

OPTN Membership and Professional Standards Committee (MPSC)

Meeting Summary

February 23-25, 2021

Conference Call with GoToTraining

Ian Jamieson, Chair

Heung Bae Kim, MD, Vice Chair

Introduction

The Membership and Professional Standards Committee (MPSC) met by conference call in open and closed session via Citrix GoToTraining on February 23-25, 2021, and discussed 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. Final Rule and NOTA Training
6. Update on ABO Project
7. Update on Living Donor Event Project
8. Public Comment Proposal: Clarify Multi-Organ Allocation Policy
9. Public Comment Proposal: Strategic Plan
10. Refusal Codes Feedback Request
11. Policy 14.8.B Living Donor Specimen Collection and Storage Implementation
12. Other Significant Items

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

1. Membership Requirements Revision Project

Phased Approach to Bylaw Revisions: Staff reviewed the project's previously proposed timeline:

- **Phase 1.A (Winter 2021 Public Comment):** Includes proposed revisions to Appendices A, B, and D. The phase also consists of a Request for Feedback on a proposed framework for establishing Organ-Specific Program Requirements (Appendices E-J). Staff explained that the proposal for revisions to appendices A, B, and D is currently on hold pending HRSA review and feedback, and the Request for Feedback document is now out for public comment.
- **Phase 1.B (Summer 2021 Public Comment):** Includes revisions to Appendix K and Appendix C and was to be sent out for the next public comment cycle.
- **Phase 2:** Includes finalizing a framework and distributing a proposal for Organ-Specific Program Requirements (Appendices E – J). This phase will require collaboration with the various organ-specific committees.

Project Status and Next Steps

Staff reported that staff and MPSC leadership have agreed to place the Membership Requirements Revision Project on hold while the MPSC awaits the results of HRSA's review of the proposed language for Phase 1.A. Staff anticipate the project may be delayed until at least the next public comment cycle, if

not later. HRSA has indicated that its review could potentially identify changes to the proposed language, which the MPSC would need to address before the proposal could go out for public comment. Staff shared that the MPSC would focus on the Performance Monitoring Enhancement Project to meet established public comment deadlines. Staff and the MPSC reviewed the next steps of the project:

- The Membership Requirements Revision Subcommittee meeting scheduled for March 10, 2021, will be canceled.
- The MPSC will discuss the public comment feedback on a framework for establishing Organ-Specific Program Requirements during the MPSC meeting on March 25, 2021. Staff suggested that the MPSC members ask colleagues to submit feedback for the "Request for Feedback" document.

A committee member asked about the details of organ-specific feedback and how to access the "Request for Feedback" document. Staff responded that the request for feedback focuses on obtaining community input on currency requirements, types of logs that primaries should produce, etc. The staff mentioned that anyone could access the "Request for Feedback" document in the public comment section on the OPTN website.

The Membership Requirements Revision Subcommittee will meet on March 31, 2021, to "wrap up" the project.

Pancreas Islet Requirements

Staff provided an update on the pancreas islet requirements and noted the Pancreas Transplantation Committee had sponsored a proposal for changes to the minimum membership requirements for islet transplant programs. Staff explained that the proposal was approved at the December 2018 Board meeting, and is expected to be implemented by June 2021. Staff shared that the FDA is considering and expected to approve an Investigational New Drug (IND) application that classifies islets as a drug. Staff reported that the implementation is currently on hold, pending feedback from HRSA.

2. Performance Monitoring Enhancement Project

Staff provided an overview of the progress on this project and reviewed the project plan leading up to public comment in the summer 2021. The SRTR director provided an overview of the data analysis requested by the subcommittee on the possible thresholds for the four metrics the subcommittee is investigating for inclusion in the transplant program performance monitoring scorecard. The Committee is considering two tiers of review, a red intervention zone where the program would interact with the MPSC and a yellow cautionary zone where a notice would be sent to the program with an offer of performance improvement assistance. The Committee previously requested data showing the number of programs that fell within fixed difference thresholds of 3%, 5%, 7%, and 10% from the national average for 90-day survival, and 1-year conditional on 90 day survival and the number of programs that fell within 1.5, 2.0, 2.5 and 3.0 standard deviations from the national average for waitlist mortality and offer acceptance. The data the SRTR provided to the Committee also showed the probability of being lower than the threshold at 50%, 75%, and 90%. The Committee then split into two breakout sessions for an in-depth discussion of the data analysis for abdominal organs and thoracic organs. The goal for the breakout sessions was to provide feedback on the data analysis for the organ types assigned to the group. The feedback will be used to inform the Performance Monitoring Enhancement Subcommittee's future deliberations on proposed thresholds.

