OPTN Organ Procurement Organization Committee
Meeting Summary
April 21, 2023
Detroit, Michigan

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Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met in Detroit, Michigan and via Citrix GoToMeeting teleconference on 04/21/2023 to discuss the following agenda items:

1. Welcome, Housekeeping, and Icebreaker
2. Modify Organ Offer Acceptance Limits: Project Update
3. Post Cross Clamp Test Results: Project Update
4. OPTN Membership and Professional Standards Committee (MPSC) Referral: Pronouncement of Donation After Circulatory Death (DCD)
5. OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC): Request for Feedback
6. DTAC – Update on Post Public Comment Changes (Endemic Disease Proposal)
7. Policy Oversight Committee Update
8. MPSC – Allocation Review Subcommittee Update
9. MPSC – OPO Performance Metrics Update
10. Imminent and Eligible Death Definitions
11. Multi-Organ Clarification – 1 Year Monitoring Report
12. Continuous Distribution of Lungs: Efficiency Discussion
13. OPTN Patient and Donor Family Representatives Education
14. Dual Kidney in Continuous Distribution
15. Open Discussion

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

1. Welcome, Housekeeping, and Icebreaker

Committee leadership and Staff welcomed the members, provided an overview of the agenda and meeting facilities, and led an icebreaker exercise. Staff also provided an update on the new Committee roster that will go into effect on July 1, 2023.

Summary of discussion:

There were no additional questions or comments.

2. Modify Organ Offer Acceptance Limits: Project Update

The Workgroup Chair and Research staff provided an overview of the Workgroup discussions, data request, and feedback from other OPTN Committees. The purpose of this project is to modify *OPTN Policy 5.6.C: Organ Offer Acceptance Limit* to only allow a transplant program to have one organ offer acceptance for each organ type for any one candidate. This would eliminate the scenario where a transplant program can be primary for offers from two different donors and wait to determine which organ to accept for their candidate and declining the second offer.

Presentation Summary:

The Workgroup Chair recognized the Workgroup membership which is made up of representatives from various OPTN stakeholder committees. He added that monthly Workgroup meetings have taken place for the last five months.

Research staff noted that multiple acceptance events between March 15, 2021 and September 15, 2022 occurred 811 times for liver, 62 times for lung, and 4 times for heart. Concurrent acceptors for lungs tended to have relatively high lung allocation scores (65.52% had a lung allocation score (LAS) of 50 or greater).

Research staff noted the outcomes for livers that were concurrently accepted were 50.74% (823) “transplanted with another candidate,” 35.02% (568) “transplanted with acceptor,” 8.08% (131) “organ not recovered,” 4.93% (80) “recovered for transplant but not transplanted,” and 1.23% (20) “recovered not for transplant.” The most common refusal reason for recovered livers concurrently accepted then declined was “candidate transplanted or pending transplant” (49.5% - 450), followed by “candidate ill, unavailable, refused, or temporarily unsuitable” (15.84% - 144).

Research staff noted that the outcomes for lungs that were concurrently accepted were 34.68% (43) “transplanted with acceptor,” 33.87% (42) “organ not recovered,” 25.81% (32) “transplanted with another candidate,” 3.23% (4) “recovered for transplant but not transplanted,” and 2.42% (3) “recovered not for transplant.” The most common refusal code for recovered lungs concurrently accepted and then declined was, “candidate transplanted or pending transplant” (38.89%), followed by “organ size” (13.89%).

Research staff provided the following conclusions:

- Concurrent acceptance events most frequently occur for liver (811)
- The majority of candidates that concurrently accept organs are highly medically urgent (Lung allocation score of 50+, Liver Status 1A/1B or MELD/PELD 35+, and Heart Status 1 or 2)
- Lungs concurrently accepted are most frequently transplanted with acceptor
- The majority of livers concurrently accepted are transplanted with another candidate
- For lungs and livers declined by concurrent acceptors the most frequently occurring refusal reason is “Candidate transplanted or pending transplant”
- On average, lungs are declined around 5 hours before cross clamp and 12 hours before for those transplanted to another candidate
- On average, livers are declined around 1.5 hours before cross clamp and 2 hours before for those transplanted to another candidate
- Out of sequence bypass codes are utilized 16% of the time for livers concurrently accepted then declined which is almost double the national rate for all accepted liver
- The cold ischemic time for transplanted livers that were declined by the concurrent acceptor was slightly longer than those that were transplanted with the concurrent acceptor (6 vs 5.72 hours)

The Workgroup Chair highlighted the options discussed by the Workgroup. He added that these are not stand-alone options as the Workgroup has discussed hybrid options following feedback from other OPTN Committees.

Option 1

Modify existing OPTN *Policy 5.6.C: Organ Offer Acceptance Limit* to only allow a transplant hospital to have one organ offer acceptance for each organ type for any one candidate. Staff noted this would not

include a provisional yes acceptance and it does not prevent additional organ offers from being received.

Option 2

Add a timeframe prior to scheduled donor organ recovery to decide on an offer if there is more than one offer for a candidate. Staff noted that previous recommendations included 4 or 6 hours. Staff also noted if the Committee chooses to pursue this option, there is a data field in the OPTN Donor Data and Matching System that allows the OPO to enter the donor recovery date/time. This is currently an optional field so the Committee will need to determine if this needs to be a required field, particularly if OPOs and transplant programs are going to have timeframe requirements in policy.

Option 3

Evaluate medical urgency criteria to determine if candidates with higher statuses should still be allowed to have two concurrent primary acceptances.

