that describe systems performance.

The SRTR Director reviewed the Performance Metrics Explorer Dashboard with the Committee and illustrated how metrics could be placed into the scorecard diagram. Waitlist Mortality, Offer Acceptance, 1-month Outcomes, 1-year Outcomes and 3-year Outcomes were used in this example. The SRTR Director also reviewed the difference between a metric, a scorecard, and a composite with the Committee, noting that metrics on a scorecard should measure distinct and independent aspects of a program's performance. The SRTR Director provided the Committee with a link to the MPSC metrics explorer application, which allows Committee members to explore the correlation between different metrics. The SRTR Director provided an overview of use of the application. The SRTR Director also described the current MPSC flagging criteria and the computer simulation used previously to determine the criteria. He also noted that the SRTR had recently launched an interactive visualization of the Program Specific Reports (PSR) and presented an example to demonstrate how to use the interactive visualization. Finally, the SRTR Director reiterated that the Committee could determine the flagging thresholds and boundaries once the metrics are identified for inclusion in the scorecard. The Committee members offered the following comments following the presentation:

- o A Committee member asked about how the Committee is involved in making decisions about risk-adjustment for metrics. The SRTR Director responded that the risk-adjustment models are available on the SRTR website, and the models are rebuilt every three years and refit every six months. Feedback from the Committee is welcomed.

- o Another Committee member noted that there are still challenges with specific subjective variables in the risk-adjusted models that are not validated during site surveys and the weights given to those variables. The Committee member also noted another challenge of the data is currency and how data is often delayed. The SRTR Director agrees that data quality and currency are essential. HRSA and the Committee have made suggestions in the past such as removal of the Karnovsky score based on the subjectivity of that variable. Currency is a difficult problem to address with the tension between having enough data and focusing on current performance.

- o Another Committee member stated that there are many factors that influence program performance. The metrics currently available are sufficient and the member advises using a few metrics such as waitlist mortality and post-transplant outcomes, but also use a dashboard of additional metrics as additive information.

- o The Vice-Chair asked if there is a way that a combination of all metrics can be used to determine program performance. He also asked if we have looked at programs reviewed in the past to determine what combination of metrics define a program that required MPSC intervention. Using a variety of all metrics could help the MPSC determine specific aspects of performance that programs under review have struggled with. The Vice-Chair would be interested in a tool that evaluates multiple metric correlation rather than just the correlation of two measures. He suggested creating a scoring system for multiple metrics and applying it to known programs that have been under review in the past to help evaluate the inclusion of certain metrics.

- o Another Committee member agreed that a composite score can be a great way to incorporate many factors and may offset some of the disparities in different programs. It may be helpful for a patient to look at an overall score over dashboard metrics. The MPSC member also suggested incorporating a regional or Donation Service Area (DSA) score that can incorporate the

performance of the OPO and the transplant programs and can be used to intervene with multiple organizations in the region or DSA. The SRTR Director responded that the SRTR could develop DSA and regional metrics.

- o A Committee member stated that the interactive tool is phenomenal. The interactive tool could have a specific interface and show metrics relative to the audience (patient, program, etc.) to add value to the patient, the program, and the OPO. That type of tool could be used in the program's own quality efforts. Some of the metrics may provide a program with information about what type of program they are rather than just being used for flagging purpose. For example, with waitlist mortality, there are programs that are willing to take higher risk patients to give them a shot at transplant even though that patient may be at higher risk of dying on the waiting list. The metrics could be used to develop program profiles that help the program determine areas the program would like to improve on such as becoming a more aggressive program.
- o Another Committee member agrees with composites to be able to look at different variables and systemic issues.

The subcommittee will consider this feedback during its next meeting.

