OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
July 25-27, 2023
Detroit, Michigan

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Introduction

The Membership and Professional Standards Committee (MPSC) met in-person in Detroit, and via Webex in both open and closed session on July 25-27, 2023. The following agenda items were discussed during open session:

1. OPO Performance Monitoring Project
2. Performance Monitoring Enhancement (PME) Project Update
3. HRSA Comments
4. Report of Investigative Activity
5. Feedback on Hearing Process
6. Feedback on Patient Safety Intake Form Revisions
7. Educational Initiatives
8. Preparing for Regional Meetings – What You Need to Know

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

1. OPO Performance Monitoring Project

The OPTN Contractor staff presented an update on the status of the Organ Procurement Organization (OPO) Performance Monitoring Project and stated that there is a project workgroup underway that will develop a proposal or concept paper by the 2024 winter public comment cycle. The OPTN Contractor also updated the committee on the OPTN Board of Director's (BOD) recommended priorities of project work that were discussed at the June BOD meeting. With the recommendations of the BOD and previous MPSC discussions in mind and considering the timeline for the project, the Committee must determine an initial charge for the workgroup.

Presentation summary:

The OPTN Contractor Member Quality summarized the MPSC report to the BOD regarding the MPSC work on allocations review and OPO performance monitoring and provided a summary of the feedback received from the BOD on allocation efficiency and the suggested priorities for the OPO Performance Monitoring Enhancement project.

Staff displayed a graphic of the parts of the donation process that are the OPOs responsibility and that OPOs can impact based on previous MPSC blue sky discussions and the initial timeline for the project and posed the questions:

- What should be our priority to measure?
- What process do we need to standardize for efficiency and to be able to adequately evaluate OPO performance?

- What data needs to be collected and defined to support evaluation of OPO performance?

The Scientific Registry of Transplant Recipients (SRTR) presented information on what data would need to be collected and why that data is necessary to evaluate OPO performance.

The MPSC currently looks at the donor-to-transplant process focusing on Deceased Donor Yield, whereas Center for Medicaid and Medicare Services (CMS) looks at the Potential Donors to Actual Donors that result in a transplant. The current metrics being used may have limitations because the practices of the transplant hospitals vary, and some contributions to these metrics are out of the OPO's control. He also noted that the potential donor data used by CMS to evaluate OPO performance is obtained from Centers for Disease Control (CDC) data that is two years old.

The SRTR recommends the use of a metric measuring conversion from potential donors to actual donors to measure OPO performance. To develop this metric, the MPSC would need to define a "potential donor." The SRTR outlined some first steps for the MPSC to consider which included:

- Determining the definition of a potential donor. The SRTR suggests an in-patient death under the age of 75 ventilated during terminal hospitalization that is without an absolute contraindication to donation.
- Determining the numerator or "success" measure, specifically defining an actual donor based on what is in the control of the OPO.
- Determining and defining variables to include in risk-adjustment to evaluate the likelihood of a potential donor becoming an actual donor.
- Last step in the process is defining how an OPO would be identified for review.

He also provided a list of currently available OPTN data that can be considered and provided the pros and cons of each and displayed an example data capture form that would capture an OPOs' decision points from potential donor to actual donor. He noted one of the benefits of this form is the possibility of capturing why an OPO determined that a potential donor did not become a donor. The SRTR representative concluded that metrics that isolate the role of the OPO should be targeted.

Summary of discussion:

Decision #1: The Committee agreed that the work group should initially focus on defining standard processes and consistent definitions for essential data points for the referral to authorization phases of the donation process and develop proposal for new data collection. The new data collection will eventually support the development of metric(s) and any needed risk adjustment.

The Committee agreed on this initial charge after consideration of the many areas of focus that were identified during the MPSC blue sky discussion at its May 4, 2023, meeting and the BOD discussion at its June 26, 2023, meeting. The Committee considered which phases of the donation process could benefit the most from standardization based on current variability in OPO practice, would most support progress in developing a foundation for an OPO performance metric that supports the OPTN goal of maximizing organ utilization, and could be accomplished within the proposed timeline for a concept paper in January 2024.

In addition, a committee member raised a question about potential risk adjustment for sex, race, and ethnicity, noting a concern that use of these characteristics in risk adjustment could discourage the development of process improvements by OPOs to serve the population in their community. The SRTR responded that they follow the recommendations from the National Quality Forum and that social mechanisms, as well as biological mechanisms, can be important to consider. Additionally, SRTR noted

that the decision to donate is based on trust and there needs to be a recognition that there are certain components of the population who based on historical racism and sexism has resulted in a lack of trust in the healthcare system. In addition, providing OPOs the donation rate by ethnicity can help OPOs identify areas for improvement.

The Committee also discussed:

- The importance of accurate time stamps for the steps in the process to be able to determine elapsed time between steps, for example time of initial referral to time of first offer.
- Consideration of adjustments that consider the unique aspects of donation after circulatory death (DCD) donors.
- Consideration of risk adjustment for registration rates.
- Potential for engaging transplant programs on the donor side to collect data to validate potential donor data.
- Need for stakeholder engagement throughout the project.