The Workgroup Chair provided an overview of the feedback received from other OPTN Committees:

- *Liver Committee*
  - Favored hybrid of option 1 and 3 as not to disadvantage the sicker candidates if one of the offers is ultimately turned down
  - Acknowledged logistical challenges created by multiple acceptances

- *Lung Committee*
  - Favored hybrid of options 1, 2 and 3
  - Timeframe – sometimes OR is not set for 24 hours
  - DCD consideration
  - Convert LAS threshold to LCAS (Lung Committee)

- *Kidney Committee*
  - No substantive feedback

- *Transplant Coordinators Committee*
  - Recommendation to include exception for DCD donors
  - Future use of alternative methods of DCD (e.g., normothermic regional perfusion)
  - Comment about whether including proposed exceptions will help (67% of candidates with concurrent acceptances are higher status)
  - Recognized challenges created by late turndowns

Summary of Discussion:

The Workgroup Chair asked members about the options being considered so the Committee can finalize a path forward for this project and begin working on policy language modifications. He asked if a DCD exception should be considered and whether there should be a timeframe added to policy.

A member commented that liver allocation is really the issue and creating an exception for higher MELD/PELD and Status 1A/1B candidates would only reduce the number of concurrent acceptances by 33% and not truly address the problem.

Staff noted that median MELD at transplant (MMaT) also creates a scenario where a candidate might have a MELD of 35 on one match run and a MELD of 32 on another. Staff noted that Workgroup discussions determined that if a threshold of MELD 35 is established, the candidate would need to have at least a MELD score of 35 on both match runs to qualify for the exception.

A member asked if higher status candidates would really be disadvantaged if they already have a primary offer and they typically get a lot of offers being higher on the match run. He added that other candidates are being disadvantaged when a transplant program is holding onto two primary acceptances for a single candidate. Staff noted that candidates can still receive offers and transplant programs can enter a provisional yes acceptance.

A member noted that the OPTN Liver and Intestinal Organ Transplantation Committee had concerns about the deaths on the waiting list for higher status liver candidates. A member responded that when a liver is turned down late in the process, it jeopardizes all organs because of the challenges to reallocate. He added that non-utilization rates are increasing while transplant centers wait for the perfect organ because they are getting so many offers. He added that the risks created by allowing two acceptances is greater than potentially disadvantaging someone by not allowing the practice to continue.

A member commented that the community should expect similar challenges with continuous distribution of lungs. He added that more lung programs are open to local recovery and shipping.

A member commented about a recent presentation on outcomes for liver acuity circles and how more livers are being transplanted with candidates further down the list. She suggested that it might be due to late liver turndowns.

A member noted that negotiating the donor recovery time with multiple cases disadvantages organs in general. He added that OPOs have a responsibility to move forward with organ placement. While transplant programs are advocating for their patients, holding two acceptances is preventing other candidates from becoming the primary offer and holding up organ recovery from a second donor.

A member noted that the data does not show an increase in non-utilization. However, this is due to the efforts of the OPOs to anticipate late turndowns and spending time and effort getting the organs placed.

A member suggested that after hearing the feedback from the other Committees, the Committee should consider option 1 while allowing for higher status liver and lung candidates. HRSA staff noted that the concern from the Liver Committee focused on receiving an initial offer then having a huge delay in setting the recovery time while other offers are coming in. A member responded that transplant programs will still be allowed to decline a primary offer if a better offer is received with an early recovery time, they just can't have two concurrent primary acceptances.

A member recommended an exception for DCD donors because transplant centers might quickly decline hard-to-place organs. Another member responded that if a transplant center has two offers and one is a DCD donor, they are more likely to decline the DCD donor. A member recommended not including an exception for DCD because the sicker candidates are getting the most offers and do not typically accept for DCD donors.

Members were supportive of option 1 which would only allow one primary acceptance with no exceptions for DCD or higher status candidates. This will allow OPOs to set a recovery time and move forward with organ placement. Another member noted that with broader distribution case times are increasing and placing a burden on donor families.

A member suggested that Committee members reach out to their liver programs to gain support for the proposal. A member added that the data clearly show a problem and should be a focus of the discussions. Another member suggested the development of talking points for members to use.

SRTR staff asked members how they were defining case times that are lasting 4-5 days. A member responded that case time is typically defined as time from authorization to cross clamp.

Next steps:

Staff will draft revised policy language in preparation for a Committee vote during the May 11, 2023 conference call.

3. Post Cross Clamp Test Results: Project Update

Information Technology (IT) staff provided an overview of this project.

Presentation summary:

IT staff noted that presentations are being made to various OPTN Committees to solicit input on the project plan. They added that additional enhancements are being made to allow OPTN Donor Data and Matching System Mobile capability for transplant centers as well as audit reports. Lastly, IT staff noted that education and training will be developed prior to implementation scheduled for the end of 2023.

Summary of discussion:

Several members expressed full support for this effort. A member added that it is important for OPOs to have audit reports to indicate that the testing results were communicated.

4. OPTN Membership and Professional Standards Committee (MPSC) Referral: Pronouncement of Donation After Circulatory Death (DCD)

Staff provided an overview of a memorandum sent to Committee leadership regarding the policy addressing medical personnel employed by both OPOs and transplant centers.

Presentation summary:

Staff noted that the MPSC is required to identify when the review of existing policy or development of policy is necessary to address patient safety issues.

Staff provided an overview of the issue which included the following:

- OPOs employ or contract with multiple physicians that are hospital intensivists to provide on-call medical director services who may need to participate in DCD pronouncement of death, when not on-call for the OPO, as part of the donor's hospital healthcare team.
- The MPSC believes the language in *Policy 2.15.G: Pronouncement of Death* is broad and does not provide adequate clarity for OPOs and the MPSC to determine if the policy has been violated.

