OPTN Membership and Professional Standards Committee (MPSC)
Meeting Summary
May 4, 2023
Chicago, IL

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Introduction

The Membership and Professional Standards Committee (MPSC) met in-person in Chicago, Illinois, and via Citrix GoToTraining in both open and closed session on May 4, 2023. The following agenda items were discussed during the meeting:

1. Require Reporting of Patient Safety Events Project
2. OPO Performance Monitoring
3. Allocations Review Project (Open Session)

1. Require Reporting of Patient Safety Events Project

The Committee reviewed the purpose and proposal of the Require Reporting of Patient Safety Events project and were asked to discuss the following in breakout groups:

- Definition for near miss events (near miss transplant of wrong organ or wrong candidate)
    - Suggested options
        - An error caught when a recipient is brought into the surgery holding area prior to operating room (OR)
        - An error caught during the pre-transplant verification upon organ receipt, as outlined in OPTN Policy 5.8: *Pre-Transplant Verification*
        - An error caught between the index verification and secondary verification
            - Suggested by OPTN Living Donor Committee
- Broadening a current living donor reporting requirement to "a living donor is added to the waiting list within two years after donation"
    - Suggested by OPTN Living Donor Committee
- Inclusion of transportation events as required reports
    - "An organ did not arrive when it was expected without communication from the OPO, resulting in the intended candidate not receiving a transplant from the intended donor"
    - Include "an organ was delivered to the wrong transplant hospital" as well?
- Inclusion of ABO typing/subtyping discrepancies as required reports
    - "An ABO typing/subtyping discrepancy caught after the OPO's deceased donor blood type and subtype verification process, as outlined in OPTN Policy 2.6.C: *Reporting of Deceased Donor Blood Type and Subtype*"
    - Where in the process is it too late to identify these issues?

Summary of discussion:

Near Miss Events

Members could not reach a consensus on the definition they'd like to use for when near miss errors for wrong organ or wrong candidate are identified. Members noted that the pre-transplant processes vary for living and deceased donors, as well as for kidney candidates and heart or lung candidates.

Some members suggested using the current definition, which is an error caught after the recipient is brought into the surgery holding area prior to OR. This would be the best definition to collect the data in a uniform fashion; however, this does not capture the errors that are caught after the patient has been taken into the OR and, depending on organ type, some patients go straight into the OR.

Others suggested defining near miss errors as errors caught between the index verification and the secondary verification. This would remove some of the variation when candidates for different organs are brought into the OR or surgical holding area; however, these processes vary between transplant hospitals so it may not result in good data.

Another group of members suggested modifying the definition, "an error caught during the pre-transplant verification upon organ receipt, as outlined in OPTN Policy 5.8: Pre-Transplant Verification", to "an error caught during the pre-transplant verification". This removes "upon organ receipt" and allows the definition to be tied to both steps in the process that are outlined in OPTN policy while also being broad. It would then capture an error caught during the pre-transplant verification process prior to organ receipt through the pre-transplant verification process upon organ receipt, although that could still mean that surgery for a heart or lung patient could have started by that time. Members noted that these steps in the process are really the last safety net to catch the wrong organ or wrong candidate errors.

Members mentioned that this process really starts with calling the patient to report to the hospital for transplant, and if the wrong patient is called in then that error could escalate into a transplant of the wrong organ or transplant into the wrong recipient.

Broadening Living Donor Reporting Requirement

Members unanimously agreed that this reporting requirement should be broadened to any living donor added to the wait list within two years after organ donation for any organ, not just to the wait list for the organ they donated. Members explained that if there were a chance a living donor would need an organ at any time because of their donation then they would want to know about it, especially because that could insinuate something may have been missed during the evaluation process.

A member also suggested that this could be a technology solution. If an individual donates their organ, their social security number is input in the database and the system could flag if the social security number is used when adding a candidate to the wait list. Or there could be a question added to waitlist forms to indicate if the patient is a prior living donor.

A member stated that two years after donation may be too short of a period and suggested that five years after donation may be better. Staff stated that this could be a question the Committee poses to the community in their proposal, but the Living Donor Committee has been considering expanding the length of follow-up data collection for living donors.

Transportation Events

Members thought that these events are important to capture so the Committee can understand the magnitude of transportation issues. Some members suggested that these events should be posed as

questions to the community during public comment so feedback can be provided about which are high level patient safety issues.

