OPTN Transplant Coordinators Committee
Meeting Summary
September 27, 2022
Chicago, IL

Stacy McKean, RN, Chair
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Introduction

The Transplant Coordinators Committee (the Committee) met in Chicago, IL and via Citrix GoToMeeting teleconference on 09/27/2022 to discuss the following agenda items:

1. Welcome and Introductions
2. Introduction to Continuous Distribution
3. National Academies of Science, Engineering, and Medicine (NASEM) Report Recommendations
4. Open Discussion
5. Review of the National Liver Review Board
6. Review of Liver and Intestine Variance
7. Continuous Distribution of Liver and Intestines
8. Update Data Collection for Lung Mortality Models
9. Revise Lung Review Board Guidance for Continuous Distribution
10. Update on Multi-Organ (MOT) Allocation for Continuous Distribution of Lungs
11. Update on Kidney and Pancreas Continuous Distribution
12. Modify Waiting Time for Candidates Affected by Race-Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations
13. Update on Kidney Paired Donation Policy

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

1. Welcome and Introductions

Committee leadership and staff welcomed the Committee, and Committee members introduced themselves to each other.

Summary of discussion:

The Committee had no questions or comments.

2. Introduction to Continuous Distribution

The Committee received an introductory presentation on Continuous Distribution.

Presentation Summary:

In 2018, the Board of Directors approved a "continuous distribution" model as a framework for future policy development of organ allocation. The current system places candidates into rank-ordered classifications reviewed in sequence. The new framework ranks all candidates using a composite allocation score (CAS), without categorizing into classifications. The composite score is determined by multiple factors called "attributes," that are weighted against each other during the calculation.

Continuous distribution is flexible and can apply all organ types. The framework is also more equitable, as no one factor will determine a candidate's place on the match run. Finally, continuous distribution is agile, and the framework will be more responsive and adaptable to future changes.

In continuous distribution, every patient will receive a composite allocation score, composed of attributes that fall into several allocation goals:

Medical Urgency + Post-transplant Survival + Candidate biology + Patient Access + Placement efficiency = Composite Allocation Score

- Each attribute will have a specific weight relative to the entire formula. Some attributes will have more effect than others on the total score.
- The more points a candidate receives in their CAS, the higher they will be on a match run for an organ offer

Each attribute is assigned a rating scale and a weight.

- The rating scale of an attribute determines how points are assigned for that attribute
    - Rating scales are data based
    - Example: how many more points should a calculated panel reactive antibody (CPRA) 100 percent patient receive than a CPRA 50 percent
- The weight of an attribute determines how important that attribute is relative to other attributes
    - Weights are values-based decisions
    - Example: all else equal, should pediatric patients have higher priority than prior living donors?

Weight modifiers will also allow allocation to be more nimble, based on donor characteristics. Currently, Kidney allocation and candidate prioritization differs depending on the donor kidney's kidney donor profile index (KDPI). Weight modifiers can replicate this, and mathematically modify the relative importance of each attribute based on KDPI.

Progress to date:

- Lung continuous distribution: implementation in development
- Kidney-pancreas continuous distribution: modeling and analysis
- Liver and intestine continuous distribution: identifying attributes
- Heart continuous distribution: starting soon

Summary of discussion:

The Chair asked if there were any lessons learned with continuous distribution of Lung that could be helpful to other organs. Staff responded that the timeline for implementation of Continuous Distribution was intentionally staggered to allow lessons learned early on to be applied to other organs. Staff explained that the mathematical optimization the Massachusetts Institute of Technology (MIT) was able to provide was very useful and will be used in creating and evaluating other organ allocation policies.

The Chair asked if the committee would be able to review initial organ offer data and change the weights based on initial outcomes. Staff answered that yes, weights can be changed relatively quickly if unexpected or unwanted outcomes arise. Adding new attributes is more complicated, but adjustments to the existing attributes and weights are fairly easy from an IT standpoint.

A member brought up continuous distribution from the pediatric lens and asked for clarification on how these candidates will be affected. Staff responded that in general, pediatric candidates benefit from

continuous distribution because additional pediatric priority is incorporated into the system. The member added that consideration for pediatric candidates must be carefully considered, especially in the case of post-transplant survival, and advocated for looking at a longer post-transplant survival period for pediatrics in the modeling.

There was no further discussion.

3. National Academies of Science, Engineering, and Medicine (NASEM) Report Recommendations

Staff provided an overview of the NASEM Report's recommendations and alignment of NASEM recommendations with OPTN projects currently in development.

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:

The Chair asked if the recommendation for donor care units are taken into consideration in allocation, especially when a donor care unit may be in a different location than the donor hospital. Staff responded that this is currently unclear and will be up to the community to decide. Donor care units make the most sense located near airports to get surgical teams in and out. Staff added that efficiency must be balanced with equity, making sure that donor care units are incentivized but the areas they are located in are not given additional advantages within the allocation process.

A member asked about tracking data on organ acceptance, specifically organs accepted by centers further down on the offer sequence. Staff responded that reports on this data is available to transplant centers, and that further research is being conducted.

4. Open Discussion

Committee leadership opened the floor for general discussion on best practices, potential issues, and general feedback.

Summary of discussion:

The Chair asked members if they are talking about the NASEM report at their centers. Several members responded that their hospitals are taking the recommendations and data into account. A member described that her center is reviewing their protocols to try to improve equity in access to transplant care at all stages. She referenced the recent white paper, *Transparency in Program Selection*, put out for public comment by the OPTN Ethics Committee, and described a concern that the information in the paper does not address the issues she sees at her center and would create an additional administrative burden instead of providing targeted, helpful education. Staff responded that the white paper is intended to help transplant programs, and does not impose any requirements on centers.

Staff asked if centers are seeing any specific barriers to access for non-US residents in their areas. A member responded that psychosocial and logistical barriers pose access issues at her center. Several members discussed Hepatitis B as a concern for their programs, both from the patient access side and the program administration side. Specifically, members described frustration that they are required to provide documentation as to why a patient may not have gotten a Hepatitis B vaccine, but the specifics of sufficient documentation are unclear. Also, members pointed out that the requirements/data fields in their electronic medical record systems and UNOS computer systems do not match up. Members expressed confusion regarding the data definition of Hepatitis B vaccination, which right now may vary by center. Members pointed to this as an opportunity to clarify to achieve better compliance with policy. The Chair stated that involvement with specific workgroups is a great opportunity to have these specific concerns heard and allow progress to be made.

Next Steps:

Staff will bring the committee's concerns regarding Hepatitis B to the OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC).