Staff noted that DCD donors have increased significantly in the last 10 years, comprising 13.6% of all deceased donors in 2012 rising to 30% of all deceased donors in 2021. This trend is expected to continue as OPOs continue efforts to increase the number of deceased donor organs available for transplant.

- In addition to *Policy 2.15.G Pronouncement of Death, Policy 2.14.A: Conflicts of Interest* addresses who cannot be involved in the organ recovery and transplantation of organs.
- The policies regarding who can participate in the pronouncement of death, regardless of the type of death, should be consistent.

The MPSC recommends revisions to Policy 2.14.A to clearly outline permissible and prohibited behavior by individuals that may be employed at a donor hospital and by the OPO in the context of donor pronouncement of death. The MPSC and Policy Oversight Committee (POC) requests a response by May 9, 2023, addressing the following questions.

- Does the Committee agree with problem – including reasoning?
- Does the Committee consider this urgent?
- Does the Committee agree it is in their purview or if other perspectives are needed?

Summary of discussion:

A member asked how often this situation has come up to warrant this referral. MPSC staff responded that there have been several member questions as well as a couple of cases where the MPSC wasn't sure how to determine if there were any conflicts of interest that violated OPTN policy.

A member noted that her OPO abides by the second bullet in Policy 2.14.A where "the physician who declares the time of the potential deceased donor's death" cannot perform the organ recovery or transplant. The first bullet that states "the potential deceased donor's attending physician at the time of death" cannot perform the organ recovery or transplant can be challenging. She provided an example of a heart patient who had an aneurysm rupture and eventually became a donor, and the attending physician was a heart transplant surgeon. The attending was not part of the death declaration and being the patient's attending physician had no bearing on the declaration of death. She added that the concern from the MPSC is there should be a valid and unbiased declaration of death and the focus should be on the second bullet point.

A member asked if there are situations where the OPO medical director may also be the physician of record or is this more a situation where the OPO may provide a consultation agreement with a donor hospital to provide DCD care. MPSC staff responded that it could be both because there isn't a clear policy definition of an organ procurement team, and they are reviewing potential conflicts of interest. Therefore, the MPSC is looking for language that is clear when reviewing referred cases where a person is in a certain role that they shouldn't be in during the organ donation process.

A member expressed concern about establishing prohibitions and making the process more difficult or making someone think there is a conflict of interest when there hasn't been one in the past. A member added that his OPO follows hospital policy and some states allow a nurse practitioner to declare death, so he suggested consideration of language that does not restrict it to only physicians.

A member noted that there is a lot of attention to what death means and how it is declared. He added that he doesn't want the responsibility to declare a DCD death to fall on the OPOs. He recommended language that states that the declaring physician cannot be actively serving in a role with the OPO or transplant program.

A member expressed concern about keeping the attending physician piece because at the time someone is admitted they might not be immediately referred to the OPO. Once the OPO becomes involved is the recommendation that the hospital change the attending physician. The member added that just because an individual is the attending doesn't mean they have to be the one to declare death.

A member made a recommendation to simplify the policy language by stating if an individual is working in the capacity for the OPO or transplant center at time of death, they cannot be involved in the declaration of death. Another member agreed and noted that the policy language needs to clearly define the roles in order to maintain public trust.

A member suggested the following language: The physician who declares at the time of the potential deceased donor's death cannot be involved in the recovery or transplantation of organs.

The Committee agreed to the following responses to the MPSC referral:

- Agree that the policy needs to be clarified
- Not an urgent issue and should be an easy modification

- Agree to sponsor the project

5. OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC): Request for Feedback

Presentation summary:

DTAC staff presented two proposals scheduled for Summer 2023 public comment and requested feedback from the OPO Committee.

Endemic Guidance Documents Revisions

Staff noted that the guidance is intended to address the following:

- More complex scientific or clinical situations and allow for clinical decision-making
- Includes member obligations that are not readily apparent from the policy or bylaw and are being communicated to a broad public audience for the first time
- Highly controversial issues

DTAC will condense and update the following into an overall guidance document for endemic diseases in both living and deceased donors:

- Guidance for Identifying Risk Factors for Mycobacterium tuberculosis (MTB) During Evaluation of Potential Living Kidney Donors
    - Update to include the changes to nomenclature (tuberculosis infection instead of latent tuberculosis infection)
    - Update Testing (language around preferred testing is slightly outdated)
    - Update report of donor derived infections
    - Refresh epidemiology
    - Add section on deceased donors
- Identifying risk factors for West Nile Virus in living donors
    - Updated to include deceased donors
    - Update summary section
    - Update epidemiology figures
- Recognizing and testing for Chagas disease
    - Update donor screening section if proposal is approved
- Recognizing seasonal and geographically endemic infections in living donors

HIV Positive versus HIV Infected Concept Paper

DTAC staff noted that the concept paper is a request for information from the community that will help DTAC assess the desire for a testing algorithm to deem a donor HIV positive but HIV uninfected and whether this algorithm should only apply to pediatric donors.

Summary of discussion:

Endemic Guidance Documents Revisions

There were no comments and discussions related to the revisions to the guidance documents.

HIV Positive versus HIV Infected Concept Paper

A member commented that her OPO has had this happen several times in the past year with co-infected Hepatitis C (HCV) patients so it might be interesting to collect how often that is occurring.

A member noted that when OPOs receive a positive serology test result for HIV, they consider the donor HIV positive regardless of the results of western blot testing. Another member noted that is done only if

an OPO knows the donor is HIV positive, as there are often times false positives. A member responded that if they have any positive serology results they run it as a Hope Act donor even if it's a false positive. A member provided an example of negative result donor being retested due to the 96-hour requirement and the results came back positive in the donor operating room.