Next step:

The OPTN Contractor staff will schedule the initial work group meeting in mid-August to begin work on the development of a concept paper to be released for public comment in January 2024.

2. Performance Monitoring Enhancement (PME) Project Update

OPTN Contractor staff provided an update on the MPSC Performance Monitoring Enhancement project and asked if additional MPSC members were interested in volunteering on the Subcommittee. The MPSC reviewed updated data on the number of programs flagged for performance metrics, received an overview of the offer acceptance review process, and received a presentation from Scientific Registry of Transplant Recipients (SRTR) on an aggregate analysis of elements that contribute to being flagged or being high performing for post-transplant outcomes.

Data Summary:

- Review of updated data
    - July 2023 Flags (718 total programs)
        - 113 total flags for 96 individual active programs
            - 3 kidney and 2 liver programs are inactive or withdrawn.
            - 12 programs were flagged for more than 1 metric – 4 heart, 4 kidney, 1 liver, and 3 lung programs.
        - 83 programs flagged based on the adult criteria and 30 programs were flagged based on the pediatric criteria.
- SRTR presentation on aggregate analysis of elements that contribute to being flagged and high performing for post-transplant outcomes.
    - Does overall patient risk differ by SRTR Tier?
        - Generally, the risk profile of patients does not tend to vary dramatically across the SRTR Tiers
        - No real distribution in patient risk between flagged and non-flagged programs
    - Are there any relevant non-adjustment variables? The three unadjusted variables that had the highest correlation with the probability of being in SRTR Tier 5 for heart programs were:
        - Donation after circulatory death (DCD) donor

        - Center Volume
        - Transplant Recipient Follow-up (TRF) 1 Year: Malignancy
    - Are there any relevant interactions? How to interpret (example):
        - In the kidney deceased donor programs, one of the interactions that was significant was an interaction between the donor history of cancer and the end-stage renal disease (ESRD) time.
        - Interaction is an average at the center (not a patient-level interaction)
        - Interpretation for this example: When centers accept kidneys from donors with a history of cancer, those centers that accept them for candidates with longer ESRD time show up more often in SRTR Tier 5.
        - This is still correlation, further exploration of this type of finding is needed to understand mechanisms.

Summary of discussion:

Decision #1: The Committee discussed the updated data on the number of programs flagged for performance metrics. There was no decision made.

Decision #2: The Committee discussed the organ offer acceptance review process for programs that are flagged. The Committee suggested that resources for programs to review their organ offer acceptance should be included in the next MPSC Chair email communication. There was no decision made.

Decision #3: The Committee discussed the SRTR analysis of elements that contribute to being flagged or being high performing for post-transplant outcomes. There was no decision made.

Decision #1: The Chair asked what the percent breakdown is for pediatric programs being flagged versus percent of adult programs being flagged. Staff did not prepare that data for this meeting but can provide the information to Committee. Staff also noted that the number of pediatric components flagged has remained steady compared to previous cycles.

A member asked if there were any programs that stood out that had more than one metric flagged. Staff stated that there were four heart, four kidney, one liver, and three lung programs that were flagged for more than one metric. Staff noted that an area of interest is whether there is overlap in programs identified for 90-day and 1-year conditional on 90-day survival. Only one program was flagged for both post-transplant outcomes measures; however, a fair number of programs were identified for both offer acceptance and post-transplant outcomes so that seems to be where the largest overlap occurred in this SRTR report.

A member stated that in any organ group, you can see the breakdown of each individual metric and the MPSC needs to pay attention to the number of programs flagged for offer acceptance since it is a new metric that the MPSC has not monitored previously. Staff noted that it is not surprising that offer acceptance is the highest number of flags, especially for kidney programs. When the MPSC was considering monitoring offer acceptance, they found that there is enormous variation between programs in their offer acceptance practices and kidney programs had the most variation.

Staff also noted that, as part of the review process for post-transplant outcomes, it is likely that programs that are flagged in this SRTR reporting cycle are either currently under review or were recently under review and released. When a program is released from review, the program is given a pass for two cycles, even if there is a flag, because the MPSC is looking at more recent data and would have

already reviewed the events that occurred during that time period. Staff mentioned that there are 16 programs this cycle (July 2023) that had not previously been identified for post-transplant outcomes.

A member stated that, when looking at these outcomes, the numbers change based on the time interval the program is looking at because there are natural ebbs and flows within the program. The member mentioned that it is better to look at the cumulative sum control chart (CUSUM) to see changes and understand which trend direction the program is heading. Staff agreed that the CUSUM is a great tool for the program to look at to evaluate their performance. Sometimes programs do provide their CUSUM to show improvement. Since there is a one-year data lag for post-transplant outcomes, the MPSC reviews more recent data and can request CUSUM data to determine whether programs under review have shown improvement. Staff noted, however, that programs are not required to submit their CUSUMs and are not penalized if they do not provide them when asked since those charts were developed by the SRTR for transplant programs' internal quality program use.

A member asked if they can always assume that being flagged for offer acceptance means offer acceptance rate ratio is too low and that there is not a threshold for too high since that would be a good result. Staff affirmed that if a program is flagged for offer acceptance that means the offer acceptance rate ratio is too low.