5. Review of National Liver Review Board

The Committee reviewed the Liver and Intestinal Transplantation Committee's *Continued Review of National Liver Review Board (NLRB) Guidance* proposal.

Presentation Summary:

The National Liver Review Board (NLRB) is responsible for reviewing model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) exception score requests The NLRB uses OPTN guidance to review exception cases that don't meet standardized criteria in OPTN policy

The purpose of this proposal is to ensure guidance remains updated, clear, and aligned with current research so the appropriate candidates receive MELD or PELD exceptions.

This proposal will provide guidance on cystic fibrosis (CF), hepatic adenomas (HA), and Budd-Chiari syndrome. Current CF policy does not consider pediatric-specific population; adding pediatric specific guidance enables this population of candidates to access MELD or PELD exception scores. Guidance on HA and Budd-Chiari Syndrome will make guidance more succinct and clear. Updates will allow this guidance to meet current clinical understanding.

Proposed Cystic Fibrosis Guidance:

- CF is genetic disorder that can lead to chronic damage in the liver
- Current CF standardized exception policy aimed at lung-liver transplant candidates and is not pediatric specific
- Committee proposes new pediatric specific guidance for CFLD candidates meeting one of these criteria:
    - Portal hypertension with complications and patient has failed or is not a candidate for medical, endoscopic or surgical interventions to prevent or treat these complications
    - Growth failure as a result of liver disease, defined by age and sex-specific weight, length/height, weight-for-length, and/or body mass index (BMI) percentiles or moderate to severe malnutrition
    - Forced expiratory volume at 1 second (FEV1) less than 70% or evidence of decline in FEV1 of greater than or equal to 5% per year

Proposed Hepatic Adenomas Guidance:

- Hepatic adenomas (HA) are rare benign nodules occurring principally in women taking oral contraceptives
- Current NLRB guidance for multiple hepatic adenomas recommends candidates with HA and malignant transformation proven by biopsy or glycogen storage disease (GSD) be considered for a MELD exception
- Proposed changes:
    - Remove unnecessary intro paragraph to make guidance more succinct
    - Update criteria to better capture population of candidates needing MELD exception
    - Remove reference to “multiple” hepatic adenomas

Proposed Budd-Chiari Syndrome Guidance:

- Budd-Chiari syndrome is a medical condition characterized by hepatic vein thrombosis
- Proposed changes:
    - Remove unnecessary intro paragraph to make guidance more succinct
    - Add failed surgical management as qualifying criterion
    - Remove requirement for programs to provide etiology of hypercoagulable state
    - Remove the criterion related to decompensated hepatic hydrothorax requiring thoracentesis, which is already covered in guidance for hepatic hydrothorax

Transplant programs and NLRB reviewers will need to be familiar with updated guidance.

The Liver Committee is seeking feedback on the proposed changes, including:

- The proposed creation of guidance for pediatric candidates with CF, specifically the proposed FEV1 thresholds set at less than 70% or greater than or equal to a 5% annual decline.
- The proposed changes to guidance for candidates with hepatic adenomas.
- The proposed changes to guidance for candidates with Budd Chiari.

<u>Summary of discussion:</u>

One member expressed support for the proposed changes to adult exceptions, noting that more succinct exceptions are easier to utilize and apply. The member asked for clarification as to whether these exceptions would be automatic, and the presenter explained that these would be reviewed, but that the guidance will provide improved consistency across cases.

A member recommended that the Liver Review Board keep track of the number and type of appeals and re-applications needed for different disease types, so that the Liver Committee could review and

determine if the guidance and policy are appropriate or need to be updated. It was clarified that this information is reviewed, particularly for efficiency and appeals.

A member asked for clarification on the surgical intervention question and related response options.

One member expressed support for standardizing cystic fibrosis pediatric exceptions, sharing that this exception should be more standardized. The member expressed support for consistency in appeals.

6. Review of Liver and Intestine Variance

The Committee reviewed the OPTN Liver and Intestinal Transplantation Committee's *Review of Liver and Intestines Variances in OPTN Policy* proposal.

Presentation Summary:

This proposal will align expiration dates of four current OPTN liver allocation variances, which will allow the OPTN Liver and Intestinal Organ Transplantation Committee to consider which aspects of the four variances require incorporation into permanent OPTN policy, as they develop the new points-based allocation framework. Specifically, this proposal will extend the expiration dates of all four variances to expire upon implementation of continuous distribution of liver and intestinal organs:

- 9.12.B: Blood Type Variance
    - Implemented for Hawaii in 1994; extended to include Puerto Rice as part of acuity circles
    - For blood type O donors in HI and PR, variance removes priority for O and B candidates to include any blood type recipients in the same classifications
- 9.12.D: HI and PR Access for Medically Urgent Candidates
    - Provides additional access to donors for Status 1A/1B and MELD/PELD 37+ candidates in HI and PR due to geographic isolation
- 9.12.C: Region 8 Split Liver Variance
    - Permits transplant programs in Region 8 to offer second segment of split liver to candidate at same transplant program or affiliated transplant program after being offered to MELD/PELD 33+ and Status 1A/1B within 500 nautical miles (NM) of donor hospital
- 9.12.A: Open Split Liver Variance
    - If transplant program transplants right lobe or right tri-segment into index candidate, can transplant left lobe or left lateral segment into other candidate on match at same transplant program

Extending and aligning the end dates for the four variances will allow the Committee to consider how to incorporate the variances into continuous distribution as they develop the points-based framework.

This proposal will not change the content of any of the variances. OPOs will need to be familiar with the variances and continue to work with transplant programs who are participating in the variances to allocate livers and intestines accordingly. Participating transplant programs will continue to submit required data for the duration of variances.

Summary of discussion:

The Committee had no questions or comments.

7. Continuous Distribution of Liver and Intestines

The Committee reviewed the OPTN Liver and Intestinal Transplantation Committee's *Continuous Distribution of Livers and Intestines* concept paper.

Presentation Summary:

This concept paper will introduce the liver and intestinal organ transplant communities to continuous distribution, provide and update the community on the progress to date, and seek community feedback to help inform the new allocation framework. This concept paper provides an overview of continuous distribution and the policy development approach, summarizes attributes under consideration, outlines how attributes align with NOTA and the Final Rule, and seeks community feedback.

The primary goal of CD is to remove the hard boundaries that exist in the current allocation system and create a more flexible, points-based system for allocation.

