

OPTN Organ Procurement Organization Committee

Meeting Summary

October 6, 2022

Richmond, Virginia

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Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met in Richmond, Virginia and via Citrix GoToMeeting teleconference on 10/6/2022 to discuss the following agenda items:

1. Welcome and Introductions
2. Enhancements to the OPTN Donor Data and Matching System Clinical Data Collection
3. Modify Organ Offer Acceptance Limits
4. National Academies of Science, Engineering, and Medicine (NASEM) Report
5. Vascular Composite Allograft (VCA) Guidance Document
6. Utilization Considerations Workgroup Updates
7. Lung Continuous Distribution
8. Expedited Liver Placement – 1 Year Monitoring Report
9. Research Department Orientation
10. OPTN Histocompatibility Committee – HLA Confirmatory Testing Project
11. Released Organ and Kidney Pancreas Circles-Based Allocation – 1 Year Monitoring Report
12. Multi-Organ Clarification – 6 Month Monitoring Report

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

1. Welcome and Introductions

Committee leadership welcomed the Committee members, and Committee members introduced themselves.

Summary of discussion:

The Committee had no questions or comments.

2. Enhancements to the OPTN Donor Data and Matching System Clinical Data Collection

Proposal summary:

The purpose of this proposal is to streamline communication of key clinical donation after circulatory death (DCD) donor information. This will provide easily accessible information, and support more efficient donor evaluation.

This data is not currently collected. The addition of this information will help reduce back and forth communications between the OPO and transplant program regarding the DCD donor and will provide a snapshot of the DCD donor progression. The intent is to improve organ offer evaluation and the efficiency of organ placement.

This proposal will add the following data elements:

- Withdrawal of Life Sustaining Medical Support, Date/Time
- Cessation of Circulation, Date/Time
- Flush Time (In Situ), Date/Time
- Oxygen Saturation (SpO₂)

Summary of public comment sentiment:

The majority of written comments were received in the last three days of public comment. Public comment sentiment was largely supportive, with one opposition vote in Region 4. There was also largely support across all member types. Public comment sentiment was largely submitted by transplant hospital and OPO participants.

The following organizations were supportive of proposal and provided comments

- American Society of Transplantation (AST)
- Association Society of Transplant Surgeons (ASTS)
- International Society for Heart and Lung Transplantation (ISHLT)
- The Organization for Transplant Professionals (NATCO)
- Association of Organ Procurement Organizations (AOPO)
- American Nephrology Nurses Association (ANNA)
- Kidney Donor Conversations

The OPTN Lung Transplantation Committee, OPTN Pancreas Transplantation Committee, and OPTN Liver and Intestinal Transplantation Committees were supportive of the proposal and provided comments.

Major themes in public comment included:

- Normothermic Regional Perfusion data collection
- Link between electronic donor records and OPTN Donor Data and Matching System
- Support for a separate page within the OPTN Donor Data and Matching System for DCD information

Supportive comments emphasized benefits to streamlining communication and more efficiency allocation. Commenters agreed that the proposed DCD data is vital.

Regional comments for discussion include:

- Region 3 – opportunities for DCD donation are lost when centers refuse an offer during organ recovery (OR). OPOs should record this information to help generate data to understand late turn downs
 - Need for established guidelines for DCD organs declined in the OR
- Region 5 – suggestion to add a line for the initiation of cardiopulmonary bypass for DCDs using NRP, as this is essential to determining warm ischemic time (WIT)
- Region 6 – suggestion to make these required fields and adding the use of NRP or OCS
- Region 7 – suggestion that the agonal phase needs to be clearly defined, as there is too much variability in how different OPOs calculate timing
- Region 10 – suggestion that there be a data field to show the difference in systolic and diastolic blood pressure, as it can be a better measure of perfusion rhythm

Committee comments for discussion include:

- OPTN Liver Committee – suggestion that pre-withdrawal information, such as vital sign prior to withdrawal and at the time of withdrawal, may be beneficial. This information will be more

important with greater use of warm perfusion due to a greater separate between procurement and transplant

- OPTN Lung Committee – suggestion to capture the utilization of that technique while it is in use in order to help guide developing policy in this space
- OPTN Pancreas Committee – suggestion to include NRP information and a few pediatric questions related to this, such as duration of extracorporeal membrane oxygenation (ECMO).
 - Some question of how to define WIT, as it varies across programs and OPOs