Abdominal Breakout Session

The abdominal group reviewed the data analysis for kidney and liver thresholds for the post-transplant metrics of 90-day survival and 1 year conditional on 90-day survival and the pre-transplant metrics of waitlist mortality and offer acceptance.

Members expressed concern with use of the waitlist mortality metric for kidney, in particular. One member noted that the purpose for using certain metrics might be different for different organs. The member noted that kidney programs do not have complete control of the patient care for candidates on the waiting list, but the program does have control over who is listed, who is made inactive, who is delisted, and when a patient is listed. These areas could be improved. Another member noted that if a program lists everyone who is referred, it may not be realistic or fair to some patients to allow them to think they are going to get a transplant if they are a patient, such as a 65 year old diabetic, that realistically will not get a transplant before they die unless the patient has a living donor. Use of this metric will also encourage maintenance of the waiting list through re-evaluation of listed patients. Another member noted that a concern with the waitlist mortality metric is that co-morbidities that develop while on the waiting list, such as a candidate that has a heart attack, are not captured because the model risk adjusts based on known risks at time of listing and continues to look for death of a patient that is removed for too sick for transplant. Members stated concerns with liver waitlist mortality also noting the shortage in hepatologists that affects access to care and the timing of referral of patients to a program. The group noted that concerns raised with the waitlist mortality metric could be considered in determining the threshold for this metric.

Some concern was raised with the offer acceptance metric since programs can adjust their filters to keep from being identified, which could reduce access to transplant. Others noted that this metric is one that programs have sole control over. Members noted that use of the offer acceptance metric would incentivize programs to evaluate their organ declines and determine opportunities for improvement. It would also encourage programs to use realistic offer filters to eliminate offers that the program is not likely to accept leading to more efficient and timely allocation of organs.

Members noted that the pre- and post-transplant metrics are in many ways two sides of the same coin and suggested that based on the community's performance on post-transplant survival, the post-transplant threshold could be significantly decreased while focusing on improving pre-transplant performance driving programs to apply improvement efforts to the pre-transplant side. This strategy should encourage behavior that will result in increased transplants.

For the post-transplant metrics, the group discussed a higher percentage difference from the national average with a lower probability. The lower probability would allow more opportunity to capture underperformance in small volume programs since the low volume of data makes it harder for the SRTR to have a high degree of certainty about small volume programs' hazard ratios. Two kidney programs were identified at 50% probability that program performance was greater than 3% lower than the national average. In response to questions from the group, the SRTR director noted that these two kidney programs had 10 and 9.5 more graft failures in the first 90 days than expected.

In a straw poll, 95% of the group members supported recommending that the Subcommittee consider a threshold for kidney and liver post-transplant survival of 50% probability that a program's 90-day and 1-year conditional on 90 day survival is 3% below the national average.

Members requested historical performance data showing where programs that the Committee has expressed concerns about previously, would fall on these graphs. In addition, the members asked the SRTR to provide the Bayesian curves for 2.5, 2, and 1.5 standard deviations for the waitlist mortality and offer acceptance metrics for consideration by the Performance Monitoring Enhancement Subcommittee.

Thoracic Breakout Session

The thoracic group reviewed the data analysis for heart and lung thresholds for the post-transplant metrics of 90-day and 1-year conditional on 90-day survival and the pre-transplant metrics of waitlist mortality and offer acceptance.