3. Encouraging Self Reporting of Potential Patient Safety Issues

The Committee received an update from staff on OPTN/HRSA contract task 3.6.7, the plan for incentives to increase self-reporting. Staff updated the Committee on the progress of initiatives under this contract task:

- Discovery in the Community: Staff invited fifteen members, eleven OPOs and four transplant centers to participate in key informant interviews with eleven scheduled so far in November. Staff will solicit feedback on possible incentives and barriers to increasing voluntary self-reporting as well as what assistance members would prefer the OPTN offer.
- Data reporting on patient safety reports received and outcomes: The Committee reviewed and provided feedback on the final data report, which was based on MPSC feedback from the July meeting. The report is designed to allow the MPSC to effectively evaluate progress on encouraging self-reporting, assess consistency in decision making, determine if changes need to be made to MPSC processes, evaluate recommendations for alternative monitoring approaches, and if there are any areas for additional education or suggested policy changes. Staff plan to provide the report to the MPSC twice annually in October and February.

  - o Staff reviewed data collected from the patient safety reporting system used to compile the report by type of case, by year in a rolling two-year window. Trends will be apparent with complete annual data.
  - o Staff clarified unspecified members are classified as non-self-reports as they are not members of the OPTN.
  - o Feedback from the committee was collected on the specific data tables in the current draft report and will be taken into account and incorporated as appropriate in the next draft.
  - o Case detail cannot be easily summarized due to uniqueness. Classifications by category removes context, but the report permits a high-level view of activity, patterns, and trends. Full annual data will be available and trends visible in the February version.
  - o A committee member asked for clarification on whether TIEDI data or patient safety portal reporting qualified as self-reporting. Staff confirmed discrepancies in TIEDI reporting do not automatically reach the Committee for review and verified HLA events should be reported in the

patient safety portal. The committee member suggested education on HLA self-reporting was needed.

- Changes to MPSC Processes: The Committee changed an operational rule in December 2019 to close with no action self-reports that addressed the issue with a Root Cause Analysis (RCA) and Corrective Action Plan (CAP) and where there was no likely recurrence. Due to COVID-19, self-reports without additional concerns are currently placed on the consent agenda as close with no action. The Committee will revisit data in February 2021 to determine whether the change will be permanent. Staff continue to assess all reports for patient safety implications and in some cases seek guidance from MPSC members.
  - The staff is examining current processes with plans to utilize the data report to develop process improvements. The staff is also investigating the possibility of numerically scoring events based on multiple factors including, but not limited to, policy, member history, and if a corrective action plan was submitted. Events would reach the Committee based on severity and score of an event.
  - The staff is considering creating an Informational Agenda comprised of reports that did not receive a formal inquiry or review by the Committee. This agenda would allow the Committee to see the range of reports, including issues involving non-members, so that the Committee may see the health of the system. The Informational Agenda would include reports without OPTN policy or bylaw implications that did not result in organ discard and did not pose an immediate or significant patient safety concern. The data would provide visibility for system health issues that were not significant patient safety concerns.
  - Staff is exploring reorganizing committee meetings, possibly to look for an opportunity to review members holistically, and review similar issues grouped together and removing the need for the current separate agendas.

4. Educational Referrals

The October MPSC meeting ended with a discussion around educational referrals. The purpose of this 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.

Staff gave an update on existing referrals that were discussed at the July MPSC meeting. Staff have decided not to pursue any new Simultaneous Liver Kidney (SLK) educational resources at this time, considering that only about 1% of SLK recipients were listed as "ineligible" and transplanted, which was a heavily discussed topic at the July meeting. Staff are currently collaborating with the Communications department to determine the best method to recirculate existing SLK resources. Staff are also working with the Communications department on creating a regular educational offering to highlight recent regulatory changes and changes on the horizon. Conversations are being held around how aggregate allocations data can most effectively be shared with the MPSC and transplant community.

MPSC members were asked to share ideas for new educational resources to benefit the transplant community. The Committee Chair advocated for education to be provided on the minimum requirements for primary physicians and surgeons. A Committee member proposed the idea for clarification to be provided on the continuous allocation model, specifically how backup and reallocation is going to function. Another Committee member suggested the topic of providing education on O2 requirements relating to lung allocation scores. A staff member shared that the help documentation on this topic was updated recently, but we can discuss further options for education.