A member asked why there are already flagged programs for waitlist mortality when the waitlist mortality metric will not be implemented until next year. Staff explained that the SRTR provides this data to the MPSC so the MPSC can evaluate how many programs would have been identified for pretransplant (waitlist) mortality if the metric was in effect today. Staff mentioned that the MPSC Performance Monitoring Enhancement Subcommittee will work to develop the review process for pre-transplant (waitlist) over the next year prior to implementation of that metric next July.

Staff also noted that programs have been receiving information on the SRTR secure site since June 2022, about whether they meet the criteria for all four metrics. This is for the benefit of the programs, so they can be aware and work on improvements before the metric is implemented.

Decision #2: A member stated that the MPSC had previously discussed including data for programs that are not currently using offer filters on what their offer acceptance rate ratio would be if they were using filters. The member stated that their review of a program would be different if a program would no longer be flagged if they implemented offer filters as opposed to a program still being flagged for offer acceptance even if they were to use offer filters, meaning there would need to be a little bit more scrutiny during the review.

Staff stated that they could investigate including that information; however, one of the problems with that data is that it is so variable. Staff may be able to get that data on an individual program if they applied all the recommended filters, but if the program does not want to accept all the filters, then there could be many variations of the effect on the program's offer acceptance rate. For the time being, staff will be providing members with their recommended offer filters and see if they apply them or request an explanation as to why they are not using offer filters.

A member asked how many kidney programs are not using offer filters at this point. Staff stated that 142 (about 62 percent) out of 230 kidney programs are currently using offer filters, so there is still a fair number of kidney programs who are not using filters. There has been an increase in use since the Offer Acceptance Collaborative. Staff also noted that there are some programs that do not have any recommended filters so likely will not reach 100 percent of programs using offer filters.

A member asked if a filtered offer is included as an offer in the program's offer acceptance. Staff stated that a filtered offer is not counted in a program's offer acceptance rate ratio, since it would never become an actual offer.

A member asked if there have been any discussions about organ offer filters for non-kidney organs. Staff explained that there is active discussion around filters for other organs; however, they do not have dates for when those offer filters will be available. The member stated that would be helpful. For example, when listing patients for livers, programs must set an age range that is the same for both donation after circulatory death (DCD) and donation after brain death (DBD) which is not how programs practice. So, if programs are receiving a lot of offers that are outside of their age criteria but other programs may be accepting those offers because they are using pumps, then that could affect the program's organ offer acceptance rate ratio. Staff stated that the Board of Directors approved an OPTN Operations and Safety Committee proposal for default kidney filters, which should increase the number of programs using filters. Default filters will be applied, and programs will need to opt out if the program does not want to use them. Staff stated that conversations are actively occurring regarding when filters can be rolled out for other organs, even if they are the most high-level filters and then the filters can evolve like they did for kidney.

A member stated that there was some discussion about the length of time that programs could opt out of the filters and asked if the initial timeframe of three months had been changed. Staff stated that the final decision was six months, so the default kidney offer filters will be applied and the programs will need to adjust the filters or opt out every six months. The member stated that is much more reasonable than the three-month time frame.

A member suggested that the resources available for reviewing offer acceptance should be included in the MPSC Chair email communications that are sent out after each in-person MPSC meeting. More members of the community see those as compared to the general UNOS email communications. Staff stated they will make a note to include that in the email that will be sent out after this meeting.

A member asked if there was any consideration of delaying monitoring for a year after the new performance metrics are implemented. This would give them an opportunity to internally review their data. Staff stated that it has been a year and a half since the proposal was approved by the Board of Directors. The Committee made the decision to delay implementation for the pre-transplant metrics that programs had not been held accountable for in the past. The implementation of the pre-transplant metrics was scheduled so that no program would be held accountable based on data that was collected prior to the Board approval of the proposal. Staff mentioned that there was delay in the implementation to provide programs with the opportunity to evaluate their performance and there have been multiple communications reminding the community that these metrics were being implemented.

A member stated that, for lung programs specifically, the MPSC should consider breaking down the reported donor offer acceptance into total and DBD donors. The member stated that their program receives a good percentage of DCD offers with donors that are relatively neurologically intact with their reflexes, which skews the acceptance rate. Staff stated that they believe there is a subgroup on the SRTR site for DCD donors for lung. That data is available, and staff will be providing programs with not only their overall offer acceptance rate ratio but also their performance in those subgroups that SRTR produces. Programs will also be provided with information on the available tools to evaluate why their offer acceptance may be lower than others.

A member stated that it would be nice if a DCD donor could be removed from this dataset if the donor does not proceed to death and therefore, does not become a donor. In this situation, an organ procurement organization (OPO) made offers, but they ended up not being a donor. Staff stated that,

for each organ, if that organ from that donor is not transplanted, then those offers are not included in the offer acceptance dataset. That would also cover situations where an organ may not be suitable for transplant, and no one accepts it.