Stakeholder comments for discussion:

- AST - Recommendation to collect the following in minutes/seconds”
 - Explant time for each organ procured*
 - Time from incision to organ flush with preservative solution
 - Time from flush with preservative solution to placement on a perfusion device
- ASTS - Uploading of the individual DCD worksheet in the attachments is likely to be more efficient and expedient to the evaluating transplant center than creating a new page for such information to be uploaded
- ISHLT – it may be helpful to include organ specific fields in a parsimonious manner.
 - Details about type, temperature, and amount of flush solution are important for risk stratification for primary graft dysfunction.
 - The method of cerebral "protection" during NRP could be crucial and timing of each step
 - It may be helpful to capture peak lactate serum levels.

Post-public comment changes for consideration:

Rationale for additional data must include purpose and intent, reliability, availability, and burden.

Potential post-public comment changes for discussion include:

- Addition of a validator question
 - Controlled DCD – Yes/No
- Add NRP information
 - If yes, to controlled DCD
 - NRP recovery – Yes/No
 - Initiation of reperfusion – Date/Time

3. Summary of discussion:

Staff confirmed with the Committee that the proposed data elements would not be required fields. Several members commented that the information would help transplant programs identify the agonal phase as they evaluate offers. A member noted that the intent is to provide the information and allow transplant centers to make their own interpretation. Another member noted that the agonal phase is defined in OPTN policy, but it is not universally accepted.

A member noted that some centers might be interested in knowing the explant time and how that differs from recovery time. Another member commented that it would be challenging for OPOs to collect and report this information. There was a suggestion to have the system calculate flush time to perfusion start time, which some OPOs collect for kidneys.

The Committee discussed the public comment feedback about NRP information. The Vice Chair commented that NRP technology needs to evolve before committing resources to adding additional data into the system. The Committee did agree that basic NRP information should be added to the

proposal as a starting point for NRP data collection. This would include whether NRP recovery was used as well as the date/time of initiation of NRP perfusion. A member noted that ECMO technology is used for NRP and that the Committee needs to ensure that the definition of ECMO in the DDR is clear and is referring to treatment during hospitalization and not the NRP process. Staff agreed to review the DDR definition to ensure that it is clear.

The Committee also agreed that NRP information should be collected for both controlled and uncontrolled DCD. This was proposed as a validator question during public comment, but the Committee subsequently agreed that while uncontrolled DCD donations are not common, it could happen prior to NRP and the information should be collected for both types of donors.

The Committee reviewed the data definition for NRP and agreed to the following definition:

- Normothermic regional perfusion (NRP) - the act of restoring the flow of oxygenated blood to the solid organs following declaration of death to reduce warm ischemic injury in donation after circulatory death (DCD) organ transplantation.

The Committee voted unanimously to submit the following data collection to the OPTN Board of Directors for review in December 2022:

- Controlled DCD – Yes/No
- Withdrawal of Life Sustaining Medical Support, Date/Time
- Cessation of Circulation, Date/Time
- Flush Time (In Situ), Date/Time
- Oxygen Saturation (SpO2) – Serial
- NRP recovery – Yes/No
- Initiation of NRP perfusion – Date/Time

4. Modify Organ Offer Acceptance Limits

Presentation summary:

This project aims to modify *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. This will eliminate the scenario where a program can be primary for offers from two different OPOs and waiting to determine which organs to accept for their candidate. If the refusal of one of the offers is done late in the allocation and placement process, it could result in logistical challenges for the OPO.

The strategic goal of this project is to increase the number of transplants. Key metrics include a reduction in discard rates, as well as events of out of sequence placements and uses of the expedited liver pathway, which are often indicators of late turndowns. Reducing the limit on organ offer acceptances should result in fewer discards and expedited placements caused by late turndowns.

Previously, an analysis was completed utilizing deceased donor liver offers between June 13, 2018 and June 12, 2019. In this analysis, 597 candidates accepted two livers concurrently, with 256 of those candidates turning down both livers.

Metrics for the updated data request thus far include:

- Events of Concurrent Acceptance for Lung, Liver, Heart, Kidney and Pancreas
- Dispositions of Organs With Concurrent Acceptances (Not Recovered for Transplant, Discarded, Transplanted to Concurrent Acceptor, Transplanted to Another Candidate)
- Refusal reasons for Organs eventually turndown by Concurrent Acceptor
- Discard Reasons for Organs Discard With Concurrent Acceptances

- Additional metrics?