The Committee Chair proposed improving common practices between local organ procurement teams and OPOs. A referral regarding the timeframe(s) for which Primary Non-Function (PNF) patients should

be relisted was suggested. Lastly, the Committee recommended education around reporting discrepancies in TIEDI versus the patient safety portal, specifically noting that information in TIEDI is not necessarily reviewed by staff or considered a self-reported event. Staff will continue to work on these educational opportunities and the Committee will be updated on progress.

5. Other Significant Items

- The Vice Chair provided a brief overview from the Policy Oversight Committee. His presentation included strategic policy priorities and where the MPSC projects fit into the overall project timeline.
- Committee members were informed of the creation of a Vascularized Composite Allograft (VCA) Committee workgroup that will be considering the development of genitourinary membership requirements. Committee members who were interested in representing the MPSC on the workgroup responded through a poll.

Upcoming Meetings

- o November 9, 2020, 2-4:00pm, ET, Conference call
- o December 15, 2020, 1-3:00pm, ET, Conference call
- o January 19, 2021, 2-4:00pm, ET, Conference call
- o February 23-25, 2021, Chicago
- o March 25, 2021, 1-3:00pm, ET, Conference call
- o April 22, 2021, 1-3:00pm, ET, Conference call
- o May 25, 2021, 2-4:00pm, ET, Conference call
- o June 24, 2021, 1-3:00pm, ET, Conference call
- o July 20-22, 2021, Chicago

Attendance

- **Committee Members**
  - Sanjeev K. Akkina
  - Nicole Berry
  - Christina D. Bishop
  - Errol Bush
  - Matthew Cooper
  - Theresa M. Daly
  - Maryjane A. Farr
  - Richard N. Formica Jr
  - Adam M. Frank
  - Catherine Frenette
  - Jonathan A. Fridell
  - PJ Geraghty
  - David A. Gerber
  - Alice L. Gray
  - John R. Gutowski
  - Edward F. Hollinger
  - Ian R. Jamieson
  - Christy M. Keahey
  - Mary T. Killackey
  - Heung Bae Kim
  - Jon A. Kobashigawa
  - Anne M. Krueger
  - Jules Lin
  - Didier A. Mandelbrot
  - Virginia(Ginny) T. McBride
  - Clifford D. Miles
  - Saeed Mohammad
  - Willscott E. Naugler
  - Matthew J. O'Connor
  - Nicole A. Pilch
  - Steve Potter
  - Jennifer K. Prinz
  - Scott C. Silvestry
  - Lisa M. Stocks
  - Parsia A. Vagefi
  - Gebhard Wagener
- **HRSA Representatives**
  - Marilyn Levi
  - Adriana Martinez
  - Arjun U. Naik
  - Raelene Skerda
- **SRTR Staff**
  - Nicholas Salkowski
  - Jon J. Snyder
  - Bryn Thompson

- o Andrew Wey

- o **UNOS Staff**
  - o Stephanie Anderson
  - o Sally Aungier
  - o Matt Belton
  - o Nicole Benjamin
  - o Tameka Bland
  - o Tory Boffo
  - o Jadia Bruckner
  - o Robyn DiSalvo
  - o Nadine Drumn
  - o Demi Emmanouil
  - o Amanda Gurin
  - o Asia Harris
  - o Danielle Hawkins
  - o David Klassen
  - o Kay Lagana
  - o Krissy Laurie
  - o Trung Le
  - o Marc Leslie
  - o Ellen Litkenhaus
  - o Jason Livingston
  - o Maureen McBride
  - o Anne McPherson
  - o Sandy Miller
  - o Amy Minkler
  - o Steven Moore
  - o Alan Nicholas
  - o Delaney Nilles
  - o Jacqui O'Keefe
  - o Rob Patterson
  - o Michelle Rabold
  - o Liz Robbins
  - o Sharon Shepherd
  - o Leah Slife
  - o Tynisha Smith
  - o Olivia Taylor
  - o Stephon Thelwell
  - o Roger Vacovsky
  - o Marta Waris
  - o Betsy Warnick
  - o Trevi Wilson
  - o Emily Womble
  - o Karen Wooten
- o **Other Attendees**
  - o None