Overall, continuous distribution will result in:

- More equity for candidates
- Increased transparency in the allocation system
- More flexibility for future changes (will be easier to improve the system moving forward)

In the current state offers are made to all candidates within one classification before any candidate in the next classification is considered. Hard boundaries are inherent in a classification based system that prevents candidates from moving between classifications, irrespective of other factors

A continuous distribution framework will eliminate the hard boundaries in the current system. Instead, candidates will receive points based on various candidate and donor-specific factors. Candidates will be ranked based on the number of points they are assigned for each of these factors or attributes, adding up to a single composite allocation score (CAS). A candidate's composite allocation score will determine the order in which the candidate will receive an organ offer.

The CAS is the foundation of the continuous distribution system. The CAS will be used to rank candidates based on a number of different factors or attributes that align with the five identified goals of NOTA and the final rule. These goals include:

- Medical urgency – prioritize those with high mortality on the waitlist
- Post-transplant survival – increase graft and recipient post-transplant survival (longevity matching)
- Candidate biology – increase transplant opportunities for candidates who are medically harder to match
- Patient access – promote appropriate transplant access for all candidates
- Placement efficiency – consider resource requirements needed to match, transport, and transplant an organ

Candidates will be assigned a certain number of points for each of these goals. The scores across the goals are then combined to calculated the overall CAS. The number of points provided for each goal is calculated based on the attribute or factors that align with that particular goal.

Currently, the Liver Committee is focusing on which attributes should be included in the first iteration of CD. The attributes are criteria used to classify, sort, and prioritize candidates. Examples of attributes include MELD or PELD, blood type compatibility, and distance between transplant program and donor hospital.

Once the list of attributes has been created, the Liver Committee will then build rating scales to determine how each attribute will be incorporated in the new allocation system. Developing these rating scales will be a mathematically-based process that will use available data, research and modeling.

Next, the Liver Committee will then determine how much weight or relative priority should be assigned to each attribute. The Liver Committee will utilize a few tools to develop this aspect of the proposal including a structured, pair-wise comparison survey that we'll ask the community to complete to get a sense for how the community would weight the different attributes. The Liver Committee will also utilize upcoming analysis that will look at how different attributes would be weighted under the current system would look if we converted it directly from classifications to a points-based framework.

Thus far, the Committee has primarily focused on identifying the attributes that exist in current policy and categorizing them into each goal:

- Medical urgency
    - Status 1A/1B, MELD/PELD
    - Candidate diagnosis points (Status 1B)
    - Liver-intestine registration
- Candidate biology
    - Candidate blood type
- Patient access
    - Candidate age
    - Waiting time
    - Liver-intestine registration
- Placement efficiency
    - Travel efficiency
    - Proximity efficiency

The Committee also has identified a number of attributes that don't exist in current policy but might make sense to incorporate into a points-based framework:

- Medical urgency
    - Hepatocellular carcinoma (HCC) stratification
    - Optimized prediction of mortality (OPOM)
- Post-transplant survival
    - Post-transplant survival
- Candidate biology
    - Donor-recipient size matching
    - Frailty
    - Surgical complexity/re-transplant
    - Human Leukoctye Antigen (HLA) sensitization
- Patient access
    - Candidate social determinants of health
    - Prior living donor
    - Willingness to accept a split liver transplant
    - Supply/demand

For the past few months, the Liver Committee has been focusing on these attributes not currently included in policy. The conversation has focused on which of these attributes the Liver Committee should consider including in the first iteration of CD. The Liver Committee is focused on balancing the feasibility of the attribute compared to its benefit.

The Liver Committee is considering the following questions with regard to attributes:

- What solutions, if any, have already been developed?

- Are there competing solutions to this problem?
- What research exists to show this is an effective solution(s)?
- What would the committee need to do to develop a solution?
- How complex are potential solutions?
- Are there options that can be more easily incorporated than others?
- How does the solution align with Final Rule, NOTA, committee/community sentiment?
- Does the OPTN currently collect necessary data? If not, what needs to be collected?
- Would the attribute benefit from additional time and research before incorporating into liver allocation

The Liver Committee seeks feedback on which new attributes the Committee should consider including in the first iteration of continuous distribution:

- HCC stratification
- OPOM
- Post-transplant survival
- Donor-recipient size matching
- Frailty
- Surgical complexity or re-transplant
- Candidate social determinants of health
- Prior living donor
- Willingness to accept a split liver transplant
- Supply/demand

Summary of discussion:

One member commended the Liver Committee on their work to improve access for liver candidates, and supported the direction the Committee is going with respect to continuous distribution. The member expressed curiosity about the role of post-transplant survival metrics in liver allocation.

A member shared that their program has noticed that the six minute walk can often be indicative of post-transplant outcomes, particularly noting that patients with a shorter six minute walk tend to have longer recovery periods with increased risk of complications. The member provided an example that some younger patients on ECMO had aggressive physical therapy, and then walked 150 to 300 feet while on ECMO for the 6 minute walk test, and post-operation would recover faster than another patient with IPF on high flow that could only walk 15 to 20 feet. The member added that the six minute walk can provide some insight in post-transplantation recovery. Another member agreed, sharing that their program utilizes the six minute walk to evaluate frailty in their renal and KP patients, and found that those patients who perform poorly on the six minute walk generally have worse outcomes post-transplant. The member recommended that the six minute walk not only be considered to measure frailty for medical urgency, but also for post-transplant outcomes when considering its use in an allocation model. The member noted the trade-off – there is a point with very frail patients where their medical urgency is very high but their relative outcomes are likely going to be low.

One member commented on the objectivity of the six minute walk for lung patients, noting that there are specific certifications for physical therapists when mobilizing ECMO patients, and that few physical therapists in the country actually have this certification. The member pointed out that catering to objectivity could be difficult for most centers who don't have access to these physical therapists, and that this would need to be considered in attempts to make that test consistent and objective. Another

member pointed out patient safety needs to be considered, particularly with respect to mobilizing liver patients to assess frailty, particularly if they have liver disease because of hepatic encephalopathy.

A member asked how the Liver Committee plans to operate willingness to accept a split liver as an attribute, and noted that appropriate consideration is needed. The member expressed support as well for HCC stratification, noting that certain HCC patients are more urgent than others. The member finally added that a prior living donor should always get priority as well, regardless of the organ donated.

8. Update Data Collection for Lung Mortality Models

The Committee reviewed the OPTN Lung Transplantation Committee's *Update Data Collection for Lung Mortality Models* proposal.