Decision #3: A member asked if this analysis shows that heart transplants from DCD donors are higher risk than from DBD donors. A SRTR representative stated that the correlation in this association is that programs that are in SRTR Tier 5 are performing more DCD donor transplants as a proportion of their total transplants. That does not necessarily say anything at the individual level about the riskiness of the DCD donor because the MPSC is looking at this at an aggregate level. The SRTR representative stated that there may be more exploration of this topic because, from their understanding, DCD donors are generally higher risk at the individual level and this data is showing that higher performing programs are able to do more transplants from DCD donors. The member clarified that SRTR cannot say yet whether utilizing a heart from a DCD donor carries more operative risk than using a heart from a DBD donor. The SRTR representative stated that they have not yet added it to the SRTR risk-adjusted models to see what effect using DCD hearts has at the individual level but that is going to be the next step. A member stated that there is a sense in the heart transplant community that there is more primary graft dysfunction in the DCD donor population, but it would be nice to have the data.

A member asked if the DCD donors are being broken down between Organ Care System (OCS) versus Normothermic Regional Perfusion (NRP), at least for thoracic transplants, in the risk-adjusted model. The SRTR representative stated that they are not sure if they have that level of detail in the data but will investigate it. The member stated that this data could provide information to transplant programs that will help the program determine their level of resources and whether overall cost of procurement increases or decreases risk.

A member stated that they do not believe the OPTN or SRTR is collecting data regarding preservation technologies, so it is hard to know whether it was NRP, OCS, or Paragonix. The Chair stated that it is currently not a granular data field within the OPTN Computer System. Staff stated that there is going to be more data collected starting in September on perfusion so the OPTN can have that data. A member also noted that this data collection will not be as granular as the heart community needs, but it is a start and can be refined later.

A member asked if the idea behind this analysis was to identify new variables to add to the SRTR risk-adjusted model or was it just to get a general analysis. The SRTR representative stated that the purpose of the analysis was more general. The SRTR wanted to analyze additional information on what might be the reason for a program being identified in SRTR Tier 5 or MPSC flagging. The SRTR representative also noted that most of these variables would not be included in the risk-adjusted model because they would not be known at the time of transplant and a lot of the significant variables for other organs had to do with cause of graft failure.

A member asked if there were any findings in SRTR Tier 5 lung programs and if any risk was found to be associated with DCD donors. The member also noted, hearing some of the comments from MPSC members with heart expertise, that it may be worthwhile trying to partition out some of the DCD lung outcomes. If a DCD donor is a lung donor but not a cardiac donor, the lungs come out relatively quickly compared to if there is a DCD cardiac procurement with NRP, whether there is venting, or who is doing the cardiac NRP and cardiac procurement.

The SRTR representative concluded that:

- Overall riskiness of patients transplanted does not vary substantially across tiers of performance.
- Further exploration is needed of variables and interactions identified, but concretely:

- DCD donation will be tested for inclusion in heart risk adjustment for program-specific reports (PSRs)
- Impacts of center volume should be further explored, particularly for smaller volume program types.

Next Steps:

- Development of pre-transplant mortality rate ratio education resources
  - Staff will collect effective practices from programs with better-than-expected performance on pre-transplant mortality rate ratio
- Subcommittee will begin work on review process for pre-transplant mortality.
- Next monitoring plan will be produced for October 2023 MPSC meeting.

3. HRSA Comments

The Senior Advisor in the HRSA Division of Transplantation introduced himself and thanked committee members for their time and effort they would be giving to the OPTN during their term on the MPSC. He described the role of the MPSC as critical in OPTN oversight as the Board operating committee that helps the Board monitor member performance, improve quality, and ensure compliance with OPTN requirements.

He pointed out the Senate Finance Committee identified concerns with MPSC processes and specifically a lack of transparency with some processes. He explained that HRSA is reviewing the OPTN MPSC processes and the patient safety process to explore whether there are any gaps that need to be addressed.

HRSA will be asking for information on all of the cases reported to the OPTN for MPSC review and will be monitoring the outcomes of those cases. They are going to be asking for this information to monitor triage process, the justifications for actions or non- action, and processes used by the OPTN contractor to support all of this activity.

He stated that HRSA has encouraged the OPTN contractor to bring triage protocols and staff practices used to manage cases prior to being sent to the committee for deliberation to the MPSC for review and potential sign-off. He encouraged members to review these protocols and processes carefully to determine if they really reflect their concerns as a member of the MPSC.

HRSA will be increasing its ex-officio members on the committee by two additional staff, who were introduced.

He also briefly described the OPTN modernization project that includes -

- Ensure the IT system is secure, user friendly, and reflective of modern technology.
- Improve data accessibility for patients, providers, and other stakeholders.
- Achieve OPTN board independence.
- Ensure the OPTN is effective and accountable in its implementation of organ policy and operations.
- OPTN supports a culture of quality improvement innovation.

There were no questions following the comments, but members were encouraged to provide feedback on the OPTN Modernization Initiative website at https://www.hrsa.gov/optn-modernization.

4. Report of Investigative Activity

Staff presented a summary of investigative activity from May and June 2023. The report included the number of reports staff received, modes of receipt, reporting and subject member type, general

classification of the issue, and how many cases staff referred to the MPSC, closed without sending to the MPSC, or are still actively investigating. The majority of the presentation focused on reports that staff did not refer to the full MPSC for review, and the reasons staff did not refer those cases. Reasons for non-referral included an inability to substantiate the claim, and a lack of patient safety issue or policy noncompliance.