Summary of discussion:

Research staff requested initial feedback from Committee members about data that would be important for this project. A member noted that the timing of late turndowns is important, as it demonstrates the extent of the problem. Another member suggested reviewing if a transplant center has accepted an offer and subsequently declines the others, whether they use the “transplanted” code or turn it down for another reason.

5. NASEM Report

Presentation summary:

The NASEM Ad Hoc Committee on a Fairer and More Equitable, Cost-Effective, and Transplant System of Donor Organ Procurement, Allocation, and Distribution issued a report “Realizing the Promise of Equity in the Organ Transplantation System” in February 2022. The OPTN Executive Committee responded to the report in April 2022, highlighting ongoing OPTN work that aligns with NASEM recommendations and offering corrections. The NASEM Committee leadership presented recommendations to the OPTN Board of Directors in June 2022.

The transplant system requires input and collaboration from the various organizations involved, including the Centers for Medicare and Medicaid Services (CMS), the Department of Health and Human Services (HHS), the Health Resources and Services Administration (HRSA), and the OPTN.

NASEM recommendations fell into three main categories: improving equity, using more donated organs, and improving the system and system performance. The OPTN has several projects currently in development that align with these goals:

- Increase equity in organ allocation algorithms
 - Kidney:
 - Implemented policy requiring use of race-neutral eGFR calculations in July 2022
 - KDPI and Estimated Post-transplant Survival (EPTS) mapping tables updated annually
 - Liver
 - Approved changes to the Model for End-Stage Liver Disease (MELD) to address sex-based disparity in June 2022
 - Median MELD at Transplant (MMaT) updated quarterly
 - Lung
 - Implemented updates to prediction models in 2021
 - Heart
 - Updating adult status qualifications
 - All organs: ongoing Social Determinants of Health Special Study Projects
 - All organs: shift into continuous distribution allocation frameworks, an equity project
 - Multi-organ: approved changes to balance access between kidney-alone and MOT candidates in June 2022
 - Other:
 - Equity in access to transplant dashboard available on the OPTN site
 - Added additional patient representatives to OPTN committees in July 2022
 - *Transparency in Program Selection* White Paper currently out for public comment
- Use more donated organs

- Improve the use of organs:
 - Donation after Circulatory Death (DCD) Collaborative increased recovery and transplant of DCD organs
 - Ethical considerations of normothermic regional perfusion (NRP) in DCD
- Make it easier for transplant centers to say “yes” to organ offers
 - Kidney Offer Filters – national rollout January 2022; concept paper on optimizing use out for public comment (PC)
 - *Redefining Provisional Yes and the Approach to Organ Offer and Acceptance* concept paper out for PC
 - OPTN predictive analytics pilot project
 - Approved Standardize Kidney Biopsy Requirements and Reporting in June 2022
 - Enhancements to OPTN Donor Data Collection out for PC
 - Deceased Donor HIV Positive Test Result Clarification - new project
- Improve system and system performance
 - Standardized metrics to track performance – new metrics approved
 - Pre-transplant mortality rate ratio
 - Offer acceptance rate ratio
 - 90-day graft survival hazard ratio
 - 1-year conditional graft survival hazard ratio
 - Embed continuous quality improvement efforts in system
 - OPTN Individual Member Focused Improvement – IMFI
 - OPTN Collaborative Improvement Projects
 - Improve the OPTN policy-making process
 - Pursuing resources from the National Quality Forum
- Other recommendations:
 - Allocate kidneys based on time spent on dialysis (do not count waiting time prior to dialysis initiation)
 - Allocate kidneys based on survival benefit scores
 - Currently prioritize the highest quality kidneys for those with best estimated post-transplant survival
 - Survival benefit would account for odds of survival with and without transplantation
 - Evaluate the use of race as a weighting factor in clinical equations
 - Incorporate Cystatin C testing into kidney disease evaluation

Next steps include asking OPTN Committees to recommend project ideas based on these recommendations. The Policy Oversight Committee will prioritize potential committee projects.

Summary of discussion:

One member suggested sharing best practices or guidance on donor care units (DCUs). DCUs have the potential to help with efficiency by having set OR times, staff trained in the donation process, and having biopsies read on site. Another member noted that regardless of where donor care units are located, allocation should be based on the original donor hospital.