The group initially considered potential thresholds for heart programs. One member noted that in considering thresholds for post-transplant survival, the group should consider the survival benefit, noting that the survival rates for heart transplant are remarkably high. He further stated that the thresholds should be set to encourage the increased use of higher risk donors thereby increasing transplants. The member suggested using a 75% probability and moving the percentage out to a clinically meaningful threshold of 3% or 5% lower than the national average. It was noted that neither of the thresholds suggested identified any programs. The chair stated that the Committee is expected to evaluate programs for patient safety, noting that patient safety concerns were raised for a program discussed the day before. The MPSC will need to justify to the public how the thresholds we set fulfill that obligation to monitor patient safety. Another member asked whether the analysis could be run for earlier cohorts in order to see where programs the MPSC has had concerns about in the past fall within these thresholds.

The group considered whether it was necessary to review both graft survival and patient survival for heart. The SRTR representative stated that graft and patient survival are closely aligned for heart so it would be unusual for a program to be identified for one and not the other. The group recommended that only patient survival be used to identify programs for the red intervention zone and yellow cautionary zone. The group discussed whether there should be different thresholds for 90-day survival and 1-year conditional survival. Concern was expressed that risk factors associated with some rare, severe disease process are not adequately adjusted for in the model. However, it was noted that if a program is identified incorrectly in the red intervention zone, the program would have an opportunity provide information and if found to be taking appropriate action, would be released from review. However, on the other side, if the Committee picks a threshold that does not identify any programs, programs that do need help will be missed. For both heart and lung programs, the group recommended 75% probability that a program's 90 day and 1 year conditional on 90 day patient survival is 5% below the national average for the intervention red zone and 3% below the national average for the yellow cautionary zone. The group felt that loosening the thresholds for post-transplant and focusing on offer acceptance on the pre-transplant side would encourage an increase in transplantation.

The thoracic group expressed concerns with the waitlist mortality metric, noting that there are factors that are not included in the risk adjustment. Based on these concerns, the group suggested a higher standard deviation from the national average than for the offer acceptance metric. For waitlist mortality, the group supported the use of 3.0 standard deviation for the red intervention zone and 2.5 standard deviation for the yellow cautionary zone for both heart and lung programs. For offer acceptance, the group suggested 2.5 standard deviations for the red intervention zone and 1.5 for the yellow cautionary zone.

3. Encouraging Self Reporting of Potential Patient Safety Issues

Staff notified the MPSC that the US Senate Finance Committee served UNOS with a subpoena, compelling UNOS to turn over case files from MPSC reviews of all Organ Procurement Organizations (OPOs) from the last 5-10 years, including documents that are typically protected by peer review.

Staff also summarized the Encouraging Self-Reporting Contract task requirements. The task requires UNOS to develop a plan with input from the MPSC to address OPTN member self-reporting of potential

patient safety issues. Staff reviewed the MPSC's previous discussions and recommendations about the project, including but not limited to the following:

- Intensify communication efforts around the project and MPSC processes, such as the MPSC's process to close self-reported issues with no action, if certain criteria are met
- Re-evaluate methods for sharing data with the community, such as an aggregate data report
- Provide members with assistance on their RCAs and CAPs
- Update the Patient Safety Portal for a better user experience, and create an online anonymous reporting platform
- Support for continuing the project despite COVID and the need to obtain member feedback.

Staff then presented the MPSC with findings from the recently conducted discovery phase key informant interviews, as described below:

- Members want further guidance and clarity on what exactly to self-report
- The MPSC should provide data to members on what is reported
- Email as a communication method is overused and not effective
- Members must have institutional support to self-report
- The MPSC should better communicate its process to close self-reports with no action
- CMS regulatory changes may make it less likely for OPOs to report

Staff highlighted some of the project's challenges, namely the difficulty staff have had in successfully sharing data with the community and the regulatory environment, such as the new CMS OPO performance metrics and the US Senate Finance Committee subpoena. Staff proposed revising the scope of the project to refocus efforts on things that are within the OPTN and MPSCs control. Staff discussed some of the recommendations for the revised project scope, which included:

- Omitting requests for member to submit additional data
- Expanding staff assistance to members when potential issues are identified
- Evaluate new ways to share information without jeopardizing peer review
- Communications efforts: letter templates, promote MPSC process, etc.