Summary of discussion:
Staff explained that they will continue to bring these to the Committee, so members have an opportunity to ask questions about certain cases and processes. Staff explained that there is no action to take right now, and it is currently easier to share high level summaries of the issues being presented but staff hope to do more with these data moving forward. For now, staff will continue with the current structure and present the data to the committee and ask for suggestions, process issues, and input on staff's reasons for non-referral.

A committee member said he had no questions about anything on the report, but wanted to know if the presentation is in the packet on the website to be able to review ahead of time. Staff explained that the presentation will be uploaded, but staff did not get it up before the packet was finalized. Another staff member stated that staff may need to refine the cadence. The data are currently presented the following month but depending on the meeting schedule staff do not always have enough time to prepare the data and run the report. Staff are discussing whether to continue trying to get the data to the committee in real time or hold the presentation until the following month.

A committee member requested the average turnaround time for the cases. Staff explained that they are currently developing that metric. The team who performs the investigations is currently understaffed with a great deal of turnover, so cases have experienced a much longer turnaround time than is normal.

A committee member stated that it would be great to review the presentations offline to better be able to determine if there are trends in the data that speak to things that need to be discussed, such as the willingness to test donors for unique situations that might not be required by OPTN policy and whether that decision is appropriate. The member explained that such a situation might not fall under normal MPSC review, but since data is being collected, it warrants discussion.

5. Feedback on Hearing Process

Staff provided an overview of the Hearing Process including the historical process and the changes being proposed based on feedback received from members who participated in hearings. Hearings are offered when the MPSC is considering recommending that the Board of Directors place a member on Probation or declare a Member Not in Good Standing.

Summary of discussion:

Decision #1: The Committee agreed that the proposed hearing process was appropriate, and the OPTN's use of external counsel will be determined on a case-by-case basis.

Prior to the 2018 rewrite of Appendix L, the OPTN Bylaws included a lot of detailed specifics on how a hearing was conducted. The changes to the bylaws removed much of that detail so that the MPSC could improve the process.

Staff described the proposed process. When offering future hearings, at the end of an interview the MPSC would discuss the specific topics that are needed in a hearing presentation and that information would be provided to the member. During the hearing there would be presentations by the OPTN and a presentation by the member. Each would have no less than 60 minutes to present. The OPTN presentation would cover the facts of the case, the applicable OPTN obligations, process steps, and the MPSC's recommendation for an adverse action. The member presentation would focus on the MPSC concerns and requests highlighting the items they were asked to address, and then any additional progress since their last submission and any other information the member would want to include. After the two presentations, there would be a question-and-answer session focusing on addressing the committee's concerns. After initial deliberation, there would be an opportunity for the MPSC to invite the member back in the room for any additional clarification or if there were remaining questions the committee did not get addressed. At the conclusion, the MPSC would give reasons for its decision tied to the presentation and the responses of the member. The member may still have outside counsel. The OPTN could determine the need for outside counsel depending on the situation.

Benefits of the new process would include removing some of the similarities to litigation and court, providing members with uninterrupted time to present rather than a strict testimony format, and providing the member with better areas of focus. The MPSC would be the one asking all the questions and we would not be holding examination and cross examination by counsel.

Staff asked the MPSC if they had any concerns with this format or other suggestion or changes, they would like to see. An MPSC member gave feedback that they were heartily in favor of the direction we are moving and agreed that the previous hearing process was very contentious and a tough atmosphere to be in, even when you were not the member directly involved. The same MPSC member asked if the MPSC has to start with an action of probation to request an interview? Staff clarified that the MPSC does not need to have an adverse action on the table to have an interview. The MPSC can request an interview without any recommended action and then at the end of the interview the committee could decide the appropriate action. If the MPSC recommends probation, then the MPSC cannot recommend a more severe action without another interview. If the MPSC recommends member not in good standing, then the committee could move forward with either member not in good standing or probation. Staff also explained that we want to try to avoid repetitiveness between the interview and the hearing by really confirming with the committee what the concerns are that the member still needs to address during the hearing.

A committee member asked if there was a reason that they were initially set up differently? Staff explained that it was initially set up to try and provide a member a kind of due process before any public actions were taken. At the beginning it was conservatively set up like this to sort of be the trial before the action goes to the Board of Directors. As the committee work has evolved and as we have conducted more of them, it seemed like it would be better to allow the committee and the member to really have a good dialogue and get all the information they needed rather than focusing in on a number of witnesses to testify. There is nothing in the contract that says our process needs to be a more of a legal process.

Staff asked for feedback from the MPSC on whether they need external counsel representing the committee. An MPSC member said no, he believes it just creates additional cost for the hearing and then staff and committee members are the ones needing to prepare them and get them up to speed. The Vice Chair of the MPSC agreed but observed that there might be a case that really puts the committee and its individual members at risk so they would like the ability to retain external council if

needed. Staff affirmed that the standard process will be a discussion with this committee when offering a hearing to help guide that decision making process.