Another member commented about the ongoing transportation issues. Additionally, he noted that the committee could focus on rules of engagement between OPOs and transplant hospitals.

A member commented about the lack of a 500 nautical mile (nm) allocation circle for kidney allocation. Allocating “nationally” outside of 250 nm requires OPOs to work through a lot more transplant hospitals

in order to get kidneys placed. Another member added a comment about the ongoing transportation issues with greater distances. He added that while the data shows more transplants, the discard rates continue to be too high. This might require engagement with the airlines to address some of the transportation challenges so discard rates can be addressed.

A member commented about the ongoing issues with late turndowns. She suggested publishing information about late turndowns in an attempt to change behavior. Another member noted that the first step should be to understand why kidneys are being discarded. For example, where the process break down that led to the discard occurred in order to evaluate how to make improvements to the system.

6. VCA Guidance Document

Presentation summary:

This project aims to update *Guidance on Optimizing VCA Recovery from Deceased Donors*. The Policy Oversight Committee approved this project on September 12.

This project will provide clear and accurate guidance to the transplant community regarding the VCA recovery process, and aim to provide transplant professionals with best practices to improve processes for VCA recovery.

Recommendations within guidance will be updated. The audience will include OPOs, donor hospitals, and transplant programs. The scope includes both deceased and living VCA donors. The additions and updates include updated background information and data, as well as guidance specific to the VCA type.

The guidance document is made of the following components:

- Strategic Decision to Participate in VCA Donation
- Planning and Hospital Partnerships
- Registering a Deceased VCA Donor and Accessing the VCA Candidate List
- Family Support and Authorization Approach
- Criteria for the Evaluation of Donors for VCA Transplantation
- VCA Recovery Considerations
- Post-Recovery Considerations
- Media and Public Relations Strategy

Questions for the OPO Committee:

- Do you use this guidance document?
- What information should be added to make this guidance document more useful?
- Any suggestions for additional topics?

Summary of discussion:

One member noted that his OPO has not used the guidance document due to the small number of VCA programs in the western United States. Another member noted that his OPO has had a few opportunities to offer VCA grafts but the distance was too great.

The Committee briefly discussed the consent process for VCA donors. One member noted that they do a separate consent process for VCA for every donor. However, there is not a clear understanding of how many centers are doing VCA transplants so it would be helpful if they could just show up on the match run. Additionally, since there are not a lot of candidates listed for VCA transplant, it can be cumbersome

to get to them. Staff noted that VCA allocation would be implemented in the OPTN Computer System in 2023.

7. Utilization Considerations Workgroup Updates

Presentation summary:

The Utilization Considerations Workgroup will focus on the aspects of kidney and pancreas allocation that fall outside of the composite allocation score while transitioning to a continuous distribution framework

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

The Utilization Considerations Workgroup will discuss each topic and develop recommendations, which will be sent to the Kidney and Pancreas Committees to approve

- Approved recommendations will be incorporated into the main Kidney and Pancreas Continuous Distribution proposal, currently slotted for August 2023 Public Comment

The Utilization Considerations Workgroup will review and provide input on certain operational factors, and discuss and develop solutions for others

This Workgroup has a somewhat limited scope, focusing on mapping the current policy to a continuous distribution framework with few modifications. This will involve minimal changes to current operational requirements as outlined in policy, and utilize data already available to review.

Topics for discussion include:

- Review Pancreas Committee Recommendation: Facilitated Pancreas
 - Feedback provided on timing, qualifying criteria, and alignment to the Pancreas Committee at 9/21 meeting
- Review Kidney and Pancreas Committee Recommendation: Released Organs
 - Feedback provided on efficiency of released organ match run and concerns for gaming at 9/21 meeting
 - Upcoming discussions: potential to roll over certain offer declines from original match run to the released match run
- Operationalization of Dual Kidney Allocation
 - Upcoming discussions: data review, operationalizing dual kidney in continuous distribution, and efficiency
- National Kidney Offers and Operationalization of the Kidney Minimum Acceptance Criteria Screening Tool

Summary of discussion:

There were no comments and questions from the Committee members.

8. Lung Continuous Distribution

Presentation summary:

OPO education for the implementation of the Lung Continuous Distribution will include:

- Information about the placement efficiency attribute of continuous distribution and preparing for implementation
- Changes to the match run view in the system
- Continuous distribution and multi-organ offers

What are the other education needs of OPOs related to Lung Continuous Distribution?