A member noted that donors with a positive Covid test can sometimes have a false positive HIV test result.

A member asked if this could potentially lead to requirements for other testing such as Hepatitis B (HBV) and HCV. DTAC staff noted that it is one of the concerns from the Centers for Disease Control and Prevention (CDC) representatives and the reason why they are looking for an algorithm specifically for HIV since it is the only test where the OPTN prohibits the use of a regular match run to allocate organs. She added that the decision whether to accept organs from HCV and HBV positive donors is up to medical discretion.

A member expressed support for this effort because her OPO has had multiple false positives, and it would be beneficial to move forward without going through the Hope Act because it limits the number of potential recipients. DTAC staff noted that the goal is to collect information from the community to demonstrate to the CDC that there is a need for a pathway to address false positive HIV test results.

A member suggested the discussion questions not single out pediatric donors if the goal is to identify false positive results, because it would apply to adults as well.

6. DTAC – Update on Post Public Comment Changes (Endemic Disease Proposal)

DTAC staff provided an overview of the DTAC's post public comment changes related to their Chagas and Strongyloides screening proposal. DTAC removing the proposed requirement for T.cruzi (Chagas) screening results to be available pre-transplant.

DTAC staff noted there was concern about the availability of Strongyloides testing since there is no Federal Drug Administration (FDA) cleared licensed or approved screening tests. She noted that DTAC has representatives from the FDA, and they were able to formulate a plan to allow for the use of 510(k) exempt tests and laboratory developed tests (LDTs) for Strongyloides to ensure the testing is available to all OPOs.

A member thanked DTAC for listening to the previous concerns because the proposed changes would have been difficult for OPOs to implement.

A member expressed concerns about the requirement for confirmatory testing and whether other labs besides the CDC can perform them. DTAC staff noted there is no timeline requirement for confirmatory testing and OPOs have the option of submitting two different antibody diagnostic testing for Chagas as well.

7. Policy Oversight Committee Update

Presentation summary:

The presentation involved the POC's role in the policy development process, including the following:

- New project review
- Pre-public comment review
- Policy priorities
- Benefit scoring
- Post-implementation monitoring

Summary of discussion:

There were no comments and questions from the Committee members.

8. MPSC – Allocation Review Subcommittee

Presentation summary:

MPSC staff provided an overview of the work of the Allocations Review Subcommittee. Allocation case types include the following:

- Allocation out of sequence
- Actual vs intended transplants
- Ineligible simultaneous liver-kidney transplants

MPSC staff noted the large increase in the number of allocations out of sequence (AOOS) and formed this subcommittee to review the increase and evaluate the MPSC's processes for monitoring. They provided data that showed the percentage of transplanted organs that were allocated out of sequence.

MPSC staff noted that the subcommittee is working to determine the root cause of the increase. They noted that in most instances, OPOs are attempting to allocate hard-to-place organs, decrease cold ischemic time (CIT), or place organs after "late declines" by transplant programs.

The MPSC is focusing on improving monitoring of allocations out of sequence by:

- Evaluating aggregate data to identify any concerning patterns and trends in AOOS
- Creating specific triggers to identify individual allocations requiring in-depth review
- Evaluating data to identify donor characteristics that suggest an organ will be harder to place and may not require in-depth review
- Considering possible definitions of "late decline" and inquiring with transplant programs accordingly
- Considering increased data collection that can improve allocation monitoring and make recommendations to the OPTN Data Advisory Committee as needed

Summary of discussion:

A member noted that OPOs do not want to allocate organs out of sequence, but policies favor equity instead of the utilization of technology to keep up with the policies and providing the tools to allocate according to the match run. He added that when reviewing AOOS, the transplant center behavior and decision-making needs to be considered. When OPOs are working down the match run and trying to get responses from transplant centers, it could take 12-15 hours to get through 30 candidates on the match run. He added that transplant centers play an equal, if not greater role, in the challenges to get organs placed in a timely manner. Lastly, he added that he hopes this is looked at as a system issue and not just an OPO issue.

MPSC staff acknowledged that in 99% of the cases reviewed, the OPO did what was necessary to get the organ placed and avoid non-use, but they still want to identify the reasons for AOOS to better inform the process.

9. MPSC - OPO Performance Metrics Update

Presentation summary:

MPSC staff provided an overview of the discussions to evaluate potential changes to OPTN OPO performance metrics. This work is the result of recommendations from the OPTN Ad Hoc System Performance Committee report to develop additional measures of OPO performance.[1]

MPSC staff provided an overview of the scope of this project which includes the following:

- MPSC principles for evaluation of performance metric. To evaluate member performance, the MPSC should use metrics that:
    - Measure activities that are clearly within OPTN authority,
    - The member can impact,
    - The member is responsible for,
    - Have a clearly desired outcome,
    - Are risk adjusted, and
    - Incentivize behavior that will increase transplantation
- MPSC will consider metrics that align with these principles and supports looking at potential data collection and development of new metric(s) that reflect OPO performance.

MPSC staff posed the following questions for the Committee's consideration:

- What aspects of OPO process should MPSC monitor in order to holistically evaluate OPO performance?
- Recognizing that currently available data is a significant barrier to implementing metrics, any suggestions for data sources/collection?
- What level of collaboration would the OPO Committee be interested in for the OPO performance monitoring enhancement project?
- Other questions or feedback for the MPSC to consider?

The Chair noted that the OPO Committee needs to be actively involved in the development of OPTN OPO performance monitoring enhancements. He added that having available data will be challenging, especially with the way CMS is currently collecting data using hospital deaths.