Members noted that the harm being done is non-utilization, which is a patient safety issue for the candidate who did not receive that organ. These transportation events are at least capturing the first level of information for the cause of non-utilization.

Members supported including "an organ was delivered to the wrong transplant hospital" and "an organ failed to be delivered to the transplant hospital".

Other members also suggested modifying the initial proposed transportation event to "an organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue". With most OPOs and hospitals using trackers now, it's uncommon for there to be no communication from the OPO of a delay. Members also wanted to capture that the organ was not transplanted into the intended candidate because of the transportation issue, instead of other complications that may arrive after receipt of the organ.

ABO Typing/Subtyping Discrepancies

Members agreed that these ABO typing and/or subtyping errors or discrepancies should be reported; however, the language of the event should be clear about who is responsible for reporting the error. Members agreed with the proposed event language for OPOs but mentioned that it also needs to be crafted around the needs of the transplant program to encompass their responsibilities.

Next Steps:

Since the Committee did not reach consensus on the near miss definition, the transportation events, or the ABO typing/subtyping discrepancy events, staff will distribute a poll with the options discussed to gain consensus for what the Committee would like to include in the proposal.

The Committee will review and vote to submit the policy language for the Summer 2023 public comment cycle during their 5/22/23 meeting.

2. OPO Performance Monitoring

Presentation on Centers for Medicare and Medicaid Services (CMS) Outcome Measures

Representatives of the Clinical Standards Group, Survey Operations Group and Quality, Safety and Oversight team from CMS provided an overview of CMS' oversight of OPOs; the new CMS OPO outcome measures and the data CMS uses for the outcome measures including how it is obtained and analyzed; and an update on the implementation process, particularly for OPOs that fall within Tier 2 and Tier 3 during the interim assessment years and the recertification cycle. The CMS representatives reviewed the CMS definitions for donor, organ, assessment period/final assessment period, and donor potential contained in 42 CFR §486.302. They reviewed the three CMS outcomes measures of donation rate, transplantation rate, and kidney transplantation rate and noted that the transplantation rate is risk adjusted for the average age of the donor potential. The kidney transplantation rate is used only for the Hawaii OPO. The data sources for the CMS outcomes measures include OPTN data on transplants and actual donors, the publicly available Centers for Disease Control's Detailed Multiple Cause of Death (MCOD) file which contains county-level mortality data derived from death certificates, and hospital level death counts from Medicare inpatient claims. The inpatient claims data is gathered through an ad hoc request to CMS' Health Care Quality, Analytics, and Reporting.

The CMS representatives described the benchmarks and tiers used by CMS to evaluate OPO performance. There are two benchmarks. The lower benchmark is the median which differentiates the

lowest performing group of OPOs from the high performers. The highest performing group are identified by using the lowest rate among the top 25% of OPOs. The lowest rate for the top 25% is calculated by taking the total number of Donation Service Areas (DSAs) multiplied by .25 and rounded to the closest integer. Donation rates and transplantation rates in each DSA are separately ranked and the threshold is the rate that corresponds to that integer when counting down the ranking. CMS calculates a 95 percent confidence interval for each DSA's donation and transplantation rates using a one-sided test. CMS uses three tiers in its evaluations. Tier 1 includes OPOs whose performance on both outcomes measures is not statistically below the lowest rates among the highest 25% of all OPOs. Tier 2 includes OPOs whose performance on both outcomes measures is above the median, but one measure does not meet the Tier 1 criteria. Tier 3 includes OPOs whose performance on one or both measures fall below the median or the OPO does not meet other CMS conditions for coverage.

The CMS representatives reviewed the effect of the Tier placement on OPO recertification. OPOs that fall within Tier 1 are automatically recertified for another four years. OPOs that fall within Tier 2 are not automatically recertified and must compete for a DSA. OPOs that fall within Tier 3 and OPOs that have serious deficiencies under other CMS Conditions of Coverage will be decertified and will lose their DSA. There is a formal appeals process for decertified OPOs. Under 42 CFR §486.318, OPOs receive annual performance reports based on the new outcome measures each spring. The report issued this year is the first one for the 2026 certification cycle. OPOs will receive interim reports in 2023, 2024 and 2025 and the final report for recertification will be issued in 2026. Annual public aggregated OPO performance reports and a User's Guide with the details on computing the outcomes measures are posted on the Quality, Certification and Oversight (QCOR) website. A CMS representative reviewed how to get to the performance report and the User's Guide on the website and then reviewed the information provided in the performance report Excel file. A CMS representative provided an overview of the standard OPO survey process conducted every four years. The unannounced standard survey determines whether the OPO meets all applicable statutory and regulatory requirements. OPO agreements are renewed following a determination of full compliance by the OPO. The last standard surveys were conducted in 2022 and the next will be in 2026. The representative reviewed a visual illustration of the survey process from pre-survey preparation through the exit conference. The CMS representative also briefly described the complaint survey process and compared the two types of surveys.