Summary of discussion:

One member suggested providing a visual demonstration and representation of what the attributes are and how they are weighted. He further added that many staff members would be explaining the changes to other people so a clear way to demonstrate that would be helpful.

A member commented that having test sites would be helpful so OPO staff can see the changes to the match run. Another member added that side-by-side examples would be helpful.

9. Expedited Liver Placement – 1 Year Monitoring Report

Presentation summary:

This policy was implemented to address organs turned down late in the OR. This policy aimed to reduce discards and promote equity, by establishing an expedited pathway for liver placement. Candidates can opt into receiving expedited offers. A bypass pathway still exists. The data report only measures organs that utilized the expedited liver process once turned down during organ recovery.

This report is the one-year monitoring report. However, because the pathway is infrequently used and time allowed, the report includes 447 days of data in both the pre and post policy era to capture as many uses of the expedited pathway as possible

- Pre-era: January 2, 2020 to March 24, 2021
- Post-era: March 25, 2021 to June 15, 2022

Because the expedited pathway did not exist before the implementation of this policy, it is not always possible to compare all metrics to the pre-policy era. Comparisons have only been made when they are plausible. How many livers were turned down in the OR or what happened to such livers cannot be measured.

- Out of sequence placements are defined as match runs with final acceptances where OPO’s bypassed the potential recipient due to transportation logistics

Results:

- The frequency of out of sequence placements increased from 6.81% to 8.07% after this policy was implemented.
- The number of transplants increased, but the overall liver utilization decreased and the discard rate increased post-policy implementation
 - There are a number of potential reasons for these trends, including the numerous liver policies and the COVID-19 pandemic that occurred during this timeframe
 - Trend in number of transplants could have a variety of causes, including the long standing increase in transplants overall

Utilization:

- Utilization of the expedited pathway generally increased over the first 8 months after implementation before stabilizing over the next 7 months, and falling in the final month
- Pathway is associated with high discard rates of 58.15 percent

- Bypass pathway has a much lower discard rate but isn't a fair comparison to the expedited pathway because it is generally only used if there is a high chance of it resulting in a transplant
- Use of the standard and bypass pathways increased in the post-policy era
 - Post-policy, the bypass pathway was utilized 816 times whereas the expedited pathway was only utilized 589

Challenges to Utilization and Discard:

- The most frequent reason for in-OR turn downs was “donor age or quality,” which could indicate a number of reasons that donors were turned down in the OR
- No significant difference in donor weight, height, and age between donors used in the expedited match and those for whom the standard match was used
- 21.11 percent of the donors for whom the expedited pathway process was initiated for whom the expedited pathway was initiated were DCD, compared to 13.54 percent of donors for whom only the standard match process was used
- Median percentage of livers a center turns down later is 4.6 percent, with a mean of 6.3 percent.
 - A small number of centers turning down 20 percent or more of livers in the OR and resulting in an expedited match run
 - Whether a late turn down liver results in an expedited match run, and therefore appears in this chart, depends on whether the OPO chooses to use the expedited pathway so there may be more livers turned down in the OR than this chart shows
- Percentage of liver candidates ever waiting by region who opted in to receiving expedited offers varied from 42.56 percent to 78.41 percent
 - The majority of candidates ever waiting during the post-policy implementation period opted into the expedited liver pathway
- Median difference between the sequence number of the recipient and the expedited pathway initiation was 50.5
 - For half of livers for whom the expedited pathway was initiated, over 50.5 offers had to be made before an acceptance was received

Key takeaways:

- Pathway is under-utilized in situations where its use is recommended.
 - Use increased in first three months before stabilizing
- Pathway is associated with high discard rate (58.15%)
- Out of Sequence placements increased after implementation from 6.81% to 8.07%
- With the exception of donor type, donor characteristics are similar between the expedited and standard pathways.
 - The only exception is that DCD donors make up a greater proportion of donors allocated in the expedited pathway than in the standard pathway.

Summary of discussion:

One member noted that transplant centers are not using the system as intended. If they opt in for too many patients for fear of missing an offer, it makes the process inefficient. Another member expressed concern about the high discard rate when the expedited pathway is used. He added it was important to acknowledge and potentially exploring.