Following the presentation, the Committee members had questions and offered feedback on the impact of the subpoena on the peer review process and the self-reporting project.

Many committee members supported the idea of continuing self-reporting and reported that "firewalling" confidential information could incentivize members to self-report. However, some committee members reported that if the disclosed information is used against the member, then it could have an opposite effect. One committee member stated that that the MPSC's approach is most important and should move towards performance improvement, rather than a political approach.

A committee member compared the project to other federal agency reporting systems, and provided the example of the Aviation Safety Reporting System. The Committee member explained that this has proven to be an effective method of self-reporting because the agency focuses on finding solutions.

A committee member suggested a public statement could be provided to OPTN members explaining that the self-reporting process could result in "no action" being taken against them. Staff responded that the information is public and has been mentioned at Regional Meetings. However, extra steps need to be taken to ensure the public are receiving that information.

Another committee member stated, “the primary barrier to self-reporting is the inability to see the change” and suggested that a public statement be made to discuss what has been improved as a result of self-reporting.

Committee members also asked questions about the subpoena, including whether OPOs would be notified about which of their information may be turned over. Staff advised that OPOs would need to reach out to UNOS General Counsel directly to discuss what information may be produced. Committee members also asked if UNOS could claim privilege or if the risk for litigation would increase as a result of disclosing confidential information. Staff responded that while the US Senate Finance Committee has rules governing confidentiality of such information, UNOS does not have any ability to ensure the documents will be kept confidential once they are turned over. Staff also noted that members would need to consult with their institution’s own legal counsel to assess whether there is any increased risk for litigation because of the subpoena.

Staff also requested feedback on ways to incentivize members to self-report and ways that staff can provide more support to the MPSC:

- One committee member recommended calling members to ask questions to help identify potential system problems.
- Another committee member suggested staff have set criteria or guidelines while making calls to members
- A representative from SRTR advised the committee of the current political environment and suggested that they be cautious of reaching out to members. Some would consider that conflicting activities and would seek to criticize these processes.

Staff concluded the presentation and committee members had no additional feedback or questions at this time.

4. Educational Referrals

The purpose of the Educational Referrals 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. Educational recommendations from committee members can take several forms, including but not limited to online courses or modules, online articles, email newsletters, and conference presentations. The Committee was updated on one completed and two in-process community education efforts, the latter of which were efforts previously recommended by Committee members.

When asked “From your perspective, on what topics do members need additional education or clarification” and “What education or information would be valuable for the transplant community”, several committee members volunteered ideas and recommendations. One committee member advocated for guidance on best practices regarding the new blood banking requirements for living donors. Another Committee member supported this idea.

Another suggestion was to engage in more strategic collaborations to help advertise new educational materials to members. Several committee members commended formatting improvements made in recent educational offerings. Staff will continue to work on these educational opportunities and will report to the Committee on progress made.

5. Final Rule and NOTA Training

Staff provided a review of OPTN governance policies during the MPSC meeting. Staff reviewed the 10-step process for policy development and explained that all proposed policies must explicitly demonstrate that all proposed changes are authorized by and comply with the OPTN governance

requirements. Staff also reviewed the four OPTN Policy Development Governance buckets and provided a brief summary of each:

- National Organ Transplant Act (NOTA): Staff explained that NOTA established the OPTN and outlines the OPTN's duties and responsibilities.
- OPTN Final Rule: Staff defined the Final Rule as a federal rule issued by DHHS that grants the OPTN authority to do many types of projects. Staff provided examples of projects, which included Membership, Testing, Data Collection, and Allocation.
- OPTN Contract: Staff reviewed the OPTN and UNOS' contractual obligations related to the MPSC, which were to develop proposals with consideration of NOTA and OPTN Final Rule requirements, and document deliberation and rationale of proposals.
- OPTN Policies & Bylaws: Staff explained the difference between OPTN policies and OPTN bylaws, and provided examples of each.

The MPSC participated in an Authority Analysis Exercise and were tasked with determining whether an example project, provided by staff, was considered within the scope of the OPTN's authority. Staff ended the exercise and explained why the example project was not within the scope of the OPTN's authority. Staff concluded the presentation, reviewed key takeaways for committee members, and asked the MPSC if they had any questions. The MPSC had no questions at this time.