Presentation Summary:

The purpose of this proposal is to update data collection on disease severity of lung candidates. This proposal will:

- Remove data collection not used to calculate lung composite allocation score (CAS)
- Revise data collection to improve data quality
- Add data collection on clinical criteria that may warrant future inclusion in lung CAS
- Assign values for candidates on extracorporeal membrane oxygenation (ECMO) or high flow nasal cannula (HFNC) to be used in calculating allocation score

These scores are used for lung allocation, and include estimates of waiting list and post-transplant survival. The estimates are calculated based on clinical information on lung candidates. Coefficients used in calculations are based on mortality models. The data collection on additional clinical criteria will enable the OPTN to consider their inclusion in the models in the future.

The data proposed to be removed include:

- Percent Predicted Forced Vital Capacity
- Post Bronchodilator Actual FEV1
- Pre Bronchodilator Percent Predicted FEV1
- Post Bronchodilator Percent Predicted FEV1
- Requires Supplemental O2: How was the value obtained

The proposed data revisions include:

- Lung Diagnosis Code: Add Combined Pulmonary Fibrosis and Emphysema
- Diabetes: Change "insulin dependent" to "treated with insulin"
- Assisted Ventilation: Add hospitalization status for intermittent mechanical
- Requires Supplemental O2: Allow more detailed data entry by oxygen delivery device and candidate activity level
- Six Minute Walk Distance: Change placement in system and clarify definition

Data additions for all lung candidates include:

- Recurrent Pneumothoraces
- Bronchopleural Fistula
- Massive Hemoptysis
- Exacerbations
- Prior Lung Surgery*
- Pleurodesis

- Prior Cardiac Surgery*
- Microbiology*
- Diffusing Capacity of the Lungs for Carbon Monoxide
- Mean Right Atrial Pressure
- Pulmonary Vascular Resistance

For candidates with a diagnosis of pulmonary hypertension (PH), the Lung Committee proposes collecting the following additional data elements:

- New York Heart Association (NYHA) Functional Classification
- B-type natriuretic peptide (BNP) and N-terminal-prohormone BNP (NT-proBNP)
- Pericardial effusion

Detailed data definitions are in the proposal on the OPTN site. Diagnosis specific definitions of exacerbations include: chronic obstructive pulmonary disease, interstitial lung disease, and cystic fibrosis. The six minute walk is defined as total exertional distance on a flat surface.

This proposal includes assigning values for parts of the lung composite allocation score for certain candidates:

- Candidates receiving over 26.33 L/min of supplemental oxygen
- Candidates on ECMO
- Candidates on high flow nasal cannula

This is because we are proposing to expand data collection for values currently used to calculate the allocation score, but we don't yet have enough information to know how to incorporate that data into the allocation score.

For supplemental oxygen values over 26.33 L/min:

- Currently, the maximum value that can be entered for supplemental oxygen is 26.33 L/min, based on policy implemented in 2012.
- If supplemental oxygen is entered as a percentage, a value of 100% is converted to a maximum L/min score of 26.33 L/min.
- This proposal would allow transplant programs to enter up to 100 L/min for supplemental oxygen to reflect the capacity of oxygen delivery devices currently in use
- However, a maximum value of 26.33 L/min would be used to calculate the patient's allocation score.
- This is because the mortality models are currently based on a maximum value of 26.33 L/min for this covariate, so there is not adequate information on how to incorporate values above 26.33 L/min into the allocation score calculations.

For candidates on ECMO, the OPTN Thoracic Committee previously advised transplant programs to report candidates on ECMO as on "continuous mechanical ventilation" for assisted ventilation and 100% for supplemental oxygen

- Transplant programs will now be able to indicate that their candidates are on ECMO
- These candidates will receive the maximum score for supplemental oxygen so that transplant programs can report accurate information on supplemental oxygen without it negatively impacting the candidate's score

For candidates on HFNC, transplant programs will be enter both the L/min and % of FiO2 for candidates on HFNC. However, only one of these values will be used in the allocation score. The OPTN computer system will use the most beneficial value.

Lung transplant programs will need to learn changes to data collection. Most of the revised data fields are used to calculate the lung CAS and are required. New data collection is not required, but is recommended.

The OPTN Lung Committee asks for the following feedback:

- Are the proposed data changes and data definitions clear?
- What clinical parameters would you add to the diagnosis-specific data definitions of exacerbations?
- Is it clear how data should be submitted related to assisted ventilation and supplemental oxygen, and how values will be incorporated into the CAS?
- Are there any other clinical criteria that should be added to better estimate a candidate's waiting list survival or post-transplant outcomes?

Summary of discussion:

One member asked if there was a way to predict what the candidate scores will be when placement efficiency is not factored in until the match run. Staff shared that each program will have the ability to view the calculated sub scores for all currently registered candidates starting on September 28, 2022. It will not include the score aspects that are calculated at the time of the match run.

One member noted that when lung candidates are listed, they are given a functional status based on the walk distance and questioned how that will affect pulmonary hypertension candidates. The Committee member explained that those patients alone would use the New York Heart Association (NYHA) functional classification as part of the listing. The member also noted that this is data collection to evaluate for possible inclusion in future mortality models.

One member expressed support for the changes, as the data elements will more accurately reflect the risks that patients encounter and will hopefully end up in the mortality models. She added that the benefit of only removing five data elements and adding fourteen new ones will hopefully outweigh the added data burden. Another member added that the risk of data entry errors are always a consideration when adding additional data.

9. Revise Lung Review Board Guidance for Continuous Distribution

The Committee reviewed the OPTN Lung Transplantation Committee's *Revise Lung Review Board Guidelines, Guidance, and Policy for Continuous Distribution* proposal.

Presentation Summary:

The Board of Directors approved significant lung allocation changes in December 2021, with the passage of Establish Continuous Distribution of Lungs. That change established a Lung Review Board to evaluate requests for exceptions to components of the new lung composite allocation score (CAS). The OPTN Lung Transplantation Committee proposes updating the Lung Review Board guidelines, guidance, and policy to ensure as consistent a review as possible in the continuous distribution framework. The proposal will include:

- Operational guidelines cover representation, responsibilities & process
- Clinical guidance includes updates for pulmonary hypertension exceptions
- Policy changes align requirements with other organ review boards

As each organ allocation system shifts towards developing a continuous distribution system, there is an opportunity to shift also towards a more consistent review board framework across organs. Clinical guidance updates respond to the shift form current lung allocation score (LAS) to the new lung CAS.