Following another review of the tiers, the CMS representative noted that OPOs that fall within Tier 3 will receive a notice of the initial de-certification determination and have a right to appeal. If the OPO does not appeal or the de-certification decision is upheld on appeal, the OPOs DSA is opened for competition. A de-certified OPO is not permitted to compete for its open DSA or any other open DSA. An OPO competing for the open DSA must submit information and data to CMS and will have to compete for the entire DSA. An OPO cannot compete for a portion of the DSA. To compete for an open DSA, an OPO must meet the Tier 1 or Tier 2 performance requirements. If no OPO competes for an open DSA, CMS has the authority to designate coverage of the full DSA or part of a DSA to one or more OPOs. Under 42 CFR §486.316, OPOs can seek a 1-year extension of the agreement cycle if there is an extraordinary circumstance beyond the control of the OPO that affects the data in the final assessment period. The OPO must request the extension withing 90 days of the end of the final assessment period. CMS is also requiring that OPOs incorporate data on the outcome measures into their Quality Assessment and Performance Improvement (QAPI). If the outcome measure in each assessment period is statistically significantly lower than the top 25%, the OPO must identify opportunities for improvement and the OPO will need to implement changes that will lead to improvement on the measures.

In closing, the CMS representatives suggested that OPO performance analysis by all agencies should use consistent definitions and terms and reporting of any information must utilize complete and current data sets. In addition, CMS requests that the Scientific Registry of Transplant Recipients (SRTR) analysis be complimentary to the CMS measures to provide OPOs additional detail about their performance in obtaining and placing organs from their DSA. The CMS representatives provided a few initial suggestions, including analysis of race/ethnicity, rural vs. urban, or hospital-level data. CMS representatives also recommended a review of the latest research, referencing new research by Brianna Dolby and Ray Lynch utilizing the CALC methodology that provides greater details for OPOs to assess their performance. The CMS representatives then fielded questions from the Committee.

The Chair opened with several questions. She first asked a clarifying question about whether 25 OPOs would be decertified. CMS representatives responded that if this year was a recertification year, 24 OPOs are in Tier 3. The CMS representative then noted that this year's report is the first interim report in a four-year cycle so there will be two additional annual interim reports and then a final report. CMS is hoping to see a lot of movement between tiers as well as within the tiers based on QAPI adjustments made by OPOs. The Chair noted that she is concerned that it might not be easy for an OPO to dramatically shift their donation and transplantation rates.

The Chair then asked whether CMS had reviewed the geography of the OPOs that would be decertified. She further stated that there could be large geographic swaths of the country that would no longer have certified OPOs and is wondering if it would be feasible for other OPOs to take over these large geographic areas without creating chaos in how organ donors are handled. CMS representatives stated that they are aware of and considering these issues. They also advised that this year's data is from 2021 which was during the period when COVID was prevalent, so it is possible that COVID played a part in the results. In response to the concern that an OPO may not be able to dramatically shift its tier, the CMS representatives noted that a review of the results in previous years shows that a significant number of OPOs have moved from one tier to another in just one year and they are hopeful that OPOs will show improvement through QAPI. Additionally, CMS has a Quality Improvement Organization (QIO) Program that can help OPOs improve.

The Chair then asked for additional information on the appeals process and whether an OPO would be allowed to continue to function during the appeals process. The CMS representatives responded that the details of the appeals process are still being discussed so they will not be able to fully address that question but that generally with any health care provider or supplier, the entity is allowed to continue to function until there is a final decision by CMS to end a Medicare agreement with that entity.