A member commented that this effort is a good idea, because OPOs are responsible for facilitating donations, but expressed concern about OPOs being held accountable for what transplant centers do. He added that potential donor data is a challenge with CMS getting the information from hospital deaths. OPOs have experience with death record reviews and have a sense of their potential donors, but he also noted concern about the value of reviewing data a year and a half later.

The member added that donors are the responsibility of OPOs while and organs transplanted really falls on the transplant programs. Additionally, how OPOs perform with regards to referrals and authorizations is extremely important. He added that, like the earlier discussion about offer limits, there are small details within the process when combined could have a significant impact on OPOs and unintentionally impede transplantation by creating barriers. He suggested adding a metric that addresses the relationship between transplant centers and OPOs.

[1] https://optn.transplant.hrsa.gov/media/3015/201906_spc_boardreport.pdf

A member asked if the MPSC is working with the SRTR Review Committee to review the feedback from the SRTR Consensus Conference. SRTR staff noted there were a lot of recommendations from the consensus conference and creating a list of priorities which are listed in the published manuscript.[2]

SRTR staff asked if the OPO community was open to doing some primary data collection to help create these new metrics. For example, the previous comment about death reviews and how that data does not currently get submitted to the SRTR. A member responded that it is complicated because there is a lot of mistrust in the OPO community. For example, if an OPO approaches every family but has low authorization rates, will that information be used against them in the future. He added that all OPOs need to have a standard definition for any data being submitted so it is consistent across all OPOs.

SRTR staff noted that data to evaluate true donor potential would be an improvement over what is currently collected and could be used to compare to the CMS data. A member responded that the idea is to remove OPOs from the process of providing self-reported data and using independent institutions such as the National Quality Forum and others.

A member noted that the Association of Organ Procurement Organizations (AOPO) is working on standard definitions but acknowledged that not all OPOs are members of AOPO.

A member asked if it was possible to overlay the allocation review discussion with OPO performance to review a metric about how effective OPOs are at placing hard-to-place organs by whatever means necessary. For example, if all those kidneys are not utilized there would be no discussion about policy violations, however they are getting transplanted so there is an opportunity to learn from the OPOs that are effective at placing them. MPSC staff responded that the purpose for doing two presentations was the recognition of overlap between the two issues so there will be an element of allocation reviews during the performance metrics discussions.

SRTR staff noted that to improve the data capture, there are some things that could be tackled based on experience working with various OPOs in the past. The goal is to tell a better story to counter the negative press about the OPO system as well as the overall transplant system. He noted an SRTR project working with the Region 8 OPOs where they learned that regardless of what electronic donor record system is used, there are data fields that are similar and could provide an opportunity to better standardize the information. He used a few examples of currently available data which could help with the collection of OPO data, including the following:

- *Cause of death* - The Region 8 project was able to capture this information within 12-15 classifications. He noted that it was captured in different ways (text fields, ICD-10 codes) so standardizing the reporting of principle cause of death across all OPOs would be beneficial. He added that once that is done, it would make it easier to risk adjust across OPOs.
- *Hospital unit where death occurred* – helpful with predicting donation.
- *Decline in authorization* – reason for the decline.
- *Co-morbidities* – help identify whether the patient will proceed to donation.

[2] Snyder JJ, Schaffhausen CR, Hart A, Axelrod DA, Dils D, Formica RN Jr, Gaber AO, Hunt HF, Jones J, Mohan S, Patzer RE, Pinney SP, Ratner LE, Slaker D, Stewart D, Stewart ZA, Van Slyck S, Kasiske BL, Hirose R, Israni AK. Stakeholders' perspectives on transplant metrics: the 2022 Scientific Registry of Transplant Recipients' consensus conference. Am J Transplant. 2023 Mar 21:S1600-6135(23)00355-6. doi: 10.1016/j.ajt.2023.03.012. Epub ahead of print. PMID: 36958628.

SRTR staff also noted that collecting whether the patient was ever on a ventilator would be helpful information, as this is one of the shortcomings of the CMS data collection since it doesn't identify how many reported deaths were ventilated.

A member asked if the SRTR envisions a standardized way for OPOs to report 100% of all death notices to the OPTN through an electronic health information exchange system. SRTR staff responded that standardized definitions would require training and education and it is helpful that most OPOs are using one of two electronic donor record systems. This would allow for the transfer of key fields into the OPTN system.

A member expressed support and considered it an investment to standardize definitions and data reporting across all OPOs. He added that if the MPSC can figure out a meaningful way to measure OPOs it would be a great place to start. He further added that he hoped the OPO Committee will have considerable input on these future changes.

SRTR staff noted the Region 8 project created some mock data capture instruments to illustrate the type of data that could be valuable and offered to share that with the committees. He added that they developed a flow chart that shows the questions and the potential categories as part of an initial proposal. MPSC staff added that any proposal that would evaluate additional data collection would also include the ability to monitor the accuracy of the data.

A member expressed support for standardized language but also asked how to bring individual constituents and groups together to identify the donation rate. He added that the community should not lose sight of the increase in the kidney non-use rate because so much time and effort is spent on other efforts. SRTR staff responded that they are willing to help with efforts to bring the data from the various groups together.

10. Imminent and Eligible Death Definitions

Staff provided an overview of recent conversations with Health Resources and Services Administration (HRSA) staff regarding the collection of imminent and eligible death data.

Presentation summary:

Staff noted that previous committee discussions concluded the data is not as valuable in identifying true donor potential and has been criticized for being "self-reported" data. However, HRSA staff recommended the OPTN continue to collect the data since it is used for various purposes.