A member noted that her OPO would use the expedited pathway because the recovering center is not interested in the liver. However, if the recovering center has a candidate further down the list that will take the liver, they will allow them to use it because there is no guarantee that a plane will be available to ship the liver to another center.

A member noted that the expedited pathway is a tool, and that efficiency and utility are not the same. If your OPO is in a region where 75% of the liver patients are opted in to receive expedited liver offers, then the OPO is still working down a substantial list.

A member suggested having the ability to expedite placement prior to the OR. This is the timeframe where a lot is happening with getting OR times set which sets up the potential for delays. This also contributes to family constraints and declines and having the ability to use the expedited pathway 4 hours prior to the OR would help OPOs with allocation.

A member commented that defining a late turndown would be extremely helpful. If a family does not want to move forward with donation due to the delay, this would not show up as a discarded liver.

A member noted that when discussing equity it is usually focused on organ distribution. However, we do not talk about equity for donor families who might lose the opportunity to provide the gift of organ donation.

A member asked if there have been discussions around some of the centers that have a high rate of late turndowns leading to expedited placement. Staff noted that the OPTN Membership and Professional Standards Committee (MPSC) has been reviewing some data.

10. Research Department Orientation

The Committee was oriented to the processes, functions, and ongoing work of the Research Department, as well as the Research Department's role in OPTN Committee support.

Summary of discussion:

A member asked if the Research Department tracks data requests where the data is not available. She added that the OPTN Donor Data and Matching System does not collect the amount of data collected within the OPO electronic medical records (EMR). She suggesting working with some of the EMR vendors to enhance the quality of the data being collected so that transplant centers can review the information. Research staff agreed to look into how supplemental sources of data are used.

11. Histocompatibility Committee – HLA Confirmatory Testing Project

Presentation summary:

The Histocompatibility Committee aims for this project to be released in the January 2023 public comment cycle. This project was initiated when a Histocompatibility Lab Director wrote the Histocompatibility Committee expressed concern about the current lack of required redundancy for HLA typing, as compared to ABO typing. Both are critical to patient and donor compatibility.

Concerns and risks discussed include:

- Inclusion of incorrect HLA typing in the match run may mean offers are given to patients highly sensitized against the donor
- Virtual crossmatching or assessment of immunologic risk requires correct HLA typing to determine candidate/donor matches and DSA
 - This affects both acceptance/rejection of an organ offer and peri-transplant care for the recipient

- Crossmatches and confirmatory typings often occur after transplant for hearts and lungs
 - Potential for hyperacute or accelerated rejection

Recommended steps to mitigate these risks include increasing safeguards to ensure correct donor HLA typing, including some redundancy in the system of HLA typing and requiring confirmatory HLA typing in policy.

Histocompatibility recommendations:

- Deceased donors should have two HLA samples run, drawn at two separate times, similar to ABO
 - Possibly further discussion on best practices for different sample types or assays
 - Did not want to create requirements that would increase the time to allocation or burden on staff
- Both samples should be typed at a molecular level for all loci
- Require raw HLA typing data to be uploaded for both samples

Confirmatory HLA typing policy:

- The laboratory must ensure that each deceased donor's HLA type is determined by testing at least two separate deceased donor samples.
- The deceased donor samples must:
 - Be obtained on two separate occasions
 - Be submitted as separate samples
- Both typing results would be required at the same reporting timeframe as current policy
 - Necessary to ensure typings are not discrepant and to ensure efficiency and safety
 - Samples able to be run in parallel so as not to increase turnaround time for HLA typing

Questions for discussion:

- Are you aware of any potential logistical barriers to this requirement?

Summary of discussion:

A member expressed concern about doubling HLA testing and the associated cost increase. The Histocompatibility Chair responded that increasing patient safety will provide greater confidence that labs and transplant teams can move forward safely with virtual crossmatch assessments. A member commented that most of her transplant centers are comfortable with virtual crossmatching but acknowledged that many centers are not. She asked if there has been any conversations with transplant centers that do not accept virtual crossmatching. The Histocompatibility Committee Chair responded that the trust issue is the limitation, especially with highly sensitized patients. He further noted that CMS is reviewing their regulations regarding the use of virtual crossmatching, which could lead to more acceptance of the practice.

A member asked if the errors found were due to testing or analysis errors. If it is analysis errors, then there could potentially be two wrong test results. The Histocompatibility Chair responded that there is always the potential for two wrong results if there is poor interpretation. The hope is that labs are utilizing the best practices and ensuring accuracy while redundant testing will reduce common errors.