Another member asked a specific question about hospital-based OPOs. If a hospital-based OPO is in Tier 3 and a non-hospital based OPO competes for the open DSA, will the hospital-based structure for that DSA be retained or will the DSA move to a non-hospital-based structure? CMS representatives noted that this is one of the questions they are considering internally. Many of the questions being asked will be contained in a Request for Information to gather more information on these issues. They noted that one of their colleagues that was not able to attend would likely be better able to answer this question. The representatives noted they welcome feedback and if the Committee member wants to send that question to them, they can provide more information.

The member asked another question about whether in the instance of a Tier 1 or Tier 2 OPO making a successful bid for a Tier 3 OPO DSA, would the metrics isolate the outcomes of the previous Tier 3 OPO from those of the new OPO or are the metrics of the new OPO's old territory and new territory combined to be representative of the new OPO. CMS representatives responded that in instances where an OPO merges or has competed and obtained a new DSA, the data would be kept separate until there is a full year of data under the new entity, then it would be combined.

Another member noted that based on the mater, there will always be 50% of the OPOs that fall under the median in Tier 3 and asked whether this would be used for one cycle or will this process continue through multiple cycles, thereby eventually reducing the number of OPOs to one. A CMS representative responded that there will always be a Tier 3. CMS understand the consequences to the nation if all OPOs in Tier 3 are decertified over multiple cycles and is discussing processes for the future. The Director of the SRTR noted there are some nuances to the answer to the MPSC member's question. The tier boundaries are established based on the prior year's distribution on the performance metrics. Use of the previous year's distribution in addition to the 95% confidence interval that overlaps the boundary could result in less than 50% of the OPOs being significantly below the median. It is possible that the percentage of OPOs in Tier 3 can change. If all OPOs improve, those boundaries will continue to move and there will continue to be around 40% that are in the Tier 3 range, if one factors in the confidence intervals. Theoretically, it is possible to have no OPOs significantly below the boundaries if all OPOs improve to have the same performance, but that requires an assumption that the top OPOs do not get any better. A CMS representative noted that it has been brought to their attention by multiple parties that eventually CMS would get to the point where good performing OPOs are being decertified. That is not what CMS wants. CMS needs to hold the OPOs that are consistently underperforming accountable and be able to decertify them. The metrics, the median, and the calculations may change in future but for this cycle, these measures are needed to be able to decertify those consistently poor performing OPOs that are not making efforts to improve their performance. CMS is aware that this will decrease the number of OPOs, especially since statutory requirements do not allow CMS to certify any new OPOs. CMS is looking at these statutory requirements with Congress to see if there is a way to change them. Another CMS representative noted that it is their hope that the low performing OPOs will improve but if there is no improvement, then will remove those consistently low-performing OPOs.

Another member asked how Donation after Circulatory Death (DCD) donors are calculated in the donation rate. A CMS representative stated that they are not able to speak to the adjustments specifically but additional information on the donation rate can be found in the User Guide. She noted members can submit questions that the CMS representatives are unable to answer today to the OPO Resources email box and a response will be provided.

Another member asked about metrics and accountability for donor hospitals since OPO performance is affected by the ability of donor hospitals to identify and refer potential donors. CMS representatives responded that the donor hospitals have their own set of Conditions for Participation and requirements, and there are additional requirements for transplant hospitals. The representatives participating in the meeting are strictly involved with OPOs and their responsibilities under the Conditions for Coverage. However, they have been asked this question before and do understand the role that the hospitals play in OPO performance.

An SRTR representative provided feedback on the CMS definition of "Donor," specifically the inclusion of donors that solely have a pancreas procured for research where no organ for human transplant is procured. The SRTR representative also raised a concern with the lack of robust risk adjustment since the transplantation rate is only adjusted for age. CMS representatives thanked him for the feedback.

A Committee member asked a couple of questions. First, do OPOs need to consistently be in Tier 3 over multiple years or only for one year to be decertified? CMS representatives replied that the report issued during the survey year, in this case the 2026 report, would be used to determine whether an OPO will be recertified. The reports issued in previous years are interim reports. The member further asked whether there are any common characteristics of OPOs that are consistently in Tier 1. Are they smaller OPOs as opposed to larger, more complex OPO or OPOs that deal with a mixed urban and rural population? CMS representatives responded that they do not consider the size of the OPO, in that they expect the OPO

would be staffed appropriately to provide the services required for their patient population. The representatives did not believe that they are considering the characteristics of OPOs that fall within each tier, but suggested the Committee member send the question to the resource mailbox so the team can consider and address the question collectively. The SRTR Director noted that the SRTR had previously expressed concerns and has published that the 75th percentile boundary for the Tier 1 designation is biased against larger OPOs. He stated that it is easier for smaller OPOs to meet that boundary. CMS representatives encouraged continued submission of concerns as opportunities become available for public comment. Those comments will be considered as CMS continues to develop the OPO program and determines what it will look like in future cycles.