The proposed operational guidelines are as follows:

- Representatives of active lung transplant programs serve on review board for 2-year terms
- Immediate past chair of Lung Committee serves as review board chair for 2-year term
- Nine reviewers are assigned to each exception request
    - Alternate will be assigned if primary is out of the office
    - Reviewers will be replaced if they do not vote after 3 days and voting closes after 5 days
- Chair is voting member of review board and serves as liaison to Lung Committee
- Primary representative must have at least five years of post-training transplant experience
    - Alternate representative must have at least three years of post-training transplant experience
- At least three pediatric programs should be represented on the review board at any given time

The proposed clinical guidance include:

- Candidates with pulmonary hypertension meeting certain criteria may qualify for a higher allocation score
- Programs may request waiting list survival and post-transplant outcomes exception scores to be at the national 90th percentile
- Updates current guidance to reflect replacement of lung allocation score with composite allocation score

The proposed policy changes will remove language that is duplicative with the operational guidelines, and change the timeline for a second appeal from 14 days to 7 days. This will align timelines to make both first and second appeals all the same and promote consistency between lung and other organ review boards.

Active lung transplant programs will have opportunities to appoint review board representatives to 2-year terms every 5 years. Appointed representatives will be expected to actively participate.

The Lung Committee seeks the following feedback:

- Should the Committee add information in the guidance on how to request a priority 1 equivalent score for pediatric candidates in the new allocation system?
- Should the Chair be a voting member of the Lung Review Board?
- Is it clear how the appeals process works?
- Do lung transplant programs anticipate any barriers to participating in the new Lung Review Board or using the updated exceptions process?

<u>Summary of discussion:</u>

One member noted that geographical location, adult versus pediatric lung programs, and lung program size should be considered when it comes to the representation on the review board. The member also asked if clinical guidance would be provided to help determine what score to request. The response to this question was that the guidance would focus on how to request the score.

One member expressed support for allowing the Chair of the review board to be a voting member unless there is a reason why they should abstain from voting. The member noted that it should be clear if quorum is required for approval or denial of the score request. The member expressed support that

the appeals process is clearly written and the deadlines for the decision are appreciated. The member commented that there should be a process for notifying the alternates that they may be needed during a specific time period. Finally, the member offered that the final review of appeals should be within a reasonable amount of time, anything over 14 days might have an impact on certain patient populations.

10. Update on Multi-Organ (MOT) Allocation for Continuous Distribution of Lungs

The Committee reviewed the OPTN Lung Transplantation Committee's proposal to *Update Multi-Organ Allocation for Continuous Distribution of Lungs*.

Presentation Summary:

In December 2021, the OPTN Board of Directors approved the *proposal Establish Continuous Distribution of Lungs*. The proposal updated lung multi-organ allocation policies to reflect that lung candidates will be ranked according to a composite allocation score. Current multi-organ allocation policies use classifications, distance, and lung allocation score thresholds to indicate when an organ procurement organization must offer another organ along with a lung. The continuous distribution proposal replaced these thresholds with a composite allocation score threshold for required multi-organ offers. The score threshold was selected to preserve eligibility for required multi-organ offers for about 95 percent of patients who receive lung multi-organ transplants in the current allocation system. Updated analysis with more recent data suggested that the selected threshold would not maintain access for as many patients as originally expected.

The purpose of this proposal is to update lung multi-organ allocation to maintain access to transplant with implementation of continuous distribution. This proposal will change lung CAS threshold for required heart-lung, lung-liver, and lung-kidney shares from 28 to 25 and clarify the heart-lung policy. The intent is for the threshold to capture around 95 percent of patients who received lung multi-organ transplants in the current allocation system. An analysis of the updated cohort indicated that a CAS of 28 would not meet that goal, but that a CAS of 25 would be more appropriate.

This analysis used the calculated lung CAS subscore of patients who received lung multi-organ transplants between 1/1/2011 and 5/24/2022. The subscore does not include points for CPRA, prior living donor, and placement efficiency. A CAS threshold of 28 would be expected to capture only about 76 percent of those patients who previously received lung multi-organ transplants. A CAS threshold of 25 would be expected to capture 95 percent of those patients who previously received lung multi-organ transplants.

The clarifications to heart-lung policy will indicate that once the OPO shifts to the lung match run after making required offers to heart and heart-lung candidates, then the OPO must offer organs to lung-alone and heart-lung candidates on the lung match run until offers have been made to all heart-lung candidates meeting the CAS threshold. At that point, the OPO must continue offering to heart and heart-lung candidates. If the lungs are placed with lung-alone candidates on the lung match run, then the OPO can proceed with heart-alone allocation. The clarifications will emphasize that the OPO must always follow the match run.

Education will be provided as part of implementation of continuous distribution of lungs. Required shares will be indicated on the match run.

The Lung Committee seeks feedback on the following questions:

- Does the score threshold of 25 appropriately balance access to transplant between lung multi-organ and other single-organ candidates?

- Once all organs are in continuous distribution, how might the Committee update lung multi-organ allocation across a continuous spectrum?

Summary of discussion:

One member asked and received clarification that this proposal addresses not just heart-lung combinations, but also lung-liver and lung-kidney combinations. Another member noted that the challenge with heart-lung combinations is that the lung allocation score (LAS) might be high but the heart status is lower, therefore preventing the candidates from receiving the lungs. The member added support for the change in order to capture 95% of that population of patients.

One member asked about the status of multi-organ allocation for more than two organs since there are currently no policies addressing them. Another member noted the challenge with those candidates within the framework of broader distribution is that they might be farther down on the match run and other organs may have already been placed.

11. Update on Kidney and Pancreas Continuous Distribution

The Committee reviewed the Kidney and Pancreas Transplantation Committee's *Update on Kidney and Pancreas Continuous Distribution*

Presentation Summary:

This Update will inform the community on the progress to date on the continuous distribution projects. This paper highlights further detail on proposed attributes and rating scales, an overview of AHP exercise results, considerations for allocation components to outside of the composite allocation score, and details on the Committee's first modeling request.

Continuous distribution will:

- Provide a more equitable approach to matching kidney and pancreas candidates and donors
- Remove hard boundaries between classifications that prevent kidney and pancreas candidates from being prioritized further on the match run
- Consider multiple patient attributes all at once through a composite allocation score instead of within categories by sequence
- Establish a system that is flexible enough to work for each organ type

The Kidney and Pancreas Committees have completed identifying the attributes and rating scales to include in the first iteration of CD. In 2022, the Kidney and Pancreas Committees collected community feedback on the prioritization of those attributes through Public Comment and the Analytic Hierarchy Process (AHP) values prioritization exercises. The Values prioritization exercise asked participants to weigh attributes against each other. The full reports for both the Kidney and Pancreas AHP exercises can be found on the OPTN website. The Kidney and Pancreas Committees used that feedback to build draft framework scenarios to submit their first modeling request.