6. Update on ABO Project

In 2019, the MPSC reviewed two cases involving patient safety events related to ABO discrepancies. At that time, the MPSC also began discussing ways to increase transparency by publishing information about issues the Committee reviewed. The MPSC formed a workgroup consisting of OPO, blood bank and HLA subject matter experts. The Workgroup planned to review issues regarding causes of blood type discrepancies and describe methods to address conflicting and indeterminate blood type results, and publish an article in the American Journal of Transplantation. Workgroup members reviewed eight ABO discrepancy cases, but there were not enough cases to allow for a high-level data review while following confidential peer review principles. Feedback from the Workgroup will be used to develop better ways to inform the transplant community about blood typing issues and hazards without writing an article. The Workgroup also evaluated the current available education offerings, a guidance document, and policy, and provided recommendations for improvements. The Workgroup will also help the OPO Committee evaluate the existing policy and guidance document.

7. Update on Living Donor Event Project

Staff provided an update on the project for increasing MPSC transparency by publishing information about living donor events. The Committee has reviewed enough of different types of living donor events that some kind of data aggregation should be possible. The Living Donor Event Project Subcommittee determined to move forward with a paper on living donor deaths within two years of donation, which leaves potential for an additional review of aborted procedures. At this time, the Subcommittee has collected a spreadsheet of living donor deaths reported 2007-2019, including 76 deaths with a varied amount of information. The group reviewed documentation for data points such as: specific cause of death, MPSC requests for additional information, and MPSC actions. They are currently looking for themes in cases, and may take a closer look at certain cases to look for ways members have addressed potential for recurrence.

8. Public Comment Proposal: Clarify Multi-Organ Allocation Policy

The MPSC heard a presentation from the Vice Chair of the Organ Procurement Organization (OPO) Committee (Chair) titled “Clarify Multi-Organ Policy.” This proposal is presently out for public comment. Following the presentation, the MPSC offered questions and comments.

- The proposal is a good first step and will provide more consistency in multi-organ allocation across the country. However, multiple MPSC members agreed that specific medical eligibility and safety net criteria similar to those created for simultaneous liver-kidney allocation need to be developed for sharing kidneys with other organs.
- Most candidates receiving heart transplants are at status 1, 2, or 3, which means there could still be a lot of kidneys going to heart candidates. The lack of a safety net for heart recipients who need a kidney after their heart transplant means that transplant programs may request a kidney with the heart even for candidates experiencing short-term loss in kidney function. Lastly, in the new heart allocation policy, status 5 is the dual organ category, but the status will lose its meaning because a patient at status 5 will not be able to receive a dual organ offer.
- Reviewing the effects of the policy change and sharing that data with the community for transparency will be important. An MPSC member reported longer allocation times for abdominal organs under the current policy when a multi-organ candidate on a thoracic match run needs an abdominal organ. Another MPSC member suggested stratifying multi-organ allocation data by KDPI to evaluate the KDPIs of kidneys allocated for multi-organ vs. single-organ transplants.

9. Public Comment Proposal: Strategic Plan

Staff presented an overview of the 2021-2024 OPTN Strategic Plan, currently out for public comment. The overview began with a timeline of steps already taken, including review by the Executive Committee and Board of Directors, as well as virtual collaboration and prioritization exercises with six groups consisting of 90 total OPTN leaders. Staff reviewed the 2018-2021 OPTN Strategic Goals and noted that the key change to the proposed 2021-2024 plan is to combine the current goal to promote efficiency in donation and transplantation with the goal to increase the number of transplants, including reallocation the 10% assigned weight to the efficient goal to increase the number of transplants, taking that allocation from 40-50%. Staff provided additional information on each proposed strategic goal and highlighted key initiatives that may be of importance to the MPSC.