The Chair interjected to note that some of the Committee members' questions may not seem to be focused on the metrics but the significant changes that will be created by the CMS metrics will ultimately become the responsibility of the MPSC to oversee and regulate. In addition, the effect of the CMS metrics will impact how the MPSC develops OPO performance metrics. She summarized that it appears that an OPO can be in Tier 1 for four years and if it falls within Tier 3 in that last year of 2026, the OPO would be decertified. Also, it sounds like a large swath will be decertified leading to the creation of more large OPOs which under the CMS metrics are likely to not perform as well. She then asked a clarifying question. If an OPO is decertified and no one bids on it, is it going to be assigned to another OPO that may not want to take over that area? CMS representatives responded that CMS is still working on the details on how to assign a DSA where there are no bids. The ratings and performance of the OPOs will be considered in deciding which OPO will take over that area. The CMS representatives expressed appreciation for the feedback provided regarding a consistently Tier 1 OPO that is in Tier 3 in the recertification year and will take the concern back to our colleagues. If an OPO that has consistently been in Tier 1 and then is in Tier 3 at the recertification year, CMS would want to know why that occurred. They further noted that in the recertification year, an OPO could also move from Tier 3 to Tier 1. CMS staff are discussing what the appeals process will look like and what conversations would occur during those appeals.

A HRSA representative thanked the CMS representatives for their participation and presentation to the MPSC. He noted that it is very helpful for MPSC members to understand how CMS is implementing its regulation. He also requested that the MPSC consider how its work on OPO performance metrics can be complimentary to the CMS regulation, support OPO improvement, and help decrease the number of OPOs that fall with Tier 3.

OPO Performance Monitoring Project Discussions

The MPSC also participated in small group blue sky discussions of the characteristics of a well-performing OPO. Prior to breaking into small groups, staff reviewed information on OPTN authority, the OPTN strategic plan, the OPTN Ad Hoc Systems Performance committee recommendations, and the MPSC principles for choosing metrics. The SRTR Director reviewed the process for organ donation, noting that the process defines where the MPSC should identify metrics. The flow of the donation process is from in-hospital deaths to potential donor to authorization for donation to organs recovered, and finally, to transplants. The SRTR Director noted that the donation process provides the context for a couple of broad metrics. If the OPTN could devise a way to capture data throughout this process, the SRTR could define various metrics that would help OPOs understand how they are doing relative to their peers. The SRTR has been focused on the broad metric regarding the movement from a potential donor to having organs recovered for purposes of transplant, referred to as donor conversion. Another broad metric, currently used by the MPSC, is the OPO's performance on organ yield, which is the number of organs that are transplanted from an individual donor. The SRTR believes that the organ yield metric is a systems performance metric rather than an OPO performance metric because transplant programs must

accept organs for an OPO to perform well. The SRTR Director believes that the MPSC should focus on the broad donor conversion metric to evaluate OPO performance. The SRTR Director noted that the CMS focus is measuring how many potential donors result in transplant, jumping over the middle boxes of authorization and organ recovery. Focusing on the more granular steps in the process will provide more information to OPOs on how to improve.

The SRTR Director then focused on the data available in the OPTN data set, and in other datasets, for each of the steps in the donation process. Granular, comprehensive data is not currently available in the OPTN data set. OPTN data on referrals is aggregate monthly data, and data for potential donors and authorizations is limited to imminent and eligible deaths, which has fallen out of favor due to subjectivity that results in difficulty applying the definitions. The SRTR Director then reviewed data from two OPOs to illustrate that data gathered by OPOs is consistent with other available data. He also reviewed the difference between donor numbers under the CMS and OPTN definitions of a donor.