The overall, unweighted ratings for the Kidney AHP exercise revealed that a medically urgent (no dialysis access) candidate (Medical Urgency) received the highest rating, while a very nearby candidate (Placement efficiency) received the lowest rating.

The overall, unweighted ratings for the Pancreas AHP exercise revealed that an extremely (biologically) difficult to match candidate (Candidate biology (which includes blood type and CPRA)) received the highest rating, while a very nearby candidate (Placement efficiency) received the lowest rating.

Data, public comment, and AHP results were considered in order to finalize rating scale recommendations for outstanding attributes and develop a draft framework for modeling. The Kidney

and Pancreas Committees submitted the first round of modeling, with the goal of testing the effects of extreme case scenarios. These decisions are not final.

The following rating scales were utilized in modeling:

- Kidney
    - Medical urgency – binary
    - HLA matching – 0, 1, or 2 DR mismatch
    - EPTS/KDPI – continuous longevity matching
    - Blood type – current screening and blood type points
    - CPRA – steep non-linear curve
    - Prior living donor – binary
    - Pediatrics – binary
    - Kidney after liver safety net – binary
    - Qualifying time – linear, exceed 100 percent beyond 10 years, with no ceiling
    - Proximity efficiency – piecewise linear, 50 nautical mile inner plateau, with 75 percent at 250 nautical miles, 25 percent at 500 nautical miles, and 0 percent at 5181 nautical miles
- Pancreas
    - Blood type – relax KP screening and identical before compatible
    - CPRA – steep non-linear curve
    - Prior living donor – binary
    - Pediatrics – binary
    - Kidney after liver safety net – binary
    - Qualifying time – linear to curve, with an inflection point of 90 percent at 5 years, and a shallower line beyond 5 years to the maximum
    - Proximity efficiency – piecewise linear, 50 nautical mile inner plateau, with 25 percent at 250 nautical miles, and 0 percent at 5181 nautical miles
    - Whole pancreas, not pancreas islet - binary

Current kidney allocation and prioritization differs depending on the donor kidney's KDPI. To replicate this, the Kidney Committee is incorporating weight modifiers depending on donor factors. These weight modifiers are included in the KPSAM modeling and serve to replicate priority in existing KDPI sequences for kidney. Similarly, the Pancreas Committee will also be incorporating weight modifiers for donor factors specific to pancreas, namely donor age and BMI. It is of note that these weight modifiers prioritize whole pancreas candidates for donor age less than or equal to 45 and BMI less than or equal to 30, and prioritize islet candidates for donors age greater than 45 or BMI greater than 30.

The following five scenarios were submitted for modeling with the Kidney-Pancreas Simultaneous Allocation Model (KPSAM):

- Current classifications-based policy, to use as a baseline
- Combined AHP results scenario, utilizing the community's AHP results combined with the Kidney and Pancreas Committee-specific results to model draft weights for each attribute
    - Incorporates some differences in allocation, such as expanded longevity matching, pediatric priority for KDPI 35-85 percent kidneys, and a steeper CPRA curve
- Increased longevity matching, utilizing increased weights for DR matching and longevity, attributes under post-transplant survival
- Increased placement efficiency, to determine impact of increased weight on efficiency

- Increased weight modifier for high KDPI kidneys, to focus on increased proximity efficiency for high KDPI and hard to place kidneys

The concept paper also includes an overview of allocation components that fall outside of the composite allocation score, to include:

- Dual kidney
- En bloc
- Facilitated pancreas
- Mandatory kidney-pancreas (KP) offers
- National offers
- Screening and filters
- Released organs
- Review boards

Results of the first modeling request are expected later this fall. The Kidney and Pancreas Committees will review and make adjustments as needed and re-submit for additional modeling. The Kidney and Pancreas Committees will continue to update the community on the progress of the project, and public comment received will be reviewed and considered in the development of the framework and proposal.

Summary of discussion:

A member asked how longevity matching would work for pediatric patients, since they are not assigned an EPTS. It was clarified that there is a separate pediatric attribute, which will allow pediatric patients to receive appropriate priority. It was also clarified that the OPTN Pediatric Transplantation Committee submitted a data request recently to see if EPTS was a strong predictor for pediatric patients, and found that it was not. The Pediatric Committee recommended to the Kidney and Pancreas Transplantation Committees that pediatric patients be assigned an EPTS score of 1.

One member noted that current kidney allocation gives living donors significant priority, to boost them to the top of the match run. The member expressed concern that living donors may not see this same priority in continuous distribution. Another member agreed, and stressed this importance of prior living donor priority. It was clarified that prior living donors, like pediatrics, will be given priority via the prior living donor attribute, and that the Kidney and Pancreas Committees will need to determine how much weight is appropriate to give to prior living donor priority in order to ensure prior living donors are prioritized similar to their current level of priority.

A member noted that during the development of KAS250, there was a lot of work done to match KDPI and EPTS to increase longevity, promote utilization, and help suppress some of the re-transplantation rates. The member emphasized the importance of longevity matching.

One member pointed out that, with the implementation of Lung Continuous Distribution, programs will be able to see their candidate's base CAS score, built from the candidate's score on the candidate-specific attributes. The member recommended that something similar be included in the implementation of Kidney and Pancreas Continuous Distribution, as this could help programs manage their lists, if they are able to gain a sense of each patient's general score and where they may show up on a match run. The member added that it would be helpful if that field could be imported into hospital and program data bases, so that programs could manage that on their own end.

12. Modify Waiting Time for Candidates Affected by Race-Inclusive estimated Glomerular Filtration Rate (eGFR) Calculations

The Committee reviewed the Kidney and Minority Affairs Committee's proposal, *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations*.

Presentation Summary:

The *Establish OPTN Requirement for Race-Neutral eGFR Calculations* was implemented prospectively on July 27, 2022, and prohibits the use of race variables in eGFR calculations. During winter 2022, the Kidney and Minority Affairs Committees asked the community if the OPTN should consider developing a pathway for transplant centers to modify waiting time for kidney candidates who could have begun accruing waiting time at an earlier date if race-neutral eGFR calculation was used – if yes, how could this be done. The community indicated interest, but did not provide detailed feedback.

Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations provides an opportunity for transplant hospitals to apply race- neutral calculations to candidates already registered to the waiting list. The Kidney and Minority Affairs Committees seek further input on this proposal to develop an equity- driven solution.