6. Feedback on Patient Safety Intake Form Revisions

Staff presented the Intake Form used by the Patient Safety team to triage reports. Staff explained the purpose of the form, which is for Compliance & Safety Investigators to triage the reports that are received. It helps guide assessment of potential risk, containment plan, and/or response. Staff provided the former and revised forms to committee members, highlighting that the new form asks specific questions regarding the allegation to guide the investigators to a consistent risk level. The risk levels tell the investigators who to notify and when. Staff then provided an overview of the risk levels, namely that risk level 1 is the highest risk level. This risk level was established based on HRSA criteria and additional case types brought to the committee including: living donor death within one month of donation, unintentional transplant of the wrong recipient, unintentional transplant of the wrong organ, unintentional ABO incompatible transplant, failure to obtain donor authorization, failure to obtain brain death documentation, confirmed unintentional HIV transmission, or any event that poses a serious to time-sensitive risk to patient health or public safety.

Summary of discussion

A committee member asked about the question related to other investigations by Incident handling and the criteria for selecting timeframe, using 6 months and 5 or more events? Staff responded that they would like the committee's input on those numbers. The timeframe and number of events were a best determination. Staff then explained that they would prefer to have a number to give them a threshold that the member has crossed. This sets minimum criteria that directs the investigator to conduct additional review of the member. This consistency will be helpful for OPTN contractor staff. This can be changed when the committee reviews this guidance every fall, at a minimum. Staff further explained that they receive pushback from members when the event in question is not a policy violation, and they ask staff to identify the applicable policy regarding the situation. This is in the spirit of more consistency and transparency. Staff can say that the OPTN has "x" many reports regarding this member and the committee has approved of the minimum number for triggering an investigation.

Another committee member asked if there is a question regarding an internal escalation by the member and staff explained that there is not a question on the form, but that question will be asked during investigation.

A committee member asked if the transplant of the wrong organ into an organ recipient is a risk level 1, noticing it was separate from the HRSA events. Staff responded that it is, but it's separate from the HRSA criteria because not every HRSA criteria event is a level 1. Just because HRSA reporting is required does not automatically make an event a risk level 1.

Another committee member asked how staff define an investigation, and whether every report filed is an investigation. Staff responded that every report that gets filed gets reviewed. Every report has an intake form completed and at least a preliminary investigation because staff are going to try to verify what they can in the OPTN systems. If you are seeing closed on the Patient Safety Portal, that is not a determination of our investigation status.

That same member followed up on the "minimum number" and wanted to stress that there are programs that do a lot more donations and transplants than other programs. With the dramatic size differences in OPOs and transplant hospitals, a number would penalize larger programs while smaller

programs get extra grace. Staff responded that getting an inquiry from the OPTN contractor is not a penalty but a way for staff to gather more information. Increasing the risk level does not indicate any wrongdoing, only that investigators will look into the report more quickly. The committee member commented that she remained uncomfortable with a raw number instead of a rate or ration. Staff continued to explain that the intake form is staff's initial assessment of risk; this is not a final determination of risk. Staff use tool to decide how quickly to get the review started. It is not a final MPSC review.

HRSA requested clarification around the HIV transmission cases and whether they are unanticipated donor positive tests. Staff explained that this criterion is a confirmed unintentional transmission.

The vice chair shared that he would provide his comments later, stating that the comments were related to form structure.

7. Educational Initiatives

A staff member updated the Committee on the MPSC's current policy, education, and communication efforts. The purpose of the discussion was for Committee members to review and discuss each ongoing initiative, and to provide feedback on suggested or proposed new policy changes, educational efforts, programming improvements, or community communication. The staff member discussed each ongoing effort and the MPSC had questions and offered feedback.

Recommendations for Policy Improvements

Staff provided guidance around the situations for when the MPSC could recommend a policy change. She reviewed the new MPSC policy referral process for reporting all potential policy issues and referrals to the Policy Oversight Committee (POC) before they are referred onto the other policy making committees.

Update on MPSC 2022 MPSC Recommendations

Staff updated the committee on two recommendations that were established by the MPSC in 2022. These included:

- Recommendation to OPO Committee to address late turndowns and non-utilization due to duplicate acceptances.
    - A work group that included MPSC members was formed to address this issue. It developed a proposal that is going out for public comment this cycle. This proposal is titled 'Modify Organ Acceptance Limit' and the MPSC will review it and provide feedback during the August meeting.
- Recommendation to the Ad hoc Disease Transmission Advisory Committee (DTAC) to clarify HIV results.
    - The DTAC has worked with the CDC, FDA, and NIH on testing guidance for considering if the HOPE Act requirements apply to donors with one positive HIV test result or a clinical determination based on all available tests. This work helps to distinguish if a donor is HIV positive or HIV infected and how the organ must be allocated. The DTAC is releasing a concept paper for public comment that the MPSC will review during its August meeting.