The SRTR Director noted that the portion of the donation process that is under the control of the OPO, in line with the MPSC principles, is converting potential donors to actual donors. There are smaller components of that broader metric that the MPSC can discuss but that portion of the donation process is most under the control of the OPO. The SRTR Director described the steps the MPSC will need to walk through to develop a metric. The steps in order are defining the denominator, defining the numerator, determining how to calculate the metric, including factors to be included in risk adjustment, and lastly, developing the rule the MPSC will use to identify OPOs for review. The big question for the MPSC is how to define a potential donor. He described the definition developed during the Region 8 pilot. The potential donor definition the Region 8 OPOs developed includes in-hospital deaths under the age of 76 that were ventilated during the terminal hospitalization and that are without absolute contraindications for donation. The MPSC would need to develop detailed guidance to define ventilation and the absolute contraindications for donation. The SRTR Director noted that there are International Classification of Diseases, 10th Revision (ICD-10) Diagnosis Codes, Current Procedureal Terminology (CPT) Codes, and ICD-PCS Procedure Codes that indicate ventilation during the terminal hospitalization. He further noted that there are vast differences in the likelihood that a patient will proceed to donation based on the cause of death. The Region 8 pilot OPOs produced a Death Categorization and Guidance for consistency in defining causes of death. Finally, the SRTR Director questioned how to define a donor for purposes of determining OPO success. The two options include an authorized potential donor, where authorization to pursue was obtained including first-person or next-of-kin authorization or the OPTN definition of a donor that at least one organ was procured for the purpose of transplant.

Following this presentation, the MPSC broke into five groups and discussed the goals of MPSC monitoring of OPOs:

- What are the characteristics that make an OPO well-performing?
- What points of the donation process should be monitored to holistically evaluate performance of an OPO?
- Consider aspects of donation process that OPOs have responsibility for and can impact.
- Consider consistency/variation in OPO processes/performance.

Although the groups considered these questions from different perspectives, there were some themes that emerged from the discussions. The characteristics of a well-performing OPO include:

- On-site or donation conversations. How does the OPO preserve the donation opportunity including outreach plans and interventions with families and with the critical care team.

- Referrals including the rate of referral, timely referrals and interactions with the donor hospital when there are missed referrals or referrals are dropped by the OPO. There is a wide variation between OPOs in how a referral is defined.
- Potential donor. There is a lot variation between OPOs regarding a definition of a potential donor. Successful OPOs rule patients in for donation rather than ruling them out. A standardized definition of a potential donor is needed.
- Donor management. More standardization and consistency in the management of donors is needed, including consideration of donor recovery centers.
- Authorization. Members noted that there are buckets within a potential authorization rate including families interested in donation regardless, registry conversions, and incidences where there is no designation.
- Converting potential donors to donors. The demographics of the population affects the ability to convert potential donors to donors. One group noted that the factors that affect a conversion rate include communication of expectations to donor hospitals, communications with donor families, authorizations, and communication with transplant hospitals to get organs placed for transplant.
- Efficiency metrics including decreasing case times and effective quality improvement programs. Effective quality improvement programs include data driven activities, staffing, and training.

Some other factors discussed by individual groups included evaluation of allocation processes such as how many organs allocated or attempts to allocate; relationships between OPOs and transplant hospitals which can impact transplant rates, procurement and non-use rates; accountability for donor hospitals for timely referral, referral rates, clinical support of patient, and planned donation conversations. One group suggested consideration of a donor hospital accountability demonstration project using transplant hospitals or developing awards for donor hospitals. Another group referenced the use of metric subcategories such as performance on DCD donors or use of perfusion. Finally, one group focused on potential metrics or data elements including:

- Standardized definition of cause of death
- Donor hospital accountability for timely referral, clinically supporting patient, and planned donation
- Response to referral
- Number of donation conversations
- Authorization rate
- Allocated organs or attempted allocations
- Stand alone conversion rate for registered donors
- Granular level data on why organs not allocated
- Reason and timing of late declines
- Redundant and back-up allocation

The Committee closed out its consideration of the OPO Performance Monitoring Enhancement project with a discussion on collaboration with other OPTN committees. Staff described presentations to the Data Advisory Committee (DAC) in February and the OPO Committee in April. The DAC expressed interest in collaboration with the MPSC on data sources and collection. The OPO Committee expressed interest in participation in the project. Staff also noted that the Patient Affairs Committee has also expressed an interest in participating in this project. The Committee was asked for feedback on the

formation of a work group with representatives from other interested committees. The Committee endorsed the formation of a work group. One member suggested including a representative from the Transplant Coordinators Committee (TCC) and further suggested the representative should be a coordinator with experience in taking call from OPOs.