Summary of discussion:

Staff noted that imminent and eligible data will be part of the MPSC's evaluation of OPO performance metrics.

SRTR staff noted that one of the recommendations from the SRTR consensus conference was to remove the reporting of eligible death. However, he added that the data is still useful for identifying comorbidities and contraindications to transplant and should be retained in OPTN policy to help evaluate exclusions for donation rates.

There were no comments or questions from the members.

11. Multi-Organ Clarification – 1 Year Monitoring Report

Research staff presented the highlights from the 1-year monitoring report for the policy change to clarify multi-organ allocation. The policy addresses multi-organ combinations containing a heart, lung and heart-lung where the candidate also requires a kidney or a liver. The policy set criteria that a

candidate must meet in these circumstances for it to be required that a kidney or liver is offer with the heart, lung or heart-lung when possible.

- For heart candidates to receive the kidney or liver offer they must be within 500 NM an adult status 1, 2, or 3 or a pediatric status 1A or 1B
- For lung candidates to receive the kidney or liver offer they must be within 500 NM have an LAS of > 35 or be under the age of 12
- For heart-lung candidates to receive the kidney or liver offer they must meet the conditions of either a heart candidate or a lung candidates listed above.

Candidates that meet these conditions are considered "required shares."

<u>Summary of Data:</u>

The monitoring request for this policy was to review heart-kidney, heart-liver, lung-kidney, lung-liver candidates, and recipients by transplants, waiting list additions and waiting list removals (specifically those removed for death or too sick). The metrics of interest was the share type (required or permissible), medical urgency for all organs, age group (pediatric or adult), distance from donor to transplant hospital and OPTN region.

The presentation highlighted the main points from the full report which was provided to the Committee prior to the meeting.

Because most organ combinations, with the exception of heart-kidney, had a small number of events, the metrics were evaluated collectively or by primary thoracic organ.

The metrics were evaluated across the pre-policy era from March 12, 2021-February 9, 2022 and post-policy era from implementation on February 10th, 2022 to January 10th, 2023.

Highlights of the data include the following:

Multiple Organ Thoracic Transplants

- There was an increase in multiple organ thoracic transplants from the pre-policy era with 389 (6.7%) thoracic transplants to post-policy era with 487 (7.6%) of thoracic transplants. This increase was also consistent across the primary organs.

- Heart multiple organ transplants increased from 10.48% to 11.72%, lung increased from 1.04% to 1.31% and heart-lung increase from no multiple organ transplants to three multiple organ transplants in the post-policy era.

- There were no heart-lung transplants in the pre-policy era. While in all eras for all primary organ the majority of multiple organ transplants were required shares, the number and proportion of permissible shares did increase for heart and lung multiple organ transplants.

- The proportion and number of transplants where the recipient LAS was less than 50 increased in the post policy era. The median LAS for multiple organ recipients also decreased from 75.62 in the pre-policy era to 54.2 in the post-policy era.

- The proportion and number of transplants where the recipient was in adult status 5 increased notably in the post policy era while all other statuses remained relatively consistent across eras.

- The proportion and number of transplants where the recipient had a MELD/PELD of 15-19 increased considerably in the post policy era. There was also a slight increase in those with a MELD/PELD of 25 or greater at transplant

- All pediatric recipients received either a heart-kidney or heart-liver transplant throughout both eras. The total number of pediatric recipients decreased across the eras from 12 (3.08%) to 8 (1.64%). This trend was also consistent across the transplant type received.
- For heart-kidney and lung-kidney there was an increase in the number of transplants occurring outside of 500NM from the donor hospital in the post-policy era.

Waiting List Additions

- There was an increase in heart multiple organ registrations from 583 to 609 listings in the post-policy era. While multiple organ listings for lung and heart-lung remained relatively similar across eras.
- There was an increase in heart multiple organ registrations from 583 to 609 listings in the post-policy era. While multiple organ listings for lung and heart-lung remained relatively similar across eras.
- The proportion and number of registrations where the candidates LAS at list was 50+ also decreased in the post-policy era (Pre: 50% (28), Post: 36.54% (19)).
- The proportions of listings in for adult status 1, 3, and 6 decreased. The proportions of listings in all pediatric statuses remained relatively consistent.
- The number of liver candidates listed for multiple organs with a MELD/PELD of less than 25 increased.
- There was only one pediatric registration of a lung-kidney in the pre-policy era and none in the post-policy era. The number of pediatric listings decreased for heart-kidney from 8 to 4 in the post-policy and increased for heart-liver from 10 to 13 in the post policy.

Waiting List Removals

- The majority of removals for multiple organ heart and lung candidates were due to transplants across all eras. Removal due to death or too sick decreased for both heart and lung multiple organ candidates from the post-policy era to the pre-policy era.
- As many heart candidates are listed as inactive before being removed due to death or too sick – the equivalent of about 70% of listings removed for death or too sick in both eras - the last known active status before removal is reported for these events. There was an increase in removals due to death or too sick for candidates whose last known active status was adult status 2 (Pre: 19 and Post: 31). There was also a considerable decrease in removals due to death or too sick for candidates whose last known active status was adult status 3 and 4. The LAS for all 22 lung multiple organ candidates removed for death or too sick was 30+ at the time of removal (Pre: 10, Post:12).
- The majority of candidates removed for death or too sick had a MELD/PELD at removal or last known MELD/PELD of <20.

Conclusion

- There has been a considerable increase in multiple organ transplants containing a heart and/or a lung since the implementation of this policy. The change was largely driven by the increase in permissible share type transplants.