Proposed 2021-2024 OPTN Strategic Goals:

- Goal 1: Increase the number of transplants (50%)
 - Key Initiative for the MPSC: Improve metrics and monitoring approaches for increased collaboration and performance improvement activities when assessing transplant program and OPO performance.
- Goal 2: Increase equity in access to transplants (30%)
 - Key initiative for the MPSC: Improve equity in transplant opportunities for multi-organ and single organ candidates
- Goal 3: Promote living donor & transplant recipient safety (10%)
 - Key initiative for the MPSC: Enhance sharing of knowledge about safety events, near misses, and effective practices across the transplant community
- Goal 4: Improve waitlisted patient, living donor and transplant recipient outcomes (10%)
 - Key initiative for the MPSC: Include recipient longevity in transplant center metrics

The MPSC reviewed the proposed Strategic Goals and offered feedback and questions:

- A committee member stated that the new strategic goals are “ambitious and great”. He also asked about the OPTN’s intent to focus on disparities in access for pre-waitlist patients. The Committee member provided an example of the difficulty with access to liver transplant waitlists for patients with diseases. Staff reported that it is not currently within the scope of the OPTN to develop policies for pre-waitlist factors. However, this is an area that the OPTN is researching to understand better the links between populations. Staff also mentioned the “Social Determinants of Health Study,” which is a new area of research for the OPTN that could also “shed some light” on the OPTN’s current policies.
- A committee member recommended adding a sub initiative that includes “extending donor criteria” to increase the number of transplants.
- Another committee member suggested communicating with the Ethics Committee to review the language in a sub-initiative, which involves developing policies to allow deceased donor kidneys to begin KPD chains. The Committee member stated that the MPSC should be conscious about public perception of such an initiative.
- A committee member stated the importance of being ambitious in formation of strategic goals.
- A committee member reported that Goal 3 provides a unique opportunity to gain buy in across the transplant community.

Staff concluded the discussion and the MPSC provided no additional feedback.

10. Refusal Codes Feedback Request

Staff presented an overview of the Data Advisory Committee’s Refusal Codes Project, which is presently posted for public feedback. The overview included background information, the purpose and goals of the project, along with a summary of prior feedback provided by the community. They also described the top concerns: refusal codes are too vague, confusing, and outdated. Data shows that the top 6 refusal codes used in 2018 accounted for 96.14% of all refusal reasons that year. The remaining combined codes (17) accounted for 3.82% of refusals.

The MPSC reviewed a list of the proposed refusal code by categories offered feedback for each:

- **Candidate Specific Reasons**
Staff reported that the MPSC had previously suggested that the refusal codes “candidate requires different laterality” and “candidate requires multiple organ transplant” should be separate refusal codes. Staff shared that those codes are now split into two separate codes in the proposal. The MPSC had no additional feedback.
- **Crossmatch Related Reasons**
 - The MPSC suggested a new refusal code should be added to the category - “No time for Crossmatch.” A committee member provided an example of when the code would be appropriate to use (ex. OPO cannot accommodate a crossmatch request). He also stated this is a common occurrence in heart programs.
 - The MPSC agreed that the refusal code “positive physical crossmatch” is a term that is becoming more widely used but needs further clarification. MPSC members supported the use of the following language: “Prospective Crossmatch (Physical Crossmatch)”.
- **Disease Transmission Risk**
 - One committee member suggested a new refusal code should be added to the category - “Cancer risk.” She advised that suspected risk for malignancy is a common reason for a refusal in lung programs.

- A committee member suggested further clarification is needed between center refusal and recipient refusal.
- Donor and Candidate Matching
 - Staff explained that the MPSC had previously suggested splitting donor height and weight refusal codes, as shown in the proposed list.
 - Several MPSC members suggested adding a new refusal code to the category - "organ size" because more programs are using projected organ size to determine transplant candidacy.
- Donor Specific Reasons

Staff reviewed new codes in this category with the MPSC. The MPSC had no additional suggestions for this category.
- Logistics

Staff mentioned previous feedback from the MPSC, which suggested the addition of a refusal code related to "unable to meet OR requirements and OPO demand." Staff shared that new codes have been added to the proposal in response to the suggestion.
- Organ-Specific Regions

Staff reviewed the organ-specific refusal codes. The MPSC had no additional feedback.
- Other

Staff explained the use of the "Other" category and related refusal codes. The MPSC had no additional suggestions.