A Committee member asked about whether this project is high priority in light of the information provided by CMS. Staff responded that the Committee has expressed an interest in moving quickly on this project, and therefore, the work on the project will be labor intensive.

An OPO representative noted the CMS timeline. The measurement year for the 2026 outcome measures is this year and the data for the performance year will be from 2024.

3. Allocations Review Project (Open Session)

Staff reviewed data slides on the monthly percentage of allocations out of sequence from July 1, 2018, to October 31, 2022, and the number of allocation deviations reviewed by the MPSC since 2017. Staff also briefly reviewed the types of allocation deviations the MPSC currently reviews and the goals for this project, including short-term goals focused on tweaks to the current system to deal with the increased number of allocations out of sequence and longer-term goals that would focus on what is the ideal process for review of allocation deviations. One of the goals is to identify ways to address transplant program behavior that might result in allocations out of sequence. The Committee has expressed interest in potential inquiries to transplant programs regarding late declines.

Research staff presented information on previous data analyses on late responses and late turndowns to help the Committee better understand what data is available, insights into late declines, and any limitations of this data. These presentations will inform Committee data requests.

The two analyses focused on late responses as defined in policy and on late turndowns based on data to inform how the Committee will define “late.”

The first presentation provided information on an analysis of late responses as defined by policy. Policy provides transplant programs one hour from receipt of offer to provide a response. The analyses also reviewed use of bypass codes in the context of the one-hour time limit. There is a bypass code specifically for late responses, but OPOs do not use it very often. “Other Specify” bypasses spike directly before the one-hour time limit. This bypass code requires submission of reason in a text box. A review of the text indicates that “exceeded time limit” is provided in the vast majority of the text fields for the “Other Specify” bypass code.

The second presentation focused on late turndowns. The analysis presented was done for the OPO Committee in conjunction with its project on expedited liver allocation that was implemented in March 2021. The definition of a turndown for this analysis is when a primary acceptance, not a provisional yes, is then refused. A “late” turndown for this analysis is based on how the timing affects organ non-use. The data is stratified based on when the turndown occurred relative to cross-clamp. Data was presented on the prevalence of liver turndown over time, the non-use rate of livers with a turndown, and turndown rates based on time before or after clamp. The analysis was restricted to the evaluation of turndowns within 12 hours of cross-clamp because some data submitted to the OPTN reflects a turndown at times that are non-sensical, such as a turndown happening over a week after clamp. This is likely a reflection of when the OPO finalizes the match run. Staff noted that timestamp data is useful but often messy, so if the Committee uses this data, it may need to ignore outliers. The system from which we are gathering this data is set up to facilitate allocation. When looking at the definition of “late,” the Committee should be deliberate about the time points included in the definition such as initial

notification, clamp date, initial response etc. and the purpose of defining late. Late can be defined as reflected in policy, by adverse effects on outcomes, or on some other factor. The Committee needs to be explicit of what will be considered "late."

Summary of Discussion

One member had questions about a figure that provided the overage average of late turndowns rather than the change over time. Staff acknowledged it would be helpful to show the change over time and also noted that the analysis may be more helpful if it is done using continuous line rather than buckets of time.

One member noted that data on turn downs before cross clamp may be a bit artificial and not reflect the effort expended by OPOs because the OPO may have had to delay cross clamp because of the turn down. Based on previous discussions on efficiencies in the donation process, it would be interesting to look at case times for allocations where there were turndowns pre-clamp versus those where the organ was not turned down after final acceptance to determine if there is any difference. This data will allow the Committee to determine if those turn downs are prolonging the process thereby introducing inefficiencies. The case time would be determined by measuring the time of brain death declaration to cross clamp. The member noted it would be more difficult for DCD donors. The SRTR Director noted that there are indications of when the OPO took over a donor in the Donor Management Data Collection effort. However, not all hospitals participate in that data collection effort. The brain death declaration time is in the data set but might not reflect when the OPO takes over care of the donor. The OPO member noted that in previous reviews of this data, generally the brain death declaration and authorization times are really close together. Another OPO member suggested using authorization time for DCD donors, but it was noted that with DCD, the family may have given authorization but does not want to withdraw support for two or three days.