A member commented about the integrity of data entry and how ABO verification requires two different users. He asked if there has been any discussion about requiring HLA results to be entered by two different users instead of the proposed one user. He further added that efficiencies could be gained if there was increased accountability on the transplant centers.

A member commented that this could potentially delay subsequent donors by as much as two hours. Additionally, he added that there is a small number of errors and this requirement would create significant burden financially and operationally. Another member noted that her OPO performs crossmatching for all their local centers and they would need to increase staffing to handle it.

A member asked if there has been any discussion about pediatric donors and the limited amount of testing materials. The Histocompatibility Committee Chair noted that there would need to be a conversation with labs on the minimum amount of material required for testing.

The Committee Chair commented that this would definitely increase costs and case times. While there is support for patient safety, the increase in case times could have a negative impact. Another member added that we need to balance the risk of a discrepancy with the potential for losing a donor due to delayed case times.

12. Released Organ and Kidney-Pancreas Circles-based Allocation – 1 Year Monitoring Report

Presentation summary:

The Kidney and Pancreas Circles-based Allocation was implemented in March 15, 2021, and replaced donor service area (DSA) and region with allocation based around a 250 nautical mile circle around the donor hospital. Proximity points are assigned based on distance between listing center and donor hospital. This policy increased prioritization for pediatric candidates and prior living donors, and established a new released organ pathway for kidney and pancreas. The goal of this project was to increase equity in access to transplant and minimize the negative impact of broader sharing on organ utilization and system inefficiency.

Cohort:

- Pre-policy: March 15, 2020 – March 14, 2021
- Post-policy: March 15, 2021 – March 14, 2022

Metrics include:

- Waiting list trends
- Transplant trends
- Donor utilization
- Post-transplant outcomes
- Released organs

Key takeaways include:

- Kidney
 - Increased transplant rates for pediatric candidates and candidates with CPRA 80-97%
 - Increase cold ischemic time as well as rate of delayed graft function
 - Increased discard rates across all KDPI Groups
- Pancreas and Kidney-Pancreas
 - Kidney-pancreas and pancreas transplant volumes remained stable, despite KPSAM projections of an increase in KP
 - While more pancreata were allocated outside the donor hospital's DSA, the majority stayed within 250 NM.
 - Median distance from donor hospital increased for KP and decreased for PA.
 - Pancreas discard rate increased

Summary of discussion:

A member asked if the increase in kidney transplants was directly related to the increase in donors. Another member added that with donors and transplants increasing, what are the next steps to address logistical issues. Research staff responded that the continuous distribution group will be addressing the issue, particularly with regards to distance. The hope is that continuous distribution will be based more on candidate criteria and less on distance.

The Committee Chair commented that OPOs are pushing the envelope in order to get kidneys placed, and that marginal kidneys might be contributing to the number of discards.

13. Multi-Organ Clarification – 6 Month Monitoring Report

Presentation summary:

This proposal updated multi-organ policies to establish requirements for sharing a kidney or liver with a thoracic organ. Heart, lung, or heart-lung are considered the primary organs – the organ that pulls the secondary organ in a multiple organ offer/transplant. The following are required shares:

- Heart
 - Within 500 NM
 - Adult status 1, 2, or 3
 - Pediatric status 1A or 1B
- Lung
 - Within 500 NM
 - Lung allocation score (LAS) greater than 35
 - Lung candidates under 12 years old
- Heart-lung
 - Within 500 NM
 - Adult heart status 1, 2, or 3
 - Pediatric heart status 1A and 1B
 - LAS greater than 35
 - Lung candidates under 12 years old

This analysis looked at metrics regarding multiple organ transplants, OPTN Waiting List additions and removals (with a particular interest in those removed due to death or too sick) stratified by:

- Share type (transplants)
- Medical urgency by organ
- Age group
- Distance (transplants)

Due to small numbers only select metrics could be broken out by multiple organ combination. Metrics were compared across the following eras -

- Pre-Policy: October 12, 2021 - February 9, 2022
- Post-Policy: February 10, 2022 - June 10, 2022