Implementation could occur at the end of this year pending approval from HRSA. Staff concluded the presentation, and the MPSC had no other questions at this time.

11. Policy 14.8.B Living Donor Specimen Collection and Storage Implementation

Based on questions received from committee members, the staff updated the MPSC on OPTN policy changes related to Living Donor Programs and Donor Specimen Storage, which is pending implementation. Staff expects the policy change will be implemented on June 1, 2021.

Staff explained that the policy change requires a 10-year storage of both deceased and living donor specimens. The changes align the policy with the U.S 2020 U.S. Public Health Service (PHS) Guideline for assessing solid organ donors and monitoring transplant recipients for HIV, HBV, and HCV infection, as required by the Final Rule. Additionally, the policy change brings consistency and additional patient safety to Living Donor Programs while also minimizing the potential for disease transmission. Staff mentioned that several concerns were raised during public comment and afterwards during the PHS webinar. Staff provided details on where the MPSC could access a recording of the webinar and an online PHS guidelines toolkit.

Staff explained that the Disease Transmission Advisory Committee (DTAC) recognizes the public's concerns about the policy change, and is working to implement a data analysis on deceased donor post-transplant blood specimens. Staff explained that the data analysis would help assess possible disease transmission.

The MPSC shared the following concerns about the policy change:

- The policy change would impose on living donors by requiring that they have a blood sample on file. This could discourage potential donors.
- The policy change would produce challenges with the tracking, management, and storage of specimens.

- The policy does not provide guidance on storing and maintaining the viability of the specimens.
- The suggested timeline of implementation on June 1 is too soon, with little education on a rollout plan.
- There isn't enough information on how the samples would be used

A committee member also asked if Organ Procurement Organizations (OPOs) would receive additional funding to assist with managing, storing, and tracking specimens. The MPSC chair responded that OPOs would not receive additional financing (unfunded mandate).

The MPSC Chair stated that these concerns have been discussed during the MPSC leadership calls with HRSA.

12. Other Significant Items

None

Upcoming Meetings

- March 25, 2021, 1-3:00pm, ET, MPSC Conference call
- April 22, 2021, 1-3:00pm, ET, MPSC Conference call
- May 25, 2021, 2-4:00pm, ET, MPSC Conference call
- June 24, 2021, 1-3:00pm, ET, MPSC Conference call
- July 20-22, 2021, Location TBD, MPSC Meeting

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
 - Michael Gautreaux
 - 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
 - Zoe Stewart Lewis
 - Lisa M. Stocks
 - Parsia A. Vagefi
 - Gebhard Wagener
 - Rajat Walia
- **HRSA Representatives**
 - Marilyn Levi
 - Arjun U. Naik
 - Raelene Skerda

- **SRTR Staff**
 - Nicholas Salkowski
 - Jon J. Snyder
 - Bryn Thompson
 - Andrew Wey
- **UNOS Staff**
 - Anne Ailor
 - Sally Aungier
 - Sandy Bartal
 - Matt Belton
 - Nicole Benjamin
 - Tameka Bland
 - Tory Boffo
 - Shawn Brown
 - Robyn DiSalvo
 - Nadine Drumn
 - Demi Emmanouil
 - Katie Favaro
 - Amanda Gurin
 - Asia Harris
 - Danielle Hawkins
 - David Klassen
 - Kay Lagana
 - Krissy Laurie
 - Trung Le
 - Ann-Marie Leary
 - Ellen Litkenhaus
 - Jason Livingston
 - Anne McPherson
 - Sandy Miller
 - Amy Minkler
 - Steven Moore
 - Sara Moriarty
 - Alan Nicholas
 - Delaney Nilles
 - Jacqui O'Keefe
 - Rob Patterson
 - Michelle Rabold
 - Liz Robbins
 - Sharon Shepherd
 - Leah Slife
 - Tynisha Smith
 - Olivia Taylor
 - Stephon Thelwell
 - Roger Vacovsky
 - Gabe Vece
 - Marta Waris
 - Betsy Warnick

- Trevi Wilson
- Emily Womble
- Karen Wooten
- **Other Attendees**
 - None