Another Committee member suggested that the Committee focus on post-cross clamp turndowns that occur after the policy time frame. The Committee would inquire with programs as to why they turned the organ down late given that it could directly or indirectly contribute to the non-use of organs. If programs are notified of their late turndown rate, it could raise program awareness of this issue.

Committee members noted the difficulty in determining a late turndown for kidneys versus other organs since acceptances are not entered prior to cross clamp for kidneys.

The Committee expressed an interest in an analysis of kidney late turndowns as reflected in the second presentation. The analysis should reflect a continuous distribution of turn downs and data on case times. Staff will also provide an analysis of the turndown rate by program. Based on the differences between kidney and liver, staff may solicit additional input from the Committee as work progresses on the data analysis.

Upcoming Meetings

- May 22, 2023, 3-5pm, ET, Conference Call
- June 21, 2023, 3-5pm, ET, Conference Call
- July 25-27, 2023, Detroit, MI
- November 1-3, 2023, Chicago, IL

Attendance

- **Committee Members**
  - Maher Baz
  - Alan Betensley
  - Timothy Bunchman
  - Anil Chandraker
  - Todd Dardas
  - Robert Fontana*
  - Reginald Gohh
  - Barbara Gordon
  - Robert Harland
  - Rick Hasz
  - Kyle Herber
  - Victoria Hunter
  - Ian Jamieson
  - Christopher Jones
  - Andrew Kao
  - Catherine Kling*
  - Michael Kwan
  - Dianne LaPointe Rudow
  - Carolyn Light
  - Melinda Locklear
  - Gabriel Maine
  - Kenneth McCurry*
  - Nancy Metzler
  - Dan Meyer
  - Bhargav Mistry*
  - Regina Palke
  - Michael Pham*
  - Elizabeth Rand
  - Sara Rasmussen*
  - Pooja Singh*
  - Zoe Stewart Lewis
  - Laura Stillion
  - Sean Van Slyck
  - J. David Vega
  - Candy Wells*
- **HRSA Representatives**
  - Jim Bowman*
  - Shannon Dunne*
  - Marilyn Levi*
  - Christopher McLaughlin*
  - Adriana Martinez*
  - Arjun Naik*

- **SRTR Staff**
  - Ryo Hirose*

- Jonathan Miller
- Jon Snyder
- Bryn Thompson*
- David Zaun*

- **UNOS Staff**
  - Robert Albertson*
  - Sally Aungier
  - Matt Belton
  - Tameka Bland*
  - Tory Boffo*
  - Kate Breitbeil*
  - Rebecca Brookman
  - Roger Brown*
  - Robyn DiSalvo*
  - Nadine Drumn*
  - Demi Emmanouil*
  - Katie Favaro*
  - Liz Friddell*
  - Jasmine Gaines*
  - Rebecca Goff*
  - Katrina Gauntt*
  - Lauren Guerra*
  - Isaac Hager*
  - Asia Harden*
  - Rachel Hippchen*
  - Madeline Holder*
  - Robert Hunter*
  - David Klassen*
  - Krissy Laurie
  - Trung Le*
  - Ann-Marie Leary
  - Jason Livingston
  - Carlos Martinez*
  - Maureen McBride
  - Cassandra McCharen*
  - Sandy Miller*
  - Amy Minkler*
  - Sara Moriarty*
  - Heather Neil*
  - Alan Nicholas*
  - Yawah Nicholson*
  - Delaney Niiles
  - Samantha Noreen*
  - Anne Paschke*
  - Rob Patterson*
  - Logan Saxer*
  - Laura Schmitt

- Sharon Shepherd
- Kay Sheranek*
- Dale Smith
- Stephon Thelwell*
- Marta Waris*
- Trevi Wilson*
- Claudia Woisard*
- Emily Womble*
- Amanda Young*

- **Other Attendees**
  - Shone Carter, CMS *
  - Beth Chalick-Kaplan, CMS *
  - Tom Duvall, CMS *
  - Miriam Godwin, CMS *
  - Heather Lang, CMS *
  - Lauren Oviatt, CMS *
  - Melissa Rice, CMS *
  - Roxanne Rocco, CMS *
  - Kristin Shifflett, CMS *
  - Annette Snyder, CMS *

** Participated Virtually*