Status of Policy Referrals

Staff explained that since the process was formalized, six policy referrals have been sent to other committees. These referrals include:

- Standardize Reporting Information to Patient Safety Contacts (referred to DTAC). The DTAC reviewed and agreed to work on this referral. A work group was formed that includes MPSC members. The workgroup met in July and plans to seek project approval from the POC in August.
- Clarify Requirements for Reporting Post-Transplant Diseases (referred to DTAC). The DTAC agreed with the confusion in the current language and is planning to prioritize this project after the Patient Safety Contact reporting project. The Committee did not have any questions or feedback on this referral.
- Review Prohibited Vessel Storage Policies (referred to DTAC. Through review and discussion, the DTAC agreed with the value this revision would add to transplant programs and their patients, however, they are faced with challenges as the inclusion of HCV+ vessels would require a revision to the 2020 PHS Guidelines established by the CDC. In relation to other vessel policy referrals submitted to the Operations and Safety Committee (OSC), they expressed their support for this policy modification. If the necessary changes were made in the PHS guidelines, this could be addressed as a joint effort from the OSC and DTAC. The Committee did not have any questions or feedback on this referral.
- Create a Centralized Vessel Storage Reporting Mechanism (referred to the OSC). The OSC agreed that this referral was relevant to their work but given their existing workload did not feel like they could prioritize or slate this referral into their committee work at the time of discussion. When the OSC concludes kidney offer filters and determines the next steps for other projects, they will reevaluate this referral to consider how and when it can be undertaken. The Committee did not have any questions or feedback on this referral.
- Align Organ Packaging Labels with OPTN Policy Requirements (referred to the OSC). The OSC agrees with the need for consistency in the labels and has agreed to take on this project, but for the same reasons mentioned above, they have not slated this referral into their current workload. The Committee did not have any questions or feedback on this referral.
- Consider Clarifying DCD Conflict of Interest Policies (referred to the OPO committee). The OPO Committee was receptive of this referral and agreed to take on the project seeking POC approval in August. If approved, this policy modification is slated for the Winter 2024 public comment cycle. The Committee did not have any questions or feedback on this referral.

Potential Policy Referral

Staff discussed a potential policy referral with the Committee. She noted that this potential policy referral arose through a case submitted through the patient safety portal where conflicting information was given to a transplant hospital regarding whether the blood typing was done pre- or post-transfusion. OPTN Policy 2.6 *Deceased Donor Blood Type Determination* does not specify if the donor blood draw occurs pre- or post-transfusion, which can lead to patient safety risks as this can affect patient ABO results.

The Committee offered the following feedback on the referral to consider clarifying blood typing requirements:

- A Committee member asked if it was required to say if the blood typing is pre or post transfusion. A staff member stated that currently the policy does not specify.
- The MPSC Chair stated that this is something that occurs often and is an important policy change.
- A Committee member explained that in certain cases, having this requirement could put OPOs in a difficult situation.
- Other Committee members agreed that this is an important issue and that there needs to be standardization in how the information is presented.
- The Committee agreed this policy referral can be appropriately handled by the Operations and Safety Committee.

Additional Policy Referrals

The Committee discussed additional policy referrals, which included:

- A policy for pumps, especially with greater sharing and its impact on allocations. Kidneys can travel longer distances if they are being pumped.
- A committee member mentioned data about blood type A subtyping, which has decreased from 70% to 50%. She stated that the policy needs to be either subtyped or documented why it was not subtyped. A lot of the A2 kidneys can go to minority patients and if they are not being subtyped then it is going to have negative implications for those recipients.
- More regulation on what is considered safe subtyping. There is potential for it to not be read correctly.
- OPOs are lacking policy to navigate challenges when they have to recover organs in challenging ways (NRP, DCD, etc.).

MPSC Educational Initiatives

Staff discussed a current MPSC educational initiative. She explained that the MPSC has been working on a patient safety project and provided an update on current educational efforts related to the project. She also provided an update on the work of the Patient Safety Committee Workgroup and next steps. Staff asked for volunteers who would be interested in participating in the workgroup. At this time, the MPSC had no additional questions or feedback about the patient safety project.

Ongoing Educational Efforts

Staff updated the Committee about ongoing educational efforts. Some of these efforts included various poster and oral presentations at conferences by staff and Committee members. Staff also provided information about future educational efforts at conferences in 2024. Staff encouraged Committee members to reach out if they would like to participate in any of these educational efforts on behalf of the MPSC.

Email Communication

Staff discussed a change the MPSC has made to its operations. She explained that the MPSC is now engaging in more open and direct communication to the community. At the December 2022 Board meeting, the MPSC's report to the board proposed an email communication to the community providing reminders based on topics the committee discussed. This allows for greater transparency with the community and the opportunity to send notifications about potential issues in a more expediated

manner. The MPSC had no additional feedback on email communication process but provided feedback on other educational referral and email communication ideas which included:

- Email communication with information on all the toolkits and resources that are available for the Performance Metrics.
- Email communication explaining the importance of double verification of resources to avoid any last-minute problems with procurement.
- Email communication stating that late turn downs is an area of interest within the MPSC.
- A committee member also suggested asking a question about referral ideas when wrapping up cases. Another suggestion was for Committee members to put educational referral ideas in the report when reviewing cases.