- This shift may have contributed to the decrease in the median LAS for multiple organ lung recipients at transplant and an increase in multiple organ recipients with adult heart status5 at transplant in the post-policy era. However important to note this increase seen was not as significant in the 1-year monitoring as it was in the 6 months so it appear to be stabilizing.
- Another trend of note is removals due to death or too sick have decreased for heart and lung multiple organ waiting list registrations since policy implementation.
- Although numbers remain small and it's difficult to discern the true impact of the policy, all available data has indicated the policy was successful in transitioning heart and lung multiorgan transplant requirements to the NM radius while maintaining overall historical trends seen with those multiple organ transplants.

Summary of discussion:

Committee members had no questions or comments.

12. Continuous Distribution of Lungs: Efficiency Discussion

Staff provided an overview of the challenges being noted by both transplant programs and OPOs since the implementation of lung continuous distribution on March 9, 2023.

Presentation summary:

Staff highlighted the concerns from the lung transplant program perspective:

- Mixed feedback on higher vs. lower offer volume
  - Higher offer volume for programs with the most medically urgent candidates (e.g. on Extracorporeal membrane oxygenation)
  - Some programs with only outpatient candidates seeing lower offer volume
  - Increase in higher sequence offers
  - Some receiving more DCD and multi-organ offers
  - Observing more out-of-sequence allocation
- Request for more information available at time of offer, particularly if needed to justify traveling farther to procure the lungs.

Staff provided an overview of a joint OPO and Lung Committee leadership call. The leadership of both committees acknowledged that future discussions should focus on donor acceptance criteria, offer notification limits, offer filters for lung, and lung donor testing. They also acknowledged that it is still early in implementation and that members will probably adjust to the changes.

Summary of discussion:

A member commented that the allocation process for heart and lung match runs is complex, which has been made more complex with continuous distribution.

A member noted that offer notifications can be set broad, particularly for kidney offers. Another member noted that OPOs should not send out a large number of offers because you want the transplant programs to take the offers seriously. A member responded that transplant programs also take the entire hour to respond when coordinators really need answers in a timely manner. The member added that OPOs and transplant centers need to work together to identify the appropriate balance.

A member commented that lung programs are experiencing what abdominal transplant programs have been experiencing with the number of offers. Staff noted that for offer notification limits, "local" for lungs is defined as 1,000 nautical miles to align with the previous allocation distance for lungs and the

distance should probably be revisited for continuous distribution. A member added that the increased use of machine preservation might impact lung transplant program decision-making. For example, a lung program might not be willing to travel 2000 miles for a cold-stored lung but would for a lung placed on machine preservation.

A member noted that previous OPO feedback during the development of continuous distribution included a recommendation to increase the weight given for the placement efficiency attribute. He added that with limited weight being placed on placement efficiency, it is essentially a national list that provides exposure to more lung offers. He added that his OPO has seen up to 35 centers within the top 80-90 candidates on their lung match runs.

A member recommended moving forward with offer filters for lungs. He added that at some point there needs to be some accountability for transplant programs to manage their lists by using reasonable acceptance criteria. OPO coordinators are dealing with complex allocation policies and doing the best they can to get organs placed. Another member added that broader distribution, while great in theory because it gets organs offered to the sickest patients, is operationally too complex and is leading to an increase in discards, late declines, and other logistical issues.

A member agreed with the recommendation for offer filters for lungs and incorporating offer acceptance rates that should be transparent and published. Staff noted that data could be provided to centers so they can better manage their acceptance criteria. A member added that offer filters should be done in a timely manner and not follow the deliberate approach taken for kidney offer filters. Staff agreed with this comment because kidney offer filters have provided lessons that can be applied to other organ systems.

A member suggested educating members during the regional meetings. She added that many programs are unaware of how acceptance criteria can help them with offers and there should be some acknowledgement from each program that they are aware of them.

13. OPTN Patient and Donor Family Representatives Education

Staff provided an overview of an educational resource being developed for OPTN patient and donor family volunteers. The purpose of this education is to provide an overview of the entire process involved in a transplant – from donor referral to recovery, placement, and transplant.

<u>Presentation summary:</u>

Staff provided information that has been drafted to highlight the following steps in the process:

- Donor referral process
- Consent
- Donor management
- Organ allocation
- Organ recovery

<u>Summary of discussion:</u>

Committee members provided the following feedback:

Donor Referral Process

- A member suggested removing the reference to brain death and brain trauma and instead focus on ventilator status.
- A member suggested stating that every OPO is required to report every death and imminent death within a certain timeframe.

- A member asked about the level of detail needed for this effort. He suggested specifying that all potential donors are assessed for any risk factors for organ donation and that organ function is assessed and shared with transplant centers.

Consent

- A member suggested changing consent to authorization since that is the correct terminology used for organ donation. He added caution about specifying that OPOs obtain authorization from family members because prior first-person authorization does not require family or next of kin approval. He added that OPOs are simply notifying the family that their loved one is registered as an organ donor.
- A member suggested changing "life support" to "medical ventilation." Another member suggested removing the reference to families being in the room when life-sustaining medical support is removed since that is not always an option, especially with DCD donation.

Donor Management

- A member noted that transplant centers, not OPOs, make the decision about whether an organ is transplantable or not. The OPOs ensure the organ is safe and allow the transplant centers to make the decision.
- A member noted that her OPO stopped providing a timeline to families because of how much case times have increased. She added that donor management is a long process and can change at any time.
- A member suggested changing "pursue organs" to "will attempt to utilize all medically suitable organs" or something similar.

Organ Allocation

- A member noted this process varies from OPO to OPO. He suggested keeping the information as basic as possible and suggested reaching out to OPOs and asking for samples of their current materials.
- A member suggested adding information about the logistics involved in organ allocation.