This proposal attempts to address waiting time modification for registered Black kidney candidates affected by race-inclusive eGFR calculations

- Provide a pathway for affected candidates to regain any time lost due to use of race-inclusive eGFR calculations
- Increase equity in access to transplantation by providing programs the opportunity to request eGFR waiting time modifications for affected registered candidates

There are several aspects to this proposal, including the qualifying population, required documentation, and timeframe.

- Waiting time will be restored to registered Black kidney candidates whose waiting time was affected by race-inclusive eGFR calculations, and meet documentation and timeframe criteria
- Required documentation:
    - Option 1: candidate's eGFR values for Black and non-Black candidates
    - Option 2: candidate's eGFR with a race-inclusive calculation and a re-estimation of GFR with a race-neutral calculation
- Programs will have a 365 day period to submit eGFR waiting time modifications. Affected candidates may regain all lost waiting time, with no maximum time limits

The Kidney and Minority Affairs Committees offer the following rationale for limited scope:

- Black kidney candidates have been negatively impacted by the common and long-standing use of race in estimation of GFR values
- Opportunity to propose a solution that supports increased equity in access to transplantation for a historically disadvantaged population.

While transplant hospitals are not required to submit eGFR waiting time modifications, the Kidney and Minority Affairs Committees encourage member participation in this opportunity. Participating programs will be responsible for assessment of their waiting lists for qualifying candidates and submission of required documentation.

The Kidney and Minority Affairs Committees seek feedback on the following questions:

- Do community members agree with the proposed eGFR waiting time modification pathway?

- Do community members propose an alternative eGFR waiting time modification pathway?
- Should programs be required to assess their waiting lists and submit eGFR waiting time modifications for affected Black kidney candidates?
- What kind of education resources would assist programs in participating?
- What potential unintended consequences or challenges should be considered during this proposal's development? Do those consequences or challenges outweigh the benefits of the proposed waiting time modification pathway?
- Are there other waiting time modification scenarios that the members would like the committees to consider?
- Does the community agree with the proposed scope, timeframe and required documentation?

Summary of discussion:

One member commented that this proposal has the potential to create logistical issues and increase burden and work load for transplant programs. For example, if a patient had a qualifying eGFR a year ago, then the transplant program would need to go through numerous lab values to determine when they met the criteria for a race neutral eGFR. The member further noted that it can be more complicated if the patient had tests done at an outside lab.

One member commented that currently wait time starts when a candidate is listed or at the initiation of dialysis. She expressed concern about identifying a qualifying eGFR result two years prior to the dialysis start date because it could disadvantage some patients. The member also noted that there are wide variations in the number of black kidney transplant candidates at transplant programs. The member shared that her transplant program is approximately 80% black candidates, and that this would be a huge administrative burden. Another member noted a high percentage of black kidney transplant candidates at his center as well.

One member noted that review of social economic data would show that black candidates are disadvantaged not just for access to transplant, but to healthcare in general. While it may be an administrative burden, it is the right thing to do for this population of candidates. The member explained that these candidates have been historically disadvantaged and this would create equal advantage for them.

One member expressed concern about the 365-day timeframe and the fact that this is not mandatory, noting that this could cause further disparity because some transplant programs will make the adjustment while others will not. Additionally, patients may not be aware of this when they are evaluating transplant programs. Finally, the member expressed concern about how this might affect candidates that were listed after the most recent policy changes in 2018.

Several members agreed that the proposal should be mandated, though this could be very difficult for transplant programs operationally and logistically.

One member commented that it is unclear how far back transplant programs need to go to identify a qualifying eGFR. This could add to the inconsistent application of this policy change. The member recommended incorporating some guideline on how far back a program needs to look. Another member pointed out that, if it's not a requirement, many candidates would be further disadvantaged by inconsistent application of the waiting time modification policy.

One member recommended that programs be given the option to unlock certain forms and update the waiting times themselves, and allow programs to be audited on their modifications at their regular site survey. The member added that paper is very burdensome, and that a paper form could be difficult. Some members agreed.

One member added that programs could end up saying that they reviewed their list without actually reviewing it. Members supported programs providing an attestation that they have review all of their candidates.

One member commented that in order to assist transplant programs, reports should be made available to programs. It was noted that the reports can provide a certain amount of information, however the OPTN does not collect which formula was used and if it was inclusive or exclusive of race. Members agreed that any assistance to transplant programs to make the process less cumbersome would be helpful. Members noted that the volume of patients to review is the issue, not the process, and that education may not make much of a differences. Members recommended leveraging EMRs to compile a list of candidates and potentially find records for candidates, including finding the earliest example of GFR hitting below a certain threshold.

One member suggested that the committee review data to identify the impact of this change. For example, does it impact wait time by six months or two years?

13. Update on Kidney Paired Donation Policy

The Committee reviewed the OPTN Kidney Transplantation Committee's *Update on Kidney Paired Donation Policy* proposal.

Presentation Summary:

The proposal will:

- Establish more efficient timeframe for OPTN KPD exchanges
- Increase fairness to patients
    - Reduce risk of an exchange breaking due to candidate illness, donor unavailability, etc.
    - Prevent termination of an exchange due to non-response
- Ensure holistic informed consent for participants in any KPD program
- Emphasize donor autonomy and ensure transplant programs have explicit conversations regarding expectations
- Align policy language with other OPTN Policies to provide clarity

This proposal will condense match offer and exchange deadlines in the OPTN KPDPP:

- Each transplant hospital receiving a match offer must report to the OPTN a preliminary response within two business days of receiving the match offer, as is required by current OPTN policy
- The matched candidate's transplant hospital and the matched donor's transplant hospital must agree in writing upon the contents required in the crossmatch kit, instructions for the donor, and the addresses at which to send completed blood samples within three business days of receiving the match offer, shortened from the current deadline of four business days
- The matched donor's transplant hospital must report to the OPTN the agreed upon date of the crossmatch and make the matched donor's records accessible to the matched candidate's transplant hospital within three business days of receiving the match offer, shortened from four business days
- The matched candidate's transplant hospital must report to the OPTN results of the crossmatch, review the matched donor's records, and confirm acceptance or report a refusal of the match offer to the OPTN within 10 business days of receiving the match offer, shortened from 15 business days

The proposal will also introduce two new deadlines for transplant and recovery. Within 60 calendar days of receiving the match offer:

- Donor's transplant hospital must recover the kidney from the matched donor
- Candidate's transplant hospital must transplant into the candidate

This proposal will modify the OPTN KPDPP extension request policy, such that an extension is granted if any of the transplant hospitals in the exchange fail to respond to the request.