Multi-organ thoracic transplants

- Increase in multi-organ thoracic transplants from pre-policy (6.3 percent of thoracic transplants) to the post-policy era (8.4 percent)
 - Heart multi-organ transplants increased from 9.43 percent to 13.29 percent
 - Lung multi-organ transplants increased from .93 percent to 1.4 percent

- Heart-lung multi-organ transplants increased from none pre-policy to two post-policy, at 9.09 percent of all hear lung transplants
- The number and proportion of permissible shares increased for heart and lung multiple organ transplants
- Proportion and number of transplants where the recipient LAS was less than 50 increased in the post-policy era, and the median LAS for multi-organ recipients decreased from 58 in the pre-policy era to 40.26 in the post-policy era
- Proportion and number of transplants where the recipient was status 3 or status 5 increased in the post-policy era
- The proportion and number of transplants where the recipient had a MELD/PELD of 15-19 increased considerably in the post policy era
 - Increase in those with a MELD/PELD of 25 or greater at transplant
- In the post-policy era, three recipients were inactive for kidney at the time of transplant
- There were four recipients in the pre-policy era and four recipients in the post-policy era of a heart multiple organ transplants who were pediatric candidates at time of transplant
- 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

- Increase in heart multiple organ registrations from 184 to 234 listings in the post-policy era
- Proportion and number of registrations where the candidates LAS at list was 40+ also decreased in the post-policy era (Pre: 54.55 percent, post: 47.06 percent)
- Proportion of registrations stayed relatively consistent across all statuses with a small jump in registrations for adult status 5
- Number of liver candidates listed for multi-organs with a MELD/PELD of less than 25 increased
- Pediatric listings for multiple organ increased from 4 listings to 10 listings, this referring to candidates under the age of 18 at time of listing
 - All pediatric listings were either heart-liver or heart-kidney

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 heart multiple organ candidates from the post-policy era to the pre-policy era
- Heart status at removal:
 - Increase in removals due to death or too sick for candidates whose last known active status was adult status 2
 - Decrease in removals due to death or too sick for candidates whose last known active status was adult status 4
- LAS at removal for multi-organ lung and heart-lung candidates removed due to death or too sick was greater than 50 for all six candidates
- Only one pediatric multiple organ candidate also listed for heart was removed due to death or too sick in the post-policy era
- Majority of candidates removed for death or too sick had a MELD/PELD at removal or last known MELD/PELD of <20.

Key takeaways:

- Increase in multiple organ transplants containing a heart and/or lung in part driven by an increase in permissible shares
 - Decrease in median LAS at transplant
 - Increase in heart status 4/5 at transplant
- Transplant was the main reason for candidate removal from waiting list for multiple organ thoracic candidates
 - Removals due to death or too sick decreased for heart and remained consistent for lung
- Small numbers make it difficult to determine the true impact of this policy. Further analysis and data are needed.

Summary of discussion:

A member asked how other OPOs are handling solitary kidneys as backups when the next liver candidate is an SLK candidate. A member responded that his OPO does due to concern about missing the opportunity to transplant a liver. He acknowledged some pushback from transplant programs but are upfront about the situation and wait for anatomy. Another member noted that her OPO crossmatches all kidneys prior to the OR and do not hold them. A member commented that it might be worth knowing how many were intended multi-organ transplants that end up being single organ transplants.

Upcoming Meeting

- November 17, 2022 (Teleconference)

Attendance

- **Committee Members**
 - Kurt Shutterly
 - PJ Geraghty
 - Bruce Nicely
 - Clint Hostetler
 - Donna Smith
 - Doug Butler
 - Erin Halpin
 - Meg Rogers
 - Valerie Chipman
 - Sharyn Sawczak
 - David Marshman (Virtual)
 - Debra Cooper (Virtual)
 - Judy Storfjell (Virtual)
 - Larry Suplee (Virtual)
 - Leslie McCloy (Virtual)
 - Sam Endicott (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
 - Kayla Temple
 - Katrina Gauntt
 - Lauren Mauk
 - Roger Brown
 - James Alcorn
 - Kevin Daub
 - Elizabeth Suskind
 - Heather Carlson-Jaquez
 - Tony Ponsiglione (Virtual)
 - Kaitlin Swanner (Virtual)
 - Alex Carmack (Virtual)
 - Isaac Hager (Virtual)
 - Kelley Poff (Virtual)
 - Samantha Weiss (Virtual)
 - Krissy Laurie (Virtual)
- **Other Attendees**

- John Lunz