Organ Offer Acceptance

- A member suggested mentioning that OPOs don't just confirm acceptance of offers but also put a lot of effort into identifying several backup offers.

<u>Next steps:</u>

Staff will reach out to the committee to review the remaining sections of this educational document which includes the coordination of recovery time and organ recovery.

14. Dual Kidney in Continuous Distribution

Staff provided an overview of the Utilization Considerations Workgroup's focus to address aspects of kidney and pancreas allocation that falls outside of the composite allocation score but require modification to transition to the continuous distribution framework. This includes the following:

- Practical focus on utility and efficiency
- Diverse, practical allocation-experienced perspectives
- Operational topics include dual kidney allocation, minimum acceptance criteria screening, facilitated pancreas, etc.

Staff is seeking feedback from the Committee regarding dual kidney allocation.

Presentation summary:

Staff provided an overview of the current state of dual kidney allocation. Dual is a classification for kidneys with a KDPI of 35-100% (sequence C and D) where centers opt in to receive dual offers and the candidate will appear twice on match run – once for single and again for dual. Staff noted that data shows nearly half of duals (44.44%) are allocated from the single sequences. When candidates appear twice on the match run, the match runs are longer and less efficient. Monitoring reports and anecdotal feedback shows clear need for a new system of dual kidney allocation.

The Workgroup recommends the following framework where dual kidneys are allocated from a specific dual kidney match run:

- In order to offer kidneys as dual, the host OPO would need to run a new, dual-specific match run
    - Improved efficiency for the original, single kidney match run and the dual kidney match run:
        - Candidates only appear once on the original match run, which reduces calls and increases efficiency
        - Dual kidney match run includes several layers of efficiency, including filtering and screening
- Specific criteria dictates when an OPO may begin allocating the kidneys as dual kidneys

Staff noted that the Workgroup developed two sets of criteria to determine when an OPO may begin dual kidney allocation

- The OPO is not required to allocate kidneys as dual at this point, but is given the discretion to do so

The Workgroup agreed on several considerations:

- Criteria should differ between different KDPI
- Cold ischemic time is a crucial consideration
- Post-OR information, such as biopsy results, should be considered

The dual kidney criteria being considered include:

- The first set of criteria relates to findings that are concerning in any donor, regardless of KDPI
- The second set of criteria relates to findings that are concerning in higher KDPI donors

Summary of discussion:

A member asked how these changes will impact en-bloc kidneys from small donors and suggested they be placed using a single match run. He added that if a transplant center does a range refusal on the single kidney match run, they should be prompted to indicate interest in dual kidneys.

A member asked about the 2 for 1 concept and whether it is the answer to the problem. He asked if this was a cold ischemic time or marginal kidney issue because not all transplant centers will take 2 for 1 kidneys and his OPO has a difficult time placing dual kidneys.

Another member who serves on this workgroup responded that part of the proposal is to require transplant programs to indicate if they are willing to accept dual kidneys. She added that another component will be the ability for a transplant center to respond at the time of the offer that they decline for a single kidney but are willing to accept for a dual. Additionally, the rationale for the four-hour timeframe is that a lot of transplant centers will not make a decision until they see the biopsy results.

A member asked if this was an attempt to solve a problem that doesn't really exist. He added that the resources for this change might not align with the limited number of dual kidneys performed each year. He further added that his high volume OPO might allocate three dual kidneys a year.

A member responded by noting this is an effort to adjust policy to align with upcoming continuous distribution for kidneys so it is an issue that needs to be addressed in preparation for those changes.

15. Open Discussion

Summary of Discussion:

A member commented that she understands the idea of the tiered system to measure OPO performance, but there is way more pressure on OPOs to meet those numbers than there should be. She added that the transplant center partners play a big role in the number of transplants and there should be recognition of what OPOs can and cannot do. She added that operating room time is a challenge, and we should work with our hospital partners to make more time available. She added that extended case times are difficult for families and OPOs can't force families to delay donation for extra days to allow time for logistics.

A member commented that in order to maximize donation and increase transplants, there needs to be a collaboration between OPOs, transplant centers, and donor hospitals.

A member asked if any other committee members had received a request for a research proposal related to partial heart transplantation. HRSA staff noted they are aware of this and have been informed by the Federal Drug Administration (FDA) that it is considered tissue which falls under the purview of the FDA.

Upcoming Meeting

- May 11, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Bruce Nicely
  - Clint Hostetler
  - Doug Butler
  - Erin Halpin
  - Leslie McCloy
  - Meg Rogers
  - Sam Endicott
  - Valerie Chipman
  - Sharyn Sawczak
  - David Marshman (Virtual)
  - Donna Smith (Virtual)
  - Debra Cooper (Virtual)
  - Judy Storfjell (Virtual)
  - Larry Suplee (Virtual)
  - Sue McClung (Virtual)
- **HRSA Representatives**
  - Jim Bowman (Virtual)
  - Mesmin Germain (Virtual)
  - Adriana Martinez (Virtual)
  - Vanessa Arriola (Virtual)
- **SRTR Staff**
  - Ajay Israni (Virtual)
  - Nick Wood (Virtual)
  - David Zaun (Virtual)
  - Katie Audette (Virtual)
- **UNOS Staff**
  - Robert Hunter
  - Lauren Mauk
  - Kayla Temple (Virtual)
  - Taylor Livelli (Virtual)
  - Katrina Gauntt (Virtual)
  - Roger Brown (Virtual)
  - James Alcorn (Virtual)
  - Kevin Daub (Virtual)
  - Sharon Shepherd (Virtual)
  - Krissy Laurie (Virtual)
- **Other Attendees**
  - Lori Markham (Virtual)