This proposal also includes several updates to KPD informed consent policies, including:

- Clarify informed consent requirements are applicable for any KPD program
- Align KPD Donor informed consent requirements with Living Donation policy to be more inclusive of financial risk and potential resources available to mitigate donation-related costs
- Require paired donor's signature to confirm the donor has been informed that they may withdraw participation in the KPD program at any time, for any reason
- Modified informed consent requirements for bridge donors:
    - Remove requirement to provide estimate of how long a bridge donor can expect to wait before undergoing surgery
    - Emphasize the bridge donor's autonomy to determine how long they are willing to wait
    - Require documentation of the donor's estimate in the medical record

This proposal will update the definition of "bridge donor," and include a few additional clarifying updates to KPD policy:

- Cross reference in OPTN Policy 14.6.B: Placement of Non-Directed Living Donor Organs to note that these requirements do not apply to non-directed donors participating in a KPD program
- Minor language alignments to OPTN Policy 13.7.G: OPTN KPD Waiting Time Reinstatement

The Kidney Committee seeks feedback on the following questions:

- Do the deadlines provide sufficient time to perform the required tasks and review the match offer?
    - Is the 60 day deadline from time of match offer to recovery and transplant surgery appropriate?
    - Should the deadline for the provision of a preliminary response be shortened to one business day from receipt of match offer, or is two business days more appropriate?
    - Should clinical donor information, such as renal images, be specified as required donor information made accessible to the matched candidate's transplant hospital within the three business day deadline?
- How can overuse of extension requests be discouraged? How can better performance be incentivized in the program?
- Should policy specify that transplant programs obtain a signature from bridge donors confirming informed consent and the estimated period of willingness to be a bridge donor?

<u>Summary of discussion:</u>

One member expressed support for the proposed changes. The member agreed that renal imaging should be required, and noted that many other KPD programs utilize an image uploader that allows

programs to easily access and view that information and make informed offer decisions off the bat. The member added that having that information upfront can prevent last minute exchange failures, and noted that most surgeons want to review the actual images themselves. The member agreed that the renal images should be available within three business days from time of match offer.

A member asked for clarification on the rationale to require centers to obtain a signature from bridge donors with a statement of willingness on how long they are willing to participate as a bridge donor. The member explained that this seems counterintuitive, as programs continuously educate donors on their right to change their mind at any time, and informed consent should be an ongoing process. The member added that operationally, requiring a written signature is outdated, and that electronic signature capture technology can be difficult for institutions to implement. The member shared that their program has maintained many of their telehealth services, particularly for donors farther away to reduce their travel and costs. The member expressed support for all other proposed changes.

Several members remarked that 60 days from time of match offer to surgery seems too long, noting that the extended time before recovery and transplant is inefficient, and creates a window of opportunity for something to happen to the candidates or donors in the exchange. One member pointed out that, typically, an exchange can happen in a matter of weeks in most other paired donation programs, though most other programs frontload a lot of the patient information gathering and sharing. Members agreed that 60 days from time of match offer to scheduled surgery is too long. Members agreed that a lot can happen in 60 days, and noted that an extended window from time of match offer to surgery can increase the potential for something to happen with the candidate or the donor that could result in the exchange needing to be terminated. Another member pointed out that tighter deadlines could encourage participation in the OPTN KPD Program, as it makes the program more aggressive.

One member recommended that the timeframe be shortened to 45 days to surgery, and others agreed that the timeframe could be tightened to 30 days to transplant and recovery. Another member noted that 30 days could be difficult for smaller programs, but that it's a good goal for programs to meet.

One member expressed concern for including policy language that requires a surgery to happen within 60 days, noting that there could be potential for donors to sense an element of pressure or coercion. Another member agreed. The member explained that operationally, it makes sense to reduce the timeframe, but that the language should be mindful of that.

One member recommended requiring the surgery to be "scheduled" within 60 days, to allow for necessary variations. The member provided a scenario, that a program schedules the surgery for 59 days after time of match offer, but a deceased donor kidney comes in and the surgeon needs to push the living donor surgery back a couple of days. The member added that wiggle room would be helpful, and that the language could instead require that the programs plan to have the surgery within 60 days. Another member recommended that the approach be instead requiring that all centers involved in an exchange need to agree upon a surgery date within a certain time frame, instead of requiring that surgery needs to happen within a certain date. The member added that this would be reasonable particularly with long chains. The member agreed that leaving this broad could potentially run the risk of the surgery not occurring for months, or something occurring with the candidate or donor that prevent the exchange.

A member suggested whittling down the 60 day deadline and instead require programs to agree on a surgery date within 30 days of the offer, to keep the deadlines tight. The member reiterated their concern about requiring a surgery to occur within a specific timeframe.

Members agreed that two business days is an appropriate amount of time for programs to review an offer and provide a preliminary response, keeping in mind smaller centers with fewer surgeons.

Members agreed that programs could be required to provide a reason for their extension request, and that this could potentially reduce the overuse of extension requests. One member recommended providing a limit to how many times a program can request an extension. Another member pointed out that programs could be tracked on their use of the extension request, such that programs who are always extending or declining offers late could be identified. Members recommended potential reasons for extension request could include patient unavailability, surgeon unavailability, additional testing required, donor unavailability, and operating room unavailability. One member recommended an open text field be provided as well, for programs to provide a narrative.

A member suggested that OPTN Policy differentiate between general KPD policy and OPTN KPD pilot program specific policy. The member asked if there was talk of the OPTN KPD Program dropping the "pilot" from the name, and the room agreed that the OPTN KPD program should no longer be considered a pilot.

One member noted that the OPTN KPD Program needs to become a more competitive program, particularly in the context of other KPD programs. Another member agreed, noting that during the COVID-19 pandemic, matches were run once a month, which dis-incentivized programs to add more candidate and donor pairs. Members agreed that a lot of buy in is involved for programs to join a KPD program.

Upcoming Meeting

- October 20, 2022- Conference call

Attendance

- **Committee Members**
  - Stacy McKean
  - Natalie Santiago-Blackwell
  - Angele Lacks
  - Ashley Anne Hamby
  - Ashley Cardenas
  - Brenda Durand
  - Donna Campbell
  - Karl E. Neumann
  - Kelsey McCauley
  - Madison Salazar
  - Melissa Walker
  - Sergio Manzano
  - Valinda Jones
- **HRSA Representatives**
  - Megan Hayden
  - Vanessa Arriola
- **UNOS Staff**
  - Kayla Temple
  - Alex Carmack
  - Joann White
  - Lauren Mauk
  - Shelby Jones
  - Terry Cullen