Intra-Aortic Balloon Pump (IABP) Concern

The MPSC Vice Chair shared a concern regarding systemic gaming of the use of IABP's. He stated that the Heart Committee expressed concern that this policy is being inappropriately used to escalate patient's status. He provided background information on the topic and noted that it was discussed at the leadership level. He also noted that upon leadership review, which includes the data from the Heart Committee, data does not clearly indicate any misuse of the device or policy.

- A staff member stated that this is a concern that the MPSC should be aware of as Committee members are engaging in the community and attending regional meetings. Staff also shared that if there are any concerns of gaming, inappropriate use of a device, inappropriate escalation of patient care or patient mistreatment, members are encouraged to submit these concerns to the Patient Safety Portal, and we can ensure they are thoroughly investigated on the individual level.
- An MPSC member provided feedback and stated that the vast majority of transplants are now status 2 and exceptions and the regional review board were passing over 95% of those. The review boards have gotten tighter on approvals, but it is still excessive. The amendment going out is to try to get people back to prior behaviors using medical therapy first, then mechanical support. There were no additional questions raised by the MPSC at this time.

8. Preparing for Regional Meetings – What You Need to Know

Staff provided a brief overview of the information that will be presented during the MPSC Update at regional meetings. The regional meeting presentation will include an update on the work of the MPSC Allocation Review Subcommittee and the MPSC OPO Performance Monitoring Workgroup, as well as a review of the MPSC's Require Reporting of Patient Safety Events proposal that is currently out for public comment.

Staff who attend the regional meetings will also provide a departmental update on the collaborative efforts currently underway along with resources for the community to use for opportunities for improvement. There was no discussion.

Upcoming Meetings

- August 29, 2023, 2-4:00pm, ET, Conference Call
- September 27, 2023, 2-4:00pm, ET, Conference Call
- November 1-3, 2023, Chicago, IL
- December 6, 2023, 2-4:00pm, ET, Conference Call

- March 5-7, 2024, Detroit, MI
- July 23-25, 2024, Detroit, MI

Attendance

- **Committee Members**
  - Maher Baz*
  - Alan Betensley
  - Kristine Browning
  - Anil Chandraker
  - Chad Ezzell
  - Robert Fontana
  - Rich Formica
  - Roshan George
  - Darla Granger
  - Dipankar Gupta
  - Shelley Hall
  - Robert Harland
  - Rich Hasz
  - Kyle Herber
  - Victoria Hunter
  - Michelle James
  - Peter Kennealey
  - Catherine Kling
  - Peter Lalli
  - Raymond Lee
  - Carolyn Light
  - Scott Lindberg
  - Melinda Locklear
  - Maricar Malinas
  - Amit Mathur*
  - Deborah McRann
  - Nancy Metzler
  - Saeed Mohammad
  - Regina Palke*
  - Martha Pavlakis
  - Deirdre Sawinski*
  - Malay Shah*
  - Zoe Stewart Lewis
  - J. David Vega
  - Mark Wakefield
  - Candy Wells
  - James Yun
- **HRSA Representatives**
  - Adrienne Goodrich-Doctor*
  - Jim Bowman*
  - Shannon Dunne*
  - Marilyn Levi
  - Chris McLaughlin*

- Arjun Naik*
- Kala Rochelle*
- Daniel Thompson*

- **SRTR Staff**
  - Ryutaro Hirose*
  - Jonathan Miller
  - David Zaun*

- **UNOS Staff**
  - Robert Albertson*
  - Stephanie Anderson*
  - Sally Aungier
  - Sandy Bartal*
  - Dawn Beasley*
  - Matt Belton
  - Tameka Bland*
  - Tory Boffo*
  - Rebecca Brookman
  - Elinor Carmona*
  - Aileen Corrigan-Nunez
  - Tommie Dawson*
  - Robyn DiSalvo
  - Nadine Drumn*
  - Katie Favaro
  - Michelle Furjes*
  - Jasmine Gaines*
  - Shavon Goodwyn*
  - Asia Harden*
  - Madeline Holder*
  - Margaret Kearns*
  - Elias Khalil*
  - Lee Ann Kontos*
  - Krissy Laurie
  - Trung Le*
  - Ellen Litkenhaus*
  - Ann-Marie Leary
  - Jason Livingston
  - Carlos Martinez*
  - Maureen McBride*
  - Jon McCue*
  - Amy Minkler*
  - Heather Neil*
  - Delaney Nilles
  - Samantha Noreen*
  - Jacqui O'Keefe
  - Rob Patterson*
  - Michelle Rabold*
  - Shawn Richman*

- Logan Saxer*
- Laura Schmitt
- Sharon Shepherd
- Susie Sprinson
- Michael Stanley
- Juanita Street*
- Stephon Thelwell
- Melissa Tisdale*
- Marta Waris
- Betsy Warnick
- Trevi Wilson*
- Claudia Woisard
- Emily Womble
- Karen Wooten
- Amanda Young*

- **Other Attendees**
  - Jamie Bucio (Invited)
  - Ashley Cardenas (Invited)
  - Theresa M. Daly (Invited)
  - Todd Dardas (Invited)
  - Micah Davis (Invited)

* Attended virtually